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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 414, 424, 455, 484, and 498

[CMS-1828-F]

RIN 0938-AV53

Medicare and Medicaid Programs; Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements; Provider Enrollment; and Other Medicare and Medicaid Policies

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

ACTION: Final rule.

SUMMARY: This final rule sets forth routine updates to the Medicare home health payment rates in accordance with existing statutory and regulatory requirements. In addition, this final rule finalizes permanent and temporary behavior adjustments and recalibrates the case-mix weights and update the functional impairment levels; comorbidity subgroups; and low-utilization payment adjustment (LUPA) thresholds for CY 2026. This final rule also finalizes changes to the face-to-face encounter policy and changes to the Home Health Quality Reporting Program (HH QRP) and the expanded Health Value-Based Purchasing (HHVBP) Model requirements. In addition, it updates the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP). Lastly it finalizes: a technical change to the HH conditions of participation; updates to DMEPOS supplier conditions of payment; updates to

provider and supplier enrollment requirements; and changes to DMEPOS accreditation requirements.

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

FOR FURTHER INFORMATION CONTACT: For general information about the Home Health Prospective Payment System (HH PPS), send your inquiry via email to HomeHealthPolicy@cms.hhs.gov.

For information about the Home Health Quality Reporting Program (HH QRP), send your inquiry via email to HHQRPquestions@cms.hhs.gov.

For more information about the expanded Home Health Value-Based Purchasing Model (HHVBP), please visit the Expanded HHVBP Model webpage at https://www.cms.gov/priorities/innovation/innovation-models/expanded-home-health-value-based-purchasing-model or send your inquiry via email to HHVBPquestions@cms.hhs.gov.

Frank Whelan (410) 786-1302, for Medicare provider and supplier enrollment and DMEPOS accreditation inquiries.

Katie Parker (410) 786-0537, Emily Calvert (410) 786-4277, or Jessica Martindale (410) 786-1558 for DMEPOS Prior Authorization inquiries.

Alexander Ullman at (410) 786-9671 or DMEPOS@cms.hhs.gov, for DMEPOS Competitive Bidding Program inquiries.

For information about the Home Health Conditions of Participation, send your inquiry via email to healthandsafetyinquiries@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary
- A. Purpose and Legal Authority
- B. Summary of the Provisions of this Final Rule
- C Summary of the Regulatory Impact Analysis

II. Home Health Prospective Payment System
- A. Overview of the Home Health Prospective Payment System
- B. Monitoring the Effects of the Implementation of the PDGM
- C. Final CY 2026 Payment Adjustments Under the HH PPS

D. Final CY 2026 Home Health Low Utilization Payment Adjustment (LUPA) Thresholds, Functional Impairment Levels, Comorbidity Sub-Groups, and Case-Mix Weights
E. Final CY 2026 Home Health Payment Rate Updates
F. Final Regulation Change to Face-to-Face Encounter
III. Home Health Quality Reporting Program (HH QRP)
A. Background and Statutory Authority
B. Summary of the Provisions
C. Quality Measures Currently Adopted for the CY 2026 HH QRP
D. Removal of the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID-19 Vaccine) Measure bBeginning with the CY 2026 HH QRP
E. Removal of Four Standardized Patient Assessment Data Elements Beginning with the CY 2026 HH QRP
F. Amending the Data Non-Compliance Reconsideration Request Policy and Process Beginning with the CY 2026 HH QRP
G. Updates to Requirements for OASIS All-Payer Data Submission
H. HHCAHPS Survey Updates
I. HH QRP Quality Measure Concepts Under Consideration for Future Years – Request for Information
J. Potential Revision of the Final Data Submission Deadline Period from 4.5 Months to 45 Days—Request for Information (RFI)
K. Advancing Digital Quality Measurement in the HH QRP – Request for Information
L. Form, Manner, and Timing of Data Submission Under the HH QRP
M. Policies Regarding Public Display of Measure Data for the HH QRP
IV. The Expanded Home Health Value-Based Purchasing (HHVBP) Model
A. Background
B. Finalized Changes to HHVBP Measure Removal Factors
C. Finalized Changes to the Expanded HHVBP Model's Applicable Measure Set
D. HHVBP Quality Measure Concepts Under Consideration for Future Years – Request for Information
V. Updates to the Home Health Agency Conditions of Participation (CoPs) to Align with the OASIS All-Payer Submission Requirements
A. Statutory Authority and Background
B. Updates to the Home Health Agency CoPs to Align with the OASIS All-Payer Submission Requirements (§§ 484.45(a) and 484.55(d)(1)(i))
VI. Provider Enrollment, Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Accreditation Policies, and DMEPOS Prior Authorization
A. Provider Enrollment
B. DMEPOS Supplier Accreditation Process
C. Finalized Exemption Process for Prior Authorization of Certain DMEPOS Items (§ 414.234(c)(1) and (c)(1)(ii))
VII. DMEPOS Competitive Bidding Program
A. Background
B. Determining Payment Amounts and the Number of Contracts Awarded for the DMEPOS CBP
C. Adjustments to SPAs
D. Bid Limits and Conditions for Awarding Contracts if Savings are Not Expected
E. Revising the Definition of Item Related to Medical Supplies
F. Remote Item Delivery (RID) CBP
G. Payment for Continuous Glucose Monitors and Insulin Infusion Pumps
H. Revising the Submission of Financial Document Requirements for the DMEPOS CBP
I. Revising the CDRD Evaluation and Notification Process for the DMEPOS CBP
J. Bid Surety Bond Review Process

K. Tribal Exemption from Participating in the DMEPOS CBP
L. Addition of a Termination Clause for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) Supplier Contracts
M. Technical Change to § 414.408(h)(8)
N. Definitions of Competition and Adjusted and Unadjusted Fee Schedule Amounts under § 414.402
VIII. Collection of Information Requirements
A. Statutory Requirement for Solicitation of Comments
B. Information Collection Requirements (ICRs)
IX. Regulatory Impact Analysis
A. Statement of Need
B. Overall Impact
C. Detailed Economic Analysis
D. Regulatory Review Cost Estimation
E. Alternatives Considered
F. Accounting Statements and Tables
G. Regulatory Flexibility Act (RFA)
H. Unfunded Mandates Reform Act (UMRA)
I. Federalism
J. Unleashing Prosperity Through Deregulation
K. Conclusion
X. Response to Comments

I. Executive Summary

A. Purpose and Legal Authority

1. Home Health Prospective Payment System (HH PPS)

As required under section 1895(b) of the Social Security Act (the Act), this final rule updates the CY 2026 Medicare payment rates for home health agencies (HHAs). In this final rule, we also finalize permanent and temporary adjustments to the CY 2026 home health base payment rate to account for the difference between assumed versus actual behavior changes on estimated aggregate expenditures for home health payments as a result of the change in the unit of payment to 30 days and the implementation of the Patient Driven Groupings Model (PDGM). In addition, this rule finalizes the recalibrated PDGM case-mix weights and updates the low-utilization payment adjustment (LUPA) thresholds, functional impairment levels, and comorbidity adjustment subgroups under sections 1895(b)(4) of the Act for 30-day periods of care in CY 2026. This rule finalizes an update to the CY 2026 fixed-dollar loss (FDL) ratio for outlier payments (so that outlier payments as a percentage of estimated total payments are projected not to exceed 2.5 percent, as required by section 1895(b)(5)(A) of the Act).

Additionally, this rule finalizes changes to the face-to-face encounter policy at 42 CFR 424.22(a)(1)(v) to align with section 3708 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act).

2. Home Health (HH) Quality Reporting Program (QRP)

In accordance with the statutory authority at section 1895(b)(3)(B)(v) of the Act, we are finalizing updated quality reporting policies. We are finalizing the proposal to remove the COVID-19 Vaccine: Percent of Patients Who Are Up to Date measure and the item related to the measure and corresponding data element beginning with the CY 2026 HH QRP. CMS is also finalizing the proposal to remove four assessment items: one Living Situation item, two Food items, and one Utilities item beginning with the CY 2026 HH QRP. We are also finalizing the proposal to revise the policy to allow for providers to submit a request for reconsideration of an initial determination of noncompliance if they can demonstrate full compliance. In very limited circumstances, HHAs will be permitted to request an extension to file a reconsideration request if the HHA was affected by an extraordinary circumstance beyond the control of the HHA (that is, a natural or man-made disaster such as a cyber-attack, hurricane, tornado, or earthquake) during the 30-day reconsideration period. CMS is also finalizing a revised Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) Survey beginning with the April 2026 sample month. This rule also updates regulatory text to account for all-payer data submission of OASIS data. In a request for information (RFI) included in the CY 2026 HH PPS proposed rule, we sought information on a change to the final data submission deadline period from 4.5 months to 45 days. We also sought feedback on the digital quality measurement (dQM) transition for HHAs. We solicited feedback from the public on the current adoption of health information technology (IT) and standards including Fast Healthcare Interoperability Resources (FHIR), including related challenges or barriers HHAs are facing. Finally, we sought input on future HH QRP quality measure (QM) concepts of interoperability, cognitive function, nutrition,

and patient well-being. A summary of the comments submitted in response to these RFIs is included in this final rule.

3. Expanded Home Health Value-Based Purchasing (HHVBP) Model

In accordance with the statutory authority at section 1115A of the Act, we are finalizing our proposals to do the following for the expanded HHVBP Model: (1) add a new measure removal factor for the expanded HHVBP Model applicable measure set and (2) make changes to the expanded HHVBP Model applicable measure set. Additionally, we included in the proposed rule a request for information (RFI) related to potential future performance measure concepts and we summarize comments received in response to this RFI in this final rule.

We proposed to add a new measure removal factor for the expanded HHVBP Model applicable measure set for measures that are not feasible to implement. We proposed to remove three HHCAHPS Survey-based measures, to align with proposed changes to the HHCAHPS survey. We proposed the addition of four new measures. These additions include the claims-based Medicare Spending Per Beneficiary Post-Acute Care (MSPB-PAC) measure, and three OASIS-based function measures: Improvement in Bathing, Improvement in Upper Body Dressing, and Improvement in Lower Body Dressing. Due to these proposed changes to the applicable measure set, we also proposed revising the weights of the individual HHVBP measures as well as the measure categories. As noted above, we are finalizing these proposals without modification.

4. Updates to the Home Health Agency CoPs to Align with the OASIS All-Payer Submission Requirements

We are finalizing the technical regulation text changes to the Home Health Conditions of Participation (CoP). These technical changes update terminology in the Home Health CoPs to further clarify that the requirement for reporting OASIS information applies to all HHA patients receiving skilled services.

5. Medicare and Medicaid Provider Enrollment

Consistent with section 1866(j) of the Act, we proposed and are finalizing several Medicare provider enrollment provisions to strengthen and clarify certain aspects of the provider enrollment process. These include but are not limited to: (1) modifying grounds for denying, revoking, or deactivating a provider's or supplier's Medicare enrollment; and (2) expanding the reasons for which CMS can apply a retroactive effective date for provider and supplier revocations. These changes are necessary to help ensure that payments are made only to qualified providers and suppliers, which we believe would assist in protecting the Trust Funds and Medicare beneficiaries.

We are also finalizing a technical correction to one of our Medicaid provider enrollment provisions in 42 CFR 455.416 to further clarify the scope of § 455.416(c).

6. DMEPOS Supplier Accreditation Organizations

Consistent with provisions in section 1834(a)(20) of the Act, we proposed and are finalizing revisions and additions to a number of our regulations regarding DMEPOS supplier accreditation and, in particular, requirements that an organization must meet to become and remain a CMS-approved DMEPOS accrediting organization (AO). Our finalized provisions include but are not limited to: (1) requiring DMEPOS suppliers to be surveyed and reaccredited every year (as opposed to the current 3-year cycle); (2) eliminating inconsistencies among AOs in how they oversee DMEPOS suppliers; and (3) strengthening our ability to take action against poorly performing DMEPOS AOs. We believe these changes will help ensure that DMEPOS AOs closely oversee DMEPOS suppliers for compliance with the DMEPOS quality standards.

7. DMEPOS Prior Authorization

In section V.C. of this final rule, we are finalizing regulations regarding granting and withdrawing exemptions from mandatory prior authorization requirements for certain DMEPOS suppliers.

8. DMEPOS Competitive Bidding Program

We are finalizing the proposed changes to regulations at subpart C of 42 CFR 414 we believe are necessary for the effective implementation of the DMEPOS Competitive Bidding Program (CBP) mandated by section 1847(a) of the Act.

a. Determining Payment Amounts and the Number of Contracts Awarded for the DMEPOS CBP

We are finalizing the provisions for how single payment amounts (SPAs) are calculated and how CMS determines the number of contracts to award in each "competition," which refers to the CBPs competitive bidding area (CBA) and product category combination.

b. Adjustments to SPAs

We are finalizing the regulation to acknowledge the challenge and uncertainty a bidder may face when factoring inflation into its bid. We believe that adding an annual increase to the SPAs to account for inflation will be consistent with Medicare making annual covered item updates for other DMEPOS items and services. This will account for inflation in the cost of doing business for suppliers submitting bids for furnishing items under a multi-year contract.

c. Bid Limits and Conditions for Awarding Contracts if Savings are Not Expected

We are finalizing the regulation to revise the methodology used to establish bid limits and establish the conditions for determining when contracts cannot be awarded in accordance with section 1847 (b)(2)(A)(iii) of the Act because the total amounts to be paid to contract suppliers in a CBA are expected to be less than the total amounts that would otherwise be paid. These changes will better ensure DMEPOS CBP is responsive to rising costs over time while still ensuring alignment with the statutory requirement for achieving savings.

d. Revising the Definition of "Item" Related to Medical Supplies

This final rule specifies that ostomy, tracheostomy, and urological supplies are medical equipment items mandated for inclusion under the DMEPOS CBP by section 1847(a)(2)(A) of the Act.

e. Remote Item Delivery (RID) CBP

This final rule creates two new definitions under § 414.402 for "Remote item delivery CBP" and "Remote item delivery item" for the purpose of establishing one or more RID CBPs wherein contract suppliers would be responsible for furnishing the items and services under the product category primarily on a mail order basis to all Medicare beneficiaries regardless of where they live in the CBA, but could also furnish the items on a non-mail order basis. Any competitively bid item furnished on a non-mail order basis would also need to be furnished by a contract supplier. For a given product category, we could implement one nationwide RID CBP that would include all areas (all States, territories, and the District of Columbia) or we could implement multiple RID CBPs covering different regions of the country. Items included in a nationwide or regional RID CBP will be those that are typically furnished to beneficiaries from remote supplier locations that are hundreds of miles on average from the beneficiary residence where the items are delivered.

f. Payment for Continuous Glucose Monitors and Insulin Infusion Pumps

The final rule will make payment under the DMEPOS CBP for certain continuous glucose monitors and insulin infusion pumps and all necessary supplies and accessories on a bundled monthly rental basis. The technology of products used by beneficiaries to help manage diabetes continues to change rapidly, and without frequent and substantial servicing to ensure that the devices continue to function correctly, the beneficiary might not receive information they need to make correct diabetes treatment decisions or the dosage of insulin administered by the insulin pump could be incorrect, putting the beneficiary in imminent danger. This final rule will eliminate the need to wait 5 years to replace equipment, allowing beneficiaries to use the latest technologically updated items. Payment for continuous glucose monitors and insulin infusion pumps and all necessary supplies and accessories that are not furnished under the DMEPOS CBP would also be made on a bundled monthly rental basis in the same amounts established for continuous glucose monitors and insulin infusion pumps under the DMEPOS CBP.

g. Revising the Submission of Financial Documents for the DMEPOS CBP

The final rule streamlines the requirements and evaluation of the DMEPOS CBP financial standards, while still ensuring that suppliers that are offered contracts are financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract performance period.

h. Revising the Covered Document Review Date Evaluation and Notification Process for the DMEPOS CBP

The final rule streamlines the process for evaluating and notifying a bidder who submitted a covered document by the covered document review date if a covered document(s) is missing.

i. Bid Surety Bond Review Process

The final rule codifies the bid surety bond rider process that occurred during the DMEPOS CBP round in 2021 and to correct a regulatory citation error from previous rulemaking.

j. Tribal Exemption from Participating in the DMEPOS CBP

The final rule adds a Tribal exception to the DMEPOS CBP regulations.

k. Addition of a Termination Clause for the DMEPOS CBP Supplier Contracts

The final rule adds a termination clause to the DMEPOS CBP contracts that could be utilized during a public health emergency (PHE), when CMS determines that credible evidence exists of an access problem for beneficiaries, and when CMS believes the termination of an entire DMEPOS CBP contract, the termination of a competition on a DMEPOS CBP contract, or the termination of a defined area(s) within a CBA could improve the situation for the applicable competition(s) or defined areas (for example, ZIP codes) within a CBA.

l. Technical Change to § 414.408(h)(8)

The final rule makes a technical change to § 414.408(h)(8) so that it correctly refers to paragraph (h)(8)(ii) instead of paragraph (h)(7)(ii).

m. Adding Definitions of Adjusted Fee Schedule, Amount Competition, and Unadjusted Fee Schedule Amount to § 414.402.

The final rule adds definitions of "Adjusted fee schedule amount," "Competition," and "Unadjusted fee schedule amount" to § 414.402 for the purpose of simplifying the regulation text for subpart F.

B. Summary of the Provisions of this Final Rule

1. Home Health Prospective Payment System (HH PPS)

In section II.B.1. of this final rule, we discuss comments related to the monitoring and data analysis on the PDGM utilization.

In section II.C.1. of this final rule, we finalized a -1.023 percent permanent adjustment and a -3.0 percent temporary adjustment to the base payment rate under the HH PPS.

In section II.D. of this final rule, we finalized the recalibrated CY 2026 PDGM case-mix weights and updates to the low-utilization payment adjustment (LUPA) thresholds, functional impairment levels, and comorbidity adjustment subgroups.

In section II.E. of this final rule, we update the home health wage index. We also update the CY 2026 national, standardized 30-day period payment rates and the CY 2026 national per-visit payment amounts by the home health payment update percentage. The final home health payment update percentage for CY 2026 is 2.4 percent. Additionally, this rule finalizes the CY 2026 fixed dollar loss (FDL) ratio to ensure that aggregate outlier payments are projected not to exceed 2.5 percent of the total aggregate payments, as required by section 1895(b)(5)(A) of the Act.

In section II.F. of this final rule, we finalized changes to the face-to-face encounter policy at 42 CFR 424.22(a)(1)(v).

2. Home Health Quality Reporting Program (HH QRP)

In section III. of this final rule, we are finalizing the proposal to remove the COVID-19 Vaccine: Percent of Patients Who Are Up to Date measure and the item related to the measure.

We are also finalizing the proposal to remove four assessment items: one Living Situation item, two Food items, and one Utilities item. CMS is finalizing the proposal to implement a revised HHCAHPS Survey beginning with the April 2026 sample month. We are finalizing the proposal to revise the policy to allow providers to submit a request for reconsideration of an initial determination of non-compliance with the HH QRP data submission requirements. They can request this if they believe that they can demonstrate full compliance. We also are finalizing that, in very limited circumstances, the HHA could request an extension to file a reconsideration request if the HHA was affected by an extraordinary circumstance beyond the control of the HHA, (that is, a natural disaster or man-made disaster such as a cyber-attack, hurricane, tornado, or earthquake) during the 30-day period for requesting reconsideration of the initial determination.

We summarize input received on a series of RFIs. In the CY 2026 HH PPS proposed rule, we sought information on a change to the final data submission deadline period from 4.5 months to 45 days. We also sought feedback on the digital quality measurement (dQM) transition for HHAs. We solicited feedback from the public on current adoption of health IT and standards, including Fast Healthcare Interoperability Resources (FHIR), and what related challenges or barriers HHAs are facing. Finally, we sought input on future HH QRP quality measure (QM) concepts of interoperability, cognitive function, nutrition, and patient well-being.

3. Expanded Home Health Value Based Purchasing (HHVBP) Model

In section IV. of this final rule, we finalize a proposal to add a new measure removal factor for the expanded HHVBP Model applicable measure set. This ninth measure removal factor will allow CMS to propose the removal of a measure when it is no longer feasible to implement the measure specifications. We also finalize proposed changes to the expanded HHVBP Model applicable measure set and changes to measure weights. We are removing three HHCAHPS Survey-based measures to align with finalized changes to the HHCAHPS Survey. We also finalize the proposed addition of four new measures. These additions include the claims-

based Medicare Spending Per Beneficiary Post-Acute Care (MSPB-PAC) measure, and three OASIS-based function measures: Improvement in Bathing, Improvement in Upper Body Dressing, and Improvement in Lower Body Dressing. Due to these changes to the applicable measure set, we also finalize proposed revisions to the weights of the individual HHVBP measures and the measure categories.

We also summarize public comments received in response to an RFI included in the proposed rule related to potential future measure concepts for the expanded HHVBP Model.

4. Updates to the Home Health Agency Conditions of Participation (CoPs) to Align with the OASIS All-Payer Submission Requirements

In section V. of this rule, we finalized technical regulation text changes to § 484.45 and § 484.55 of the Home Health Conditions of Participation (CoPs) to align with the OASIS all-payer submission requirements. These technical changes update terminology in the Home Health CoPs to further clarify that the requirement for reporting OASIS information applies to all HHA patients receiving skilled services.

5. Medicare and Medicaid Provider Enrollment

We finalized several Medicare provider enrollment provisions to strengthen and clarify certain aspects of the provider enrollment process. These include, but are not limited to, the following:

- Modifying grounds for denying, revoking, or deactivating a provider's or supplier's Medicare enrollment.
- Expanding the reasons for which CMS can apply a retroactive effective date for provider and supplier revocations.
- Expanding the reasons for which CMS can apply a stay of enrollment.
- Requiring providers and suppliers to report any adverse legal actions imposed against them, their owners, their managers, etc. within 30 days instead of the current 90 days.

We believe these revisions would help keep unqualified providers and suppliers out of the Medicare program, which, in turn would prevent improper Medicare payments to such parties.

6. DMEPOS Supplier Accreditation Organizations

DMEPOS suppliers are required to be accredited by a CMS-approved accrediting organization to enroll in and bill Medicare. The purpose of accreditation is to confirm, typically through an on-site survey of the supplier, that the supplier meets the DMEPOS quality standards. Regulations promulgating our accreditation requirements were enacted in 2006 but have not been updated since then. We are concerned there may be instances where: (1) AOs are accrediting DMEPOS suppliers that do not meet the quality standards; and (2) DMEPOS suppliers are falling out of compliance with the quality standards (sometimes for extended periods) after becoming accredited. To enhance our ability to ensure that AOs are performing DMEPOS accreditation functions effectively and thoroughly, including verifying suppliers' compliance with the quality standards, we are finalizing proposals that add a number of provisions to our DMEPOS accreditation regulations. Among our finalized provisions are as follows:

- Requiring DMEPOS suppliers to be surveyed and reaccredited every year (as opposed to the current 3-year cycle).
- Reducing inconsistencies among AOs in how they oversee DMEPOS suppliers.
- Requiring AOs to furnish more detailed information to CMS when applying or reapplying for approval to become or remain a DMEPOS AO.
- Facilitating greater CMS oversight of the DMEPOS AOs.

We believe these and other changes to the DMEPOS accreditation process would help ensure that unqualified DMEPOS suppliers are not accredited and do not, in turn, receive Medicare payments.

7. DMEPOS Prior Authorization

In section V.C. of this final rule, we are finalizing regulations regarding granting and withdrawing exemptions from mandatory prior authorization requirements for certain DMEPOS suppliers.

8. DMEPOS Competitive Bidding

a. Determining Payment Amounts and the Number of Contracts Awarded for the DMEPOS CBP

Currently SPAs for the lead item (defined under § 414.402 as the item in the product category with the highest total allowed charges nationwide) are calculated using the maximum winning bid submitted by bidders whose composite bids for the product category that includes the lead item are equal to or below the pivotal bid for that product category. In the final rule, we are revising this calculation to use the 75th percentile of winning bids for the lead item by bidders whose composite bids for the product category that includes the lead item are equal to or below the pivotal bid for that product category. We are also finalizing our proposal to change the way the SPAs are calculated for the non-lead items in a product category in certain CBAs. Currently, the ratio multiplied by the SPA for the lead item to calculate the SPA for the non-lead item is based on the average of the 2015 fee schedule amounts for all areas (that is, all states, the District of Columbia, Puerto Rico, and the United States Virgin Islands) for the non-lead item divided by the average of the 2015 fee schedule amounts for all areas for the lead item. This formula uses average fee schedule amounts rather than fee schedule amounts for specific areas, which results in cases where the SPA for a non-lead item can be higher than the fee schedule amount that would otherwise be paid. To address this situation in CBAs other than remote item delivery CBAs, we are finalizing our proposal to calculate the ratio based on the 2015 fee schedule amounts for each specific area rather than the average of the 2015 fee schedule amounts for all areas. Additionally, the final rule would revise how CMS determines the number of DMEPOS CBP contracts to award to DMEPOS suppliers by using contract supplier utilization information from previous rounds of the DMEPOS CBP for product categories previously included under the CBP as well as information on current supplier utilization for new product categories.

b. Adjustments to SPAs

We are finalizing our proposal to apply an annual update factor to SPAs, starting with year two of the DMEPOS CBP contracts.

c. Bid Limits and Conditions for Awarding Contracts if Savings are Not Expected

We are finalizing our proposal to amend 42 CFR 414.414(f) so contracts could be awarded in a CBA if the amounts to be paid are no greater than 110 percent of the amounts that would otherwise be paid for the items. This rule clarifies that the amounts that would otherwise be paid include payment amounts adjusted in accordance with §414.210(g). This rule also finalizes our proposal to modify 42 CFR 414.412(b) to establish bid limits both for items included in the CBP for the first time and for items that have previously been included in the CBP. For items included in the CBP for the first time, the bid limits would be the amounts otherwise paid for the items. For items that have previously been included in the CBP, the bid limits would be the most recent SPA for the items plus 10 percent, or if it has been more than a year since the SPA was last in effect, the inflation-adjusted SPA plus 10 percent. However, we are finalizing that in no event would the bid limit be allowed to exceed the unadjusted fee schedule amount. In addition, this rule finalizes a technical correction to add reference to subpart Q ("Payment for Lymphedema Compression Treatment Items") to 42 CFR 414.414(f).

d. Payment for Continuous Glucose Monitors and Insulin Infusion Pumps

We are finalizing our proposal to make payment under the DMEPOS CBP for certain continuous glucose monitors and insulin infusion pumps and all necessary supplies and accessories on a bundled monthly rental basis. We are finalizing our proposal that payment for continuous glucose monitors and insulin infusion pumps and all necessary supplies and accessories that are not furnished under the DMEPOS CBP would also be made on a bundled monthly rental basis with payments limited to the amounts established for continuous glucose monitors and insulin infusion pumps under the DMEPOS CBP.

e. Revising the Definition of "Item" As Related to Medical Supplies

We are finalizing our proposal to revise the definition of "item" at § 414.402 to clarify that section 1847(a)(2) of the Act includes ostomy, tracheostomy, and urological supplies as "items" subject to the DMEPOS CBP. We are finalizing our proposal that "medical supplies" under this section is a category of items separate from durable medical equipment that includes ostomy, tracheostomy, and urological supplies.

f. Remote Item Delivery (RID) CBP

We are finalizing our proposal to create two new definitions under § 414.402 for the purpose of establishing a RID CBP(s) wherein contract suppliers would be required to furnish the items primarily on a mail order basis under the product category to all Medicare beneficiaries regardless of where they live in the CBA. While we expect that the majority of items would be furnished on a mail order basis, a RID competition would not exclude items in the product category that are furnished on a non-mail order basis. Items included in a RID CBP would be those that are typically furnished to beneficiaries from remote supplier locations that are hundreds of miles on average from the beneficiary residence where the items are delivered.

g. Revising the Submission of Financial Document Requirements for the DMEPOS CBP

We are finalizing our proposal to no longer require the submission of a tax return extract, income statement, balance sheet, or statement of cash flows for the purpose of implementing the financial standards mandated by section 1847(b)(2)(A)(ii) of the Act. This final rule will reduce the burden on suppliers submitting bids under the DMEPOS CBP. However, we are finalizing our proposal to continue requiring suppliers to submit a credit report with a numerical credit score and/or rating from one of the four approved credit reporting agencies during the bid window, and by the CDRD if the supplier wants to be eligible for the process for reviewing covered documents. Additionally, we are finalizing our proposal to continue using a five-tier scoring system in the evaluation of the credit report with a numerical credit score and/or rating, which will be utilized to establish a financial score that will indicate if a supplier is financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract

performance period. We are also finalizing our proposal to no longer use a supplier's financial score to assist in determining the capacity to assign to each supplier to meet projected beneficiary demand. Furthermore, we are finalizing our proposal to have suppliers attest to the fact that they meet the small supplier threshold in the DMEPOS Bidding System (DBidS), or any successor system, if applicable.

h. Revising the CDRD Evaluation and Notification Process for the DMEPOS CBP

Since the inception of the DMEPOS CBP, when a bidder has submitted at least one covered document by the CDRD, CMS has notified the bidder within 90 days after the CDRD if they were missing a covered document by the close of the bid window or if a covered document was missing by the CDRD. We are finalizing our proposal that when a bidder has submitted at least one covered document by the CDRD, CMS will notify the bidder within 90 days after the CDRD if they have any missing covered document(s) by the close of the bid window. The supplier will have 10 days after such notification to provide the missing covered document(s).

i. Bid Surety Bond Review Process

CMS applied a bid surety bond rider process during bid evaluation for the DMEPOS CBP round in 2021, and we are finalizing our proposal to codify this process in regulation for all future rounds. Additionally, we are finalizing our proposal to correct a technical error in 42 CFR 414.412(g) that happened as a result of a paragraph redesignation in 83 FR 57072.

j. Tribal Exemption from Participating in the DMEPOS CBP

We are finalizing our proposal to add an exception to the DMEPOS CBP that will allow Medicare payment to Indian Health Service (IHS) and tribally operated facilities and suppliers as noncontract suppliers to furnish competitively bid items and services to American Indian/Alaska Native (AI/AN) Medicare beneficiaries who reside in a CBA during a round of the DMEPOS CBP.

k. Addition of a Termination Clause for the DMEPOS CBP Supplier Contracts

We are finalizing the proposed changes in § 414.422 to have the option to unilaterally terminate or modify each applicable DMEPOS CBP supplier contract to allow any Medicare enrolled DMEPOS supplier to furnish the applicable items and services to Medicare beneficiaries if CMS determines that due to a PHE, contract suppliers are unable to furnish certain items and services to beneficiaries in certain areas impacted by a PHE (PHE-impacted area) as required under their respective DMEPOS CBP supplier contracts.

CMS is finalizing the rule in § 414.422 to have the option to remove items and services furnished in a PHE-impacted areas from the DMEPOS CBP when all of the following qualifying criteria are met: (1) the Secretary declares a PHE; (2) CMS determines that verifiable evidence exists of a DMEPOS access problem for beneficiaries for a certain competition or defined area(s) within the competition's CBA; (3) CMS determines that awarding additional DMEPOS CBP supplier contracts, per § 414.414(i), will not address the access concerns; and (4) CMS determines terminating or modifying each impacted DMEPOS CBP supplier contract to exclude certain competition(s) or defined area(s) within the competition's CBA from the DMEPOS CBP would alleviate access concerns.

After termination and/or modification of all applicable DMEPOS CBP supplier contracts, CMS is finalizing the proposed changes in § 414.422 to revert back to the general fee-for-service program requirements set forth in 42 CFR part 414 Subpart D for the applicable competition(s) or defined area(s) within a CBA.

l. Technical Change to § 414.408(h)(8)

We are finalizing our proposal to make a technical change to § 414.408(h)(8) so that it correctly refers to paragraph (h)(8)(ii) instead of paragraph (h)(7)(ii).

m. Adding Definitions of Adjusted Fee Schedule Amount, Competition, and Unadjusted Fee Schedule Amount to § 414.402

This final rule adds definitions of "Adjusted fee schedule amount," "Competition," and "Unadjusted fee schedule amount" to § 414.402 for the purpose of simplifying the regulation text for subpart F.

C. Summary of the Regulatory Impact Analysis

TABLE 1: SUMMARY OF ECONOMIC COSTS AND TRANSFERS, BY PROPOSED PROVISION

Provision Description	Costs and Cost Savings	Transfers	Other Notes
CY 2026 HH PPS Payment Rate Update		The overall economic impact related to the changes in payments under the HH PPS for CY 2026 is estimated to be -220 million (-1.3 percent). The $220 million decrease in estimated payments for CY 2026 reflects the effects of the CY 2026 final home health payment update percentage of 2.4 percent ($405 million increase), an estimated -0.9 percent decrease* that reflects the effects of the permanent adjustment ($150 million decrease), an estimated -2.7 percent decrease* that reflects the effects of the temporary adjustment ($460 million decrease) and an estimated -0.1 percent decrease that reflects the effects of an updated FDL ($15 million decrease). *The estimated -0.9 percent decrease and the -2.7 percent decrease related to the finalized behavior assumption adjustments includes all payments, while the finalized -1.023 percent permanent adjustment and the -3.0 percent temporary adjustment only applies to the national, standardized 30-day period payments and does not impact payments for 30-dav periods which are LUPAs.	To ensure that home health payments are consistent with statutory payment authority for CY 2026.
HH QRP	The total economic impact of the policies in this final rule including the removal of one Living Situation item, two Food items, and one Utilities item as well as the proposal to remove the patient COVID-19 vaccination item, which is proposed for implementation in CY 2026 will result in a reduction in costs of $17,810,282.		Remove anticipated burden related to the implementation of these items in the OASIS assessment tool.
Expanded HHVBP Model		The overall economic impact of the expanded HHVBP Model for CY s 2024 through 2027 is an estimated $3.376 billion in total savings to FFS Medicare from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the HH industry. As for payments to HHAs, there are no aggregate increases or decreases expected to be applied to HHAs competing in the expanded Model.	
HH CoP Technical Updates	No costs expected.		Alignment with all-payer requirements provides clarification to HHAs regarding which patients they must collect and submit OASIS information on.

Provision Description	Costs and Cost Savings	Transfers	Other Notes
Medicare and Medicaid Provider Enrollment		We anticipate average annual transfers from providers and suppliers to the Federal Government of approximately $2.2 billion.	To help ensure that payments are made only to qualified providers and suppliers, which we believe would assist in protecting the Trust Funds and Medicare beneficiaries.
DMEPOS Supplier Accreditation	We estimate a combined average annual cost burden to DMEPOS suppliers and DMEPOS AOs of approximately $128.3 million.	We anticipate the following average annual transfers: + $165.8 million in transfers from DMEPOS suppliers to DMEPOS AOs in the form of accreditation fees the suppliers pay to the AOs. + $3.8 million in transfers from DMEPOS AOs to DMEPOS suppliers in the form of refunds if the AO's approval as a DMEPOS AO is terminated or suspended. + $664 million in transfers from DMEPOS suppliers to the Federal government based on DMEPOS supplier revocations.	To help better ensure that: (1) DMEPOS AOs are fully qualified to conduct DMEPOS accreditation activities; and (2) all DMEPOS suppliers meet the DMEPOS quality standards.
DMEPOS Prior Authorization	The overall economic impact of the DMEPOS Prior Authorization Exemption provisions is an estimated $2,497,392 in total savings as a result of reduced workload to the DMEPOS Medicare Administrative Contractors ($2,243,074) and reduced supplier burden by compliant suppliers not submitting requests for prior authorization ($254,318).		To reduce supplier burden by not requiring compliant DMEPOS suppliers to submit requests for prior authorization.
DMEPOS Competitive Bidding Program		No economic impact of this regulatory action, thus no associated transfers.	To support the ongoing cost savings and guaranteed beneficiary access offered by the previously implemented DMEPOS CBP. Also, to improve flexibility in providing beneficiaries with the most appropriate medical devices by modifying the payment category of continuous glucose monitors and insulin infusion pumps.

II. Home Health Prospective Payment System

A. Overview of the Home Health Prospective Payment System

1. Statutory Background

Section 1895(b)(1) of the Act requires the Secretary to establish a Home Health Prospective Payment System (HH PPS) for all costs of home health services paid under Medicare. Section 1895(b)(2)(A) of the Act requires that, in defining a prospective payment amount, the Secretary shall consider an appropriate unit of service and the number, type, and duration of visits provided within that unit, potential changes in the mix of services provided within that unit and their cost, and a general system design that provides for continued access to quality services. In accordance with the statute, as amended by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), we issued a final rule which appeared in the July 3, 2000, **Federal Register** (65 FR 41128) to implement the HH PPS legislation.

Section 5201(c) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted February 8, 2006) added new section 1895(b)(3)(B)(v) to the Act, requiring home health agencies (HHAs) to submit data for purposes of measuring health care quality, and linking the quality data submission to the annual applicable home health payment update percentage increase. This data submission requirement is applicable for CY 2007 and each subsequent year. Pursuant to section 1895(b)(3)(B)(v)(I) of the Act, if an HHA does not submit quality data, the home health market basket percentage increase is reduced by 2 percentage points. In the November 9, 2006, **Federal Register** (71 FR 65935), we issued a final rule to implement the pay-for-reporting requirement of the DRA, which was codified at § 484.225(h) and (i) in accordance with the statute. The pay-for-reporting requirement was implemented on January 1, 2007.

Section 51001(a)(1)(B) of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115-123) amended section 1895(b) of the Act to require a change to the home health unit of

payment to 30-day periods beginning January 1, 2020. Section 51001(a)(2)(A) of the BBA of 2018 added a new subclause (iv) under section 1895(b)(3)(A) of the Act, requiring the Secretary to calculate a standard prospective payment amount (or amounts) for 30-day units of service furnished that end during the 12-month period beginning January 1, 2020, in a budget neutral manner, such that estimated aggregate expenditures under the HH PPS during CY 2020 are equal to the estimated aggregate expenditures that otherwise would have been made under the HH PPS during CY 2020 in the absence of the change to a 30-day unit of service. Section 1895(b)(3)(A)(iv) of the Act requires that the calculation of the standard prospective payment amount (or amounts) for CY 2020 be made before the application of the annual update to the standard prospective payment amount as required by section 1895(b)(3)(B) of the Act.

Additionally, section 1895(b)(3)(A)(iv) of the Act requires that in calculating the standard prospective payment amount (or amounts), the Secretary must make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of service under section 1895(b)(2)(B) of the Act and case-mix adjustment factors established under section 1895(b)(4)(B) of the Act. Section 1895(b)(3)(A)(iv) of the Act further requires the Secretary to provide a description of the behavior assumptions made in notice and comment rulemaking. CMS finalized these behavior assumptions in the CY 2019 HH PPS final rule with comment period (83 FR 56461).

Section 51001(a)(2)(B) of the BBA of 2018 also added a new subparagraph (D) to section 1895(b)(3) of the Act. Section 1895(b)(3)(D)(i) of the Act requires the Secretary annually to determine the impact of differences between assumed behavior changes, as described in section 1895(b)(3)(A)(iv) of the Act, and actual behavior changes on estimated aggregate expenditures under the HH PPS with respect to years beginning with 2020 and ending with 2026. Section 1895(b)(3)(D)(ii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more permanent increases or decreases to the standard prospective payment amount (or amounts) for applicable

years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. Additionally, section 1895(b)(3)(D)(iii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more temporary increases or decreases to the payment amount for a unit of home health services for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. Such a temporary increase or decrease shall apply only with respect to the year for which such temporary increase or decrease is made, and the Secretary shall not take into account such a temporary increase or decrease in computing the payment amount for a unit of home health services for a subsequent year. Finally, section 51001(a)(3) of the BBA of 2018 amends section 1895(b)(4)(B) of the Act by adding a new clause (ii) to require the Secretary to eliminate the use of therapy thresholds in the case-mix system for CY 2020 and subsequent years.

Division FF, section 4136 of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117-328) amended section 1834(s)(3)(A) of the Act to require that, beginning with 2024, the separate payment for furnishing negative pressure wound therapy (NPWT) be for just the device and not for nursing and therapy services. Payments for nursing and therapy services are to be included as part of payments under the HH PPS. The separate payment for 2024 was required to be equal to the supply price used to determine the relative value for the service under the Medicare Physician Fee Schedule (as of January 1, 2022) for the applicable disposable device updated by the percentage increase in the Consumer Price Index for All Urban Consumers (CPI-U). The separate payment for 2025 and each subsequent year is to be the payment amount for the previous year updated by the percentage increase in the CPI-U (United States city average) for the 12-month period ending in June of the previous year reduced by the productivity adjustment as described in section 1886(b)(3)(B)(xi)(II) of the Act for such year. The CAA, 2023 also added section 1834(s)(4) of the Act to require that beginning with 2024, as part of

submitting claims for the separate payment, the Secretary shall accept, and process claims submitted using the type of bill that is most commonly used by HHAs to bill services under a home health plan of care.

2. Current System for Payment of Home Health Services

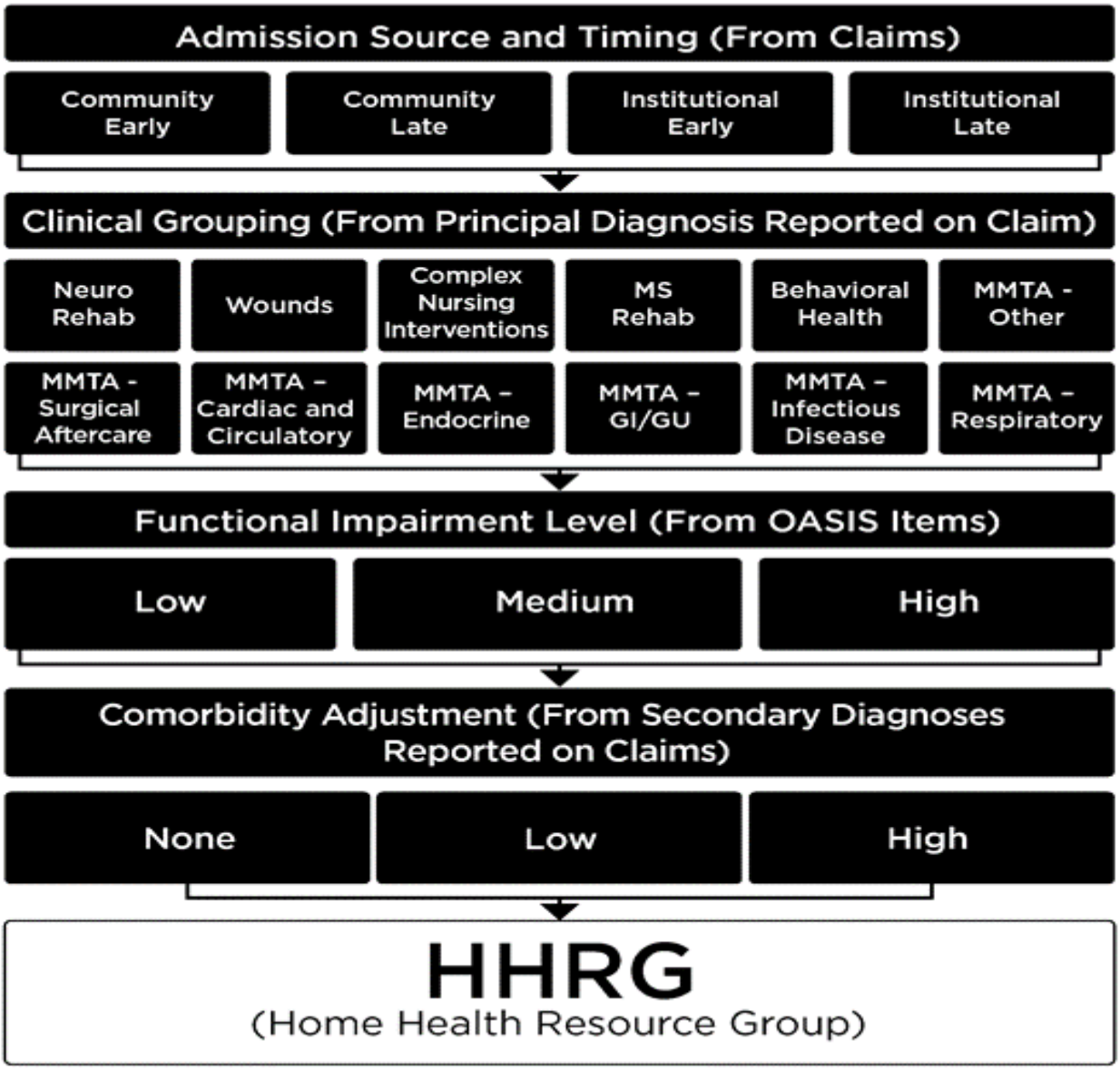
For home health periods of care beginning on or after January 1, 2020, Medicare makes payment under the HH PPS on the basis of a national, standardized 30-day period payment rate that is adjusted for case-mix and area wage differences in accordance with section 51001(a)(1)(B) of the BBA of 2018. The national, standardized 30-day period payment rate includes payment for the six home health disciplines (skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, and medical social services). Payment for non-routine supplies (NRS) is also part of the national, standardized 30-day period rate. Durable medical equipment (DME) provided as a home health service, as defined in section 1861(m)(5) of the Act, is paid the fee schedule amount or is paid through the competitive bidding program and such payment is not included in the national, standardized 30-day period payment amount. Additionally, the 30-day period payment rate does not include payment for certain injectable osteoporosis drugs and disposable negative pressure wound therapy (dNPWT) devices, but such drugs and devices must be billed by the HHA while a patient is under a home health plan of care, as the law requires separate consolidated billing of certain osteoporosis drugs and dNPWT devices.

To better align payment with patient care needs and to better ensure that clinically complex and ill beneficiaries have adequate access to home health care, in the CY 2019 HH PPS final rule with comment period (83 FR 56406), we finalized case-mix methodology refinements, including the removal of therapy thresholds, through the Patient-Driven Groupings Model (PDGM) for home health periods of care beginning on or after January 1, 2020. The PDGM did not change eligibility or coverage criteria for Medicare home health services, and as long as the individual meets the criteria for home health services as described at 42 CFR 409.42, the

individual can receive Medicare home health services, including therapy services. For more information about the role of therapy services under the PDGM, we refer readers to the Medicare Learning Network (MLN) Matters article SE20005 available at https://www.cms.gov/regulations-and-guidanceguidancetransmittals2020-transmittals/se20005. To adjust for case-mix for 30-day periods of care beginning on and after January 1, 2020, the HH PPS uses a 432-category case-mix classification system to assign patients to a home health resource group (HHRG) using patient characteristics and other clinical information from Medicare claims and the Outcome and Assessment Information Set (OASIS) instrument. These 432 HHRGs represent the different payment groups based on five main case-mix categories under the PDGM, as shown in figure 1. Each HHRG has an associated case-mix weight that is used in calculating the payment for a 30-day period of care. For periods of care with visits less than the low-utilization payment adjustment (LUPA) threshold for the HHRG, Medicare pays national per-visit rates based on the discipline(s) providing the services. Medicare also adjusts the national standardized 30-day period payment rate for certain intervening events that are subject to a partial payment adjustment. For certain cases that exceed a specific cost threshold, an outlier adjustment may also be available.

Under this case-mix methodology, case-mix weights are generated for each of the different PDGM payment groups by regressing resource use for each of the five categories (admission source, timing, clinical grouping, functional impairment level, and comorbidity adjustment) using a fixed effects model. A detailed description of each of the case-mix variables under the PDGM have been described previously, and we refer readers to the CY 2021 HH PPS final rule (85 FR 70303 through 70305) for further information.

FIGURE 1: CASE-MIX VARIABLES IN THE PDGM



Notes: MMTA (Medication Management, Teaching and Assessment), MS (Musculoskeletal), GI (Gastrointestinal tract), GU (Genitourinary system)

B. Monitoring the Effects of the Implementation of the PDGM

1. Routine PDGM Monitoring

The CY 2026 HH PPS proposed rule (90 FR 29108) included analysis of Medicare home health benefit utilization, including overall total 30-day periods of care and average periods of care per HHA user; distribution of the type of visits in a 30-day period of care; the percentage of periods that receive the LUPA; estimated costs; the percentage of 30-day periods of care by

clinical group, comorbidity adjustment, admission source, timing, and functional impairment level; and the proportion of 30-day periods of care with and without any therapy visits, nursing visits, and/or aide/social worker visits. We also included monitoring of home health visits using telecommunications technology and remote patient monitoring.

Comment: Commenters discussed the home health utilization trends presented in the monitoring concurrently with comments regarding access to the benefit and the majority of commenters stated the opinion, as they have in prior years, that a decline in utilization is not necessarily related to a reduced need for home health services.

Response: We will continue to monitor and analyze home health utilization trends, potential access issues, and other vulnerabilities within the home health payment system. We address and provide more detailed responses regarding certain utilization trends, access concerns, and reported potential vulnerabilities within the home health payment system in the comment summaries in subsequent sections of this rule.

C. CY 2026 Payment Adjustments Under the HH PPS

1. Behavior Adjustments Under the HH PPS

a. Background

As discussed in section II.A.1. of this final rule, starting in CY 2020, the Secretary was required by section 1895(b)(2)(B) of the Act to change the unit of payment under the HH PPS from a 60-day episode of care to a 30-day period of care. CMS was also required to make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of payment and the case-mix adjustment factors that eliminated the use of therapy thresholds. In the CY 2019 HH PPS final rule with comment period (83 FR 56455), we finalized three behavior change assumptions which were also described in the CY 2022 and 2023 HH PPS rules (86 FR 35890, 87 FR 37614, and 87 FR 66795 through 66796). In the CY 2020 HH PPS final rule with comment period (84 FR 60519), we included these behavior change assumptions in the calculation of the 30-day budget neutral payment amount for CY 2020, finalizing a

negative 4.36 percent behavior change assumption adjustment ("assumed behaviors"). We did not propose any changes for CYs 2021 and 2022 related to the behavior change assumptions finalized in the CY 2019 HH PPS final rule with comment period, or to the negative 4.36 percent behavior change assumption adjustment, finalized in the CY 2020 HH PPS final rule with comment period.

In the CY 2023 HH PPS final rule (87 FR 66796), we stated that we had concluded, based on our annual monitoring at that time, that the three expected behavior changes did in fact occur as a result of the implementation of the PDGM and that other behaviors, such as changes in the provision of therapy and changes in functional impairment levels, had also occurred. We reminded readers that in the CY 2020 HH PPS final rule with comment period (84 FR 60513), we interpreted actual behavior changes to encompass behavior changes that were previously outlined as assumed by CMS, as well as any other behavior changes even if they were not identified at the time we established the 30-day payment rate for CY 2020. In the CY 2023 HH PPS final rule (87 FR 66796), we reviewed evidence indicating that the number of therapy visits declined in CYs 2020 and 2021. That evidence also indicated a slight decline in therapy visits beginning in CY 2019 after we finalized our policy removing therapy thresholds prior to implementing the PDGM. In section II.B.1. of the CY 2025 HH PPS proposed rule (89 FR 55318), our analysis showed that the actual 30-day periods remained similar to the simulated 30-day periods. CMS is required, by law, to account for actual behavior changes related to the implementation of the PDGM and change to a 30-day unit of payment. Additionally, the statute instructs us to ensure that estimated aggregate expenditures under the PDGM are equal to the estimated aggregate expenditures that otherwise would have been made under the prior system.

Although our analysis examines particular actual behavior changes, some of which were part of our original assumed behavior assumptions (for example, in the volume of visits for LUPAs, therapy visits, etc.), the finalized methodology captures the entirety of all behavior changes in order to calculate estimated aggregate expenditures.

Section 4142(a) of the CAA, 2023 required CMS to present, to the extent practicable, a description of the actual behavior changes occurring under the HH PPS from CYs 2020 through 2026. The provision also required CMS to provide datasets underlying the simulated 60-day episodes and discuss and provide time for stakeholders to provide input on and ask questions about the payment rate development for CY 2023. CMS accordingly posted online both the supplemental limited data set (LDS) and descriptive files and the description of actual behavior changes that affected CY 2023 payment rate development. Additionally, on March 29, 2023, CMS conducted a webinar entitled "Medicare Home Health Prospective Payment System (HH PPS) Calendar Year (CY) 2023 Behavior Change Recap, 60-Day Episode Construction Overview, and Payment Rate Development." The webinar was open to the public and discussed the actual behavior changes that we determined had occurred after we implemented the PDGM; our approach used to construct simulated 60-day episodes using 30-day periods; payment rate development for CY 2023; and information on the supplemental data files containing information on the simulated 60-day episodes and actual 30-day periods used in calculating the permanent adjustment to the payment rate. Materials from the webinar, including the presentation and the CY 2023 descriptive statistics from the supplemental LDS files containing information on the number of simulated 60-day episodes and actual 30-day periods in CY 2021 that were used to construct the permanent adjustment to the payment rate, as well as information such as the number of episodes and periods by case-mix group, case-mix weights, and simulated payments, can be found on the Home Health Patient-Driven Groupings Model webpage at https://www.cms.gov/medicare/payment/prospective-payment-systems/home-health/home-health-patient-driven-groupings-model.

b. Method to Annually Determine the Impact of Differences Between Assumed Behavior Changes and Actual Behavior Changes on Estimated Aggregate Expenditures

In the CY 2023 HH PPS final rule (87 FR 66804), we finalized the methodology to evaluate the impact of the differences between assumed and actual behavior changes on

estimated aggregate expenditures. In the CY 2024 HH PPS final rule (88 FR 77687 through 77688), we provided an overview of the methodology with more details for each step of the calculation.

Under the prior 153-group system (and the first three years for assessments associated with the PDGM completed prior to CY 2023), HHAs submitted the Outcome and Assessment Information Set (OASIS) instrument version D. However, effective January 1, 2023, HHAs were required to submit an updated version of the OASIS instrument, OASIS–E. This would mean for purposes of calculating the behavior adjustments, we would use the CY 2023 OASIS-E assessments and CY 2023 claims in CY 2025 rulemaking. Therefore, in the CY 2025 HH PPS final rule (89 FR 88364), we finalized two additional methodological assumptions related to mapping and imputation of OASIS-D responses from OASIS-E. We refer readers to the CY 2023, CY 2024, and CY 2025 HH PPS final rules for further information about the methodology.

c. Calculating Permanent and Temporary Payment Adjustments

To adjust the base payment rate based on increases or decreases in estimated aggregate expenditures that result from differences between assumed behavior changes and actual behavior changes related to the implementation of the PDGM and the change to a 30-day unit of payment for 2020 through 2026, we calculate one or more permanent prospective adjustments by calculating the percent change between the actual 30-day base payment rate and the recalculated ("repriced") 30-day base payment rate. We then convert the percent change into an adjustment factor and apply it in the annual rate update process.

To account for increases or decreases in estimated aggregate expenditures that result from differences between assumed behavior changes and actual behavior changes from 2020 through 2026, we calculate one or more temporary prospective adjustments by calculating the dollar amount difference between the estimated aggregate expenditures from all 30-day periods using the recalculated 30-day base payment rate, and the aggregate expenditures for all 30-day periods using the actual 30-day base payment rate for each of those years once data is available (87 FR

66804). In other words, when determining the dollar amount of aggregate expenditures in prior years that we must offset in future years, we use the full dataset of actual 30-day periods using both the actual and recalculated 30-day base payment rates to ensure that the utilization and distribution of claims are the same. In accordance with section 1895(b)(3)(D)(iii) of the Act, each temporary adjustment applies prospectively but, as its name suggests, only with respect to the year for which such temporary increase or decrease is made. Therefore, after we determine the dollar amount we plan to reconcile in a given year, we calculate a temporary adjustment factor to be applied to the base payment rate for that year. The temporary adjustment factor is based on an estimated number of 30-day periods in the rate setting year using historical data trends, and as applicable, controls for any permanent adjustment factor, case-mix weight recalibration neutrality factor, wage index budget neutrality factor, and the home health payment update. The temporary adjustment factor is applied last since the adjustment applies only to the respective year. That is, the temporary adjustment is not permanently fixed into future base payment rates. We refer readers to the CY 2024 HH PPS final rule (88 FR 77689 through 77694) for analysis of CYs 2020 through 2022 claims and the CY 2025 HH PPS final rule (89 FR 88366 through 88369) for analysis of CY 2023 claims. Additionally, at the end of this section we provide a summary table for the permanent adjustment and temporary dollar amounts calculated for each year.

d. CY 2024 Final Claims Results

We continue the practice of using the most recent complete home health claims data available at the time of rulemaking. This CY 2026 final rule thus uses the most current CY 2024 data for determining any permanent and temporary adjustments to the CY 2026 payment rate using the methodology finalized in the CY 2023 HH PPS final rule (87 FR 66804). This section of this final rule updates the calculations in the CY 2026 HH PPS proposed rule (90 FR 29129) as we have updated these calculations between the proposed and final rules in previous years. However, while we consider the claims data and the permanent and temporary adjustments

results complete for CY 2026, any adjustments to payment rates for future payment years may be subject to additional considerations such as permanent adjustments taken in previous years.

The claims data used in rulemaking is released twice each year in the HH PPS LDS file, one for the proposed and one for the final. Accordingly, the HH PPS LDS file released with this final rule includes two files: the actual CY 2024 30-day periods and the CY 2024 simulated 60-day episodes.

We remind readers that a data use agreement (DUA) is required to purchase the CY 2026 final HH PPS LDS file using the CMS-R-0235A form under OMB control number 0938-0734. Access will be granted for both the 30-day periods and the simulated 60-day episodes under one DUA. Visit the HH PPS LDS webpage for more information.[1] In addition, the final CY 2026 Home Health Descriptive Statistics from the LDS Files spreadsheet is available on the HH PPS Regulations and Notices webpage,[2] does not require a DUA, and is available at no cost to interested parties. The spreadsheet contains information on the number of simulated 60-day episodes and actual 30-day periods in CY 2024. The spreadsheet also provides information such as the number of episodes and periods by case-mix group, case-mix weights, and simulated payments.

e. Applying the Methodology to CY 2024 Data to Determine the CY 2026 Permanent and Temporary Adjustments

As noted, section 1895(b)(3)(D)(i) of the Act requires us to annually determine the impact of differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures, beginning with 2020 and ending with 2026. For this final rule, we update our calculations presented in the CY 2026 HH PPS proposed rule (90 FR 29129) that we had proposed using to determine the CY 2026 permanent and temporary adjustments using the most up to date claims data at the time of this final rule. This is similar to what we have done

[1] https://www.cms.gov/research-statistics-data-and-systems/files-for-order/limiteddatasets/home_health_pps_lds.
[2] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HomeHealthPPS/Home-Health-Prospective-Payment-System-Regulations-and-Notices.

in previous final rules to update the proposed rule calculations. However, we do not finalize these calculated adjustments , as we explain later in this section and in the final decision section.

We begin by applying the methodology finalized in the CY 2023 HH PPS final rule and described most recently in the CY 2024 HH PPS final rule (88 FR 77687 through 77688), as well as applying the two new assumptions related to the OASIS-E mapping in the CY 2025 HH PPS final rule (89 FR 88360 through 88365). We simulated 60-day episodes using actual CY 2024 30-day periods to determine what the permanent and temporary payment adjustments should be to offset for such increases or decreases in estimated aggregate expenditures as a result of the impact of differences between assumed behavior changes and actual behavior changes.

Using the final CY 2024 dataset, as this is the most complete claims data for this final rule, we began with 8,275,089 30-day periods of care and dropped 495,480 30-day periods of care that had a claim occurrence code 50 date after October 31, 2024. We also excluded 842,772 30-day periods of care that had a claim occurrence code 50 date before January 1, 2025, to ensure the 30-day period will not be part of a simulated 60-day episode that began in CY 2024. Applying the additional exclusions and assumptions as described in the finalized methodology (87 FR 66804), an additional 4,892 30-day periods were excluded.

Additionally, we excluded 211,506 simulated 60-day episodes, which consist of 393,108 30-day periods of care where no OASIS information was available in the Chronic Conditions Warehouse (CCW) Virtual Research Data Center (VRDC), a recent start of care/resumption of care (SOC/ROC) OASIS was not available, a wage index was not available, or the episode could not be grouped to a Health Insurance Prospective Payment System (HIPPS) code due to a missing primary diagnosis or other reason. Our simulated 60-day episodes of care produced a distribution of two 30-day periods of care (70.7 percent) and single 30-day periods of care (29.3 percent) that was similar to what we found when we simulated two 30-day periods of care for implementation of the PDGM. After all exclusions and assumptions were applied, the final

dataset for this final rule included 6,538,837 actual 30-day periods of care and 3,849,780 simulated 60-day episodes of care for CY 2024.

Using the final dataset for CY 2024 (6,538,837 actual 30-day periods which made up the 3,849,780 simulated 60-day episodes) and the previously finalized methodology, we determined the estimated aggregate expenditures under the pre-PDGM HH PPS were lower than the actual estimated aggregate expenditures under the PDGM HH PPS. As shown in table 2, aggregate expenditures under the PDGM were higher than if the 153-group payment system were still in place in CY 2024 and therefore, we determined the CY 2024 30-day base payment rate should have been $1,914.73 based on the difference between the assumed behavior changes and the actual behavior changes.

We then take the recalculated CY 2023 base payment of $1,875.46 (as published in the CY 2025 HH PPS final rule (89 FR 88366)) and applied the CY 2024 case-mix weights recalibration neutrality factor (1.0124), the CY 2024 wage index budget neutrality factor (1.0012), the CY 2024 labor-related share budget neutrality factor (0.9998), and the CY 2024 home health payment update factor (1.030). We determined the CY 2024 base payment rate for assumed behavior would have been $1,957.63.

To convert this base payment rate to a payment adjustment, we calculated the percent change between the two payment rates ($1,914.73 and $1,957.63)—which is equal to -2.191%. We also calculated the difference in aggregate expenditures in dollars for all CY 2024 PDGM 30-day claims using the those payment rates: the CY 2024 PDGM payment rate that is budget neutral to the aggregate expenditures generated from the CY 2024 simulated 60 day episodes ($1,914.73) and the CY 2024 PDGM payment rate that incorporates the permanent adjustment calculations through CY 2023 data. This difference is shown as the retrospective dollar amount that will be recouped with one or more temporary adjustments in future years. Our results for the CY 2024 annual (single year) permanent and temporary adjustment calculations using CY 2024 final claims data and the methodology in our proposed rule are shown in table 2. We reiterate

that, as we explain further in later sections, that we are not finalizing the permanent or temporary payment calculated. Instead, the calculations that follow are being presented to be consistent with how we have updated these adjustments between the proposed and final rules in previous rulemaking.

TABLE 2: PERMANENT AND TEMPORARY ADJUSTMENT CALCULATIONS USING FINAL CY 2024 DATA

	Budget neutral 30-day Payment Rate with Assumed Behavior Changes	Budget neutral 30-day Payment Rate with Actual Behavior Changes	CY 2024 Only Adjustment
Base Payment Rate	$1,957.63*	$1,914.73	**Permanent** -2.192%
Aggregate Expenditures	$16,559,413,199**	$15,689,133,244	**Temporary** -$870,279,955

Source: CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW July 11, 2025.
*The $1,957.63 (shown in table 2) is equal to the recalculated budget neutral 30-day base payment rate of $1,875.46 for CY 2023 multiplied by the CY 2024 recalibration factor (1.0124), CY 2024 wage index budget neutrality factor (1.0012), CY 2024 labor-related share budget neutrality factor (0.9998), and the CY 2024 home health payment update factor (1.030).
**The estimated aggregate expenditures for assumed behavior ($16.6 billion), uses the actual CY 2024 payment rate of $2,038.13 as finalized in the CY 2024 HHA PPS final rule (88 FR 77746).

As shown in table 2, a permanent prospective adjustment of -2.192 percent to the CY 2026 30-day payment rate (assuming all adjustments from prior years were applied) for CY 2024 would be required to adjust for such increases in estimated aggregate expenditures in future years. We remind readers, the permanent prospective adjustment of -2.192 percent is for illustrative purposes only and the annual (single year) permanent adjustment cannot be added to previous annual adjustments. Our final estimate of the CY 2024 base payment rate ($2,038.13) resulted in excess expenditures of approximately $870 million in CY 2024.

We now have 5 years of claims data (CYs 2020 through 2024) under the PDGM, and we have applied three permanent adjustments to the 30-day payment rate (CYs 2023 through 2025) that together partially account for the behavior changes we observed in the data, which we summarize in table 3. We reiterate that, as we explain further , we are not finalizing the permanent or temporary payment for CY 2024 reflected as follows. And we remind readers these annual adjustments cannot be added or multiplied together to determine the total permanent

adjustment needed for CY 2026 because each individual year requires an assumption that all prior adjustments were taken.

TABLE 3: TOTAL ANNUAL PERMANENT ADJUSTMENT FOR CLAIMS IN EACH YEAR FOR CYs 2020 - 2024

Claims Data	Annual Permanent Adjustment	HH PPS Final Rule Citation
CY 2020	-6.52%	87 FR 66805
CY 2021	-1.42%	87 FR 66806
CY 2022	-1.767%	88 FR 77692
CY 2023	-1.004%	89 FR 88366
CY 2024	-2.192%	TBD

Note: These annual permanent adjustments are for illustrative purposes only and are not what was implemented.

f. CY 2026 Permanent Adjustment and Temporary Adjustment Calculations

In the preceding section we updated the analysis in the proposed rule using CY 2024 final claims data to determine the difference in expenditures between the 30-day periods and the simulated 60-day episodes. We now update the analysis in the proposed rule using CY 2024 final claims data converting that difference into permanent and temporary payment adjustment. We reiterate that, as we explain further, we are not finalizing the permanent or temporary payment calculated in this section.

Again, that analysis included simulations that assumed the full -3.95 percent payment adjustment (the calculated CY 2025 permanent adjustment) was already taken. We note that CMS implemented a payment adjustment of -1.975 percent for CY 2025, rather than the -3.95 percent we calculated (89 FR 88373), so the calculations set forth later in this section would be the remaining adjustments not applied in previous years (that is, CYs 2020 through 2023 claims data), as well as the adjustment needed to account for CY 2024 claims. In calculating the full permanent adjustment needed to the CY 2026 30-day payment rate, we compare estimated aggregate expenditures under the PDGM and the prior system. Unlike the annual adjustments described in table 3, we do not assume the full adjustment from prior years had been taken.

As discussed in section II.C.1.d. of this final rule, using the final dataset for CY 2024 (6,538,837 actual 30-day periods which made up the 3,849,780 simulated 60-day episodes) we

determined the CY 2024 30-day base payment rate would have been $1,914.73 if calculated based on actual behavior compared to assumed behavior. We then compared the $1,914.73 CY 30-day base payment rate based on actual behavior to the CY 2024 30-day base payment rate of $2,038.13 we paid based on assumed behaviors. The percent change, as summarized in table 4, between the actual CY 2024 base payment rate of $2,038.13 (based on assumed behaviors) and the CY 2024 recalculated base payment rate of $1,914.73 (based on actual behaviors) is the total permanent adjustment reflecting CYs 2020 through 2024 claims.

TABLE 4: TOTAL PERMANENT ADJUSTMENT FOR CYs 2020 THROUGH 2024 CLAIMS

Actual CY 2024 Base Payment Rate (Assumed Behavior)	Recalculated CY 2024 Base Payment Rate (Actual Behavior)	Total Permanent Prospective Adjustment
$2,038.13	$1,914.73	-6.055%*

Source: CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW July 11, 2025.
*This is the total permanent adjustment based on CY 2024 data which includes the previous permanent adjustment of -2.89% applied. However, as described later, we recognize that for CY 2026 we must also account for adjustment made in CY 2025.

As shown in table 4 a permanent prospective adjustment of -6.055 percent to the CY 2024 30-day payment rate is required to offset for such increases in estimated aggregate expenditures in future years. To illustrate this calculation:

$$\frac{(\$1{,}914.73 - \$2{,}038.13)}{\$2{,}038.13} = -6.055\%$$

As we stated in the CY 2025 HH PPS final rule (89 FR 88373), applying a -1.975 percent (half of the final calculated -3.95 percent) permanent adjustment to the CY 2025 30-day payment rate did not adjust the rate fully to account for differences in behavior changes on estimated aggregate expenditures in CYs 2020, 2021, 2022, and 2023. Using CY 2024 claims data, as shown in table 4, a permanent prospective adjustment of -6.055 percent to the CY 2024 30-day payment rate is required to offset for such increases in estimated aggregate expenditures for CYs 2020 through 2024. We remind readers adjustment factors are multiplied in this payment system and individual numbers (that is, percentages) cannot be added or subtracted together to determine the final adjustment. Therefore, we cannot determine the CY 2026 final permanent adjustment,

which will include estimated aggregate expenditures in CY 2024, by simply subtracting the -1.975 percent applied in CY 2025 from the total permanent adjustment of -6.055 percent as shown in table 4.

Instead, we account for the permanent adjustment applied in CY 2025 of -1.975 percent when we calculate the CY 2026 permanent adjustment by solving the following equation $(1 - 0.01975) \times (1 - x) = (1 - 0.06055)$. To illustrate this calculation we used the following approach.

$$x = 1 - \left(\frac{1-0.06055}{1-0.01975}\right)$$

$$x = 1 - 0.95838$$

$x = 0.04162$ (that is, 4.162 percent)

As shown previously, this methodology would suggest a -4.162 percent permanent adjustment for CY 2026. Accounting for the previous permanent adjustments applied to the 30-day payment rate in CYs 2023, 2024, and 2025, we can simulate the permanent adjustment calculation with the simulated annual permanent adjustment percentage shown previously for CY 2026:

Annual Permanent Adjustments Calculated[3]:

CY 2020 Claims = −6.52% (87 FR 66805)

CY 2021 Claims = −1.42% (87 FR 66806)

CY 2022 Claims = −1.767% (88 FR 77692)

CY 2023 Claims = −1.004% (89 FR 88366)

CY 2024 Claims = −2.192% (Table 3)

Permanent Adjustments Applied:

CY 2023 Rate = −3.925% (88 FR 66808)

CY 2024 Rate = −2.890% (88 FR 77697)

CY 2025 Rate = −1.975% (89 FR 88373)

[3]The annual permanent adjustments are for illustrative purposes only and the annual (single year) permanent adjustments cannot be combined to calculate the total permanent adjustment proposed and finalized in rulemaking.

Illustrative Equation:

(1−0.0652)(1−0.0142)(1−0.01767)(1-0.01004)(1-0.02192) =

(1−0.03925)(1−0.0289)(1-0.01975)(1-x)

Solving, x = 4.162%.

In table 5, we provide the base payment rate for what CMS actually paid, the recalculated base payment rate for what CMS should have paid, the total permanent adjustments calculated from the base payment rates (accounts for any adjustments taken prior), and the permanent adjustment applied.

TABLE 5: SUMMARY OF PERMANENT ADJUSTMENTS FOR CYs 2020 – 2026

Claims Analysis Year	Base Payment Rate used to pay HHAs in the Claims Analysis Year	Base Payment Rate that Reflects what CMS Should Have Paid	Total Permanent Adjustment*	Permanent Adjustment CMS Finalized and Implemented in Rulemaking
CY 2020	$1,864.03	$1,742.52	-6.52%	n/a
CY 2021	$1,901.12	$1,751.90	-7.85%	-3.925% (88 FR 66808)
CY 2022	$2,031.64	$1,839.10	-5.78%	-2.890% (88 FR 77697)
CY 2023	$2,010.69	$1,873.17	-3.95%	-1.975% (89 FR 88373)
CY 2024	$2,038.13	$1,914.73	-4.162%	See final decision
CY 2025	TBD	TBD	TBD	TBD
CY 2026	TBD	TBD	TBD	TBD

Note: With the prospective payment systems, the claims data analyzed differ from the rulemaking cycle. For example, CY 2020 claims are used in CY 2022 rulemaking.
*The total permanent adjustment accounts for prior adjustments that were finalized and implemented through rulemaking.

In the CY 2023, 2024, and 2025 HH PPS final rules (87 FR 66790, 88 FR 77696, 89 FR 88373), we acknowledged that the full permanent adjustment in a single year may be burdensome for some providers. As shown in table 5, we finalized only half of the permanent adjustment percentages in CYs 2023 through 2025 final rules. We explained in the CY 2023, 2024, and 2025 HH PPS final rules (87 FR 66808, 88 FR 77697, 89 FR 88373) that when we apply a reduced permanent adjustment, we may need to continue to implement a reduction in future years to satisfy the statutory requirements. However, we recognize that only applying half of the calculated permanent adjustments in previous years has contributed to the significant growth of the temporary adjustment. In the CY 2026 HH PPS proposed rule (90 FR 29133), we

proposed to apply the full permanent adjustment we (then) calculated of -4.059 percent, noting that we would update this percentage using more complete claims data in the final rule, to satisfy the statutory requirements at section 1895(b)(3)(D) of the Act to offset any increases or decreases on the impact of differences between assumed behavior and actual behavior changes on estimated aggregate expenditures, reduce the need for any future large permanent adjustments, and help slow the accrual of the temporary payment adjustment amount. Using more complete claims data, and as calculated previously, the permanent adjustment to the CY 2026 30-day payment rate would be a reduction of 4.162 percent.

As described previously in this final rule, to account for such increases or decreases in estimated aggregate expenditures as a result of the impact of differences between assumed behavior changes and actual behavior changes in any given year from 2020 to 2026, we calculate one or more temporary prospective adjustments by calculating the dollar amount difference between the estimated aggregate expenditures from all 30-day periods using the recalculated 30-day base payment rate, and the aggregate expenditures for all 30-day periods using the actual 30-day base payment rate for that year. In other words, when determining the temporary retrospective dollar amount, we used the full dataset of actual 30-day periods using both the actual and recalculated 30-day base payment rates to ensure that the utilization and distribution of claims are the same. We refer readers to the CY 2024 HH PPS final rule (88 FR 77689 through 77694) for analysis of CYs 2020 through 2022 claims, the CY 2025 HH PPS final rule (89 FR 88366 through 88369) for analysis of CY 2023 claims, and section II.C.1.d. of this final rule for the analysis of CY 2024 claims. Table 6 provides a summary of the temporary adjustment dollar amount for CYs 2020 through 2026 as shown in the CY 2026 proposed rule (90 FR 29132).

TABLE 6: SUMMARY OF TEMPORARY ADJUSTMENTS DOLLAR AMOUNTS FOR CYs 2020 – 2026

Claims Analysis Year	Dollar Amount
CY 2020	-$873,073,121
CY 2021	-$1,211,002,953

Claims Analysis Year	Dollar Amount
CY 2022	-$1,405,447,290
CY 2023	- $971,431,113
CY 2024 – this final rule	- $870,279,955
CY 2025	TBD
CY 2026	TBD
Total (through CY 2024)	-$5,331,234,432

Source: CY 2020 Home Health Claims Data, Periods that begin and end in CY 2020 accessed on the CCW July 12, 2021. CY 2021 Home Health Claims Data, Periods that end in CY 2021 accessed on the CCW July 15, 2022. CY 2022 Home Health Claims Data, Periods that end in CY 2022 accessed on CCW July 15, 2023. CY 2023 Home Health Claims Data, Periods that end in CY 2023 accessed on CCW July 11, 2024. CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on CCW July 11, 2025.
Note: The anticipated temporary adjustments of approximately $5.3 billion (through CY 2024) will require temporary adjustment(s) to the base payment rate to offset for such increases in estimated aggregate expenditures. The dollar amount will be converted to a factor when implemented in future rulemaking.

Our analysis continues to show estimated aggregate expenditures are higher under the PDGM than if those same claims were paid under the prior 153-group system, though the data also show that the permanent adjustments we implemented in CY 2023 and CY 2024 successfully brought estimated aggregate expenditures closer to the statutorily required budget neutrality. In the CY 2022 HH PPS proposed rule (86 FR 65884), the CY 2023 HH PPS proposed rule (87 FR 37608), the CY 2024 HH PPS proposed rule (88 FR 43664), the CY 2025 HH PPS proposed rule (89 FR 55320), and CY 2026 HH PPS proposed rule (90 FR 29119), our analysis has shown that the annual national standardized 30-day period payment rate has exceeded the average estimated 30-day period cost. In addition, MedPAC has continued to find that FFS Medicare payments for home health care are substantially in excess of costs.[4]

Given these facts, we exercised our authority under section 1895(b)(3)(D)(iii) of the Act to propose applying "one or more" temporary adjustments to begin recoupment of the retrospective overpayments for CYs 2020 through 2024. Even though we have not yet calculated the temporary dollar amounts for CYs 2025 through 2026, we have done so for CYs 2020 through 2024, and the cumulative amount is substantial. Beginning to adjust the base payment rate now to account for the calculated temporary dollar amount to date may help reduce the need for a larger reduction in future years. We estimated that collecting the full temporary dollar

[4] https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch7_MedPAC_Report_To_Congress_SEC.pdf

amount of $5,331,234,432 in a single year (as shown in table 6) would require an approximate 34 percent reduction to the CY 2026 base payment rate. Additionally, we anticipate that we will need to make additional adjustments for CYs 2025 and 2026, once data for those years are available.

We have stated in past rules that implementing both the permanent and temporary adjustments in the same year may be burdensome to HHAs; however, in the CY 2026 HH PPS proposed rule (90 FR 29133), we proposed to implement a -5.0 percent temporary adjustment (rather than the estimated 34 percent) along with the permanent adjustment to reduce larger temporary adjustments in future years. Beginning to apply only a portion of the temporary adjustment in CY 2026 balances the underlying statutory goal of budget neutrality against any hardship to HHAs.

We proposed implementing a 5.0 percent reduction in CY 2026, that is equivalent to a 0.9500 temporary adjustment factor, to the CY 2026 national, standardized payment rate. Using historical trends, we estimated 7,723,632 number of 30-day periods will occur in CY 2026. Using this estimated utilization, a 5.0 percent reduction to the CY 2026 30-day payment rate would collect approximately $786 million of the total temporary adjustment dollar amount, equating to about 14.7 percent of the total $5.3 billion shown in table 6. In doing so, however, we will need to account for the remaining temporary adjustment dollar amount for CYs 2020 through 2024, plus any possible adjustments for CY 2025 and 2026, in future years. It is important to note that the estimated $786 million dollar amount anticipated to be collected by the implementation of the temporary adjustment factor is based on an estimate of the number of 30-day periods that will occur in CY 2026. It may not reflect the actual dollar amount to be collected if the actual number of 30-day periods and other utilization trends in CY 2026 differ from what was estimated. In other words, CMS will calculate the actual amount collected from the temporary adjustment in CY 2026 and credit it to the overall cumulative temporary dollar amount.

In accordance with section 1895(b)(3)(D)(iii) of the Act, we proposed applying the temporary adjustment on a prospective basis and only with respect to the year for which such a temporary increase or decrease is made. This means we will not include the -5.0 percent temporary adjustment applied for CY 2026 when calculating the CY 2027 base payment rates. However, to continue recoupment of the retrospective overpayments we may propose additional temporary adjustments in future rulemaking, whether -5.0 percent or a different amount. We will continue to analyze the data each year through CY 2026 claims as required by law, and in a time and manner deemed appropriate we would propose one or more additional temporary adjustments to account for retrospective overpayments. We refer readers to section II.E.3.b. of this final rule for the CY 2026 base payment rates with and without the temporary adjustment.

We solicited comments on the proposals to apply the permanent adjustment of -4.059 percent (-4.162 percent using more complete claims data) and the -5.0 percent temporary adjustment to the CY 2026 home health base payment rate. One commenter, the Medicare Payment Advisory Commission (MedPAC), supported the proposed permanent and temporary payment adjustments for CY 2026. MedPAC stated that the reduction to the base payment rate is generally consistent with their most recent recommendation calling for a seven percent reduction. They also stated that the home health base payment rate currently exceeds the estimated cost of a typical 30-day payment period by 33 percent. We received numerous comments opposing the permanent and temporary adjustment proposals as summarized as follows.

(1) Excluding Data from HHAs with Anomalous Behavior

Comment: Several commenters expressed concerns that the data used in the calculation is being influenced by potential fraudulent behavior and anomalous utilization from some home health agencies, as evidenced by potential cost report fraud and outlier billing patterns, specifically in Los Angeles (LA) County, and should not be included in the methodology used to set a national base payment rate. Many commenters also stated that the adjustments should target

agencies committing billing fraud, rather than making "blanket adjustments" to the home health payment rate based on HHAs who reduced therapy visits in order to increase payments.

Additionally, commenters stated that cost reports are largely non-representative of actual costs to provide care. They stated that the underreporting of costs can be due to the design and/or misunderstanding of the intent of the cost reports themselves; however, the commenter acknowledged that it is also a consequence of more providers not giving the cost reports the attention that they deserve. Commenters also cited lack of auditing by CMS to ensure cost reports are completely and accurately filled out.

A commenter stated that the current strategy creates a feedback loop whereby reduced reimbursements result in HHAs being less capable of providing the same number of therapy visits, triggering CMS to further reduce reimbursements because fewer visits are provided. Similarly, a commenter suggested CMS review the home health agency admission criteria to ensure that agencies are not exclusively admitting patients that may perform favorably on OASIS outcomes assessments and/or have a lower probability of hospitalization as a consideration for targeted payment adjustments.

Response: Both cost reports and claims are used as part of the rate setting for home health. We remind commenters that each HHA Medicare cost report is required to be certified by the Officer or Director of the home health agency as being true, correct, and complete, with potential penalties should any information in the cost report be a misrepresentation or falsification of information. Specifically, 42 CFR 413.24(f)(4)(iv)(B) states that misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine and/or imprisonment under federal law. Furthermore, if services identified in this report were provided or procured through the payment directly or indirectly of a kickback or were otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result. CMS must rely on the accuracy and completeness of cost report data when analyzing home health costs. Using HHA Medicare cost

report data as one piece of the methodology to establish the case-mix relative weight aligns with the use of this data in determining the base payment amount under the HH PPS.

As discussed in the CY 2019 final rule (83 FR 56451), we use a trimming methodology described in detail in the ‘‘Analyses in Support of Rebasing & Updating Medicare Home Health Payment Rates’’ Report available at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/homehealthpps/downloads/analyses-in-support-of-rebasing-and-updating-the-medicare-home-health-payment-rates-technical-report.pdf. This methodology trims out values that fall in the top or bottom 1 percent of the distribution across all HHAs (that is, possible “questionable” data). Normalizing data by trimming out missing or extreme values is a widely accepted methodology both within CMS and amongst the health research community. In eliminating missing or questionable data with extreme values from the data we obtain a more robust measure of average costs per visit that is reliable for the purposes of establishing base payment amounts and case-mix weights under the HH PPS.

Furthermore, not all anomalous billing patterns indicate fraudulent practice, and we would need further evidence to determine which providers with anomalous billing patterns can be connected to fraudulent practices. Excluding data some commenters view as “anomalous” from the calculation of the national 30-day base payment rate, would thus require CMS to develop a new policy, including thresholds for determining deviations excluded from the analytical sample.

As always, we encourage providers to fill out the Medicare cost reports as accurately as possible. We note that there are efforts to monitor cost reports if there are concerns over the reported information. CMS audits home health cost reports through the Medicare Administrative Contractors (MACs) and the Center for Program Integrity (CPI). The cost report certification and associated penalties generally encourages HHAs to accurately represent the incurred costs of providing home health care. Any additional thresholds used for the exclusion criteria based on data anomalies would need to be discussed during notice and comment rulemaking. We have not

proposed such considerations previously and we decline to do so now because we must balance commenter concerns about reducing the number of claims through too many exclusions, which could also impact the results, with commenter concerns about possible fraudulent behavior which may be limited to a small subset of providers.

We do consider anomalous patterns to determine whether we should review cost reports and claims and might initiate investigation for evidence of fraud, waste, and abuse. CPI determines which providers may warrant program integrity actions. We generally have not excluded providers accused of fraud, waste, and abuse from samples before completing the adjudicatory process, and decline to do so for LA county claims. In addition, excluding all LA County claims might be overinclusive: anomalies have not shown up in the data from all home health providers in LA county, and even for those with anomalous data, investigation might vindicate their claims.

In previous rules, commenters have suggested targeted payment adjustments to certain providers, even under the previous 153-group payment system. We addressed these suggestions in the CY 2016 HH PPS and CY 2019 HH PPS final rules (80 FR 68421 and 83 FR 56455, respectively). In those rules we stated that this strategy is not viable, given the widespread nature of coding changes and improvements, small sample sizes of agencies with significant nominal case-mix across different classes of agencies, and difficulty in precisely distinguishing the agencies that engage in abusive coding and other behaviors from all others. Additionally, we reiterate that we are required to make temporary and permanent payment adjustments to the national, standardized 30-day period payment rate based on the impact of differences between assumed versus actual behavior change, in accordance with sections 1895(b)(3)(D)(ii) and (iii) to offset for such increases or decreases in estimated aggregate expenditures. These adjustments are not intended to account for coding abuses by specific HHAs, but rather overall behavior changes CMS observes across the system.

Cost report fraud and abusive billing behavior are concerns that need to be addressed by the appropriate channels with the authority to apply enforcement action, such as the hotline for reporting fraud at the following website: https://www.cms.gov/medicare/medicaid-coordination/center-program-integrity/reporting-fraud

(2) Provider Margins and Access

Comment: Commenters expressed concerns that CMS does not consider all-payer margins when considering application of the behavior payment adjustments. Commenters suggested that CMS should consider all-payer margins as these are much lower than Medicare margins and therefore CMS should not apply a downward adjustment to the payment rate because this would result in all-payer margins going even lower and will cause HHAs to go out of business. Some commenters referenced analysis from the CMS Office of the Actuary (OACT)[5] regarding providers with negative total facility margins. Commenters stated that OACT estimated that over one-third of HHAs have negative total profit margins with simulations suggesting that measure approaches nearly 45 percent by 2027 and nearly 60 percent by 2040. One commenter stated that this likely means agencies will place a heavier emphasis on keeping higher margins and reduce services to patients generating smaller payments, while another commenter stated directly that their agency will be forced to reduce their geographic service region, particularly the rural areas, in order to avoid financial losses. Some commenters also stated the adjustments would inhibit providers from investing in needed technology such as remote patient monitoring, electronic health records, and artificial intelligence that could ultimately save Medicare money. Commenters stated again that CMS needs to consider all-payer margins for home health rather than simply Medicare FFS margins. We also received several comments stating that further payment rate reductions will affect other payers that use Medicare as a benchmark to set payment (for example, Medicare Advantage (MA) plans).

[5] https://www.cms.gov/files/document/simulations-affordable-care-act-medicare-payment-update-provisions-part-provider-financial-margins.pdf-0

Response: We have considered OACT's report, which projected the impact of certain updates the Affordable Care Act made to Medicare payment rates on Part A provider financial margins.[6] We note that HHAs that are hospital-based have shown negative margins for numerous consecutive years, which MedPAC has suggested can be traced to how hospital-based HHAs allocate overhead costs from its parent hospital instead of the actual costs of providing home health care for which the home health payment system is meant to account.[7] Our analysis from the CY 2024 HH PPS final rule, shown in Table B6 (88 FR 77695), indicates that even prior to the PDGM, approximately 20 to 23 percent of freestanding HHAs had margins below zero percent, indicating that this phenomenon pre-dated the PDGM, and is not the result of the behavior adjustments related to the initial behavior assumptions applied in CY 2020 (88 FR 77695). In addition, the OACT report indicated that the percentage of HHAs with negative total facility margins was similar in 2011 and 2023.

With respect to the comment that CMS must look at the HHA's overall financial condition (that is, overall margins) or consider MA rates when setting FFS payment rates, we have never endorsed the view that Medicare funds allocated for FFS should be used to subsidize reimbursement rates from other payers, a policy that would be inconsistent with our obligation to be responsible stewards of the Medicare Trust Funds and would ultimately increase costs to Medicare beneficiaries, taxpayers, or both.

Comment: Many commenters noted a decrease in the number of HHAs, with some claiming that CMS data suggests that over 1,000 HHAs have closed between 2019 and 2024, and that home health users decreased by 20 percent. A commenter stated that hundreds of counties have become "home health deserts", meaning areas with a lack of HHAs, and specifically with declines in the number of HHAs of 40 percent or more. Several commenters also presented post-inpatient hospitalization discharge analysis showing declines in home health usage. Commenters

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[6] Ibid.

[7] https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch7_MedPAC_Report_To_Congress_SEC.pdf

stated that this would then increase overall Medicare spending, as beneficiaries would be forced to receive care in more expensive facilities such as hospitals and skilled nursing facilities. One commenter stated that the proposed rule fails to address previous evidence from providers, hospitals, and patients showing declining access to the benefit. Another commenter noted that HHAs would not be able to maintain the current level of access to care, particularly in an environment that far outweighs increases in payment and surges in administrative and staffing costs, which have more than doubled in recent years. Another commenter recommended CMS conduct a comprehensive impact analysis to determine how access has been affected before finalizing the proposed behavior adjustments. Commenters state that the behavior adjustments should not be applied to mitigate further closures of HHAs thereby creating access issues for beneficiaries.

Response: The CMS market saturation data set suggests that the change in the number of Medicare-certified HHAs is relatively small: the data reflects a 2.5 percent decrease from 2020-2025.[8] MedPAC suggests that much of the decline in the volume of home health use has been driven by a reduction in the number of beneficiaries in FFS Medicare, as a growing share of beneficiaries enroll in MA. [9] When controlling for FFS enrollment, the number of 30-day periods in 2023 decreased by 1.8 percent. At the same time, the share of FFS beneficiaries using home health has also declined, falling 2.3 percent in 2023.[10]

Using the CMS saturation data[11] within 2024, we do see some evidence of a reduction in the number of HHAs in certain geographic areas. The geographic areas that experienced decreases in providers serving the CBSA relative to 2023 are also likely to have a relatively low number of providers, such as Salisbury, Maryland and Hood River, Oregon. There are also areas

[8] https://data.cms.gov/summary-statistics-on-use-and-payments/program-integrity-market-saturation-by-type-of-service/market-saturation-utilization-core-based-statistical-areas
[9] https://www.medpac.gov/wp-content/uploads/2025/06/Jun25_ExecutiveSummary_MedPAC_Report_To_Congress_SEC.pdf
[10] Ibid.
[11] https://data.cms.gov/summary-statistics-on-use-and-payments/program-integrity-market-saturation-by-type-of-service/market-saturation-utilization-core-based-statistical-areas

that saw a decrease in providers, with an accompanying increase in number of home health users and increase in total payment change, such as Thomasville, Georgia and Clewiston, Florida. The dataset provides an incomplete view of how HHAs entering or exiting the market may affect home health use and total payments in the area. The differences in changes in total payments in the area and the resulting geographic market dynamics will likely vary based on the hospitals operating in the area, number of competing HHAs operating in the area, number of Medicare FFS beneficiaries, penetration of MA enrollment, number of post-acute facilities, dual-eligible beneficiaries, Medicaid policy for the state, as well as many other factors. While we agree that there are data that support some areas with reductions in HHAs, we note that this may not be solely attributable to the payment adjustments as there are other factors, as described previously, that could contribute to the ebb and flow of HHAs entering and exiting the market.

Commenters presented an analysis similar to the post-discharge analysis that we discussed in the CY 2025 HH PPS final rule (89 FR 88372). We found that 76 percent of acute inpatient hospital referrals have home health claims within 7 days of discharge compared to 62.6 percent of referrals from short-stay acute inpatient stays presented by the commenters.

We also presented the percentage of Medicare FFS home health claims within seven days of discharge by the preceding claim type in Figure 8 of the CY 2025 HH PPS final rule (89 FR 88372). In our analysis we found an average of 80 percent, 79 percent, and 75 percent using home after discharge to home health for 2018 (pre-PDGM), 2020 (PDGM), and 2023 (PDGM) respectively for Medicare FFS beneficiaries (89 FR 88372). In addition, MedPAC noted that data reported by HHAs to CMS indicate that 96.1 percent of home health services were initiated in a timely manner in 2023, a rate that was stable relative to 2022. As such, we do not believe that access has been compromised greatly since the implementation of the behavior adjustments, nor do we see statistical evidence presented by commenters, rather, anecdotal evidence.

(3) Methodological Concerns

Comment: Commenters suggested technical flaws in the methodology to determine the impact of differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures. These commenters also recommended changes to the methodology for the calculation of the permanent and temporary adjustments. Specifically, some commenters stated that CMS should account for decreases in home health payments from CYs 2020 through 2024, shrinking FFS enrollment, and payment offsets occurring through lower MA benchmarks.

Response: Commenters have suggested that there are technical flaws in the methodology in previous rulemaking (87 FR 66797). Specifically, previous commenters suggest that the methodology does not compare behaviors assumed by CMS in establishing the CY 2020 rate to actual behaviors observed on aggregate expenditures. We have responded to these concerns in past rulemaking stating that CMS is not required to correct or quantify each original assumption regarding HHA behavior change, but rather, ensure that the payment rate is accurately accounting for all behaviors related to the implementation of the PDGM and the 30-day unit of payment that actually occurred in a given year. We remind commenters that the changes in the aggregate expenditures under the PDGM between different years are not part of the repricing process and therefore not a variable in the methodology used to calculate the permanent and temporary adjustments. CMS continues to reiterate that the methodology is technically accurate in that it captures actual changes in behavior that have been explained in previous rulemaking, as well as this final rule. As required by law, our methodology compares aggregate expenditures between the actual 30-day periods and simulated 60-day episodes paid under the prior payment system within a single claims' year to determine what the payment rate should be to ensure that payments under the two systems would be equal.

We recognize the overall decline of home health utilization and payments over time, decreasing Medicare FFS enrollment, and the growing share of enrollment in MA. In their most recent report, MedPAC states that when controlling for FFS enrollment, the number of 30-day

periods in 2023 decreased by 1.8 percent from 2022.[12] However, we remind commenters that the statutory requirements for the permanent and temporary adjustments do not state that we need to account for changes in MA benchmarks. When setting home health payment rates, we look only at Medicare FFS home health payments , not MA payment rates, and have a legal obligation to reimburse costs for expenditures made under Medicare FFS based on 42 CFR part 413.5. In addition, it is unclear how we would separate out total home health expenditures from MA as individual provider payments differ amongst varying MA plans. Furthermore, home health payments from MA plans are not available in encounter claims and provider payments from different MA plans are considered proprietary information, which CMS cannot access.

Comment: Commenters suggested that CMS not apply the exclusions finalized in the CY 2023 final rule (87 FR 66804) for pricing simulated 60-day episodes, stating that excluded episodes have different characteristics than those included and introduce systemic bias undermining the accuracy of CMS's calculations. Commenters expressed concern over the increasing percentage of 30-day periods excluded from the sample. Commenters recommended that we include data that is currently excluded in our process for creating simulated 60-day episodes.

Response: We previously explained that the exclusion criteria in the finalized methodology dropped 30-day periods of care that had a claim occurrence code 50 after October 31, 2024, and before January 1, 2024, to ensure the 30-day period will not be part of a simulated 60-day period that began in 2023 and to ensure a simulated 60-day episode (simulated from two 30-day periods) does not overlap years (90 FR 29129). Additional exclusions include 60-day periods where no OASIS information was available, a recent SOC/ROC OASIS was not available, a wage index was not available, or the episode cannot be grouped to a Health Insurance Prospective Payment System (HIPPS) code due to a missing primary diagnosis or other reason. All the exclusion criteria are applied because the criteria are needed to

[12] MedPAC - March 2025 Report to Congress Chapter 7

appropriately price the simulated 60-day episodes for within the year the claims would have been paid. It is not relevant whether the 30-day periods that are excluded have different case-mix characteristics or higher visits if the 30-day periods are not able to be repriced accordingly as a simulated 60-day period. As stated in previous rulemaking (87 FR 66804), without these exclusions, we would not be confident we were appropriately grouping 30-day periods into simulated 60-day episodes. The excluded 30-day periods would need to show large differences compared to the episodes that were not excluded in order to significantly change the estimated aggregate expenditures from the 60-day episodes to produce significant revisions to our calculations. Additionally, the permanent adjustment is based on the percentage change between the payment rates (which utilizes the same claims), and the temporary adjustment is based on the aggregate expenditures of all claims (that is, no exclusions) using the two payment rates (that is, the actual payment rate and the budget neutral payment rate with the permanent adjustment applied). Therefore, we do not believe that the small portion of excluded claims significantly biased our results.

Comment: A commenter noted roughly 40 percent of the diagnoses previously allowed under the prior payment system are no longer accepted as a primary diagnosis under the PDGM. This commenter stated that this change may impact coding behavior and could potentially lead to the simulated 60-day episodes being inaccurately assigned.

Response: We refer readers to the CY 2023 HH PPS final rule (87 FR 66803) for a detailed response to this comment. In that rule, we stated that, while we acknowledge 41 percent (29,948) of all the diagnosis codes are not assigned a clinical group under the PDGM, we disagree that those unassigned codes would have created any significant difference in assigning the clinical level in the 153-group case-mix system. For example, out of all the diagnosis codes available in the final grouper for the 153-group case mix system, only 22 percent (15,936) of the diagnosis codes could potentially contribute to the clinical score. Of those codes which could

have contributed to the clinical score, only 6.99 percent (1,114) of the diagnosis codes are not accepted as a principal diagnosis under the PDGM.

Comment: Several commenters suggested that when simulating 60-day episodes we should update the calculation of payment under the prior system by including an update for recalibration of case-mix group weights and fixed dollar loss (FDL) for outlier payments. Commenters raised concerns about recalibration not controlling for the impact of COVID-19. Commenters claim that this introduces challenges in determining whether changes were due to PDGM or pandemic-related disruptions. These commenters stated that during the COVID-19 pandemic, hospitals discharged differently and there were more staffing shortages and telehealth substitution for visits, which was not representative of long-term care delivery. Commenters specifically noted that CMS did not apply any COVID-specific exclusions, implement control periods, spillover analysis, or validation checks in the methodology. Commenters referred to these issues as a methodological gap that undermines the validity of CMS's behavior adjustment calculations.

Response: If we were to implement an updated FDL instead of using the finalized CY 2020 final rule FDL to determine outlier payments under the simulated episodes, it is unclear whether it would be an accurate representation to retrospectively assign the necessary FDL to hit a 2.5 percent target for the years after CY 2020. In addition, updating the FDL for the 153-group payment system would require an iterative process to adjust the PDGM FDL used in repricing to also hit the 2.5 percent target of total PDGM expenditures. We note that the 2.5 percent is only a target amount that is set prospectively and is never reconciled and adjusted for.

If we were to implement recalibration of case-mix weights (including early vs. late visits or admission source) when determining aggregate payments under the 60-day payment system, the aggregate expenditures would not change because we would implement the recalibration of case-mix weights in a budget neutral manner. In other words, although the case-mix weights themselves may increase or decrease from year-to-year, we correspondingly offset any estimated

increases or decreases in total payments under the HH PPS, as a result of the case-mix recalibration, by applying a budget neutrality factor to the national, standardized payment rate. Recalibrating the pre-PDGM case-mix weights to reflect changes due to COVID-19 would not increase the aggregate payments estimated for simulated 60-day periods paid under pre-PDGM. Since we are comparing a single year of data priced under the PDGM and 153-group case-mix system, COVID-19 wouldn't bias the PDGM payments differently than the 153-group or vice-versa. In the CY 2022 HH PPS final rule (86 FR 62249), we discussed the influence of the COVID-19 PHE on home health utilization and finalized a proposal to recalibrate the PDGM case-mix weights, functional impairment levels, and comorbidity subgroups while maintaining the LUPA thresholds for CY 2022. We stated that, because there are several factors that contribute to how the case-mix weight is set for a particular case-mix group (such as the number of visits, length of visits, types of disciplines providing visits, and non-routine supplies) and the case-mix weight is derived by comparing the average resource use for the case-mix group relative to the average resource use across all groups, we believed the COVID-19 PHE would have impacted utilization within all case-mix groups similarly. Therefore, the impact of any reduction in resource use caused by the COVID-19 PHE on the calculation of the case-mix weight would be minimal since the impact would be accounted for both in the numerator and denominator of the formula used to calculate the case-mix weight.

Comment: Many commenters recommended that CMS apply the Patient Driven Payment Model (PDPM) parity adjustment methodology used in the CY 2023 Skilled Nursing Facility (SNF) PPS final rule (87 FR 47502) to the PDGM data.

Response: As we stated in the CY 2023 HH PPS final rule (87 FR 66802), the SNF PPS and HH PPS are different; SNFs are paid a per-diem payment with different case-mix variables, and HHAs are paid under a bundled payment system. In addition, unlike the requirements of the SNF PPS parity adjustment, CMS is required, by law, to account for behavior changes related to the implementation of the PDGM, which CMS did by comparing actual PDGM claims to what

the same utilization (for example, visits, OASIS responses, etc.) would look like under a 60-day unit of payment.

Comment: Commenters stated that relying on a simulation of payments under the pre-PDGM payment system establishes a budget neutrality target that places an artificial limit on current PDGM payments.

Response: We finalized the methodology for estimating payments under the PDGM and simulated 60-day periods in the pre-PDGM system in the CY 2023 final rule (87 FR 66804). While it is unclear why the commenter states repricing establishes a budget neutrality target that places an artificial limit on current PDGM payments, we would like to remind commenters that repricing compares expenditures paid under the PDGM and pre-PDGM systems to determine if we are paying more under the PDGM than we otherwise would have absent the new payment system (that is, the 153-group system). Then if it is determined that we are paying more under the PDGM then we determine what the recalculated PDGM budget neutral payment rate for the claims year would be. Regardless of the magnitude and frequency of individual behavior change (for example, changes in LUPAs, therapy, etc.), the occurrence of any behavior change is captured by the methodology to determine the impact on aggregate expenditures. The methodology does not cap or limit the increase of expenditures in a given year as it uses the actual utilization for that year to reprice claims. Meaning, if utilization goes up from one year to another, expenditures in turn increase as well, so we disagree with commenters that state we are limiting PDGM payments as the expenditures are directly tied to the services that providers are, or are not, providing.

(4) Suggested Change in Timeframe for Behavior Change Adjustments

Comment: Several commenters suggested that the behavior change observed after CY 2021 is no longer related to the implementation of the PDGM and change in the unit of payment and that we stop the adjustments after this timeframe. Commenters pointed out factors such as differences in visit thresholds for assigning case-mix adjusted claims as LUPAs between

simulated 60-day episodes and actual 30-day periods, bias in timing assignment for episodes, potential bias in clinical group assignments for acuity, mapping limitations for assumptions cross-walking OASIS-E to OASIS-D responses for missing OASIS items, and overall mismatch of patterns between 2019 60-day episodes and simulated 60-day episodes, such as therapy thresholds. Commenters reminded CMS that the law requires that any permanent or temporary payment adjustment be related to only the impact of differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures that could occur as a result of the implementation of the new case-mix system and change in the unit of payment. Commenters mentioned additional changes that influenced behavior change beyond the implementation of the PDGM: application of the permanent adjustments reducing payments to a point where providers had to make business decisions to ensure adequate provision of services, recalibration and LUPA updates, introduction of the OASIS-E in CY 2023, expansion of the HHVBP Model, and increased MA penetration, among other things. Commenters stated that CMS should not consider behavior change that could be unrelated to the implementation of the PDGM when calculating the permanent and temporary adjustments, as this would be counter to what the law requires. Commenters stated that the exclusion of data from CY 2022 and beyond would result in the need for a 1 percent increase to the 30-day payment rate in CY 2026 and necessitate recalculating the temporary adjustment amounts for CYs 2020 and 2021 to offset the amount already collected in CY 2025 because the base rate for 2025 was set too low. Similarly, other commenters requested CMS pause the permanent adjustment this year until stable, post-pandemic data can be evaluated. This commenter suggested this data collection would begin in 2023.

Response: For the reasons described later in section, we agree with commenters in part and will not finalize the proposed -4.059% permanent payment adjustment based on the analysis in the proposed rule that concluded a -4.059% permanent adjustment was necessary to account for behavior changes from CY 2024 (based on the updated calculations described previously in

this final rule, the final calculation results in a -4.162% reduction). We will instead finalize a -1.023 percent permanent adjustment (see calculation in the final decision), which is based only on changes in estimated aggregate expenditures that we previously calculated for CYs 2020 through 2022 and finalized through notice and comment in rulemaking for CY 2023 and 2024 (FR 87 66886 and FR 88 77869).

In the CY 2026 proposed rule (90 FR 29119 through 29126), we discussed various trends identified in monitoring changes related to the PDGM using analysis of CY 2024 claims. We agree with commenters to the extent that this data might suggest that there were large changes at the start of the PDGM. These changes, that may indicate that HHAs were adapting to the implementation of a new case-mix system, have decreased in magnitude (90 FR 29121 through 29125) to the extent we believe that the implementation of the PDGM is the reason for these changes through CY 2022; however, as discussed by commenters, CMS implemented policy changes in CYs 2023 through 2025 that could have prompted behavior change not directly attributable to the PDGM.

CMS policy changes implemented in CYs 2023 through 2025 might make it difficult to precisely distinguish the behavior changes related to the extenuating factors such as those mentioned by commenters and those behavior changes related to the implementation of the PDGM, based on analysis included in the proposed rule. These policy changes include recalibration of case-mix weights and LUPA visit thresholds finalized in the CY 2023, 2024, and 2025 final rules; reassignment of certain ICD-10-CM codes related to the PDGM clinical groups and comorbidity groups in the CY 2023 final rule; finalizing permanent adjustments in the CY 2023, 2024, and 2025 final rules; and the introduction of OASIS-E in 2023 and finalized mapping of OASIS-E to OASIS-D in the CY 2025 final rule for calculating functional points for functional impairment levels during repricing; and the expanded HHVBP Model.

Because it is difficult to definitively isolate the behaviors directly related to the PDGM implementation after CY 2022, we are only finalizing a permanent adjustment based on data

from CYs 2020 through 2022. As required by law, we will continue to analyze data through CY 2026 claims to determine if any additional permanent adjustments are needed to account for the impact of assumed versus actual behavior change related to the implementation of the PDGM and the change to a 30-day unit of payment on estimated aggregate expenditures. Further, when analyzing the overall home health trends, such as the distribution of 30-day periods of care by the twelve PDGM clinical groups, distribution of 30-day periods of care by admission source and timing, distribution of 30-day periods of care by functional impairment level, distribution of 30-day periods with therapy and non-therapy visits, and average therapy visits per 30-day period by clinical group (Tables 6, 8, 9, 10, and Figure 3 in 90 FR 29121 through 29125), we see indicators that suggest provider behavior changed more significantly in the years immediately following the implementation of the PDGM, but has decreased in magnitude overall starting in CY 2023.

We disagree with commenters to the extent they suggest that we should not rely on data from CY 2022 but should only use CYs 2020-2021 claims for calculating the behavior adjustments. As noted previously and as shown in the CY 2026 HH PPS proposed rule (90 FR 29119 through 29126), our analysis supports that the observed behavior changes in CYs 2020 through 2022 are attributable to the implementation of the PDGM and the 30-day unit of payment. Therefore, since the observed behavior change directly attributable to the implementation of the PDGM transpired in CYs 2020 through 2022, and not CYs 2020 and 2021 as the commenters suggest, we disagree with commenters that a 1 percent increase in the 30-day payment rate in CY 2026 is warranted. We are also recalculating the temporary adjustments for CYs 2023 and 2024 (see Table 7). For those reasons, instead of the -4.059% adjustment we proposed, we will finalize the -1.023% remaining adjustment for CY 2026 (see calculation in the final decision later in this section).

Comment: A commenter requested CMS adopt a phased approach to implementing the temporary adjustment, moderating the annual impact to providers, and requested CMS propose a

timeframe for collecting the temporary adjustment amount in order to allow providers to business plan.

Response: We recognize the rationale for this commenter's request and stated in the proposed rule that implementing both the permanent and temporary adjustments in the same year may be burdensome to HHAs, hence why we proposed only to implement a smaller temporary adjustment (rather than the estimated 34 percent) along with the permanent adjustment, which should lessen any hardship to HHAs, as well as reduce larger temporary adjustments in future years. We did not propose that the -5.0 percent temporary adjustment would be applied each year after CY 2026, rather that we would continue to analyze the data each year through CY 2026 claims as required by law, and in a time and manner deemed appropriate we would propose one or more temporary adjustments to account for retrospective overpayments. We will take into consideration the suggestion to develop a timeframe for these adjustments in order to create a more stable business planning environment.

Comment: Commenters recommended that CMS also not make temporary adjustments based on data from CY 2022 and beyond. Commenters describe how the data is not appropriate for determining behavior change due to PDGM versus other unrelated factors as summarized in the preceding comment.

Response: We thank commenters for the recommendation and have considered how to recalculate the temporary adjustments based on the various reasons raised by the commenters. We agree that there have been multiple other factors that likely have affected changes in provider behavior, separate and distinct from the implementation of the PDGM and the change to a 30-day unit of payment in CY 2020. As discussed in this final rule, we believe that the majority of change in response to the PDGM and the change to a 30-day unit of payment occurred in CYs 2020 through -2022. As such, we have recalculated the temporary adjustment amount using the inalized methodology for CYs 2020 through 2022 (see Table 7).

Final Decision: As discussed in the comment/responses on the permanent and temporary behavior adjustments, there are several factors that make it difficult to determine changes resulting from the implementation of PDGM and non-PDGM-related behaviors, such as the recalibration of case-mix weights and LUPA visit thresholds and changes in the distribution of 30-day periods by PDGM clinical groups, therapy visits, admission source and timing, and functional impairment level beginning in CY 2023. Additionally, we have observed a decrease in the magnitude of these changes in our monitoring beginning in CY 2023. As such, we are only finalizing the remaining permanent adjustment needed to account for behavior change attributable to the implementation of the PDGM calculated using only the claims experience for CYs 2020 through 2022.

Permanent Adjustment

Based on consideration of the public comments and reevaluation of PDGM trends, we are finalizing for CY 2026 the following:

- We exercise the authority expressly delegated under the statute to apply permanent adjustments "at a time and in a manner appropriate" to apply the remaining permanent adjustment of -1.023 percent (see the following calculations) to account for behavior change related to the implementation of the PDGM in CYs 2020 through 2022.

- We exercise the same authority not to apply any permanent adjustment based on CY 2023 or 2024 data. In future rulemaking, we will provide additional analysis on 2023 and 2024 data to support that behavior changes in these years are attributable to factors beyond the implementation of the PDGM and a 30-day unit of payment. However, we will continue to annually analyze the data through CY 2026 claims, as required by law, to determine if any additional permanent adjustments would need to be made based on the impact of assumed versus actual behavior change on estimated aggregate expenditures resulting from the implementation of the PDGM and the 30-day unit of payment.

- The CY 2026 permanent adjustment is calculated using the permanent adjustments already applied to the CYs 2023, 2024, and 2025 finalized payment rates and to determine the payment rate reduction needed for CYs 2020 through 2022. These steps are summarized in the following:

When calculating the payment rate reduction for CYs 2020 through 2022, we multiply the annual permanent adjustment factors calculated for each of those years (accounting for -6.52 percent or 0.9348 finalized for CY 2020 claims, -1.42 percent or 0.9858 finalized for CY 2021 claims, and -1.767 percent or 0.9823 finalized for CY 2022 claims) which is approximately a cumulative payment rate reduction of -9.480 percent or 0.9052 needed to account for behavior change and the difference in aggregate expenditures for CYs 2020 through 2022.

Total Permanent Adjustment needed for CYs 2020 through 2022 =

0.9348 x 0.9858 x 0.9823 = 0.9052

We determine what payment rate reduction is needed through a permanent payment adjustment, by dividing the payment rate reduction needed for CYs 2020 through 2022 by the cumulative payment rate reduction already applied from the permanent adjustments implemented in prior final rules. When calculating the cumulative payment reduction applied, we account for the -3.925 percent or 0.96075 applied in CY 2023 final rule, -2.890 percent or 0.97110 applied in CY 2024 final rule, and -1.975 percent or 0.98025 applied in CY 2025 final rule, to calculate the cumulative permanent payment adjustment applied to be 0.91456. When we divide 0.9052 (payment rate reduction needed for CY 2020 through 2022) by 0.91456 (payment rate reduction applied in CYs 2023 through 2025 final rules), we determine that -1.023 percent or 0.9898 needs to be applied as a permanent adjustment to the CY 2026 30-day payment rate and to reach the payment rate reduction needed for CYs 2020 through 2022.

Total Permanent Adjustment applied in CYs 2023 through 2025 =

0.96075 x 0.97110 x 0.98025 = 0.91456

Total Permanent Adjustment [to be applied] for CY 2026 =

0.9052 / 0.91456 = 0.98977

1-0.98977 = 1.023 percent

We determine that a permanent adjustment of -1.023 percent applied to CY 2026 30-day payment rate is needed to account for behavior change for CYs 2020 through 2022 based on the repricing methodology finalized in the CY 2023 final rule. Therefore, we are finalizing a -1.023 percent permanent adjustment to the CY 2026 30-day payment rate.

We note that the law requires us to annually determine the impact of differences between assumed behavior changes and actual behavior changes on estimated aggregate expenditures through CY 2026 claims. That is, we will continue to apply the finalized methodology through CY 2026 claims. However, while the law requires us to continue to evaluate the need for any additional permanent adjustments in future rulemaking, we reiterate that any additional permanent adjustment(s) would be related to actual behavior change resulting only from the implementation of the PDGM and the change in the unit of payment as required by law.

Though we are calculating and only finalizing the remaining permanent adjustment for CYs 2020-2022 in this final rule, we may still see an accrual in the temporary adjustment dollar amount. In other words, while the permanent adjustment accounts for the prospective payment amount needed to prevent future overpayments, the temporary adjustment will account for the prior overpayment and difference between expenditures for actual and recalculated budget neutral payment rates.

Temporary Adjustment

Finalizing applying a permanent adjustment of -1.023 percent to CY 2026 for CYs 2020 through 2022 means we need to reconcile the difference between the finalized budget neutral rate and the new budget neutral rate for CY 2023 to calculate the new temporary adjustment dollar amounts. In the CY 2025 final rule, we compared the difference in the actual CY 2023 payment rate of $2,010.69 and the PDGM budget neutral rate of $1,875.46. Since we are finalizing a permanent adjustment of -1.023 percent to account for behavior change in CYs 2020 through

2022 claims, this means, the recalculated budget neutral rate for CY 2023 should be $1,894.43. We determined what the budget neutral rate for CY 2023 should be by adjusting what the actual CY 2023 finalized payment rate was and accounting for the permanent adjustment already applied to the CY 2023 payment rate and the remainder needed to apply to CY 2023 for the payment rate reduction needed for CYs 2020 through 2022.

$2,010.69 x (1 – (1-0.9052/0.96075) = $1,894.43

For the recalculated budget neutral CY 2024 payment rate, we update the CY 2023 recalculated budget neutral payment rate by applying the CY 2024 case-mix weights recalibration neutrality factor (1.0124), the CY 2024 wage index budget neutrality factor (1.0012), the CY 2024 labor-related share budget neutrality factor (0.9998), and the CY 2024 home health payment update factor (1.030). We determined the recalculated budget neutral CY 2024 base payment rate would have been $1,977.43.

$1,894.43 x (1.0124) x (1.0012) x (0.9998) x (1.030) = $1,977.43

Using the recalculated budget neutral payment rates for CY 2023 and 2024, we determine the new temporary adjustments for those two years by comparing what the difference in aggregate expenditures would have been for those two years when comparing expenditures with the actual payments and estimated expenditures with payments under the recalculated budget neutral payment rate. We present the new temporary adjustments for CY 2023 and 2024 in Table 7.

TABLE 7: TEMPORARY ADJUSTMENT DOLLAR AMOUNTS RECALCULATED FOR CYS 2020 – 2026

Claims Analysis Year	Dollar Amount
CY 2020	-$873,073,121
CY 2021	-$1,211,002,953
CY 2022	-$1,405,447,290
CY 2023	-$836,208,180
CY 2024 – this final rule	-$430,435,218
CY 2025	TBD
CY 2026	TBD
Total (through CY 2024)	-$4,756,166,762

Source: CY 2020 Home Health Claims Data, Periods that begin and end in CY 2020 accessed on the CCW July 12, 2021. CY 2021 Home Health Claims Data, Periods that end in CY 2021 accessed on the CCW July 15, 2022. CY 2022 Home Health Claims Data, Periods that end in CY 2022 accessed on CCW July 15, 2023. CY 2023 Home

Health Claims Data, Periods that end in CY 2023 accessed on CCW July 11, 2024. CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on CCW July 11, 2025.
Note: The anticipated temporary adjustments of approximately $4.7 billion (through CY 2024) will require temporary adjustment(s) to the base payment rate to offset for such increases in estimated aggregate expenditures. The dollar amount will be converted to a factor when implemented in future rulemaking.

In this final rule, we exercise our authority under section 1895(b)(3)(D)(iii) of the Act to apply "one or more" temporary adjustments to begin recoupment of the retrospective overpayments for CYs 2020 through 2024. However, we have considered commenters' concerns about the magnitude of a -5.0 percent temporary adjustment in tandem with any finalized permanent adjustment. As such, we are finalizing implementing a 3.0 percent reduction in CY 2026, that is equivalent to a 0.9700 temporary adjustment factor, to the CY 2026 national, 30-day payment rate. By implementing a -3.0 percent temporary adjustment, we can begin recoupment of retrospective overpayments. We determined that the total temporary adjustment dollar amount is approximately $4.7 billion through CY 2024 and that implementing a -3.0 percent temporary adjustment may allow us to recoup $471 million of this total dollar amount. We estimate we will be able to recoup $471 million if CY 2026 claims have approximately 7.7 million case-mix adjusted 30-day periods. Any additional temporary adjustments needed to recoup the total temporary adjustment will be discussed in future rulemaking. Also, in response to comments, we will consider a schedule for the temporary adjustment in future rulemaking as well.

We will continue with our monitoring of the trends in home health utilization, including the number of visits, diagnosis reporting, and other data that we present in our monitoring section to analyze behavior changes that are and are not related to the implementation of the PDGM and the 30-day unit of payment. We will present this analysis in future rulemaking along with our calculations of the impact of the difference between assumed versus actual behavior change on estimated aggregate expenditures to ensure that any potential future adjustments would be the result of the implementation of the PDGM and the 30-day unit of payment.

D. CY 2026 Home Health Low Utilization Payment Adjustment (LUPA) Thresholds, Functional Impairment Levels, Comorbidity Sub-Groups, and Case-Mix Weights.

1. Final CY 2026 PDGM LUPA Thresholds

Under the HH PPS, LUPAs are paid when a certain visit threshold for a payment group during a 30-day period of care is not met. In the CY 2019 HH PPS final rule with comment period (83 FR 56492), we finalized a policy setting the LUPA thresholds at the 10th percentile of visits or two visits, whichever is higher, for each PDGM payment group. This means the LUPA threshold for each 30-day period of care varies depending on the PDGM payment group to which it is assigned. If the LUPA threshold for the payment group is met under the PDGM, the 30-day period of care will be paid the full 30-day period case-mix adjusted payment amount (subject to any partial payment adjustment or outlier adjustments). If a 30-day period of care does not meet the PDGM LUPA visit threshold, then payment will be made using the per-visit payment amounts as described in section II.E.4.c. of this final rule. For example, if the LUPA visit threshold is four, and a 30-day period of care has four or more visits, it is paid the full 30-day period payment amount; if the period of care has three or fewer visits, payment is made using the per-visit payment amounts.

In the CY 2019 HH PPS final rule with comment period (83 FR 56492), we finalized our policy that the LUPA thresholds for each PDGM payment group will be reevaluated every year based on the most current utilization data available at the time of rulemaking. However, as CY 2020 was the first year of the new case-mix adjustment methodology, we stated in the CY 2021 HH PPS final rule (85 FR 70305 and 70306) that we will maintain the LUPA thresholds that were finalized and shown in table 17 of the CY 2020 HH PPS final rule with comment period (84 FR 60522) for CY 2021 payment purposes. We stated at that time, we did not have sufficient CY 2020 data to reevaluate the LUPA thresholds for CY 2021.

In the CY 2022 HH PPS final rule with comment period (86 FR 62249), we finalized the proposal to recalibrate the PDGM case-mix weights, functional impairment levels, and comorbidity subgroups while maintaining the LUPA thresholds for CY 2022. We stated that because there are several factors that contribute to how the case-mix weight is set for a particular

case-mix group (such as the number of visits, length of visits, types of disciplines providing visits, and non-routine supplies) and the case-mix weight is derived by comparing the average resource use for the case-mix group relative to the average resource use across all groups, we believe the COVID-19 PHE would have impacted utilization within all case-mix groups similarly. Therefore, the impact of any reduction in resource use caused by the PHE on the calculation of the case-mix weight will be minimized since the impact will be accounted for both in the numerator and denominator of the formula used to calculate the case-mix weight. However, in contrast, the LUPA thresholds are based on the number of overall visits in a particular case-mix group (the threshold is the 10th percentile of visits or 2 visits, whichever is greater) instead of a relative value (like what is used to generate the case-mix weight) that will control for the impacts of the COVID-19 PHE. We noted that visit patterns and some of the decrease in overall visits in CY 2020 may not be representative of visit patterns in CY 2022. Therefore, to mitigate any potential future and significant short-term variability in the LUPA thresholds due to the COVID-19 PHE, we finalized the proposal to maintain the LUPA thresholds finalized and displayed in table 17 in the CY 2020 HH PPS final rule with comment period (84 FR 60522) for CY 2022 payment purposes.

For CY 2024, we proposed to update the LUPA thresholds using CY 2022 Medicare home health claims (as of March 17, 2023) linked to OASIS assessment data. We believed that CY 2022 data would have been more indicative of visit patterns in CY 2024 rather than continuing to use the LUPA thresholds derived from the CY 2018 data pre-PDGM. Therefore, we finalized a policy to update the LUPA thresholds for CY 2024 using data from CY 2022.

For CY 2025, we proposed to update the LUPA thresholds using CY 2023 home health claims utilization data (as of March 19, 2024), in accordance with our policy to annually recalibrate the case-mix weights and update the LUPA thresholds, functional impairment levels and comorbidity subgroups. Therefore, we finalized the functional points and functional

impairment level updates for CY 2025 as proposed, using updated CY 2023 claims data (as of July 11, 2024).

For CY 2026, we proposed to update the LUPA thresholds using CY 2024 home health claims utilization data (using more complete CY 2024 claims data as of July 11, 2025), in accordance with our policy to annually recalibrate the case-mix weights and update the LUPA thresholds, functional impairment levels, and comorbidity subgroups. After reviewing the CY 2024 home health claims utilization data, we determined that LUPA visit patterns in 2024 were similar to visits in 2023 and a total of 18 case-mix groups have a decline in their LUPA threshold of a single visit. The proposed LUPA thresholds for the CY 2026 PDGM payment groups with the corresponding Health Insurance Prospective Payment System (HIPPS) codes and the case-mix weights can be found in the CY 2026 HH PPS proposed rule (90 FR 29145).

We solicited public comment on the proposed updates to the LUPA thresholds for CY 2026. The following is a summary of the comments we received and our responses:

Comment: The majority of the commenters expressed support for the proposed updates to the LUPA thresholds and recognized that these updates are necessary to help align payments more closely with evolving care delivery and improve payment accuracy. However, multiple commenters expressed concern that ongoing upward adjustments to some of the LUPA thresholds seem to be arbitrary and not fully supported by clinical evidence. As such, these commenters recommended that the LUPA thresholds remain static or clinically justified, and that there be an established monitoring system that is able to identify providers with abnormally low LUPA rates in an effort to ensure care delivery reflects medical appropriateness rather than potential payment manipulation.

Response: We thank the commenters for their feedback and their support for the annual update of the LUPA thresholds. Our policy is that the LUPA thresholds for each PDGM payment group will be reevaluated every year based on the most current utilization data available at the time of rulemaking. While the visit patterns and utilization data do not constitute clinical

evidence, we note that the LUPA thresholds are annually updated to correspond with the visit patterns associated with each home health resource group, which we do monitor and include in the rule. More specifically, the visit patterns/utilization data serve as the most accurate method to update the LUPA thresholds, as the LUPA rates correspond to provider behavior that correlates with the visit patterns/utilization data as opposed to clinical standards. We could consider a separate monitoring system for those providers who have abnormally low LUPA rates in future rulemaking. However, this could potentially require collaboration on potential program integrity efforts. We also note that low LUPA rates do not necessarily mean that a provider is acting inappropriately. We believe updating the LUPA thresholds is the most accurate way to reflect the provision of home health visits based on the most current utilization data available at the time of rulemaking.

Final Decision: We are finalizing the proposal to update the LUPA thresholds for CY 2026 using CY 2024 claims data (as of July 11, 2025). The final LUPA thresholds for the CY 2026 PDGM payment groups with the corresponding Health Insurance Prospective Payment System (HIPPS) codes and the case-mix weights are listed in table 8 and are also available on the HHA Center web page, located at https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/home-health-agency-center.

2. Final CY 2026 Functional Impairment Levels

Under the PDGM, the functional impairment level is determined by responses to certain OASIS items associated with activities of daily living and risk of hospitalization; that is, responses to OASIS items M1800-M1860 and M1033. A home health period of care receives points based on each of the responses associated with these functional OASIS items, which are then converted into a table of points corresponding to increased resource use. The sum of all these points results in a functional impairment score which is used to group home health periods into a functional level with similar resource use. That is, the higher the points, the more the response is associated with increased resource use, or increased impairment. The three functional

impairment levels of low, medium, and high were designed so that approximately one-third of home health periods from each clinical group falls within each level. This means home health periods in the low impairment level have responses for the functional OASIS items that are associated with the lowest resource use, on average. Home health periods in the high impairment level have responses for the functional OASIS items that are associated with the highest resource use on average.

For CY 2026, we proposed to use CY 2024 claims data to update the functional points and functional impairment levels by clinical group. The CY 2018 HH PPS proposed rule (82 FR 35320) and the technical report from December 2016, posted on the Home Health PPS Archive web page, located at https://www.cms.gov/medicare/home-health-pps/home-health-pps-archive, provides a more detailed explanation as to the construction of the functional impairment levels using the OASIS items. We proposed to use the same methodology previously finalized to update the functional impairment levels for CY 2026. The final updated OASIS functional points table and the table of functional impairment levels by clinical group for CY 2026 are listed in tables 8 and 9, respectively.

TABLE 8: FINAL OASIS POINTS TABLE FOR CY 2026

	Responses	CY 2026 Points	Percent of Periods with this Response Category*
M1800: Grooming	0 or 1	**0**	**23.2%**
	2 or 3	**3**	**76.8%**
M1810: Current Ability to Dress Upper Body	0 or 1	**0**	**17.5%**
	2 or 3	**5**	**82.5%**
M1820: Current Ability to Dress Lower Body	0 or 1	**0**	**8.5%**
	2	**4**	**64.1%**
	3	**12**	**27.4%**
M1830: Bathing	0 or 1	**0**	**2.2%**
	2	**2**	**9.4%**
	3 or 4	**10**	**48.7%**
	5 or 6	**17**	**39.8%**
M1840: Toilet Transferring	0 or 1	**0**	**59.4%**
	2, 3 or 4	**6**	**40.6%**
M1850: Transferring	0	**0**	**1.0%**
	1	**1**	**17.3%**
	2, 3, 4 or 5	**4**	**81.7%**
M1860: Ambulation/Locomotion	0 or 1	**0**	**2.8%**
	2	**5**	**13.1%**
	3	**1**	**66.2%**
	4, 5 or 6	**20**	**17.8%**
M1033: Risk of Hospitalization	Three or fewer items marked (Excluding responses 8, 9 or 10)	**0**	**56.4%**

	Four or more items marked (Excluding responses 8, 9 or 10)	**12**	**43.6%**

Source: CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed from the CCW on July 11, 2025.
Note: For item M1860, the point values for response 2 is worth more than the point values for response 3. There may be times in which the resource use for certain OASIS items associated with functional impairment will result in a seemingly inverse relationship to the response reported. However, this is the result of the direct association between the responses reported on the OASIS items and actual resource use.

TABLE 9: FINAL THRESHOLDS FOR FUNCTIONAL IMPAIRMENT LEVELS BY CLINICAL GROUP, FOR CY 2026

Clinical Group	Level of Impairment	CY 2026 Points
MMTA – Other	Low	**0-30**
	Medium	**31-45**
	High	**46+**
Behavioral Health	Low	**0-31**
	Medium	**32-46**
	High	**47+**
Complex Nursing Interventions	Low	**0-31**
	Medium	**32-54**
	High	**55+**
Musculoskeletal Rehabilitation	Low	**0-31**
	Medium	**32-45**
	High	**46+**
Neuro Rehabilitation	Low	**0-34**
	Medium	**35-52**
	High	**53+**
Wound	Low	**0-33**
	Medium	**34-52**
	High	**53+**
MMTA - Surgical Aftercare	Low	**0-30**
	Medium	**31-42**
	High	**43+**
MMTA - Cardiac and Circulatory	Low	**0-28**
	Medium	**29-43**
	High	**44+**
MMTA - Endocrine	Low	**0-27**
	Medium	**28-41**
	High	**42+**
MMTA - Gastrointestinal tract and Genitourinary system	Low	**0-34**
	Medium	**35-48**
	High	**49+**
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases	Low	**0-32**
	Medium	**33-46**
	High	**47+**
MMTA - Respiratory	Low	**0-33**
	Medium	**34-46**
	High	**47+**

Source: CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed from the CCW on July 11, 2025.

We solicited public comment on the proposed updates to the functional points and the thresholds for functional impairment levels by clinical group. The following is a summary of the comments we received and our responses:

Comment: Several commenters opposed the proposed updates to the CY 2026 functional impairment points and levels. These commenters described the proposed changes to functional impairment scoring as arbitrary, nontransparent, and reflecting changes that are not aligned with actual patient characteristics. Several of these commenters cited that high acuity patients (providing examples such as beneficiaries with multiple sclerosis) will require constant supervision and are misclassified into low functional levels, which ultimately results in underpayment. Some commenters objected to the division of patients into evenly distributed impairment categories and stated that this approach does not reflect the increasing acuity of all functional levels. Some commenters also questioned whether CMS uses discharge assessments instead of the Start of Care (SOC) OASIS items, which they state leads to potentially misrepresenting resource needs. Some commenters also emphasized that they believe the point value changes in OASIS scoring devalues clinically significant indicators including indicators such as ambulation or therapy needs, leading to a risk in undermining access to medically necessary services. As such, these commenters suggested that CMS provide greater transparency in methodology, reevaluate impairment thresholds, and incorporate social determinants of health into the scoring process to more accurately capture the complexities of home health patients.

Response: We appreciate the commenters' feedback and recommendations. We note that we proposed and finalized the methodology which utilizes those OASIS items specifically related to functional status, as well as the use of the start of care OASIS for calculating the functional impairment level in the CY 2019 HH PPS final rule (83 FR 56454). At this time, we do not use OASIS items associated with social determinants of health but could consider this in future rulemaking. We use the follow-up OASIS near the time of recertification for the third and fourth 30-day periods of care. This helps to ensure that the functional impairment level is determined to correspond with expected resource use. We do not use the discharge OASIS given the beneficiary would no longer be receiving home health services. Still, we maintain that annual recalibration is vital to ensuring the most accurate and current assessment of the relationship

between resource use and functional points, functional impairment levels, comorbidities, utilization thresholds, and case-mix weights. We contend that the use of the most up-to-date data in revising functional impairment levels is integral to ensure that all variables used in the case-mix adjustment process align with the actual costs of delivering home health services. Also, we note that the functional impairment levels are structured so that approximately one-third of periods within each clinical group are assigned to low, medium, and high categories, as this ensures that the case-mix system appropriately reflects differences in functional impairment. This classification of functional impairment has been a fundamental component of the HH PPS since its implementation and remains essential under the PDGM. Previously, the HH PPS grouped home health episodes using functional scores based on functional OASIS items with similar average resource use within the same functional level, with approximately a third of episodes classified as low functional score, a third of episodes classified as medium functional score, and a third of episodes classified as high functional score. Likewise, the PDGM groups home health periods of care using functional impairment scores based on functional OASIS items with similar resource use and have three levels of functional impairment severity: low, medium, and high. However, the PDGM differs from the previous HH PPS functional variable, in that the three functional impairment level thresholds in the PDGM vary between the clinical groups. As such, the PDGM functional impairment structure accounts for patient characteristics within each clinical group that are associated with increased resource use due to functional impairment. This ensures that payment is more accurately aligned with patient characteristics, including beneficiaries who have greater need with activities of daily living (ADLs) and who are more functionally impaired. Updating the functional impairment levels based on the most current OASIS and claims data ensures that the payment system captures changes in functional impairment and the associated increases in resource use. Regardless of whether patients entering home health are more impaired due to shifts in the broader health care system or any other influence, the functional levels capture the relationship between functional status as indicated on

the OASIS with resource use captured on claims. While we acknowledge commenters' concerns, we emphasize that the proposed recalibration is designed to strengthen the alignment between payment and patient characteristics, not to diminish access to medically necessary services. As such, updating the functional levels would specifically capture any changes in functional impairment and any changes in resource use associated with ADLs.

Final Decision: We are finalizing the functional points and functional impairment level updates for CY 2026 as proposed, using updated CY 2024 claims data (as of July 11, 2025).

3. Final CY 2026 Comorbidity Subgroups

Thirty-day periods of care receive a comorbidity adjustment category based on the presence of certain secondary diagnoses reported on home health claims. These diagnoses are based on a home-health specific list of clinically and statistically significant secondary diagnosis subgroups with similar resource use, meaning the diagnoses have at least as high as the median resource use and are reported in more than 0.1 percent of 30-day periods of care. Home health 30-day periods of care can receive a comorbidity adjustment under the following circumstances:

- *High comorbidity adjustment:* There are two or more secondary diagnoses on the home health-specific comorbidity subgroup interaction list that are associated with higher resource use when both are reported together compared to when they are reported separately. That is, the two diagnoses may interact with one another, resulting in higher resource use.
- *Low comorbidity adjustment:* There is a reported secondary diagnosis on the home health-specific comorbidity subgroup list that is associated with higher resource use.
- *No comorbidity adjustment:* A 30-day period of care receives no comorbidity adjustment if no secondary diagnoses exist or do not meet the criteria for a low or high comorbidity adjustment.

In the CY 2019 HH PPS final rule with comment period (83 FR 56406), we stated that we will continue to examine the relationship of reported comorbidities on resource utilization and make the appropriate payment refinements to help ensure that payment is in alignment with

the actual costs of providing care. For CY 2026, we proposed to use the same methodology used to establish the comorbidity subgroups to update the comorbidity subgroups using CY 2024 home health data with linked OASIS data.

For CY 2026, we proposed to update the comorbidity subgroups to include 20 low comorbidity adjustment subgroups and 100 high comorbidity adjustment interaction subgroups. The proposed CY 2026 low comorbidity adjustment subgroups and the high comorbidity adjustment interaction subgroups including those diagnoses within each of these comorbidity adjustments was included in the CY 2026 HH PPS proposed rule (90 FR 29136).

We solicited comments on the proposed updates to the low comorbidity adjustment subgroups and the high comorbidity adjustment interactions for CY 2026. Using more updated claims data (as of July 11, 2025), for CY 2026 there are 20 low comorbidity subgroups, and 98 high comorbidity subgroups as shown in tables 10 and 11.

TABLE 10: LOW COMORBIDITY ADJUSTMENT SUBGROUPS FOR CY 2026

Low Comorbidity Subgroup	Description
Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae
Circulatory 10	Varicose Veins and Lymphedema
Circulatory 2	Hemolytic, Aplastic, and Other Anemias
Circulatory 9	Other Venous Embolism and Thrombosis
Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease
Gastrointestinal 2	Intestinal Obstruction and Ileus
Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter
Heart 11	Heart Failure
Heart 5	Atherosclerotic Heart Disease with Angina
Musculoskeletal 1	Lupus
Neoplasms 17	Secondary neoplasms of respiratory and GI systems.
Neoplasms 18	Secondary Neoplasms of Urinary and Reproductive Systems, Skin, Brain, and Bone
Neoplasms 2	Malignant Neoplasms of Digestive Organs, includes Gastrointestinal Cancers
Neoplasms 6	Malignant neoplasms of trachea, bronchus, lung, and mediastinum
Neurological 10	Diabetes with neuropathy
Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
Skin 4	Stages Two-Four and unstageable pressure ulcers by site

Source: CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW July 11, 2025.

TABLE 11: HIGH COMORBIDITY ADJUSTMENT SUBGROUPS FOR CY 2026

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
1	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Circulatory 10	Varicose Veins and Lymphedema
2	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
3	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
4	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
5	Behavioral 2	Mood Disorders, includes Depression and Bipolar Disorder	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
6	Behavioral 4	Psychotic, major depressive, and dissociative disorders, includes unspecified dementia, eating disorder and intellectual disabilities	Circulatory 10	Varicose Veins and Lymphedema
7	Behavioral 4	Psychotic, major depressive, and dissociative disorders, includes unspecified dementia, eating disorder and intellectual disabilities	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
8	Behavioral 4	Psychotic, major depressive, and dissociative disorders, includes unspecified dementia, eating disorder and intellectual disabilities	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
9	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes
10	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Heart 11	Heart Failure
11	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Heart 12	Other Heart Diseases
12	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Infectious 1	C-diff, MRSA, E-coli
13	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Neurological 10	Diabetes with neuropathy
14	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
15	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Respiratory 2	Whooping cough
16	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
17	Cerebral 4	Sequelae of Cerebrovascular Diseases, includes Cerebral Atherosclerosis and Stroke Sequelae	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
18	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia

Source: CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW July 11, 2025.

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
19	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
20	Circulatory 1	Nutritional, Enzymatic, and Other Heredity Anemias	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
21	Circulatory 10	Varicose Veins and Lymphedema	Endocrine 1	Hypothyroidism
22	Circulatory 10	Varicose Veins and Lymphedema	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance
23	Circulatory 10	Varicose Veins and Lymphedema	Heart 8	Other Pulmonary Heart Diseases
24	Circulatory 10	Varicose Veins and Lymphedema	Heart 9	Valve Disorders
25	Circulatory 10	Varicose Veins and Lymphedema	Musculoskeletal 4	Lumbar Spinal Stenosis
26	Circulatory 10	Varicose Veins and Lymphedema	Neurological 10	Diabetes with neuropathy
27	Circulatory 10	Varicose Veins and Lymphedema	Renal 1	Chronic kidney disease and ESRD
28	Circulatory 10	Varicose Veins and Lymphedema	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
29	Circulatory 10	Varicose Veins and Lymphedema	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis
30	Circulatory 10	Varicose Veins and Lymphedema	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
31	Circulatory 10	Varicose Veins and Lymphedema	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
32	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Neoplasms 2	Malignant Neoplasms of Digestive Organs, includes Gastrointestinal Cancers
33	Circulatory 2	Hemolytic, Aplastic, and Other Anemias	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
34	Circulatory 4	Hypertensive Chronic Kidney Disease	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
35	Circulatory 4	Hypertensive Chronic Kidney Disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
36	Circulatory 4	Hypertensive Chronic Kidney Disease	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers

Source: CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW July 11, 2025.

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
37	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension	Circulatory 9	Other Venous Embolism and Thrombosis
38	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
39	Circulatory 7	Atherosclerosis, includes Peripheral Vascular Disease, Aortic Aneurysms and Hypotension	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
40	Circulatory 9	Other Venous Embolism and Thrombosis	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease
41	Circulatory 9	Other Venous Embolism and Thrombosis	Heart 11	Heart Failure
42	Circulatory 9	Other Venous Embolism and Thrombosis	Musculoskeletal 4	Lumbar Spinal Stenosis
43	Circulatory 9	Other Venous Embolism and Thrombosis	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
44	Circulatory 9	Other Venous Embolism and Thrombosis	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
45	Endocrine 1	Hypothyroidism	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
46	Endocrine 1	Hypothyroidism	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
47	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
48	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
49	Endocrine 3	Type 1, Type 2, and Other Specified Diabetes	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
50	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter
51	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Neoplasms 2	Malignant Neoplasms of Digestive Organs, includes Gastrointestinal Cancers
52	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Neurological 10	Diabetes with neuropathy
53	Endocrine 4	Other Combined Immunodeficiencies and Malnutrition, includes graft-versus-host-disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
54	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia

Source: CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW July 11, 2025.

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
55	Endocrine 5	Obesity, and Disorders of Metabolism and Fluid Balance	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
56	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
57	Heart 10	Dysrhythmias, includes Atrial Fibrillation and Atrial Flutter	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
58	Heart 11	Heart Failure	Neoplasms 2	Malignant Neoplasms of Digestive Organs, includes Gastrointestinal Cancers
59	Heart 11	Heart Failure	Neoplasms 6	Malignant neoplasms of trachea, bronchus, lung, and mediastinum
60	Heart 11	Heart Failure	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
61	Heart 11	Heart Failure	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
62	Heart 12	Other Heart Diseases	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
63	Heart 12	Other Heart Diseases	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
64	Heart 5	Atherosclerotic Heart Disease with Angina	Neurological 4	Alzheimer's disease and related dementias
65	Heart 7	Chronic Ischemic Heart Disease	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
66	Heart 8	Other Pulmonary Heart Diseases	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
67	Heart 8	Other Pulmonary Heart Diseases	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
68	Infectious 1	C-diff, MRSA, E-coli	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
69	Infectious 1	C-diff, MRSA, E-coli	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
70	Infectious 1	C-diff, MRSA, E-coli	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
71	Infectious 1	C-diff, MRSA, E-coli	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
72	Musculoskeletal 3	Joint Pain	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers

Source: CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW July 11, 2025.

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
73	Musculoskeletal 3	Joint Pain	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
74	Musculoskeletal 4	Lumbar Spinal Stenosis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
75	Musculoskeletal 4	Lumbar Spinal Stenosis	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
76	Neoplasms 17	Secondary neoplasms of respiratory and GI systems.	Neoplasms 2	Malignant Neoplasms of Digestive Organs, includes Gastrointestinal Cancers
77	Neoplasms 17	Secondary neoplasms of respiratory and GI systems.	Renal 1	Chronic kidney disease and ESRD
78	Neurological 10	Diabetes with neuropathy	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
79	Neurological 10	Diabetes with neuropathy	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
80	Neurological 12	Nondiabetic neuropathy	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease
81	Neurological 12	Nondiabetic neuropathy	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
82	Neurological 4	Alzheimer's disease and related dementias	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
83	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia
84	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Respiratory 4	Bronchitis, Emphysema, and Interstitial Lung Disease
85	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis
86	Neurological 5	Spinal Muscular Atrophy, Systemic atrophy and Motor Neuron Disease	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
87	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Neurological 8	Epilepsy
88	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD
89	Neurological 7	Paraplegia, Hemiplegia and Quadriplegia	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
90	Renal 1	Chronic kidney disease and ESRD	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis

Source: CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW July 11, 2025.

Comorbidity Subgroup Interaction	Comorbidity Group	Description	Comorbidity Group	Description
91	Renal 1	Chronic kidney disease and ESRD	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
92	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis
93	Renal 3	Other disorders of the kidney and ureter, excluding chronic kidney disease and ESRD	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
94	Respiratory 2	Whooping cough	Skin 4	Stages Two-Four and unstageable pressure ulcers by site
95	Respiratory 5	Chronic Obstructive Pulmonary Disease, and Asthma, and Bronchiectasis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
96	Respiratory 9	Respiratory Failure and Atelectasis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
97	Skin 1	Cutaneous Abscess, Cellulitis, and Lymphangitis	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers
98	Skin 3	Diseases of arteries, arterioles and capillaries with ulceration and non-pressure chronic ulcers	Skin 4	Stages Two-Four and unstageable pressure ulcers by site

Source: CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW July 11, 2025.

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

Comment: Commenters broadly expressed support for CMS's proposal to implement the proposed low and high comorbidity adjustments using CY 2024 claims data. Commenters stated these adjustments would result in more accurate payments, reflecting the resources required to effectively manage patients with these conditions. Additionally, commenters indicated that the proposed changes to the comorbidity subgroups should reflect the actual costs of providing care.

Response: We thank commenters for their support.

Comment: A commenter expressed concern for the elimination of certain diabetic subgroups and the removal of *Endocrine 2* from the low comorbidity list, citing that these actions may result in adverse consequences for beneficiaries that require intensive diabetes management. Another commenter recommended that CMS expand subgroup coding logic to include additional conditions such as rheumatic mitral and aortic valve disease, diabetes with mononeuropathy, and cystitis. Several commenters also raised concerns about inconsistencies with the high comorbidity pairings specifically as it relates to instances in which certain behavioral and circulatory conditions are paired with only one skin subgroup, *Skin 3* or *Skin 4*, despite comparable clinical risks. As such, these commenters recommended CMS expand pairings to better capture patient complexity and increase the alignment for current comorbidity adjustments so that there is arguably a more adequate reflection to the costs of patients with multiple chronic conditions in an effort to reduce systematic underpayment and potential access barriers. One commenter suggested refining the case-mix adjustment methodology, particularly as it related to the admission source variable and suggested that shifts from inpatient to outpatient and ambulatory surgical center settings alter the distribution of clinical complexity in ways not fully reflected in historical data.

Response: We appreciate commenters' review of the proposed comorbidity subgroup refinements. As outlined in the CY 2020 final rule with comment period (84 FR 60510) and

further detailed in the technical report *Overview of the Home Health Groupings Model*,[13] the home health specific comorbidity list is a result of principles of patient assessment by providers, as well as the evaluation of body systems and their associated diseases, conditions, and injuries, as this framework was specifically used to develop the clinically relevant categories that resultingly identify relationships that are tied to increased resource usage. We also acknowledge commenters' concerns regarding the elimination of certain diabetic subgroups and the removal of *Endocrine 2* from the low comorbidity list. However, we remind commenters that only the subgroups of diagnoses representing more than 0.1 percent of periods of care, and demonstrating at least the median resource use, will qualify for a low comorbidity adjustment. That said, the specific subgroups, including rheumatic mitral and aortic valve disease, diabetes with mononeuropathy, and cystitis, that do not meet these statistical and utilization thresholds ultimately do not qualify for inclusion in the payment adjustment, even if clinically complex. As a result, this ensures that payment adjustments are based on demonstrated cost patterns rather than clinical potential alone. In instances where the data does not demonstrate the requisite frequency or resource use associated with the condition, such diagnoses are not included in the adjustment. For example, in response to concerns about behavioral and circulatory conditions being paired with only one skin subgroup, *Skin 3* or *Skin 4*, despite comparable clinical risks, we again want to remind commenters that subgroup combinations are determined by observed utilization and statistical significance. If specific conditions do not meet the required thresholds in relation to particular ulcer types, they are not included in those pairings. Finally, we acknowledge the one commenter suggestion to refine the case-mix adjustment methodology, particularly regarding the admission source variable. We will continue to monitor these trends and assess whether refinements to the admission source variable are warranted in future rulemaking to ensure that the case-mix adjustment methodology remains accurate and responsive to evolving patterns of care.

[13] https://www.cms.gov/medicare/payment/prospective-payment-systems/home-health-pps/home-health-pps-archive

Final Decision: We are finalizing the updated comorbidity adjustment subgroups and the high comorbidity adjustment interactions using CY 2024 home health data. For CY 2026, the final updated comorbidity adjustment subgroups include 20 low comorbidity adjustment subgroups as identified in table 10 and 98 high comorbidity adjustment interaction subgroups as identified in table 11. The final CY 2026 low comorbidity adjustment subgroups and the high comorbidity adjustment interaction subgroups including those diagnoses within each of these comorbidity adjustments will also be posted on the HHA Center web page at *https://www.cms.gov/Center/Provider-Type/Home-Health-Agency-HHA-Center.*

4. Final CY 2026 PDGM Case-Mix Weights

As finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56502), the PDGM places patients into meaningful payment categories based on patient and other characteristics, such as timing, admission source, clinical grouping using the reported principal diagnosis, functional impairment level, and comorbid conditions. The PDGM case-mix methodology results in 432 unique case-mix groups called home health resource groups (HHRGs). We also finalized a policy in the CY 2019 HH PPS final rule with comment period (83 FR 56515) to annually recalibrate the PDGM case-mix weights using a fixed effects model with the most recent and complete utilization data available at the time of annual rulemaking. Annual recalibration of the PDGM case-mix weights ensures that the case-mix weights reflect, as accurately as possible, current home health resource use and changes in utilization patterns. To generate the proposed recalibrated CY 2026 case-mix weights, we used CY 2024 home health claims data with linked OASIS data (as of March 13, 2025). We included the proposed case-mix weights in table 25 of the proposed rule (90 FR 29145). In this final rule, we update these case-mix weights with claims data as of July 11, 2025, as shown in table 13. These data are the most current and complete data available at the time of this rulemaking.

The claims data provide visit-level data and data on whether non-routine supplies (NRS) were provided during the period and the total charges of NRS. We determine the case-mix

weight for each of the 432 different PDGM payment groups by regressing resource use on a series of indicator variables for each of the categories using a fixed effects model as described in the following steps:

Step 1: Estimate a regression model to assign a functional impairment level to each 30-day period. The regression model estimates the relationship between a 30-day period's resource use and the functional status and risk of hospitalization items included in the PDGM, which are obtained from certain OASIS items. We refer readers to table 25 of the proposed rule for further information on the OASIS items used for the functional impairment level under the PDGM. We measure resource use with the cost-per-minute + NRS approach that uses information from 2022 home health cost reports. We use 2022 home health cost report data because it is the most complete cost report data available at the time of rulemaking. Other variables in the regression model include the 30-day period's admission source, clinical group, and 30-day period timing. We also include home health agency level fixed effects in the regression model. After estimating the regression model using 30-day periods, we divide the coefficients that correspond to the functional status and risk of hospitalization items by 10 and round to the nearest whole number. Those rounded numbers are used to compute a functional score for each 30-day period by summing together the rounded numbers for the functional status and risk of hospitalization items that are applicable to each 30-day period. Next, each 30-day period is assigned to a functional impairment level (low, medium, or high) depending on the 30-day period's total functional score. Each clinical group has a separate set of functional thresholds used to assign 30-day periods into a low, medium, or high functional impairment level. We set those thresholds so that we assign roughly a third of 30-day periods within each clinical group to each functional impairment level (low, medium, or high).

Step 2: A second regression model estimates the relationship between a 30-day period's resource use and indicator variables for the presence of any of the comorbidities and comorbidity interactions that were originally examined for inclusion in the PDGM. Like the first regression

model, this model also includes home health agency level fixed effects and includes control variables for each 30-day period's admission source, clinical group, timing, and functional impairment level. After we estimate the model, we assign comorbidities to the low comorbidity adjustment if any comorbidities have a coefficient that is statistically significant (p-value of 0.05 or less) and which have a coefficient that is larger than the 50th percentile of positive and statistically significant comorbidity coefficients. If two comorbidities in the model and their interaction term have coefficients that sum together to exceed $150 and the interaction term is statistically significant (p-value of 0.05 or less), we assign the two comorbidities together to the high comorbidity adjustment.

Step 3: After Step 2, each 30-day period is assigned to a clinical group, admission source category, episode timing category, functional impairment level, and comorbidity adjustment category. For each combination of those variables (which represent the 432 different payment groups that comprise the PDGM), we then calculate the 10th percentile of visits across all 30-day periods within a particular payment group. If a 30-day period's number of visits is less than the 10th percentile for their payment group, the 30-day period is classified as a Low Utilization Payment Adjustment (LUPA). If a payment group has a 10th percentile of visits that is less than two, we set the LUPA threshold for that payment group to be equal to two. That means if a 30-day period has one visit, it is classified as a LUPA and if it has two or more visits, it is not classified as a LUPA.

Step 4: Take all non-LUPA 30-day periods and regress resource use on the 30-day period's clinical group, admission source category, episode timing category, functional impairment level, and comorbidity adjustment category. The regression includes fixed effects at the level of the home health agency. After we estimate the model, the model coefficients are used to predict each 30-day period's resource use. To create the case-mix weight for each 30-day period, the predicted resource use is divided by the overall resource use of the 30-day periods used to estimate the regression.

The case-mix weight is then used to adjust the base payment rate to determine each 30-day period's payment. Table BBB shows the coefficients of the payment regression used to generate the weights, and the coefficients divided by average resource use.

TABLE 12 - Coefficient of Payment Regression and Coefficient Divided by Average Resource Use for PDGM Payment Group

Variable	Coefficient	Percentage of 30-Day Periods for this Model	Coefficient Divided by Average Resource Use
Clinical Group and Functional Impairment Level (MMTA - Other - Low is excluded)			
MMTA - Other - Medium Functional	$152.49	1.4%	0.0000
MMTA - Other - High Functional	$323.26	1.2%	0.0000
MMTA - Surgical Aftercare - Low Functional	-$14.66	1.2%	0.0000
MMTA - Surgical Aftercare - Medium Functional	$168.01	1.2%	0.0000
MMTA - Surgical Aftercare - High Functional	$402.61	1.1%	0.0001
MMTA - Cardiac and Circulatory - Low Functional	-$30.27	6.0%	0.0000
MMTA - Cardiac and Circulatory - Medium Functional	$138.35	5.7%	0.0000
MMTA - Cardiac and Circulatory - High Functional	$323.13	5.9%	0.0000
MMTA - Endocrine - Low Functional	$478.58	2.5%	0.0001
MMTA - Endocrine - Medium Functional	$554.47	2.2%	0.0001
MMTA - Endocrine - High Functional	$692.45	2.4%	0.0001
MMTA - Gastrointestinal tract and Genitourinary system - Low Functional	-$40.67	1.8%	0.0000
MMTA - Gastrointestinal tract and Genitourinary system - Medium Functional	$139.65	1.6%	0.0000
MMTA - Gastrointestinal tract and Genitourinary system - High Functional	$323.13	1.7%	0.0000
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Low Functional	$0.88	1.6%	0.0000
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - Medium	$156.16	1.7%	0.0000
MMTA - Infectious Disease, Neoplasms, and Blood-Forming Diseases - High Functional	$413.75	1.4%	0.0001
MMTA - Respiratory - Low Functional	-$13.88	2.5%	0.0000
MMTA - Respiratory - Medium Functional	$162.68	2.4%	0.0000
MMTA - Respiratory - High Functional	$342.72	2.2%	0.0000
Behavioral Health - Low Functional	-$79.11	0.7%	0.0000
Behavioral Health - Medium Functional	$149.22	0.8%	0.0000
Behavioral Health - High Functional	$285.85	0.7%	0.0000
Complex - Low Functional	-$34.30	0.9%	0.0000
Complex - Medium Functional	$211.56	0.9%	0.0000
Complex - High Functional	$154.56	0.9%	0.0000
MS Rehab - Low Functional	$44.59	7.3%	0.0000
MS Rehab - Medium Functional	$192.84	7.2%	0.0000
MS Rehab - High Functional	$423.12	6.8%	0.0001
Neuro - Low Functional	$200.62	3.7%	0.0000
Neuro - Medium Functional	$374.49	3.9%	0.0000
Neuro - High Functional	$624.31	3.4%	0.0001

Source: *CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW July 11, 2025.*

Variable	Coefficient	Percentage of 30-Day Periods for this Model	Coefficient Divided by Average Resource Use
Clinical Group and Functional Impairment Level (MMTA - Other - Low is excluded)			
Wound - Low Functional	$729.09	4.9%	0.0001
Wound - Medium Functional	$867.08	4.5%	0.0001
Wound - High Functional	$1,100.51	4.6%	0.0001
Admission Source with Timing (Community Early is excluded)			
Community - Late	-$573.64	63.9%	-0.0001
Institutional - Early	$352.41	18.7%	0.0000
Institutional - Late	$234.26	6.1%	0.0000
Comorbidity Adjustment (No Comorbidity Adjustment - is excluded)			
Comorbidity Adjustment - Has at least one comorbidity from comorbidity list, no	$97.92	45.4%	0.0000
Comorbidity Adjustment - Has at least one interaction from interaction list	$343.30	18.7%	0.0000
Constant	$1,578.29		
Average Resource Use	$1,725.37		
Number of 30-day Periods	7,600,103		
Adjusted R-Squared	0.3086		

Source: *CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW July 11, 2025.*

The final updated case-mix weights for CY 2026 are listed in table 13 and will also be posted on the HHA Center web page[14] upon display of this final rule.

14 https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/home-health-agency-center

TABLE 13 – CASE-MIX WEIGHTS AND LUPA THRESHOLDS FOR EACH HHRG PAYMENT GROUP

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1FC11	Behavioral Health - High	Early - Community	0	1.0804	4
1FC21	Behavioral Health - High	Early - Community	1	1.1372	4
1FC31	Behavioral Health - High	Early - Community	2	1.2794	4
2FC11	Behavioral Health - High	Early - Institutional	0	1.2847	4
2FC21	Behavioral Health - High	Early - Institutional	1	1.3414	4
2FC31	Behavioral Health - High	Early - Institutional	2	1.4837	4
3FC11	Behavioral Health - High	Late - Community	0	0.7480	2
3FC21	Behavioral Health - High	Late - Community	1	0.8047	2
3FC31	Behavioral Health - High	Late - Community	2	0.9469	2
4FC11	Behavioral Health - High	Late - Institutional	0	1.2162	3
4FC21	Behavioral Health - High	Late - Institutional	1	1.2730	3
4FC31	Behavioral Health - High	Late - Institutional	2	1.4152	3
1FA11	Behavioral Health - Low	Early - Community	0	0.8689	3
1FA21	Behavioral Health - Low	Early - Community	1	0.9257	3
1FA31	Behavioral Health - Low	Early - Community	2	1.0679	3
2FA11	Behavioral Health - Low	Early - Institutional	0	1.0732	3
2FA21	Behavioral Health - Low	Early - Institutional	1	1.1299	3
2FA31	Behavioral Health - Low	Early - Institutional	2	1.2721	2
3FA11	Behavioral Health - Low	Late - Community	0	0.5364	2
3FA21	Behavioral Health - Low	Late - Community	1	0.5932	2
3FA31	Behavioral Health - Low	Late - Community	2	0.7354	2
4FA11	Behavioral Health - Low	Late - Institutional	0	1.0047	3
4FA21	Behavioral Health - Low	Late - Institutional	1	1.0614	2
4FA31	Behavioral Health - Low	Late - Institutional	2	1.2036	3
1FB11	Behavioral Health - Medium	Early - Community	0	1.0012	4
1FB21	Behavioral Health - Medium	Early - Community	1	1.0580	4
1FB31	Behavioral Health - Medium	Early - Community	2	1.2002	3
2FB11	Behavioral Health - Medium	Early - Institutional	0	1.2055	3

Source: *CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW July 11, 2025.*

LUPA Visit Threshold (LUPAs have fewer visits than the threshold)	HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
2	2FB21	Behavioral Health - Medium	Early - Institutional	1	1.2622	4
2	2FB31	Behavioral Health - Medium	Early - Institutional	2	1.4045	4
2	3FB11	Behavioral Health - Medium	Late - Community	0	0.6688	2
3	3FB21	Behavioral Health - Medium	Late - Community	1	0.7255	2
2	3FB31	Behavioral Health - Medium	Late - Community	2	0.8677	2
2	4FB11	Behavioral Health - Medium	Late - Institutional	0	1.1370	3
2	4FB21	Behavioral Health - Medium	Late - Institutional	1	1.1938	3
3	4FB31	Behavioral Health - Medium	Late - Institutional	2	1.3360	4
3	1DC11	Complex - High	Early - Community	0	1.0043	2
3	1DC21	Complex - High	Early - Community	1	1.0611	2
2	1DC31	Complex - High	Early - Community	2	1.2033	2
2	2DC11	Complex - High	Early - Institutional	0	1.2086	3
2	2DC21	Complex - High	Early - Institutional	1	1.2653	3
3	2DC31	Complex - High	Early - Institutional	2	1.4076	3
3	3DC11	Complex - High	Late - Community	0	0.6719	2
3	3DC21	Complex - High	Late - Community	1	0.7286	2
4	3DC31	Complex - High	Late - Community	2	0.8708	2
3	4DC11	Complex - High	Late - Institutional	0	1.1401	2
3	4DC21	Complex - High	Late - Institutional	1	1.1969	2
4	4DC31	Complex - High	Late - Institutional	2	1.3391	2
4	1DA11	Complex - Low	Early - Community	0	0.8949	2
4	1DA21	Complex - Low	Early - Community	1	0.9516	2
2	1DA31	Complex - Low	Early - Community	2	1.0938	2
2	2DA11	Complex - Low	Early - Institutional	0	1.0991	3
3	2DA21	Complex - Low	Early - Institutional	1	1.1559	3
3	2DA31	Complex - Low	Early - Institutional	2	1.2981	3
3	3DA11	Complex - Low	Late - Community	0	0.5624	2
3	3DA21	Complex - Low	Late - Community	1	0.6192	2

Source: *CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW July 11, 2025.*

Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)	HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026
0.8972	4	3DA31	Complex - Low	Late - Community	2	0.7614
0.9540	3	4DA11	Complex - Low	Late - Institutional	0	1.0306
1.0962	4	4DA21	Complex - Low	Late - Institutional	1	1.0874
1.1015	3	4DA31	Complex - Low	Late - Institutional	2	1.2296
1.1582	4	1DB11	Complex - Medium	Early - Community	0	1.0374
1.3004	4	1DB21	Complex - Medium	Early - Community	1	1.0941
0.5647	2	1DB31	Complex - Medium	Early - Community	2	1.2363
0.6215	2	2DB11	Complex - Medium	Early - Institutional	0	1.2416
0.7637	2	2DB21	Complex - Medium	Early - Institutional	1	1.2984
1.0330	3	2DB31	Complex - Medium	Early - Institutional	2	1.4406
1.0897	3	3DB11	Complex - Medium	Late - Community	0	0.7049
1.2320	3	3DB21	Complex - Medium	Late - Community	1	0.7616
0.9949	4	3DB31	Complex - Medium	Late - Community	2	0.9039
1.0517	4	4DB11	Complex - Medium	Late - Institutional	0	1.1731
1.1939	3	4DB21	Complex - Medium	Late - Institutional	1	1.2299
1.1992	4	4DB31	Complex - Medium	Late - Institutional	2	1.3721
1.2559	4	1HC11	MMTA - Cardiac - High	Early - Community	0	1.1020
1.3982	4	1HC21	MMTA - Cardiac - High	Early - Community	1	1.1588
0.6625	2	1HC31	MMTA - Cardiac - High	Early - Community	2	1.3010
0.7192	2	2HC11	MMTA - Cardiac - High	Early - Institutional	0	1.3063
0.8614	2	2HC21	MMTA - Cardiac - High	Early - Institutional	1	1.3630
1.1307	3	2HC31	MMTA - Cardiac - High	Early - Institutional	2	1.5053
1.1875	3	3HC11	MMTA - Cardiac - High	Late - Community	0	0.7696
1.3297	3	3HC21	MMTA - Cardiac - High	Late - Community	1	0.8263
1.3161	4	3HC31	MMTA - Cardiac - High	Late - Community	2	0.9685
1.3728	4	4HC11	MMTA - Cardiac - High	Late - Institutional	0	1.2378
1.5151	4	4HC21	MMTA - Cardiac - High	Late - Institutional	1	1.2946
1.5203	4	4HC31	MMTA - Cardiac - High	Late - Institutional	2	1.4368

Source: *CY 2024 Home Health Claims Data,*

Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)	HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)
1.5771	4	1HA11	MMTA - Cardiac - Low	Early - Community	0
1.7193	4	1HA21	MMTA - Cardiac - Low	Early - Community	1
0.9836	3	1HA31	MMTA - Cardiac - Low	Early - Community	2
1.0404	3	2HA11	MMTA - Cardiac - Low	Early - Institutional	0
1.1826	3	2HA21	MMTA - Cardiac - Low	Early - Institutional	1
1.4519	4	2HA31	MMTA - Cardiac - Low	Early - Institutional	2
1.5086	4	3HA11	MMTA - Cardiac - Low	Late - Community	0
1.6508	4	3HA21	MMTA - Cardiac - Low	Late - Community	1
1.1921	4	3HA31	MMTA - Cardiac - Low	Late - Community	2
1.2489	4	4HA11	MMTA - Cardiac - Low	Late - Institutional	0
1.3911	4	4HA21	MMTA - Cardiac - Low	Late - Institutional	1
1.3964	3	4HA31	MMTA - Cardiac - Low	Late - Institutional	2
1.4531	4	1HB11	MMTA - Cardiac - Medium	Early - Community	0
1.5954	4	1HB21	MMTA - Cardiac - Medium	Early - Community	1
0.8597	3	1HB31	MMTA - Cardiac - Medium	Early - Community	2
0.9164	3	2HB11	MMTA - Cardiac - Medium	Early - Institutional	0
1.0586	3	2HB21	MMTA - Cardiac - Medium	Early - Institutional	1
1.3279	3	2HB31	MMTA - Cardiac - Medium	Early - Institutional	2
1.3847	3	3HB11	MMTA - Cardiac - Medium	Late - Community	0
1.5269	3	3HB21	MMTA - Cardiac - Medium	Late - Community	1
1.2361	5	3HB31	MMTA - Cardiac - Medium	Late - Community	2
1.2929	4	4HB11	MMTA - Cardiac - Medium	Late - Institutional	0
1.4351	4	4HB21	MMTA - Cardiac - Medium	Late - Institutional	1
1.4404	4	4HB31	MMTA - Cardiac - Medium	Late - Institutional	2
1.4971	4	1IC11	MMTA - Endocrine - High	Early - Community	0
1.6393	4	1IC21	MMTA - Endocrine - High	Early - Community	1
0.9036	3	1IC31	MMTA - Endocrine - High	Early - Community	2
0.9604	3	2IC11	MMTA - Endocrine - High	Early - Institutional	0

Source: *CY 2024 Home Health Claims Data, Periods*

Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)	HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)
1.1026	3	2IC21	MMTA - Endocrine - High	Early - Institutional	1
1.3719	4	2IC31	MMTA - Endocrine - High	Early - Institutional	2
1.4286	3	3IC11	MMTA - Endocrine - High	Late - Community	0
1.5709	4	3IC21	MMTA - Endocrine - High	Late - Community	1
1.1020	3	3IC31	MMTA - Endocrine - High	Late - Community	2
1.1588	3	4IC11	MMTA - Endocrine - High	Late - Institutional	0
1.3010	2	4IC21	MMTA - Endocrine - High	Late - Institutional	1
1.3063	3	4IC31	MMTA - Endocrine - High	Late - Institutional	2
1.3630	3	1IA11	MMTA - Endocrine - Low	Early - Community	0
1.5053	3	1IA21	MMTA - Endocrine - Low	Early - Community	1
0.7696	2	1IA31	MMTA - Endocrine - Low	Early - Community	2
0.8263	2	2IA11	MMTA - Endocrine - Low	Early - Institutional	0
0.9685	2	2IA21	MMTA - Endocrine - Low	Early - Institutional	1
1.2378	3	2IA31	MMTA - Endocrine - Low	Early - Institutional	2
1.2946	3	3IA11	MMTA - Endocrine - Low	Late - Community	0
1.4368	3	3IA21	MMTA - Endocrine - Low	Late - Community	1
0.8912	2	3IA31	MMTA - Endocrine - Low	Late - Community	2
0.9479	2	4IA11	MMTA - Endocrine - Low	Late - Institutional	0
1.0902	3	4IA21	MMTA - Endocrine - Low	Late - Institutional	1
1.0954	3	4IA31	MMTA - Endocrine - Low	Late - Institutional	2
1.1522	3	1IB11	MMTA - Endocrine - Medium	Early - Community	0
1.2944	3	1IB21	MMTA - Endocrine - Medium	Early - Community	1
0.5587	2	1IB31	MMTA - Endocrine - Medium	Early - Community	2
0.6155	2	2IB11	MMTA - Endocrine - Medium	Early - Institutional	0
0.7577	2	2IB21	MMTA - Endocrine - Medium	Early - Institutional	1
1.0270	3	2IB31	MMTA - Endocrine - Medium	Early - Institutional	2
1.0837	3	3IB11	MMTA - Endocrine - Medium	Late - Community	0
1.2259	3	3IB21	MMTA - Endocrine - Medium	Late - Community	1

Source: *CY 2024 Home Health Claims Data,*

Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)	HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)
0.9957	3	3IB31	MMTA - Endocrine - Medium	Late - Community	2
1.0524	2	4IB11	MMTA - Endocrine - Medium	Late - Institutional	0
1.1947	3	4IB21	MMTA - Endocrine - Medium	Late - Institutional	1
1.1999	3	4IB31	MMTA - Endocrine - Medium	Late - Institutional	2
1.2567	3	1JC11	MMTA - GI/GU - High	Early - Community	0
1.3989	4	1JC21	MMTA - GI/GU - High	Early - Community	1
0.6632	2	1JC31	MMTA - GI/GU - High	Early - Community	2
0.7200	2	2JC11	MMTA - GI/GU - High	Early - Institutional	0
0.8622	2	2JC21	MMTA - GI/GU - High	Early - Institutional	1
1.1315	3	2JC31	MMTA - GI/GU - High	Early - Institutional	2
1.1882	3	3JC11	MMTA - GI/GU - High	Late - Community	0
1.3304	3	3JC21	MMTA - GI/GU - High	Late - Community	1
1.1546	2	3JC31	MMTA - GI/GU - High	Late - Community	2
1.2113	2	4JC11	MMTA - GI/GU - High	Late - Institutional	0
1.3535	2	4JC21	MMTA - GI/GU - High	Late - Institutional	1
1.3588	3	4JC31	MMTA - GI/GU - High	Late - Institutional	2
1.4156	3	1JA11	MMTA - GI/GU - Low	Early - Community	0
1.5578	3	1JA21	MMTA - GI/GU - Low	Early - Community	1
0.8221	2	1JA31	MMTA - GI/GU - Low	Early - Community	2
0.8788	2	2JA11	MMTA - GI/GU - Low	Early - Institutional	0
1.0211	2	2JA21	MMTA - GI/GU - Low	Early - Institutional	1
1.2903	3	2JA31	MMTA - GI/GU - Low	Early - Institutional	2
1.3471	3	3JA11	MMTA - GI/GU - Low	Late - Community	0
1.4893	3	3JA21	MMTA - GI/GU - Low	Late - Community	1
0.9153	2	3JA31	MMTA - GI/GU - Low	Late - Community	2
0.9720	2	4JA11	MMTA - GI/GU - Low	Late - Institutional	0
1.1142	2	4JA21	MMTA - GI/GU - Low	Late - Institutional	1
1.1195	3	4JA31	MMTA - GI/GU - Low	Late - Institutional	2

Source: *CY 2024 Home Health Claims Data,*

Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)	HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)
1.1763	3	1JB11	MMTA - GI/GU - Medium	Early - Community	0
1.3185	3	1JB21	MMTA - GI/GU - Medium	Early - Community	1
0.5828	2	1JB31	MMTA - GI/GU - Medium	Early - Community	2
0.6395	2	2JB11	MMTA - GI/GU - Medium	Early - Institutional	0
0.7818	2	2JB21	MMTA - GI/GU - Medium	Early - Institutional	1
1.0510	3	2JB31	MMTA - GI/GU - Medium	Early - Institutional	2
1.1078	3	3JB11	MMTA - GI/GU - Medium	Late - Community	0
1.2500	3	3JB21	MMTA - GI/GU - Medium	Late - Community	1
1.0053	2	3JB31	MMTA - GI/GU - Medium	Late - Community	2
1.0620	2	4JB11	MMTA - GI/GU - Medium	Late - Institutional	0
1.2042	2	4JB21	MMTA - GI/GU - Medium	Late - Institutional	1
1.2095	3	4JB31	MMTA - GI/GU - Medium	Late - Institutional	2
1.2663	3	1KC11	MMTA - Infectious - High	Early - Community	0
1.4085	3	1KC21	MMTA - Infectious - High	Early - Community	1
0.6728	2	1KC31	MMTA - Infectious - High	Early - Community	2
0.7295	2	2KC11	MMTA - Infectious - High	Early - Institutional	0
0.8718	2	2KC21	MMTA - Infectious - High	Early - Institutional	1
1.1410	3	2KC31	MMTA - Infectious - High	Early - Institutional	2
1.1978	3	3KC11	MMTA - Infectious - High	Late - Community	0
1.3400	3	3KC21	MMTA - Infectious - High	Late - Community	1
1.1021	4	3KC31	MMTA - Infectious - High	Late - Community	2
1.1589	3	4KC11	MMTA - Infectious - High	Late - Institutional	0
1.3011	3	4KC21	MMTA - Infectious - High	Late - Institutional	1
1.3064	4	4KC31	MMTA - Infectious - High	Late - Institutional	2
1.3631	4	1KA11	MMTA - Infectious - Low	Early - Community	0
1.5053	4	1KA21	MMTA - Infectious - Low	Early - Community	1
0.7696	2	1KA31	MMTA - Infectious - Low	Early - Community	2
0.8264	2	2KA11	MMTA - Infectious - Low	Early - Institutional	0

Source: *CY 2024 Home Health Claims Data,*

Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)	HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)
0.9686	2	2KA21	MMTA - Infectious - Low	Early - Institutional	1
1.2379	3	2KA31	MMTA - Infectious - Low	Early - Institutional	2
1.2946	3	3KA11	MMTA - Infectious - Low	Late - Community	0
1.4369	3	3KA21	MMTA - Infectious - Low	Late - Community	1
0.9148	3	3KA31	MMTA - Infectious - Low	Late - Community	2
0.9715	3	4KA11	MMTA - Infectious - Low	Late - Institutional	0
1.1137	3	4KA21	MMTA - Infectious - Low	Late - Institutional	1
1.1190	3	4KA31	MMTA - Infectious - Low	Late - Institutional	2
1.1758	3	1KB11	MMTA - Infectious - Medium	Early - Community	0
1.3180	3	1KB21	MMTA - Infectious - Medium	Early - Community	1
0.5823	2	1KB31	MMTA - Infectious - Medium	Early - Community	2
0.6390	2	2KB11	MMTA - Infectious - Medium	Early - Institutional	0
0.7813	2	2KB21	MMTA - Infectious - Medium	Early - Institutional	1
1.0505	3	2KB31	MMTA - Infectious - Medium	Early - Institutional	2
1.1073	3	3KB11	MMTA - Infectious - Medium	Late - Community	0
1.2495	3	3KB21	MMTA - Infectious - Medium	Late - Community	1
1.0031	4	3KB31	MMTA - Infectious - Medium	Late - Community	2
1.0599	4	4KB11	MMTA - Infectious - Medium	Late - Institutional	0
1.2021	3	4KB21	MMTA - Infectious - Medium	Late - Institutional	1
1.2074	4	4KB31	MMTA - Infectious - Medium	Late - Institutional	2
1.2641	4	1AC11	MMTA - Other - High	Early - Community	0
1.4064	4	1AC21	MMTA - Other - High	Early - Community	1
0.6707	2	1AC31	MMTA - Other - High	Early - Community	2
0.7274	2	2AC11	MMTA - Other - High	Early - Institutional	0
0.8696	2	2AC21	MMTA - Other - High	Early - Institutional	1
1.1389	3	2AC31	MMTA - Other - High	Early - Institutional	2
1.1957	3	3AC11	MMTA - Other - High	Late - Community	0
1.3379	3	3AC21	MMTA - Other - High	Late - Community	1

Source: *CY 2024 Home Health Claims Data,*

Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)	HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)
1.1134	3	3AC31	MMTA - Other - High	Late - Community	2
1.1701	3	4AC11	MMTA - Other - High	Late - Institutional	0
1.3124	3	4AC21	MMTA - Other - High	Late - Institutional	1
1.3176	4	4AC31	MMTA - Other - High	Late - Institutional	2
1.3744	4	1AA11	MMTA - Other - Low	Early - Community	0
1.5166	3	1AA21	MMTA - Other - Low	Early - Community	1
0.7809	2	1AA31	MMTA - Other - Low	Early - Community	2
0.8377	2	2AA11	MMTA - Other - Low	Early - Institutional	0
0.9799	2	2AA21	MMTA - Other - Low	Early - Institutional	1
1.2492	3	2AA31	MMTA - Other - Low	Early - Institutional	2
1.3059	3	3AA11	MMTA - Other - Low	Late - Community	0
1.4481	3	3AA21	MMTA - Other - Low	Late - Community	1
0.9067	3	3AA31	MMTA - Other - Low	Late - Community	2
0.9635	3	4AA11	MMTA - Other - Low	Late - Institutional	0
1.1057	3	4AA21	MMTA - Other - Low	Late - Institutional	1
1.1110	3	4AA31	MMTA - Other - Low	Late - Institutional	2
1.1677	3	1AB11	MMTA - Other - Medium	Early - Community	0
1.3099	4	1AB21	MMTA - Other - Medium	Early - Community	1
0.5742	2	1AB31	MMTA - Other - Medium	Early - Community	2
0.6310	2	2AB11	MMTA - Other - Medium	Early - Institutional	0
0.7732	2	2AB21	MMTA - Other - Medium	Early - Institutional	1
1.0425	3	2AB31	MMTA - Other - Medium	Early - Institutional	2
1.0992	3	3AB11	MMTA - Other - Medium	Late - Community	0
1.2415	3	3AB21	MMTA - Other - Medium	Late - Community	1
1.0090	3	3AB31	MMTA - Other - Medium	Late - Community	2
1.0658	3	4AB11	MMTA - Other - Medium	Late - Institutional	0
1.2080	3	4AB21	MMTA - Other - Medium	Late - Institutional	1
1.2133	4	4AB31	MMTA - Other - Medium	Late - Institutional	2

Source: *CY 2024 Home Health Claims Data,*

Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)	HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)
1.2700	4	1LC11	MMTA - Respiratory - High	Early - Community	0
1.4123	4	1LC21	MMTA - Respiratory - High	Early - Community	1
0.6766	2	1LC31	MMTA - Respiratory - High	Early - Community	2
0.7333	2	2LC11	MMTA - Respiratory - High	Early - Institutional	0
0.8755	2	2LC21	MMTA - Respiratory - High	Early - Institutional	1
1.1448	3	2LC31	MMTA - Respiratory - High	Early - Institutional	2
1.2016	3	3LC11	MMTA - Respiratory - High	Late - Community	0
1.3438	3	3LC21	MMTA - Respiratory - High	Late - Community	1
1.1481	3	3LC31	MMTA - Respiratory - High	Late - Community	2
1.2049	3	4LC11	MMTA - Respiratory - High	Late - Institutional	0
1.3471	2	4LC21	MMTA - Respiratory - High	Late - Institutional	1
1.3524	4	4LC31	MMTA - Respiratory - High	Late - Institutional	2
1.4091	4	1LA11	MMTA - Respiratory - Low	Early - Community	0
1.5513	4	1LA21	MMTA - Respiratory - Low	Early - Community	1
0.8156	2	1LA31	MMTA - Respiratory - Low	Early - Community	2
0.8724	2	2LA11	MMTA - Respiratory - Low	Early - Institutional	0
1.0146	2	2LA21	MMTA - Respiratory - Low	Early - Institutional	1
1.2839	3	2LA31	MMTA - Respiratory - Low	Early - Institutional	2
1.3406	3	3LA11	MMTA - Respiratory - Low	Late - Community	0
1.4828	4	3LA21	MMTA - Respiratory - Low	Late - Community	1
0.9063	2	3LA31	MMTA - Respiratory - Low	Late - Community	2
0.9630	2	4LA11	MMTA - Respiratory - Low	Late - Institutional	0
1.1052	2	4LA21	MMTA - Respiratory - Low	Late - Institutional	1
1.1105	3	4LA31	MMTA - Respiratory - Low	Late - Institutional	2
1.1673	3	1LB11	MMTA - Respiratory - Medium	Early - Community	0
1.3095	3	1LB21	MMTA - Respiratory - Medium	Early - Community	1
0.5738	2	1LB31	MMTA - Respiratory - Medium	Early - Community	2
0.6305	2	2LB11	MMTA - Respiratory - Medium	Early - Institutional	0

Source: *CY 2024 Home Health Claims Data,*

Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
0.7728	2
1.0420	3
1.0988	3
1.2410	3
1.0121	3
1.0689	3
1.2111	3
1.2164	3
1.2731	4
1.4154	4
0.6797	2
0.7364	2
0.8786	2
1.1479	3
1.2047	3
1.3469	3
1.1600	5
1.2167	4
1.3590	4
1.3642	5
1.4210	5
1.5632	5
0.8275	2
0.8843	2
1.0265	3
1.2958	4
1.3525	4
1.4947	4

Source: *CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW, July 11*

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)
2LB21	MMTA - Respiratory - Medium	Early - Institutional	1
2LB31	MMTA - Respiratory - Medium	Early - Institutional	2
3LB11	MMTA - Respiratory - Medium	Late - Community	0
3LB21	MMTA - Respiratory - Medium	Late - Community	1
3LB31	MMTA - Respiratory - Medium	Late - Community	2
4LB11	MMTA - Respiratory - Medium	Late - Institutional	0
4LB21	MMTA - Respiratory - Medium	Late - Institutional	1
4LB31	MMTA - Respiratory - Medium	Late - Institutional	2
1GC11	MMTA - Surgical Aftercare - High	Early - Community	0
1GC21	MMTA - Surgical Aftercare - High	Early - Community	1
1GC31	MMTA - Surgical Aftercare - High	Early - Community	2
2GC11	MMTA - Surgical Aftercare - High	Early - Institutional	0
2GC21	MMTA - Surgical Aftercare - High	Early - Institutional	1
2GC31	MMTA - Surgical Aftercare - High	Early - Institutional	2
3GC11	MMTA - Surgical Aftercare - High	Late - Community	0
3GC21	MMTA - Surgical Aftercare - High	Late - Community	1
3GC31	MMTA - Surgical Aftercare - High	Late - Community	2
4GC11	MMTA - Surgical Aftercare - High	Late - Institutional	0
4GC21	MMTA - Surgical Aftercare - High	Late - Institutional	1
4GC31	MMTA - Surgical Aftercare - High	Late - Institutional	2
1GA11	MMTA - Surgical Aftercare - Low	Early - Community	0
1GA21	MMTA - Surgical Aftercare - Low	Early - Community	1
1GA31	MMTA - Surgical Aftercare - Low	Early - Community	2
2GA11	MMTA - Surgical Aftercare - Low	Early - Institutional	0
2GA21	MMTA - Surgical Aftercare - Low	Early - Institutional	1
2GA31	MMTA - Surgical Aftercare - Low	Early - Institutional	2
3GA11	MMTA - Surgical Aftercare - Low	Late - Community	0
3GA21	MMTA - Surgical Aftercare - Low	Late - Community	1

Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)	HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)
0.9406	4	3GA31	MMTA - Surgical	Late - Community	2
0.9973	4	4GA11	MMTA - Surgical	Late - Institutional	0
1.1396	4	4GA21	MMTA - Surgical	Late - Institutional	1
1.1448	4	4GA31	MMTA - Surgical	Late - Institutional	2
1.2016	5	1GB11	MMTA - Surgical	Early - Community	0
1.3438	5	1GB21	MMTA - Surgical	Early - Community	1
0.6081	2	1GB31	MMTA - Surgical	Early - Community	2
0.6649	2	2GB11	MMTA - Surgical	Early - Institutional	0
0.8071	2	2GB21	MMTA - Surgical	Early - Institutional	1
1.0764	4	2GB31	MMTA - Surgical	Early - Institutional	2
1.1331	4	3GB11	MMTA - Surgical	Late - Community	0
1.2753	4	3GB21	MMTA - Surgical	Late - Community	1
1.0265	5	3GB31	MMTA - Surgical	Late - Community	2
1.0833	4	4GB11	MMTA - Surgical	Late - Institutional	0
1.2255	4	4GB21	MMTA - Surgical	Late - Institutional	1
1.2308	5	4GB31	MMTA - Surgical	Late - Institutional	2
1.2875	5	1EC11	MS Rehab - High	Early - Community	0
1.4297	5	1EC21	MS Rehab - High	Early - Community	1
0.6940	2	1EC31	MS Rehab - High	Early - Community	2
0.7508	2	2EC11	MS Rehab - High	Early - Institutional	0
0.8930	2	2EC21	MS Rehab - High	Early - Institutional	1
1.1623	4	2EC31	MS Rehab - High	Early - Institutional	2
1.2190	4	3EC11	MS Rehab - High	Late - Community	0
1.3613	4	3EC21	MS Rehab - High	Late - Community	1
1.2766	4	3EC31	MS Rehab - High	Late - Community	2
1.3333	4	4EC11	MS Rehab - High	Late - Institutional	0
1.4756	4	4EC21	MS Rehab - High	Late - Institutional	1
1.4808	5	4EC31	MS Rehab - High	Late - Institutional	2

Source: *CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW July 11*

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)
1EA11	MS Rehab - Low	Early - Community	0
1EA21	MS Rehab - Low	Early - Community	1
1EA31	MS Rehab - Low	Early - Community	2
2EA11	MS Rehab - Low	Early - Institutional	0
2EA21	MS Rehab - Low	Early - Institutional	1
2EA31	MS Rehab - Low	Early - Institutional	2
3EA11	MS Rehab - Low	Late - Community	0
3EA21	MS Rehab - Low	Late - Community	1
3EA31	MS Rehab - Low	Late - Community	2
4EA11	MS Rehab - Low	Late - Institutional	0
4EA21	MS Rehab - Low	Late - Institutional	1
4EA31	MS Rehab - Low	Late - Institutional	2
1EB11	MS Rehab - Medium	Early - Community	0
1EB21	MS Rehab - Medium	Early - Community	1
1EB31	MS Rehab - Medium	Early - Community	2
2EB11	MS Rehab - Medium	Early - Institutional	0
2EB21	MS Rehab - Medium	Early - Institutional	1
2EB31	MS Rehab - Medium	Early - Institutional	2
3EB11	MS Rehab - Medium	Late - Community	0
3EB21	MS Rehab - Medium	Late - Community	1
3EB31	MS Rehab - Medium	Late - Community	2
4EB11	MS Rehab - Medium	Late - Institutional	0
4EB21	MS Rehab - Medium	Late - Institutional	1
4EB31	MS Rehab - Medium	Late - Institutional	2
1BC11	Neuro - High	Early - Community	0
1BC21	Neuro - High	Early - Community	1
1BC31	Neuro - High	Early - Community	2
2BC11	Neuro - High	Early - Institutional	0

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
2BC21	Neuro - High	Early - Institutional	1	1.5376	4
2BC31	Neuro - High	Early - Institutional	2	1.6798	4
3BC11	Neuro - High	Late - Community	0	0.9441	2
3BC21	Neuro - High	Late - Community	1	1.0009	3
3BC31	Neuro - High	Late - Community	2	1.1431	3
4BC11	Neuro - High	Late - Institutional	0	1.4124	4
4BC21	Neuro - High	Late - Institutional	1	1.4691	4
4BC31	Neuro - High	Late - Institutional	2	1.6113	4
1BA11	Neuro - Low	Early - Community	0	1.0310	4
1BA21	Neuro - Low	Early - Community	1	1.0878	4
1BA31	Neuro - Low	Early - Community	2	1.2300	4
2BA11	Neuro - Low	Early - Institutional	0	1.2353	4
2BA21	Neuro - Low	Early - Institutional	1	1.2920	4
2BA31	Neuro - Low	Early - Institutional	2	1.4343	4
3BA11	Neuro - Low	Late - Community	0	0.6986	2
3BA21	Neuro - Low	Late - Community	1	0.7553	2
3BA31	Neuro - Low	Late - Community	2	0.8975	2
4BA11	Neuro - Low	Late - Institutional	0	1.1668	4
4BA21	Neuro - Low	Late - Institutional	1	1.2236	3
4BA31	Neuro - Low	Late - Institutional	2	1.3658	4
1BB11	Neuro - Medium	Early - Community	0	1.1318	4
1BB21	Neuro - Medium	Early - Community	1	1.1886	4
1BB31	Neuro - Medium	Early - Community	2	1.3308	4
2BB11	Neuro - Medium	Early - Institutional	0	1.3361	4
2BB21	Neuro - Medium	Early - Institutional	1	1.3928	4
2BB31	Neuro - Medium	Early - Institutional	2	1.5350	5
3BB11	Neuro - Medium	Late - Community	0	0.7993	2
3BB21	Neuro - Medium	Late - Community	1	0.8561	2

Source: *CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW July 11, 2025.*

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
3BB31	Neuro - Medium	Late - Community	2	0.9983	2
4BB11	Neuro - Medium	Late - Institutional	0	1.2676	4
4BB21	Neuro - Medium	Late - Institutional	1	1.3243	4
4BB31	Neuro - Medium	Late - Institutional	2	1.4665	4
1CC11	Wound - High	Early - Community	0	1.5526	4
1CC21	Wound - High	Early - Community	1	1.6093	4
1CC31	Wound - High	Early - Community	2	1.7516	4
2CC11	Wound - High	Early - Institutional	0	1.7568	5
2CC21	Wound - High	Early - Institutional	1	1.8136	4
2CC31	Wound - High	Early - Institutional	2	1.9558	4
3CC11	Wound - High	Late - Community	0	1.2201	3
3CC21	Wound - High	Late - Community	1	1.2769	3
3CC31	Wound - High	Late - Community	2	1.4191	3
4CC11	Wound - High	Late - Institutional	0	1.6884	4
4CC21	Wound - High	Late - Institutional	1	1.7451	4
4CC31	Wound - High	Late - Institutional	2	1.8873	4
1CA11	Wound - Low	Early - Community	0	1.3373	4
1CA21	Wound - Low	Early - Community	1	1.3941	4
1CA31	Wound - Low	Early - Community	2	1.5363	4
2CA11	Wound - Low	Early - Institutional	0	1.5416	4
2CA21	Wound - Low	Early - Institutional	1	1.5983	4
2CA31	Wound - Low	Early - Institutional	2	1.7405	4
3CA11	Wound - Low	Late - Community	0	1.0048	3
3CA21	Wound - Low	Late - Community	1	1.0616	3
3CA31	Wound - Low	Late - Community	2	1.2038	3
4CA11	Wound - Low	Late - Institutional	0	1.4731	4
4CA21	Wound - Low	Late - Institutional	1	1.5298	4
4CA31	Wound - Low	Late - Institutional	2	1.6721	4

Source: *CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW July 11, 2025.*

HIPPS	Clinical Group and Functional Level	Admission Source and Timing	Comorbidity Adjustment (0 = none, 1 = single comorbidity, 2 = interaction)	Recalibrated Weight for 2026	LUPA Visit Threshold (LUPAs have fewer visits than the threshold)
1CB11	Wound - Medium	Early - Community	0	1.4173	4
1CB21	Wound - Medium	Early - Community	1	1.4741	4
1CB31	Wound - Medium	Early - Community	2	1.6163	4
2CB11	Wound - Medium	Early - Institutional	0	1.6215	4
2CB21	Wound - Medium	Early - Institutional	1	1.6783	4
2CB31	Wound - Medium	Early - Institutional	2	1.8205	4
3CB11	Wound - Medium	Late - Community	0	1.0848	3
3CB21	Wound - Medium	Late - Community	1	1.1416	3
3CB31	Wound - Medium	Late - Community	2	1.2838	3
4CB11	Wound - Medium	Late - Institutional	0	1.5531	4
4CB21	Wound - Medium	Late - Institutional	1	1.6098	4
4CB31	Wound - Medium	Late - Institutional	2	1.7520	4

Source: CY 2024 Home Health Claims Data, Periods that end in CY 2024 accessed on the CCW July 11, 2025.

Changes to the PDGM case-mix weights are implemented in a budget neutral manner by multiplying the CY 2026 national standardized 30-day period payment rate by a case-mix budget neutrality factor. Typically, the case-mix weight budget neutrality factor is also calculated using the most recent, complete home health claims data available. For CY 2026, we will continue the practice of using the most recent complete home health claims data at the time of rulemaking, which is CY 2024 data. The case-mix budget neutrality factor is calculated as the ratio of 30-day base payment rates such that total payments when the CY 2026 PDGM case-mix weights (developed using CY 2024 home health claims data) are applied to CY 2024 utilization (claims) data are equal to total payments when CY 2025 PDGM case-mix weights (developed using CY 2023 home health claims data) are applied to CY 2024 utilization data. This produced a proposed case-mix budget neutrality factor for CY 2026 of 1.0051.

We invited public comments on the CY 2026 proposed case-mix weights and proposed case-mix weight budget neutrality factor. The following is a summary of the comments we received and our responses:

Comment: Several commenters expressed support for the proposed case-mix weights using the most current data available for recalibration.

Response: We thank the commenters for their support.

Comment: Several commenters expressed concern over the proposed recalibration of the PDGM case-mix weights, stating that they believe this proposal relies on potentially fraudulent claims data (including the data particularly from Los Angeles County, COVID-19 pandemic-era anomalies and outdated assumptions) which may potentially reward outlier behavior while penalizing providers that are compliant. A few commenters suggested that weights should be frozen at CY 2020 levels until potentially problematic claims (claims that have billing patterns based on excessive recertification rates and abnormal use of high reimbursement codes) are excluded. Several commenters also mentioned that they believe CMS's methodology blends behavior assumptions with recalibration, which ultimately results in "double counting" and

misclassification of provider behavior. Some commenters stated that this methodology results in the current weights undervaluing high acuity cases, including patients with heart failure, COPD, diabetes, and complex postsurgical recovery, as well as the therapy related groupings. Commenters further suggested that undervaluation has already reduced access to therapy services, particularly for patients that require intensive speech language, swallowing, or mobility interventions. Commenters also posited that annual recalibration creates volatility, complicates financial and operational planning, and thus, requested that CMS increase transparency by publishing multiyear comparative tables, impact simulations, and clearer explanations of OASIS mapping assumptions. Some commenters cited that rising patient acuity, operational expenses, and workforce shortages present justifications for higher payment levels and thus stated that recalibration should not be constrained by budget neutrality. Commenters further stated that budget neutrality reallocates points in ways that diminish the weight of important clinical factors (such as ambulation, which potentially leads to adverse outcomes like increased falls and hospitalizations). Other commenters noted that the combined effect of recalibration and other adjustments contributes to substantial year-to-year payment variances, which they state may disproportionately disadvantage HHAs that are mainly serving medically complex or rural populations.

Response: CMS appreciates commenters' feedback regarding the proposed recalibration of the PDGM case-mix weights. While we understand concerns about data integrity, behavior assumptions, and the impact on high acuity patients, ultimately, we continue to believe that annual recalibration is essential to ensure that weights reflect current utilization patterns and patient characteristics. Recalibration only considers patient characteristics and associated resource use to ensure that the case-mix weights accurately reflect the types of patients HHAs are servicing. The behavior adjustments only ensure that Medicare is not paying any more under the PDGM than it would have under the prior 153-group system.

If CMS were to prolong recalibration beyond an annual schedule, this would not accurately reflect year-to-year changes in resource use associated with patient characteristics. That said, for CY 2026, the use of CY 2024 claims represents the most complete and current data available. Also, as it relates to commenters' concerns regarding fraudulent/anomalous claims, we would like to note that the recalibration methodology finalized in the CY 2019 HH PPS rule (83 FR 56502) is applied nationally and is based on the aggregate relationship between patient characteristics and observed resource use. Therefore, any stated "undervaluation" would be the result of what is being reported by HHAs. To add, program integrity issues are addressed through separate oversight channels and do not alter the statutory requirement for recalibrations to be implemented in a budget-neutral manner, as required by section 1895(b)(3)(A)(i) of the Act. Finally, we acknowledge that annual recalibration may contribute to year-to-year variability, but the overarching intent is to align payments as closely as possible with actual resource use as reported by HHAs. While we understand commenters' concerns about HHAs serving mainly medically complex or rural populations potentially being disproportionately disadvantaged, the case-mix weights are universally applied to the national, standardized 30-day payment rate. Nevertheless, CMS will continue to evaluate ways to improve transparency while monitoring broader system trends such as rising acuity, workforce shortages, and operational costs.

Final Decision: We are finalizing the recalibrated case-mix weights for CY 2026, updated with claims data as of July 11, 2025. We did not receive any comments on the proposed case-mix weight budget neutrality factor. Therefore, we are finalizing the proposal to implement the changes to the PDGM case-mix weights in a budget neutral manner by applying a case-mix budget neutrality factor to the CY 2026 national, standardized 30-day period payment rate. Using the most updated data at the time of rulemaking, the final case-mix budget neutrality factor for CY 2026 will be 1.0052.

E. CY 2026 Home Health Payment Rate Updates

1. Final CY 2026 Home Health Market Basket Update for HHAs

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for home health be increased by a factor equal to the applicable home health market basket update for those HHAs that submit quality data as required by the Secretary. In the CY 2024 HH PPS final rule (88 FR 77726), we finalized a rebasing of the home health market basket to reflect 2021 cost report data. We also finalized a policy for CY 2024 and subsequent years that the labor-related share will be 74.9 percent, and the non-labor-related share will be 25.1 percent. A detailed description of how we rebased the home health market basket and labor-related share is available in the CY 2024 HH PPS final rule (88 FR 77726 through 77742).

In the CY 2015 HH PPS final rule (79 FR 38384), we finalized our methodology for calculating and applying the productivity adjustment. As we explained in that rule, section 1895(b)(3)(B)(vi) of the Act, requires that, in CY 2015 (and in subsequent calendar years, except CY 2018 (under section 411(c) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted April 16, 2015)), the market basket percentage under the HH PPS as described in section 1895(b)(3)(B) of the Act be annually adjusted by changes in economy-wide productivity. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as equal to the 10-year moving average of change in annual economy-wide private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). The Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the United States economy. We note that previously, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021, release of productivity data, BLS replaced the term “multifactor productivity” with “total factor productivity” (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as “private nonfarm business total

factor productivity". We refer readers to https://www.bls.gov for the BLS historical published TFP data. A complete description of IHS Global Inc.'s (IGI) TFP projection methodology is available on the CMS website at https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information.

The proposed home health market basket update for CY 2026 was based on the estimated home health market basket percentage increase, specified at section 1895(b)(3)(B)(iii) of the Act, of 3.2 percent (based on IHS Global Inc.'s first quarter 2025 forecast with historical data through fourth quarter 2024). The estimated CY 2026 proposed home health market basket percentage increase of 3.2 percent was then reduced by a productivity adjustment, in accordance with section 1895(b)(3)(B)(vi) of the Act. Based on IGI's first quarter 2025 forecast, the proposed productivity adjustment was estimated to be 0.8 percentage point for CY 2026. Therefore, the proposed CY 2026 home health market basket update was 2.4 percent (3.2 percent market basket percentage increase, reduced by a 0.8 percentage point productivity adjustment). Furthermore, we proposed that if more recent data became available (for example, a more recent estimate of the market basket percentage increase and/or productivity adjustment), we would use such data, if appropriate, to determine the final CY 2026 market basket percentage increase and productivity adjustment in the final rule.

Section 1895(b)(3)(B)(v) of the Act requires that the home health percentage update be decreased by 2 percentage points for those HHAs that do not submit quality data as required by the Secretary. For HHAs that do not submit the required quality data for CY 2026, the proposed home health payment update percentage was 0.4 percent (2.4 percent minus 2 percentage points). We invited public comments on the proposed CY 2026 home health market basket percentage increase and productivity adjustment. The following is a summary of the comments received and our responses:

Comment: Multiple commenters stated that they support CMS' proposal and application of the CY 2026 market basket update but expressed concerns that the proposed market basket

update of 3.2 percent for CY 2026 would fail to adequately address the inflationary pressures and cost increases experienced by HHAs.

Commenters cited organization-specific experience and data demonstrating that the proposed update does not align with the increased cost of skilled care experienced by the home health industry, particularly for labor costs amid continued recruitment challenges, and stated that they believe it to be inconsistent with price trends evidenced in Bureau of Labor Statistics (BLS) data. They emphasized that it is critically important for the annual payment update to accurately reflect price growth in the cost of care to ensure that beneficiaries needing home health services have access to care and to support the viability of this important Medicare benefit over time. Multiple commenters noted that they expect actual inflation costs to far exceed the proposed market basket update, creating a widening gap between Medicare payments and the actual cost of providing home health services.

Several commenters urged CMS to reassess the market basket construction, forecasting methodology, whether the reliance on the Employment Cost Index is capturing shifts to contract labor and other changes to the home health workforce, and to consider methodological refinements and greater transparency.

Response: We appreciate the comments regarding the proposed CY 2026 HH PPS market basket update and recognize the concerns raised about inflationary pressures affecting HHAs. Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts be increased by a factor equal to the applicable home health market basket update for those HHAs that submit quality data as required by the Secretary. The home health market basket is a fixed-weight, Laspeyres-type price index, which measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (such as shifts in the occupational mix of the workforce) purchased over time relative to the base period are appropriately not measured. The home health market basket was last rebased to reflect a 2021 base year effective for CY 2024 (88 FR 77726).

We continue to believe that the home health market basket cost weights accurately reflect the cost structure of HHAs, allowing for an accurate estimate of the price pressures that HHAs will face in CY 2026. Since the home health market basket update is required to be set prospectively, it relies on a mix of historical data for part of the period for which the update is calculated and forecasted data for the remainder. As a result, the market basket percentage increase reflects expectations of trends, which may periodically differ from actual experience due to unforeseen events and short-term volatility.

The forecasted data are provided by IHS Global Inc. (IGI), a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets. In the CY 2026 HH PPS proposed rule, we proposed that if more recent data become available, we would use such data, if appropriate, to derive the final CY 2026 home health market basket update for the final rule.

In this final rule, we have incorporated the most recent historical data and forecasts provided by IGI to capture the expected price and wage pressures facing HHAs in CY 2026. The CY 2026 market basket update in this final rule reflects historical data through the second quarter of 2025 and forecasted data for the third quarter of 2025 through the fourth quarter of 2026. Accordingly, the final CY 2026 market basket update reflects an updated and revised outlook on the U.S. economy.

Based on IGI's third quarter 2025 forecast with historical data through second quarter 2025 of the 2021-based home health market basket percentage increase for CY 2026 is 3.2 percent, reflecting forecasted compensation price growth of 3.3 percent. We will continue to evaluate opportunities to enhance transparency around the market basket and to assess whether refinements to inputs or methods are warranted. Any changes deemed necessary would be proposed through notice and comment rulemaking.

Comment: Several commenters noted that in every year from 2021 through 2024, actual inflation has outpaced the CMS market basket adjustment for the home health industry.

Commenters emphasized that CYs 2021 and 2022 alone represented a shortfall of over 5 percentage points and, unless corrected, the forecast error compounds underpayments with each successive year which could result in significant cumulative underpayment by the year 2030.

Multiple commenters referenced the precedent for CMS to implement forecast error corrections, noting that in the FY 2024 Skilled Nursing Facility Prospective Payment System final rule CMS finalized a 3.6 percentage points market basket forecast error adjustment for SNFs. They stated that the cumulative shortfall in the SNF updates, preceding the implementation of the market basket forecast error adjustment, was less than the shortfall experienced by home health providers over the CY 2021-2022 period and noted that CMS subsequently finalized additional forecast error adjustments for SNFs in FY 2025 and FY 2026.

Several commenters recommended that CMS exercise its authority to implement a one-time market basket forecast error adjustment to payments in CY 2026 to account for previous forecast errors in home health market basket updates. They stated that this additional funding would enable home health providers to recruit and retain staff and be competitive in their local labor markets, while supporting improved access to care.

Response: A forecast error for a market basket update is equal to the actual market basket percentage increase for a given year less the forecasted market basket percentage increase. Due to the uncertainty regarding future price trends, forecast errors can be both positive and negative, as has occurred since the implementation of the HH PPS.

We acknowledge that over most of the history of the HH PPS, forecast errors have been smaller in magnitude, with the largest error prior to 2021 being an over forecast of 1.2 percentage points in 2009. As noted by commenters, more recently the home health market basket has been under forecast, with the largest forecast errors occurring in 2021 and 2022. The cumulative forecast error since HH PPS inception (fiscal year 2002 to CY 2024, excluding CY 2018 and CY 2020 when the market basket update was statutorily mandated) is −0.1 percent. The recent forecast errors were largely a function of uncertainty in the overall economy and the

health sector specifically due to the nature of the COVID-19 PHE and the unforeseen rapidly accelerating inflationary environment.

In contrast to the SNF PPS, there is currently no mechanism to adjust for a market basket forecast error in the home health prospective payment system. Any changes in this respect would require careful consideration of the statutory and regulatory frameworks specific to the HH PPS, and any changes deemed necessary would be proposed through notice and comment rulemaking.

Comment: Numerous commenters opposed the proposed 0.8 percentage point productivity adjustment for CY 2026, arguing that this adjustment fails to account for home health-specific productivity factors. Commenters noted that the proposed 2026 productivity adjustment of 0.8 percentage point is among the highest historically applied without adequate justification or transparency and suggested that the 10-year moving average used to determine the productivity adjustment may be influenced by unprecedented pandemic-related fluctuations. Several commenters expressed their belief that the productivity adjustment methodology is fundamentally flawed when applied to healthcare settings. One commenter cited that since 2014, the BLS' estimate of the annual percentage change in the private nonfarm business sector total factor productivity has ranged from -0.9 to 3.8, while CMS's computed productivity adjustment ranged from 0 to 0.8 percentage point. Commenters highlighted that CMS has applied the productivity adjustment exclusively to restrict increases in Medicare payments, and that in the one year where productivity in the non-farm business sector declined, CMS set the productivity adjustment to 0 rather than increasing payments.

Multiple commenters emphasized that industry-specific challenges prevent hospitals and HHAs from achieving productivity improvements consistent with the private nonfarm business sector. They stated that the private nonfarm sector encompasses a broad range of industries, some with stable and predictable production processes and outputs, while healthcare providers operate in complex environments characterized by unpredictable patient volumes, rising input costs, varying patient acuity levels, and regulatory requirements. Therefore, they posited that the

use of the Total Factor Productivity (TFP) adjustment holds healthcare providers to an unreasonable standard by requiring that they mimic productivity gains obtained in industries that operate very differently.

Numerous commenters noted their belief that the cumulative effect of these reductions year over year, combined with the asymmetric treatment of declines in economy-wide productivity, leads to an increasing gap between payments and the cost of providing services, leaving healthcare providers increasingly underfunded and ultimately restricting the amount of care they can provide. Commenters suggested CMS reconsider the use or magnitude of the productivity adjustment or otherwise take these criticisms into account when considering decisions that affect payment where flexibility is afforded.

Response: Section 1895(b)(3)(B)(vi) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the HH PPS market basket increase factor. As required by statute, the CY 2026 productivity adjustment is derived based on the 10-year moving average growth in economy-wide private nonfarm business TFP for the period ending in CY 2026. We recognize the concerns of commenters regarding the appropriateness of the productivity adjustment; however, we are required under section 1895(b)(3)(B)(vi) of the Act to apply the specific productivity adjustment described here.

We have always made available on the CMS website the general method for calculating the productivity adjustment. This includes providing a link to the most recent BLS historical TFP data, which allows interested parties to obtain historical TFP annual index levels for 1987 through 2024. We also provided the IGI projection model (https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/medicareprogramratesstats/downloads/tfp_methodology.pdf), which is used to derive annual TFP growth rates for 2025 and 2026. The annual index level derived from this method is then interpolated to quarterly levels, and the CY 2026 productivity adjustment is equal to the percent change in the 40-quarter moving average projected level for the period ending December

31, 2026, relative to the 40-quarter moving average projected level for the period ending December 31, 2025. We believe our methodology for the productivity adjustment is consistent with section 1886(b)(3)(B)(xi)(II) of the Act which states that the productivity adjustment is equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period).

At the time of this final rule, the CY 2026 productivity adjustment reflects BLS historical TFP data through 2024 (released on March 21, 2025) and IGI's forecasted TFP growth for 2025 and 2026. The average annual growth rate of historical TFP published by BLS for 2017 through 2024 is currently 0.9 percent and IGI is projecting average TFP growth of about 0.3 percent for 2025 and 2026 based on IGI's third-quarter 2025 forecast. Combining the historical and projected TFP data over the entire 10-year time period results in a compound annual growth rate of TFP of 0.8 percent for 2026. The productivity adjustment (based on the 10-year period ending with CY 2026) for the CY 2026 final rule is the same as the CY 2026 proposed rule. The 0.8percent productivity adjustment in the CY 2026 final rule is larger than the productivity adjustment in prior final rules for CY 2023 and CY 2024 mainly due to the incorporation of updated BLS historical data.

In response to commenters' concerns about the productivity adjustment only being applied if it reduces the payment update, we note that the productivity adjustment was established under the Affordable Care Act with a specific policy intent to encourage efficiency improvements in healthcare delivery by linking Medicare payment updates to economy-wide productivity gains. The statutory language in section 1886(b)(3)(B)(xi)(II) of the Act requires that the Secretary reduce (not increase) the market basket percentage increase by changes in economy-wide productivity, therefore, only positive productivity adjustments are applied.

Final Decision: Consistent with section 1895(b)(3)(B)(vi) of the Act, and as outlined previously in section IV.B.1. of this final rule, we are finalizing the home health payment update

methodology. The market basket percentage increase for CY 2026 for the HH PPS is based on IGI's third quarter 2025 forecast of the home health market basket percentage increase, which is estimated to be 3.2 percent. As outlined earlier in this section, we are applying a 0.8 percentage point productivity adjustment to the CY 2026 home health market basket percentage increase. Therefore, the final CY 2026 home health market basket update is equal to 2.4 percent.

2. Final CY 2026 Home Health Wage Index

a. Background

Sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act require the Secretary to provide appropriate adjustments to the proportion of the payment amount under the HH PPS that account for area wage differences, using adjustment factors that reflect the relative level of wages and wage-related costs applicable to the furnishing of home health services. Since the inception of the HH PPS, we have used inpatient hospital wage data in developing a wage index to be applied to home health payments. We proposed to continue this practice for CY 2026, as it is our belief that, in the absence of home health-specific wage data that accounts for area differences, using inpatient hospital wage data, including any changes made by the Office of Management and Budget (OMB) to Metropolitan Statistical Area (MSA) definitions, is appropriate and reasonable for the HH PPS.

In general, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On April 10, 2018, OMB issued OMB Bulletin No. 18-03, which superseded the August 15, 2017, OMB Bulletin No. 17-01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04 which superseded the April 10, 2018, OMB Bulletin No. 18-03. These bulletins established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of OMB Bulletin No. 18–04 may be obtained at https://www.bls.gov/bls/omb-bulletin-18-04-revised-delineations-of-

metropolitan-statistical-areas.pdf. In the CY 2021 HH PPS final rule (85 FR 70298), we finalized our proposal to adopt the revised OMB delineations with a 5 percent cap on wage index decreases in CY 2021.

On July 21, 2023, OMB issued Bulletin No. 23-01, which updates and supersedes OMB Bulletin No. 20-01, issued on March 6, 2020. OMB Bulletin No. 23-01 establishes revised delineations for the MSAs, Micropolitan Statistical Areas, Combined Statistical Areas, and Metropolitan Divisions, collectively referred to as Core Based Statistical Areas (CBSAs). According to OMB, the delineations reflect the 2020 Standards for Delineating Core Based Statistical Areas (CBSAs) (the "2020 Standards"), which appeared in the Federal Register (86 FR 37770 through 37778) on July 16, 2021, and application of those standards to Census Bureau population and journey-to-work data (for example, 2020 Decennial Census, American Community Survey, and Census Population Estimates Program data). A copy of OMB Bulletin No. 23-01 is available online at https://www.bls.gov/bls/omb-bulletin-23-01-revised-delineations-of-metropolitan-statistical-areas.pdf.

In the CY 2025 HH PPS final rule (89 FR 88354), we finalized our proposal to adopt the revised OMB delineations from OMB Bulletin 23-01 with a 5 percent cap on wage index decreases at the CBSA level as well as at the county level. In that final rule we stated that we believe it is important for the HH PPS wage index to use the latest OMB delineations available in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. We also stated that we believe using the most current OMB delineations will increase the integrity of the HH PPS wage index by creating a more accurate representation of geographic variation in wage levels.

b. Five Percent Cap on Wage Index Decreases

In the CY 2023 HH PPS final rule (87 FR 66851 through 66853), we finalized a policy that the CY HH PPS wage index will include a permanent 5 percent cap on wage index decreases for CY 2023 and each subsequent year. Specifically, we finalized, for CY 2023 and subsequent

years, the application of a permanent 5 percent cap on any decrease to a geographic area's wage index from its wage index in the prior year, regardless of the circumstances causing the decline. That is, we finalized a policy requiring that a geographic area's wage index for CY 2023 will not be less than 95 percent of its final wage index for CY 2022, regardless of whether the geographic area is part of an updated CBSA, and that for subsequent years, a geographic area's wage index will not be less than 95 percent of its wage index calculated in the prior CY.

Previously this methodology was applied to all counties that make up a CBSA or statewide rural area. However, in the CY 2025 HH PPS final rule (89 FR 88418 through 88421), because of the adoption of the revised OMB delineations from OMB Bulletin 23-01, we finalized a policy applying this methodology to individual counties. Specifically, we finalized a policy applying the 5 percent cap to counties that moved from a CBSA or statewide rural area with a higher wage index value into a new CBSA or rural area with a lower wage index value, so that the county's CY 2025 wage index would not be less than 95 percent of the county's CY 2024 wage index value under the old delineation despite moving into a new delineation with a lower wage index.

Due to the way that we proposed calculating the 5 percent cap for counties that experienced an OMB designation change, some CBSAs and statewide rural areas could have had more than one wage index value. Specifically, some counties that changed OMB designations had a wage index value that was different than the wage index value assigned to the other constituent counties that made up that CBSA or statewide rural area that they moved into after the application of the 5 percent cap. However, for home health claims processing, each CBSA or statewide rural area can have only one wage index value assigned to that CBSA or statewide rural area. Therefore, we finalized a policy, beginning in CY 2025, that counties that have a different wage index value than the CBSA or rural area into which they are designated after the application of the 5 percent cap will use a wage index transition code. These special codes are five digits in length and begin with "50" and the remaining digits are unique for that code. The

50XXX wage index transition codes are used only in specific counties; counties located in CBSAs and rural areas that do not correspond to a different transition wage index value will still use the CBSA number.

We also finalized a policy applying the 5 percent cap to these specific counties that correspond to a different wage index value due to a delineation change until the county's new wage index is more than 95 percent of the wage index from the previous calendar year. In order to capture the correct wage index value, an HHA will continue to use the assigned 50XXX transition code on home health claims for services in these counties until the county's wage index value calculated for that calendar year using the new OMB delineations is not less than 95 percent of the county's capped wage index from the previous calendar year.

For CY 2026, the 5 percent cap on wage index decreases will continue to be calculated at the county level as well as the CBSA and statewide rural area level. While some counties that required a transition code for CY 2025 will continue to use the same transition code for CY 2026, other counties that required a transition code in CY 2025 will no longer require a transition code in CY 2026. In the counties that will no longer require a transition code beginning in CY 2026 wage index, the CY 2026 wage index of the CBSA or rural area that the county was redesignated into has a wage index value higher than 95 percent of the county's CY 2025 wage index. Therefore, these counties will use the CBSA or rural county code of the area they were redesignated into based on OMB Bulletin No. 23-01.

The complete list of counties and corresponding transition codes can be found as a separate tab in the calendar year's wage index file located on the CMS website at https://www.cms.gov/medicare/payment/prospective-payment-systems/home-health-pps/home-health-pps-wage-index.

c. Final CY 2026 HH PPS Wage Index

The appropriate wage index value is applied to the labor portion of the HH PPS rates based on the site of service for the beneficiary (defined in section 1861(m) of the Act as the

beneficiary's place of residence). For CY 2026, we proposed to base the HH PPS wage index on the FY 2026 hospital pre-floor, pre-reclassified wage index for hospital cost reporting periods beginning on or after October 1, 2021, and before October 1, 2022 (FY 2022 cost report data). The final CY 2026 HH PPS wage index will not take into account any geographic reclassification of hospitals, including those in accordance with sections 1886(d)(8)(B) or 1886(d)(10) of the Act but will include the 5 percent cap on wage index decreases as discussed previously.

There exist some geographic areas where there are no hospitals, and thus, no hospital wage data on which to base the calculation of the HH PPS wage index. To address those geographic areas in which there are no inpatient hospitals, and thus, no hospital wage data on which to base the calculation of the CY 2026 HH PPS wage index, we proposed to continue to use the same methodology discussed in the CY 2007 HH PPS final rule (71 FR 65884) to address those geographic areas in which there are no inpatient hospitals.

For urban areas without inpatient hospitals, we use the average wage index of all urban areas within the State as a reasonable proxy for the wage index for that CBSA. For CY 2026, the only urban area without inpatient hospital wage data is Hinesville, GA (CBSA 25980). Using the average wage index of all urban areas in Georgia as a proxy, we proposed the CY 2026 wage index value for Hinesville, GA would be 0.8800. With updated wage data, the final CY 2026 HH PPS wage index value for Hinesville, GA will be 0.8779.

For rural areas that do not have inpatient hospitals, we use the average wage index from all contiguous Core Based Statistical Areas (CBSAs) as a reasonable proxy. The term "contiguous" means sharing a border (72 FR 49859). In the CY 2025 HH PPS final rule (89 FR 88422), we finalized a policy that rural North Dakota will become a rural area without a hospital from which hospital wage data can be derived. Therefore, in order to calculate the wage index for rural area 99935, North Dakota, we finalized using as a proxy, the average pre-floor, pre-reclassified hospital wage data from the contiguous CBSAs: CBSA 13900-Bismark, ND, CBSA

22020-Fargo, ND-MN, CBSA 24220-Grand Forks, ND-MN, and CBSA 33500, Minot, ND. Using this methodology, we proposed that the CY 2026 HH PPS wage index for rural North Dakota would be 0.8346. With updated wage data, the CY 2026 HH PPS final wage index value for rural North Dakota will be 0.8329.

Previously, the only rural area without a hospital from which hospital wage data could be derived was rural Puerto Rico. However, for rural Puerto Rico, we did not apply this methodology due to the distinct economic circumstances that exist there (for example, due to the proximity of almost all of Puerto Rico's various urban and non-urban areas to one another, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas). Instead, we used the most recent wage index previously available for that area, which was 0.4047. Beginning in CY 2025, due to the adoption of the revised OMB delineations, there is now a hospital in rural Puerto Rico from which hospital wage data can be derived. Therefore, we finalized a policy that the wage index for rural Puerto Rico will now be based on the hospital wage data for the area instead of the previously available wage index of 0.4047. The CY 2025 final unadjusted wage index value for rural Puerto Rico was 0.2510. However, because 0.2510 is more than a 5 percent decline in the area's CY 2024 wage index, the 5 percent cap was applied and the final CY 2025 5 percent cap adjusted wage index for rural Puerto Rico was set equal to 95 percent of the CY 2024 wage index, which resulted in a final wage index value of 0.3845.

The unadjusted CY 2026 proposed wage index for rural Puerto Rico was 0.2452. However, because 0.2452 is more than a 5 percent decline in the CY 2025 wage index, we proposed that the CY 2026 5 percent cap adjusted wage index for rural Puerto Rico be set equal to 95 percent of the CY 2025 wage index, which resulted in a proposed wage index value of 0.3653. The unadjusted CY 2026 final wage index for rural Puerto Rico is 0.2443. However, because 0.2443 is more than a 5 percent decline in the CY 2025 wage index, we are finalizing

the CY 2026 5 percent cap adjusted wage index for rural Puerto Rico, set equal to 95 percent of the CY 2025 wage index, which will result in a final wage index value of 0.3653.

Additionally, due to the adoption of the revised OMB delineations in the CY 2025 HH PPS final rule, Delaware, which was previously an all-urban state, now has one rural area with a hospital from which hospital wage data can be derived. As such, we proposed that the CY 2026 wage index for rural Delaware would be 1.0133. With updated wage data, the CY 2026 HH PPS final wage index value for rural Delaware will be 1.0095.

Finally, the Northern Mariana Islands and American Samoa are rural areas with no hospital data from which a wage index can be calculated. Consistent with our established methodology, we compute an appropriate wage index for rural areas with no hospital using the average wage index values from contiguous CBSAs, to represent a reasonable proxy. Therefore, we proposed that HHAs that provide services in the Northern Mariana Islands and American Samoa will use CBSA 99965 (Guam) and receive the wage index assigned to CBSA 99965 (Guam) of 0.9611. While we appreciate that the islands of the Pacific Rim are not actually contiguous, we believe that same principle applies here, and that Guam is a reasonable proxy for American Samoa and the Northern Mariana Islands. We believe that CBSA 99965 (Guam) represents a reasonable proxy because the islands are located within the Pacific Rim and share a common status as United States Territories.

We solicited comments on the proposed CY 2026 HH PPS wage index. The following is a summary of the comments we received and our responses:

Comment: Several commenters were opposed to the proposed wage index updates, particularly in rural areas. These commenters expressed concern that wage index changes in rural areas would worsen rural access to care issues. A commenter stated that the current method of adjusting labor costs using the hospital wage index does not accurately account for increased travel costs and lost productivity in serving rural areas. This commenter recommended a population density adjustment, stating that travel costs are increased because of the time and

mileage involved for home health personnel to travel from patient to patient to provide services in areas with lower population densities, while, in densely populated areas, these costs are significantly reduced because of the relative proximity of beneficiaries to the home health agency.

Response: We appreciate commenters' concerns regarding the wage index values assigned to rural areas. As discussed in the CY 2022 HH PPS final rule (86 FR 62285), we do not believe that a population density adjustment is appropriate at this time. Rural HHAs continually cite the added cost of traveling from one patient to the next. However, urban HHAs cite the added costs associated with needed security measures and traffic congestion. The home health wage index values in rural areas are not necessarily lower than the home health wage index values in urban areas. The home health wage index reflects the wages that inpatient hospitals pay in their local geographic areas. We continue to believe that in the absence of home health specific data, the pre-floor, pre-reclassified hospital wage index is appropriate for the geographic adjustment of home health claims.

Comment: Several commenters expressed concern that home health providers are unable to benefit from IPPS hospital wage index policies such as reclassification and the rural floor. A commenter recommended that all providers should be guaranteed that their wage index value does not drop below the rural wage index value applicable in the state of operation. A few commenters requested that CMS modify its wage index policy to incorporate hospital reclassifications to ensure fair geographic payment adjustments. Another commenter stated that the significant variance in the wage index values assigned to IPPS hospitals and HHAs and hospices makes it much more difficult for home health and hospice providers to recruit nurses and other professional and para-professional staff when hospitals can offer those same individuals a much higher salary and benefit package due to this large variance in the wage index values.

Other commenters recommended that CMS institute a floor policy in the HH PPS. Several commenters located in Puerto Rico recommended that CMS implement a National Wage Index Floor of 0.6000. These commenters believe that a national wage index floor would stabilize Medicare home health payments and also improve parity within the national Medicare HH PPS. A few commenters also recommended a 0.8000 floor in the HH PPS wage index similar to the hospice floor.

Response: We thank the commenters for their recommendations. We continue to believe that the regulations and statutes that govern the HH PPS differ from the hospital and hospice regulations and statutes, such that there would be differences between how these payment systems apply wage index policies including geographic reclassification, or the rural floor. Section 4410(a) of the Balanced Budget Act of 1997 provides that the area wage index applicable to any hospital that is located in an urban area of a state may not be less than the area wage index applicable to hospitals located in rural areas in that State. This rural floor provision is specific to hospitals. The reclassification provision at section 1886(d)(10)(C)(i) of the Act states that the Medicare Geographic Classification Review Board shall consider the application of any subsection (d) hospital requesting the Secretary change the hospital's geographic classification for purposes of payment under the IPPS. This reclassification provision is only applicable to hospitals as defined in section 1886(d) of the Act. In addition, we do not believe that using hospital reclassification data would be appropriate as these data are specific to the requesting hospitals.

Additionally, the application of the hospice floor is specific to hospices and does not apply to HHAs. The hospice floor was developed through a negotiated rulemaking advisory committee, under the process established by the Negotiated Rulemaking Act of 1990 (Pub. L. 101–648). Committee members included representatives of national hospice associations; rural, urban, large, and small hospices; multi-site hospices; consumer groups; and a government representative. The Committee reached consensus on a methodology that resulted in the hospice

wage index. We continue to believe the use of the pre-floor and pre-reclassified hospital wage index results in the most appropriate adjustment to the labor portion of the home health payment rates.

Comment: Several commenters expressed concern with the wage index values assigned to their specific geographic areas. A commenter recommended that the wage index value for rural Hawaii match or exceed the wage index value assigned to rural California. A few commenters expressed concern with the wage index value assigned to rural Puerto Rico after the adoption of the delineations from OMB Bulletin No. 23-01.

Response: We appreciate the concerns expressed by commenters regarding wage index values in specific geographic areas, including rural Hawaii and rural Puerto Rico. While we understand these concerns, we believe that the permanent 5 percent cap policy provides an adequate safeguard against any significant payment reductions in CY 2026 while improving the accuracy of the payment adjustment for differences in area wage levels.

Comment: Several commenters recommended far-reaching revisions and reforms to the HH PPS wage index methodology. A commenter stated that the pre-floor, pre-reclassified hospital wage index is inadequate for adjusting home health costs and recommended that CMS develop and implement a wage index model that is consistent across all provider types so that all providers have a level playing field from which to compete for personnel. Another commenter recommended that CMS develop a home health wage index and retire the use of the hospital wage index to determine the home health wage index. This commenter stated that until a new home health wage index can be implemented, they support CMS' proposal to continue using OMB's most recent statistical area delineations for the hospital wage index. A commenter stated that the current wage index fails to capture real costs in high-price markets such as New York City, creating structural underpayments that destabilize safety-net providers. This commenter believes that as with PDGM itself, COVID-19 pandemic-era data should be excluded from wage index calculations and that without meaningful reform to the wage index methodology, providers

in many regions will continue to face structural disadvantages that further limit their ability to deliver care. Another commenter recommended changes to the wage index methodology including using state-specific data such as BLS wage surveys, accounting for housing and transportation costs, and exploring payment adjustments for high-cost areas.

Response: We thank the commenters for their recommendations. While we did not propose any changes to the wage index methodology in the proposed rule, we may consider these recommendations in future rulemaking.

Comment: A few commenters expressed support for the finalized 5 percent cap policy. However, other commenters recommended updates to the finalized 5 percent cap policy. A commenter recommended lowering the threshold of the cap to 2 percent. This commenter believes that lowering the cap to 2 percent would protect HHAs who operate with negative or razor-thin operating margins and are still experiencing multiple negative consequences due to the COVID-19 pandemic.

Response: We appreciate commenters' recommendations for changes to the 5 percent cap policy. However, in the CY 2026 HH PPS proposed rule, we did not propose to make changes to this policy. Therefore, these comments are outside the scope of the proposed rule. Any changes to the finalized 5 percent cap policy would need to go through notice and comment rulemaking. However, we continue to believe that a 5 percent cap would most effectively mitigate any significant decreases in a geographic area's wage index for a calendar year, while still balancing the importance of ensuring that area wage index values accurately reflect relative differences in area wage levels. Furthermore, we believe that the 5 percent cap on wage index decreases provides a degree of predictability in payment changes for providers and allows providers time to adjust to any significant decreases they may face year to year.

Final Decision: After consideration of public comments, we are finalizing our proposal to base the HH PPS wage index on the FY 2026 hospital pre-floor, pre-reclassified wage index for hospital cost reporting periods beginning on or after October 1, 2021, and before October 1, 2022

(FY 2022 cost report data). The final CY 2026 HH PPS wage index will include the 5 percent cap on wage index decreases.

Additionally, using our established methodology for rural areas with no hospitals, we are finalizing including in the CY 2026 HH PPS wage index the wage indexes for the Northern Mariana Islands and American Samoa. Consistent with our established methodology, we compute an appropriate wage index for rural areas with no hospital using the average wage index values from contiguous CBSAs to represent a reasonable proxy. We believe that CBSA 99965 (Guam) represents a reasonable proxy because the islands are located within the Pacific Rim and share a common status of US territories. Therefore, HHAs that provide services in the Northern Mariana Islands and American Samoa should use CBSA 99965 (Guam) and should receive the wage index assigned to CBSA 99965 (Guam) of 0.9611.

The final HH PPS wage index file applicable for CY 2026 (January 1, 2026, through December 31, 2026) is available on the CMS website at https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/home-health-agency-center.

3. Final CY 2026 Home Health Payment Update

a. Background

The HH PPS has been in effect since October 1, 2000. As set forth in the July 3, 2000, final rule (65 FR 41128), the base unit of payment under the HH PPS was a national, standardized 60-day episode payment rate. As finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56406), and as described in the CY 2020 HH PPS final rule with comment period (84 FR 60478), the unit of home health payment changed from a 60-day episode to a 30-day period effective for those 30-day periods beginning on or after January 1, 2020.

As set forth in § 484.220, we adjust the national, standardized prospective payment rates by a case-mix relative weight and a wage index value based on the site of service for the beneficiary. To provide appropriate adjustments to the proportion of the payment amount under

the HH PPS to account for area wage differences, we apply the appropriate wage index value to the labor portion of the HH PPS rates. In the CY 2024 HH PPS final rule (88 FR 77676), we finalized the rebasing of the home health market basket to reflect 2021 Medicare cost report data. We also finalized a policy that, for CY 2024 and subsequent years, the labor-related share will be 74.9 percent, and the non-labor-related share will be 25.1 percent. The following are the steps we take to compute the case-mix and wage-adjusted 30-day period payment amount for CY 2026:

- Multiply the national, standardized 30-day period rate by the patient's applicable case-mix weight.
- Divide the case-mix adjusted amount into a labor (74.9 percent) and a non-labor portion (25.1 percent).
- Multiply the labor portion by the applicable wage index based on the site of service of the beneficiary.
- Add the wage-adjusted portion to the non-labor portion, yielding the case-mix and wage adjusted 30-day period payment amount, subject to any additional applicable adjustments.

We provide annual updates of the HH PPS rate in accordance with section 1895(b)(3)(B) of the Act. Section 484.225 sets forth the specific annual percentage update methodology. In accordance with section 1895(b)(3)(B)(v) of the Act and § 484.225(i), for an HHA that does not submit home health quality data, as specified by the Secretary, the unadjusted national prospective 30-day period rate is equal to the rate for the previous calendar year increased by the applicable home health payment market basket , minus two percentage points. Any reduction of the percentage change will apply only to the calendar year involved and will not be considered in computing the prospective payment amount for a subsequent calendar year.

The final claim that the HHA submits for payment determines the total payment amount for the period and whether we make an applicable adjustment to the 30-day case-mix and wage-adjusted payment amount. The end date of the 30-day period, as reported on the claim, determines which calendar year rates Medicare will use to pay the claim.

We may adjust a 30-day case-mix and wage-adjusted payment based on the information submitted on the claim to reflect the following:

- A LUPA is provided on a per-visit basis as set forth in §§ 484.205(d)(1) and 484.230.
- A partial payment adjustment as set forth in §§ 484.205(d)(2) and 484.235.
- An outlier payment as set forth in §§ 484.205(d)(3) and 484.240.

b. Final CY 2026 National, Standardized 30-Day Period Payment Amount

Section 1895(b)(3)(A)(i) of the Act requires that the standard prospective payment rate and other applicable amounts be standardized in a manner that eliminates the effects of variations in relative case-mix and area wage adjustments among different HHAs in a budget-neutral manner. To determine the CY 2026 national, standardized 30-day period payment rate, we will continue our practice of using the most recent, complete utilization data at the time of rulemaking; that is, we are using CY 2024 claims data for CY 2026 payment rate updates. We apply a permanent adjustment factor, a case-mix weights recalibration budget neutrality factor, a wage index budget neutrality factor, the home health payment update percentage, and a temporary adjustment factor to update the CY 2026 payment rate. As discussed in section II.C.1. of this final rule, we are finalizing the implementation of a permanent adjustment of -1.023 percent to ensure that estimated aggregate expenditures under the PDGM are equal to the estimated aggregate expenditures that otherwise would have been under the 153-group payment system as required by law. The final permanent adjustment factor is 0.98977. As discussed previously, to ensure the changes to the PDGM case-mix weights are implemented in a budget neutral manner, we apply a case-mix weight budget neutrality factor to the CY 2026 national, standardized 30-day period payment rate. The final case-mix weight budget neutrality factor for CY 2026 is 1.0052.

Additionally, we apply a wage index budget neutrality factor to ensure that wage index updates and revisions are implemented in a budget neutral manner. To calculate the wage index budget neutrality factor, we first determine the payment rate needed for non-LUPA 30-day

periods using the CY 2026 wage index (with the 5 percent cap) so those total payments are equivalent to the total payments for non-LUPA 30-day periods using the CY 2025 wage index (with the 5 percent cap) and the CY 2025 national standardized 30-day period payment rate adjusted by the case-mix weights recalibration neutrality factor. Then, by dividing the payment rate for non-LUPA 30-day periods using the CY 2026 wage index with the 5 percent cap on wage index decreases) by the payment rate for non-LUPA 30-day periods using the CY 2025 wage index (with the 5 percent cap on wage index decreases), we obtain a wage index budget neutrality factor of 1.0025. We then apply the wage index budget neutrality factor of 1.0025 to the 30-day period payment rate.

Next, we update the 30-day period payment rate by the final CY 2026 home health payment update percentage of 2.4 percent. As discussed in section II.C.1. of this final rule, we also finalizing the implementation of a temporary -3.0 percent reduction to the CY 2026 base payment rate. The final temporary adjustment factor is 0.97000. Per section 1895(b)(3)(D)(iii) of the Act a temporary adjustment is to be applied for the applicable year and not included when computing a payment rate for a subsequent year. In other words, the temporary adjustment factor for CY 2026 should not be included in the starting payment rate for CY 2027. Therefore, we have calculated the CY 2026 national, standardized 30-day period payment with and without the temporary adjustment factor. The CY 2026 national standardized 30-day period payment rate without a temporary adjustment is only for illustrative purposes. The actual CY 2026 national standardized 30-day period payment rate includes the final temporary adjustment and is calculated in table 14.

Next, we update the 30-day period payment rate by the final CY 2026 home health payment update percentage of 2.4 percent. The CY 2026 national standardized 30-day period payment rate is calculated in table 14.

TABLE 14: CY 2026 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT

CY 2025 National Standardized 30-Day Period Payment	Permanent Adjustment Factor	CY 2026 Case-Mix Weights Recalibration Neutrality Factor	CY 2026 Wage Index Budget Neutrality Factor	CY 2026 HH Payment Update Factor	CY 2026 National, Standardized 30-Day Period Payment (Without Temporary Adjustment)	Temporary Adjustment Factor	CY 2026 National, Standardized 30-Day Period Payment (With Temporary Adjustment)
$2,057.35	0.98977	1.0052	1.0025	1.024	$2,101.26	0.97000	$2,038.22

The CY 2026 national standardized 30-day period payment rate for an HHA that does not submit the required quality data will be updated by 0.4 percent (the final CY 2026 home health payment update percentage of 2.4 percent minus 2 percentage points) and is shown in table 15.

TABLE 15: CY 2026 NATIONAL, STANDARDIZED 30-DAY PERIOD PAYMENT AMOUNT FOR HHAS THAT DO NOT SUBMIT THE QUALITY DATA

CY 2025 National Standardized 30-Day Period Payment	Permanent Adjustment Factor	CY 2026 Case-Mix Weights Recalibration Neutrality Factor	CY 2026 Wage Index Budget Neutrality Factor	CY 2026 HH Payment Update Factor Minus 2 Percentage Points	CY 2026 National, Standardized 30-Day Period Payment (Without Temporary Adjustment)	Temporary Adjustment Factor	CY 2026 National, Standardized 30-Day Period Payment (With Temporary Adjustment)
$2,057.35	0.98977	1.0052	1.0025	1.004	$2,060.22	0.97000	$1,998.41

c. Final CY 2026 National Per-Visit Rates for 30-day Periods of Care

The national per-visit rates are used to pay LUPAs and are also used to compute imputed costs in outlier calculations. The per-visit rates are paid by type of visit or home health discipline. The six home health disciplines are as follows:

- Home health aide (HH aide).
- Medical Social Services (MSS).
- Occupational therapy (OT).
- Physical therapy (PT).

- Skilled nursing (SN).
- Speech-language pathology (SLP).

To calculate the final CY 2026 national per-visit rates, we started with the CY 2025 national per-visit rates. Then we applied a wage index budget neutrality factor to ensure budget neutrality for LUPA per-visit payments. We calculated the wage index budget neutrality factor by simulating total payments for LUPA 30-day periods of care using the CY 2026 wage index with the 5 percent cap on wage index decreases and comparing it to simulated total payments for LUPA 30-day periods of care using the CY 2025 wage index with the 5 percent cap. By dividing the total payments for LUPA 30-day periods of care using the CY 2026 wage index by the total payments for LUPA 30-day periods of care using the CY 2025 wage index, we obtained a wage index budget neutrality factor of 1.0005. As a reminder, the wage index budget neutrality factors for the national, standardized 30-day period amount and the national LUPA per-visit rates are not equal because they are calculated differently. The wage index budget neutrality factor for the LUPA per-visit payments is calculated by simulating total payments for LUPA 30-day periods while the 30-day period budget neutrality factor is calculated by simulating payments for non-LUPA 30-day periods.

The LUPA per-visit rates are not calculated using case-mix weights. Therefore, no case-mix weight budget neutrality factor is needed to ensure budget neutrality for LUPA payments. Additionally, we are not applying the permanent adjustment or the temporary adjustment to the per-visit payment rates but only to the case-mix adjusted 30-day payment rate. Lastly, the per-visit rates for each discipline are updated by the final CY 2026 home health payment update percentage of 2.4 percent. The national per-visit rates are adjusted by the wage index based on the site of service of the beneficiary. The per-visit payments for LUPAs are separate from the LUPA add-on payment amount, which is paid for periods that occur as the only period or initial period in a sequence of adjacent periods. The final CY 2026 national

per-visit rates for HHAs that submit the required quality data are updated by the final CY 2026 home health payment update percentage of 2.4 percent and are shown in table 16.

TABLE 16: FINAL CY 2026 NATIONAL PER-VISIT PAYMENT AMOUNTS

HH Discipline	CY 2025 Per-Visit Payment Amount	CY 2026 Wage Index Budget Neutrality Factor	CY 2026 HH Payment Update Factor	CY 2026 Per-Visit Payment Amount
Home Health Aide	$78.20	1.0005	1.0240	$80.12
Medical Social Services	$276.85	1.0005	1.0240	$283.64
Occupational Therapy	$190.08	1.0005	1.0240	$194.74
Physical Therapy	$188.79	1.0005	1.0240	$193.42
Skilled Nursing	$172.73	1.0005	1.0240	$176.96
Speech-Language Pathology	$205.22	1.0005	1.0240	$210.25

The CY 2026 per-visit payment rates for HHAs that do not submit the required quality data will be updated by 0.4 percent, which is the final CY 2026 home health payment update percentage of 2.4 percent minus 2 percentage points and are shown in table 17.

TABLE 17: FINAL CY 2026 NATIONAL PER-VISIT PAYMENT AMOUNTS FOR HHAS THAT DO NOT SUBMIT THE REQUIRED QUALITY DATA

HH Discipline	CY 2025 Per-Visit Payment Amount	CY 2026 Wage Index Budget Neutrality Factor	CY 2026 HH Payment Update Factor Minus 2 Percentage Points	CY 2026 Per-Visit Payment Amount
Home Health Aide	$78.20	1.0005	1.0040	$78.55
Medical Social Services	$276.85	1.0005	1.0040	$278.10
Occupational Therapy	$190.08	1.0005	1.0040	$190.94
Physical Therapy	$188.79	1.0005	1.0040	$189.64
Skilled Nursing	$172.73	1.0005	1.0040	$173.51
Speech-Language Pathology	$205.22	1.0005	1.0040	$206.14

We solicited comments on the proposed CY 2026 30-day home health payments rates and per-visit payment rates, but did not receive comments on this proposal.

Final Decision: We are finalizing the updates to the CY 2026 national, standardized 30-day period payment rates and the CY 2026 national per-visit payment amounts as proposed, using the final CY 2026 market basket update.

d. LUPA Add-On Factors

Prior to the implementation of the 30-day unit of payment, LUPA episodes were eligible for a LUPA add-on payment if the episode of care was the first or only episode in a sequence of adjacent episodes. As described in the CY 2008 HH PPS final rule, the average visit lengths in these initial LUPAs are 16 to 18 percent higher than the average visit lengths in initial non-LUPA episodes (72 FR 49848). LUPA episodes that occur as the only episode or as an initial episode in a sequence of adjacent episodes are adjusted by applying an additional amount to the LUPA payment before adjusting for area wage differences.

In the CY 2014 HH PPS final rule (78 FR 72305), we changed the methodology for calculating the LUPA add-on amount, whereby we finalized the approach of multiplying the per-visit payment amount for the first skilled nursing (SN), physical therapy (PT), or speech language pathology (SLP) visit in LUPA episodes that occur as the only episode or an initial episode in a sequence of adjacent episodes by 1 + the proportional increase in minutes for an initial visit over non-initial visits. Specifically, we updated the analysis using 100 percent of LUPA episodes and a 20 percent sample of non-LUPA first episodes from CY 2012 claims data. At that time, we finalized add-on factors: 1.8451 for SN; 1.6700 for PT; and 1.6266 for SLP. In the CY 2019 HH PPS final rule with comment period (83 FR 56440), in addition to finalizing a 30-day unit of payment, we finalized our policy of continuing to multiply the per-visit payment amount for the first SN, PT, or SLP visit in LUPA periods that occur as the only period of care or the initial 30-day period of care in a sequence of adjacent 30-day periods of care by the appropriate add-on factor (using the already established LUPA add-on factors of 1.8451 for SN, 1.6700 for PT, and 1.6266 for SLP) to determine the LUPA add-on payment amount for 30-day periods of care under the PDGM.

In the CY 2025 HH PPS final rule (89 FR 88426 through 88427), in an effort to enhance the accuracy and relevance of LUPA add-on factors to reflect current healthcare practices and costs, we finalized updates to the LUPA add-on factors for PT, SN, and SLP, which had not been revised since the CY 2014 HH PPS final rule (using CY 2012 claims data). We finalized the

proposal to use the same methodology to establish the LUPA add-on amount for CY 2014, using updated claims data.

Specifically, we updated the LUPA add-on factors by using 100 percent of LUPA periods and a 100 percent sample of non-LUPA first periods from CY 2023 claims data (as of September 11, 2024). Our analysis found that the average excess of minutes for the first visit in LUPA periods that were the only period or an initial LUPA in a sequence of adjacent periods are 29.91 minutes for the first visit if SN, 28.08 minutes for the first visit if PT, and 31.57 minutes for the first visit if SLP. The average minutes for all non-first visits in non-LUPA episodes are 41.54 minutes for SN, 45.11 minutes for PT, and 47.15 minutes for SLP. To determine the LUPA add-on factors for each discipline, we calculated the ratio of the average excess minutes for the first visits in LUPA claims to the average minutes for all non-first visits in non-LUPA claims. We then added one to these ratios to obtain the final add on factors. Therefore, beginning in CY 2025 the final LUPA add on factors for SN, PT, and SLP are 1.7200 for SN; 1.6225 for PT; and 1.6696 for SLP.

Additionally, as outlined in the CY 2025 HH PPS proposed rule (89 FR 55378), in order to implement Division CC, section 115, of the Consolidation Appropriations Act (CAA), 2021, CMS finalized changes to the regulations at § 484.55(a)(2) and (b)(3) that allowed occupational therapists to conduct initial and comprehensive assessments for all Medicare beneficiaries under the home health benefit when the plan of care does not initially include skilled nursing care, but included OT, as well as either PT or SLP (86 FR 62351). This change necessitated the establishment of a LUPA add-on factor for calculating the LUPA add-on payment amount for the first skilled OT visit in LUPA periods that occur as the only period of care or the initial 30-day period of care in a sequence of adjacent 30-day periods of care. However, at the time of the implementation, we stated in the CY 2022 HH PPS final rule (86 FR 62289), there was not sufficient data regarding the average excess minutes for the first visit in LUPA periods when the initial and comprehensive assessments are conducted by occupational therapists. Therefore, we

finalized a policy using the PT LUPA add-on factor as a proxy. We also stated in the CY 2022 final rule that we will use the PT LUPA add-on factor as a proxy until we have CY 2022 data to establish a more accurate OT add-on factor for the LUPA add-on payment amounts (86 FR 62289). Ultimately, we refrained from using CY 2022 data (and instead utilized the PT LUPA add-on factor as a proxy for the OT LUPA add-on factor), as we marked the first year that occupational therapists were permitted to conduct the initial assessment. We wanted to extend our analysis to ensure we had sufficient data to reflect OT time spent conducting initial assessments to establish a discrete OT LUPA add-on factor (86 FR 62240).

In the CY 2025 HH PPS final rule (89 FR 88427), we finalized a proposal to discontinue use of the PT LUPA add-on factor as a proxy and established a definitive LUPA add-on factor for occupational therapy. We used the same methodology used to establish the LUPA add-on amount for CY 2014, as described previously for the SN, PT, and SLP add-on factors. Specifically, we updated the analysis using 100 percent of LUPA periods and a 100 percent sample of non-LUPA first periods from CY 2023 claims data. Using updated analysis (as of September 11, 2024), we found that the average excess of minutes for the first OT visit in LUPA periods that were the only period or an initial LUPA in a sequence of adjacent periods is 33.28 minutes for the first visit. The average number of minutes for all non-first visits in non-LUPA periods is 45.98 minutes for OT. To determine the LUPA add-on factor for OT to account for the excess minutes during the first visit in a LUPA period, we finalized calculating the ratio of the average excess minutes for the first visits in LUPA claims to the average minutes for all non-first visits in non-LUPA claims. We then added one to this ratio to obtain the final add on factor of 1.7238 for OT. Therefore, the OT LUPA factor of 1.7238 is used when occupational therapy is the first skilled visit in a LUPA period that occurs as the only period or an initial period in a sequence of adjacent periods.

TABLE 18: LUPA ADD-ON FACTORS

Discipline	LUPA Add-on Factors
SN	1.7200

PT	1.6225
SLP	1.6696
OT	1.7238

4. Payments for High-Cost Outliers under the HH PPS

a. Background

Section 1895(b)(5) of the Act allows for the provision of an addition or adjustment to the home health payment amount otherwise made in the case of outliers because of unusual variations in the type or amount of medically necessary care. Under the HH PPS and the previous unit of payment (that is, 60-day episodes), outlier payments were made for 60-day episodes whose estimated costs exceed a threshold amount for each HHRG. The episode's estimated cost was established as the sum of the national wage-adjusted per-visit payment amounts delivered during the episode. The outlier threshold for each case-mix group or PEP adjustment is defined as the 60-day episode payment or PEP adjustment for that group plus a fixed-dollar loss (FDL) amount. For the purposes of the HH PPS, the FDL amount is calculated by multiplying the home health FDL ratio by a case's wage-adjusted national, standardized 60-day episode payment rate, which yields an FDL dollar amount for the case. The outlier threshold amount is the sum of the wage and case-mix adjusted PPS episode amount and wage-adjusted FDL amount. The outlier payment is defined as a proportion of the wage-adjusted estimated cost that surpasses the wage-adjusted threshold. The proportion of additional costs over the outlier threshold amount paid as outlier payments is referred to as the loss-sharing ratio.

As we noted in the CY 2011 HH PPS final rule (75 FR 70397 through 70399), section 3131(b)(1) of the Affordable Care Act amended section 1895(b)(3)(C) of the Act to require that the Secretary reduce the HH PPS payment rates such that aggregate HH PPS payments were reduced by 5 percent. In addition, section 3131(b)(2) of the Affordable Care Act amended section 1895(b)(5) of the Act by redesignating the existing language as section 1895(b)(5)(A) of the Act and revised the language to state that the total amount of the additional payments or payment adjustments for outlier episodes could not exceed 2.5 percent of the estimated total HH

PPS payments for that year. Section 3131(b)(2)(C) of the Affordable Care Act also added section 1895(b)(5)(B) of the Act, which capped outlier payments as a percent of total payments for each HHA for each year at 10 percent.

As such, beginning in CY 2011, we reduced payment rates by 5 percent and targeted up to 2.5 percent of total estimated HH PPS payments to be paid as outliers. To do so, we first returned the 2.5 percent held for the target CY 2010 outlier pool to the national, standardized 60-day episode rates, the national per visit rates, the LUPA add-on payment amount, and the NRS conversion factor for CY 2010. We then reduced the rates by 5 percent as required by section 1895(b)(3)(C) of the Act, as amended by section 3131(b)(1) of the Affordable Care Act. For CY 2011 and subsequent calendar years we targeted up to 2.5 percent of estimated total payments to be paid as outlier payments, and apply a 10-percent agency-level outlier cap.

In the CY 2017 HH PPS proposed and final rules (81 FR 43737 through 43742 and 81 FR 76702), we described our concerns regarding patterns observed in home health outlier episodes. Specifically, we noted the methodology for calculating home health outlier payments may have created a financial incentive for providers to increase the number of visits during an episode of care in order to surpass the outlier threshold and simultaneously created a disincentive for providers to treat medically complex beneficiaries who require fewer but longer visits. Given these concerns, in the CY 2017 HH PPS final rule (81 FR 76702), we finalized changes to the methodology used to calculate outlier payments, using a cost-per-unit approach rather than a cost-per-visit approach. This change in methodology allows for more accurate payment for outlier episodes, accounting for both the number of visits during an episode of care and the length of the visits provided. Using this approach, we now convert the national per-visit rates into per 15-minute unit rates. These per 15-minute unit rates are used to calculate the estimated cost of an episode to determine whether the claim would receive an outlier payment and the amount of payment for an episode of care. In conjunction with our finalized policy to change to a cost-per-unit approach to estimate episode costs and determine whether an outlier episode should

receive outlier payments, in the CY 2017 HH PPS final rule we also finalized the implementation of a cap on the amount of time per day that would be counted toward the estimation of an episode's costs for outlier calculation purposes (81 FR 76725). Specifically, we limit the amount of time per day (summed across the six disciplines of care) to 8 hours (32 units) per day when estimating the cost of an episode for outlier calculation purposes.

In the CY 2017 HH PPS final rule (81 FR 76724), we stated that we did not plan to re-estimate the average minutes per visit by discipline every year. Additionally, the per unit rates used to estimate an episode's cost were updated by the home health update percentage each year, meaning we would start with the national per visit amounts for the same calendar year when calculating the cost-per-unit used to determine the cost of an episode of care (81 FR 76727). We would continue to monitor the visit length by discipline as more recent data becomes available and may propose updating the rates as needed in the future.

In the CY 2019 HH PPS final rule with comment period (83 FR 56521), we finalized a policy to maintain the current methodology for payment of high-cost outliers upon implementation of PDGM beginning in CY 2020 and calculated payment for high-cost outliers based upon 30-day period of care. Upon implementation of the PDGM and 30-day unit of payment, we finalized the FDL ratio of 0.56 for 30-day periods of care in CY 2020. In the CY 2025 HH PPS final rule (89 FR 88354), using CY 2023 claims data (as of July 11, 2024) we finalized the FDL ratio of 0.35 for CY 2025.

b. Final FDL Ratio for CY 2026

For a given level of outlier payments, there is a trade-off between the values selected for the FDL ratio and the loss-sharing ratio. A high FDL ratio reduces the number of periods that can receive outlier payments but makes it possible to select a higher loss-sharing ratio, and therefore, increase outlier payments for qualifying outlier periods. Alternatively, a lower FDL ratio means that more periods can qualify for outlier payments, but outlier payments per period must be lower.

The FDL ratio and the loss-sharing ratio are selected so that the estimated total outlier payments do not exceed the 2.5 percent aggregate level (as required by section 1895(b)(5)(A) of the Act). Historically, we have used a value of 0.80 for the loss-sharing ratio, which we believe preserves incentives for agencies to attempt to provide care efficiently for outlier cases. With a loss-sharing ratio of 0.80, Medicare pays 80 percent of the additional estimated costs that exceed the outlier threshold amount.

Using CY 2024 claims data (as of March 13, 2025) and given the statutory requirement that total outlier payments do not exceed 2.5 percent of the total payments estimated to be made under the HH PPS, we proposed an FDL ratio of 0.46 for CY 2026. CMS stated that we would update the FDL, if needed, in the final rule once we have more complete CY 2024 claims data.

We solicited comments on the proposed CY 2026 FDL. The following is a summary of the comments we received and our responses:

Comment: Several commenters opposed the proposed update to the CY 2026 FDL. A commenter recommended maintaining the current FDL for CY 2026. Other commenters expressed concern that CMS is raising the FDL based on potentially fraudulent data, specifically in what they describe as high fraud areas such as LA County. These commenters recommended excluding suspect claims so that legitimate HHAs are not penalized based on flawed data. Another commenter suggested that raising the FDL will make it harder to qualify for outlier payments and could harm agencies caring for high acuity patients.

Response: We remind commenters that the FDL is set such that outlier payments do not exceed 2.5 percent of total home health payments. A high FDL ratio reduces the number of episodes that can receive outlier payments but makes it possible to select a higher loss-sharing ratio, and therefore, increase outlier payments for qualifying outlier episodes. Alternatively, a lower FDL ratio means that more episodes can qualify for outlier payments, but outlier payments per episode must then be lower. We appreciate the commenters' concerns regarding potential fraudulent billing and its potential impact on the proposed FDL. However, as discussed

previously, outlier billing patterns are not always indicative of fraudulent practice. CMS currently includes the most recent and complete claims data when updating the FDL. If CMS excluded the claims the commenter views as outliers from the calculation of the FDL, CMS would need to make thresholds for determining what qualifies as an outlier to be excluded from the analytical sample. In addition, dropping providers with anomalous billing patterns can cause the sample to be much smaller relative to the most recent and complete claims for that given year. It is important to note that providers that have anomalous billing patterns will need further evidence to state definitively whether their activities cannot be connected to fraudulent practices. Depending on the circumstance, anomalous patterns can prompt further review and initiate investigation for evidence of fraud, waste, and abuse.

We appreciate commenters sharing insight into how we can address concerns about potential fraud in the home health market. Cost report fraud and abusive billing behavior are concerns that need to be addressed through the appropriate channels with the authority to pursue enforcement action, such as the hotline for reporting fraud at the following website: https://www.cms.gov/medicare/medicaid-coordination/center-program-integrity/reporting-fraud.

Furthermore, we are statutorily required to ensure that total outlier payments do not exceed the 2.5 percent aggregate level (as required by section 1895(b)(5)(A) of the Act). In the CY 2019 HH PPS final rule with comment period (83 FR 56521), we finalized a policy to maintain the current methodology for payment of high-cost outliers upon implementation of the PDGM beginning in CY 2020 and calculated payment for high-cost outliers based upon 30-day periods of care. We have used the most recent claims data to calculate the FDL ratio since that time. In the CY 2026 HH PPS proposed rule, we stated that we would use the most recent claims data available which is CY 2024 claims data. Using CY 2024 claims data, we found that the FDL ratio would need to be increased from the final CY 2025 FDL of 0.35 to 0.37.

Final Decision: With updated CY 2024 claims data (as of July 11, 2025) and given the statutory requirement that total outlier payments not exceed 2.5 percent of the total payments estimated to be made under the HH PPS, we are finalizing an FDL ratio of 0.37 for CY 2026.

F. Change to Face-to-Face Encounter Regulations

As a condition for payment, section 6407(a) of the Affordable Care Act (Pub. L. 111-148, March 23, 2010) requires that prior to certifying a patient's eligibility for the home health benefit, the physician must document that the physician himself or herself or a non-physician practitioner (NPP) has had a face-to-face encounter with the patient. In the Home Health Prospective Payment System Rate Update for Calendar Year 2011; Changes in Certification Requirements for Home Health Agencies and Hospices final rule (75 FR 70427) (hereinafter referred to as the CY 2011 HH PPS final rule), we established that the certifying physician must document the face-to-face encounter regardless of whether the physician himself or herself or one of the permitted NPPs performed the face-to-face encounter. Sections 6407(a)(1)(B) and 6407(a)(2)(B) of the Affordable Care Act further describe NPPs who may perform this face-to-face patient encounter.

In the Medicare Program, Home Health Prospective Payment System Rate Update for Calendar Year 2012 final rule (hereinafter referred to as the CY 2012 HH PPS final rule), we stated that the Medicare home health benefit relies on the patient's physician to determine eligibility for home health services (76 FR 68596), noting that this type of physician involvement is critical from both a quality of care and program integrity perspective. Prior to enactment of section 6407(a) of the Affordable Care Act regarding the home health face-to-face encounter provision, the patient's physician often relied on information provided by an HHA when making decisions about patient care. In the CY 2012 HH PPS final rule (76 FR 68597), we stated that, in addition to the certifying physician and allowed NPPs, the physician who cared for the patient in an acute or post-acute care facility, and who had privileges in such facility, could also perform the face-to-face encounter and inform the certifying physician, who would document the

encounter as part of the certification of eligibility, and that encounter supported the patient's homebound status and need for skilled services. During the CY 2012 HH PPS rulemaking comment period, stakeholders requested that CMS allow any physician to complete the face-to-face encounter, rather than limiting it to the certifying physician or allowed NPP; however, CMS referred commenters to the CY 2011 HH PPS final rule where we stated we did not believe that we had the statutory authority to allow for this additional flexibility (76 FR 68596). The Affordable Care Act established the requirement for a physician face-to-face encounter prior to certifying a patient's eligibility for home health services, along with other program integrity provisions, to address concerns surrounding ineligible patients receiving home health services and concerns that physicians who had no firsthand knowledge of the patient's clinical condition were certifying the patient's eligibility for home health. In the CY 2011 HH PPS final rule, we described research that showed fewer re-hospitalizations when the home health patient had a recent encounter with the physician responsible for the home health care plan. As such, 42 CFR 424.22(a)(1)(v)(A) requires that a face-to-face encounter be performed by the certifying physician; the certifying allowed practitioner (nurse practitioner, clinical nurse specialist, physician assistant); or a certified nurse midwife. Additionally, 42 CFR 424.22(a)(1)(v)(C) requires that a face-to-face encounter be performed by the certifying physician or allowed practitioner unless the encounter is performed by a certified nurse midwife or a physician, physician assistant, nurse practitioner, or clinical nurse specialist with privileges who cared for the patient in an acute or post-acute care facility from which the patient was directly admitted to home health and who is different from the certifying practitioner.

Section 3708 of the Coronavirus Aid, Relief, and Economic Security Act, 2020 (CARES Act) (Pub. L.116-136, March 27, 2020) amended sections 1814(a) and 1835(a) of the Act to allow nurse practitioners (NPs), clinical nurse specialists (CNSs), and physician assistants (PAs) (as those terms are defined in section 1861(aa) of the Act), to order and certify patients for eligibility under the Medicare home health benefit and establish a plan of care. Since its

implementation in the March 31, 2020 COVID-19 interim final rule with comment period (85 FR 27550), CMS has received requests from stakeholders to change the current face-to-face encounter policy to allow any practitioner to perform the face-to-face encounter and not limit this regulation to the certifying practitioner, a permitted NPP, or a physician or allowed practitioner with privileges who cared for the patient in an acute or post-acute care facility from which the patient was directly admitted to home health, as set out at § 424.22(a)(1)(v)(C). Commenters have stated that the CARES Act language allows this additional flexibility. Additionally, commenters have stated, and CMS agrees, that the current regulation text at § 424.22(a)(1)(v)(A)(1) through (4) can be read to allow NPs, CNSs, and PAs to perform the face-to-face encounter regardless of whether they certify the patient for home health services, but limits the provision of the face-to-face encounter to the certifying physician or a physician, with privileges, who cared for the patient in an acute or post-acute care facility from which the patient was directly admitted to home health. Therefore, stakeholders have requested that any physician, in addition to NPs, CNSs, and PAs, be allowed to perform the face-to-face encounter regardless of whether they are the certifying practitioner or whether they cared for the patient in the acute or post-acute facility from which the patient was directly admitted to home health and who is different from the certifying practitioner. Some commenters have referenced situations in which a patient sees a physician in the same practice as the patient's primary care physician (PCP), but where the patient's PCP was unavailable to see the patient on a particular date.

As stated in the CY 2026 proposed rule, we agree that it would be reasonable for the patient's PCP to certify eligibility under the Medicare home health benefit and establish the plan of care even though a different physician or allowed practitioner in the same practice conducted the face-to-face encounter. However, we note that it would not be appropriate for a practitioner who specializes in optometry to certify a patient for home health services that are needed due to orthopedic reasons. These are only a couple of examples of circumstances that could occur, and

we do not enumerate in this rulemaking all situations in which the certifying provider may be different than the provider who conducted the face-to-face encounter.

Regarding our original concern in limiting the face-to-face encounter to the certifying provider (or the provider who cared for the patient in the inpatient facility), we still believe physician or allowed practitioner involvement is critical from both a quality of care and program integrity perspective. However, we note that additional program integrity protections exist currently in the certification policies. To be eligible for Medicare home health services, in accordance with § 424.22(a)(1)(iv) a patient must be under the care of a physician or an allowed practitioner. Additionally, in accordance with § 424.22(a)(1)(v), the face-to-face encounter documentation must be related to the primary reason the patient requires home health services, occur in the required time frame by an allowed provider type, and the certifying practitioner must include a signature and the date of the encounter as part of the certification. Furthermore, our subregulatory guidance in the Medicare General Information, Eligibility and Entitlement Manual (Pub. 100-01, chapter 4, section 30.1) provides that physicians and allowed practitioners should complete the certification when the plan of care is established, or as soon as possible thereafter, and that it is not acceptable to wait until the end of the required time frame to complete the requirements. As such, the certification also cannot be completed after a patient is discharged from home health services.

Additionally, our subregulatory guidance in the Medicare General Information, Eligibility and Entitlement Manual (Pub. 100-01, chapter 4, section 30.1), the Medicare Benefit Policy Manual (Pub. 100–02, chapter 7, section 30.5), and the Medicare Program Integrity Manual (Pub. 100–08, chapter 6 section 6.2.1 and 6.2.3) also supports our program integrity and quality goals. Specifically, the subregulatory guidance provides additional details on requirements that include the following: specific signature and date requirements; a requirement for an actual clinical note from the certifying practitioners for the face-to-face encounter visit; specific information that must be present in face-to-face encounter documentation; a requirement

that a new face-to-face encounter is required if the patient's condition has changed; a requirement that home health eligibility must be supported by other medical entries in the certifying provider's medical record for the patient and this documentation must be available for medical reviews as needed; and a requirement that documentation of the face-to-face encounter can only be from physicians or allowed NPPs who do not have a financial relationship with the HHA.

We also stated in the CY 2026 proposed rule that we believe the regulations at 42 CFR 424.22(a)(1), in conjunction with the Medicare home health eligibility requirements at 42 CFR 424.22(c), finalized in the CY 2019 final rule (83 FR 56627), provide sufficient preservation of our original intent of ensuring that the home health benefit relies on the patient's physician (or subsequently, the allowed practitioner) to determine eligibility for home health services, and that the physician or NPP performing the face-to-face encounter should be a practitioner who is most knowledgeable and has firsthand information of the patient's current clinical condition when certifying the patient's eligibility for home health services and establishing a patient's plan of care.

As such, we proposed to revise § 424.22(a)(1)(v)(A) to state that the face-to-face encounter must be performed by one of the following: a physician, a nurse practitioner, a clinical nurse specialist, or a physician assistant as defined at 42 CFR 484.2; or a certified nurse-midwife as defined in section 1861(gg) of the Act as authorized by State law. We also proposed to remove § 424.22(a)(1)(v)(C), which limits the face-to-face encounter to the certifying physician or allowed practitioner unless the encounter is performed by either of the following:

- A certified nurse midwife as described in paragraph (a)(1)(v)(A)(4) of this section.
- A physician, physician assistant, nurse practitioner, or clinical nurse specialist with privileges who cared for the patient in the acute or post-acute facility from which the patient was directly admitted to home health and who is different from the certifying practitioner.

We stated that this additional flexibility should decrease ambiguity regarding which providers are able to complete the face-to-face encounter and potentially improve access to home health services by increasing the number of providers allowed to perform the face-to-face encounter. We noted that these revisions would also address concerns that the current regulations do not align with the CARES Act language.

We solicited comments on these proposed revisions to 42 CFR 424.22(a)(1)(v) and the proposed removal of § 424.22(a)(1)(v)(C).

Comment: All commenters expressed strong support for the proposed changes that would expand who can conduct face-to-face encounters. Some commenters specifically expressed appreciation that CMS proposed these changes after they were suggested by stakeholders in past comments and letters to CMS. Commenters consistently praised CMS for aligning regulations with the CARES Act provisions and simplifying the process, which addresses timely care initiation while maintaining program integrity. Additionally, commenters stated that the proposed changes would improve access to care and administrative efficiency due to operational flexibility, streamlined processes, and reduce administrative complexity. They also stated that the proposed changes would improve workforce optimization allowing for team-based care and resource utilization, especially in complex care settings, rural areas, HHAs with staffing challenges, and when managing referrals from various settings.

Response: We thank commenters for their support.

Comment: A few commenters requested that CMS provide additional clarification and guidance related to implementation details, documentation requirements, and acceptable formats to ensure consistent application across contractors, specifically as they relate to facility and community referrals, MACs, and auditors. Another commenter requested clarification regarding the requirement that face-to-face encounters need to be related to the primary reason for home health services, mentioning that this requirement has been interpreted by HHAs to mean that the primary diagnosis needs to be in perfect alignment with the face-to-face encounter. Additionally,

a few commenters asked clarifying questions related to the proposed face-to-face encounter changes as follows: Will HHAs be required to delay sending the certification statement until the completed face-to-face encounter documentation is received, or can a handoff be documented in other ways? If documentation of collaboration is required, will it suffice for the HHA to record the process, or must a formal order be signed by both the certifying provider and the face-to-face encounter provider? If a specialist performs the face-to-face encounter, will HHAs be required to demonstrate how that specialist is involved in the patient's plan of care? And will CMS mandate that Medicare Advantage (MA) plans align their requirements with CMS policy, or should HHAs prepare for distinct processes across MA plans? A few commenters requested guidance on whether CMS intends to issue parameters to guide how HHAs and practitioners demonstrate that the face-to-face encounter is conducted by the most knowledgeable practitioner, especially in situations where care is shared among providers. These commenters also requested that CMS maintain flexibility for HHAs and practitioners to determine, based on clinical judgment and care team structure, which practitioner is best positioned to perform the face-to-face encounter while still meeting eligibility and certification requirements. One commenter also recommended that educational materials related to regulatory changes be made available in Spanish to avoid errors in the interpretation of documentation requirements.

Response: We thank the commenters for their recommendations. We will take all these suggestions into consideration when updating subregulatory guidance with additional clarifying information and examples if needed. Additionally, we have issued instructions in the past to the contractors who perform medical reviews to ensure compliance with this regulation, and we will continue to educate MACs and auditors to further support consistent application of existing regulations and this added flexibility. We would like to remind readers that these changes only add flexibility to the face-to-face encounter and do not otherwise change the intent, documentation requirements, or acceptable formats of the face-to-face encounter. We refer readers back to our subregulatory guidance in the Medicare General Information, Eligibility and

Entitlement Manual (Pub. 100-01, chapter 4, section 30.1), the Medicare Benefit Policy Manual (Pub. 100–02, chapter 7, section 30.5), and the Medicare Program Integrity Manual (Pub. 100–08, chapter 6, sections 6.2.1 and 6.2.3) for additional details on our program integrity, quality goals, and requirements for the face-to-face encounters.

We also remind commenters that diagnosis codes are not required to be on the face-to-face documentation and do not exactly have to match the primary diagnosis for which the patient is receiving home health services. Rather, the face-to-face documentation has to sufficiently demonstrate that the encounter was related to the primary reason that home health services were needed (42 CFR 424.22(a)(1)(v)). With respect to the specific questions on timing of the face-to-face encounter and certification statement, the HHA's method of recording collaboration between providers including specialists, and how HHAs and practitioners can demonstrate the most knowledgeable practitioner, we remind readers again that these changes allow for additional flexibility with respect to the practitioners who can complete the face-to-face encounter; the intent and guidelines of the face-to-face encounter and other payment policies are otherwise unchanged. Additionally, a condition of participation for HHAs includes care coordination, such as assuring communication with all physicians or allowed practitioners involved in the plan of care and integrating orders from all physicians or allowed practitioners involved in the patient's plan of care to assure the coordination of all services and interventions. We agree with the commenter that HHAs should use clinical judgment to determine what practitioner is the most appropriate to perform the face-to-face encounter, and we intend to maintain this flexibility for HHAs; however, the documentation needs to support that the physician completing the face-to-face encounter has firsthand information of the patent's primary reason for needing home health services and also is the most appropriate (that is, the most knowledgeable) provider to complete the face-to-face encounter. Lastly, regarding Medicare Advantage plan requirements, this is outside the scope of our proposed policy, as this policy only applies to Medicare FFS home health payment requirements.

Comment: A commenter requested that the face-to-face encounter requirement be eliminated, noting their belief that it creates an administrative burden due to diverting limited resources from patient care to paperwork navigation and creating unnecessary obstacles for patients and providers, causes access to care concerns due to delays and disruptions to care, and is ineffective in achieving the original intent of the requirement, which was to reduce fraud, waste, and abuse. This commenter suggested that CMS focus its program integrity efforts on targeting "bad providers" instead of implementing broad requirements that burden "good providers" and prioritize outcomes over administrative processes.

Response: We appreciate the commenter's feedback; however, the face-to-face encounter requirement is set forth in section 1814(a)(2)(C) of the Act, and, because this is a statutory requirement, we must require this encounter as a condition for payment and have no regulatory discretion to eliminate it. As such, we refer readers back to the CY 2011 HH PPS final rule, where we cited research that supports that recent physician involvement results in significantly better patient outcomes and decreased hospitalizations compared to patients who did not receive a face-to-face physician visit during their episode of care (Wolff et al., 2009, p. 11511). Additionally, the CY 2011 HH PPS final rule addressed concerns about feasibility by providing increased flexibility to the time frames in which face-to-face encounters are completed in order to address access to care risks, especially those faced in rural areas, and accounted for administrative burden. Care coordination, including assuring communication with all physicians or allowed practitioners involved in the plan of care, is a condition of participation and the responsibility of the HHA. Additionally, we note that these changes provide additional flexibility by allowing more providers to conduct the face-to-face encounter.

Comment: A few commenters requested that telehealth face-to-face encounters be permitted to reduce burden on beneficiaries and improve access to care. One commenter requested that Puerto Rico be given this flexibility to utilize telehealth face-to-face encounters due to the recurring natural disasters that they face.

Response: We thank commenters for their suggestions. Telehealth face-to-face encounters can be performed at an approved originating site as specified in the Medicare Benefit Policy Manual (Pub. 100–02, chapter 7, section 30.5.1.1).

Final Decision: We are finalizing the changes to the face-to-face encounter regulations as proposed.

III. Home Health Quality Reporting Program (HH QRP)

A. Background and Statutory Authority

The HH QRP is authorized by section 1895(b)(3)(B)(v) of the Act. Section 1895(b)(3)(B)(v)(II) of the Act requires that, for 2007 and subsequent years, each home health agency (HHA) submit to the Secretary in a form and manner, and at a time, specified by the Secretary, such data that the Secretary determines are appropriate for the measurement of health care quality. To the extent that an HHA does not submit data in accordance with this clause, the Secretary shall reduce the home health market basket percentage increase applicable to the HHA for such year by 2 percentage points pursuant to section 1895(b)(3)(B)(v)(I) of the Act. As provided at section 1895(b)(3)(B)(vi) of the Act, depending on the market basket percentage increase applicable for a particular year, as further reduced by the productivity adjustment (except in 2018 and 2020) described in section 1886(b)(3)(B)(xi)(II) of the Act, the reduction of that increase by 2 percentage points for failure to comply with the requirements of the HH QRP may result in the home health market basket percentage increase being less than 0.0 percent for a year, and may result in payment rates under the HH PPS for a year being less than payment rates for the preceding year. Section 1890A of the Act requires that the Secretary establish and follow a pre-rulemaking process, in coordination with the consensus-based entity (CBE) with a contract under section 1890 of the Act, to solicit input from certain groups regarding the selection of quality and efficiency measures for the HH QRP. The HH QRP regulations can be found at 42 CFR 484.245 and 484.250.

B. Summary of the Provisions

In accordance with the statutory authority at section 1895(b)(3)(B)(v) of the Act, we proposed the following policies in the proposed rule: We proposed to remove the "COVID-19 Vaccine: Percent of Patients Who Are Up to Date" measure and the item related to the measure and corresponding data element. CMS proposed the removal of four assessment items: one Living Situation item, two Food items, and one Utilities item. We also proposed to revise the

policy to allow providers that fail to provide complete, timely data to CMS to submit a request for reconsideration if they can demonstrate full compliance. We noted in the proposed rule that in very limited circumstances, we would permit the HHA to request an extension to file a reconsideration request if the HHA was affected by an extraordinary circumstance beyond the control of the HHA (that is, a natural disaster such as a hurricane, tornado, or earthquake) during the 30-day reconsideration period. We also proposed to implement a revised HHCAHPS Survey beginning with the April 2026 sample month. The proposed rule also included a proposal to update regulatory text to account for all-payer data submission of OASIS data. As part of the request for information (RFI) contained in the proposed rule, we sought feedback on a potential change to the final data submission deadline from 4.5 months to 45 days after the close of the period. We also sought feedback on the digital quality measurement (DQM) transition for HHAs. We solicited feedback from the public on the current adoption of health IT and standards, including Fast Healthcare Interoperability Resources (FHIR), and what related challenges or barriers HHAs are facing. Finally, we sought input on future HH QRP quality measure (QM) concepts of interoperability, cognitive function, nutrition, and patient well-being.

For a detailed discussion of the considerations we historically use for measure selection for the HH QRP quality, resource use, and other measures, we refer readers to the CY 2016 HH PPS final rule (80 FR 68695 through 68696). In the CY 2019 HH PPS final rule with comment period (83 FR 56548 through 56550), we finalized the factors we consider for removing previously adopted HH QRP measures.

C. Quality Measures Currently Adopted for the CY 2026 HH QRP

The HH QRP currently includes 19 measures for the CY 2026 program year, as described in table C-19.

TABLE C-19: MEASURES CURRENTLY ADOPTED FOR THE CY 2026 HH QRP

Short Name	Measure Name & Data Source
QM Name	**OASIS-based**
Ambulation	Improvement in Ambulation/Locomotion (CBE #0167).
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (CBE #0674).
Bathing	Improvement in Bathing (CBE #0174).
Bed Transferring	Improvement in Bed Transferring (CBE # 0175).
Patient COVID-19 Vaccination	COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues- Post Acute Care (PAC) HH QRP.
DC Function	Discharge Function Score
Dyspnea	Improvement in Dyspnea.
Influenza	Influenza Immunization Received for Current Flu Season
Oral Medications	Improvement in Management of Oral Medications (CBE #0176).
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care
Timely Care	Timely Initiation of Care (CBE #0526).
TOH-Provider	Transfer of Health Information to Provider-Post-Acute Care[1]
TOH-Patient	Transfer of Health Information to Patient-Post-Acute Care[1]
QM Name	**Claims-based**
DTC	Discharge to Community-Post Acute Care (PAC) Home Health (HH) Quality Reporting Program (QRP) (CBE #3477)
MSPB	Total Estimated Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) HH QRP.
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for HH Quality Reporting Program.
PPH	Home Health Within Stay Potentially Preventable Hospitalization
QM Name	**HHCAHPS-based**
CAHPS Home Health Survey	CAHPS® Home Health Care Survey (experience with care) (CBE #0517)[2] - How often the HH team gave care in a professional way. - How well did the HH team communicate with patients. - Did the HH team discuss medicines, pain, and home safety with patients. - How do patients rate the overall care from the HHA. - Will patients recommend the HHA to friends and family.

[1] Data collection delayed due to the COVID-19 public health emergency for the TOH-Patient and TOH-Provider.

[2] The HHCAHPS has five components that together are used to represent one CBE-endorsed measure.

D. Removal of the "COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date" (Patient/Resident COVID-19 Vaccine Measure) Beginning with the CY 2026 HH QRP

In the CY 2026 HH PPS proposed rule, we proposed to remove the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date" measure ("Patient/Resident COVID-19 Vaccine" measure) beginning with the CY 2026 HH QRP under removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program (§ 484.245(b)(3)(viii)). We noted that the estimated burden of collecting this information annually across all 11,904 active HHAs is 47,168 hours at a cost of $4,326,249 and referred readers to section VII of the proposed rule for more details on the estimated burden reduction related to the proposal.

When we adopted the Patient/Resident COVID-19 Vaccine measure, COVID-19 continued to be a major challenge for HHAs, with older adults at a significantly higher risk of mortality, severe disease, and death following infection (88 FR 77762). We refer readers to the CY 2024 HH PPS final rule, where we adopted Patient/Resident COVID-19 Vaccine measure into the HH QRP for further background on the adoption of this measure (88 FR 77762 through 77764). Since that time, HHAs have expressed concerns about data collection challenges and increased provider burden in collecting patient immunization data.[15] Providers were required to integrate the required Patient/Resident COVID-19 Vaccine OASIS item into their assessment instrument and ensure accurate assessment for all their patients. While preventing the spread of COVID–19 remains a public health goal, the number of COVID-19 cases and deaths[16] is declining, and as noted in the proposed rule, we believe the continued costs and burden to providers of reporting this measure outweigh the benefit of continued information collection on

[15] Standing Technical Expert Panel for the Development, Evaluation, and Maintenance of Post-Acute Care (PAC) and Hospice Quality Reporting Program (QRP) Measurement Sets Summary Report December 15, 2023. *https://www.cms.gov/files/document/december-2023-pac-and-hospice-cross-setting-tep-summary-report.pdf-1*

[16] Provisional COVID-19 Deaths, by Week, in The United States, Reported to CDC. Accessed on March 18, 2025, via https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00

COVID-19 vaccination coverage among patients in HHAs. For the COVID-19 items collected at transfer of care, death at home, and discharge, we estimate a decrease in clinician cost of $4,326,249 or $363 ($4,326,249/11,904) for each of the 11,904 active HHAs. We refer readers to section VII.A.3. of the proposed rule for more details on this estimated burden reduction.

We proposed that, effective with assessments completed on or after the date of publication of this CY 2026 HH PPS final rule, the data from the "Patient/Resident COVID-19 Vaccination is Up to Date" OASIS item (O0350) would no longer be used in the calculation of the Patient/Resident COVID-19 Vaccine measure, and the measure itself would be withdrawn pursuant to measure removal factor eight (set out at 42 CFR 484.245(b)(3)(viii)). We proposed to remove the Patient/Resident COVID-19 Vaccination is Up to Date item (O0350) from the OASIS effective April 1, 2026, since it is not technically feasible to remove the item earlier. However, under our proposal, until this item can be removed from the OASIS, HHAs would be permitted to submit any valid response (0 – No, 1-Yes, or dash) on a Transfer, Death at home, or Discharge OASIS assessment, without any future quality measure implications. Note that the item must be completed with one of these three valid responses (must not be left blank) in order for the submitted assessment not to be rejected by the iQIES under existing submission specification edits.

We invited public comments on our proposal to remove the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure from the HH QRP beginning with the CY 2026 HH QRP. The following is a summary of the comments received and our responses:

Comment: A majority of commenters supported CMS's proposal to remove the Patient/Resident COVID-19 Vaccine measure from the HH QRP, with most citing the collection burden associated with the measure as support for its removal. Many commenters highlighted that there are many other sources that provide national COVID-19 vaccination rates. Some cited the end of the public health emergency and the reduced need to track COVID-19 vaccination rates through a standalone process. Some commenters also recommended that, given the

expected timeframe for removal of this measure, CMS should clearly explain how providers could reduce their burden associated with the proposal to make the Patient/Resident COVID-19 Vaccination is Up to Date OASIS item (O0350) voluntary.

Response: We thank commenters for their support. We agree that the burden associated with this measure, including the resources spent by HHA staff in trying to ascertain patients' vaccination status, outweighs the benefit of its continued inclusion in the program, particularly given the end of the COVID-19 PHE,[17] the decrease in COVID-19 cases, as well as the availability of treatments for COVID-19. We will ensure that HHAs understand that submission of the Patient/Resident COVID-19 Vaccination OASIS item (O0350) is voluntary with the final posting of this final rule through a range of CMS communication methods. This will allow for providers to immediately reduce efforts in collecting the O0350 item by providing any valid response until the item is removed with the implementation of OASIS E2 on April 1, 2026.

Comment: A few commenters opposed the proposed removal of the Patient/Resident COVID-19 Vaccine measure from the HH QRP. These commenters cited the continued recommendation by the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP) in 2025 for adults and especially adults 65 or older to receive the COVID-19 vaccine due to higher rates of hospitalization and deaths amongst this population associated with COVID-19. Another commenter noted that this measure offers valuable information to clinicians entering a patient's home and helps providers to better understand a patient's risk of contracting or transmitting COVID-19.

Response: We appreciate the commenters' concerns for providers and patients in home health. We note that since the end of the COVID-19 PHE, there has been an increase in the availability of treatments, including antiviral medications used to treat mild to moderate COVID-19 in vulnerable populations.[18] The CDC has also recently updated its adult and child

17 https://archive.cdc.gov/www_cdc_gov/coronavirus/2019-ncov/your-health/end-of-phe.html
18 COVID-19 Treatment Options, *https://www.cdc.gov/covid/treatment/index.html.*

immunization schedules to apply individual-based decision-making to COVID-19 vaccination.[19] As we stated in the proposed rule, because the number of COVID-19 cases and deaths is declining and the availability of treatments has increased, we believe the threat to vulnerable populations, such as HH patients, is also reduced. There has also been a reduction in risk to HH providers treating patients in homes. On these bases, we believe the continued costs and burden to providers of reporting this measure outweigh the benefit of continued information collection on COVID-19 vaccination coverage among patients in HHAs.

Final Decision: After consideration of the public comments, we are finalizing our proposal to remove the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure from the HH QRP beginning with the CY 2026 HH QRP. Beginning with patients discharged on or after April 1, 2026, HHAs would not be required to collect and submit the Patient/Resident COVID-19 Vaccine measure data to CMS. Until that time and with the posting of this final rule, HHAs may submit any valid response (0 – No, 1-Yes or dash) on a Transfer, Death at home, or Discharge OASIS assessment, without any future quality measure implications.

E. Removal of Four Standardized Patient Assessment Data Elements Beginning with the CY 2026 HH QRP

In the CY 2025 HH PPS final rule (88 FR 88433 through 88439), we finalized the adoption of four items as standardized patient assessment data elements under the social determinants of health (SDOH) category: one item for Living Situation (R0310); two items for Food (R0320A and R0320B); and one item for Utilities (R0330). As finalized in the CY 2025 HH PPS final rule, HHAs would be required to report these data elements using the OASIS beginning with patients discharged in the CY 2027 HH QRP and each program year after (89 FR 88433 through 88439).

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[19] https://www.cdc.gov/media/releases/2025/cdc-immunization-schedule-adopts-individual-based-decision.html#:~:text=Unlike%20the%20COVID%2D19%20primary,physicians%2C%20nurses%2C%20and%20pharmacists.

In the proposed rule, we proposed to remove the four standardized patient assessment data elements under the SDOH category, as we acknowledged the burden associated with these items. We noted that we continuously look for ways to balance the need for data collection regarding quality care and the burden of data collection on health care providers. CMS has a goal to facilitate improved health care delivery by requiring different systems and software applications to communicate and exchange data. Therefore, we noted we will work towards the workflow for these specific data elements being part of a low burden interoperable electronic system. The focus will turn towards how these data and associated recommendations exchanged can improve care coordination, efficiency, reduction in errors and patient experience.

As health IT advances and interoperability of data becomes more standardized, the burden to collect and share clinical data on these and other relevant patient information will become less burdensome, allowing for better outcomes for HH patients and their families. The objectives of the HH QRP continue to be the improvement of care, quality and health outcomes for all patients through transparency and quality measurement, while not imposing undue burden on essential health providers. HHAs and providers across the
industry play a vital role in improving the health of all patients, including those who may be experiencing unstable housing, food insecurity or challenges paying utilities. At the same time, we recognized the burden that the collection of the additional data will impose on already overextended staff. We also acknowledged the additional cost and resources HHAs will bear for training HH staff and altering their workflows if they are required to collect and submit these items. The objectives of the HH QRP continue to be the improvement of care, quality and health outcomes for all patients through transparency and quality measurement. The estimated savings from not collecting this information annually across all 11,904 HHAs is 158,835 hours, with total savings of $13,484,033 (or $1,133 per HHA). We referred readers to section VII.A.3. of the proposed rule for more details on this estimated burden reduction.

We proposed that HHAs would no longer be required to collect and submit Living Situation (R0310), Food (R0320A and R0320B), and Utilities (R0330) beginning with patients discharged on or after April 1, 2026. We noted that these items would not be required to meet HH QRP requirements beginning with the CY 2026 HH QRP.

We invited public comments on our proposal to remove four standardized patient assessment data elements collected under the SDOH category from the HH QRP beginning with the CY 2026 HH QRP**.** The following is a summary of the comments received and our responses:

Comment: A slight majority of commenters expressed their support for the proposal to remove the four standardized patient assessment data elements focused on collecting information related to SDOH. These commenters often acknowledged the importance of better understanding of SDOH in addressing healthcare challenges and noted that there may be less burdensome methods for obtaining SDOH data.

Response: We thank commenters for their support of our proposal to remove these four SDOH items from the standardized patient assessment data elements collected and submitted using the OASIS. We continue to monitor the HH QRP data collection requirements to look for ways to reduce the administrative burden, where appropriate, while maintaining a high standard of quality care. We agree that removing these items at this time will alleviate some of the burden on HH providers associated with HH QRP data collection and submission requirements. We intend to align the HH QRP more closely with our overarching goal for improved health care delivery through health IT advances and low-burden interoperable electronic systems. As we stated in the CY 2026 HH PPS proposed rule (90 FR 2908), we plan to refocus efforts on how data elements can improve care coordination, efficiency, reduction in errors, and patient experience.

Comment: Many commenters opposed CMS' proposal to remove the four SDOH items from the HH QRP. Many commenters who opposed the SDOH items' proposed removal shared

that collecting these data allows HHAs to identify barriers to care access and adherence to care plans. Some commenters further stated that they are already collecting SDOH data on their patients to support efforts of nurses, social workers, and care managers. A commenter stated that these items are particularly useful in rural HHAs to address deficits in rural patients' living situations. A few commenters stated these SDOH items were particularly important in caring for patients with complex or chronic conditions and geriatric patients. These commenters noted that integration of SDOH into care planning can result in cost savings by reducing readmissions and emergency department visits while improving patients' post-care outcomes.

Response: We appreciate the commenters' concerns and feedback regarding the importance of collecting these SDOH items from HH patients and acknowledge the value that commenters ascribe to the collection of this information for discharge planning and care coordination. We recognize commenters' experiences using SDOH data to improve outcomes and facilitate high quality care through improved coordination between HH providers. We also acknowledge feedback from commenters that healthcare outcomes may be different for those patients experiencing unstable housing, food insecurity, or challenges paying utilities. However, in reviewing the data collection and reporting requirements for the CY 2027 HH QRP, we determined that these SDOH items should be removed from the OASIS prior to the start of data collection and submission. We have re-evaluated the value of adding these SDOH items to the OASIS for the purposes of the HH QRP against their need at this time. We considered that HHA have not yet begun to report these data, we do not currently have a specific use for these items in the HH QRP, these SDOH items are not clinical items related to direct patient care, and we have refocused efforts on modernization of health care and health care systems which may support less burdensome ways of collecting SDOH data in the future. We continuously review and reassess the balance of data collection and HH provider burden for the HH QRP, and at this time, determined these SDOH items should be removed prior to implementation.

The objectives of the HH QRP continue to be the improvement of care, quality, and health outcomes for all patients through transparency and quality measurement, while balancing burden for HHAs and their staff. As outlined in our RFI in the CY 2026 HH PPS proposed rule (90 FR 29108), we are refocusing our efforts to advance the digital quality measurement transition to include ways for data elements, such as those related to SDOH, to be collected as part of a low-burden interoperable electronic system. Given these administrative goals and efforts to reduce burden for HHAs, we do not believe that the collection of SDOH items via the OASIS assessment outweighs the cost and burden of collecting them at this time.

Comment: Some commenters noted that SDOH screening has already been integrated into many HHAs care coordination workflows and that removing the SDOH items without a plan would disrupt current care processes.

Response: The purpose of the HH QRP data is to meet CMS quality reporting requirements. Even though we will no longer require HHAs to collect and submit these four items to CMS using the OASIS, HHAs can still collect and use SDOH information and share it with local agencies, in compliance with applicable laws governing confidentiality and privacy of patient information, if they believe this would be beneficial.

We understand implementation efforts to collect and submit any data elements for the purposes of meeting HH QRP requirements are inherently burdensome for HHAs and their staff, particularly adopting and implementing new data elements since they involve adjustments to health IT systems and electronic health record (EHRs), workflows, and staff training. We are always reviewing and reassessing this balance of data collection and HH provider burden for the HH QRP. For the four SDOH items, we reconsidered the value of their collection and submission to us for the purposes of the HH QRP against their need at this time. We specifically considered that these items are not clinical in nature. While they reflect certain aspects of a resident's health that may inform clinical decisions, they are not factors within the scope of care that an HHA and its staff provide.

Comment: A few commenters who opposed our proposal to remove the four SDOH items noted that these items are critical for risk adjustment and evaluating HHA performance across demographic groups.

Response: We wish to clarify that these four SDOH items are not currently being used for risk adjustment for any HH QRP measures, and we do not currently utilize them for evaluating HH performance across demographic groups. Furthermore, there are no current plans for utilizing the four SDOH items in risk adjustment models or to report HH performance stratified by these elements, either publicly or in confidential feedback reports. While we finalized the adoption of the four SDOH items in the CY 2025 HH PPS final rule (88 FR 88433 through 88439), these items were not yet available on the OASIS. Because data collection has not begun and we do not have an active use for these items, we have re-evaluated the value of adding them to the OASIS at this time.

Final Decision: After consideration of the public comments, we are finalizing our proposal to remove four standardized patient assessment data elements (one item for Living Situation (R0310); two items for Food (R0320A and R0320B); and one item for Utilities (R0330)) collected under the SDOH category from the HH QRP beginning with the CY 2026 HH QRP without modification.

F. Amending the Data Non-Compliance Reconsideration Request Policy and Process Beginning with the CY 2026 HH QRP

1. Background

The HH QRP reconsiderations and appeals process was finalized in the CY 2013 HH PPS final rule (77 FR 67096). At the conclusion of the required quality data reporting and submission period, we review the data received from each HHA during that reporting period to determine if the HHA met the HH QRP reporting requirements. HHAs that are found to be non-compliant with the HH QRP reporting requirements for the applicable calendar year will receive a 2-percent point reduction to its market basket percentage update for that calendar year. In the CY

2018 HH PPS final rule (82 FR 52738 through 51740), CMS finalized a process for HHAs to request and for us to grant exceptions and extensions for the reporting requirements of the HH QRP for one or more quarters beginning with the CY 2019 HH QRP when there are certain extraordinary circumstances outside the control of the HHA. When an exception or extension is granted, we finalized that we would not reduce the HHA's PPS payment for failure to comply with the requirements of the HH QRP.

In that rule, we finalized a policy that, in very limited circumstances, CMS could grant a request by an HHA to extend the proposed deadline for their reconsideration requests (82 FR 52738 through 51740). We stated that, to extend the deadline, HHAs would have to request an extension and demonstrate that "extenuating circumstances" existed which prevented the filing of the reconsideration request by the proposed 30-day deadline (82 FR 52738 through 51740).

In the CY 2018 HH PPS final rule (82 FR 51752), we codified the reconsideration policy and process for HHAs at § 484.250. As codified, our regulation at § 484.250 addressed how we send our written notification of non-compliance to an HHA, the process for an HHA to request reconsideration, what information an HHA must include with its reconsideration request (for example, documentation that demonstrates the HHA's compliance HH QRP requirements), and how we would notify the HHA of our final decision regarding its reconsideration request. In 2019, we moved the regulatory text to § 484.245 and updated and clarified the regulatory text in the CY 2020 HH PPS final rule (84 FR 60645).

As we noted in the proposed rule, we became aware that there were inconsistencies in our preamble and regulation text regarding HHA requests for reconsideration. On this basis, in the proposed rule, we sought to address those inconsistencies.

2. HH QRP Reconsideration Policy: Amending and Codifying Requirements Related to Requests for Extension to File Reconsideration Request Beginning with the CY 2027 HH QRP

As noted previously, in the CY 2018 HH PPS final rule (82 FR 51738 through 51740), we provided that, in very limited circumstances, we may grant a request by an HHA to extend

the deadline to submit its reconsideration request, so long as the HHA requested the extension and demonstrated that extenuating circumstances existed that prevented it from filing a reconsideration request by the 30-day deadline (82 FR 51738 through 51740). However, we did not codify this policy – permitting HHAs to request an extension to file their reconsideration request – in our regulation text at § 484.245(d).

In implementing this finalized policy, we have noted an area where further clarity would be beneficial to HHAs. Specifically, we have noted that HHAs may benefit from clearly demarcated deadlines. Although we believe an HHA would have an interest in asking for an extension to file a reconsideration request prior to the deadline, our policy currently does not specify a deadline for an HHA to submit its request for such an extension (82 FR 51738 through 51740). in order to support such a request, the HHA must demonstrate that extenuating circumstances existed that prevented filing the reconsideration request by the 30-day deadline (82 FR 51738 through 51740). However, we have not specified a deadline from when the extenuating circumstances occurred. We believe HHAs may benefit from further specificity by setting a deadline for submitting a request to extend the deadline to file a reconsideration request.

On this basis, we proposed to amend our reconsideration policy as codified at § 484.245(d) to permit a HHA to request, and CMS to grant, an extension to file a request for reconsideration of a non-compliance determination if, during the period to request a reconsideration as set forth in § 484.245(d), the HHA was affected by an extraordinary circumstance beyond the control of the HHA (for example, a natural or man-made disaster such as a cyber-attack, hurricane, tornado, or earthquake). We proposed that the HHA submit its request for an extension to file a reconsideration request to CMS via email no later than 30 calendar days from the date of the written notification of non-compliance. We proposed that the HHA's extension request, submitted to CMS, must contain all of the following information: (1) the CCN for the HHA; (2) the business name of the HHA; (3) the business address of the HHA; (4) certain contact information for the HHA's chief executive officer or designated personnel; (5)

a statement of the reason for the request for the extension; and (6) evidence of the impact of the extraordinary circumstances, including, for example, photographs, newspaper articles, and other media. We proposed to codify this process at § 484.245(d)(5).

We further proposed that we would notify the HHA in writing of our final decision regarding its request for an extension to file a reconsideration of the non-compliance request via an email from CMS. We proposed to notify the HHA via email because this would allow for more expedient correspondence with the HHA, given the 30-day reconsideration timeframe. We proposed to codify this process at § 484.245(d)(6).

We noted that we considered proposing similar modifications across all post-acute care setting quality reporting programs to more closely align the reconsideration processes.

We invited comments on these proposals to amend the HH QRP reconsideration policy to permit HHAs to request an extension to file a reconsideration request beginning with the CY 2027 HH QRP and to codify this proposed policy and process at § 412.634(d)(5) and (d)(6). The following is a summary of the comments received and our responses:

Comments: All commenters supported the proposal to amend the current reconsideration policy to permit HHAs to request an extension to file a reconsideration request, citing the increasing number of natural and man-made emergencies that could require HHAs to submit such a request.

Response: CMS thanks commenters for their support of the proposed updates to the current reconsideration policy that would permit HHAs to request an extension to file a reconsideration request.

Final Decision: After consideration of the public comments received, we are finalizing these proposals to amend the HH QRP Reconsideration policy to permit HHAs to request an extension to file a reconsideration request beginning with the CY 2027 HH QRP and to codify this proposed policy at § 484.245(d)(5) and (d)(6).

3. Codifying the Bases on Which CMS Can Grant a Reconsideration Request

As discussed previously, in the CY 2013 HH PPS final rule, we stated that, after we reviewed an HHA request for reconsideration, we may reverse our initial finding of non-compliance if: (1) the HHA provides proof of compliance with all requirements during the reporting period; or (2) the HHA provides adequate proof of a valid or justifiable excuse for non-compliance if the HHA was not able to comply with requirements during the reporting period (77 FR 67096). We also stated that we will uphold an initial finding of non-compliance if the HHA cannot show any justification for non-compliance (77 FR 67096).

As previously discussed, we codified our reconsideration policy at § 484.245(d) in the CY 2013 HH PPS final rule (77 FR 67096). Our regulation at § 484.245(d)(3) requires that an HHA's request for reconsideration includes accompanying documentation that demonstrates the HHA's compliance with the HH QRP requirements. Then, we will notify the HHA in writing regarding our final decision on its reconsideration request (§ 412.634(d)(4)).

We noted in the proposed rule that we believe it would be beneficial for HHAs if we codify our specific bases for granting a reconsideration request in our regulation at § 484.245(d). These have not been previously outlined in regulatory text and CMS has outlined these details for clarity for any HHA seeking an extension in the reconsideration process.

On these bases, we proposed to modify our reconsideration policy to provide that we will grant a timely request for reconsideration and reverse an initial finding of non-compliance, only if CMS determines that the HHA was in full compliance with the HH QRP requirements for the applicable program year. We would consider full compliance with the HH QRP requirements to include CMS granting an exception or extension to HH QRP reporting requirements under our extraordinary circumstance exception and extension (ECE) policy at § 484.245(c). However, to demonstrate full compliance with our ECE policy, the HHA would need to comply with our ECE policy's requirements, including the specific scope of the exception or extension as granted by CMS.

We proposed to amend §484.245(d)(4) to codify this modified policy. We noted that we considered proposing similar modifications across all post-acute care setting quality reporting programs to more closely align the reconsideration processes.

We invited comments on these proposals to amend the bases by which we grant a reconsideration request under the HH QRP reconsideration policy and to codify this proposed policy at § 484.245(d)(5). The following is a summary of the comments received and our responses:

Comment: All commenters supported CMS's proposal to clarify the current data non-compliance reconsideration policy. Some commenters noted that this update was needed, with HHAs facing a range of disasters more frequently. Many commenters also expressed that the consistency of the policy across care settings was also welcomed. One commenter requested that CMS further provide technical assistance and practical examples of acceptable supporting documentation, especially for smaller agencies that may lack compliance resources. Another commenter sought to determine CMS's plans to update guidance to surveyors in light of this policy update.

Response: CMS thanks commenters for their support of the updates to the data non-compliance reconsideration request policy and process. CMS will seek to ensure the requirements of acceptable supporting documentation as part of the reconsideration process are available to stakeholders. CMS will also ensure all stakeholders engaged in the reconsiderations process have clear guidance on how this update affects current processes that evaluate HHA compliance.

Final Decision: After consideration of the public comments received, we are finalizing our proposals to amend the bases by which we grant a reconsideration request under the HH QRP reconsideration policy and to codify this proposed policy at § 484.245(d)(5).

G. Updates to Requirements for OASIS All-Payer Data Submission

1. Statutory Authority and Background

Section 1891(d) of the Act, cross-referencing section 1891(c)(2)(C)(i)(I) of the Act (section 4021(b) of Pub. L. 100–203 (December 22, 1987)) requires the Secretary to develop a comprehensive assessment for Medicare-participating HHAs. In 1993, CMS (then known as HCFA) developed an assessment instrument that identified each patient's need for home care and the patient's medical, nursing, rehabilitative, social and discharge planning needs. As part of this assessment, Medicare-certified HHAs were required to use a standard core assessment data set, the Outcome and Assessment Information Set (OASIS). As part of the home health assessment, the statute requires a survey of the quality of care and services furnished by the agency as measured by indicators of medical, nursing, and rehabilitative care provided by the HHA. OASIS is the designated assessment instrument for use by an HHA in complying with the requirement and HHAs must submit the data collected by the OASIS assessment to CMS as an HHA condition of participation (42 CFR part 484.45).

Section 704 of the Medicare Prescription Drug Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173, December 12, 2003) "suspended" the legal authority of the Secretary to require HHAs to report non-Medicare and non-Medicaid patient data to CMS until at least 2 months after the Secretary published final regulations on CMS's collection and use of OASIS data following the submission of a report to Congress on the study required under section 704(c) of the MMA. Subsequently, CMS conducted the study from 2004 to 2005 and submitted a report[20] to Congress in 2006 titled "The OASIS Study: The Costs and Benefits Associated with the Collection of Outcome and Assessment Information Set (OASIS) Data on Private Pay Home Health Patients – Report to Congress." While the 2006 report recommended that the suspension continue, the passage of the Improving Medicare Post-Act Care Transformation (IMPACT) Act (Pub. L. 113-115) in 2014 required CMS to create a uniform quality measurement system that allows CMS to compare outcomes across post-acute care (PAC) providers.

[20]https://www.cms.gov/files/document/cms-oasis-study-all-payer-data-submission-2006.pdf

The final ruletitled, “Medicare Program; Calendar Year (CY) 2023 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Program Requirements; Home Health Value-Based Purchasing Expanded Model Requirements; and Home Infusion Therapy Services Requirements”[21] finalized the requirement for HHAs to report OASIS data on all patients, regardless of payer, for the applicable 12-month performance period (example July 1, 2025 – June 30, 2026) (87 FR 66862). With the CY 2025 HH PPS final rule, CMS established that start of care (SOC) is the first assessment that can be submitted for a non-Medicare/non-Medicaid patient, either on or after January 1, 2025, for the phase-in (voluntary) period or on or after July 1, 2025, for the mandatory period. CMS would use the M0090 “Date Assessment Completed” date of the SOC assessment to identify non-Medicare/non-Medicaid patient assessments in the phase-in and mandatory periods (89 FR 88439 through 88441). This ended the suspension of the OASIS data collection on non-Medicare and non-Medicaid HHA patients. As discussed in the final rule, the most accurate representation of the quality of care furnished by HHAs is best captured by calculating the assessment-based measures rates using OASIS data submitted on all HHA patients receiving skilled care, regardless of payer.

2. Updates to the Home Health Agency CoPs to Align with the OASIS All-Payer Submission Requirements (§§ 484.45(a) and 484.55(d)(1)(i))

Section 484.45(a) of the HHA CoPs currently requires an HHA to encode and electronically transmit each completed OASIS assessment to the CMS system, regarding each beneficiary, with respect to which information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the beneficiary. To align with the transition to OASIS all-payer submission requirements as outlined in the CY 2023 Home Health PPS final rule, we proposed at § 484.45(a) to remove the term “beneficiary” and replace it with the term “patient.”

[21] https://www.federalregister.gov/documents/2022/11/04/2022-23722/medicare-program-calendar-year-cy-2023-home-health-prospective-payment-system-rate-update-home

Patients must receive, and an HHA must provide, a comprehensive assessment no later than 5 calendar days after the start of care. The comprehensive assessment not only examines patients' current health, psychosocial, functional, and cognitive status, but also must incorporate the most current version of the OASIS data items. This includes clinical record items, patient history, supportive assistance, etc. Currently, the comprehensive assessment, including administration of OASIS, must be updated and revised as frequently as the patient's condition warrants, but not less frequently than the last five days of every 60 days beginning with the start-date of care. Language at § 484.55(d)(1)(i) references a "beneficiary elected transfer" in reference to one scenario in which an OASIS assessment would be updated. To support the transition to OASIS all-payer submission requirements, we also proposed to remove the term "beneficiary" at § 484.55(d)(1)(i).

We noted that these technical changes to update terminology would further clarify that the requirement for reporting OASIS information applies to all HHA patients receiving skilled services and align the language in the CoPs with the requirements finalized in the CY 2023 and CY 2025 Home Health PPS final rules. We noted that this policy would not change current patient exemptions for OASIS, which are as follows: patients under the age of 18; patients receiving maternity services; and patients receiving only personal care, housekeeping, or chore services.

H. HHCAHPS Survey Updates

a. Survey and Measure Changes

Based on feedback from patients and interested parties, CMS launched an effort to update and shorten the Home Health Consumer Assessment of Healthcare Providers and Systems (HHCAHPS) survey. CMS conducted a mode experiment with 100 HHAs in 2022. The experiment tested a web-mail mode and a revised survey instrument. The revised survey is shorter than the current survey and includes new questions on topics suggested by interested

parties. Specifically, the changes proposed to the survey and the quality measures derived from testing included the following:

- Addition of three new questions to assess new topics of importance to patients:

++ Whether the care provided helped the patient take care of their health.

++ Whether the patient's family/friends were given sufficient information and instructions.

++ Whether the patient felt the staff cared about them "as a person."

- Removal of questions or topics of less importance to patients (that is, six questions about medications were reduced to two questions).

- The following 4 questions were removed:

++ Whether someone asked to see all the prescription and over-the-counter medicines the patient was taking.

++ Whether the patient is taking any new prescription medicines or whether the patient's medicines have changed.

++ Whether home health providers talked to the patient about the purpose for taking new or changed prescription medicines.

++ Whether home health providers talked to the patient about when to take the medicines.

- Removal of questions not currently used in public reporting composites (that is, three questions on which type of staff served the patient—nurse, physical or occupational therapist, and home care aide).

- Removal of one question which did not perform well in testing to stand alone or fit into one of the revised composite measures:

- Whether the patient got information about what care and services they would get when they first started getting home health care.

- Minor text changes to selected existing questions to help clarify the question or response options, based on feedback from patients.

The revised HHCAHPS Survey, including the revised Care of Patients and Communications between Providers and Patients measures, and the three stand-alone measures that remain from the current Specific Care Issues measure were reviewed as part of the 2025 Measures Under Consideration list (MUC2024-054, -055, -061, -062, & -063) through the Pre-Rulemaking Measure Review (PRMR) Post-Acute Care/Long-Term Care (PAC/LTC) Committee. The PRMR PAC/LTC Committee recommended four out of the five measures without any conditions and one of the measures with conditions, such as stratifying the survey data for analysis and including greater detail about the types of medications. For more information, please see https://p4qm.org/sites/default/files/2025-02/PRMR-2024-2025-MUC-Recommendations-Report-Final.pdf. Since the publication of the proposed rule, the HHCAHPS Survey and measures went through consensus-based entity re-evaluation as described here: *https://p4qm.org/EM*. As of August 7, 2025, the updated HHCAHPS measures were endorsed with a condition that a robust logic model illustrating the actions accountable entities can take to improve patient experience is included in the next measure evaluation in 2030. Due to the very favorable recommendations from the PRMR, we proposed to move forward with the five measures. CMS proposed to implement the revised HHCAHPS Survey beginning with the April 2026 sample month. Table C-20 provides a comparison of the current and proposed HHCAHPS Survey measures. Proposed to move forward with the five measures. CMS proposed to implement the revised HHCAHPS Survey beginning with the April 2026 sample month. Table C-20 provides a comparison of the current and revised or new HHCAHPS Survey measures.

TABLE C-20: CURRENT AND REVISED OR NEW HHCAHPS SURVEY MEASURES

Measure	Item(s) in Current Measure	Item(s) in Revised or New Measure
Care of Patients	• In the last 2 months of care, how often did home health providers from this agency seem informed and up to date about all the care or treatment you got at home? (Q9)	• In the last 2 months of care, how often did home health staff from this agency seem to be aware of all the care or treatment you were getting at home? (Q6)
	• In the last 2 months of care, how often did home health providers from this agency treat you as gently as possible? (Q16)	• In the last 2 months of care, how often did home health staff from this agency treat you with care – for example, when moving you around or changing a bandage? (Q7)
	• In the last 2 months of care, how often did home health providers from this agency treat you with courtesy and respect? (Q19)	• In the last 2 months of care, how often did home health staff from this agency treat you with courtesy and respect? (Q10)
	• N/A (not on current survey)	• In the last 2 months of care, how often did you feel that home health staff from the agency cared about you as a person? (Q11)
	• N/A (not on current survey)	• In the last 2 months of care, how often have the services you received from this agency helped you take care of your health? (Q13)
	• In the last 2 months of care, did you have any problems with the care you got through this agency? (Q24)	• N/A (removed from revised survey)
Communications between Providers and Patients	• When you first started getting home health care from this agency, did someone from the agency tell you what care and services you would get? (Q2)	• N/A (removed from revised survey)
	• In the last 2 months of care, how often did home health providers from this agency keep you informed about when they would arrive at your home? (Q15)	• In the last 2 months of care, how often did home health staff from this agency keep you informed about when they would arrive at your home? (Q5)
	• In the last 2 months of care, how often did home health providers from this agency explain things in a way that was easy to understand? (Q17)	• In the last 2 months of care, how often did home health staff from this agency explain things in a way that was easy to understand? (Q8)
	• In the last 2 months of care, how often did home health providers from this agency listen carefully to you? (Q18)	• In the last 2 months of care, how often did home health staff from this agency listen carefully to you? (Q9)
	• N/A (not on current survey)	• In the last 2 months of care, did home health staff from this agency provide your family or friends with information or instructions about your care as much as you wanted? (Q12)

Measure	Item(s) in Current Measure	Item(s) in Revised or New Measure
	• In the last 2 months of care, when you contacted this agency's office did you get the help or advice you needed? (Q22)	• When you contacted this agency's office, did you get the help or advice you needed? (Q16)
	• When you contacted this agency's office, how long did it take for you to get the help or advice you needed? (Q23)	• N/A (removed from revised survey)
Specific care issues	• When you first started getting home health care from this agency, did someone from the agency talk with you about how to set up your home so you can move around safely? (Q3)	• When you first started getting home health care from this agency, did someone from the agency talk about ways to help make your home safer? For example, they may have suggested adding grab bars in the shower or removing tripping hazards. (Q2) • Removed composite; reporting as standalone item
	• When you started getting home health care from this agency, did someone from the agency talk with you about all the prescription and over-the-counter medicines you were taking? (Q4)	• Has someone from the agency ever reviewed the prescribed and over-the-counter medicines you were taking? For example, they might have asked you to show them your medicines and talked with you about how and when to take each one. (Q3) • Removing composite; reporting as standalone item
	• When you started getting home health care from this agency, did someone from the agency ask to see all the prescription and over-the-counter medicines you were taking? (Q5)	• N/A (removed from revised survey)
	• In the last 2 months of care, did home health providers from this agency talk with you about the side effects of these medicines? (Q14)	• In the last 2 months of care, did home health staff from this agency talk with you about any side effects of your medicines? (Q4) • Removing composite; reporting as standalone item
	• In the last 2 months of care, did you and a home health provider from this agency talk about pain? (Q10)	• N/A (removed from revised survey)
	• In the last 2 months of care, did home health providers from this agency talk with you about the purpose for taking your new or changed prescription medicines? (Q12)	• N/A (removed from revised survey)

Measure	Item(s) in Current Measure	Item(s) in Revised or New Measure
	• In the last 2 months of care, did home health providers from this agency talk with you about when to take these medicines? (Q13)	• N/A (removed from revised survey)
Overall rating	• We want to know your rating of your care from this agency's home health providers. Using any number from 0 to 10, where 0 is the worst home health care possible and 10 is the best home health care possible, what number would you use to rate your care from this agency's home health providers? (Q20)	• We want to know your rating of your care from this agency's home health staff. Using any number from 0 to 10, where 0 is the worst home health care possible and 10 is the best home health care possible, what number would you use to rate your care from this agency's home health staff? (Q14)
Willingness to recommend	• Would you recommend this agency to your family or friends if they needed home health care? (Q25)	• Would you recommend this agency to your family or friends if they needed home health care? (Q17)

b. Impact on Public Reporting and Star Ratings

HHCAHPS Survey measure scores are calculated across four rolling quarters and are published quarterly for all HHAs over the reporting period. The Summary Star Rating is currently based on the Overall Rating of Care and the three composite measures that are equally weighted. We proposed calculating the Summary Rating based on the Overall Rating of Care, the two modified composite measures (Care of Patients and Communications between Providers and Patients), and the three new stand-alone measures related to talking about home safety, reviewing prescribed and over-the-counter medicines, and talking about medicine side effects. In the calculation of the Summary Star Rating, we proposed that the Overall Rating of Care and two modified composite measures would each have a weight of 1 and each of the three new stand-alone measures would have a weight of one-third. The Summary Star Ratings will continue to be calculated using four rolling quarters and will be publicly reported for all HHAs with 40 or more completed surveys over the reporting period. Star Ratings are updated every quarter. To determine what impact the changes to the survey measures will have on public reporting, CMS considered the nature of the measure change. As Talk About Home Safety, Review Medicines, and Talk About Medicine Side Effects are new measures for the HHCAHPS Survey, since they

will be reported individually, we will have to wait to introduce public reporting until we have four quarters of data. Although the revised Care of Patients measure is conceptually similar to the current Care of Patients measure, we believe the change (adding two new questions and dropping one question) is substantive and the revised measure should be treated as new for purposes of public reporting and Star Ratings. Similarly, the revised Communications Between Providers and Patients measure is also conceptually similar to the current Communications Between Providers and Patients measure; however, the change (dropping two questions and adding one new question) is substantive and the revised measure should be treated as new for purposes of public reporting and Star Ratings. As such, we proposed waiting to publicly report the new versions of Care of Patients and Communications Between Providers and Patients until we have four quarters of data. We anticipate that the first Care Compare refresh in which publicly reported measures scores will be updated to include the new measures will be October 2027, with scores calculated using data from Q2 2026 through Q1 2027. In the interim period, measure scores will be made available to HHAs confidentially via their Provider Preview reports on the HHCAHPS Survey website after two full quarters of data are submitted.

We believe the change to the Overall Rating measure (minor wording change from "provider" to "staff") is non-substantive (i.e., does not meaningfully change the measure) and along with the unchanged Willingness to Recommend the Agency measure, both measures can continue to be publicly reported in the transition period between the current and new surveys. During the transition period, scores and Star Ratings for the Overall Rating and Willingness to Recommend measures will be calculated by combining scores from quarters using the current and new survey and continue to be reported.

c. Survey Administration Changes

No survey administration changes were proposed with the new survey.

d. Case-mix and Mode Adjustments

Prior to public reporting, HHAs' HHCAHPS Survey scores are adjusted for the effects of case mix. Case mix refers to characteristics of the patient that are not under control of the HHA that may affect reports of home health experiences. Case-mix adjustment is performed within each quarter of data after data cleaning. The current case-mix adjustment model includes the following variables: patient age, patient education, self-reported overall health, self-reported mental health, diagnosis of schizophrenia or dementia, whether the patient lives alone, whether the patient or a proxy answered the survey, and language in which the survey was completed. The model used and adjustments are updated quarterly and are available on the HHCAHPS website at this link: https://homehealthcahps.org/General-Information/Archived-Publicly-Reported-Data Based on testing the revised survey in a 2022 Mode Experiment, CMS reviewed the variables included in the case-mix adjustment models currently in use for the HHCAHPS Survey to determine if any changes needed to be introduced along with the revised survey. We found that while no case-mix variables need to be added, and the diagnosis adjustments were no longer significant. As such, CMS proposed to drop the adjustment for diagnoses of schizophrenia or dementia with the revised survey.

Using data from the 2022 Mode Experiment, CMS also tested for whether there were impacts in how someone responds to the survey based on the mode of survey administration. Mode effects were observed with the 2022 Mode Experiment, so CMS proposed to add a mode adjustment in addition to the case-mix adjustment, with the revised survey. Case-mix adjustment will be performed within each quarter of data after data cleaning and before mode adjustment. When we make mode adjustments, it is necessary to choose one mode as a reference mode. One can then interpret all adjusted responses from all modes as if they had been surveyed in the reference mode. CMS will use mail-only as the reference mode for the HHCAHPS Survey, because it is the most used mode for HHCAHPS. The choice of mail mode as the reference mode does not indicate that mail mode is preferable to other approved modes in any way. In the 2022 HHCAHPS Survey mode experiment, telephone-only respondents were more negative in

their evaluations of care relative to mail-only respondents across the HHCAHPS measures. The mode adjustments are generally small—most are around 2 percentage points.

Please see the HHCAHPS Revised Survey Mode Adjustments on https://homehealthcahps.org for the mode adjustments if these measures are finalized through rulemaking.

We invited public comment on the HHCAHPS Survey proposals. The following is a summary of the comments received and our responses:

Comment: Most commenters expressed support for revising the HHCAHPS Survey to make it shorter and simpler. Some commenters noted that these changes represent a meaningful step toward making the instrument more patient-centered and less burdensome. Some commenters expressed strong support for adding the three new HHCAHPS Survey items noting that ensuring family caregivers are better equipped to meet the needs of the individuals they care for is critical for home health care and the new items strengthen the survey's relevance to patients.

Response: We thank the commenters for their support.

Comment: A few commenters asked for a crosswalk and dry run period so agencies are not penalized during the transition to the new survey in April 2026, as well as information for vendors to prepare to administer the updated survey for their client agencies.

Response: The revised HHCAHPS Survey instrument and crosswalks between the original and proposed publicly reported measures are available on the HHCAHPS website at https://homehealthcahps.org/Survey-and-Protocols/Survey-Materials. CMS conducted a focused HHCAHPS Survey Vendor Update Training in late August 2025 to help the approved survey vendors prepare for the transition. There will also be an opportunity for survey vendors to submit test files to ensure they are properly formatted. Additionally, the updated XML data file layouts and XML file schemas used for data submission are available on the HHCAHPS website at https://homehealthcahps.org/Data-Submission/Data-Submission-Resources.

Comment: A few commenters voiced concerns about the proposed measure changes to the HHCAHPS Survey, specifically eliminating three composite measures: Care of Patients, Communication between Providers and Patients, and Specific Care Issues. A commenter supported the removal of the four medication questions that are currently included in the Specific Care Issues measure.

Response: The Specific Care Issues measure is being retired because four of the seven items that made up this measure have been removed from the updated HHCAHPS Survey with the remaining three survey items being reported as individual measures. As we were shortening the survey, we removed four of the six current HHCAHPS Survey questions related to medications patients are taking that were previously included in the Specific Care Issues measure. The Care of Patients and the Communications Between Providers and Patients measures are not being retired. However, CMS will not be able to report them publicly until there are at least 12 months of data that reflect the survey updates.

Comment: A commenter suggested freezing the HHCAHPS Star Ratings on the website during the transition period to the new measures and caveating the changes on the Care Compare website.

Response: We will take into consideration feedback on how the HHCAHPS data are reported during the transition period.

Comment: A commenter asked whether the following question was tested: In the last 2 months of care, did home health staff from this agency provide your family or friends with information or instructions about your care as much as you wanted? Another commenter noted that they found the phrase "as much as you wanted," when referring to the amount of information sharing a patient desired from home health staff, to be a challenging for assessing quality. This commenter also noted that the phrasing "helped you take care of your health," could be interpreted by respondents in a variety of ways. This same commenter also

recommended that the following question focus on the plan of care: In the last two months of care, how often did you feel that home health staff from the agency care about you as a person?

Response: All three questions were developed based on important aspects of home health care identified during a literature review and focus groups with home health patients. Questions were cognitively tested with home health patients and their family members through both one-on-one interviews with an experienced interviewer and as part of the 2022 mode experiment. Patients felt that home health agencies should give pamphlets and information to the family members and friends that help with the person's care, such as spouses and children, which led to the development of the question "In the last two months of care, did home health staff from this agency provide your family or friends with information or instructions about your care as much as you wanted". When asked what the phrase "helped you take care of your health" meant in the question "In the last 2 months of care, how often have the services you received from this agency helped you take care of your health" patients explained that that they were thinking about the ways the care they received helped them to walk better, helped their wounds to heal, and helped with their diets and overall health. Patients understood the question "In the last two months of care, how often did you feel that home health staff from the agency cared about you as a person" to mean whether staff took the time to get to know them on a personal level or form a personal connection with them, for example, treating them like people and not "like a number". Results from several rounds of interviews consistently showed that questions were well understood and supported by patients and their families.

Comment: Several commenters requested CMS to add the web mode of survey administration, stating that the HHCAHPS Survey should be offered in an electronic format delivered by email or text.

Response: A web-based mode was tested during the 2022 mode experiment with very few respondents opting to complete via web. Obtaining email addresses for sample members was

challenging and not routinely available. CMS will continue to evaluate the possibility of a web-based mode for this population in the future.

Comment: A few commenters did not support the removal of the case-mix adjustment for patients with diagnoses of schizophrenia or dementia as they believed communication challenges with individuals with these diagnoses would not be accounted for without the adjustment.

Response: In the most recent mode experiment, despite robust statistical testing, the potential schizophrenia and dementia adjusters were no longer statistically significant and did not show an impact on responses. Since these patients are most likely to have proxy respondents, this helps with the validity of these patients' responses.

Comment: A couple of commenters were concerned about the increased cost to agencies for retraining staff and revising their systems for the new survey.

Response: The updated HHCAHPS Survey instrument should not require any changes to existing data that HHAs provide their HHCAHPS Survey vendors. The approved survey vendors will need to update their systems and materials.

Comment: A commenter suggested fielding both the revised and original survey items concurrently during a transition period.

Response: Many agencies having very small sample sizes and given the expense of running two instruments simultaneously, CMS has elected to phase out the current survey and phase in the new survey rather than run two separate surveys concurrently.

Comment: A commenter suggested that CMS eliminate the "Overall Rating" and "Willingness to Recommend" stating that the responses to these questions do not always align with the responses to other more specific questions in the survey. Another commenter asked that these questions be at the beginning of the survey.

Response: CMS administers these two standard questions across all of its CAHPS surveys to provide a cross-provider metric. These questions also capture a combined assessment of a patient's entire home health experience, integrating all aspects of their interactions with the

home health agency and staff. To keep CAHPS surveys fairly short, we are unable to ask questions that encompass all aspects of care. We agree that the home health-specific survey measures and individual items are critical and CMS will, therefore, continue to report these as well. Overall rating questions are generally at the end of all CAHPS surveys so a respondent can provide an overall assessment of their experiences after thinking about more specific aspects of their care.

Comment: A commenter recommended that CMS ensure that the Spanish HHCAHPS Survey is not simply a literal translation, but one that is culturally and linguistically validated; raised challenges in Puerto Rico related to internet connectivity, mail access, and responsiveness to phone calls; and suggested that survey vendors conducting telephone outreach in Puerto Rico be required to use a Puerto Rico area code (787) when placing calls.

Response: The Spanish translation was developed by a reliable translation service provider and thoroughly reviewed by native Spanish speakers. The translation service was asked to retain phrasing from the current HHCAHPS Survey instrument as much as possible since that translation was reviewed and cognitively tested specifically with patients in Puerto Rico to ensure that they could understand the questions. We appreciate the challenges of conducting both mail and telephone surveys in Puerto Rico and encourage agencies there to work closely with their HHCAHPS Survey vendors to implement mixed-mode surveys (i.e., mail survey with telephone follow-up of non-respondents), which give patients a choice of how to respond. We have provided vendors with your suggestion to use a Puerto Rico area code when making outbound calls. Agencies in Puerto Rico should work with their vendors to implement this and any other measures (within HHCAHPS protocols) to help maximize response rates.

Final Decision: After consideration of the public comments we received, we are finalizing our proposal to update the HHCAHPS measures beginning with the April 2026 sample month.

I. HH QRP Quality Measure Concepts Under Consideration for Future Years – Request for Information (RFI)

In the CY 2026 HH PPS proposed rule (), we sought input on the importance, relevance, appropriateness, and applicability of each of the quality measure concepts under consideration listed in Table C-21 for future years of the HH QRP. In the CY 2024 HH PPS proposed rule (88 FR 43738 through 43740), we included an RFI on a set of principles for selecting and prioritizing HH QRP measures, identifying measurement gaps, and suitable measures for filling these gaps. We refer readers to the CY 2024 HH PPS final rule (88 FR 77773 through 77774) for a summary of the public comments received in response to the RFI.

We sought input on four concepts for future measures for the HH QRP in the CY 2026 HH PPS proposed rule.

1. Interoperability

We sought input on the quality measure concept of interoperability, focusing on information technology (IT) systems' readiness and capabilities in the HH setting. Title XXX of the Public Health Service Act defines "interoperability" in part, and with respect to health IT, as health IT that enables the secure exchange of electronic health information with, and use of electronic health information from, other health IT without requiring special efforts by the user.[22] The definition further states that interoperability of health IT allows for complete, including by providers and patients, access, exchange, and use of electronically accessible health information for authorized uses under applicable State or Federal law.[23] We requested input and comment on approaches to assessing interoperability in the HH setting, for instance, measures that address or evaluate the level of readiness for interoperable data exchange, or measures that evaluate the ability of data systems to securely share information across the spectrum of care.

2. Cognitive Function

[22] 21st Century Cures Act, 42 U.S.C. 300jj(9) (2016).
[23] 21st Century Cures Act, 42 U.S.C. 300jj(9) (2016).

Illnesses associated with limitations in cognitive function, which may include stroke, traumatic brain injuries, dementia, and Alzheimer's disease, affect an individual's ability to think, reason, remember, problem-solve, and make decisions. The IMPACT Act identifies cognitive function as a key quality measure domain, and an area for inclusion as a standardized assessment data element.

Two sources of information on cognitive function currently collected in HHAs are the Brief Interview for Mental Status (BIMS) and Confusion Assessment Method (CAM©).[24] Both the BIMS and CAM have been incorporated into the OASIS. Scored by providers via direct observation, the BIMS is used to determine orientation and the ability to register and recall new information. The CAM assesses the presence of inattention, disorganized thinking, and level of consciousness.

The BIMS and CAM include items representing different aspects of cognitive function, from which quality measures may be constructed. Although these instruments have been subjected to feasibility, reliability, and validity testing, additional development and testing would be required prior to transforming the concepts reflected in the BIMS and CAM (example temporal orientation, recall) into fully specified measures for implementation in the HH QRP.

This RFI requested input on cognitive functioning measures that may be available for immediate use, or that may be adapted or developed for use in the HH QRP, using the BIMS or the CAM. In addition to comment on specific measures and instruments, CMS sought input on the feasibility of measuring improvement in cognitive functioning during a HH stay, which typically averages 56 days;[25] the cognitive skills (example executive functions) that are more likely to improve during an HHA stay; conditions for which measures of maintenance – rather

[24] Centers for Medicare & Medicaid Services. Long-Term Care Hospital Continuity Assessment Record and Evaluation (CARE) Data Set Version 5.0. Effective October 1, 2022. https://www.cms.gov/files/document/ltch-care-data-set-version-50-planned-discharge-final.pdf.

[25] Based on home health episodes ending in CY2021 (the most recent year for which complete data are available).

than improvement in cognitive functioning – are more practical; and the types of intervention that have been demonstrated to assist in improving or maintaining cognitive functioning.

3. Well-Being

We sought input on a quality measure concept of well-being. Well-being is a comprehensive approach to disease prevention and health promotion, as it integrates mental, social, and physical health while emphasizing preventative care to proactively address potential health issues.[26] This comprehensive approach emphasizes person-centered care by promoting well-being of patients and their family members. We sought comments on tools and measures that assess for overall health, happiness, and satisfaction in life that could include aspects of emotional well-being, social connections, purpose, fulfillment, and self-care.

4. Nutrition

Finally, we sought input on a quality measure concept of nutrition. Assessment for nutritional status may include various strategies, guidelines, and practices designed to promote healthy eating habits and ensure individuals receive the necessary nutrients for maintaining health, growth, and overall well-being. This also includes aspects of health that support or mediate nutritional status, such as physical activity and sleep. In this context, preventable care plays a vital role by proactively addressing factors that may lead to poor nutritional status or related health issues. These efforts not only support optimal nutrition but also work to prevent conditions that could otherwise hinder an individual's health and nutritional needs. We sought feedback on tools and frameworks that promote healthy eating habits, exercise, nutrition, or physical activity for optimal health, well-being, and best care for all.

[26] Well-Being Concepts. CDC Archives. WHPL_Canon_WB_Well-Being_Concepts___HRQOL___CDC_2017.pdf

TABLE C-21: MEASURE CONCEPTS UNDER CONSIDERATION FOR FUTURE YEARS OF THE HH QRP

Quality Measure Concepts
Interoperability
Cognitive Function
Well-being
Nutrition

1. Interoperability

Most commenters on the interoperability measure concept stressed the value and importance of advancing interoperability in healthcare in general and in home health specifically. Many commenters shared that national standards will be critical for any interoperability measure concept. Most commenters also shared that federal funding was needed to ensure that home health could have the same advances in health record systems seen in hospital and physician practices. Numerous commenters cited the HITECH Act (Pub. L. 111-5), that subsidized the adoption and implementation of certified electronic health record (EHR) systems for hospitals and physician practices but that was not available to home health, behavioral health, and other post-acute care settings. They note, without this funding, HHAs have not had access to the same level of financial or technical support to build and maintain an interoperable infrastructure. Many commenters specifically noted that HH was behind in the development of health IT deployment and this would be a barrier to any measure.

Those who support the development of an interoperability measure concept outlined criteria that must be considered. Some shared that any measure must evaluate both technical readiness or capability and the processes or practices of data exchange. Others shared that a measure should address interoperability between health care providers, between providers and patients, and between providers and payers. One commenter noted that the exchange of information needs to account for clinical as well as social determinants of health information. A number of commenters highlighted the work of The Post-Acute Care Interoperability (PACIO)

project[27] that supports development of FHIR (Fast Healthcare Interoperability Resources) technical implementation guides and suggested any interoperability work builds on these ongoing efforts. One commenter shared that this measure concept should include caregiver information in electronic health records. Another advocated for building out a measure process based on the Trusted Exchange Framework Common Agreement (TEFCA) initiative.

Several commenters who stressed the importance of interoperability also noted that they didn't support an interoperability measure concept for HH due to what they described as significant financial and operational barriers to advancing standardized interoperability in HH. They argue that home health agencies currently are largely not at the appropriate level of technology adoption for interoperable data exchange or measures that evaluate the ability of data systems to securely share information across providers and with patients.

2. Cognitive Function

Commenters shared that addressing cognitive function in home health care is a critical clinical area. Many commenters shared that the OASIS tool already has several tools that evaluate aspects of cognitive function. The PHQ 2-9©, Brief Interview for Mental Status (BIMS©), and Confusion Assessment Method (CAM©) were often referenced, and commenters shared that those tools would not be sufficient to address the range of issues that encompass cognitive function. One commenter highlighted that the current tools are not effective in assessing mild cognitive impairment that can affect activities of daily living or instrumental activities of daily living. Several commenters particularly note that these tools were intended to assess some areas of cognition but not intended for performance measures.

Some commenters shared that the trajectory of patients with cognitive function challenges can vary and make the use of any one tool alone insufficient to address the range of cognitive function challenges. Some patients with progressive neurological conditions will have steady

27 For more information on the Post-Acute Care InterOperability (PACIO) project, see: *https://pacioproject.org/*.

decline and not likely to expect cognitive improvement. Patients with chronic conditions may complicate assessment of cognitive function and a patient's expected care path would also be progressive decline. These issues are made more challenging due to the short average length of stay that numerous commenters suggest is too short to have a meaningful impact on cognitive function.

With these considerations, many commenters stressed that CMS should not target a cognitive function measure focused on improvement but rather focus on maintenance or limiting cognitive decline. Some commenters, after considering the complexity of cognitive function, argued against developing a single measure to address this domain or to not develop this measure domain with the present challenges. One commenter shared that there would need to be additional resources for home health agencies to build expertise in addressing cognitive function needs to justify introducing a new measure related to this measure domain.

3. Well-Being

Numerous commenters provided input on the well-being measure concepts. Many commenters shared that addressing well-being could be important for home health patients. Commenters often also shared that any measure concept addressing well-being should account for what HHAs can reasonably affect with respect to well-being during a home health stay. Most commenters also shared that any measure of well-being should be an evidence-driven, validated tool.

A commenter highlighted the importance of including caregiver input on assessing patient well-being, where appropriate. Some commenters had suggestions about what kinds of tools may best address the well-being measure concept. A few commenters suggested CMS consider focusing on a patient reported outcome measure structure. Other commenters suggested specific components of the OASIS that could already be valuable as part of a wellbeing measure such as the BIMS, CAM, and PHQ 2-9 and not duplicate the value of these tools when considering a well-being concept.

Many commenters also suggested that given the timeframe of a home health stay, the focus for CMS should be on a process rather than outcome measure since the HHA would have limited ability to affect the broad concept of well-being. Others cautioned that HHAs could not address an issue as broad as well-being in the timeframe of a patient's HH care and that this measure concept should not be considered for the HH QRP.

4. Nutrition

Many commenters described the importance of nutrition in patient care and in home health specifically. Commenters share that clinicians can support patients' health by understanding their nutritional status. Commenters who supported developing a nutrition measure concept often stressed the need for using tools that were validated and reliable. Commenters suggested a range of nutrition tools such as the standardized Mini Nutritional Assessment (MNA) or Malnutrition Screening Tool (MST) that could provide reliable data. Another commenter suggested the DETERMINE nutrition risk scale as a screening tool. Another tool suggested was the hand grip strength (HGS) through purposeful activities and further referencing research that shows in older adults, a significant association between malnutrition and HGS. Yet another commenter noted that weight was collected and start of care and resumption of care and that CMS should use data already available in consideration of a new measure concept. The most commonly cited tool from commenters was the Malnutrition Care Score (MCS), an electronic clinical quality measure (eCQM) adopted into the Inpatient Quality Reporting (IQR) program for acute care hospitals. Commenters stated they favored the MCS because it assesses a different aspects of care that are essential to addressing malnutrition in any care setting. One commenter noted that the MCS addresses the malnutrition care workflow that are necessary to identify and manage malnutrition risk in a timely and effective manner. Commenters described the four steps of: 1) Screen for malnutrition risk; 2) Conduct nutrition assessment; 3) Document malnutrition diagnosis; and 4) Document nutrition care plan strong, clear, clinical processes underpinning the measure. A number

of commenters highlighted that this tool has been successfully utilized in quality reporting and therefore is key for CMS consideration for the HH QRP.

Commenters who supported a nutrition measure for HH often stressed that a measure concept related to nutrition should be a process measure because of the complex range of issues that encapsulate nutrition issues. One commenter suggested that any measure concept should also align with broader efforts to improve access to nutrition supports, such as the Supplemental Nutrition Assistance Program (SNAP) and nutrition programs authorized under the Older Americans Act. Some commenters who differed in support for the development of a nutrition measure concept were unified in arguing that CMS needed to support HH by increasing funding to address nutritional challenges. Currently, HHAs incorporate dietician or nutritionist services with no expectation of reimbursement. The commenter suggested that CMS should reimburse for dietician services and empower HHAs to more comprehensively address nutritional issues in their patients.

Several commenters did not support current development of a nutrition measure concept because of a number of factors. They cited the lack of reimbursement for services that would support nutrition interventions. They also noted that the complex issues around nutrition care would not fall within the scope of HHAs to address in the limited time frame of home health care. They often cited the current margins in HH care that are being taxed in providing the essential services of the home health benefit.

Response: We thank all the commenters for responding to this RFI. While we are not responding to specific comments in response to the RFI in this final rule, we will take this feedback into consideration for our future measure development efforts for the HH QRP.

J. Potential Revision of the Final Data Submission Deadline Period from 4.5 Months to 45 Days—Request for Information (RFI)

Section 1895(b)(3)(B)(v)(I) of the Act states that for 2007 and each subsequent year, the home health market basket percentage increase applicable under such clause for such year shall be reduced by 2 percentage points if a home health agency does not submit quality data to the

Secretary in accordance with subclause (II) for such a year. Section 1899B(f)(1) of the Act also requires the Secretary to provide confidential feedback reports to PAC providers on the performance of such PAC providers for quality, resource use, and other measures required under sections 1899B(c)(1) and (d)(1) of the Act beginning 1 year after the applicable specified application date. Further, section 1899B(g) of the Act requires the Secretary to establish procedures for making available to the public information regarding the performance of individual PAC providers for quality, resource use, and other measures required under sections 1899B(c)(1) and (d)(1) of the Act beginning not later than 2 years after the applicable specified application date. The procedures must ensure, including through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act for similar purposes, that each PAC provider has the opportunity to review and submit corrections to the data and information that are to be made public for the PAC provider prior to such data being made public.

Although assessment data submission, quarterly performance reports, and public reporting are required by statute, timing of data submission under the HH QRP is not specified. Thus, in the CY 2017 HHS PPS final rule (81 FR 76784) we finalized our proposal, to comply with the requirements of section 1899B(g) of the Act, that HHAs would have approximately 4.5 months after the reporting quarter to correct any errors of their assessment-based data to calculate the measures. During the time of data submission for a given quarterly reporting period and up until the quarterly submission deadline, HHAs could review and perform corrections to errors in the assessment data used to calculate the measures.

In the process of implementing the public reporting programs, CMS has become concerned that the time between when data are collected and when the measures are reported from those data may be too long to get the desired results in a public reporting program. Public reporting programs are designed to provide patients and their families with the most current information so they can make quality-informed decisions about where to receive their care. Currently, the largest contributing factor to the 9- month lag between end of the data collection

and when measures are publicly reported is the current 4.5-month timeframe for data submission. If the timeframe for data submission was reduced from 4.5 months to 45 days, the lag time between collection and reporting could be reduced by up to 3 months. This would result in more timely public reporting that would be more valuable for patients and families as they make decisions about where they can receive the best care.

An important consideration in reducing the data submission timeframe is the potential burden it may place on providers, which could lead to lower quality data. CMS conducted analysis to evaluate the potential impact of reducing the timeframe by determining how many charts are being submitted by 60 days currently. Using 2022 data, CMS found that only 1.3 percent of all OASIS assessments were submitted after the 60-day timeframe. Of those submissions, approximately seventy percent (or 0.9 percent of the total) were submitted between 60 days and 4.5 months and hence have potential to be impacted. Because assessments are tied to payment, providers are likely to submit assessments close to the date of service and to close out medical records once the patient is discharged from service. Therefore, we noted in the proposed rule that we believe by reducing this deadline from 135 days to 45 days, we could reduce the time between data collection and public reporting resulting in the improvement in timeliness with limited change in burden to providers.

We requested feedback on this potential future reduction of the HH QRP data submission deadline from 4.5 months to 45 days. Specifically, we requested comment on the following:

- How this potential change could improve the timeliness and actionability of HH QRP quality measures.
- How this potential change could improve public display of quality information.
- How this potential change could impact HHA workflows or require updates to Systems.

Comment: Most commenters supported a reduction in the final data submission deadline from 4.5 months, with additional recommendations related to implementation. They agreed with

the CMS assessment that timely public reporting is essential for informed consumer decision-making and enhances transparency and accountability. Some commenters stressed that with any reduction in timeframe, CMS should adopt a phased approach over several fiscal years to allow for providers and other stakeholders to adjust to the transition. Many commenters suggested that CMS should pilot the reduction in submission deadlines before moving to national implementation of the policy update, stating that this would allow CMS to evaluate the impacts and determine appropriate technical guidance, stakeholder engagement, and operational flexibility needed to successfully implement this change.

Other commenters cautioned that a transition from 4.5 months to 45 days would cause harm to a range of HHAs due to additional administrative burden. They noted that this would especially be the case for small HHAs, stand-alone HHAs that operate with limited resources, HHAs that manage coding and review in-house, HHAs experience high field staff turnover, or HHAs that lack robust EMR or analytics systems. They noted this could introduce errors and comprise the quality of OASIS data submitted. One commenter expressed concerns due to the rate cuts that are currently under consideration for HHAs. Commenters who expressed concerns with the potential reduction in the submission deadline had suggestions for how to make the transition manageable for HHAs. Many suggested that the submission deadline should be 60 days to be consistent with the data CMS cited in the original RFI, which showed that only 1.3% of data was submitted after 60 days. Other commenters noted that 60 days would be a reasonable target since the 60-day time frame would align with the current HHA episode of care, and with some HHA's expectations around HH QRP conditions of participation guidelines. A few commenters suggested 90 days to account for the current administrative burdens HHAs are managing. A few commenters cited the financial pressure currently faced by HHAs and opposed the reduction in the submission deadline over concerns that HHAs would not be able to meet the new workflow and operational challenges in the current resource environment.

Along with feedback on this RFI, numerous commenters provided feedback related to OASIS submissions. Many commenters suggested that CMS should move to a four-year cycle in updating the OASIS. One commenter requested that the timeframe for updating claims-based measures be reduced to also provide more timely information related to these measures which have grown in importance. One commenter also requested that CMS align any reconsideration updates to account for the reduction in submission deadlines.

Response: We thank all the commenters for responding to this RFI. While we are not responding to specific comments in response to the RFI in this final rule, we will take this feedback into consideration for our future measure development efforts for the HH QRP.

K. Advancing Digital Quality Measurement in the HH QRP – Request for Information

As part of our effort to advance the digital quality measurement (dQM) transition, issued an RFI in the CY 2026HH PPS proposed rule to gather broad public input on the dQM transition in HHAs.

1. Background

As we noted in the proposed rule, we are committed to improving healthcare quality through measurement, transparency, and public reporting of quality data, and to enhancing healthcare data exchange by promoting the adoption of interoperable health IT that enables information exchange using Fast Healthcare Interoperability Resources® (FHIR®) standards. Proposing to require the use of such technology within the HH QRP in the future could potentially enable greater care coordination and information sharing, which is essential for delivering high-quality, efficient care and better outcomes at a lower cost. In the CYs 2022 and 2023 HH PPS proposed rules,[28] we outlined several HHS initiatives aimed at promoting the adoption of interoperable health IT and facilitating nationwide health information exchange.

[28] "Advancing Health Information Exchange" in the CY 2022 HH PPS proposed rule (86 FR 35979) and CY 2023 HH PPS proposed rule (87 FR 37602).

Further, to inform our digital strategy, in the CY 2022 HH PPS proposed rule (86 FR 35980) we shared and sought feedback on the following:

- Our intent to explore the use of FHIR®-based standards to exchange clinical information through application programming interfaces (APIs).
- Enabling quality data submission to CMS through our internet Quality Improvement and Evaluation System (QIES).
- To work with healthcare standards organizations to ensure their standards support our assessment tools.

We considered opportunities to advance FHIR®-based reporting of patient assessment data for the submission of the OASIS. Our objective was to explore how HHAs typically integrate technologies with varying complexity into existing systems and how this affects HH workflows. In this RFI, we sought to identify the challenges and/or opportunities that may arise during this integration, and determine the support needed to complete and submit quality data in ways that protect and enhance care delivery.

We also sought input on future measures under consideration including applicability of interoperability as a future measure concept in post-acute care settings. We refer readers to section III.H.1. of this proposed rule for more information.

Any updates specific to the HH QRP program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

2. Solicitation of Comment

We sought feedback on the current state of health IT use, including electronic health records (EHRs), in HHAs:

- To what extent does your HHA use health IT systems to maintain and exchange patient records?

- If your agency has transitioned to using electronic records, in part or in whole, what types of health IT does your HHA use to maintain patient records? Are these health IT systems certified under the Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program? If your agency uses health IT products or systems that are not certified under the ONC Health IT Certification Program, please specify. Does your agency use EHRs or other health IT products or systems that are not certified under the ONC Health IT Certification Program? If no, what is the reason for not doing so? Do these other systems exchange data using standards and implementation specifications adopted by HHS? Does your agency maintain any patient records outside of these electronic systems? If so, are the data organized in a structured format, using codes and recognized standards, that can be exchanged with other systems and providers?

- Does your HHA submit patient assessment data to CMS through your current health IT system? If a third-party intermediary is used to report data, what type of intermediary service is used? How does your agency currently exchange health information with other healthcare providers or systems, specifically between HHAs and other provider types? What about health information exchange with other entities, such as public health agencies? What challenges do you face with electronic exchange of health information?

- Are there any challenges with your current electronic devices (for example, tablets, smartphones, computers) that hinder your ability to achieve interoperability, such as collecting, storing, sharing, or submitting data? Please describe any specific issues you encounter. Does limited internet or lack of internet connectivity impact your ability to exchange data with other healthcare providers, including community-based care services, or your ability to submit patient assessment data to CMS? Please specify.

- What steps does your HHA take with respect to the implementation of health IT systems to ensure compliance with security and patient privacy requirements such as HIPAA?

- Does your HHA refer to the Safety Assurance Factors for EHR Resilience (SAFER) Guides (see newly revised versions published in January 2025 at *https://www.healthit.gov/topic/safety/safer-guides*) to self-assess EHR safety practices?

- What challenges or barriers does your agency encounter when submitting quality measure data to CMS as part of the HH QRP? What opportunities or factors could improve your agency's successful data submission to CMS?

- What types of technical support, guidance, workforce trainings, and/or other resources would be most beneficial for the implementation of FHIR®-based technology in your agency for the submission of the OASIS to CMS? What strategies can CMS, HHS, or other Federal partners take to ensure that technical assistance is both comprehensive and user-friendly? How could Quality Improvement Organizations (QIOs) or other entities enhance this support?

- Is your agency using technology that utilizes APIs based on the FHIR® standard to enable electronic data sharing? If so, with whom are you sharing data using the FHIR® standard and for what purpose(s)? For example, have you used FHIR® APIs to share data with public health agencies? Does your agency use any Substitutable Medical Applications and Reusable Technologies (SMART) on FHIR® applications? If so, are the SMART on FHIR®[29] applications integrated with your EHR or other health IT?

- How do you anticipate the adoption of technology using FHIR®-based APIs to facilitate the reporting of patient assessment data could impact provider workflows? What impact, if any, do you anticipate it will have on quality of care?

- Does your facility have any experience using technology that shares electronic health information using one or more versions of the United States Core Data for Interoperability (USCDI) standard?[30]

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[29] https://smarthealthit.org/.

[30] For more information about USCDI see https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi.

- Would your HHA and/or vendors be interested in participating in testing to explore options for transmission of assessments, for example testing the transmission of a FHIR®-based assessment to CMS?

- The Trusted Exchange Framework and Common Agreement™ (TEFCA™) framework supports nationwide health information exchange by connecting health information networks (HINs) across the country.[31] Additionally, TEFCA™ facilitates FHIR exchange by requiring Qualified HINs (QHINs) to perform patient discovery for those querying for data and providing data holders with FHIR endpoints to enable point-to-point exchange via FHIR APIs. How could the TEFCA™ support CMS quality programs' adoption of FHIR®-based assessment submissions consistent with the FHIR® Roadmap (available here: https://rce.sequoiaproject.org/three-year-fhir-roadmap-for-tefca/)? How might patient assessment data hold secondary uses for treatment or other TEFCA™ exchange purposes?

- What other information should we consider that could facilitate successful adoption and integration of FHIR®-based technologies and standardized data for patient assessment instruments like the OASIS?

We invited any feedback, suggestions, best practices, or success stories related to the implementation of these technologies and noted that we would use the input to inform our future dQM transition efforts.

Comment: Many commenters expressed support for a transition to dQMs in the HH QRP, citing that using FHIR as a standard can alleviate administrative burden and improve data quality if implemented effectively. Many of these commenters supported the transition but had recommendations for CMS on successful implementation for HHAs, including a phased implementation or "glide path" approach, reporting flexibility, and adequate time to update systems after CMS finalizes a change to HH QRP requirements. Many commenters

[31] For more information about TEFCA™, see https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca.

recommended funding or incentive opportunities to obtain resources and technology for improved exchange of health information. Numerous commenters also noted that implementation and updating EHRs is resource intensive, and that HHAs, along with other PAC providers, were not included in Meaningful Use funding through the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009.

Several commenters expressed concerns about the differences in dQM and IT readiness across HHAs. They highlighted data that over time, the adoption of EHR technology has increased in the post-acute care; however, the interoperability of that technology remains limited. A commenter gave examples of HHAs still receiving records via fax and noted that many HHAs lack connectivity to EHRs. Commenters suggested that technical assistance would be needed for HHAs that were the least advanced in health IT capabilities, and to also provide opportunities for those farther along to meet today's certified EHR technology (CEHRT) standards. Some commenters went further to note that they could not support any implementation around dQMs without federal commitment of additional funding for these goals.

Commenters addressed other related issues related to a dQM's implementation. Some commented on the need to manually submit OASIS and other PAC assessment data. They recommend that CMS develop and implement standardized Application Programming Interfaces (APIs) that would allow for direct data exchange between certified EHRs and CMS systems (directly). Another commenter noted that CMS has regulations that limit use of technology in populating OASIS items from a patient's medical chart. With the ability of artificial intelligence and other technologies, they noted that HHAs could now incorporate some patient data more efficiently without removing clinician review of the data. They argued this could significantly reduce the time required to complete the OASIS.

Several commenters also provided detailed responses to the RFI's questions about their agency's current state of health IT use, challenges and/or opportunities that may arise during integration of technologies with varying complexity into existing HH systems, how it affects

workflow, and what support may be needed to complete and submit quality data in ways that protect and enhance care delivery.

Response: We thank commenters for their feedback. While we will not be responding to specific comments submitted in response to this RFI in this final rule, we intend to use this information to inform future dQM transition work and potential future rulemaking to further our efforts toward a patient-centric digital health ecosystem.

L. Form, Manner, and Timing of Data Submission Under the HH QRP

We did not propose any new policies regarding Form, Manner, and Timing of Data Submission Under the HH QRP in the proposed rule.

M. Policies Regarding Public Display of Measure Data for the HH QRP

1. Ending the Public Display of Patient/Resident COVID-19 Measure

In the CY 2024 HH PPS final rule (88 FR 77762 through 77764), we finalized our proposal to begin publicly displaying data for the Patient/Resident COVID-19 measure beginning with the January 2026 Care Compare refresh. In section III.C.2 of the CY 2026 HH PPS proposed rule, we proposed to remove the Patient/Resident COVID-19 Measure beginning with the CY 2026 HH QRP. However, we noted that effective with assessments completed on or after the date of publication of the CY 2026 HH final rule, the data from O0350 Patient's COVID-19 Vaccination is Up to Date may be submitted using any of the three valid responses (0 – No, 1-Yes, or dash) on a Transfer, Death at home, or Discharge OASIS assessment, without any future quality measure implications.

We proposed that the Patient/Resident COVID-19 measure rates would be publicly reported for the last time with the January 2026 Care Compare refresh on Medicare.gov, based on data from Q1 of 2025. We invited public comments on our proposal to end the public display of Patient/Resident COVID-19 Measure data after the January 2026 Care Compare refresh on Medicare.gov.

Comment: Some commenters supported the proposal to end of the public display of the Patient/Resident COVID-19 Measure data after the January 2026 Care Compare refresh on Medicare.gov.

Response: We appreciate commenters' support.

Final Decision: We will cease publicly reporting data for this measure after the January 2026 Care Compare refresh, as proposed.

IV. The Expanded Home Health Value-Based Purchasing (HHVBP) Model

A. Background

As authorized by section 1115A of the Act and finalized in the CY 2016 HH PPS final rule (80 FR 68624), the Center for Medicare and Medicaid Innovation (Innovation Center) implemented the Home Health Value-Based Purchasing (HHVBP) Model ("original Model") in nine states on January 1, 2016. The design of the original Model leveraged the successes and lessons learned from other CMS value-based purchasing programs and demonstrations to shift from volume-based payments to a model designed to promote the delivery of higher quality care to Medicare beneficiaries. The specific goals of the original Model were to--

- Provide higher incentives for better quality care with greater efficiency;
- Study new potential quality and efficiency measures for appropriateness in the home health setting; and
- Enhance the current public reporting process.

The original Model resulted in an average 4.6 percent improvement in HHAs' total performance scores (TPS) and an average annual savings of $141 million to Medicare without evidence of adverse risks.[32] The evaluation of the original Model also found reductions in unplanned acute care hospitalizations and skilled nursing facility (SNF) stays, resulting in reductions in inpatient and SNF spending. The U.S. Secretary of Health and Human Services (the Secretary) determined that expansion of the original Model will further reduce Medicare spending and improve the quality of care. In October 2020, the CMS Chief Actuary certified that expansion of the HHVBP Model will produce Medicare savings if expanded to all states.[33]

On January 8, 2021, CMS announced the certification of the HHVBP Model for expansion nationwide, as well as the intent to expand the Model through notice and comment

[32] https://innovation.cms.gov/data-and-reports/2020/hhvbp-thirdann-rpt.
[33] https://www.cms.gov/files/document/certification-home-health-value-based-purchasing-hhvbp-model.pdf.

rulemaking.[34] In the CY 2022 HH PPS final rule (86 FR 62292 through 62336), we finalized the decision to expand the HHVBP Model to all Medicare certified HHAs in the 50 States, territories, and District of Columbia beginning January 1, 2022. CY 2022 was a pre-implementation year. The first payment year is CY 2025 based on the first performance year which was CY 2023. Our codified policies for the expanded HHVBP Model can be found in our regulations at 42 CFR part 484, subpart F, §§ 484.300 through 484.375.

In the CY 2024 HH PPS final rule (88 FR 77676), we finalized proposals to codify in the Code of Federal Regulations (CFR) the measure removal factors finalized in the CY 2022 HH PPS final rule; to replace the two Total Normalized Composite Measures (for Self-Care and Mobility) with the Discharge Function Score measure effective January 1, 2025; to replace the OASIS-based Discharge to Community (DTC) measure with the claims-based Discharge to Community-Post Acute Care (PAC) Measure for Home Health Agencies, effective January 1, 2025; to replace the claims-based Acute Care Hospitalization During the First 60 Days of Home Health Use and the Emergency Department Use without Hospitalization During the First 60 Days of Home Health measures with the claims-based Potentially Preventable Hospitalization measure effective January 1, 2025; to change the weights of individual measures due to the change in the total number of measures; and to update the Model baseline year to CY 2023 for all applicable measures in the finalized measure set beginning with performance year CY 2025.

B. Changes to HHVBP Measure Removal Factors

In the CY 2023 HH PPS final rule (88 FR 77776), CMS finalized the codification of specific factors that CMS considers for measure removal. Currently, there are eight measure removal factors that CMS considers when determining whether to remove measures from the expanded HHVBP Model's applicable measure set. In the CY 2026 HH PPS proposed rule (90

[34] https://www.cms.gov/newsroom/press-releases/cms-takes-action-improve-home-health-care-seniors-announces-intent-expand-home-health-value-based.

FR 29184), we proposed adding and codifying an additional measure removal factor at § 484.358, Factor 9: It is not feasible to implement the measure specifications.

We noted that this new measure removal factor would enable CMS to address situations in which it is no longer feasible to continue implementing a quality measure, such as when a data collection instrument is revised in a way that no longer collects the information required for the quality measure specifications.

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

Comment: Commenters supported this proposed addition to the measure removal factors.

Response: CMS appreciates the positive comments regarding the proposed measure removal factor.

Final Decision: CMS is finalizing as proposed the proposal to add and codify at § 484.358 Measure Factor 9: It is not feasible to implement the measure specifications.

C. Changes to the Expanded HHVBP Model's Applicable Measure Set

We proposed removing three measures from the current applicable measure set and adding four measures starting in CY 2026. The proposed removal of the three measures was necessary due to revisions to the Home Health Consumer Assessment of Healthcare Providers and System® (HHCAHPS) Survey that were proposed beginning with the April 2026 sample. These proposed survey revisions prevent the three HHCAHPS Survey-based measures from being calculated as currently specified for the expanded HHVBP model.

1. Removal of Three HHCAHPS Survey-Based Measures from the Expanded HHVBP Model Applicable Measure Set

The HHCAHPS Survey, a nationally standardized and publicly reported survey, is designed to measure the experiences of people receiving home health care from Medicare-certified HHAs. It is conducted for HHAs by approved HHCAHPS Survey vendors. Currently, the expanded HHVBP Model includes five HHCAHPS Survey-based measures:

- Care of Patients
- Communications between Providers and Patients
- Specific Care Issues
- Overall Rating of Home Health Care
- Willingness to Recommend the Agency

The Care of Patients, Communications between Providers and Patients, and Specific Care Issues measures are based on multiple items from the HHCAHPS Survey while Overall Rating of Home Health Care and Willingness to Recommend the Agency are single-item measures. Elsewhere in the proposed rule, CMS proposed changes to the HHCAHPS Survey. These proposed changes would affect the survey questions used to calculate three measures that are used in the expanded HHVBP Model. CMS plans to make changes to the questions used for two of the multi-item measures (Care of Patients and Communication between Providers and Patients). In addition, the Specific Care Issues measure will no longer exist as four of the seven items used for that measure will be removed from the survey. These changes are described in section III.H. of the final rule, and will become effective beginning with the April 2026 sample month.

Given these proposed changes, we proposed to remove the following HHCAHPS Survey based measures from the HHVBP applicable measure set starting with CY 2026:

- Care of Patients
- Communications between Providers and Patients
- Specific Care Issues

We proposed to remove these three HHCAHPS Survey-based measures using the proposed and finalized Removal Factor 9: It is not feasible to implement the measure specifications. This measure removal factor is described in more detail previously in section IV.B. of this final rule. The removal of these measures is necessary because the proposed changes to the HHCAHPS Survey instrument have been finalized, as the current measure

specifications cannot be calculated using the finalized survey revisions. Because the proposed changes to the HHCAHPS Survey instrument are finalized, several of the survey questions used to calculate the Care of Patients and Communication Between Providers and Patients measures will be changed and will no longer match the measure specifications. Also, four of the seven survey items used to calculate the Specific Care Issues measure will be removed because the survey changes have been finalized, making it impossible to calculate the measure as currently specified.

While CMS could revise the HHCAHPS measures to use the proposed HHCAHPS Survey instrument changes, a full year of data with the revised HHCAHPS measures will not be available until CY 2027. Data from multiple quarters will be needed to establish benchmarks and achievement thresholds for the revised HHCAHPS Survey-based measures. Removing these three measures as part of this rulemaking cycle will give CMS the time needed to collect the required data and potentially develop updated benchmarks and achievement thresholds for revised or new measures.

If CMS decides to propose the addition of the new versions of the Care of Patients and Communications between Providers and Patients measures and individual item measures to replace the Specific Care Issues measure, CMS will do so through future rulemaking.

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

Comment: Several commenters provided feedback regarding the proposed removal of certain HHCAHPS Survey items. Most of the commenters supported the changes to the HHVBP applicable measure set. A commenter stated that they supported the removal of outdated composite measures, such as those removed in the revised HHCAHPS Survey. Another commenter supported changing the HHVBP applicable measure set based on HHCAHPS Survey changes but encouraged CMS to revise the HHCAHPS Survey-based measures rather than remove them entirely.

Response: CMS appreciates the support for aligning the HHVBP Model applicable measure set with the revised HHCAHPS Survey change. At this time, CMS is not introducing replacement measures for those based on removed elements of the HHCAHPS Survey. However, we will take these public comments into consideration as we continue to refine the HHVBP Model applicable measure set.

Comment: A few commenters opposed any measure set changes at this time.

Response: CMS notes that these measures cannot be retained in the expanded HHVBP Model given the finalized changes to the HHCAHPS Survey.

Comment: A commenter encouraged CMS to remove all HHCAHPS Survey-based measures from the calculation of HHA quality scores to focus on objective clinical measures.

Response: CMS declines to remove all HHCAHPS Survey-based measures from the calculation of HHA quality scores and believes that self-reported patient experience data remains valuable for holistically measuring quality of care. As such, the measures still calculable from the revised HHCAHPS Survey, Overall Rating and Willingness to Recommend, will remain in the expanded HHVBP Model's applicable measure set.

Final Decision: After consideration of the public comments received, CMS is finalizing the removal of three HHCAHPS Survey-based measures as proposed.

2. Addition of Medicare Spending Per Beneficiary Post-Acute Care (MSPB-PAC) to the Expanded HHVBP Model Applicable Measure Set.

We proposed adding the claims-based MSPB-PAC measure to the HHVBP applicable measure set starting in CY 2026. This cross-setting 2-year measure was required by the Improving Post-Acute Care Transformation Act of 2014 (IMPACT Act) and was added to the Home Health Quality Reporting Program on January 1, 2017.

Public comments on the CY 2025 HH PPS proposed rule (89 FR 88354) in support of adding this measure to the expanded HHVBP Model suggested that the MSPB-PAC measure

could help to identify the costs associated with the delivery of high-quality home health services, which could identify areas for improved efficiencies in resource usage.

The MSPB-PAC measure is intended to incentivize providers to redesign care systems to provide coordinated, high-quality, and cost-efficient care. It holds HHAs accountable for Medicare payments for an episode of care that includes the period during which a patient is directly under HHA care, as well as a defined period after the end of HHA treatment, which may be reflective of and influenced by the services provided by the HHA. Evaluating Medicare payments during an episode creates a continuum of accountability between providers and has the potential to improve post-treatment care planning and coordination. In conjunction with the other performance measures used in the expanded HHVBP Model, explicit measurement of costs of care will allow recognition of HHAs that provide high quality care at a lower cost.

We noted that we anticipate adding the MSPB-PAC measure would create incentives for greater care coordination to deliver high-quality care at a lower cost to Medicare and incentivize providers to find efficient ways to address patients' care needs. Incentivizing efficient resource utilization aligns with the pay-for-performance approach used in the expanded HHVBP Model. The MSPB-PAC measure would ensure that HHVBP payment adjustments consider not only patient outcomes but also HHA's ability to produce those outcomes at a lower cost.

The MSPB-PAC measure is a claims-based measure that includes price-standardized payments for Part A and Part B services. It measures Medicare spending during an episode of care relative to the Medicare spending for other HHAs. The Medicare spending measure is payment-standardized and risk-adjusted. The MSPB-PAC measure captures Medicare spending for most Part A and B services during the episode of care, excluding services that are clinically unrelated to post-acute care treatment or services over which HHAs may have limited to no influence (for example, routine management of certain preexisting chronic conditions). The episode of care window consists of a treatment period and an associated services period (from the admission to the home health services up to 30 days after the end of the home health

treatment period). The episode includes the period a patient is directly under HHA care, as well as a defined period after the end of the HHA's treatment which may be reflective of and influenced by the services rendered by the HHA.[35]

We noted that we anticipate reporting preliminary benchmarks, achievement thresholds, and improvement thresholds for the MSPB-PAC measure in the October 2025 Interim Performance Reports (IPR). The MSPB-PAC measure would use 2 years of data covering CY 2022 and CY 2023 as baseline data. Because the MSPB-PAC measure is a 2-year measure, CY 2026 performance for the measure would be calculated based on 2 years of performance data (CY 2025/2026). The MSPB-PAC measure was designed as a 2-year measure to optimize reliability. In addition, each performance year would consist of 1 year of data that does not overlap with data from the prior performance year, which provides sufficient opportunity to capture quality improvement over time.

Adding the MSPB-PAC and function measures described below would increase the number of HHAs that have sufficient data for at least five measures, the minimum required to have a payment adjustment for the expanded HHVBP Model. Increasing the number of HHAs that receive payment adjustments would allow the Model to better incentivize high-quality home health care across the country.

We invited 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 the MSPB-PAC measure, encouraging CMS to adopt MSPB-PAC to align with administrative priorities and focus on spending efficiency. They acknowledged that adding MSPB-PAC to HHVBP supported CMS's shift towards more comprehensive accountability by combining cost metrics with functional and patient-reported outcomes. They agreed the MSPB-PAC measure would advance HHVBP's

[35] See https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/2016_07_20_mspb_pac_ltch_irf_snf_measure_specs.pdf for more details on the specifications for the MSPB-PAC measure

emphasis on cost-effectiveness, which is a key indicator of value in home health care. A commenter stated that agencies that can deliver necessary care in fewer episodes should be recognized and rewarded. They also expressed appreciation that MSPB-PAC includes price-standardized payments for Part A and Part B services, and is risk-adjusted to reflect patient complexity, thereby making it an appropriate tool for assessing efficiency.

Response: CMS appreciates commenters' understanding of the value of the MSPB-PAC measure and the supportive feedback.

Comment: A few commenters encouraged CMS to ensure the new measure was validated and properly risk-adjusted to avoid unfairly penalizing agencies serving complex, high-need patients.

Response: CMS appreciates commenters' concerns. CMS is committed to ensuring fairness, accuracy, and feasibility for all quality measures used in the expanded HHVBP Model. CMS also reminds commenters that the MSPB-PAC measure is risk adjusted to account for variations in patient populations and resource utilization across PAC providers.

Comment: Multiple commenters stated that MSPB-PAC is not a measure of care quality, only of expenditures. A commenter noted that the introduction of the Patient-Driven Groupings Model (PDGM) for Medicare payment aligned payment with payment complexity and removed incentives to increase the volume of therapy visits, making the MSPB-PAC measure unnecessary. Another commenter noted that, within the PDGM, payment is determined by defined patient characteristics: admission source, clinical grouping, functional impairment level, and comorbidity adjustment. This commenter expressed concern that patients referred from acute settings or presenting with higher-acuity conditions such as wounds, neurological rehabilitation needs, or musculoskeletal impairments generate higher episodic payments due to increased resource requirements.

Response: Incentivizing care coordination and efficient resource allocation is consistent with the expanded HHVBP Model's goal of improving the quality and efficiency of Medicare

home health care, leading to better outcomes for beneficiaries and reduced costs for the Medicare program. CMS believes that the addition of MSPB-PAC will further the goal of improving the efficiency of home health care, creating incentives for coordination of care and incentivizing providers to find efficient ways to deliver high quality care. CMS acknowledges that higher-acuity patients often require more resource-intensive treatments. CMS notes that the MSPB-PAC measure is risk-adjusted to account for differences in patient acuity. In addition, clinically complex patients receive a higher payment rate under the PDGM, limiting the financial incentive to avoid these high acuity patients.

Comment: Some commenters questioned whether HHAs that spend more than the national average of MSPB-PAC will receive a lower score on the measure. They also questioned whether HHAs that spend more than the average for their cohort will receive a lower score on the measure.

Response: We appreciate the commenters' concerns. MSPB-PAC is a metric of cost-effectiveness and efficiency, and as such, lower spending results in a higher score on the measure. As with all expanded HHVBP Model measures, HHAs will receive TPS scores based on their measure performance relative to their cohort. Full measure specifications for MSPB-PAC are available at the following link: https://www.cms.gov/files/document/home-health-outcome-measures-table-oasis-e2025.pdf.

Comment: Some commenters stated that the incentive to reduce costs of care which would result from adding the MSPB-PAC measure would not necessarily lead to higher quality care for patients and would run contrary to the goals CMS has for promoting patient-centered care. Some commenters particularly noted the potential for unintended consequences associated with the introduction of the MSPB-PAC measure, stating that adding the measure would create disincentives for HHAs to admit clinically complex patients, undermining access to care for high-need patients.

Response: We appreciate these comments. As part of our ongoing monitoring of the expanded HHVBP Model, we will monitor for changes in patient characteristics that may suggest unintended consequences associated with adding the MSPB-PAC measure. We note that the MSPB-PAC measure is risk-adjusted to account for differences in patient acuity. In addition, clinically complex patients receive a higher payment rate under PDGM, limiting the potential for unintended consequences.

Comment: A commenter stated that the MSPB-PAC and DTC-PAC measures measure very similar outcomes and that only one should be added to the expanded HHVBP Model.

Response: We believe that the MSPB-PAC and DTC-PAC measures measure different dimensions of quality and efficiency. DTC-PAC is a measure of patient outcomes while MSPB-PAC is a measure of resource use and cost efficiency. The DTC-PAC measure uses inpatient hospital claims to identify episodes with an associated unplanned hospitalization and administrative data to identify patients who die within 31 days of discharge, both of which result in an episode being classified as not having a successful community discharge. The MSPB-PAC measure uses Medicare Part A and B claims to measure the average Medicare spending per patient during and after the home health stay. The goal of the DTC-PAC measure is to encourage the provision of comprehensive care that facilitates successful long-term recovery at home. The goal of the MSPB-PAC measure is to incentivize providers to improve care efficiency and coordinate services across the episode of care, ultimately reducing total Medicare spending. Analyses conducted as part of the endorsement process for the MSPB-PAC measure found a small but significant negative association between the MSPB-PAC measure scores and the DTC measure scores. These results show that MSPB-PAC and DTC-PAC measure separate dimensions of quality.[36]

36 National Quality Forum (NQF) (2021) Cost and Efficiency, Spring 2020 Cycle: CDP Report. Available from: https://digitalassets.jointcommission.org/api/public/content/926365c68be1441791340150005aacd6?v=39e48ce7

Comment: Several commenters opposed adding any additional measures to the HHVBP applicable measure set, noting that HHAs have made substantial investments in quality improvement strategies tied to the current Model's framework. Some commenters expressed concern about the burden of adding additional measures, given the proposed reductions to home health payments. Another commenter encouraged CMS to maintain a stable and predictable measure environment, requesting that CMS maintain the current measure set and weight distribution in the near term, while engaging stakeholders in a phased, transparent process for any future expanded HHVBP Model refinements.

Response: We appreciate these comments but note that one of the goals of the expanded HHVBP Model is to study new potential quality and efficiency measures for appropriateness in the home health setting. Adding the MSPB-PAC measure to the HHVBP applicable measure set is consistent with this goal. We have and will continue to engage stakeholders in the measure development and implementation processes.

Comment: Some commenters expressed concern that, as a claims-based measure, MSPB-PAC lacks real-time transparency, limiting HHAs' ability to implement timely performance improvements.

Response: We recognize commenters' concerns regarding the timeliness of public reporting data. We remain committed to ensuring providers have access to the most timely data available to support quality improvement efforts. The MSPB-PAC measure is intended to provide actionable, transparent information to providers. By evaluating a given HHA's risk-adjusted Medicare spending in a defined timeframe as compared to that of the national median HHA, the MSPB-PAC measure recognizes HHAs that deliver high quality care at lower cost to Medicare, when used in conjunction with the other quality measures in the expanded HHVBP Model. The MSPB-PAC measure will have a six-month data lag, similar to the other claims-based measures already included in the HHVBP Model applicable measure set. Additionally, as discussed in the CY 2018 HH PPS final rule (82 FR 51676), improvements in performance in the

MSPB-PAC measure over a one-year period will also be included in the two years of measure data, so providers' improvement efforts can still be reflected in their two-year measure scores.[37]

Comment: Some commenters expressed concern that MSPB-PAC reflects spending related to factors outside of HHAs' control, potentially including spending for care the patient receives after discharge that may not have been preventable.

Response: We recognize commenters' concerns. We believe providers will not be unfairly punished for spending outside of their control. The MSPB-PAC measure excludes certain services and costs that are considered clinically unrelated or beyond the provider's control. This is done so that providers are held accountable only for the costs they can reasonably manage. The episode of care definition that the MSPB-PAC measure uses includes the period a patient is directly under a provider's care, as well as a defined period after the end of that provider's treatment which may be reflective of and influenced by the services rendered by the provider.

Final Decision: After consideration of the public comments received, we are finalizing the addition of MSPB-PAC measure to the expanded HHVBP Model's applicable measure set as proposed.

3. Addition of OASIS-Based Function Measures to the Expanded HHVBP Model Applicable Measure Set

We proposed adding three OASIS-based function measures to the HHVBP applicable measure set beginning with CY 2026:

- Improvement in Bathing (based on OASIS item M1830)
- Improvement in Upper Body Dressing (based on OASIS item M1810)
- Improvement in Lower Body Dressing (based on OASIS item M1820)

These measures are intended to complement the Discharge (DC) Function Score measure added to the HHVBP applicable measure set starting with CY 2025 to provide a more holistic

37 https://www.govinfo.gov/content/pkg/FR-2017-11-07/pdf/2017-23935.pdf

picture of patients' functional status. The DC Function Score measure uses a cross-setting function item set which does not include items related to bathing or dressing.

These three measures have already been tested, validated, and implemented for other purposes within CMS models and programs. Improvement in Bathing is used in the Home Health Quality Reporting Program, the Home Health Quality of Patient Care Star Rating system and reported on Care Compare. All three of the OASIS items underlying these measures were also used in the Total Normalized Change (TNC) in Self-Care measure that were part of the CY 2023 and CY 2024 expanded HHVBP Model applicable measure set. Additionally, the underlying OASIS M1800 items are used in the Home Health Patient-Driven Groupings Model that is used for Medicare home health payments. Therefore, adding these measures to the expanded HHVBP Model would align with existing quality measurement and payment practices. Adding these measures would not create additional burden to HHAs, as the data for these measures is already collected on OASIS assessments.

In the CY 2024 HH PPS final rule (88 FR 77676), CMS finalized the policy to add the DC Function Score measure to replace the previous OASIS-based TNC measures (TNC Self-Care and TNC Mobility). That change aligned the expanded HHVBP Model with PAC quality programs. The DC Function Score measure is an OASIS-based measure that is used in the HH QRP and the expanded HHVBP Model starting in CY 2025. This measure reports the percentage of patients who meet or exceed an expected discharge function score during the reporting period. The DC Function Score measure considers two dimensions of patient function – self-care and mobility activities – using 13 OASIS items.[38]

The Model's Technical Expert Panel (TEP) has raised concerns that the DC Function Score measure does not consider bathing or dressing abilities, as these items are not available

[38] These OASIS items and activities include GG0130 Self-Care, GG0130A Eating, GG0130B Oral hygiene, GG0130C Toileting hygiene, GG0170 Mobility, GG0170A Roll left and right, GG0170C Lying to sitting on side of bed, GG0170D Sit to stand, GG0170E Bed-to-chair transfer, GG0170F Toilet transfer, GG0170I Walk 10 feet, GG0170J Walk 50 feet with two turns, GG0170R Wheel 50 feet with two turns

across all PAC settings covered by this cross-setting measure. TEP members identified the ability to bathe and dress as being critically important for home health patients. Many patients who receive home health care are recovering from an injury or illness and may have difficulty performing the tasks of bathing and dressing, requiring help from another person or special equipment to accomplish these activities. Improving patients' ability to bathe themselves contributes to patient comfort and quality of life and is often a rehabilitative goal for home health patients. These metrics also promote safer discharges from home care. Improvement in both upper and lower body dressing are important indicators of usefulness and improvement for patients, as well as indicators of being able to stay home, care for themselves, and be independent.

In 2024, TEP members supported CMS moving ahead as quickly as possible to add bathing and dressing function measures to the Model's applicable measure set to complement the DC Function measure. The TEP recommended using existing measures based on the OASIS M1800 items, which could be added sooner than future measures based on section GG items[39].

The baseline data for these three measures will cover CY 2023, which was specified as the Model baseline year in the CY 2024 HH PPS final rule. This baseline data will be used to calculate benchmarks and achievement thresholds for the proposed OASIS-based function measures. We anticipate providing HHAs with the benchmarks, achievement thresholds, and improvement thresholds for the OASIS-based function measures in the October 2025 IPRs.

Adding these three measures would increase the number of OASIS-based measures used in the Model, allowing for more robust measurement of HHA performance. The change will also allow more HHAs to have sufficient data for at least five measures, the minimum required to calculate a payment adjustment. We anticipate that HHAs that receive payment adjustments will have greater incentives to improve or maintain quality of care.

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39 The Section GG items were added to patient assessment tools for home health, skilled nursing facilities, inpatient rehabilitation facilities, and long-term care hospitals to support alignment of measurement of functional abilities and goals across post-acute care assessment instrument

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

Comment: Most of the commenters supported CMS' proposed addition of the measures of bathing and dressing to complement the DC Function measure. However, many of the supportive commenters encouraged CMS to work toward replacing these measures with GG-based counterparts.

Response: We appreciate commenters' support of these measures. CMS agrees with commenters about the desirability of section GG-based versions of these measures. Once section GG-based versions of these measures are available, we may consider proposing changing to the GG-based measures through future rulemaking.

Comment: Some commenters opposed adding any measures based on the OASIS M1800 items, even in the short-term. These commenters stated that the functional areas addressed by these measures would be better served by developing new quality measures based on the OASIS GG items. One commenter expressed concern that using the M1800-based measures could delay development and implementation of the GG-based measures.

Response: We agree with commenters about the desirability of Section GG-based versions of these measures but note that each of the M1800 item-based measures were used in the TNC in Self-Care measure that was used in the expanded HHVBP Model prior to 2025. The addition of the M1800-based measures will not delay development or implementation of the GG-based measures, as CMS will continue to work toward development of the GG-based measures, even while the M1800-based measures are publicly reported. Both the M1800 items and GG items will continue to be collected during this development period. Once section GG-based versions of these measures are available, we may consider proposing changing to the GG-based measures through future rulemaking.

Comment: A few commenters encouraged CMS to replace the DC Function measure with individual OASIS-based function measures.

Response: We finalized the proposal to add the DC Function measure to the HHVBP applicable measure set in the CY 2024 HH PPS final rule (88 FR 77676). Public comments on this change were generally supportive. CMS will not remove the DC Function measure at this time. The DC Function measure contributes valuable insights about the quality of care provided to patients. For many patients, the overall goals of HHA care may include optimizing functional improvement, returning to a previous level of independence, maintaining functional abilities, or avoiding institutionalization Unlike the individual OASIS-based function measures, the DC Function measure does not solely reflect improvement of patients at discharge, as it estimates the percentage of patients who meet, as well as exceed, an expected discharge function score. The measure gives credit for patients who, based on their own demographic and clinical characteristics, are expected to maintain, as opposed to improve in, function. We will continue to monitor performance trends of the DC Function measure.

Comment: Some commenters opposed adding any additional measures to the HHVBP applicable measure set. A few commenters cited concerns with the administrative burden of adding new measures, while another noted the investments that providers have made in quality improvement strategies based on the current measure set.

Response: We appreciate commenters' concerns about changes to the HHVBP applicable measure set. We note that these measures were used in the TNC in Self-Care measure that was part of the HHVBP applicable measure set prior to 2025, when it was replaced by the DC Function measure. As a result, CMS believe that HHAs should be able to adjust to this change in the measure set without unreasonable burden.

Comment: A commenter requested that CMS not obscure the role of the nurse in providing patient-centered care.

Response: We appreciate the comment and remain committed to supporting the contributions made by all members of an interdisciplinary patient-centered care team.

Comment: A few commenters expressed concerns about the fairness, accuracy, and feasibility of new measures. A commenter encouraged CMS to validate all proposed new measures before tying the measures to payment. Another encouraged CMS to ensure that functional measures are appropriately risk-adjusted to account for the complexity of patient populations. Another commenter encouraged CMS to adopt a perspective oriented around comprehensive care. Another commenter recommended CMS either delay the proposed changes or make at least some of the changes voluntary for the first performance year before payments are impacted.

Response: We appreciate commenters' concerns about quality measure accuracy and fairness. We remain committed to ensuring that all HHVBP applicable measures account for providers' patient populations and notes that all three of the proposed function measures are risk-adjusted. Additional information about the specifications of these function measures is available at the following link: https://www.cms.gov/files/document/home-health-outcome-measures-table-oasis-e2025.pdf. While CMS recognizes commenters' concerns about the timing of adding these measures, we do not believe the addition of these measures needs to be delayed particularly given that the three measures are included in the TNC in Self-Care measure previously used in the expanded HHVBP Model. The function measures have been thoroughly vetted and two of the measures have been utilized in HH QRP for multiple years. These function measures would add valuable information about quality of care to the expanded HHVBP Model, which we believe will be beneficial to incorporate into the Model sooner rather than later. After implementation, we will monitor performance trends for these function measures to verify that the measures are meaningfully identifying HHAs' quality of care. Therefore, CMS has decided not to delay implementation of these measure changes.

In addition, we do not believe making the new measures voluntary would be viable or beneficial to the expanded HHVBP Model or providers. The expanded HHVBP Model is designed to incentivize HHAs to provide high-quality home health care across the country.

Given the intent of the expanded HHVBP Model to improve the quality of care furnished to Medicare beneficiaries and study what incentives are sufficiently significant to encourage HHAs to provide high quality, CMS believes that it is important that none of the measures used in the Model be voluntary. Permitting HHAs to voluntarily decide whether to use the newly finalized measures would result in some HHAs receiving performance scores that are based on less complete and less representative data, reducing the impact of the Model on quality. In addition, the addition of the three finalized OASIS-based function measures to the Model increases the number of HHAs that have sufficient data available to receive a payment adjustment, which also increases the impact of the Model on quality.

Final Decision: After consideration of the public comments received, CMS is finalizing the addition of the three OASIS-based function measures to the HHVBP applicable measure set as proposed.

4. Updates to Individual Measure Weights and Category Weights

Along with the proposed revisions to the current HHVBP applicable measure set, we proposed revising the weights of the individual measures starting with the CY 2026 performance year as well as revising the measure category weights. Table D-22 has current and proposed individual measure weights and category weights.

Changes to the measure weights are necessary given the proposed changes to the expanded HHVBP Model applicable measure set. Reflecting the reduction in the number of HHCAHPS Survey-based measures, the proposed weights include a lower total weight for the HHCAHPS Survey-based measures and a higher weight for the OASIS-based and claims-based measures. In addition, some of the weight for the current claims-based measures is shifted to the MSPB-PAC measure and some weight for the OASIS-based measures is shifted to the additional function measures. As with the current measure weights, higher weight is given to claims-based measures because they may have a greater impact on reducing Medicare expenditures. For example, HHAs with better performance scores on the claims-based PPH measure have lower

rates of potentially preventable hospitalizations for their patients, reducing Medicare expenditures.

Currently, the OASIS-based, claims-based, and HHCAHPS Survey-based measures contribute 35 percent, 35 percent, and 30 percent, respectively, to the Total Performance Score (TPS) for HHAs in the larger-volume cohort. We proposed adjusting the measure category weights for the larger-volume cohort such that the OASIS-based and claims-based measure categories each contribute 40 percent, and the HHCAHPS Survey-based measure category contributes 20 percent to the TPS due to the reduction in the number of individual HHCAHPS Survey-based measures. For HHAs in the smaller-volume cohort, the OASIS-based and claims-based measures both contribute 50 percent to the TPS. We did not propose changing the measure category weights for the smaller-volume cohort as the HHCAHPS measures are not used for the smaller-volume cohort.

As proposed, changes to the applicable measure set would increase the number of OASIS-based measures from three measures to six and increase the number of claims-based measures from two to three. The number of individual measures for the HHCAHPS Survey-based measures would decrease from five to two. Note that we have changed weights for measures and measure categories in the past due to changes to the applicable measure set (for example, replacing the two TNC measures with the DC Function Score measure).

TABLE D-22--CY 2025 AND PROPOSED INDIVIDUAL MEASURE WEIGHTS AND CATEGORY WEIGHTS FOR THE EXPANDED HHVBP MODEL

Measure	CY 2025 Measure Weights		Proposed Measure Weights	
	Larger-Volume Cohort	Smaller-Volume Cohort	Larger-Volume Cohort	Smaller-Volume Cohort
Improvement in Dyspnea	6.00%	8.57%	7.00%	8.75%
Improvement in Management of Oral Medications	9.00%	12.86%	11.00%	13.75%
Discharge Function Score (DC Function)	20.00%	28.57%	15.00%	18.75%
Improvement in Bathing	-	-	3.50%	4.38%
Improvement in Upper Body Dressing	-	-	1.75%	2.19%
Improvement in Lower Body Dressing	-	-	1.75%	2.19%
Sum of OASIS-based Measures	**35.00%**	**50.00%**	**40.00%**	**50.00%**
Home Health within-stay Potentially Preventable Hospitalization (PPH)	26.00%	37.14%	15.00%	18.75%
Discharge to Community – Post Acute Care (DTC-PAC)	9.00%	12.86%	15.00%	18.75%
Medicare Spending Per Beneficiary- Post-Acute Care (MSPB-PAC)	-	-	10.00%	12.50%
Sum of Claims-based measures	**35.00%**	**50.00%**	**40.00%**	**50.00%**
Care of Patients	6.00%	0.00%	-	-

Measure	CY 2025 Measure Weights		Proposed Measure Weights	
	Larger-Volume Cohort	Smaller-Volume Cohort	Larger-Volume Cohort	Smaller-Volume Cohort
Communication Between Providers and Patients	6.00%	0.00%	-	-
Specific Care Issues	6.00%	0.00%	-	-
Overall Rating of Home Health Care	6.00%	0.00%	10.00%	0.00%
Willingness to Recommend the Agency	6.00%	0.00%	10.00%	0.00%
Sum of HHCAHPS Survey-based measures	**30.00%**	**0.00%**	**20.00%**	**0.00%**
Sum of All Measures	**100.00%**	**100.00%**	**100.00%**	**100.00%**

Comment: A few commenters supported all of the proposed changes to HHVBP Model's measure weights. Another commenter only supported modifications caused by the proposed changes to HHCAHPS Survey-based measures, as they opposed the other proposed changes to the HHVBP applicable measure set.

Response: We appreciate the comments supporting the proposed changes to HHVBP measure weights. We note that all proposed changes to measure weights are necessary given the changes to the expanded HHVBP Model's applicable measure set that are being finalized in this rule.

Comment: Several commenters disagreed with CMS's proposed measure weight changes. A commenter expressed concern about the increased weight for the OASIS-based measures. A different commenter expressed concern about the increased weight each individual HHCAHPS Survey-based measure would receive under the proposed measure category weights. Another commenter requested that measure weight changes be introduced gradually. A different commenter expressed concerns about the differential impact the revised measure weights might have on providers in Puerto Rico. A few commenters opposed any measure set or measure weight changes at this time.

Response: We appreciate the comments received on the proposed changes to the expanded HHVBP Model individual measure and category weights. We note that changes to measure weights are necessary given the changes to the expanded HHVBP Model applicable measure set that are being finalized as part of this rule. The increase in the number of total measures in the expanded model, the increase in the number of measures in the OASIS-based

and claims-based categories, and the decrease in the number of measures in the HHCAHPS Survey-based category, necessitate adjusting the weight assigned to some or all of the measures in the HHVBP Model applicable measure set.

As measures are removed and added to the expanded HHVBP Model, CMS works to balance measure weights across both measure categories and across individual measures. For example, the removal of three HHCAHPS Survey-based measures is required to align with the finalized changes to the HHCAHPS Survey, reducing the total number of HHCAHPS Survey-based measures in the HHVBP Model to two. As outlined in the proposed rule and below in section IV.C.5, CMS evaluated options which could preserve the HHCAHPS Survey-based measure category weight (30 percent) or preserve the individual HHCAHPS Survey-based measure weights (6 percent) but could not preserve both. CMS determined that these alternatives would be inconsistent with previous decisions about applying differential weights to measures, and therefore these alternatives were not proposed.

At this time, CMS has not identified any disproportionate impacts the revised measure weights would have on providers in Puerto Rico. We will continue to monitor trends in measure performance that may indicate unintended consequences from participating in the expanded HHVBP Model.

Final Decision: After consideration of the public comments received, we are finalizing the changes to the expanded HHVBP Model's individual measure weights and category weights as proposed.

5. Alternatives Considered

We considered two alternative options for revising the HHVBP measure weights prior to choosing the previously discussed proposals. Table D-23 describes these alternative options for HHAs in the larger-volume cohort, including maintaining measure category weights consistent with current measure set weights and adjusting within-category measure weights (Option 1), reducing the HHCAHPS-based measure category weight to 20 percent (Option 2), and

maintaining HHCAHPS-based measure weights consistent with current measure set weights, adjusting measure category weights accordingly (Option 3). We also considered these options for the smaller-volume cohort and came to the same conclusions. Therefore, we only provided a table with measure weighting alternatives for the larger-volume cohort.

TABLE D-23 - ALTERNATIVE INDIVIDUAL MEASURE WEIGHTS AND CATEGORY WEIGHTS CONSIDERED FOR THE EXPANDED HHVBP MODEL

Measure	Option 1 Maintain Category Weights	Option 2 Reduce HHCAHPS Category Weight	Option 3 Maintain Individual HHCAHPS Measure Weights
Improvement in Dyspnea	6.13%	7.00%	7.70%
Improvement in Management of Oral Medications	9.63%	11.00%	12.10%
Discharge Function Score (DC Function)	13.13%	15.00%	16.50%
Improvement in Bathing	3.06%	3.50%	3.85%
Improvement in Upper Body Dressing	1.53%	1.75%	1.93%
Improvement in Lower Body Dressing	1.53%	1.75%	1.93%
Sum of OASIS-based Measures	**35.00%**	**40.00%**	**44.00%**
Home Health within-stay Potentially Preventable Hospitalization (PPH)	18.00%	20.00%	16.50%
Discharge to Community – Post Acute Care (DTC-PAC)	8.50%	10.00%	16.50%
Medicare Spending Per Beneficiary- Post-Acute Care (MSPB-PAC)	8.50%	10.00%	11.00%
Sum of Claims-based measures	**35.00%**	**40.00%**	**44.00%**
Overall Rating of Home Health Care	15.00%	10.00%	6.00%
Willingness to Recommend the Agency	15.00%	10.00%	6.00%
Sum of HHCAHPS Survey-based measures	**30.00%**	**20.00%**	**12.00%**
Sum of All Measures	**100.00%**	**100.00%**	**100.00%**

We determined that these alternatives would be less consistent with previous decisions about applying differential weights to measures, and therefore these alternatives were not proposed.

We invited comments on these alternatives considered. The following is a summary of the comments we received and our responses:

Comment: A commenter recommended that CMS adopt Option 3, retaining the 6.00 percent individual measure weight for the remaining two HHCAHPS Survey-based measures.

Response: We appreciate the commenter's suggestion. However, as stated previously, we determined that the alternative measure weight options would be less consistent with previous decisions about applying differential weights to measures.

Final Decision: After consideration of the public comments received, we are finalizing the changes to the expanded HHVBP Model's individual measure weights and category weights as proposed.

D. HHVBP Quality Measure Concepts Under Consideration for Future Years – Request for Information

The expanded HHVBP Model provides an opportunity to examine a broad array of quality measures that address critical gaps in care. A comprehensive review of the Value-Based Purchasing (VBP) experience, conducted by the Office of the Assistant Secretary for Planning and Evaluation (ASPE), identified several objectives for HHVBP measures.[40] The recommended objectives emphasize measuring patient outcomes and functional status; appropriateness of care; and incentives for providers to build infrastructure to facilitate measurement within the quality framework. The study identified the following seven objectives which served as guiding principles for the development of performance measures used in the original Model:

- Use a broad measure set that captures the complexity of the HHA service provided.
- Incorporate the flexibility to include Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 measures that are cross-cutting amongst post-acute care settings.
- Develop second-generation measures of patient outcomes, health and functional status, shared decision making, and patient activation.
- Include a balance of process, outcome, and patient experience measures.
- Advance the ability to measure cost and value.
- Add measures for appropriateness or overuse.
- Promote infrastructure investments.

A central driver of the process used to select measures for the original Model was

[40] U.S. Department of Health and Human Services. Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2014). Measuring Success in Health Care Value-Based Purchasing Programs. Cheryl L. Damberg et al. on behalf of RAND Health.

incorporating innovative thinking from the field while simultaneously drawing on evidence-based literature and documented best practices. Broadly, measures were selected based on their impact on care delivery and to support the goal of improving health outcomes, quality, safety, efficiency, and experience of care for patients.

As we continue to leverage our value-based purchasing initiatives to improve the quality of care furnished across healthcare settings, we are interested in considering new performance measures for inclusion in the expanded HHVBP Model. We requested public comments on one specific performance measure as well as general comments on other potential future model concepts that may be considered for inclusion in the expanded HHVBP Model.

1. Falls with Major Injury Measure (OASIS-based and Claims-based)

Within the home health population, approximately one third of individuals over the age of 65 experience one or more falls each year.[41,42] Since 2022, CMS has reported rates for the Falls with Major Injury (FMI) measure on Care Compare. This measure is based on OASIS data.

A recent study[43] found that more than half of falls with a major injury (identified using Medicare claims data) were not reported on OASIS assessments. OIG observed that a low fall rate reported on Care Compare may reflect a provider's lack of falls reporting, rather than a low incidence of falls among its patients. OIG further observed that HHAs with low falls with major injury rates on Care Compare were more likely than other HHAs not to report falls among patients enrolled in Medicare. These findings raised concerns about the accuracy of this measure. In response to this OIG study, CMS is currently working on a respecified version of the FMI measure that uses fee-for-service claims, encounter data, and OASIS data. Using multiple data

41 Avin KG, Hanke TA, Kirk-Sanchez N, McDonough CM, Shubert TE, Hardage J, Hartley G; Academy of Geriatric Physical Therapy of the American Physical Therapy Association. Management of falls in community-dwelling older adults: clinical guidance statement from the Academy of Geriatric Physical Therapy of the American Physical Therapy Association. Phys Ther. 2015 Jun;95(6):815-34. doi: 10.2522/ptj.20140415. Epub 2015 Jan 8. PMID: 25573760; PMCID: PMC4757637.

42 Carande-Kulis V, Stevens JA, Florence CS, Beattie BL, Arias I. A cost-benefit analysis of three older adult fall prevention interventions. J Safety Res. 2015 Feb;52:65-70. doi: 10.1016/j.jsr.2014.12.007. Epub 2015 Jan 6. PMID: 25662884; PMCID: PMC6604798.

43 https://oig.hhs.gov/reports/all/2023/home-health-agencies-failed-to-report-over-half-of-falls-with-major-injury-and-hospitalization-among-their-medicare-patients/

sources will produce a more robust and complete data set, allowing the respecified FMI measure to be more accurate and include more providers. Members of the Post-Acute Care (PAC) and Home Health Cross-Setting TEP also broadly agreed that data accuracy is vitally important for the measure's aim of making cross-provider comparisons.

In addition, the respecified FMI measure includes other injuries not explicitly covered in the OASIS-based FMI measure, which uses a specific measure of falls with major injury that includes only bone fractures, joint dislocations, closed head injuries with altered consciousness, and subdural hematomas.

We requested comments related to the potential addition of the respecified FMI measure to the measure set for the expanded HHVBP Model. The following is a summary of the comments we received and our responses:

Comment: Several commenters agreed that CMS should include the Falls with Major Injury (FMI) measure in HHVBP applicable measure set in the future. Supporters agreed that the measure would improve the robustness and completeness of the data set, and that falls are a relevant concern for patients that should be tracked. A commenter suggested that CMS consider adding questions to HHCAHPS survey instrument related to falls, to complement OASIS data and improve accuracy. However, other commenters cited concerns about accuracy of reporting, the unique circumstances of episodic home health care compared to 24/7 institutional care, the potential risk of penalizing providers for factors outside of their control, potential overlap with the MSPB-PAC measure, and the possibility that providers might be discouraged from admitting high-risk patients. A commenter welcomed an opportunity for CMS to validate agencies' existing fall reporting and prevention rather than add new elements to the current FMI quality measure.

Response: CMS appreciates the public comments regarding the respecified FMI measure. CMS will consider this input while continuing to refine the expanded HHVBP Model in the future.

2. Potential Future Changes to HHCAHPS Scoring Rules and Applicable Measure Set

We sought public comments regarding two potential changes to the HHCAHPS Survey-based measures scoring rules and applicable measure set as they relate to the expanded HHVBP Model:

a. Measuring HHA Performance on Forthcoming HHCAHPS Items based only on HHA Achievement

As discussed previously within the rule, CMS anticipated proposing new HHCAHPS Survey-based measures to replace the Care of Patients, Communication Between Providers and Patients, and Specific Care Issues measures through future rulemaking. These revised HHCAHPS Survey-based measures will be based on data collected from the revised HHCAHPS Survey instrument. Data for these revised measures will be required to establish benchmarks and achievement thresholds. CMS will require 1 year of data to establish appropriate benchmarks and achievement thresholds for measuring HHAs' level of performance. By contrast, CMS will require 2 years of data to measure improvement over time and establish improvement thresholds.

Therefore, CMS sought public comments on the possibility of initially measuring HHA performance on the future HHCAHPS Survey-based measures based solely on achievement, rather than both achievement and improvement. This would allow CMS to potentially begin using the revised HHCAHPS measures in the expanded HHVBP Model starting with the CY 2028 performance year. If CMS proposes adding the achievement-based HHCAHPS Survey-based measures to the expanded HHVBP Model starting with the 2028 performance year, then benchmarks and achievement thresholds would be published in 2027, using data from 2026.

After sufficient data are available to develop appropriate improvement thresholds, CMS anticipates measuring HHA performance on these HHCAHPS Survey-

based measures based on both achievement and improvement. This change would be proposed through future rulemaking.

b. Adding to the Applicable Measure Set for the Expanded HHVBP Model the Three Remaining Items in the Specific Care Issues Measure as Single Item Measures

As discussed previously, CMS proposed and finalized the decision to modify the HHCAHPS Survey instrument. Among other changes, the proposal removed several items used in the multi-item Specific Care Issues measure. Three of the items used in the Specific Care Issues measure will remain in the HHCAHPS Survey instrument. The three items from the Specific Care Issues measure included in the revised HHCAHPS Survey instrument are as follows:

- When you first started getting home health care from this agency, did someone from the agency talk about ways to help make your home safer? For example, they may have suggested adding grab bars in the shower or removing tripping hazards.
- Has someone from the agency ever reviewed the prescribed and over -the -counter medicines you were taking? For example, they might have asked you to show them your medicines and talked with you about how and when to take each one.
- In the last 2 months of care, did home health staff from this agency talk with you about any side effects of your medicines?

CMS sought public comments on the possibility of adding these three remaining HHCAHPS Survey items to the expanded HHVBP Model as single-item measures. We also sought public comments on the possibility of giving each of these single item measures a weight of one third the weight of the other HHCAHPS items, thus maintaining the same relative weight of the Specific Care Issues measure. The following is a summary of the comments we received and our responses:

Comment: Several commenters disagreed with CMS's potential future uses for HHCAHPS Survey-based measures. A few commenters recommended CMS not include the

remaining individual items from the Specific Care Issues measure, and instead prioritize patient reported outcome measures. Several commenters discouraged CMS from reporting future HHCAHPS Survey-based measures using only achievement points. These commenters believed that incorporating achievement points and improvement points simultaneously would avoid additional disruptions, better inform agencies' decisions, and avoid disadvantaging agencies that are improving. They uniformly expressed that agencies should be given the full two-year period before the HHCAHPS Survey-based measures are reintroduced.

Response: We appreciate the public comments regarding the HHCAHPS Survey-based measures. We will consider this input while continuing to refine the expanded HHVBP Model in the future.

Comment: Several commenters offered suggestions other than those directly named in the RFI. A commenter suggested that CMS adopt comprehensive functional outcome measures that accurately capture a patient's full range of functional status, including communication, cognition, and swallowing. A few commenters opposed any additional data collection or measures.

Response: CMS appreciates the public comments submitted in response to this RFI. CMS will consider this input while continuing to refine the expanded HHVBP Model in the future.

V. Updates to the Home Health Agency Conditions of Participation (CoPs) to Align with the OASIS All-Payer Submission Requirements

A. Statutory Authority and Background

Section 1891(d) of the Act, cross-referencing section 1891(c)(2)(C)(i)(I) of the Act (section 4022(a) of Pub. L. 100–203 (December 22, 1987)), required the Secretary to develop a comprehensive assessment for Medicare-participating HHAs. Section 1891(c)(2)(C)(i)(II) of the Act also requires a survey of the quality of care and services furnished by the agency as measured by indicators of medical, nursing, and rehabilitative care provided by the HHA. Subsequently, CMS developed an assessment instrument that identifies each patient's need for home care and the patient's medical, nursing, rehabilitative, social and discharge planning needs. Part of this assessment requires Medicare-certified HHAs to use a standard core assessment data set, the Outcome and Assessment Information Set (OASIS). Thus, OASIS became the designated assessment instrument for use by an HHA in complying with these reporting requirements.

Section 704 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173, December 8, 2003) suspended the legal authority of the Secretary to require HHAs to gather or report non-Medicare and non-Medicaid patient data to CMS until certain conditions[44] were met. Subsequently, CMS conducted a study from 2004 to 2005 and submitted a report[45] to Congress which recommended that the suspension of data collection on non-Medicare and non-Medicaid patients continue. In addition, the Improving Medicare Post-Acute Care Transformation Act (IMPACT Act) (Pub. L. 113-185, October 6,

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44 Section 704(b) of the MMA suspended legal authority to require HHAs to report on non-Medicare and non-Medicaid patient data until at least two months after the Secretary published final regulations on CMS's collection and use of OASIS data for non-Medicare/Medicaid patients following the submission of a report to Congress on the study described under section 704(c) of the MMA.

45 The "OASIS Study: The Costs and Benefits Associated with the Collection of Outcome and Assessment Information Set (OASIS) Data on Private Pay Home Health Patients – Report to Congress" https://www.cms.gov/files/document/cms-oasis-study-all-payer-data-submission-2006.pdf

2014) required CMS to create a uniform quality measurement system that allows CMS to compare outcomes across post-acute care (PAC) providers, which include HHAs.

In response to the IMPACT Act, the final rule titled, "Medicare Program; Calendar Year (CY) 2023 Home Health Prospective Payment System Rate Update; Home Health Quality Reporting Program Requirements; Home Health Value-Based Purchasing Expanded Model Requirements; and Home Infusion Therapy Services Requirements" (87 FR 66790, November 4, 2022) finalized the requirement for HHAs to report OASIS data on all patients, regardless of payer, for the applicable 12-month performance period (for example, July 1, 2025 – June 30, 2026) (87 FR 66862 through 66865). With the CY 2025 HH PPS final rule (89 FR 88354, November 7, 2024), CMS established that start of care (SOC) is the first assessment that can be submitted for a non-Medicare/non-Medicaid patient, either on or after January 1, 2025, for the phase-in (voluntary) period or on or after July 1, 2025, for the mandatory reporting period (89 FR 88439 through 88441). This ended the suspension of the OASIS data collection on non-Medicare and non-Medicaid HHA patients.

B. Updates to the Home Health Agency (CoPs) to Align with the OASIS All-Payer Submission Requirements (§§ 484.45(a) and 484.55(d)(1)(i))

Section 484.45(a) of the HHA CoPs currently requires an HHA to encode and electronically transmit each completed OASIS assessment to the CMS system, "regarding each beneficiary" with respect to which information is required to be transmitted (as determined by the Secretary), within 30 days of completing the "assessment of the beneficiary." To align with the transition to OASIS all-payer submission requirements we proposed at § 484.45(a) to remove the term "beneficiary" and replace it with the term "patient."

Additionally, under section 484.55 of the HHA CoPs, all patients must receive, and an HHA must provide, a comprehensive assessment no later than 5 calendar days after the start of care. The comprehensive assessment must incorporate the most current version of the OASIS data items. This includes clinical record items, patient history, supportive assistance, etc. Section

484.55(d)(1)(i) specifies a "beneficiary elected transfer" in reference to one scenario in which an OASIS assessment must be updated. To support the transition to OASIS all-payer submission requirements, we also proposed to remove the term "beneficiary" at § 484.55(d)(1)(i).

Comment: A commenter requested additional clarification regarding the OASIS all-payer requirements. The commenter noted that the proposed policy shift would be a significant operations change for HHAs and the electronic medical record (EMR) systems they utilize. The commenter suggested CMS update the OASIS validation rules and engage EMR vendors in pilot testing.

Response: While the commenter noted the operational change that may be required, HHAs have had substantial time to prepare for the transition to the OASIS all-payer requirement as this policy was initially finalized in 2022 in the CY 2023 HH PPS final rule (87 FR 66862). With implementation of OASIS all-payer data submission, there is no required change to HHA electronic medical record systems. CMS is not introducing any new required OASIS items with the implementation of the all-payer proposal that would require a change to OASIS submission processes. With all-payer submission, HHAs will now be required to submit OASIS for patients receiving skilled care regardless of payor source using the same processes currently in place for Medicare and Medicaid patients. Lastly, all HHAs will continue to have access to technical support relative to submission of OASIS data via the QIES Technical Support Office website https://qtso.cms.gov/ and iQIES team at CMS.

After consideration of public comment, we are finalizing the technical changes to the CoPs as proposed. Thus, § 484.45(a) will state that an HHA must encode and electronically transmit each completed OASIS assessment to the CMS system, "regarding each patient" with respect to which information is required to be transmitted (as determined by the Secretary), within 30 days of completing the "assessment of the patient" and § 484.55(d)(1)(i) will state "Elected transfer." These technical changes further clarify that the requirement for reporting OASIS information applies to all HHA patients receiving skilled services and align the language

in the CoPs with the requirements finalized in the CY 2023 and CY 2025 HH PPS final rules. We emphasize that there is no change to existing policy regarding patient exemptions from OASIS, which are as follows: patients under the age of 18; patients receiving maternity services; and patients receiving only personal care, housekeeping, or chore services. Additionally, we remind readers that the OASIS submission requirements continue not to apply to patients receiving Part B outpatient therapy services provided by an HHA that elects to provide these outpatient services.[46] Patients receiving Part B outpatient therapy services would not have an HHA plan of care nor would an OASIS assessment be completed on these patients.

46 In accordance with 484.105(g) an HHA that furnishes outpatient physical therapy or speech-language pathology services must meet all of the applicable conditions of Part 484 and the additional health and safety requirements set forth in §§ 485.711, 485.713, 485.715, 485.719, 485.723, and 485.727 to implement section 1861(p) of the Act.

VI. Provider Enrollment and Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Accreditation Policies

A. Provider Enrollment

1. Medicare Enrollment

a. Background

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers into the Medicare program. The central purpose of the enrollment process is to help verify that providers and suppliers (hereafter collectively "providers" unless otherwise noted) seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet all applicable Federal and State requirements to do so. The process assists in preventing unqualified and potentially fraudulent individuals and entities from entering and improperly billing Medicare. Since 2006, we have undertaken rulemaking efforts to outline our enrollment procedures. These regulations are generally codified in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.575 and hereafter occasionally referenced as subpart P). They address, among other things, requirements that providers must meet to obtain and maintain Medicare billing privileges.

As outlined in § 424.510, one requirement is that the provider must submit to its assigned Medicare Administrative Contractor (MAC) the appropriate enrollment form, typically the Form CMS-855 (for example, the Form CMS-855A (OMB control number 0938-0685)). The Form CMS-855 collects important information about the provider. This includes, but is not limited to, general identifying information (for instance, legal business name), licensure and/or certification data, and practice locations. The application is used for various provider enrollment transactions, such as:

- Initial enrollment – The provider is -- (1) enrolling in Medicare for the first time; (2) enrolling in another Medicare contractor's jurisdiction; or (3) seeking to enroll in Medicare after having previously been enrolled:

- Change of ownership – The provider is reporting a change in its ownership;
- Revalidation – The provider is revalidating its Medicare enrollment information in accordance with § 424.515. (DMEPOS) suppliers must revalidate their enrollment every 3 years; all other providers and suppliers must do so every 5 years.);
- Reactivation – The provider is seeking to reactivate its Medicare billing privileges after it was deactivated under § 424.540. (Deactivation, an important program integrity safeguard, means that the provider's or supplier's billing privileges are stopped for one or more of the reasons outlined in § 424.540(a)(1) through (8) (for example, non-compliance with enrollment requirements). However, they can be restored (or "reactivated") upon the submission of information required under § 424.540).
- Change of information – The provider is reporting a change in its existing enrollment information in accordance with § 424.516.

After receiving the provider's initial enrollment application, CMS or the MAC reviews and confirms the information thereon and determines whether the provider meets all applicable Medicare requirements. We believe this screening process has greatly assisted CMS in executing its responsibility to prevent Medicare fraud, waste, and abuse by keeping unqualified providers out of the Medicare program.

As previously mentioned, over the years we have issued various final rules pertaining to provider enrollment. These rules were intended not only to clarify or strengthen certain components of the enrollment process but also to enable us to take further action against providers: (1) engaging (or potentially engaging) in fraudulent or abusive behavior; (2) presenting a risk of harm to Medicare beneficiaries or the Medicare Trust Funds; or (3) that are otherwise unqualified to furnish Medicare services or items. Consistent with this, and as we discuss in this section VI.A.1.c of this final rule, we proposed and are finalizing several changes to our Medicare provider enrollment regulations.

(Section VI.A.2 of this final rule addresses our proposed and finalized change to one of our Medicaid provider enrollment provisions.)

b. Legal Authorities

There are two principal categories of legal authorities for our proposed and finalized Medicare provider enrollment provisions--

- Section 1866(j) of the Act furnishes specific authority regarding the enrollment process for providers and suppliers; and
- Sections 1102 and 1871 of the Act provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

c. Medicare Provider Enrollment Provisions

This section of this final rule discusses our proposals, outlines the comments we received and responses thereto, and identifies our final provisions. A number of the comments addressed multiple proposals and topics simultaneously, particularly with respect to revocations and stays of enrollment. We will thus include all the comments and responses received on the subjects in sections VI.A.1.c.(1).(a). through (c). of this rule within section VI.A.1.c.(1).(d). of this final rule.

(1) Revocation and Denial Reasons, Revisions to Other Revocation Policies, Retroactive Revocations, and Stays of Enrollment

(a) Revocations and Denials

Under § 424.535(a), CMS may revoke a Medicare provider's enrollment for any of the reasons specified in that paragraph. These reasons include, for instance, the provider's: (i) failure to adhere to Medicare enrollment requirements; (ii) exclusion by the HHS Office of Inspector General (OIG); (iii) felony conviction within the previous 10 years; (iv) pattern of improper or abusive billing; and (v) termination by another Federal health care program. A revocation is designed to safeguard the Medicare program, the Trust Funds, and beneficiaries by removing (and preventing payment to) Medicare providers that have engaged in problematic or otherwise

non-compliant behavior. When a provider is revoked, it is generally barred from reenrolling in Medicare for a period of 1 to 10 years. The length of this "reenrollment bar" is determined based upon the severity of the basis of the revocation.

CMS also has numerous reasons in § 424.530(a) for which it can deny a provider's enrollment application, some of which duplicate our revocation grounds in § 424.535(a) (for instance, OIG exclusion, felony conviction, termination by another federal health care program). The general rationale for a denial is akin to that for a revocation: to protect the Medicare program and its beneficiaries from potentially fraudulent or abusive activity.

We have previously finalized a number of regulations adding new revocation and denial reasons to subpart P to address particular program integrity vulnerabilities and types of provider conduct. We have also used rulemaking to refine other policies regarding revocations, such as the effective dates of certain revocations. Given our continuing obligation to establish effective payment safeguards, we proposed several additions and revisions to our revocation and denial policies in part 424 subpart P.

(i) Authority to Prescribe Drugs (§§ 424.535(a)(13)(ii) and 424.530(a)(11)(ii))

Sections 424.535(a)(13)(ii) and 424.530(a)(11)(ii) permit CMS to revoke or deny a physician's or eligible professional's enrollment if the licensing or administrative body for any state where the individual practices suspends or revokes the person's ability to prescribe drugs. We have received questions regarding the term "prescribe drugs" – specifically, whether the state's prohibition: (1) must be for all drugs for § 424.535(a)(13)(ii) or § 424.530(a)(11)(ii) to potentially apply; or (2) need only apply to one drug. Our position has long been the latter, and we accordingly proposed to revise §§ 424.535(a)(13)(ii) and 424.530(a)(11)(ii) to change "prescribe drugs" to "prescribe one or more drugs." Given the seriousness of any state suspension or revocation action regarding an individual's prescribing authority, we believe a prohibition involving even one drug is sufficient to warrant revocation or denial if we deem it necessary to protect

beneficiaries and the Trust Funds.

(ii) Pattern or Practice of Prescribing (§ 424.535(a)(14))

We currently may revoke a physician's or practitioner's enrollment under § 424.535(a)(14) if the individual has a pattern or practice of prescribing Part B or D drugs that is abusive, threatens the health and safety of Medicare beneficiaries, or fails to meet Medicare requirements. This authority aims to protect Medicare beneficiaries and the Trust Funds against harmful and non-compliant prescribing practices.

Drugs associated with services covered under Part A presently do not fall within the purview of § 424.535(a)(14). This is of increasing concern to us. Although Part A does not cover many drugs that beneficiaries take at home or in outpatient facilities, it can cover drugs administered as part of an inpatient covered stay, such as at a hospital or a skilled nursing facility. We do not believe the important protections that § 424.535(a)(14) affords must depend upon the setting in which the drugs were furnished. It is the abusive or non-compliant prescribing itself, rather than the beneficiary's location or inpatient or outpatient status, that is most critical for purposes of program integrity. Beneficiaries can be endangered by prescribing during inpatient stays no less than in other environments. We accordingly proposed to revise § 424.535(a)(14) to change "Part B or D drugs" to "Medicare-covered drugs" to encompass Medicare Parts B, D, and now A.

(iii) Abuse of Billing Privileges (§ 424.535(a)(8)(i))

Section 424.535(a)(8) permits revocation of enrollment if--

- The provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service (§ 424.535(a)(8)(i)); or
- CMS determines that the provider has a pattern or practice of submitting claims that fail to meet Medicare requirements (§ 424.535(a)(8)(ii)).

Paragraph (a)(8)(i) states that situations falling within its purview include but are limited to (and are enumerated as paragraphs (a)(8)(i)(A) through (C))--

- The beneficiary is deceased;
- The directing physician or beneficiary is not in the state or country when services were furnished; or
- When the equipment necessary for testing is not present where the testing is stated to have occurred.

We have recently seen cases where providers and suppliers have submitted claims for payment involving services or items that the beneficiary states were never furnished. While the "but are not limited to" caveat in paragraph (a)(8)(i) means that paragraphs (a)(8)(i)(A) through (C) are not exclusive, we believe the seriousness of the attestation cases we have seen and the potential fraud, waste, and abuse that has resulted therefrom warrant a specific mention of this situation in paragraph (a)(8)(i). We accordingly proposed to include it in new paragraph (a)(8)(i)(D).

(b) Retroactive Revocations Bases

Section 424.535(g) addresses revocation effective dates. Paragraph (g)(1) states that except as described in paragraphs (g)(2) and (g)(3), a revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider; the revocation is thus prospective. Paragraphs (g)(2)(i) through (viii) list eight situations where the revocation effective date is retroactive, generally meaning that the revocation becomes effective back to the date on which the provider's non-adherence to Medicare requirements commenced.

The purpose of paragraph (g)(2) is to prevent payment to a provider while it is out of compliance. Assume a provider's license is revoked by the state on September 1. CMS learns of this and sends a revocation notice to the provider on September 15. If we applied paragraph (g)(1)'s prospective "30 days after mailing" timeframe, the provider could bill and be paid for services furnished between September 1 and October 15 while unlicensed, resulting in potentially thousands of dollars in improper Medicare payments. Preventing improper payments is a cornerstone of provider enrollment, and we believe that retroactive revocation effective dates

are crucial means of ensuring that taxpayer monies are paid only to legitimate, compliant providers. For this reason, we proposed several new grounds and effective dates for retroactive revocations. These will be designated as paragraphs (g)(2)(viii) through (xiv) (the requirement in current paragraph (g)(2)(viii) will be removed, as later explained) and are as follows:

- For revocations based on a lapse in the IDTF's comprehensive liability insurance under § 410.33(g)(6), the date the insurance lapsed.
- For revocations based on the provider's or supplier's submission of false or misleading information on the enrollment application, the date the application's certification statement was signed.
- For revocations based on the provider's or supplier's failure to timely report a change of ownership or adverse legal action, or a change, addition, or deletion of a practice location, the day after the date by which the provider or supplier was required to report the change, addition, or deletion.
- For revocations based on the surrender of the provider's or supplier's Drug Enforcement Administration certificate of registration in response to a show cause order, the date the certificate was surrendered.
- For revocations based on the State's suspension or revocation of the physician's or practitioner's ability to prescribe one or more drugs, the date of the suspension or revocation.
- For revocations of any of the provider's or supplier's other enrollments under § 424.535(i), the effective date of the revocation that triggered the revocation(s) of the other enrollment(s).
- For revocations based on a DMEPOS supplier's non-compliance with a condition or standard in § 424.57(b) or (c), respectively, the date on which the non-compliance began.

We proposed these particular grounds because, as we explained in the proposed rule, the revoked provider or supplier engaged in action or inaction resulting in non-compliance and/or otherwise concerning conduct. Regarding proposed paragraph (g)(2)(viii), lapsed IDTF liability

insurance could have eliminated financial protection for beneficiaries negligently harmed by a test the IDTF performed. We believe such an insurance lapse and the risk it could have posed to patients warrants a retroactive revocation effective date. Moreover, because IDTF liability insurance is required per § 410.33(g)(6), failure to maintain it means the IDTF is non-compliant with enrollment requirements; the supplier must therefore not receive payments for services furnished on or after the date the non-compliance commenced. Providing false or misleading data on the enrollment application, meanwhile, reflects in our view dishonest behavior that could have resulted in improper payments to the provider. To illustrate, assume an enrolled provider had failed to report one of its practice locations on its application, knowing that it was not a valid site. If the provider furnished services from that site, it could have received payments to which it was not entitled due to the location's non-compliance. We believe the severity of such conduct justifies a retroactive revocation.

The same concerns about potential improper payments were behind proposed new paragraph (g)(2)(x). As an example, if a provider moves its practice location without notifying CMS and the new location does not meet the definition of "operational" in § 424.502, Medicare might have been paying for services while the provider was non-compliant with enrollment requirements. Accordingly, we believe this warrants application of the revocation retroactively to the date the non-compliance began as described in proposed paragraph (g)(2)(x). As for new paragraphs (g)(2)(xi) and (xii), meeting all applicable federal and state requirements is necessary for enrollment. If an individual is prescribing or dispensing drugs while non-compliant, we believe the risk this presented to beneficiaries after the loss of DEA or state authority justifies a revocation back to the date said loss occurred. With respect to proposed paragraph (g)(2)(xiii), we believe it would be inconsistent to apply one effective date to the triggering revocation and a different, later one to others, for the same individual or provider organization is involved in all these enrollments. Proposed paragraph (g)(2)(xiv), in our view, is appropriate because the

supplier's non-compliance may have resulted in payments (on or after the date of non-compliance) to which the supplier was not entitled.

We previously noted our authority under § 424.535(a)(8) to revoke a provider for the abusive billing situations described in paragraphs (a)(8)(i) and (ii). These situations are especially disconcerting with regard to the question of improper payments. If a provider is engaging in abusive billing, this, in our view, constitutes a direct threat to the integrity of the Medicare program. To allow a provider that was revoked for submitting claims for unfurnished services to continue billing Medicare for another 30 days would run entirely counter to our role as steward of the Trust Funds. Thus, we proposed to include the revocation bases in § 424.535(a)(8) as grounds for retroactive applicability.

Under new paragraph (a)(8)(iii), the revocation effective date in paragraph (a)(8)(i) would be the earliest date of service on the claim or claims that is or are triggering the revocation. To illustrate, if CMS revokes the provider for submitting claims for non-furnished services with the claims' service dates of June 1, June 5, and June 10, the revocation date would be the earliest of them, or June 1. Considering the serious program integrity risks associated with such claims, we do not believe the effective date must be the last claimed service date, for the risk commenced with the first claim's submission. The revocation effective date under paragraph (a)(8)(ii), meanwhile, would be the last date of service on the claims in question. The reason for the different effective dates is that while (a)(8)(i) requires only one claim submission, (a)(8)(ii) requires a pattern or practice, which cannot be established via a single claim. The last claim establishes the pattern or practice, hence the need to use the date thereon as the effective date.

To further accommodate new paragraph (a)(8)(iii), we proposed to add reference to it in the previously noted opening clause of § 424.535(g)(1) as being excluded from application under paragraph (g)(1).

We also proposed several other technical changes involving retroactive revocations.

First, § 405.800(b)(2) states that a revocation is effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier, the only exceptions being the revocations referenced in current § 424.535(g)(2)(i) through (iv), which are retroactive. Given our significant changes to § 424.535(g)(2) over the years, we proposed to replace the current language of § 405.800(b)(2) with a statement that a revocation's effective date is as specified in § 424.535 (which would include § 424.535(a)(8)(iii) and (g)).

Second, § 424.57(e)(1) states that except as otherwise provided in § 424.57, a DMEPOS supplier's revocation for violating § 424.57(b) or (c) is effective 30 days after the entity is sent notice of the revocation, as specified in § 405.874. Similar to our proposed revision to § 405.800(b)(2), we proposed to modify § 424.57(e)(1) to state that the revocation effective date would be as specified in § 424.535.

Third, current § 424.535(g)(2)(viii) outlines effective dates for revocations under § 424.535(a)(23). Paragraphs § 424.535(g)(2)(viii)(A) through (C) identify three situations where a retroactive effective date applies. Section 424.535(g)(2)(viii)(D), meanwhile, states that for all standard violations not addressed in paragraphs (A) through (C), the prospective effective date in paragraph (g)(1) applies if the effective date in paragraph (g)(3) does not. We proposed two changes involving § 424.535(g)(2)(viii). One is that -- given proposed new § 424.535(g)(2)(viii) through (xiv) -- we proposed to redesignate existing § 424.535(g)(2)(viii) as new § 424.535(g)(2)(xv). The other proposed change involved replacing the reference to "paragraphs (A) and (C)" in current § 424.535(g)(2)(viii)(D) (proposed new § 424.535(g)(2)(xv)(D)) with "paragraph (g)(2)". This is because we proposed to add certain standard violations to (g)(2) in paragraphs other than current (g)(2)(viii)(A), (B), and (C).

(c) Revisions to Stay of Enrollment Authority (§ 424.541)

Along with revocations and deactivations, CMS has a third vehicle with which to prevent Medicare fraud, waste, and abuse as well as improper payments: a "stay of enrollment." Under § 424.541(a)(1) and (2), we can impose a stay against a provider if the provider:

- Is non-compliant with at least one enrollment requirement in Title 42; and
- Can remedy the non-compliance by submitting, as applicable to the situation, a Form CMS-855, Form CMS-20134, or Form CMS-588 change of information or revalidation application.

We established the stay of enrollment concept based largely on our concern that there were instances of provider non-compliance that did not necessarily warrant a measure as significant as a deactivation, much less a revocation. We believed that a more moderate CMS approach in addressing these cases would ease the burden on providers without hindering our obligation to protect the Trust Funds. To further explain the rationale behind stays of enrollment, we noted in the proposed rule several critical differences between stays and revocations and deactivations.

- Length of Action - We previously noted that a revoked provider is subject to a reenrollment bar typically lasting between 1 to 10 years. Deactivations last until the provider has reactivated its billing privileges under § 424.540; if no reactivation occurs, the deactivation remains effective indefinitely. An enrollment stay, however, lasts a maximum of 60 calendar days, during which period the provider remains enrolled in Medicare, unlike with a revocation. Described otherwise, a stay of enrollment represents a comparatively brief "pause" in the provider's enrollment that permits the provider to quickly resume compliance without the greater burdens associated with deactivations and revocations.
- Payments - Section 424.541(a)(2)(ii)(A) states that claims submitted by the provider with dates of service within the stay period will be rejected. Yet under § 424.541(a)(2)(ii)(B), these claims are eligible for payment (and may be resubmitted by the provider within applicable timeframes specified in Title 42) if--

++ CMS or its contractor determines that the provider or supplier has resumed compliance with all Medicare enrollment requirements in Title 42; and

++ The stay ends on or before the 60th day of the stay period.

This means that whereas revocations and deactivations prohibit payment for services or items furnished during the revocation or deactivation period with no possibility of retroactive payments, a stay of enrollment permits these payments if the requirements in § 424.541(a)(2)(ii)(B) are met.

- Mechanism for Resuming Compliance - A revoked or deactivated provider cannot re-enroll in Medicare (after the reenrollment bar expires) or reactivate its billing privileges until the applicable provider enrollment application process is complete, which can take considerable time. Under § 424.541(a)(5), a stay can end on the date on which CMS or its contractor determines that the provider has resumed compliance with all Medicare enrollment requirements in Title 42. For purposes of § 424.541(a)(5) only, we have interpreted the term "has resumed compliance" as meaning the provider has submitted the required application referenced in § 424.541(a)(1)(ii) (for example, Form CMS-855 change of information). This means that a stay could end within a few days, allowing the provider to rapidly resume billing.

Considering the burden-reducing aspects of the stay concept, we proposed that its scope be expanded to cover other situations – one of which is where a provider submits a revalidation or change of information application that is rejected under § 424.525(a)(1) or (2). Per these provisions, rejection is permissible if the provider does not furnish complete information on the application (or required supporting documentation under paragraph (a)(2)) within 30 calendar days of the date the Medicare contractor requested the missing or incomplete data or documentation. A deactivation often follows the rejection. Unlike cases where the provider did not submit the required revalidation or change of information at all, the provider in § 424.525(a)(1) cases did submit the application, albeit incompletely. We believe it would be inconsistent to allow the more concerning action of application non-submission to be subject to a stay and have situations where the provider actually submitted the form to result in a deactivation. Therefore, we proposed to expand § 424.541(a)(1)(i) to include instances where

the provider's change of information or revalidation application is rejected under § 424.525(a)(1) or (2)).

In addition, current § 424.541(a)(3) states that a stay of enrollment lasts no longer than 60 days from the postmark date of the notification letter, which is the effective date of the stay. We proposed two changes to this section. One was to delete existing § 424.541(a)(3) and, in new § 424.541(a)(3)(i), state that the effective date of a stay is, as applicable: (1) the date on which the provider's or supplier's non-compliance began; or (2) the date on which the provider's or supplier's change of information or revalidation application was rejected under § 424.525. Considering our concerns about payments to providers when they are non-compliant, we no longer believe commencing the stay period upon the notification letter's postmark date is appropriate. The other was to propose in new § 424.541(a)(3)(ii) that CMS may establish a stay of enrollment for any period up to a maximum of 60 days. This is consistent with current CMS practice, but we sought to make clearer that the CMS-assigned stay period need not be 60 days but can be any timeframe up to that point.

We previously noted the reference in § 424.541(a)(2)(ii)(B) regarding claim submission eligibility, with § 424.541(a)(2)(ii)(B)(*2*) referencing the end of the stay on or before the 60th day. We proposed to revise paragraph (a)(2)(ii)(B)(*2*) to replace the 60-day reference therein with the requirement that the stay must end on or before the expiration of the originally designated stay period. This would further clarify that the stay period can be less than 60 days. Meanwhile, § 424.541(a)(5) states that a stay of enrollment ends on the date on which CMS or its contractor determines that the provider or supplier has resumed compliance with all Medicare enrollment requirements in Title 42 or the day after the 60-day stay period expires, whichever occurs first. Since, again, the stay period CMS has assigned may be less than 60 days, we proposed to change "60-day period" to "CMS-assigned stay period".

(d) Comments Received

We received the following comments on the provisions addressed in section VI.A.1.c.(1). of this final rule:

Comment: A number of commenters expressed concern about our reference to beneficiary attestations in proposed new § 424.535(a)(8)(i)(D), believing this provision to be overly punitive. They stated that because of the potential for unintentional and innocuous misunderstandings and errors (as well as delays in mailing products and incorrect postal tracking), providers should be able to: (1) furnish input, documentation, and explanations to CMS; and (2) take corrective action before any revocation occurs. Some commenters added that attestations could contain unsubstantiated information given that patients may not understand or recall the items or services they received. Accordingly, the attestation alone should not be a basis for revocation without CMS performing a thorough investigation of the matter and assessing the accuracy of the attestation, with several commenters. Another commenter believed that CMS would use the provision to revoke massive numbers of providers and suppliers, with one commenter stating that stronger contractor oversight of providers would be a sounder approach.

Response: We appreciate these concerns but stress two things. First, this is not a new revocation ground; in fact, it has existed for many years. As indicated in the proposed rule and this final rule (and as correctly noted by a commenter), we currently have the authority to revoke a provider under § 424.535(a)(8)(i) in the beneficiary attestation situations addressed in proposed § 424.535(a)(8)(i)(D). We are merely adding a specific reference to situations in § 424.535(a)(8)(i)(D) to reiterate our authority in this regard given the disconcerting increase in these scenarios. Second, and notwithstanding this authority, we do not revoke providers on this basis (or any other basis under § 424.535(a)) as a matter of course. We only do so: (1) after a thorough investigation of the facts of the case; and (2) when it is truly warranted. Indeed, we fully recognize the impact of a revocation on a provider and do not take these measures lightly.

Concerning the commenters' apparent suggestion of an informal appeals process whereby documentation and an explanation could be furnished to CMS before a revocation occurs, we most respectfully disagree. Considering that we only undertake these revocations after a very careful and detailed analysis and when clearly warranted, we believe we must proceed with the revocation promptly to ensure that the Trust Funds are protected against further improper billing. We have always maintained that establishing an informal pre-revocation appeals process could encourage providers to disregard compliance with Medicare requirements until they are notified of the non-adherence, upon which they will remedy the issue and remain enrolled but then perhaps resume their prior behavior. In other words, allowing providers to always take corrective action and resume compliance before revocation gives them no incentive to remain adherent in the first place, which leaves the Medicare program at risk of billions of dollars in payments to non-compliant providers. We reiterate that with all revocations regardless of the reason, the provider has an opportunity to be heard via the appeals process in 42 CFR part 498.

Comment: Several commenters appeared to suggest that a stay of enrollment (rather than a revocation) be applied to situations involving proposed § 424.535(a)(8)(i)(D).

Response: Although we were somewhat uncertain as to the context of the commenters' specific recommendation, we respectfully do not believe a stay of enrollment would be an adequate substitution for a revocation in a § 424.535(a)(8)(i)(D) scenario. Stays are short-term measures designed to be a less serious action than a deactivation or revocation. As noted, we only undertake a revocation under § 424.535(a)(8)(i) in exceptional cases due to the provider's concerning activity. Considering the seriousness of such behavior and the consequent need to protect the Trust Funds and beneficiaries for an extended period, we believe a revocation, rather than a stay, is the most appropriate CMS action.

Comment: Several commenters stated that § 424.535(a)(8)(i)(D) appears to allow revocation based on a single beneficiary complaint or minor administrative error. Other

commenters stated that § 424.535(a)(8)(i)(D) scenarios should only result in revocation if there is a pattern of abuse, an intent to commit fraud, or a hindrance to patient care.

Response: We appreciate these comments. Section 424.535(a)(8)(i) scenarios have never required a pattern of conduct (unlike, for instance, § 424.535(a)(8)(ii)), fraudulent intent, or patient care impact. On the other hand, § 424.535(a)(8)(i) has never been intended to punish providers for small transgressions. Only in rare and exceptional circumstances have we ever revoked a provider under § 424.535(a)(8)(i), and this will be the case for § 424.535(a)(8)(i)(D). We recognize commenters' concerns and wish to assure stakeholders that we have no intention whatsoever of revoking legitimate providers under § 424.535(a)(8)(i)(D) on spurious and unfair bases.

Comment: A commenter stated that a competitor's use of § 424.535(a)(8)(i)(D) to generate false claims against the provider should itself mandate the competitor's revocation.

Response: We appreciate and will contemplate this suggestion as we continue our efforts to strengthen Medicare program integrity and the provider enrollment process.

Comment: Regarding § 424.535(a)(8)(i)(D), a commenter sought clarification regarding: (1) how CMS will distinguish between potential fraud and a mere misunderstanding or delivery delay; (2) whether there is a formal appeals process to challenge such a finding; and (3) whether provider can continue operations during an investigation or will instead face immediate suspension of billing privileges.

Response: We thank the commenter for these comments and respond as follows. First, and as already stated, CMS will carefully investigate the facts in all potential § 424.535(a)(8)(i)(D) situations. While we cannot address in detail the operational aspects of these investigations, we again assure providers that § 424.535(a)(8)(i)(D) revocations will occur only when truly justified. Second, providers can appeal any § 424.535(a)(8)(i) revocation under 42 CFR part 498. Third, if the commenter's use of "immediate suspension of billing privileges" refers to Medicare payment suspensions under 42 CFR 405.371, CMS cannot predict when the

latter provision may or will be invoked. Nor can CMS advise the provider as to whether it can or should continue its full operations during a § 424.535(a)(8)(i)(D) investigation; we believe this would be the provider's independent business decision. We can, though, state that if the provider is revoked after the investigation, it loses its Medicare billing privileges and the revocation will, per proposed § 424.535(a)(8)(iii)(A), be retroactive to the earliest date of service on the claim or claims that is or are triggering the revocation.

Comment: A commenter stated that instead of an immediate revocation under § 424.535(a)(8)(i), CMS could, while conducting an investigation, perform a pre-payment audit of the supplier's claims to ensure that CMS guidelines are being followed; this would facilitate continuity of patient care.

Response: We appreciate and may consider this suggestion as a possible action during our investigation.

Comment: A commenter supported our proposal to change the term "Part B or D drugs" in § 424.535(a)(14) to "Medicare-covered drugs".

Response: We appreciate the commenter's support.

Comment: A commenter supported our proposal to change the term "prescribe drugs" in §§ 424.535(a)(13)(ii) and 424.530(a)(11)(ii) to "one or more drugs."

Response: We appreciate the commenter's support.

Comment: A commenter opposed our proposed revision to § 424.535(a)(13), stating that a provider on this basis could be revoked for isolated or unrelated state licensing issues without any educational opportunity or appeal.

Response: We appreciate this comment. While we are respectfully uncertain as to the type and timing of the educational opportunity to which the commenter refers, we reiterate that: (1) we always carefully examine the facts of the case before undertaking revocation action; and (2) providers can appeal a § 424.535(a)(13) revocation per 42 CFR part 498.

Comment: A commenter stated that our expanded revocation reasons increase the likelihood of harsh penalties for minor or administrative errors.

Response: We respectfully disagree. We believe our revisions to § 424.535(a)(8)(i), (a)(13), and (a)(14) are relatively minor; for example, the addition of § 424.535(a)(8)(i)(D) is, as discussed, simply a reminder of our existing authority. We do not anticipate a significant increase in § 424.535(a)(8)(i), (a)(13), and (a)(14) revocations stemming from our proposals, and we will continue to exercise great care and prudence in determining whether a revocation is warranted.

Comment: Several commenters supported our proposal to include certain application rejections within the scope of enrollment stays.

Response: We appreciate the commenters' support.

Comment: While favoring our proposed expansion of the stay of enrollment's applicability, several commenters requested that CMS to go further and require a stay in the situations described in § 424.541 (and perhaps others) instead of giving the MACs discretion to impose a deactivation or revocation. A commenter stated that this would: (1) reduce burden on suppliers and better facilitate continued patient access to care; (2) reduce inconsistency among the MACs in these cases; (3) assist suppliers that are part of a group when their PTANs are deactivated upon the deactivation of the group's PTAN; and (4) allow payment for services performed. Other commenters recommended that CMS expand the reasons for which a stay can be imposed in lieu of many deactivation and revocation grounds (especially revocations with retroactive effective dates); the commenters stated that this would give suppliers time to correct the issue without the consequences of a revocation.

Response: We appreciate these comments. MACs generally do not have the discretion to choose whether to impose a stay, deactivation, or revocation. These actions are only imposed via CMS's direction (for instance, through Chapter 10 of CMS Publication 100-08 or specific CMS instruction to the MAC regarding a particular provider). Regarding the further expansion of stay

of enrollment grounds, we thank the commenters' for their recommendation and may consider it for future rulemaking.

Comment: A commenter supported our stay of enrollment proposal but requested that CMS ensure the efficiency of the existing provider enrollment process regarding stays before adding additional grounds.

Response: We appreciate the commenter's support and are confident that the MACs can operationally accommodate our new stay of enrollment basis.

Comment: A commenter requested that CMS issue guidance to MACs requiring them to follow the stay of enrollment instructions in CMS Change Request (CR) 13449.

Response: We appreciate this comment but believe it is outside the scope of this final rule.

Comment: A commenter stated that some providers that have a stay imposed against them do not receive a notification letter and therefore are: (1) unable to meet the 15-day rebuttal timeframe; and (2) uncertain as to the status of their enrollment when a claim is denied.

Response: Although we respectfully believe this comment is outside the scope of this final rule, we thank the commenter for bringing this to our attention as we continue to take steps to enhance the provider enrollment process.

Comment: Several commenters opposed the proposal to change the stay's effective date from the postmark date to the date the provider's: (1) non-compliance began; or (2) revalidation or change of information submission was rejected. They stated that this change would reduce the time the supplier has to research, address, and correct the issue causing the stay. A commenter added that: (1) our change would likely result in a stay that is more than 60 days, which would invalidate the stay of enrollment; and (2) a stay freezes payment, meaning there is no need to back-date the stay.

Response: We appreciate the commenters' feedback and recognize the potential time reduction for remedial action by the provider. Yet we reiterate that using the postmark date

permits the provider to receive payment for services furnished between the commencement of non-compliance (for example, the day after the date on which the revalidation application was due) and the postmark date. A core purpose of our provider enrollment proposals is to help halt payments to non-compliant providers, and we believe that having the postmark date as the stay effective date contradicts this. Also, this change would not result in a stay greater than 60 days because any 60-day long stay would begin on the non-compliance date. To illustrate, suppose a 60-day stay is imposed on a provider effective on the non-adherence date of April 1. The letter's postmark date is April 5. The stay would end on May 30, 60 days after the April 1 effective date. Regarding the final comment in the previous paragraph, we reemphasize most respectfully that the issue is not whether payment is frozen but whether the provider was entitled to payment in the first place; we believe the provider was not during the period between the date of non-compliance and the postmark date.

Comment: A commenter stated that a stay should only be applied when there is clear evidence of intent.

Response: We respectfully disagree. Even if a provider failed to timely submit a revalidation or change of information application for innocuous reasons, non-compliance still results and the provider is not entitled to payment absent the corrective measures permitted under § 424.541.

Comment: Several commenters requested that CMS define "rejected" in the context of CMS' proposed stay of enrollment expansion (for example, whether it references the MAC's rejection of a revalidation application).

Response: The term "rejected" for purposes of 42 CFR part 424, subpart P (which includes § 424.541) is defined in § 424.502 and further described in § 424.525.

Comment: A commenter: (1) supported our change from "60-day period" to "CMS assigned stay period"; and (2) questioned whether CMS' proposed clarification that a stay can be up to 60 days is intended to make § 424.541 consistent with CMS CR 13449.

Response: We appreciate the commenter's support and note that our change is unrelated to CR 13449. It simply incorporates our existing position into § 424.541.

Comment: Multiple commenters recommended that CMS fully implement the "state of enrollment" standard across all programs, including with respect to DMEPOS suppliers, to promote uniformity and fairness.

Response: We believe the commenters are referring to "stay of enrollment" rather than "state of enrollment." While we are respectfully unclear as to the "programs" to which the commenter is referring, stays of enrollment can apply to all Medicare provider and supplier types, including DMEPOS suppliers.

Comment: Numerous commenters opposed the concept of retroactive revocations in general. Several commenter stated that CMS' existing and proposed grounds (as well as payment collection and any additions to the Medicaid termination database) should not be implemented in a particular case if an appeal is pending. A commenter stated that CMS' proposed reasons could result in unfair and unwarranted repayments to the Medicare program. Other commenters stated that retroactive revocations: (1) should only be invoked in cases of intentional or systemic provider fraud, waste, or abuse; and (2) could financially devastate providers.

Response: We appreciate the concerns expressed. Retroactive revocations are designed to recoup payments to which the provider was not entitled due to its non-compliance. That is, and potentially excluding situations under § 424.541, once the provider is non-adherent to Medicare enrollment requirements, it cannot receive payment for services furnished beginning on or after the point the non-compliance began. Our allowance of prospective revocation dates for the grounds in proposed § 424.535(g)(viii) through (xiv) has resulted in hundreds of millions of dollars in payments to non-compliant providers; we accordingly believe we have an obligation to the American taxpayers to stop this. Indeed, we estimated in the proposed rule that our proposed grounds would annually save nearly $2.2 billion in taxpayer monies.

Insofar as appeals, and most respectfully, we historically have not delayed implementing retroactive revocations or commencing collections while appeals are pending. As the appeals process takes some time, delayed implementation could result in many millions of dollars in continued payments to non-compliant providers as well as postponed repayment of monies to which Medicare and the taxpayers are entitled. Should the revocation be reversed on appeal, repayment of any collected monies can be facilitated. Concerning the final two comments, we respectfully reiterate that the core issue is payments to non-compliant providers regardless of whether fraud is involved; allowing prospective revocations in all-non fraud cases would, as it has, lead to additional billions of dollars to these providers. While we recognize the financial impact retroactive revocations can have on providers: (1) we again note that we only revoke providers when truly necessary; and (2) a provider's vigilant and constant compliance with Medicare enrollment requirements can help avoid revocations.

Comment: A commenter: (1) expressed doubt that CMS could determine precisely when a supplier fell out of compliance with § 424.57(b) or (c); and (2) requested that CMS establish clear standards for when a retroactive revocation would apply.

Response: We thank the commenter for this feedback. As CMS always diligently and carefully reviews the facts and circumstances of all potential revocation cases before taking any action, we are confident we will be able to ascertain the point at which non-compliance commenced. As for the second comment, we are respectfully unclear as to the "standards" the commenter seeks. Our retroactive revocation grounds are detailed in § 424.535(g)(2), and a number of our underlying revocation reasons in § 424.535(a) contain factors that CMS considers in its revocation determinations.

Comment: Several commenters opposed retroactive revocations for non-compliance with a condition or standard in § 424.57(b) or (c). A commenter stated that: (1) it could be difficult for CMS to determine the date of non-compliance (for purposes of establishing the effective date);

and (2) a stay of enrollment would be a more suitable action considering that stays are designed to address non-compliance.

Response: While we appreciate the commenters' feedback, we reiterate our belief that CMS will be able to establish the proper effective date. As for the final comment, there are numerous levels of non-compliance, with some being significant enough to warrant revocation while others are not. Stays are intended to address the latter; they are generally limited to minor instances of non-compliance most typically involving failure to submit a revalidation or change of information application. In our view, violations of the DMEPOS conditions of payment and supplier standards are potentially more concerning than actions triggering a stay because they focus on supplier's inherent ability to qualify as a DMEPOS supplier. If we applied a stay to all § 424.57(b) or (c) violations, we believe suppliers would be less inclined to ensure constant adherence to the conditions and standards; they would know they could regain compliance at any time and be paid for services furnished during the stay. Given, too, that many of the supplier standards are designed to protect beneficiaries and prevent fraudulent activity, we believe retroactive revocations for § 424.57(b) and (c) violations are warranted.

Comment: A commenter supported all of our proposed retroactive revocation bases except for that involving the submission of false or misleading information on the enrollment application. The commenter was concerned that this retroactive revocation ground could be based on a small or inadvertent error by the provider. The commenter requested that CMS tailor this basis to intentional misrepresentations; other commenters, too, stated that evidence of intent should be a prerequisite for CMS action. Another commenter stated that there should be exceptions to this practice, such as if the supplier misunderstood the question or data elements on the application.

Response: We appreciate the commenter's support. Regarding the retroactive revocation basis the commenters reference, revocations under § 424.535(a)(4) are typically not imposed for minor, unintentional errors. Indeed, we take these actions infrequently and only when clearly

appropriate. In light of the seriousness of falsifying information, we believe retroactive revocations are warranted in all of these cases.

Comment: Several commenters opposed retroactive revocations for failure to submit certain changes of information. A commenter stated that in change of ownership situations: (1) state licensure or IRS delays regarding name changes (or other circumstances outside the supplier's control) could delay the provider's report of the change to CMS; and (2) it could be difficult for a large entity to report a change to numerous MACs for all of its locations. A commenter stated that retroactive revocation in these types of situations would be unfair. The commenter added that retroactive revocations on this basis could discourage providers from reporting any change due to the harsh penalties. Other commenters stated that CMS should be flexible regarding the 30-day reporting period and account for situations and extenuating circumstances beyond the provider's control and use a "good-faith effort" standard.

Response: We thank the commenters for their feedback. As with all revocations, CMS under § 424.535(a)(9) does not take action unless deemed truly necessary and only after a thorough examination of the circumstances of the case. This includes consideration of several factors outlined in § 424.535(a)(9), such as the materiality of the data and, if reported, how belatedly. Nonetheless, while we recognize that not every potential § 424.535(a)(9) case is the same: (1) it remains the provider's responsibility to timely report this information to us; and (2) numerous providers (including large entities enrolled with several MACs) do timely meet this requirement. The potential for revocation has not deterred the latter providers from fulfilling their reporting obligations, and we do not see this changing with a retroactive revocation application; in fact, we believe it will encourage providers to be more vigilant in their reporting responsibilities.

Comment: A commenter stated that providers cannot reasonably operate under the risk of losing payment for services already rendered in good faith, explaining that this would punish compliant providers and create fear and instability in the marketplace.

Response: We appreciate this concern but note that CMS has had retroactive revocation reasons in § 424.535 for numerous years. During this period, and most respectfully, we have not seen widespread fear or instability in the provider community due to retroactive revocations. We again wish to assure providers that revocations (whether retroactive or not): (1) occur very infrequently when compared to the universe of well over 2 million Medicare-enrolled providers and suppliers; and (2) are not intended to harm or cause concern for legitimate providers but only to protect Medicare, the taxpayers, and the provider community at large from non-compliant ones.

Comment: Several commenters generally stated that: (1) technical or administrative errors should not lead to severe consequences for providers; (2) the increased number of revocations under our proposals could lead to a reduction of providers and suppliers in certain areas (including low billing practitioners) and thus harm or interrupt patient care; (3) CMS' proposed retroactive revocations are based on unwarranted reasons, are too broad, and lack guardrails.

Response: We appreciate these comments and note the following. First, and as previously indicated, we only revoke providers when justified and necessary under the circumstances; again, we recognize the significant consequences of revocations on providers and do not take action on merely spurious grounds. Second, we do not foresee a substantial increase in the number of revocations under our proposals. For instance, our addition of § 424.535(a)(8)(i)(D) is merely a restatement of our existing authority under § 424.535(a)(8)(i), not an expansion of it. Other revocation proposals, such as the change from Part B or D drugs to Medicare-covered drugs in § 424.535(a)(13) and § 424.530(a)(11) are, in our view, rather modest expansions intended to address specific vulnerabilities. Even if revocations were to increase, we have implemented many revocation reasons via rulemaking over the years and have not seen resulting access to care issues. Third, we detailed in the proposed rule and this final rule our rationales for our retroactive revocation bases; as we stated, we believe these grounds are warranted, specific, and necessary to prevent improper payments to non-compliant providers.

Comment: Existing §§ 424.535(a)(4) and 424.530(a)(4) permit revocation or denial if the provider or supplier certified as "true" misleading or false information on the enrollment application to be enrolled or maintain enrollment in Medicare. Several commenters stated that before any § 424.535(a)(4) revocation is imposed: (1) the provider should have an opportunity to research and respond to the matter, since the problem could be a minor, correctable omission; and (2) the case should be reported to the Supplier Audit & Compliance Unit (SACU), which the commenters stated presently handles these investigations. Another commenter stated that CMS should define "false or misleading" as used in § 424.535(a)(4).

Response: We appreciate these comments. Respectfully, it was unclear whether they pertained to all § 424.535(a)(4) revocations (regardless of whether they were retroactive) or were limited to retroactive revocations. In either case, we refer the commenters to our prior statements in this final rule regarding a pre-revocation quasi-appeals process and remedial action. If we were to require one in all potential § 424.535(a)(4) situations, providers (especially fraudulent ones) might have little incentive to submit honest, accurate information since they could always correct it prior to any revocation.

Regarding investigations, CMS works closely with the National Provider Enrollment Contractors (NEPCs) (which process DMEPOS supplier Form CMS-855S enrollment applications (OMB Control No. 0938-1056)) in reviewing and investigating potential § 424.535(a)(4) situations. As for the final comment, we most respectfully believe that the terms "false" and "misleading" have been plain on their face since the promulgation of § 424.535(a)(4) years ago.

Comment: Several commenters expressed concern about § 424.535(i), stating that CMS should only use this authority in egregious situations. A commenter stated that it would be unfair to revoke all locations of a large supplier (especially retroactively) based on, for example, a minor instance of non-compliance at one of its locations. Another commenter stated that each site should be examined on its own merits rather than directly tied to the enrollment status of the

revoked provider unless systemic issues exist across the larger provider entity. An additional commenter stated that CMS should only revoke non-compliant locations rather than the provider's other ones, while another stated that the rule is unclear as to whether retroactive revocations would be applied to other supplier locations under the same TIN or to all supplier locations under a common ownership.

Response: We appreciate these comments. Section 424.535(i) has been effective since 2019. We have generally only invoked this provision in exceptional circumstances and not for minor matters. The overwhelming preponderance of our revocations under§ 424.535 have been limited to the non-compliant enrollment/location in question without affecting the provider's other enrollments. In fact, and as we stated in the September 10, 2019, final rule with comment period titled, "Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process" (84 FR 47794), § 424.535(i) is not an "all or nothing" provision. We do not automatically revoke all of the provider's other enrollments in § 424.535(i) situations. We instead apply and consider a series of factors outlined § 424.535(i) to each individual enrollment in determining whether that enrollment should be revoked, too.

Concerning the commenters' final comment, CMS can apply § 424.535(i) to any and all of a provider's enrollments—including those under different names, numerical identifiers, or business identities.

Comment: Several commenters stated that fraudulent activity tends to be limited to a small number of parties and not the preponderance of providers (such as community-based suppliers). Accordingly, a commenter stated, revocation policies should not indiscriminately penalize all suppliers – potentially disrupting care to thousands of beneficiaries who rely on otherwise compliant suppliers.

Response: We appreciate this comment but stress that our revocation provisions would only impact non-compliant providers. They are not meant to penalize providers that adhere to Medicare enrollment requirements.

Comment: As a concluding, overarching general comment, numerous commenters believed CMS's proposals were overly punitive towards legitimate providers. They believe that the provisions lacked due process and failed to allow providers and suppliers to correct honest mistakes before CMS takes action, with: (1) a commenter contending that the proposals would not deter fraud; and (2) another commenter stating that certified providers and certified suppliers are allowed to correct standard and condition-level deficiencies. Commenters stated that revocations in general unfairly occur based on minor transgressions and financially devastate providers. These commenters added that even if the revocation is overturned on appeal, the provider may be unable to economically recover and the burden on Medicare contractors in processing these matters can be significant. Commenters further stressed that any sanctions should be commensurate with the violation. Another commenter stated that CMS should: (1) consider the proposals' unintended consequences and update them to ensure that they exclude bad actors; (2) consider the burdens faced by solo practitioners, small groups, or independent providers; and (3) apply enforcement discretion when the totality of facts surrounding scrutinized activity does not demonstrate an intent to commit fraud or abuse. Concerning this third comment, another commenter stated that retroactive revocations should not occur if the harm to the supplier outweighs the harm to the Medicare program.

Response: We appreciate these comments and again recognize the concerns expressed by many provider and supplier types (such as individual physicians, group practices, etc.). We reiterate our statements regarding: (1) our practice of only revoking providers when truly warranted and after careful investigation; (2) the need for CMS to take prompt action to prevent payments to non-compliant providers; and (3) the reasons for no existing pre-revocation appeals process. We believe due process rights are afforded by the appeals procedures in 42 CFR part 498 and that revocations have indeed helped stem fraud, waste, and abuse and kept problematic parties out of the Medicare program; this is a central purpose of our proposed revocation provisions. In addition, we note that stays of enrollments and deactivations have been utilized in

situations where a revocation would be too severe an action or otherwise not commensurate with the violation.

Regarding the commenters' final two comments, we respectfully remind stakeholders that enforcement action cannot be limited to situations where fraud is (or was intended to be) involved. If we did place this limit, this would permit non-compliant suppliers to remain enrolled, with billions of dollars in continued payments thereto, so long as there is no fraud. As already noted, providers must always remain adherent to Medicare enrollment requirements, and they are not entitled to payment if they are non-compliant, even if no fraud is involved. In this same vein, any improper payment harms the Medicare program. While we understand the harm that providers can experience with a revocation and, as already stated, do not revoke providers unless clearly necessary, it is ultimately the provider's responsibility to ensure constant adherence to Medicare enrollment requirements. We have an obligation to place the interests of Medicare beneficiaries, the program at large, and the taxpayers at the highest level; it is with this principle in mind that we have undertaken our program integrity measures over the years.

After reviewing these comments, we are finalizing the proposals addressed in section VI.A.1.c.(1)(a) through (c) without modification.

(2) New Deactivation Authority

Regulations regarding the provider enrollment concept of deactivation are addressed in § 424.540. Deactivation means that the provider's or supplier's billing privileges are stopped but can be restored (or "reactivated") upon the submission of information required under § 424.540. One reason for which CMS can deactivate a provider or supplier is that the provider or supplier has not submitted any Medicare claims for 6 consecutive months. A core purpose of this provision is to prevent dishonest parties from: (1) deliberately obtaining multiple numbers so they could keep one 'in reserve' [for future use] if their active billing number is subject to a payment suspension; and (2) obtaining information about discontinued providers or suppliers and then, for example, using the Medicare billing number of a deceased physician Shutting down

inactive billing numbers helps stem such activities. Indeed, deactivating the provider's billing number enables CMS to not only prevent it from being accessed by other parties but also confirm via the deactivation process whether the provider or supplier is in fact operational -- specifically, whether the provider responds with a reactivation application.

The deactivation concept has only applied to Medicare billing privileges rather than the ordering, certifying, and referring of Medicare services and items. Yet improper ordering, certifying, or referring can pose significant risks to the Medicare program and its beneficiaries, and we have established a number of provider enrollment requirements to prevent this activity . These include the following:

- Under § 424.507(a) and (b), physicians and practitioners who wish to order or certify certain Medicare services and items must either opt-out of Medicare (in accordance with 42 CFR part 405, subpart D) or enroll in Medicare. Even if the individual does not seek to bill Medicare and only wants to order or certify the services and items addressed in § 424.507, the person must still enroll in Medicare by submitting a Form CMS-855O application (Medicare Enrollment Application - Registration for Eligible Ordering and Referring Physicians and Non-Physician Practitioners (OMB control number. 0938-1135)). This enables CMS to screen the person to ensure that all Medicare requirements are met, hence reducing the payment safeguard risk that an unvetted physician or practitioner intent on fraudulent or abusive conduct can order or certify these services or items.

- Under § 424.535(a)(21), CMS can revoke a physician's or eligible professional's enrollment if the individual has a pattern or practice of ordering, certifying, or referring Medicare Part A or B services or items that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements. This provision was established in response to instances of fraudulent or unnecessary ordering, certifying, and referring of Medicare services and items.

- Under § 424.542(a), a physician or other eligible professional who has had a felony conviction within the previous 10 years that CMS determines is detrimental to the best interests Medicare and its beneficiaries may not order, refer, or certify Medicare services or items. As with § 424.535(a)(21), the aim of § 424.542(a) is to prevent fraud, abuse, and beneficiary harm.

All the foregoing signifies that CMS takes improper and abusive ordering, referring, and certifying no less seriously than improper and abusive billing. The former can be as harmful to Medicare and its beneficiaries as the latter. For this reason, we do not believe that important program integrity safeguards such as deactivation must be limited to billing situations, and we accordingly proposed to address this topic in new § 424.547.

In § 424.547(a)(1)(i) and (ii), we proposed that CMS may deactivate a physician's or practitioner's ability to order, certify, or refer the Medicare services or items described in § 424.507(a) and (b) if the individual--

- Is enrolled via the Form CMS-855O application solely to order, certify, or refer Medicare services or items; and

- Has not been listed as the ordering, certifying, or referring individual on a Medicare Part A or B claim received in the previous 12 consecutive months.

To distinguish deactivations of billing privileges from those of ordering, certifying, and referring capabilities, we proposed in new § 424.547(a)(2) that for purposes of § 424.547 only, the term "deactivate" means that the physician's or practitioner's ability to order, certify, or refer Medicare services or items has been stopped but can be restored upon the submission of updated information. In a similar vein, because the current definition of deactivation in § 424.502 is limited to billing privileges, we proposed to add the following language to the beginning of this definition: "Except in the situations described in § 424.547".

We also proposed to duplicate several of § 424.540's deactivation and reactivation procedures in new § 424.547 as follows:

- In § 424.547(b)(1), we proposed that for a deactivated physician or practitioner to reactivate their ability to order, certify, or refer Medicare services and items, the individual must recertify that their enrollment information currently on file with Medicare is correct, furnish any missing information as appropriate, and be in compliance with all applicable enrollment requirements in Title 42.

- In § 424.547(b)(2), we proposed that notwithstanding § 424.547(b)(1), CMS may, for any reason, require a deactivated physician or practitioner to, as a prerequisite for reactivating the ability to order, certify, or refer, submit a complete Form CMS-855O application.

- In § 424.547(c), we proposed that the effective date of a reactivation of the ability to order, certify, or refer Medicare services and items under § 424.547 is the date on which the Medicare contractor received the individual's reactivation submission that was processed to approval.

- In § 424.547(d), we proposed to clarify that a physician or practitioner may not order, certify, or refer the Medicare services or items referenced in § 424.507(a) and (b) while deactivated under § 424.547.

We received the following comments on this proposal:

Comment: Several commenters expressed concern about the impact of our deactivation provision in proposed § 424.547 on HHAs and hospices. The commenters stated that it could prevent HHAs and hospices from billing for claims when the ordering or certifying provider was deactivated for 12 months of non-certifying, especially if the individual only performs this function on a very infrequent basis and is unaware of the 12-month provision. Commenters recommended that CMS ensure that: (1) databases identifying eligible physicians/practitioners for ordering/certifying purposes are updated; (2) use careful discretion in exercising this authority, with particular consideration for physicians employed by hospices; (3) perform targeted outreach to potentially impacted physicians (including notices thereto as they approach the 12-month period and allowing them to indicate whether they wish to remain active); (4)

ensure that the reactivation process is efficient with minimal delays; and (5) furnish training to HHAs and hospices regarding the new requirement. Another commenter stated that CMS' provision could inadvertently impact physicians who treat Medicaid or Medicare Advantage patients and requested an exceptions process (or a more nuanced threshold) that allows providers to demonstrate active practice via means other than Part B billing. An additional commenter stated that non-billing is not indicative of fraudulent activity.

Response: We thank the commenters for their feedback. As we explained in the proposed rule and this final rule, this provision is intended to prevent unscrupulous parties from accessing unused billing numbers. This is the same motivation that triggered our promulgation of § 424.540(a)(1) in 2006, which permitted a provider's deactivation for 12 consecutive months of non-billing (later revised to 6 months). While the final commenter is correct that non-billing is not necessarily indicative of fraudulent behavior, the improper accessing of unused billing numbers can be.

As for the other comments, we understand the concerns expressed about our proposal. As we implement this requirement, we will: (1) consider the commenters' third and fifth recommendations; (2) ensure that appropriate databases are updated; and (3) maintain the efficiency of the reactivation process. Regarding the second recommendation, our deactivation authority under § 424.540(a)(1) has always been discretionary, and the same will be true with § 424.547; we will exercise our authority only after careful consideration and when deemed necessary. With respect to the comment regarding Medicaid and Medicare Advantage, § 424.547's purview is limited to individuals: (1) enrolled via the Form CMS-855O solely to order, certify, and refer certain Medicare services and items; and (2) who do not themselves bill Medicare for services and items furnished. Being exclusively a Medicare fee-for-service provision of a rather restrictive scope, we do not believe it will have a significant impact on Medicaid and Medicare Advantage supplier enrollees. Given, moreover, the critical program

integrity safeguards of this provision, we are respectfully unable to carve out regulatory exceptions to § 424.547's application.

Comment: A commenter stated that our deactivation provision is contrary to CMS regulations because there is no requirement that hospice physicians or physician members of the interdisciplinary group ("IDG") must order, certify, or refer for hospice services. The commenter recommended that CMS: (1) delay this proposal to give hospices time to prepare; or (2) exempt hospice providers from this provision or apply it only to providers in higher-risk areas.

Response: While we appreciate this comment, our proposal does not in and of itself require any individual to order, certify, or refer services for payment to be made; any such requirements are addressed in other CMS regulations. It instead involves the separate issue of a lack of ordering, certifying, and referring over a 12-month period by those enrolled via the Form CMS-855O and the consequent program integrity risk due to dormant provider numbers. Due to this risk, we must respectfully decline to delay this requirement or to exempt certain physicians or practitioners therefrom. Nonetheless, we note again that this provision is discretionary, and stakeholders should not assume that deactivation will always occur in § 424.547 situations.

As a final point of clarification, we reiterate that § 424.547 applies to all the services and items referenced § 424.507. It is not limited to, for example, home health services.

Comment: A commenter believed our deactivation proposal could harm practitioners with low Medicare billing volumes but who deliver quality care, adding that any disruption in enrollment status could interrupt patient care.

Response: We thank the commenter for this feedback. However, our deactivation proposal involves ordering and certifying physicians and practitioners and not those who bill Medicare.

After reviewing these comments, we are finalizing this proposal without modification.

(3) Liability for Furnished Information

As already mentioned, current §§ 424.535(a)(4) and 424.530(a)(4) permit revocation or denial if the provider or supplier certified as "true" misleading or false information on the enrollment application to be enrolled or maintain enrollment in Medicare. We have encountered situations where a provider has another individual complete an enrollment application on the provider's behalf (for example, officer manager). The individual furnishes false or misleading information thereon, and the provider (or, if applicable, the provider's authorized official) signs the application. The provider then later states it was not responsible for the submitted false data because the other person, not the provider, had furnished it. This assertion is incorrect. Longstanding CMS policy is that the enrolling provider bears ultimate legal responsibility for the accuracy and thoroughness of all data on the application. The provider cannot transfer this responsibility to another party even if the latter completed the application. To emphasize this point, we proposed to add new paragraph (d)(10) to § 424.510. Paragraph (d)(10) would state that all providers and suppliers are legally responsible for the accuracy, completeness, and truthfulness of all information they provide on or with their applications, regardless of whether another party completed the application.

We received the following comments on this proposal:

Comment: Several commenters supported our proposed revision to § 424.510 emphasizing that providers and suppliers are legally responsible for the accuracy, completeness, and truthfulness of all information they provide on or with their applications, regardless of whether another party completed the application. A commenter stated that this is consistent with CMS' longstanding position on the matter.

Response: We appreciate the commenters' support.

Comment: Several commenters opposed our revision to § 424.510(d)(1) regarding provider responsibility for submitted data. A commenter stated that it is unfair to shift legal liability to providers for all application information since providers often rely upon billing services and outside consultants. The commenter added that this puts small suppliers at risk of

revocation for clerical errors they did not commit. Another commenter stated that providers must often rely upon third parties to accumulate data and that there are limits to the provider's ability to confirm the information's accuracy. The commenter noted that a provider should not be unduly penalized when: (1) a provider makes a good faith effort to accurately complete the application; and (2) the inaccuracy was the third party's fault.

Response: While we appreciate these comments, we respectfully do not believe our § 424.510(d)(1) addition shifts liability to the provider, for the ultimate responsibility for submitting truthful and accurate information has always rested with the provider. The provider, in fact, attests to the accuracy of the submitted data via the Form CMS-855 certification statement. We recognize that some providers use third-parties for application preparation and information gathering purposes. This is the provider's independent business decision. Yet this decision comes with the possibility that data from the third-party may be inaccurate. Should the provider elect to assume this risk, it also assumes the responsibility for the data's correctness when submitting it to Medicare. Indeed, if we absolved these types of providers from all liability for inaccurate third-party data, the provider would have no motivation to confirm it is correct or, to avoid responsibility, would always have a third-party collect and furnish the information. As we have regularly stated in the past, incorrect enrollment data can result in inaccurate payments (and even fraud, waste, and abuse), and the provider – not a third-party – must ensure its correctness.

After reviewing these comments, we are finalizing this proposal without modification.

(4) Submission of Documentation

One of the many critical functions of MACs is to validate the accuracy of the information the provider furnishes on its enrollment application (for example, the provider states it is licensed, but the MAC finds that the license has expired). If submitted data is incorrect, the potential exists for improper payments to be paid to non-compliant or unqualified providers and suppliers. Although MACs can validate certain data via electronic means, verifying

documentation from the provider is sometimes needed. Existing § 424.510(d)(2)(ii), (iii)(A), and (iii)(B) state that each submitted provider enrollment application must include the following:

- Documentation to identify the provider, such as proof of the legal business name, practice location, etc.
- All applicable Federal and State licenses and certifications
- Documentation associated with regulatory and statutory requirements needed to establish a provider's eligibility to furnish Medicare covered items or services.

This and other documentation is also identified on the Form CMS-855 enrollment applications as materials the provider must submit with its application.

Notwithstanding the documents that providers must currently submit, we remain concerned about the MACs' ability to verify all information on the applications they receive. This is especially true regarding the provider's ownership and management. Consistent with sections 1124 and 1124A of the Act, providers must report this data on their enrollment applications. Inaccurate ownership and managerial information, like other reported data, could result in improper payments (for instance, a provider's owner is excluded by the OIG, meaning the provider is not entitled to Medicare payments). To strengthen our ability to validate ownership and managerial data – as well as other information that CMS or the MAC may be unable to verify through current means -- we proposed in new § 424.510(d)(2)(iii)(C) that CMS may require the submission of any other documentation needed to validate the data on the enrollment application; this includes, but is not limited to, documentation regarding the provider's ownership or management.

We received the following comments on this proposal:

Comment: Several commenters supported our change to § 424.510 regarding CMS and MAC documentation requests. However, a commenter requested clear guidance (both sub-regulatory and via the contractors' requests to providers) on what documentation is required to

better ensure consistency among the MACs. Another commenter requested grace periods or additional technical guidance for providers in Puerto Rico.

Response: We appreciate the commenters' support. We will instruct MACs on what documentation to request and when. Concerning the final comment, we are respectfully unclear as to the types of grace periods and technical guidance the commenter is requesting. We will ensure, though, that providers (regardless of their location) understand what documentation is or may be required.

After reviewing the comments, we are finalizing this proposal without modification.

(5) Reassignment Effective Dates

In the provider enrollment context, and consistent with 42 CFR 424.80, reassignment of benefits refers to the scenario where an individual physician or non-physician practitioner has granted another Medicare-enrolled provider or supplier the right to receive payment for the physician's or non-physician practitioner's services. Existing § 424.522(a) states that a reassignment is effective beginning 30 days before the Form CMS-855R (OMB control number 0938-1179) is submitted if all applicable requirements during that period were otherwise met. However, the Form CMS-855R has been discontinued. Reassignments are now facilitated via information furnished on the Form CMS-855I (OMB control number 0938-1355) and Form CMS-855B (OMB control number 0938-1377). Accordingly, we must revise § 424.522(a) to reflect both the elimination of the Form CMS-855R and the need to establish a new reassignment effective date.

Under current § 424.520(d)(1)(i) and (ii), the effective date of billing privileges for physicians and non-physician practitioners is the later of –

- The date of filing of a Medicare enrollment application that a MAC subsequently approved; or
- The date the individual first began furnishing services at a new practice location.

Notwithstanding § 424.520(d)(1), physicians and non-physician practitioners under § 424.521(a)(1) may retroactively bill for services when they have met all program requirements and services were provided at the practice location for up to –

- 30 days before their effective date if circumstances precluded enrollment in advance of providing services to Medicare beneficiaries; or
- 90 days before their effective date if a Presidentially declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 through 5206 (Stafford Act) precluded enrollment in advance of furnishing services to Medicare beneficiaries.

As reassignments are often initiated at the same time a physician or practitioner enrolls in Medicare via the Form CMS-855I, we believe the effective dates of the initial enrollment and the reassignment should be determined in the same manner. Hence, we proposed to modify § 424.522(a) such that the reassignment's effective date and the ability to retroactively bill for services mirror the provisions in § 424.520(d)(1) and 424.521(a)(1). New § 424.522(a)(1) would state that the reassignment's effective date is the later of the two dates identified in § 424.520(d)(1)(i) and (ii). New § 424.522(a)(2) would state that retrospective billing in accordance with a reassignment is permissible if the circumstances in § 424.521(a)(1) are applicable.

We received the following comment on this proposal:

Comment: A commenter requested that CMS increase the retroactive billing date to 60 days before their effective date instead of 30 days. The commenter stated that this would: (1) ensure that providers have sufficient time to balance administrative requirements for multiple enrollments and multiple providers; and (2) align with the maximum 60-day stay of enrollment period.

Response: We appreciate this commenter's request but most respectfully must decline it. If we pushed the date back to 60 days, we may be unable to determine whether the provider was compliant with enrollment requirements between the 31st and 60th days, which would be well

before the provider submitted their enrollment application. Also, enrollment stays are very different from billing effective dates. The former effectively stops payment due to the provider's non-compliance, whereas the latter addresses the point from which a provider can begin billing. It is therefore unnecessary that their applicable timeframes match.

After reviewing this comment, we are finalizing our proposed provision without modification.

(6) DMEPOS Liability Insurance

Section 424.57(c) outlines a number of standards that DMEPOS suppliers must meet to become or remained enrolled in Medicare. One the standard, codified in § 424.57(c)(10), requires the supplier to have a comprehensive liability insurance policy of at least $300,000 that covers the supplier's place of business, customers, and employees. We have seen instances where the insurance policy is signed by a supplier employee who did not appear to have the authority to act on the supplier's behalf. Considering the importance of the liability insurance requirement, we must ensure that the supplier, through its signature on the policy, is bound by its terms. Accordingly, we propose to modify § 424.57(c)(10) such that an "authorized official" of the supplier (as that term is defined in § 424.502) must sign the liability insurance policy.

We received the following comments on our proposal:

Comment: Several commenters opposed our proposal to require an authorized official to sign the comprehensive liability insurance policy. A commenter stated that the authorized official's signature on the enrollment application is sufficient since the insurance policy must be submitted as part of the application process. Another commenter stated that this requirement could be problematic for larger, multi-layered providers because the authorized official may not be the provider's CEO or president; that is, the authorized official might not be the same person responsible for maintaining the company's liability insurance. An additional commenter stated that instead of requiring an authorized official to sign the policy, CMS should permit an approved member of management with signature authority to do so. Another commenter stated

that because some suppliers work with brokers on all insurance requirements, it may not be possible for them to comply with this requirement.

Response: We appreciate these comments and respond as follows.

First, and strictly and solely for purposes of this particular requirement, a supporting document is distinct from the Form CMS-855 application itself. A person's signature on one of these two documents does not, with respect to provider enrollment, automatically confer an authority to sign the other; for instance, an individual who currently signs the liability insurance policy may not qualify as an authorized official under § 424.502. In light of the importance of the liability insurance policy, we must ensure that the individual(s) signing both documents have the authority to do so. We cannot presume that the authorized official's signature on the Form CMS-855 means the liability insurance policy signer was similarly authorized.

Second, the definition of "authorized official" does not require an individual to explicitly have the title of chief executive officer or president *per se*. The person must merely have the authority described in that definition. Moreover, a provider can have as many authorized officials as it wishes so long as the authorized official definition is met for each. (Indeed, larger providers often have multiple authorized officials.) This means that one authorized official could sign the Form CMS-855 and another the liability policy. They need not be the same person. We believe this will help suppliers comply with this requirement.

Third, we are most respectfully uncertain as to the third commenter's reference to "approved member of management with signature authority." If the commenter is stating that any manager should be able to sign the liability policy, this would defeat the purpose of our requirement, since – unless the person is an authorized official – we have no means of knowing whether the person is truly authorized to sign policy and, possibly, who the person even is. By requiring an authorized official to sign the liability policy, we can identify the signer (since the person will be reported on the Form CMS-855) and thereby screen the individual as we do all other authorized officials.

Fourth, we appreciate the commenter's feedback regarding broker use. Yet we reiterate that the provider can have an indefinite number of authorized officials, meaning we believe the provider will be able to have at least of them sign the policy even if a broker is utilized.

After reviewing these comments, we are finalizing this proposal without modification.

(7) Adverse Legal Actions

Consistent with § 424.516(b) through (d), certain Medicare provider and supplier types, such as DMEPOS suppliers, must report any adverse actions (for example, felony convictions) imposed against them, their owners, managing employees or organizations, or corporate directors or officers within 30 calendar days of the action. However, other provider and supplier types have 90 days to report this information. To make these timeframes consistent and to ensure that we are alerted much sooner of the concerning actions, we proposed to revise § 424.516(e)(1) to require all provider and suppliers, regardless of type, to report adverse legal actions to us within 30 days.

We received the following comments on this proposal:

Comment: Several commenters opposed our requirement for all providers and suppliers to report adverse action changes within 30 days, with one commenter stating that it may create compliance burdens without clear evidence of improved oversight outcomes.

Response: We appreciate these comments but believe our proposal will indeed strengthen program integrity and provider oversight. The shorter reporting timeframe will help notify CMS much sooner of provider activity that could pose a serious risk to the Medicare program. We also reiterate that certain other provider and supplier types have long been subject to a 30-day adverse action reporting requirement, yet we are unaware of any undue burden that has resulted therefrom. We believe the same will hold true with our expansion of § 424.516(e)(1).

After reviewing these comments, we are finalizing this proposal without modification

(8) Certain Modifications to Provider Enrollment Paragraph References (§§ 424.535(a)(23) and 424.530(a)(18)) and Enrollment Provisions (§ 424.205))

Under §§ 424.535(a)(23) and 424.530(a)(18), CMS may revoke or deny a Medicare Diabetes Prevention Program (MDPP) supplier's enrollment if the supplier violates an enrollment condition or standard in § 424.205(b) or (d). Since the promulgation of § 424.205 in 2017: (1) §§ 424.535(a)(23) and 424.530(a)(18) have been established; and (2) there have been revisions to the organizational structure of § 424.205. To ensure that §§ 424.535(a)(23), 424.530(a)(18), and 424.205 accurately reflect correct paragraph designations, we proposed changes to all three.

First, the MDPP enrollment standards are now in § 424.205(c) rather than § 424.205(d). We thus proposed that references to paragraph (d) would be changed to paragraph (c) in the following regulatory provisions:

- § 424.535(a)(23)(v).
- § 424.530(a)(18)(v).
- Definition of "Coach eligibility end date" in § 424.205(a) (reference to (d)(5) would change to (c)(5)).
- § 424.205(b)(4) (reference to (d)(5) would change to (c)(5)).
- § 424.205(b)(6).
- § 424.205(c)(3) (reference to (d)(5) would change to (c)(5)).
- § 424.205(c)(6) (reference to (d)(4) would change to (c)(4)).
- § 424.205(c)(8) (reference to (d)(8)(i) would change to (c)(8)(i)).
- § 424.205(c)(8)(ii) (references to (d)(8)(i)(B) and (d)(8)(i)(C) would change to (c)(8)(i)(B) and (c)(8)(i)(C), respectively).
- § 424.205(c)(10) (reference to (d)(8) would change to (c)(8)).
- § 424.205(c)(11)(iii).
- § 424.205(d)(2) (reference to (d)(5) would change to (c)(5)).
- § 424.205(g)(1)(ii).
- § 424.205(g)(1)(v)(A) (reference to (d)(3) would change to (c)(3)).

Second, the following references in § 424.205 would be revised to reflect that section's present structure.

- In paragraph (c)(3), (e)(1) would change to (d)(1).
- In paragraph (c)(12), (g) would change to (f).
- In paragraph (c)(15), (g) would change to (f).
- In paragraph (d)(2), (e)(1) would change to (d)(1).
- In paragraphs (g)(1)(i)(A) and (B), (h)(1)(i) would change to (g)(1)(i).
- In paragraphs (g)(1)(ii)(A) and (B), (h)(1)(ii) would change to (g)(1)(ii).
- In paragraphs (g)(1)(v)(B) and (B)(2), (h)(1)(v) would change to (g)(1)(v).

Third, current § 424.205(g)(1)(i)(A) and (B) state that the MDPP supplier's failure to meet the conditions in paragraph (b) is considered an enrollment denial or revocation under, respectively, §§ 424.530(a)(1) or 424.535(a)(1). Likewise, § 424.205(g)(1)(ii)(A) and (B) state that a failure to meet the standards in paragraph (d) is considered a denial or revocation, under, respectively, §§ 424.530(a)(1) or 424.535(a)(1). We proposed to add "or § 424.530(a)(18)" after paragraph references to § 424.530(a)(1) and "or § 424.535(a)(23)" after references to § 424.535(a)(1). This is because in these situations we can deny or revoke under either the (a)(1) provisions or (a)(18)/(23).

We received no comments on these proposed changes and are therefore finalizing them without modification.

(9) Deactivation Reason Clarification

Section 424.550(b) addresses "change(s) in majority ownership" (CIMO) (as that term is defined in § 424.502) involving home health agencies (HHA) and hospices. Unless an exception applies, an HHA or hospice undergoing a CIMO must enroll in Medicare as a new HHA or hospice and undergo a state survey or accreditation. Since, in this situation, the seller will be departing the Medicare program, § 424.540(a)(8) permits CMS to deactivate the seller's billing privileges. However, § 424.540(a)(8) currently only references sellers in an HHA CIMO and not

those in a hospice CIMO. As a technical clarification, we thus proposed to include the latter within the scope of § 424.540(a)(8).

We received no comments on this proposal and are thus finalizing it without change.

2. Medicaid and CHIP Enrollment and Termination

The Medicaid program (title XIX of the Act) is a joint Federal and State health care program that (as of October 2024) covers more than 72 million low-income individuals. States have considerable flexibility when administering their Medicaid programs within a broad Federal framework, and programs vary from State to State. The Children's Health Insurance Program (CHIP) (title XXI of the Act) is a joint Federal and State health care program that (as of October 2024) provides health care coverage to over 7 million children in families with incomes too high to qualify for Medicaid, but too low to afford private coverage.

In operating Medicaid and CHIP, and as required by sections 1902(a)(78) and 2107(e)(1)(D) of the Act, respectively, each State requires providers to enroll in order to furnish, order, prescribe, refer, or certify eligibility for Medicaid or CHIP items or services in that State.[47] States may also establish their own provider enrollment requirements which must be met in addition to the applicable Federal provider enrollment requirements. Similar to Medicare provider enrollment, the purpose of the Medicaid and CHIP provider enrollment processes is to ensure that providers: (1) meet all Medicaid or CHIP requirements (and any other State-specific or Federal requirements); (2) are qualified to furnish, order, prescribe, refer, or certify Medicaid and CHIP services, items, and drugs; and (3) are eligible to receive payment, where applicable.

Different States may have different provider enrollment processes in operating their Medicaid and CHIP programs. However, all States must comply with Federal Medicaid and CHIP provider enrollment statutory and regulatory requirements, including those in part 455, subparts B and E. One requirement, outlined in section 1902(a)(39) of the Act (and applicable to

47 Section 1902(kk)(7) of the Act also requires physicians and other eligible professionals who order or refer Medicaid services and items to be enrolled in Medicaid. This requirement is made applicable to CHIP via section 2107(e)(1)(G) of the Act.

CHIP in accordance with section 2107(e)(1)(C) of the Act) is that the State must deny or terminate a provider's Medicaid or CHIP enrollment if the provider is--

- Terminated under the Medicare program, or the Medicaid program or CHIP of any other State; and
- Currently included in the termination database under § 455.417.

CMS established this termination database in accordance with sections 1902(kk)(8) and 1902(ll) of the Act. These two sections are summarized as follows:

- Require the State to report the termination of a provider under Medicaid or CHIP to the Secretary within 30 days after the effective date of the termination. However, this reporting requirement is limited to terminations for reasons specified in § 455.101, which, in turn, are restricted to terminations "for cause" (including, but not limited to, terminations for reasons relating to fraud, integrity, or quality);
- Provide that within 30 days of receiving notification of a Medicaid or CHIP provider termination, the Secretary must review the termination and, if the Secretary determines appropriate, include the termination in any database or similar system developed under section 6401(b)(2) of the Affordable Care Act.

CMS has developed and currently operates a database in accordance with these statutory provisions. It contains information on Medicaid and CHIP terminations and Medicare revocations. It enables a State to: (1) review Medicaid and CHIP terminations in other States, as well as Medicare revocations; and (2) to deny enrollment under § 455.416(c) or take its own termination action against a provider if the latter is also enrolled in the State.

The previously referenced provisions of section 1902(a)(39) are currently incorporated in § 455.416(c), though with one inadvertent exception. Rather than stating that the provider – along with being in the termination database – must be terminated under the Medicare program or the Medicaid program or CHIP of any other State, § 455.416(c) states that the provider's termination must be from Medicare and the Medicaid or CHIP program of any state. That is, the

word “and” is between the references to Medicare and Medicaid when the word “or” should be there instead, consistent with the statutory language. To correct this issue and to ensure compliance with section 1902(a)(39), we proposing to change the aforementioned “and” reference to “or.”

We received no comments on this proposal and are thus finalizing it without change.

(3) Miscellaneous Comments

We also received the following comments in response to our provider enrollment proposals:

Comment: A commenter requested that CMS streamline its provider enrollment and revalidation processes to reduce administrative burden on compliant HHAs, adding that delays in enrollment can hinder patient care.

Response: We appreciate this comment but believe it is outside the scope of this final rule.

Comment: A commenter requested that CMS facilitate a balanced appeals process that avoids harming patient care over minor administrative oversights.

Response: We appreciate this comment. However, because CMS did not propose provisions regarding its existing provider enrollment appeals process, we respectfully believe that this comment is outside the scope of this final rule.

Comment: Several commenters stated that CMS should increase the deactivation non-billing period in § 424.540(a)(1) from 6 months to 12 months, contending that some providers do not bill for 6 or more months for legitimate reasons.

Response: We appreciate this comment but believe it is outside the scope of this final rule.

Comment: Several commenters stated that CMS should: (1) work with MACs to establish clear and reasonable processing timeframes for provider enrollment and change of ownership applications, with transparent tracking of progress; and (2) require MACs to implement systems

that prevent duplicate document requests and ensure that information already submitted is appropriately retained and applied to the pending file.

Response: We appreciate this comment but believe it is outside the scope of this proposed rule.

Comment: Concerned about inconsistency among the MACs, several commenters recommended that CMS ensure that providers have access to a MAC contact person who is responsible for holding enrollment analysts accountable for timely and accurate compliance with CMS requirements. Other commenters suggested that CMS: (1) hold MACs accountable for timeliness standards for application processing as well as prompt and accurate responses suppliers; (2) ensure more training of MAC representatives; and (3) establish a reporting escalation process to trigger oversight and accountability of the MACs related to timely processing, inconsistent performance, and unreasonable delays.

Response: We appreciate this comment but believe it is outside the scope of this final rule.

Comment: A commenter stated that CMS must furnish clear guidance to any provider under a provisional period of enhanced oversight (for example, the timeline for review).

Response: We appreciate this comment but believe it is outside the scope of this final rule.

Comment: A commenter stated that with respect to the current enrollment process for larger DMEPOS suppliers, CMS should: (1) utilize a central point of contact at the supplier's corporate headquarters for documentation requests (and other requests) rather than contacting each individually enrolled site; and (2) assess the benefit of the existing site visit process.

Response: We appreciate the comment but believe it is outside the scope of this final rule.

(4) Final Provisions

Consistent with the foregoing, we are finalizing all of our proposed provider enrollment provisions without modification.

B. DMEPOS Supplier Accreditation Process

1. Introduction

a. Overview of DMEPOS Accreditation

(1) DMEPOS Suppliers

(A) Background and Program Integrity Concerns

Among the types of providers and suppliers that must enroll in Medicare to bill the Medicare program are DMEPOS suppliers. Such suppliers include, but are not limited to, the following:

- Medical supply companies that exclusively furnish DME like wheelchairs, walkers, and canes.
- Physicians and non-physician practitioners who provide DMEPOS to their own patients.
- Home health agencies (HHAs) and hospitals that provide DMEPOS to their own patients
- Oxygen and oxygen equipment suppliers.
- Prosthetists and orthotists.
- Pharmacies.

DMEPOS suppliers enroll in Medicare via the Form CMS-855S application (Medicare Enrollment Application - Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS); OMB Control No. 0938-1056). Per § 424.57(b)(1) -- and excluding locations it utilizes solely as warehouses or repair facilities -- the supplier must separately enroll each physical location it uses to furnish Medicare-covered DMEPOS.

We explained at length in the proposed rule that DMEPOS suppliers have long presented to the Medicare program a very elevated risk of fraud, waste, and abuse. In recognizing this threat, CMS has established particularly stringent requirements that DMEPOS suppliers must meet to enroll and maintain enrollment in Medicare. To illustrate, DMEPOS suppliers under §

424.518(c) are one of only six provider and supplier types that are subject to the highest and strictest level of screening during the enrollment process. (They were also one of only two types (the other being HHAs) that were originally assigned to the "high-risk" screening category when § 424.518(c) was promulgated in 2011.) This screening includes: (1) a site visit; and (2) submission of fingerprints of the supplier's 5 percent or greater owners for a Federal Bureau of Investigation (FBI) criminal background check. There are additional regulatory provisions besides the basic provider enrollment requirements in subpart P of 42 CFR part 424 (§§ 424.500 through 424.575) that DMEPOS suppliers must meet. With certain exceptions based on the type of DMEPOS supplier involved, these requirements include, but are not limited, to the following:

- Compliance with the DMEPOS supplier standards outlined in § 424.57(c).
- Acquisition and maintenance of a surety bond consistent with § 424.57(d).
- Compliance with DMEPOS quality standards.
- Accreditation by a CMS-approved DMEPOS accrediting organization.

Notwithstanding these and other DMEPOS program integrity efforts we have undertaken, serious concerns remain. We noted in the proposed rule that numerous Office of Inspector General (OIG) reports since 1998 have noted payment safeguard issues associated with DMEPOS suppliers. We specifically cited therein several recent OIG reports and alerts related to these matters.[48] We also outlined a number of recent criminal convictions involving DMEPOS suppliers.[49] Indeed, DMEPOS fraud, waste, and abuse is still a very significant problem, putting hundreds of millions (even billions) of taxpayer dollars at risk and potentially resulting in patient harm, such as when beneficiaries use unnecessary or substandard items. The OIG reiterated the problem in 2024 when it stated: "Although CMS has a number of safeguards in place to prevent bad actors from billing DMEPOS in Medicare, fraudulent billing for DMEPOS continues to be a

[48] https://oig.hhs.gov/reports/all/2024/medicare-remains-vulnerable-to-fraud-waste-and-abuse-related-to-off-the-shelf-orthotic-braces-which-may-result-in-improper-payments-and-impact-the-health-of-enrollees/#:~:; https://oig.hhs.gov/reports/all/2025/medicare-improperly-paid-suppliers-for-intermittent-urinary-catheters/; https://oig.hhs.gov/fraud/consumer-alerts/consumer-alert-catheter-scam/.
[49] 90 FR 29200-29201.

major concern. Recent cases demonstrate that DMEPOS continues to be a target of fraudulent billing and that new schemes have developed."[50]

(2) Quality Standards

Section 302(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 added section 1834(a)(20) of the Act. Section 1834(a)(20) of the Act requires the Secretary to establish and implement DMEPOS quality standards for suppliers of certain items. As authorized under section 1834(a)(20)(E) of the Act, CMS first established quality standards via sub-regulatory guidance in 2006 and has updated them as needed since then. Currently accessible at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html, these standards address matters such as the following:

- Human resources, and information management.
- Equipment and item delivery and set-up.
- Patient and caregiver training and instruction.
- Patient follow-up.

Two other sets of quality standards involve administration and finances. The administration standards require, among other things, that the supplier: (i) comply with all Medicare laws, regulations, and guidance; and (ii) implement business practices that prevent fraud, waste, and abuse. Part of this latter requirement involves the supplier using procedures and conduct that ensure its compliance with applicable laws and regulations, as well as assigning one or more company leaders to address compliance issues. The financial administration standards, meanwhile, state that the supplier must--

- Use financial management practices that ensure accurate accounting and billing.
- Keep accurate, complete, and current financial records that reflect cash- or accrual-based accounting practices.

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[50] https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000867.asp.

- Keep accounts that link equipment and items to the patient and manage patient service revenues and expenses regularly, including linking charges to patient equipment, supplies, and services with bills, receipts, and deposits.

These requirements make clear that the quality standards go beyond matters of direct patient care and equipment quality to include administrative. legal, and financial compliance as well as fraud, waste and abuse prevention. The standards as a whole are both extensive and detailed because we must confirm that the supplier is bona fide and legitimate.

(3) Accreditation

Consistent with section 1834(a)(20)(F)(i) of the Act (and with certain exceptions), DMEPOS suppliers must be accredited by a CMS-approved accrediting organization (AO) to enroll in and bill Medicare. The main purpose of accreditation is to confirm that the supplier meets the DMEPOS quality standards. The accreditation process has been in effect since 2006.

Section 424.57(c)(24) states that all DMEPOS supplier locations (owned or subcontracted) must be separately accredited in order to enroll in and bill Medicare. However, section 1834(a)(20)(F) of the Act exempts certain individuals from the accreditation requirements unless the Secretary determines the quality standards specifically apply to them. These persons include, for example, physicians and opticians.

Per section 1834(a)(20)(B) of the Act, the Secretary designates and approves DMEPOS AOs, of which there presently are eight. To become or be retained or reapproved as an AO, the AO must meet the requirements of § 424.58. As addressed in greater detail in the proposed rule and throughout section VI.B. of this final rule, these requirements include, but are not limited to, the following:

- Completing the application process, which includes submitting detailed information about the AO's operations and procedures.

- Undergoing various CMS reviews.

- Furnishing ongoing data to CMS about its activities, such as its accreditation decisions, complaints received about suppliers, etc.

In general, DMEPOS suppliers may choose the AO it wishes to accredit them. In performing its DMEPOS accreditation activities – and contingent upon CMS approval -- an AO has some discretion in the operational aspects of its review of a supplier's request for accreditation. One critical and common component of the review process is the AO's performance of an on-site survey of the supplier. Along with the AO's review of the information the supplier furnishes as part of its accreditation application, the survey enables the AO to examine first-hand the supplier's operations and credentials to help ascertain compliance with the quality standards. Per our sub-regulatory guidance, DMEPOS suppliers currently must be surveyed once every 3 years following initial accreditation.

(4) Concerns About the Existing DMEPOS Accreditation Process

The proposed rule contained a substantial number of proposed additions and revisions to our current DMEPOS accreditation process. Aside from the overarching need to improve and strengthen said process, and as we explained in the proposed rule, there were several other reasons behind our proposals.

First, we have seen an increased number of reports of accredited suppliers not meeting the quality standards, which has raised questions as to the efficacy of some AO accreditation surveys and reviews. Second, given the previously noted AO discretion in various aspects of its DMEPOS accreditation processes, we are concerned that differences between the AOs in this regard could lead to inconsistencies in how the AOs make quality standard compliance determinations. Third, although surveys are typically part of the DMEPOS accreditation process, not every supplier receives one. This is particularly true for large chain suppliers with 25 or more separately enrolled locations (such as chain pharmacies). We see this as a potential vulnerability in our enforcement of the DMEPOS accreditation requirement. Fourth, while § 424.58 outlines certain components of the DMEPOS accreditation process, it does not address

other important topics that, in our view, should be outlined in regulation. We note that CMS regulations regarding the accreditation of certified providers, certified suppliers, and home infusion therapy suppliers (found in 42 CFR part 488) contain more extensive provisions than does § 424.58; we believe some of the protections they afford the Medicare program in facilitating provider and supplier compliance should be duplicated in § 424.58. Fifth, we have since 2006 neither reapproved any AOs nor undertaken a full reassessment of the performance and suitability of our existing AOs. We believe both are now necessary – particularly considering this long passage of time -- so we can ensure the DMEPOS accreditation program is functioning effectively.

A recent criminal case underscores our concerns. In March 2025 an individual pled guilty in Federal court (Southern District of Florida) to accepting cash bribes and self-dealing as part of a conspiracy to impede and obstruct the lawful functions of the U.S. Department of Health and Human Services (HHS) and CMS in their administration and oversight of the Medicare program.[51] According to court documents, the person was a contractor for a DMEPOS AO and performed inspections of hundreds of DMEPOS suppliers for compliance with the quality standards. The individual--

- Accepted cash bribes from numerous owners of DMEPOS suppliers to facilitate and expedite the accreditation process so these companies could enroll in and bill Medicare;
- Along with the individual's immediate family, established DMEPOS companies in the names of family members to conceal the individual's own personal interest in the companies. The person then sold some of these companies to others, having increased their value as Medicare-enrolled DMEPOS suppliers; and
- Directly or indirectly owned some of the suppliers the individual surveyed.[52]

[51] https://www.justice.gov/usao-sdfl/pr/miami-inspector-pleads-guilty-scheme-obstruct-us-department-health-and-human-services.
[52] Ibid.

Considering that this case, and perhaps other situations where unqualified suppliers were accredited, may have resulted in many millions of dollars in improper Medicare payments, we believe we must exercise much closer scrutiny over DMEPOS supplier accreditation in general and DMEPOS AOs in particular to prevent such instances from occurring.

Moreover, certain CMS concerns about provider and supplier accreditation are not limited to DMEPOS suppliers. In the February 15, 2024, **Federal Register** (89 FR 11996), we published a proposed rule titled "Medicare Program; Strengthening Oversight of Accrediting Organizations (AOs) and Preventing AO Conflict of Interest, and Related Provisions". This proposed rule would update and supplement provisions in 42 CFR part 488 (hereafter simply part 488) to enhance CMS' oversight of certified provider and supplier AOs; examples of proposed enhancements included addressing conflicts of interest and establishing additional regulatory definitions and procedures for clarity and consistency. We proposed in the July 2, 2025, proposed rule to do likewise for DMEPOS accreditation by incorporating several provisions in the February 15, 2024, proposed rule into § 424.58, though with modifications to accommodate the unique characteristics of DMEPOS accreditation.

b. Legal Authorities

There are several discrete statutory authorities for our final provisions:

- Section 1834(a)(20)(A) of the Act requires the Secretary to establish and implement quality standards for the suppliers of the items and services described in section 1834(a)(20)(D) of the Act to be applied by recognized independent accrediting organizations.

- Notwithstanding section 1865(a) of the Act (regarding accreditation of providers and suppliers in general), section 1834(a)(20)(B) of the Act requires the Secretary to designate and approve one or more independent AOs for purposes of applying the quality standards referenced in section 1834(a)(20)(A) of the Act.

- Section 1834(a)(20)(F)(i) of the Act (and with certain exceptions) requires the Secretary to mandate that suppliers of the items and services described in section 1834(a)(20)(D)

of the Act submit to the Secretary evidence of accreditation by an AO designated under section 1834(a)(20)(B) of the Act.

- Sections 1102 and 1871 of the Act provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

2. DMEPOS Accreditation Proposed Provisions

Given the extent of our proposed changes to § 424.58, we proposed to entirely reorganize the current paragraph structure and designations. Except for current paragraph (a) or as otherwise noted, all finalized paragraph designations in § 424.58 are labeled as new provisions even though the provision may already exist in current § 424.58 under a different paragraph. We received over 350 timely pieces of correspondence on our proposed DMEPOS accreditation provisions. Many individual comments pertained to multiple topics discussed in this subsection VI.B.2.of this final rule. For this reason, all of the comments and responses – regardless of the regulatory provision they addressed -- are contained in section VI.B.16. of this final rule.

a. Definitions (New § 424.58(b))

We proposed several new definitions in § 424.58(b) to help clarify the regulatory provisions to which they relate.

First, we proposed to define "complaint" as an allegation from any party (and via any format) that one of the AO's accredited suppliers may be non-compliant with one or more quality standards or other applicable CMS requirement; the complaint need not involve actual or potential beneficiary harm. As part of the AO approval or reapproval process, current § 424.58(b)(1)(ix) requires the AO to establish procedures for responding to and investigating complaints against its accredited suppliers. Existing § 424.58(c)(1)(iii), meanwhile, requires the AO to monthly provide CMS with notice of such complaints. Given these requirements, we believed a clear definition of "complaint" is warranted.

Second, we proposed to define "immediate jeopardy" as a situation where the supplier's non-compliance with one or more quality standards or other applicable CMS requirement has

caused, or is likely to cause, serious injury, harm, impairment, or death to a patient or to the health and safety of the general public. This definition was needed because AOs, under current paragraph § 424.58(c)(4) thereof, must notify CMS within 2 calendar days of a supplier's deficiency that poses immediate jeopardy.

Third, we proposed to define "reasonable assurance" as meaning that an AO has demonstrated to CMS' satisfaction that--

- Its accreditation program requirements meet or exceed the Medicare program requirements;
- The suppliers the AO accredits meet or exceed Medicare requirements; and
- The AO is compliant with all provisions of § 424.58.

As discussed further in this section VI.B. of this proposed rule, we believe AOs should demonstrate that their accreditation programs comply with § 424.58 and all other CMS requirements, hence the need for a reasonable assurance definition.

Fourth, we proposed to define "unannounced survey" as meaning:

- A survey conducted without any prior notice of any type (through any means of communication or forum) to the supplier to be surveyed, such that the supplier does not expect the survey until the surveyors arrive; and
- The AO schedules its surveys so that suppliers cannot predict when they will be performed.

This definition reflects our belief that it is critical for DMEPOS supplier surveys to be unannounced (as they currently are) so that a non-compliant supplier cannot use prior notice of a survey to remedy its deficiencies solely to pass the survey, after which it may resume its non-adherence.

b. Initial Application for Approval of AO's Accreditation Program (New § 424.58(c))

Existing § 424.58(b) outlines the process by which an entity may apply or reapply to become an AO. While the processes for both are largely similar, we proposed to separate them into two paragraphs for ease of comprehension. Initial application procedures would be addressed in new paragraph (c) and reapproval application procedures in new paragraph (d).

Current § 424.58(b)(1) outlines information that AOs must submit as part of the application process. We have neither revisited these data elements via rulemaking since 2006 nor, as already stated, reapproved or fully reassessed the AOs for many years. Given this lapse, we believe that requiring AOs to submit with their applications the additional data described in this subsection (B)(2)(b) would help us: (1) better ascertain the AO's qualifications; and (2) ensure that the AO will properly and competently perform its functions and remain in compliance with the requirements of § 424.58. We accordingly proposed changes and enhancements to existing § 424.58(b)(1), which would be redesignated as new paragraph (c)(1).

(1) Reasonable Assurance Opening Statement (New § 424.58(c)(1))

We proposed that the opening part of paragraph (c)(1) would state that an AO applying for approval of its DMEPOS accreditation program must furnish "all the following information and materials to demonstrate that the DMEPOS accreditation organization provides reasonable assurance (as defined in paragraph (b) of this section) regarding its program." This language would emphasize that it would not be enough to merely submit the required information in paragraph (c)(1). Rather, the data must be sufficient to give CMS reasonable assurance.

(2) Confirmation of Compliance (New 424.58(c)(1)(iii))

Existing § 424.58(b)(1)(iii), which would become new § 424.58(c)(1)(iii), starts with language that outlines the components of the AO's required explanation of its operational processes. We proposed to revise this provision to:

- Require a detailed description of the organization's survey and other accreditation processes (not merely its operational processes) to confirm that the suppliers it accredits meet or exceed the DMEPOS quality standards and Medicare program requirements.

- Re-designate the six elements of the required description of operational processes in current § 424.58(b)(1)(iii) as new § 424.58(c)(1)(iii)(A) through (F) in the same respective order they are listed in existing (b)(1)(iii).

- Add new paragraph (c)(1)(iii)(G) to require the description to address how the AO determines whether to perform a survey in situations where it has the discretion to do so; this would have to include a suggested methodology for sampling locations for surveys under a single tax identification number or organization. This would help us understand the factors and criteria the AO will consider in its determination and, more importantly, whether it will exercise its discretion prudently.

(3) Redesignation of Existing Data Submission Provisions (New § 424.58(c)(1)(i), (ii), (iv), (v), (vi), and (vii)(A), (B), and (C))

Strictly for organizational purposes and without making any changes in content, we proposed to redesignate §§ 424.58(b)(1)(i), (ii), and (iv) through (vii)(A) through (C) (which describe additional information the AO must furnish) as new §§ 424.58(c)(1)(i), (ii), and (iv) through (vii)(A) through (C).

(4) Conflicts of Interest, Consulting Services, and Number of Surveyors (New § 424.58(c)(1)(vii)(D) and (E))

We proposed additional requirements in new § 424.58(c)(1)(vii).

New paragraph (D) would require the AO to explain in detail its policies and procedures for avoiding conflicts of interest and the appearance thereof involving individuals who conduct surveys or participate in accreditation decisions. This information must include the organization's policies and procedures for all of the following:

- The separation of its consulting services from its accreditation services.

- Protecting the integrity of the DMEPOS AO's accreditation program (including the requirements of proposed § 424.58(m) and (n) (discussed later in section VI.B. of this final rule)).

● Preventing and handling potential or actual conflicts of interest that could arise from situations where a DMEPOS AO owner, surveyor, or employee has an interest in, or relationship with, a DMEPOS supplier to which the AO provides accreditation services. Such interests or relationships include, but are not limited, to the following:

++ Being employed as a DMEPOS AO surveyor.

++ Being employed by a DMEPOS supplier that is accredited by the DMEPOS AO.

++ Having an ownership, financial, or investment interest in a DMEPOS supplier that is accredited by the DMEPOS AO.

++ Serving as a director of (or trustee) for a DMEPOS supplier that is accredited by the DMEPOS AO.

++ Serving on a utilization review committee of a DMEPOS supplier that is accredited by the DMEPOS AO.

++ Accepting fees or payments from a DMEPOS supplier or group of DMEPOS suppliers that is/are accredited by the DMEPOS AO.

++ Accepting fees for personal services, contract services, referral services, or for furnishing supplies to a DMEPOS supplier that is accredited by the DMEPOS AO.

++ Providing consulting services to a DMEPOS supplier that the DMEPOS AO accredits.

++ Having any member of their immediate family engaged in any of the previously stated activities. The term "immediate family member" would be defined in proposed § 424.58(b) as any person with whom the AO owner(s), surveyors or employees have a lineal or immediate familial or marital relationship, including a husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother–in–law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.

++ Engaging in any activities during the course of the survey of the DMEPOS supplier that would be or cause a conflict of interest.

- For notifying CMS when a conflict of interest is discovered.

We also proposed to clarify in new paragraph § 424.58(c)(1)(vii)(D)(*5*) that for purposes of said paragraph, a conflict of interest exists when a DMEPOS AO, the DMEPOS AO's successors, transferees, or assigns, the DMEPOS AO owner(s), surveyors, or employees, or the immediate family members of the DMEPOS AO owners(s), surveyors and employees have an employment, business, financial or other type of interest in or relationship with a DMEPOS supplier that the DMEPOS AO accredits.

As we explained in the proposed rule, DMEPOS AO avoidance of conflicts of interest is needed to help ensure the integrity and impartiality of its surveys and accreditation decisions. We believe our proposed provisions regarding conflicts of interest and consulting would assist in this.

Also, in new § 424.58(c)(1)(vii)(E) we proposed to require the AO to outline its policies and procedures for ensuring it always has an adequate number of surveyors.

(5) AO Program Deficiencies (New § 424.58(c)(1)(viii))

We proposed in new § 424.58(c)(1)(viii) that the AO describe its processes for identifying and correcting deficiencies within its accreditation program. It is important for AOs to very frequently review their accreditation programs for vulnerabilities and weaknesses. Without this, AOs may perform their functions in a substandard manner, which could lead to inadequate scrutiny of suppliers, the accreditation and enrollment of unqualified suppliers, and, hence, improper payments.

(6) Use of Data to Ensure Program Compliance (New § 424.58(c)(1)(ix))

Existing paragraph (b)(1)(viii) requires the AO to describe its data management, analysis and reporting system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system. We proposed to designate this paragraph as

new (c)(1)(ix) and include an additional requirement (taken from § 488.5(a)(11)(i)) that the description explain how the AO uses its data to ensure that its accreditation program adheres to Medicare program requirements.

(7) Complaint Process (New § 424.58(c)(1)(x))

Current § 424.58(b)(1)(ix) requires the AO to explain its procedures for responding to and investigating complaints against its suppliers; this includes processes for coordinating with licensing bodies, ombudsman programs, the National Supplier Clearinghouse (NSC), and CMS. A robust AO process for handling complaints is important because it involves reviewing a supplier's possible violation of a quality standard or other applicable CMS requirement. An AO's failure to properly execute this function could lead to improper Medicare payments to a non-compliant supplier. However, we believed the data that existing § 424.58(b)(1)(ix) requires is insufficient to help us to determine whether the AO would handle complaints thoroughly, consistently, and diligently. We thus proposed several changes to this paragraph, which would be designated as new § 424.58(c)(1)(x)).

First, we proposed to add procedures for closing out complaints as part of this information submission requirement.

Second, we proposed to change the NSC reference to the "applicable National Provider Enrollment contractor (NPEC)". This is because the latter entities have replaced the NSC as CMS' DMEPOS enrollment contractors.

Third, new paragraphs § 424.58(c)(1)(x)(A) and (B), respectively, would require submission of the following information:

- The steps and research the AO will undertake in its review of the complaint.
- How the AO determines whether, in accordance with a complaint, non-adherence to a quality standard or other applicable CMS requirement exists, including the data it considers in its review and when and how it would take action against the supplier.

(8) Redesignation of Additional Data Submission Provisions (New § 424.58(c)(1)(xi) through (xv))

Existing § 424.58(b)(1)(x) through (xiv) address other types of information the AO must submit, such as: (1) policies and procedures for notifying CMS of non-compliant suppliers; and (2) a list of the organization's currently accredited DMEPOS suppliers. With two exceptions, we did not propose to revise these paragraphs but only to re-designate them as new §§ 424.58(c)(1)(xi) through (xv). The two exceptions are as follows:

- In existing paragraph (xii)(B) (redesigned as new paragraph (xiii)(B)), we proposed to include each supplier's accreditation product codes as data the AO must submit with its initial or reapproval application.

- In existing paragraph (xii)(C) (redesigned as new paragraph (xiii)(C)), we proposed that the AO must also list each supplier's accreditation effective date with its initial or reapproval application.

Both requirements would help ensure that CMS has sufficient information on each supplier's accreditation type and status.

Current § 424.58(b)(1)(xv) requires the AO to agree that it will permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings. We did not propose to designate this paragraph as new § 424.58(c)(1)(xvi) because, as explained later in this final rule, we proposed to include it as part of the broader agreement the AO must sign per proposed new § 424.58(c)(1)(xxiii).

(9) Knowledge and Experience (New § 424.58(c)(1)(xvi))

Section 488.1010(a)(4), which pertains to home infusion therapy supplier accreditation, requires AOs in their applications to furnish information that demonstrates their knowledge, expertise, and experience in home infusion therapy. We proposed a similar provision in new § 424.58(c)(1)(xvi) regarding DMEPOS so we could better understand the AO's credentials and qualifications.

(10) Review Timeliness (New § 424.58(c)(xvii))

We proposed in new § 424.58(c)(xvii) that the AO furnish information about its ability to conduct timely reviews of supplier accreditation applications. This requirement would help us determine whether the AO has adequate resources to handle the accreditation requests it receives.

(11) Decision-Making Process (New § 424.58(c)(1)(xviii))

Akin to § 488.5(a)(13) concerning certified providers and suppliers, new § 424.58(c)(1)(xviii) would require the AO to describe its decision-making process, including its policies and procedures for approving, denying, or terminating a DMEPOS supplier's accreditation status. This would also include an explanation of the reasons for which the AO will deny or terminate a supplier's accreditation. We believe this information would give us a more thorough understanding of how the AO will make its decisions.

(12) Surveys (§ 424.58(c)(1)(xix))

We proposed in new § 424.58(c)(1)(xix)(A) and (B) that the AO outline its policies and procedures for the following:

- Determining whether and when a survey is performed (for example, the DMEPOS supplier is providing a new type of item). This must include the circumstances under which the AO will impose a corrective action plan (CAP) in lieu of performing a follow-up survey regarding a DMEPOS supplier deficiency.

- Ensuring that all onsite surveys are unannounced, including preventing unannounced surveys from becoming known to the supplier beforehand.

Given the aforementioned importance of surveys in determining the supplier's compliance with the quality standards – and our earlier noted view that surveys should be unannounced -- we believe § 424.58(c)(1)(xix) is needed.

(13) CAPs (§ 424.58(c)(1)(xx))

In lieu of denying or terminating a supplier's accreditation for failing to meet the quality standards, an AO may apply a CAP to the supplier. In general, a CAP permits the supplier to

attempt to remedy the problem(s) within a specified timeframe before the AO takes one of these two actions. Existing § 424.58 only references CAPs in paragraph (c)(1)(i) thereof, whereby AOs must provide to CMS various survey-related information, which includes CAPs.

To enable us to gain a clearer understanding of the AOs' CAP processes, we proposed in new § 424.58(c)(1)(xx) that the AO outline the policies and procedures via which it would apply a CAP to the supplier. This would include--

- The specific circumstances under which the AO would apply a CAP as opposed to denying or terminating accreditation, and the reason(s) for why the AO believes a CAP in these situations would be more appropriate; and
- How a CAP is developed, implemented, and enforced, including--

++ How the AO determines whether a CAP is acceptable;

++ The requirements of (and the timeframe and deadline for) the supplier's resumption of compliance;

++ How the AO ascertains whether the supplier has returned to and maintains compliance; and

++ The circumstances under which the AO will impose a CAP instead of performing a follow-up survey for a supplier deficiency.

(14) Describing and Defining DMEPOS Supplier Deficiencies (New § 424.58(c)(1)(xxi))

We proposed in new § 424.58(c)(1)(xxi) that the AO would be required to explain--

- What it considers to be a supplier deficiency and how it defines the term "deficiency"; and
- Whether the AO has different levels of DMEPOS supplier deficiencies.

We are concerned that the meaning of "deficiency" and any AO-identified levels thereof may differ among AOs, resulting in inconsistent determinations. We thus believe we must understand the AO's policies regarding deficiency classifications.

(15) Potentially Fraudulent Activity (New § 424.58(c)(1)(xxii))

We proposed in new § 424.58(c)(1)(xxii) that the AO would be required to describe its processes for: (1) detecting and addressing potential fraud, waste, and abuse by suppliers (including identifying the AO's definitions of the terms "fraud", "waste", and "abuse"); and (2) reporting this conduct to CMS, and, as applicable, law enforcement. While the AO's principal function under § 424.58 is to perform the accreditation activities described therein, we do not believe the AO should disregard possible fraud, waste, or abuse by suppliers.

(16) Agreement of Compliance (New § 424.58(c)(1)(xxiii))

(a) Introduction

To ensure that we have the DMEPOS AO's binding commitment to adhere to all CMS requirements, we proposed in new § 424.58(c)(1)(xxiii) that DMEPOS AOs must explicitly agree to certain conditions as part of the application process. (Some of § 424.58(c)(1)(xxiii)'s requirements would refer to new paragraphs in § 424.58 that will be addressed later in this section of this final rule.)

In the opening paragraph of new § 424.58(c)(1)(xxiii), we proposed that the AO's chief executive officer (CEO) (or similar official with authority to commit the organization to adhere to Medicare laws and regulations) provide written acknowledgement that, as a condition of CMS' approval or continued approval of the AO's accreditation program, the AO agrees to adhere to the provisions in § 424.58(c)(1)(xxiii). The acknowledgement, which the official must sign and date and which must be on the AO's letterhead, must list all the data elements in § 424.58(c)(1)(xxiii) and contain the AO's agreement to comply therewith.

(b) Data Submission Within 3 Business Days

We proposed in new § 424.58(c)(1)(xxiii)(A)*(1)* and *(2),* respectively, that the AO must agree to provide CMS within 3 business days of the latter's request--

- Any of the data described in § 424.58(e)(1)(i) (which involves the AO's monthly submission of information to CMS); and

- Any other information CMS deems necessary to facilitate its oversight of the AO's accreditation program.

Considering, again, our role as overseer of Medicare DMEPOS accreditation activities, we must be able to closely and constantly monitor AOs' activities via rapid access to critical information, hence the need for § 424.58(c)(1)(xxiii)(A)*(1)* and *(2)*.

(c) Immediate Jeopardy Notifications

We previously noted that existing § 424.58(c)(4) requires the AO to send written notice to CMS within 2 calendar days of identifying an accredited DMEPOS supplier's deficiency if the deficiency poses an immediate jeopardy situation; any adverse action the AO accordingly takes must also be identified. Given this provision's importance, we believe that the AO's specific agreement in proposed paragraph (c)(1)(xxiii)(B) to comply with this requirement (which would be designated as new § 424.58(e)(1)(iii)) is warranted.

(d) Notification of Change in AO Program

Current § 424.58(c)(1)(v) requires an AO to notify CMS on a monthly basis of any proposed changes to its accreditation standards, requirements, or survey process. Such changes can significantly impact the AO's accreditation program and, in turn, our responsibility for the DMEPOS accreditation program as a whole. Accordingly, we proposed in new § 424.58(c)(1)(xxiii)(C) that the AO must agree: (1) to furnish this notification to us in writing; and (2) that it will not implement such changes absent prior written notice of continued program approval from CMS consistent with § 424.58(e)(2) (discussed later in this final rule).

(e) Termination or Other Change in Supplier's Accreditation Status

As accreditation is a requirement for DMEPOS enrollment under § 424.57(c)(24), CMS must know as quickly as possible when a supplier's accreditation is terminated, revoked, withdrawn, or amended so we can take similar action concerning the supplier's enrollment; a belated notice from the AO could result in improper payments to an unaccredited supplier. We

thus proposed in new § 424.58(c)(1)(xxiii)(D) that the AO must agree to provide this notification in writing to CMS within 3 business days of the AO's action.

(f) CAP Information

Consistent with our previously mentioned rationale for proposed new § 424.58(c)(1)(xx), we proposed in new § 424.58(c)(1)(xxiii)(E) that the AO must agree to inform CMS of any decision to apply a CAP to a specific supplier within 10 calendar days of the decision. This must include--

- The reason for the decision;
- A detailed explanation and justification as to why the AO applied a CAP instead of, as applicable, denying or terminating the supplier's accreditation; and
- The details of the supplier's CAP.

(g) Data for CMS Evaluation of Performance

Section 488.5(a)(11)(ii) requires a certified provider or supplier AO to agree to submit timely, accurate, and complete data to support CMS's evaluation of the AO's performance. Data to be submitted includes, but is not limited to, provider/supplier identifying information, survey schedules and findings, and notices of accreditation decisions; the AO must submit this information according to the instructions and timeframes CMS specifies. We believe a general, overarching agreement to furnish the scope and breadth of data addressed in § 488.5(a)(11)(ii) is warranted so we can ensure that we have all information needed to execute our oversight functions. To this end, we proposed new § 424.58(c)(1)(xxiii)(F) would duplicate the requirements of § 488.5(a)(11)(ii) (with modest modifications specific to DMEPOS suppliers).

(h) AO Implementation of CMS Changes

There are instances where CMS changes its DMEPOS accreditation program requirements. Current § 424.58(c)(2) requires that within 30 calendar days of said change, the AO must submit to CMS: (i) an acknowledgment of CMS's notification of the change; (ii) a revised crosswalk reflecting the new requirements; and (iii) an explanation of how it will alter its

standards to comply with CMS's new requirements within the timeframes that CMS specifies in the notification. As it is important for AOs to implement these changes timely and fully, we believe the AO should explicitly commit to do so. We therefore proposed in new § 424.58(c)(1)(xxiii)(G) that the AO agree to adhere to the following:

- Submission of the data required in § 424.58(e)(7). (New paragraph (e)(7) would reflect current requirements in paragraph (c)(2).)
- The proposed changes must be submitted to CMS within 30 calendar days of the date of CMS' written notice to the AO.
- The AO must not implement its proposed corresponding changes without prior CMS approval.

(i) Deficiencies

We previously noted that new § 424.58(c)(1)(xxi) would require the AO to explain what it considers to be a DMEPOS supplier deficiency, how it defines the term, and whether it has different levels of deficiencies. However, and to facilitate consistency among the AOs, we believe CMS should retain the discretion to: (1) define the term deficiency; and (2) establish deficiency levels for use across all AO DMEPOS accreditation programs. Consequently, we proposed in new § 424.58(c)(1)(xxiii)(H) that the AO agree to accept and adhere to any CMS-established deficiency definitions and levels and categories thereof.

(j) Surveyors as Witnesses

Consistent with our aforementioned intention to move current § 424.58(b)(1)(xv) to new § 424.58(c)(1)(xxiii), we proposed that new § 424.58(c)(1)(xxiii)(I) would require the AO to agree that its surveyors can serve as witnesses if CMS takes an adverse action against a supplier based on an accreditation finding.

(k) Sampling

Though addressed in more detail later in this final rule, the concept of sampling involves the AO's use of a formula to determine which locations within a particular group should be

surveyed. Consistent therewith, we proposed to require the AO's agreement in new § 424.58(c)(1)(xxiii)(J) that if CMS permits the AO to perform surveys via a sampling process, the AO: (1) will submit to CMS its planned sampling methodology in detail; and (2) will not undertake sampling until CMS has approved the AO's methodology.

(l) Patient Records

As part of its survey of a supplier, the AO must examine the supplier's patient medical records to confirm that the supplier is actually serving patients and that the items and services furnished to them are legitimate. For this reason, and as stated in sub-regulatory guidance, the reviewed patient medical records must not include: (1) mock files; (2) fictional patient records; (3) simulated documentation; and (4) templates.[53] Actual records of the patients are required. Given this, we proposed in new § 424.58(c)(1)(xxiii)(K) that the AO agree not to use these four types of records in its surveys. We also proposed to include duplicate patient records as a fifth category, meaning the reviewed records must be of the supplier's own patients and not those of another supplier; this is because the latter records do not reflect the items and services that the surveyed supplier itself is furnishing.

Although we have elected to address this topic via rulemaking in new § 424.58(c)(1)(xxiii)(K), we emphasize that we retain the authority under section 1834(a)(20)(E) of the Act to establish, add, and modify DMEPOS quality standards via sub-regulatory guidance.

(m) Costs of Ad-Hoc Surveys

As discussed further in the proposed rule and this final rule, we proposed in new § 424.58(e)(8)(ii) that CMS may at any time direct the AO to perform a survey of any accredited supplier or a group thereof. We expressed concern in the proposed rule about potential delays in said surveys due to a potential disagreement between the AO and the supplier regarding which of them pays the cost of a CMS-directed survey. To help ensure that this cost issue is resolved well

[53] https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html,

beforehand, we proposed in new § 424.58(c)(1)(xxiii)(L) that the AO agree to have a binding written agreement with each supplier it accredits regarding whether the AO, the supplier, or both will assume the costs of the survey referenced in paragraph (e)(8)(ii).

(n) Truthfulness and Accuracy

To ensure that the AO understands its obligation to submit accurate and complete data to CMS at all times, we proposed in new § 424.58(c)(1)(xxiii)(M) that the AO agree to submit all required information to CMS both before and after approval of its accreditation program in a truthful, accurate, and complete manner.

(o) Compliance with § 424.58

While the components of the proposed § 424.58(c)(1)(xxiii) attestation statement include fairly specific elements (for example, an attestation to utilize CMS's deficiency definition), we emphasize that adherence to all provisions in § 424.58 is still required. We hence proposed in § 424.58(c)(1)(xxiii)(N) that the AO in its statement be required to agree to comply with all of the requirements in § 424.58 at all times; this would include agreeing to adhere to the policies, procedures, practices, and agreements it outlined under § 424.58(c) as part of its initial or reapproval application and any changes thereto made with prior CMS approval.

(17) Additional Information Needed and Withdrawal of Application (New § 424.58(c)(2) and (c)(3))

We proposed two changes in new § 424.58(c)(2) and (c)(3). First, notwithstanding the wide scope of data to be furnished per § 424.58(c)(1), CMS may need additional information to fully assess the AO's credentials. Thus, we proposed in new § 424.58(c)(2) that if CMS determines that further data is necessary to make a determination on the AO's request for approval, we would notify the organization and afford it an opportunity to provide this data. Second, we proposed in new § 424.58(c)(3) that an AO may withdraw its application for approval of its accreditation program at any time before CMS posts the notice described in § 424.58(c)(6) (discussed later in this proposed rule).

(18) Reasons for Denial

Section 424.530(a) lists 18 reasons for which CMS can deny provider or supplier enrollment applications, including those from DMEPOS suppliers. These provisions help prevent non-compliant and unqualified providers and suppliers -- or those that present a program integrity risk – from being eligible to receive Medicare payments. While DMEPOS AOs, unlike DMEPOS suppliers, neither enroll in Medicare nor receive Medicare payments, they are responsible for ascertaining quality standard compliance for potentially hundreds of suppliers that may or do bill Medicare. We thus believe it is important to have clear reasons in § 424.58 for which we can deny an AO's application for approval of its accreditation program. We must be able to protect the DMEPOS accreditation program from unqualified AOs. For reasons outlined in detail in the proposed rule, we proposed the following denial grounds in new paragraphs (c)(4)(i) through (viii), several of which duplicate those in § 424.530(a):

- Denial Reason 1 - The AO has failed to comply with all application, data, and agreement submission requirements outlined in § 424.58(c).

- Denial Reason 2 - The AO has failed to provide reasonable assurance (as defined in paragraph (b)).

- Denial Reason 3 - The current number of CMS-approved DMEPOS AOs is sufficient to ensure the continued administration of CMS' DMEPOS accreditation program.

- Denial Reason 4 - The AO's DMEPOS program was previously terminated, suspended, or placed on probation by CMS under, respectively, new § 424.58(h), (i), or (j).

- Denial Reason 5 - The AO, or any owner (as defined in § 424.502), managing employee (as defined in § 424.502), governing body member, W-2 or contracted surveyor, or W-2 or contracted health care or administrative or management services personnel thereof--

++ Is OIG-excluded;

++ Is debarred, suspended, or otherwise excluded from participating in any Federal procurement or non-procurement activity; or

++ Within the preceding 10 years:

++ Was convicted of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries;

++ Has had a Medicare enrollment revoked under § 424.535;

++ Has had a license to provide health care suspended or revoked by any State licensing authority; or

++ Has been suspended or terminated from participating in a Federal or State health care program.

- Denial Reason 6 - The AO has submitted false or misleading information on its application in order to gain CMS approval or reapproval as a DMEPOS AO.
- Denial Reason 7 - The AO is non-compliant with any provision in § 424.58.
- Denial Reason 8 - CMS otherwise determines that approval of the applicant as a DMEPOS AO would not be in the best interests of the Medicare program and its beneficiaries.

(19) Notice of Approval/Denial, Public Notice, and Length of Approval (New § 424.58(c)(5) through (7))

Existing § 424.58 does not address when and how an AO is notified of CMS' decision to approve or deny its application for approval of its accreditation program. To clarify these issues, we proposed several provisions, the rationales for each of which were outlined in the proposed rule (90 FR 29211-29212). Under § 424.58(c)(5), CMS would send notice of its decision to the AO within 210 calendar days from the date CMS determines that the AO's application is complete. The notice would include: (i) the basis for the decision; (ii) if applicable, the effective date of approval; and (iii) if applicable, the length of the approval (not to exceed 6 years). Under proposed § 424.58(c)(6), CMS would announce on its website its decision to approve or deny the application. The announcement would be posted within 210 calendar days from the date that CMS determines that the AO's application was complete. If the application is approved, the posting would also state the approval's effective date (no later than the notice's publication date)

and length (6 years or less). In addition, § 424.58(c)(7) would state that CMS may approve an accreditation program for any period up to a maximum of 6 years.

3. AO Reapproval Process (New § 424.58(d))

New § 424.58(d) would outline the procedures involving an AO's application for reapproval of its DMEPOS accreditation program. As earlier mentioned, and except as otherwise noted, these procedures would generally duplicate those for initial applications in terms of content and rationale.

We proposed in new § 424.58(d)(1)(i) that except as stated in paragraph (d)(1)(ii), an approved DMEPOS AO that seeks to continue as such must apply for reapproval of accreditation at least 9 months before its current approval term expires. This would afford CMS -- prior to the current approval's expiration -- sufficient opportunity to: (1) review the application; (2) consider the AO's qualifications and past performance; and (3) render a decision. CMS would have the discretion, though, to grant the AO an additional 30 days to reapply.

We previously noted our concern that we have not reapproved any AO since the DMEPOS accreditation program's inception in 2006. Considering this nearly two-decade period, and as explained in the proposed rule, we believe it is imperative to commence a reapproval process for all current AOs as soon as possible after the effective date of any finalization of our proposals. Hence, we proposed in § 424.58(d)(1)(ii) that CMS may require AOs to submit reapproval applications under paragraph (d) any time after January 1, 2026, which would be the effective date of our revisions to §§ 424.57 and 424.58. The application would have to be submitted within 60 calendar days of CMS' submission request; if it is not, CMS terminates the AO's DMEPOS accreditation approval.

We proposed in new § 424.58(d)(2) that as part of its reapproval application submission: (1) the AO would have to furnish all information and statements identified in § 424.58(c)(1); and (2) CMS could request additional information under § 424.58(c)(2).

We also proposed in new § 424.58(d)(3) through (7) to duplicate our proposals in § 424.58(c)(3) through (7), respectively. The same rationales would apply (for example, establishing clear reapproval application withdrawal procedures; giving CMS adequate time (a maximum of 210 days) to render its decision).

4. Ongoing Responsibilities of a CMS-Approved AO (New § 424.58(e))

Existing § 424.58(c)(1) through (6) outline activities an approved AO must undertake on an ongoing basis. These functions, some of which have already been referenced, are as follows:

- Monthly submission of data concerning the AO's activities (such as copies of surveys; notice of accreditation decisions and complaints received; information about actions taken against suppliers, etc.).
- Submission of the acknowledgment, cross walk, and explanation in response to a change in CMS requirements.
- Allowing the AOs' surveyors to serve as witnesses if CMS takes an adverse action against a supplier based on an accreditation determination.
- Notification to CMS within 2 calendar days of a supplier's immediate jeopardy deficiency.
- Within 10 calendar days of receiving CMS notice that CMS intends to withdraw the AO's approval, provide written notice of the withdrawal to all the AO's accredited DMEPOS suppliers.
- Annually furnish CMS-specified summary information regarding the prior year's accreditation activities and trends.

We proposed to include these requirements within new § 424.58(e) but to also make certain changes and additions to them.

a. Submission of Monthly Information, Requested Information, and Immediate Jeopardy Deficiencies (New § 424.58(e)(1))

There are five categories of data in current § 424.58(c)(1)(i) through (v) that the AO must furnish on a monthly basis. We proposed several revisions thereto.

First, in the opening paragraph of (c)(1) (which we are redesignating as new paragraph (e)(1)(i)), we proposed for purposes of clarity to change the reference "on a monthly basis" to "no later than the last day of each month."

Second, existing paragraph (c)(1)(i) requires monthly submission of copies of all accreditation surveys, together with any survey-related information that CMS may require (including CAPs and summaries of findings with respect to unmet CMS requirements). We proposed that paragraph (c)(1)(i) would become new paragraph (e)(1)(i)(A), with the parenthetical in the previous sentence regarding CAPs and summaries constituting new paragraph (e)(1)(i)(A*)(1)*. In new § 424.58(e)(1)(i)(A)(*2*), and for the same reason behind proposed new § 424.58(c)(1)(iii)(G), we proposed that the required data must include the instances in which the AO had the discretion to perform a survey but elected not to, including the reason(s) behind the AO's decision.

Third, we proposed to delete the requirement in current § 424.58(c)(1)(iii) of monthly notice to CMS regarding complaints. This is because we proposed in new § 424.58(e)(3) – as discussed later in this final rule--- a separate process and timeframe for the AO's submission of complaint data to CMS.

Fourth, we proposed to add new paragraph (e)(1)(i)(C) that would require monthly notice of resolved deficiencies. As already mentioned, any DMEPOS supplier deficiency is of concern to us since it involves non-compliance with the quality standards or other applicable CMS requirement. Hence, we believe CMS should be made aware of them.

We did not propose to change the general content of existing paragraphs (c)(1)(ii) and (iv) regarding the monthly reporting of accreditation decisions and adverse actions. These two provisions, with slight technical modifications, would serve as new paragraphs (e)(1)(i)(B) and (D).

Current § 424.58(c)(1)(v) requires the AO to report proposed changes to its accreditation standards or requirements or survey process on a monthly basis. It also states that CMS may withdraw its approval of the AO's accreditation program if the AO implements these changes without prior CMS approval. We proposed to delete this requirement because, as discussed later in this final rule, the question of AO process and standard changes is addressed more thoroughly in new § 424.58(e)(2).

In new § 424.58(e)(1)(ii), and for the same reasons behind proposed § 424.58(c)(1)(xxiii)(A), we proposed that--

- CMS may at any time request the AO to submit any of the information described in new paragraph (e)(1)(i) or any other data CMS deems necessary to facilitate its oversight of the AO's accreditation program; and
- The AO must furnish this data to CMS within 3 business days of the request.

We also previously discussed current § 424.58(c)(4) and its 2-day notification requirement regarding immediate jeopardy deficiencies. We proposed to retain this requirement as part of new § 424.58(e)(1)(iii).

b. AO Standard or Requirement Changes (New § 424.58(e)(2))

As mentioned earlier, existing § 424.58(c)(1)(v) requires the AO each month to notify CMS of any proposed changes to its accreditation standards, requirements, or survey process; the AO cannot implement the change without prior CMS approval. While we did not propose to revise the basic requirements of § 424.58(c)(1)(v), we believe that additional safeguards are needed so that we: (1) become aware of planned changes sooner than we presently do; (2) have enough information to fully understand the breath of the revision; and (3) have the authority to either authorize or prohibit the AO's proposed revision. Therefore, we proposed several changes to § 424.58(c)(1)(v), which would become new § 424.58(e)(2).

First, we proposed in the opening paragraph of § 424.58(e)(2) to incorporate the existing notice requirement in current § 424.58(c)(1)(v) with two additions. One would require the notice

to be written; this is current practice, but we wish to include this in regulation. To address questions from AOs regarding § 424.58(c)(1)(v)'s scope, the other addition would state that § 424.58(e)(2)'s scope includes the addition, modification, or removal of a DMEPOS product service category to the list of categories for which the AO accredits DMEPOS suppliers.

Second, we proposed in new § 424.58(e)(2)(i) that the notice must:

- Be submitted at least 60 calendar days before the proposed change's intended effective date;
- Contain a detailed explanation of the revisions and the rationale for them; and
- Include a detailed crosswalk (in table format) containing the exact language of the AO's revised accreditation requirements and the applicable Medicare requirements for each.

In new § 424.58(e)(2)(ii), we proposed that CMS would furnish the AO written approval or disapproval of the proposed change within 30 calendar days of the effective date of the revision.

In new § 424.58(e)(2)(iii), and to emphasize to AOs the need for prior CMS acquiescence, we proposed to largely restate our existing position in § 424.58(c)(1)(v) that CMS may terminate or suspend its approval of the AO if the AO implements the change before or without CMS approval.

c. Complaints (New § 424.58(e)(3))

We previously noted that existing § 424.58(c)(1)(iii) requires the AO to provide monthly notice to CMS of all complaints involving suppliers. As with certain other information falling under current § 424.58(c)(1), we are concerned that only requiring the reporting of complaints on a monthly basis could leave us unaware for weeks of allegations of suppliers' non-compliance with the quality standards or other applicable CMS requirement. Again, considering our obligation to safeguard the Trust Funds against improper payments and to protect beneficiaries, we believe complaint data should be furnished to us more frequently. We accordingly proposed the following requirements in new § 424.58(e)(3).

In paragraphs (e)(3)(i)(A) through (C) and (3)(ii), we proposed that upon receipt of a complaint, the AO must---

- Provide written notice of the complaint to CMS no later than 5 calendar days after receipt;
- In accordance with its existing policies and procedures described in paragraph (c)(1)(x), perform an initial review of the complaint to determine whether, based on the complaint and any other data, the supplier may be non-adherent to one or more quality standards or other applicable CMS requirement; and
- Within 21 days after receiving the complaint, conduct a survey of the supplier if the initial review determines that such non-compliance may exist.
- No more than 10 calendar days after completing the action in paragraph (e)(3)(i)(B) or (C) (as applicable), give CMS written notice of the result of the initial review or, as applicable, the survey. (The notice must also inform CMS of any action the AO took or intends to take regarding the supplier, such as a termination of accreditation or imposition of a CAP.)

These requirements would help ensure that: (1) we receive the complaint expeditiously; (2) it is thoroughly investigated; and (3) we are aware of the result.

d. CAPs (New § 424.58(e)(4))

We proposed in § 424.58(e)(4) that the AO must give CMS written notice of any decision to apply a CAP to a particular supplier no later than 10 calendar days after its decision. The notice must include---

- The reason for the decision;
- A detailed explanation and justification as to why the AO imposed a CAP instead of, as applicable, denying or terminating the supplier's accreditation; and
- The terms of the supplier's CAP (for example, deadline for compliance, the AO's plans for enforcement and ensuring compliance).

This would help us ascertain the AO's: (1) compliance with its CAP policies contained in its application for CMS approval or reapproval; and (2) judgment in imposing CAPs instead of denying or terminating accreditation.

e. Accreditation Denials and Terminations (New § 424.58(e)(5))

We proposed in new § 424.58(e)(5)(i) that the AO must give CMS written notice of any decision to deny, terminate, revoke, withdraw, or amend a supplier's accreditation within 5 calendar days of the decision; the notice must identify the reason for the AO's determination. Without our expeditious knowledge of such actions, an unaccredited and unqualified supplier might remain enrolled for a considerable period, possibly resulting in improper payments and beneficiary harm. Also, and as we explained in the proposed rule, this information could help CMS detect potentially systemic issues and trends among suppliers.

We recognize the relative independence that AOs must retain in their operations and particularly their accreditation decision-making, Nonetheless, there are several situations where we believe we must require that the AO take action because of the serious program integrity risk the situation entails. Thus, we proposed in new paragraphs (e)(5)(ii)(A)*(1)* through *(5)* that notwithstanding any other provision in § 424.58, an AO must deny or terminate a supplier's accreditation if--

- The supplier fails to meet the licensure requirements in § 424.57(c)(1)(ii);
- The supplier is not operational (as that term is defined in § 424.502);
- The supplier's location fails to meet the accessibility requirements in § 424.57(c)(7)(i)(B);
- The supplier's Medicare enrollment is revoked due to non-compliance with one or more DMEPOS quality standards and the reenrollment bar under § 424.535(c) has not expired; or
- Directed by CMS.

To ensure that the AO carries out a CMS-directed accreditation denial or termination, we further proposed in new paragraph (e)(5)(ii)(B) that the AO must: (1) deny or terminate the supplier's accreditation within 3 business days after receiving written notice from CMS to do so; and (2) provide CMS written notice that it has taken this action within 5 business days of receiving the written direction from CMS.

f. Annual Summary of Data and CMS Changes (New § 424.58(e)(6) and (7))

Existing § 424.58(c)(6) requires the AO to annually furnish summary data specified by CMS that relates to the past year's accreditation activities and trends. Although we did not propose to change this requirement, we did propose to designate it as new § 424.58(e)(6).

We previously noted that as part of the AO statement that proposed § 424.58(c)(1)(xxiii) would require, the AO per § 424.58(c)(1)(xxiii)(G) must – in response to CMS notification of a change in the quality standards, survey process, or other requirement – furnish CMS with corresponding changes in the AO's requirements. We proposed in new § 424.58(e)(7) to outline the required timeframe and content of this data submission.

The opening paragraph of § 424.58(e)(7)(i) would: (1) include the requirement in proposed § 424.58(c)(1)(xxiii)(G); (2) state that the AO's submission of concomitant revisions is to ensure continued comparability with the quality standards, survey process, and other requirements; and (3) require the AO to report its proposed changes to CMS no later than 30 days after receiving CMS' written notice. In addition, new paragraphs (e)(7)(i)(A) through (C) would include the data submission elements and formats required in existing § 424.58(c)(2), specifically--

- An acknowledgment of CMS's notification of the change;
- A revised crosswalk reflecting the new requirements; and
- An explanation of how the AO will modify its standards to conform to CMS's new requirements within the timeframes outlined in the notice it received from CMS.

In new § 424.58(e)(7)(ii), we proposed to state that the AO cannot implement its proposed corresponding revisions without CMS approval. This requirement would help CMS ensure that the AO understands and accurately implements CMS' revisions.

g. Performance of Surveys (New § 424.58(e)(8))

As we explained in the proposed rule, not every supplier receives an accreditation survey. For instance, CMS currently permits AOs to undertake sampling for large supplier chain surveys. Factors an AO considers in determining which chain locations are surveyed include: (1) the supplier's physical location (for instance, whether it is in a high-fraud area); and (2) the types of products the supplier furnishes.

We have received information that various DMEPOS suppliers that were not surveyed were later found to be non-compliant with the quality standards. We emphasized throughout section VI.B. of the proposed rule CMS' obligation to prevent improper Medicare payments and to protect beneficiaries. By permitting AOs to forgo surveys in certain instances, we risk the potential for patient harm and for millions of Medicare dollars to be paid to non-compliant suppliers. Believing that we must revisit the current process and establish stricter and broader requirements regarding the performance of surveys, we proposed the following requirements in new § 424.58(e)(8).

Proposed opening paragraph (e)(8) and paragraph (e)(8)(i)(A) would state that except as otherwise directed or permitted in writing by CMS (for instance, allowing sampling), the AO must perform a survey of all supplier locations for which the supplier seeks accreditation or reaccreditation with the AO. (This includes, but is not limited to, accreditations: (1) for a new item type the supplier has not previously furnished; or (2) as required under 42 CFR 424.551, discussed later in this final rule.) Per our concerns about non-surveyed suppliers, we believe the blanket survey requirement in paragraph (e)(8)(i)(A) is necessary. Nevertheless, we also recognize that isolated and limited instances of sampling or other survey exemptions could be warranted. While we were unable to specify or predict in the proposed rule what those instances

may be and do not commit to allowing survey exceptions in this final rule, we believe our administration of the DMEPOS accreditation program requires that we have the flexibility to address particular circumstances as they arise.

New paragraph (e)(8)(i)(B) would require the AO to perform all surveys as unannounced surveys. While the caveat in proposed opening paragraph of (e)(8)(i) would permit us to waive this requirement in certain situations, we do not anticipate doing so given the previously noted importance of preventing prior notice to the supplier.

In new paragraph (e)(8)(i)(C), we proposed that the AO cannot accredit the supplier location before: (1) the survey is conducted; and (2) the AO deems the supplier compliant with the quality standards. Our concern is that if we permitted accreditation (and then enrollment) prior to the survey and it is later determined that the supplier does not meet the quality standards, many thousands of dollars in improper payments to the supplier could have resulted.

We also proposed in new paragraph (e)(8)(ii) that CMS may, at any time, direct the AO to perform a survey of an accredited supplier or a group thereof. We do not believe surveys should be restricted to initial accreditation and reaccreditation situations, especially considering the aforementioned 3-year time gap between them. Suppliers must at all times be compliant with the quality standards and not merely upon initial accreditation and reaccreditation. To help verify that such adherence is always maintained, we believe we need discretion to direct an AO to conduct a survey at any time. Having to wait until reaccreditation to resurvey the supplier could lead in the interim to improper payments to a supplier that has fallen out of adherence to the quality standards.

We further proposed in new paragraph (e)(8)(iii) that when performing a survey, the AO must also confirm that the supplier is licensed in accordance with § 424.57(c). We believe most AOs perform this task during the survey, but we proposed to require this in regulation considering the importance of the supplier's compliance with State (and not only Federal) laws.

h. Surveyor Witnesses (New § 424.58(e)(9))

We have cited current requirements in § 424.58(c)(3) that the AO allow its surveyors to serve as witnesses if CMS undertakes an adverse action against a supplier in response to an accreditation finding. Consistent with our reorganization of § 424.58, we proposed to designate this requirement without change as new paragraph § 424.58(e)(9).

i. Entrance of Data into System (New § 424.58(e)(10))

Notwithstanding our proposed additional reporting requirements, we outlined our concerns in the proposed rule about our ability to access accreditation and survey data immediately. There could be instances where we need prompt information about a particular supplier in real-time and cannot wait for the AO to send it to us. Thus, we proposed in new § 424.58(e)(10) that if directed by CMS, the AO must enter accreditation, survey, product code, and other data into a CMS-designated system. This system, to which CMS and the NPECs would have access, would enable us to review accreditation data at any time. To preserve our operational flexibility, we did not detail in the proposed rule either the specific system involved or the timing, content, and extent of the data entry. We may even later determine that the data entry is unnecessary if an alternative means of accessing this information in real-time is established. The implementation of § 424.58(e)(10) is thus contingent upon CMS determining that the entry is needed, hence the "if directed" caveat at the beginning of paragraph (e)(10).

j. Adverse Actions (New § 424.58(e)(11))

As previously noted, we proposed under new § 424.58(c)(4)(v) that CMS could deny an AO's application for approval or reapproval of its accreditation program if the AO, or any AO owner, managing employee, governing body member, surveyor, or health care or administrative or management services personnel, has any of the adverse actions specified in § 424.58(c)(4)(v). Consistent therewith, we proposed in new § 424.58(e)(11) to duplicate this denial reason as a general prohibition against such relationships on an ongoing basis, not simply as part of the AO's application determination. We believe this change would further underscore the importance of ensuring that parties associated with the AO do not pose program integrity risks.

5. Continuing Federal Oversight of AOs (New § 424.58(f))

Existing § 424.58(d) outlines procedures for our ongoing review of AOs. While we intend to retain some of the provisions of this section, which would become new § 424.58(f), we proposed changes to parts of its contents and structure to improve clarity and strengthen our oversight.

The opening paragraph of current § 424.58(d) states that the paragraph establishes specific criteria and procedures for continuing oversight and for withdrawing approval of a CMS-approved DMEPOS AO. We proposed to revise this to state that CMS evaluates the performance of each CMS-approved DMEPOS accreditation program on an ongoing basis; means of monitoring include, but are not limited to, the reviews identified in proposed paragraph (f). We believe this new language would clarify that CMS' oversight procedures are not restricted to those in paragraph (f). We further proposed that existing § 424.58(d) regarding terminations of AOs be in proposed new paragraph (h). Hence, the designation of § 424.58(d) as new § 424.58(f) will not include these paragraphs or any other reference to AO terminations.

a. Equivalency Reviews (New § 424.58(f)(1))

As described in current § 424.58(d), an equivalency review involves our comparison of the AO's standards (and the AO's application and enforcement thereof) to CMS requirements and processes. Paragraphs (d)(1)(i) through (iii) outline the following instances in which CMS may perform this review: (i) CMS imposes new requirements or changes in its survey process; (ii) the AO proposes new standards or changes in its survey process; or (iii) the AO's term of accreditation expires. We believe that retaining these three paragraphs in new paragraph (f)(1) would imply that we can only perform equivalency reviews in these three situations, which is not our intention. For reasons already noted, we must be able to constantly monitor the AO's operations – even if none of the three previous scenarios apply -- and equivalency reviews are an important means of doing so. Consequently, we proposed in new paragraph (f)(1) that we may

perform an equivalency review at any time; the contingencies in existing (d)(1)(i) through (iii) would not be included in paragraph (f)(1).

b. Validation Survey of Suppliers (New § 424.58(f)(2))

Another means of validating the AO's accreditation processes is to review the AO's survey procedures. Addressed in the opening paragraph of existing § 424.58(d)(2), this can involve CMS or its designated survey team--

- Performing a survey of an accredited DMEPOS supplier;
- Examining the results of the AO's survey of a supplier; or
- Observing an AO's survey of a supplier onsite.

After the review, CMS identifies whether (as stated in current § 424.58(d)(2)(i) through (iii)), the review indicates the following:

- At least a 10 percent disparity between the AO's and CMS' respective survey findings for non-immediate jeopardy standards.
- Any disparity between the AO's and CMS' respective survey findings for standards constituting immediate jeopardy.
- Regardless of the disparity rate, there are widespread and systemic problems in the AO's processes such that accreditation by the AO no longer provides CMS with adequate assurance that suppliers meet or exceed Medicare requirements.

Additional provisions regarding CMS' performance of a supplier survey (as a means of ascertaining the AO's performance) are addressed in existing § 424.58(b)(2). Specifically, the latter states that CMS performs supplier surveys on a representative sample basis or in response to substantial allegations of non-compliance.

We proposed several modifications to the foregoing provisions to both consolidate and streamline our requirements and to enhance our ability to perform the aforementioned reviews.

First, we proposed to incorporate all provisions regarding validation surveys within new § 424.58(f)(2) rather than continue to have them split between § 424.58(b)(2) and (d). We believe this would facilitate clarity and consistency.

Second, we proposed in new paragraph (f)(2)(i) that CMS may survey suppliers to validate the AO's survey process. Such surveys can be comprehensive or focus on certain standards or requirements. We noted in the proposed rule that paragraph (f)(2)(i) would not include the three survey situations in the opening paragraph of existing § 424.58(d)(2), the provisions in § 424.58(d)(2)(i) through (iii), or references to sample bases and substantial allegations of non-compliance in § 424.58(b)(2). This is because we believe that paragraphs (b)(2) and (d)(2), as currently written, could be erroneously read as restricting our flexibility to: (1) conduct supplier surveys; and (2) reach conclusions that indicate problems with the AO's accreditation program. It is crucial, in our view, to have much wider latitude in assessing an AO's performance and to take action as needed.

Third, existing § 424.58(b)(3) through (6) state, respectively, that--

- If CMS discovers that the supplier is non-adherent to the quality standards, CMS may revoke the supplier's billing number or require the AO to perform a subsequent full survey at the AO's expense;
- A supplier selected for a validation survey must authorize: (1) the survey to occur; and (2) the CMS survey team to monitor the correction of any deficiencies found during the survey;
- If the selected supplier does not comply with the existing authorization requirements of paragraph (b)(4), it does not meet the quality standards and may have its supplier billing number revoked; and
- If the survey finds that the supplier is non-compliant with one or more quality standards, the supplier no longer meets the quality standards and may have its supplier billing number revoked.

Except for changing "supplier billing number" to "enrollment" (the latter being the more accurate term), we did not propose revisions to these requirements, which we would designate as new § 424.58(f)(2)(ii), (iii), (iv), and (v).

c. Deficiencies (§ 424.58(f)(3))

As part of the proposed statement under new § 424.58(c)(1)(xxiii), new paragraph (H) thereof would require the AO to agree to accept and adhere to any CMS-established deficiency definition as well as levels and categories of deficiencies. To reiterate CMS' discretion in both this regard as well with respect to CMS' authority to establish quality standards under section 1834(a)(20) of the Act, we proposed in new § 424.58(f)(3)(i) that CMS may--

- Define the term "deficiency";
- Establish levels and categories of deficiencies; and
- Revise the quality standards.

New § 424.58(f)(3)(ii) would require the AO in its accreditation activities to apply and adhere to: (1) any CMS-established definition of deficiency and categories and levels thereof; and (2) all CMS-established quality standards.

d. Additional Reviews (§ 424.58(f)(4))

We proposed in new § 424.58(f)(4)(i)(A) to expand upon the reviews addressed in new § 424.58(f)(1) and (2) and permit CMS – at any time and for any reason – to conduct a review of the AO's processes or performance to--

- Validate the AO's representations to CMS (for example, its statements in new paragraph (c)(1)(xxiii)); or
- Assess the AO's adherence to its own policies and procedures, the provisions of § 424.58, and all other CMS requirements.

We also proposed in new § 424.58(f)(4)(i)(B) that the scope, length, and timing of the review would lie within CMS' discretion. Furthermore, evidence of the AO's potential non-

compliance with any of the policies and requirements addressed in new § 424.58(f)(4)(i)(A) is not required for CMS to perform a review.

In new § 424.58(f)(4)(ii)(A) through (H), we proposed to list some of the types of reviews that CMS may perform either collectively or individually. Paragraphs (f)(4)(ii)(A) and (B) would respectively reference the reviews in new § 424.58(f)(1) and (2). Paragraphs (f)(4)(ii)(C) and (D) would reflect two of the previously mentioned reviews in existing § 424.58(d)(2): examining the results of an AO's surveys of suppliers and observing onsite an AO's survey of a supplier. Proposed new paragraphs (f)(4)(ii)(E) through (H) would address the following reviews of the AO's onsite operations, similar to those for certified providers and certified suppliers in 42 CFR 488.8(h):

- Conducting onsite inspections of the AO's operations and offices.
- Requesting and reviewing documents.
- Interviewing AO personnel.
- Observing AO internal meetings concerning the accreditation process.

We explained in the proposed rule that these proposals in new § 424.58(f)(4) are necessary to give us greater flexibility and more means with which to examine the AO's performance. Indeed, current § 424.58 only references equivalency reviews, supplier surveys, and the AO's periodic submission of data as vehicles via which we can perform this task. We must be able to tailor the format, timing, and scope of our reviews to address particular circumstances.

6. Terminations of CMS-Approved AO Accreditation Programs (New § 424.58(g) and (h))

a. Voluntary Terminations

Sections 488.5(c)(2), 488.8(g)(2), and 488.1045(a) outline procedures via which an AO can voluntarily terminate its existing CMS-approved certified provider/supplier or home infusion therapy supplier accreditation program. To ensure that DMEPOS AOs follow a specific,

uniform process for doing so and, more importantly, that CMS is given adequate notice thereof, we proposed to establish similar procedures in new § 424.58(g).

In paragraph (g)(1), we proposed that an AO may voluntarily terminate its CMS-approved DMEPOS accreditation program at any time. In doing so, the AO per paragraphs (g)(1)(i) and (ii), respectively, must--

- Inform CMS of its decision no less than 120 calendar days before the termination effective date; and

- Provide written notice at least 90 days before the termination effective date to each of its accredited suppliers but not before notifying CMS of its decision under the previous bullet. The notice to each supplier must--

++ Describe the provisions in proposed new paragraph (g)(2) (discussed shortly) concerning the expiration dates of the supplier's accreditation with the terminating AO; and

++ Inform the supplier that any lapse in its accreditation (including between the date its existing accreditation with the terminating AO expires and the effective date of its accreditation with a different AO) will result in the revocation of its enrollment under § 424.535.

In new paragraph (g)(2), we proposed that unless the supplier is otherwise determined to be non-adherent to the quality standards or other accreditation requirements, the supplier's accreditation with the terminating AO remains effective until the earliest of: (1) the expiration of its current term of accreditation with the terminating AO; and (2) the effective date of its accreditation with a different CMS-approved AO. We do not believe a supplier's accreditation should be correspondingly and automatically terminated when an AO voluntarily terminates its DMEPOS accreditation program. The AO's decision, in our view, is separate and distinct from the question of whether the supplier still complies with the quality standards and all other accreditation requirements. So long as the supplier remains compliant therewith, its accreditation should typically remain intact until one of the two aforementioned contingencies occurs.

b. Involuntary Terminations

(1) Reasons

Current § 424.58(d)(4)(i) and (ii) list two reasons for which CMS can terminate its approval of an AO's DMEPOS accreditation program:

- Accreditation by the AO no longer adequately ensures that its suppliers comply with the quality standards, and that failure to meet these requirements could: (i) jeopardize the health or safety of Medicare beneficiaries; and (ii) constitute a significant hazard to public health; or
- The AO has not met its obligations regarding initial application or reapproval application procedures.

We believe these termination reasons may be too limited. For example, existing § 424.58(d)(4)(i) can only apply if the failure could jeopardize beneficiaries or public health. We do not believe these two events should be the sole grounds for termination. If the program does not ensure that suppliers meet the quality standards – which is the principal reason for the DMEPOS accreditation program in the first place – that alone is of great concern because it could result in improper payments. Put otherwise, the issue is not only beneficiary safety (critical though that matter is) but also protection of the Trust Funds. With respect to § 424.58(d)(4)(ii), the AO's obligations are not restricted to those involving the initial and reapproval application processes. They instead are constant throughout the entirety of the AO's period of CMS approval and require the AO's ongoing compliance with § 424.58. We maintain that our involuntary termination reasons should be much broader so as to address the previous situations and to ensure we have the ability to safeguard the Medicare program.

We thus proposed the following provisions in new § 424.58(h).

In new paragraphs (h)(1)(i)(A) through (D), and for reasons explained in detail in the proposed rule, we proposed that we may terminate our approval of an AO's accreditation program if CMS determines that--

- The AO no longer demonstrates reasonable assurance (as defined in paragraph (b));

- The continued approval of the AO's accreditation program poses an immediate jeopardy to the patients of the entities accredited under that program or otherwise constitutes a hazard to the public health;

- The AO is non-adherent to any provision of § 424.58. This includes, but is not limited to, situations where the AO has failed to comply with--

++ A term or condition of a statement or agreement in § 424.58(c)(1)(xxiii); or

++ A policy, procedure, or practice it outlined under paragraph § 424.58(c) as part of its initial or reapproval application or CMS-approved change thereto under § 424.58(e)(2) or (e)(7); or

- A pattern or practice exists of the AO's accredited suppliers being revoked under § 424.535(a) for failing to adhere to the quality standards.

We proposed in new § 424.58(h)(1)(ii) that CMS could terminate its approval of the AO's accreditation program effective on the date of the termination notification letter to the AO (described in proposed new paragraph (h)(2)) or any date thereafter. Considering, as already stated, the risks to the Trust Funds and Medicare beneficiaries that AO non-compliance could lead to (such as continued substandard services offered by non-compliant suppliers), we believe that having to wait 30 days, 60 days, or longer before the termination is effective could result in considerable improper payments and possible patient harm. Although we are including an "or any date thereafter" caveat to § 424.58(h)(1)(ii) to account for situations where a slightly later date might be warranted, we believe these will be rare.

(2) Processes

To assist stakeholders in understanding the consequences of a termination, we proposed in new § 424.58(h)(2) through (5) to outline operational procedures for terminating an AO's approval and to address the consequent impact on suppliers; some of these provisions are akin to those in §§ 488.1030(f), 488.8(e), and 488.1045(b).

We proposed in new § 424.58(h)(2) that CMS would give written notice to the AO of its termination decision. The notice must include the reason for and effective date of the termination. We proposed in new § 424.58(h)(3) (and as with AO initial application submissions) that CMS would announce its decision (and the effective date thereof) on its website. This would help ensure the public is made aware of the termination as quickly as possible, something that may prove challenging if publication in the **Federal Register** were required.

So affected suppliers receive individualized notice beyond the CMS website announcement, we proposed in new § 424.58(h)(4) that the terminated AO must give written notice of the termination and its implications to each of its accredited suppliers within 30 calendar days after the CMS website announcement. The notice to each supplier would have to –

- Explain the provisions in § 424.58(h)(6) concerning the expiration dates of the supplier's accreditation with the terminated AO; and
- Inform the supplier that any lapse in its accreditation (including between the date its existing accreditation with the terminated AO expires and the effective date of its accreditation with a different AO) results in its enrollment being revoked under § 424.535.

We also proposed the following in new § 424.58(h)(5) and (6)(i)(A) through (C):

- The terminated AO must work collaboratively with CMS to direct its accredited suppliers to the remaining CMS-approved AOs within a reasonable period of time.
- Unless the supplier is otherwise determined to be non-adherent to the quality standards or other accreditation requirement, the supplier's accreditation with the terminated AO remains effective until the earliest of--

++ The expiration of its current term of accreditation with the terminated AO;

++ The effective date of its accreditation with a different CMS-approved AO; or

++ A date specified by CMS based on the circumstances of the termination of the AO's approval.

We believe new paragraphs (h)(4), (5), and (6)(i) would ease suppliers' transition to a new AO by: (1) explaining the implications of the termination; (2) facilitating CMS-AO collaboration; and (3) emphasizing that the supplier's accreditation does not automatically end with the AO's departure. Yet paragraph (h)(4) and the required letter would stress to the supplier that there can be no gaps in its accreditation. This may require the supplier to promptly seek accreditation with another AO before its current accreditation expires.

Should CMS specify a particular accreditation end-date per proposed paragraph (h)(6)(i), CMS under new paragraph (h)(6)(ii) would notify the affected supplier in writing thereof and identify the deadline by which the supplier must be reaccredited by a different AO.

We also proposed in new § 424.58(h)(7) that the terminated AO must refund to a supplier all payments the latter made to the AO in accordance with the supplier's request for accreditation or reaccreditation but before the AO notified the supplier of its final determination regarding the supplier's request. We do not believe an AO whose approval has been terminated should be able to keep the monies the supplier paid it when the requested service – accreditation or reaccreditation – was not fully rendered (that is, the final decision was not made). Fundamental fairness to the supplier requires, in our view, the refund of these payments.

7. AO Suspensions and Probations (New § 424.58(i) and (j))

Termination is presently the only remedy available to CMS under § 424.58 to address AO performance issues. Although we proposed in § 424.58(h)(1) to expand the grounds for which termination can apply, we recognize the seriousness of a termination and would generally only take this step in exceptional circumstances. Yet under current § 424.58, this could leave the non-compliance unresolved because of our lack of other, perhaps more suitable remedies. In other words, we do not believe AO non-compliance should only be addressable by an all-or-

nothing, termination-or-no termination approach. Having multiple available remedies would allow us to correspond our action to the relative severity of each case.

a. Suspension

We proposed in new § 424.58(i) to have the ability to suspend an AO's accreditation program. Under paragraphs (i)(1)(i) and (ii), suspension could occur if we determine that the AO no longer demonstrates reasonable assurance (as defined in paragraph (b)) or is non-compliant with any provision of § 424.58. The non-compliance can include, but is not limited to, situations where the AO has failed to--

- Comply with a term or condition of a statement or agreement in § 424.58(c)(1)(xxiii); or
- Adhere to a policy, procedure, or practice it outlined under § 424.58(c) as part of its initial or reapproval application or a CMS-approved change thereto under § 424.58(e)(2) or (e)(7).

We also proposed that CMS may suspend the AO's accreditation program if there is a pattern or practice of the AO's accredited suppliers being revoked under § 424.535 for failing to comply with the quality standards.

These grounds are also applicable to terminations but are sufficiently broad to enable us to apply a lesser sanction if the circumstances warrant. (For example, the § 424.58 non-compliance may not be significant enough to, in our view, justify a termination).

We proposed in new § 424.58(i)(2) to outline a suspension's components. Paragraph (i)(2)(i) would state that except as otherwise specified or permitted by CMS, the AO could not conduct any DMEPOS accreditation activities while suspended. We believe the opening caveat is necessary should we need the AO, despite its suspension, to perform certain functions, such as completing an ongoing survey. Proposed paragraph (i)(2)(ii), meanwhile, would state that--

- CMS determines the length of the suspension, which would be a maximum of 1 year; and

- Upon the expiration of the suspension period, CMS either lifts the suspension or terminates the AO's approval in accordance with proposed paragraph (h).

Aside from the maximum 1-year period, we do not believe a fixed suspension length should be established in regulation. Since every situation will differ, we must have the discretion to tailor the suspension length to the specific facts of the case. We believe a 1-year maximum is appropriate because if the AO cannot rectify the non-compliance within such an extensive timeframe, this indicates systemic issues that can warrant termination.

For the same reasons behind proposed paragraph (h)(2) regarding terminations, we proposed in new paragraph (i)(2)(iii) that CMS may suspend the AO's program effective the date of the suspension notification letter described in paragraph (i)(3) or any date thereafter.

We proposed in new paragraph (i)(3) that CMS would send written notice of the suspension decision to the AO. The notice would include the reason(s) for, the effective date of, the length of, and the terms of the suspension (for instance, application of a CAP; whether the AO may perform certain functions during the suspension; etc.), as well as the steps the AO must take to have the suspension lifted. To confirm that the AO received the notice, we proposed in new paragraph (i)(3)(ii) that the AO must notify CMS of this in writing within 3 calendar days of receipt.

In new paragraph (i)(3)(iii), we proposed that no later than 3 calendar days after our receipt of the acknowledgement in paragraph (i)(3)(ii), CMS would post on its website a notice of the suspension.

We proposed in new paragraph (i)(4) to address the status of the suspended AO's accredited suppliers. Akin to supplier statuses with AO voluntary and involuntary terminations, we proposed in new paragraphs (i)(4)(i)(A) through (C) that if the AO's accreditation program is suspended, the accreditation status of its suppliers remains effective through the length of the suspension unless--

- The supplier's current term of accreditation with the suspended AO expires during the suspension;

- The supplier is otherwise determined to be non-adherent to the quality standards or other accreditation requirement; or

- CMS specifies a different accreditation termination date based on the circumstances of the suspension of the AO's accreditation program.

We proposed in new paragraph (i)(4)(ii)(A) that if paragraph (i)(4)(i)(A) applies, the supplier must be reaccredited by: (1) its AO if the AO's suspension has been lifted; or (2) a different CMS-approved AO. We proposed in new paragraph (i)(4)(ii)(B) that if paragraph (i)(4)(i)(C) applies, CMS notifies the affected supplier in writing of the deadline by which the supplier must be reaccredited. In new paragraph (i)(4)(iii), we would reiterate that any lapse in the supplier's accreditation may result in the revocation of the supplier's enrollment.

We proposed in new paragraph (i)(5) to address the circumstances under which a suspension is lifted and the processes associated therewith. In paragraphs (i)(5)(i)(A) through (C), CMS would lift a suspension if all of the following are met:

- The reasons for it no longer exist.

- The AO demonstrates reasonable assurance (as defined in paragraph (b)).

- The AO is in compliance with all provisions of § 424.58.

We believe that even if the specific issue that led to the suspension has been corrected, it is possible that other instances of non-compliance exist, hence the need for paragraphs (i)(5)(i)(B) and (C).

For the same reasons behind proposed paragraphs (i)(3)(i) through (iii), we proposed in new paragraph (i)(5)(ii) that if the suspension is lifted, CMS would--

- Send the AO written notice that the suspension has been lifted;

- Require the AO to notify CMS in writing of its receipt of the notice within 3 calendar days of such receipt; and

- No later than 3 calendar days after receipt of the AO's acknowledgement, publish on its website a notice of the lifting of the AO's suspension .

We proposed in new paragraph (i)(6) to duplicate proposed paragraph (h)(7) regarding refunds. We note that the suspension would not be lifted before all required refunds to suppliers under paragraph (i)(6) have been paid.

We proposed in new paragraph (i)(7) that nothing in paragraph (i) would prohibit CMS from suspending an AO's accreditation program more than once. This would help preserve our flexibility to take the most appropriate action to address AO non-compliance; for example, a second suspension may be more appropriate than a suspension followed by a termination several years later.

b. Probation

To further enhance our ability to address AO non-compliance in a manner proportional to the degree thereof, we proposed to establish a process in new § 424.58(j) for placing an AO's accreditation program on probation in lieu of a termination or suspension.

In paragraph (j)(1), we proposed to have the discretion to place an AO's DMEPOS accreditation program on probation and require its successful completion of a CAP in the following instances-

- CMS determines that the DMEPOS accrediting organization no longer demonstrates reasonable assurance (as defined in paragraph (b) of this section).

- CMS determines that the AO is non-compliant with any provision of § 424.58. This could include the aforementioned terms, conditions, procedures, etc., described in proposed new paragraphs (h)(1)(i)(C) and (i)(1)(ii).

- CMS determines that there is a pattern or practice of the AO's accredited suppliers being revoked under § 424.535 for not complying with the quality standards.

- The suspension period for the AO under paragraph (i) has expired and CMS determines that a subsequent probationary period and associated CAP are warranted.

In paragraph (j)(2)(i), we proposed that CMS would give the AO written notice of its decision to place it on probation. The notice would include--

- The reason(s) for CMS' decision;
- The length of the probationary period, which would not exceed 1 year;
- The CAP's terms;
- The requirements and deadline for achieving compliance; and
- An explanation of how CMS would monitor the AO's efforts to resume adherence under the CAP (for example, performing reviews under paragraph (f)).

We proposed in new paragraph (j)(2)(ii) that except as otherwise prescribed in the CAP, the AO could continue its accreditation activities as normal.

We proposed in new paragraph (j)(3)(i) that when the probationary period concludes, CMS would notify the AO in writing of--

- Whether the AO is in compliance with all requirements of § 424.58;
- The reason for the determination in the previous bullet; and
- The consequences of the determination (for example, termination or suspension of accreditation, successful completion of and cessation of the probationary period and CAP).

We proposed in new paragraph (j)(3)(ii) that we may send this notice, terminate the probationary period, and end the CAP prior to the end of designated probationary period if we determine that the AO is again compliant, for this would eliminate the continued need for the probation and CAP.

8. CMS Discretion, Change in Non-Compliance Actions (New § 424.58(k))

To confirm CMS' discretion to determine which action should be imposed against an AO and, if circumstances warrant, to escalate a currently imposed action to a more significant one, we proposed the following in new § 424.58(k). First, we proposed in new paragraph (k)(1) that CMS could impose an action in § 424.58(h), (i), or (j) instead of another such action in paragraph

(h), (i), or (j) if the same ground(s) for either exists. Second, § 424.58(k)(2) would state that CMS could terminate--

- An AO's probation (either before or in accordance with the probationary period's original expiration date) and impose a suspension or termination if a ground for either of the latter actions exists; or

- An AO's suspension (either before or in accordance with the suspension's original expiration date) and impose a termination if a basis for termination exists.

9. Reconsiderations and Rebuttals (New § 424.58(l))

a. Denials and Involuntary Terminations

Current § 424.58(e)(1) outlines the reasons for which an AO may file a written request for reconsideration of a CMS determination that the AO does not provide reasonable assurance that the suppliers it has accredited meet the quality standards. The procedures of the reconsideration process are outlined in existing § 424.58(e)(2) through (9). We proposed to remove all these reconsideration provisions from § 424.58 and, in new § 424.58(l) instead utilize the reconsideration processes in 42 CFR part 498 for denied and involuntarily terminated AOs. This would afford AOs the same robust appeal rights that exist for providers and suppliers whose enrollments are denied or revoked under § 424.530 or § 424.535.

In addition, § 498.3(b) lists situations in which CMS makes an initial determination. We proposed to add new paragraphs (b)(21) and (22) to § 498.3. The former would include denials under paragraph (c)(4) or (d)(4). The latter would include involuntary terminations under paragraph (h)(1). We also proposed to state in new § 424.58(l)(1) that the AO could request a reconsideration under part 498 of any of these three initial determinations.

b. Suspensions and Probationary Periods

As explained in the proposed rule, we believe a rebuttal process would be more appropriate than a reconsideration process for AOs whose accreditation programs have been

suspended or placed on probation. It is shorter and more expedited but still affords the affected AO an opportunity to be heard.

We proposed in new paragraph (l)(2) to outline the procedures via which a DMEPOS AO may rebut a CMS suspension or probation decision. These procedures duplicate the existing rebuttal process in § 424.546 for deactivations.

We proposed in new paragraph (1)(2)(i)(A) that if an AO receives notice from CMS that its DMEPOS accreditation program has been suspended or placed on probation, the AO has 15 calendar days from the date of such notice to submit a rebuttal to CMS.

We proposed in new paragraph (l)(2)(i)(B) that CMS may, at its discretion, extend the 15-day time-period referenced in paragraph (l)(2)(i)(A).

We proposed in new paragraph (l)(2)(ii)(A) through (D) that any rebuttal must--

- Be in writing;
- Identify the facts or issues about which the AO disagrees with CMS' determination, including the reasons for disagreement;
- Include all documentation the AO wants CMS to consider in its review of its determination; and
- Be submitted in the form of a letter that is signed and dated by the AO's CEO (or similar official with authority to commit the organization to adhere to Medicare laws and regulations) or a legal representative (as defined in 42 CFR 498.10). We also proposed the provisions from § 424.546(b)(4) regarding legal representatives (for example, a required statement that the representative has the authority to represent the AO).

We proposed in new paragraph (l)(2)(iii) that the AO's failure to submit a timely and compliant rebuttal would constitute a waiver of all rebuttal rights under paragraph (l)(2).

We proposed in paragraph (l)(2)(iv) that upon receipt of a timely and compliant AO rebuttal, CMS reviews it to determine whether the imposition of the suspension or probation was proper.

We proposed in new paragraph (l)(2)(v) that CMS would not be required to delay the imposition of the suspension or probation pending the completion of CMS' review of the rebuttal.

Finally, we proposed in new paragraph (1)(2)(vi) that a CMS determination made under paragraph (l)(2) would not be an initial determination under § 498.3(b) and therefore not appealable.

10. Consulting (New § 424.58(m))

As previously mentioned, CMS issued a February 15, 2024, proposed rule addressing several topics regarding certified provider/supplier accreditation. One such subject was consulting services provided by AOs, their consulting divisions, or separate business entities to Medicare-participating health care facilities. An example of consulting services that proposed rule cited involves an AO's review of facility standards and promised early intervention and action through simulation of a real survey, such as a mock survey with comprehensive written reports of findings. This situation is of particular concern to us. The purpose of the DMEPOS accreditation survey is to objectively assess the supplier's compliance with the DMEPOS quality standards without the AO's prior aid in helping the supplier achieve such compliance. That is, the supplier should be able to adhere to the quality standards on its own merits. We believe it would be a conflict of interest if the AO had effectively "coached" the supplier on how to pass the survey that the AO later performed. In addition, the AO might be reluctant to find non-compliance on the survey – even though such non-compliance exists -- because this could reflect poorly on the AO's pre-survey assistance. Either situation could lead to an unqualified DMEPOS supplier becoming accredited and enrolled. For this reason, we believe that certain protections against this activity are warranted and thus propose the following provisions.

We proposed in new § 424.58(m)(1) to define the terms "consulting" and "consulting services" for purposes of proposed paragraph (m). The terms would mean those services furnished by a DMEPOS AO (or by its consulting division or separate business entity (such as a

company or corporation) that furnishes such services) for the review of a DMEPOS supplier's standards, processes, policies, and functions for compliance with the AO's standards, the DMEPOS quality standards, or other Medicare requirements through simulation of a real survey, such as a mock survey, with comprehensive written reports of findings and early intervention and action to correct deficiencies prior to an actual accreditation survey. Importantly, we noted in the proposed rule that this definition would not be restricted to consulting that is fee-based.

We proposed in new paragraphs (m)(2)(i) through (iii) that, except as provided in proposed § 424.58(m)(3), an AO or its consulting division or separate business entity (such as a company or corporation that provides consulting) may not provide consulting services in the following instances:

- To any new supplier before the completion of the initial accreditation survey, meaning the first accreditation survey of a supplier that has not previously received accreditation services from that AO. If a supplier is later voluntarily or involuntarily terminated from that AO's services and thereafter retains the services of that same AO or a new one, the first survey of that supplier by the same or new AO would be considered an initial accreditation survey.
- To a supplier the AO accredits within 6 months prior to the supplier's next scheduled re-accreditation survey. A re-accreditation survey would be any subsequent accreditation survey the AO performs after the initial survey.
- To a supplier to which the AO furnishes accreditation services, in response to a complaint the AO receives concerning that supplier.

In paragraphs (m)(3)(i) through (iv), we proposed the following four situations where an AO, its consulting division, or separate business entity may provide consulting services to the suppliers it accredits.

The first is during the 6-month period after an initial or re-accreditation survey is performed. The second is when CMS or its contractor receives and investigates complaints about an AO's accredited supplier where an immediate jeopardy deficiency or basis for

revocation of enrollment under § 424.535 is identified. However, the consulting may occur only after the investigation is completed and can only address those issues identified in the investigation. The third and fourth are: (1) consulting services provided to suppliers that the AO does not accredit at the time the services are furnished; and (2) general education the AO furnishes about its accreditation program.

To help us confirm the AO's compliance with paragraph (m), we proposed in paragraph (m)(4) that the AO must furnish to CMS upon CMS' request and with each initial and reapproval application under paragraphs (c) and (d) of this section, a report containing the following information:

- Whether the AO or an associated consulting division or company the AO has established furnishes consulting services.
- The names, National Provider Identifiers, and addresses of all suppliers to which the AO or its associated consulting division or company has furnished consulting services during the prior 6-month timeframe.
- The dates such services were provided to each supplier.
- Whether the AO has ever furnished, or is currently furnishing, accreditation services to any supplier identified in the report.
- For each supplier listed in the report, the dates of: (1) its most recent accreditation survey; and (2) the next re-accreditation survey due to be performed.
- A description of the consulting services provided to each supplier in the aforementioned report.

In paragraph (m)(5)(i), we proposed that the DMEPOS AO, its consulting division, or separate business entity must have and comply with the following written consulting policies and procedures. At a minimum, these policies and procedures must include the following:

● The AO's consulting services must be furnished by a separate division of the AO or separate business entity (such as a company or corporation) that is separate from the AO's accreditation division.

● The AO's consulting division or separate business entity must maintain separate staff from that of the AO's accreditation divisions to ensure that--

++ The consulting division personnel do not conduct the AO's accreditation division functions; and

++ The AO's accreditation division staff do not conduct consulting division functions.

● An AO's accreditation staff and surveyors are prohibited from marketing the AO's consulting services to the AO's accreditation clients.

To help verify the AO's compliance with paragraph (m), we also proposed in new paragraph (m)(5)(ii) that an AO that provides consulting services must submit its written consulting firewall policies and procedures to CMS by a date specified by CMS and with each application for initial approval or reapproval.

11. Other Relationships Involving Potential Conflicts of Interest (New § 424.58(n))

a. AO/Supplier Relationships (New § 424.58(n)(1))

To further preserve objectivity in AO surveys, we proposed in new § 424.58(n) to expand upon the situations described in paragraph (m) to include relationships between AO officials and the suppliers the AO accredits.

In paragraph (n)(1)(i), we proposed that if an AO owner, surveyor or employee (currently or within the previous 2 years) had an interest in or relationship with (as described in proposed § 424.58(c)(1)(vii)(D)(*3*)) a DMEPOS supplier accredited by the AO, the AO owner, surveyor, or employee would not be permitted to--

● Participate in the survey of that DMEPOS supplier;

● Have input into the results of the survey and accreditation for that DMEPOS supplier;

● Have involvement with the pre-or post-survey activities for that DMEPOS supplier; or

- Have contact with or access to the records for the survey and accreditation of that DMEPOS supplier.

We believe these prohibitions would help reduce the risk that an AO owner, surveyor, or employee will improperly influence the DMEPOS supplier's survey and accreditation.

We proposed in revised § 424.58(b) to define "immediate family member" to help explain some of the conflict-of-interest affiliations that fall within § 424.58(c)(1)(vii)(D). So as to tie this definition to proposed (n)(1), we proposed in new paragraph (n)(1)(ii) that, for purposes of new paragraph (n)(1), the term "immediate family member" would have the same meaning as that in paragraph (b).

Per proposed § 424.58(c) and (d), the conflict-of-interest information described in § 424.58(c)(1)(vii)(D) would have to be furnished with the DMEPOS AO's initial and reapproval applications. Given this data's importance and the need to always avoid conflicts-of-interest, however, we also proposed in new paragraph (n)(1)(iii) that CMS may request any and all of this information at any time outside of the initial approval and reapproval processes.

To help the public better understand the relationship between the current final rule and the February 15, 2024, proposed rule, we have prepared the following table. It identifies three sets of our final provisions that, to varying degrees, duplicate certain provisions in the February 15, 2024, proposed rule but contains several notable differences.

TABLE 24: COMPARISON BETWEEN FINAL DMEPOS ACCREDITATION PROVISIONS AND THE PROVISIONS IN THE FEBRUARY 15, 2024, PROPOSED RULE

Provision	Proposed AO DMEPOS Rule	February 15, 2024, Proposed Rule	Differences
Definition of unannounced survey	See proposed 424.58(b)	Same as proposed 424.58(b)	Only difference is change from "facility" to "DMEPOS supplier" in proposed 424.58(b) (which only applies to DMEPOS suppliers)
Consulting	Prohibit all consulting services by an AO and	Prohibit all fee-based consulting services by	DMEPOS timeframe is 6 months instead of 12

Provision	Proposed AO DMEPOS Rule	February 15, 2024, Proposed Rule	Differences
	its associated consulting divisions or companies to any DMEPOS to which the AO provides accreditation services: (1) prior to an initial accreditation survey; and (2) within 6 months of the next scheduled re-accreditation survey.	an AO and its associated consulting divisions or companies to any health care provider or supplier to which the AO provides accreditation services: (1) prior to an initial accreditation survey; and (2) within 12 months of the next scheduled re-accreditation survey.	months due to the proposed annual reaccreditations. So as to not hinder otherwise legitimate consulting arrangements, DMEPOS restrictions limited to situations involving mock surveys performed by an AO. DMEPOS prohibitions would not be limited to "fee-based" consulting. It is the consulting service itself and the impact it could have on the survey's integrity – rather than whether compensation is involved – that is our central concern.
Conflict-of-Interest (COI)	AO submission of COI policies with each initial and reapproval application and upon CMS request.	AO submission of COI policies with each initial and reapproval application.	More infrequent submissions would reduce burden.

b. NPEC/AO Relationships (New § 424.58(n)(2))

NPECs (of which there are two nationwide) process DMEPOS Form CMS-855S enrollment applications. This involves, for example, (1) verifying the data the supplier furnished on or with the application; (2) performing a site visit; and (3) ensuring the supplier meets all Medicare requirements. The latter includes confirming that the supplier is accredited per § 424.58.

None of our current DMEPOS AOs are NPECs or parents or subsidiaries thereof. Yet we remain concerned about the potential for conflicts-of-interest between AOs and CMS contractors. We believe that any CMS contractor with any oversight responsibility of DMEPOS suppliers could also present conflict-of-interest issues. These could include, but would not be

limited to, Durable Medical Equipment Medicare Administrative Contractors (DME MACs), which process DMEPOS claims, and contractors that perform site visits of DMEPOS suppliers. To illustrate, suppose a DMEPOS site visit contractor (SVC) is also a DMEPOS AO. The entity performed a survey of, and accredited, DMEPOS Supplier X. In its role as an SVC, it conducted a site visit of X 3 months later. Although X did not appear meet the definition of "operational" in § 424.502, the entity might be reluctant to make this finding because it could cast doubts on the thoroughness of its AO survey 3 months earlier. This could result in the supplier becoming enrolled and receiving payments while non-operational.

To avoid such conflict-of-interest situations and to help facilitate the impartiality of DMEPOS AO accreditation decisions, we proposed in new § 424.58(n)(2) that an entity may not serve as a CMS-approved DMEPOS AO if it is currently a CMS contractor -- or an owner or subsidiary thereof (regardless of the ownership percentage involved) -- with any oversight responsibility of DMEPOS suppliers. We also solicited comment on whether this prohibition should extend to situations where, similar to paragraph (n)(1), there are familial relationships between owners and employees of DMEPOS AOs and the CMS contractor -- for instance, whether an organization should be prohibited from being a DMEPOS AO if it has owners or employees who are immediate family members of NPEC owners or employees.

12. AO Changes of Ownership (New § 424.58(o))

Section 488.5(f) contains detailed procedures for when an AO undergoes a change of ownership (as that term is defined in § 489.18(a)(1) through (3)). We thus proposed in new § 424.58(o) that DMEPOS AO changes of ownership would be governed by § 488.5(f).

13. Requirement for Suppliers to be Accredited (Revisions to § 424.57)

As already noted, § 424.57 primarily addresses conditions of payment and supplier standards that suppliers must meet to enroll in and bill Medicare. Yet it also addresses accreditation requirements for DMEPOS suppliers; specifically, § 424.57(c)(22) states that these suppliers and all of their locations must be accredited by a CMS-approved AO to receive and

retain a supplier billing number. Given our proposed strengthening of the DMEPOS accreditation program requirements in § 424.58, we believe corresponding enhancements to § 424.57 are necessary.

a. Temporary Accreditation and Requirement of Survey (§ 424.57(c)(23))

The second sentence of 424.57(c)(23) states that the AO may accredit a new supplier location for three months after it is operational without requiring a new site visit. We proposed to remove this sentence from § 424.57(c)(23) because it contradicts proposed § 424.58(e)(8)(i)(A) and (C). Consistent with what we previously explained in this final rule, allowing a supplier to become accredited for 3 months without the important vetting of a survey and the AO's review of the survey results presents a serious risk of beneficiary harm and improper Medicare payments, which we must prevent.

b. Accreditation Frequency (§ 424.57(c)(22) and (24))

(1) Structural Change

Section 424.57(c)(24) states that all DMEPOS supplier locations, whether owned or subcontracted, must meet the quality standards and be separately accredited in order to bill Medicare. As this requirement mirrors that in § 424.57(c)(22) to some extent, we proposed to move the current language in § 424.57(c)(24) to § 424.57(c)(22). Revised § 424.57(c)(22) would state the following:

- All DMEPOS suppliers and all of their locations (whether owned or subcontracted) must meet the quality standards and be separately accredited to enroll in and bill Medicare.
- The accreditation must indicate the products and services for which the supplier is accredited in order for the supplier to receive payment for those products and services. (This language is in current § 424.57(c)(22).)
- An accredited supplier's enrollment may be denied or revoked if CMS determines that it is non-compliant with the quality standards. (This language is currently in § 424.57(c)(24).)

(2) Accreditation Periods (Revised § 424.57(c)(24))

While neither § 424.57 nor § 424.58 address the frequency with which surveys must be performed or how often a supplier must be reaccredited, we have issued sub-regulatory guidance stating that DMEPOS suppliers must undergo an unannounced survey once every 3 years following initial accreditation. Yet we reiterate that perhaps no other provider or supplier type over the decades has been the subject of CMS' provider enrollment program integrity efforts more than DMEPOS suppliers. For this and other reasons outlined in the proposed rule, we are concerned that performing DMEPOS supplier surveys only once every 3 years provides inadequate protection for the Medicare program. Again, non-compliant suppliers can endanger the Trust Funds as well as beneficiaries, and we believe the best means of ensuring suppliers' quality standard adherence is through closer and more frequent monitoring of suppliers. In our view, the longer a DMEPOS supplier goes without the scrutiny of a survey and reaccreditation, the greater the chances the supplier will fall out of compliance with the quality standards during this period. We also believe that more frequent surveys and reaccreditations will spur suppliers to maintain consistent adherence to the quality standards, for they will know their next survey would be much sooner than every 3 years.

To address what we believe is this very serious vulnerability, we proposed in revised § 424.57(c)(24) that DMEPOS suppliers must be surveyed and reaccredited at least once every 12 months. We recognize that this could prove burdensome for DMEPOS suppliers, but we again emphasize the importance of protecting the Trust Funds and the health and safety of Medicare beneficiaries.

In our later discussion of this particular proposal, the public comments we received on it, and our responses to these comments, we will occasionally refer to this as an "annual" requirement (for example, "annual reaccreditation" or "annual survey") for ease of reading. Yet we reiterate that § 424.57(c)(24) would require surveys and reaccreditations to occur "at least" every 12 months, rather than "every 12 months". The distinction is critical. Suppliers should not assume that AOs must or will wait until exactly 12 months after the supplier's previous survey to

perform the present survey. To illustrate, suppose Supplier X's reaccreditation survey occurs on June 1, 2027. X should not automatically presume that the next reaccreditation survey will take place on or even around June 1, 2028. The survey could in fact occur many weeks before that. Furthermore, we remind stakeholders of our proposal to perform ad-hoc surveys at any time and for any reason. In short, suppliers must always remain fully prepared to be surveyed and should not base the timing of its compliance with the quality standards on when it predicts the next survey will occur. Compliance is constantly required and is always subject to unannounced assessment by the AOs.

c. Changes in Majority Ownership and the "36-Month Rule"

Existing § 424.550(b)(1) states if an HHA or hospice undergoes a change in majority ownership (occasionally referenced as a "CIMO") by sale within 36 months after the effective date of the HHA's or hospice's initial enrollment in Medicare or within 36 months after the HHA's or hospice's most recent CIMO, the provider agreement and Medicare billing privileges do not convey to the HHA's or hospice's new owner. Instead, the prospective provider/owner of the HHA or hospice must: (1) enroll in Medicare as a new (initial) HHA or hospice; and (2) obtain a state survey or an accreditation from an approved accreditation organization. (This is sometimes referenced as the "36-month rule"). As defined in 42 CFR 424.502, a CIMO occurs when a party acquires more than a 50 percent direct ownership interest in an HHA or hospice during the 36 months following the HHA's or hospice's initial enrollment or most recent CIMO. CIMOs can include an acquisition of majority ownership through the cumulative effect of asset sales, stock transfers, consolidations, or mergers.

There were two principal reasons for the establishment of § 424.550(b)(1) . First, there was a trend in the HHA community whereby an HHA applied for Medicare certification, underwent a survey, and became enrolled in Medicare, but then was immediately sold. This practice enabled a purchaser of an HHA from the broker to enter Medicare with no survey, which, in turn, sometimes led that owner to soon sell the business to another party, again without

a survey. This mechanism, in short, was used to circumvent the survey process. Second, we were more broadly concerned about the lack of scrutiny of new owners as a whole, If an HHA undergoes a change of ownership, CMS generally does not perform a survey pursuant thereto. CMS consequently has no sure way of knowing whether the HHA, under its new ownership and management, is compliant with the HHA CoPs. Unless CMS can make this determination, there is a risk that the newly purchased HHA, without having been appropriately vetted, will bill for services when it is out of compliance with the CoPs. We had the same concerns regarding hospices, and in 2023 accordingly added hospices to § 424.550(b)(1)'s purview.

We have already addressed in detail the long-standing program integrity risks in the DMEPOS supplier community Enhancing this dilemma is the fact that when a DMEPOS supplier ownership change crosses the 50 percent threshold, the AO typically does not perform a survey to assess compliance with the quality standards. Therefore, we cannot determine whether the DMEPOS supplier under its new majority ownership will be committed to adhering to all Medicare requirements and to protecting beneficiaries. There have been a significant number of such DMEPOS supplier ownership changes over the years, many of which have occurred within 36 months of initial enrollment or the supplier's most recent CIMO – sometimes, in fact, within only a few months of initial enrollment or the previous sale. We believe we must ensure that DMEPOS suppliers under their new ownership receive the same level of scrutiny that initially enrolling DMEPOS suppliers do.

We accordingly proposed in new § 424.551 to mirror the provisions of existing § 424.550(b)(1) such that a DMEPOS supplier undergoing a CIMO must enroll as a new DMEPOS supplier and be newly accredited and surveyed under § 424.58. We also proposed to do the following:

- Duplicate § 424.502's definition of change in majority ownership within § 424.551 (though slightly tailored to apply to DMEPOS suppliers).

- Revise § 424.540(a)(8) to state that CMS can deactivate the enrollment of a seller of a DMEPOS supplier if the supplier undergoes a CIMO in accordance with § 424.551. (As noted in section VI.A. of the proposed rule, § 424.540(a)(8) currently includes HHAs, and we are proposing to include hospices therein, too.)

- Add new paragraph (h) to § 424.57 to emphasize that a DMEPOS supplier must comply with the provisions of § 424.551 if it undergoes a CIMO.

We noted in the proposed rule that § 424.550(b)(2) contains several exceptions to the 36-month rule. Specifically, even if an HHA or hospice undergoes a CIMO, the requirement in § 424.550(b)(1) that the HHA or hospice enroll as a new HHA or hospice and undergo a survey or accreditation does not apply if any of the following four exceptions (outlined in § 424.550(b)(1)) are implicated:

- The HHA or hospice submitted 2 consecutive years of full cost reports since initial enrollment or the last CIMO, whichever is later.

- An HHA's or hospice's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.

- The owners of an existing HHA or hospice are changing the HHA's or hospice's existing business structure (for example, from a corporation to a partnership (general or limited)), and the owners remain the same.

- An individual owner of an HHA or hospice has died.

We originally promulgated these exceptions because the HHA community had expressed concerns that the 36-month rule could inhibit bona fide HHA ownership transactions; for example, prospective new owners may not wish to have to enroll as a new HHA and will therefore decline to purchase the entity. We believed that our exceptions struck a solid balance between the need for more scrutiny of new owners via the survey process while not inadvertently obstructing legitimate transactions involving legitimate parties. Accordingly, we proposed to duplicate existing § 424.550(b)(2)(ii) through (iv) as exceptions within proposed new § 424.551,

though current § 424.550(b)(2)(i) would not be mirrored because DMEPOS suppliers do not submit cost reports.

14. Solicitation of Comments

We solicited comments from AOs, DMEPOS suppliers, and other stakeholders regarding our DMEPOS accreditation proposals. We were particularly interested in receiving comments on the following:

- The amount and types of additional information that AOs would have to submit with their initial and reapproval applications per new § 424.58(c) and (d). For instance--

++ Whether there is data we proposed to collect that is unnecessary, superfluous, or duplicative of other requested information; and

++ Whether there is information that should be submitted beyond what we are proposed to require.

- Whether there are any grounds beyond those proposed at § 424.58(e)(5) for which the AO should be required to deny or terminate a supplier's accreditation and, if so, what those grounds were.

- The requirement in proposed § 424.58(e)(8)(i) that, except as otherwise directed or permitted by CMS, the AO perform a survey of all suppliers seeking accreditation or reaccreditation with the AO.

- Whether there were any grounds beyond those listed in § 424.58(h), (i), and (j) for which CMS should be able to terminate, suspend, or place on probation the AO's accreditation program and, if so, what those grounds were.

- Whether DMEPOS suppliers should be surveyed and reaccredited under § 424.57(c)(24) less frequently than the timeframe described therein and, if so, what the survey and reaccreditation timeframe should be.

15. Costs and Savings

The collection of information and regulatory impact analysis sections of the proposed rule addressed the net cost burden associated with our DMEPOS accreditation provisions. We projected that it would exceed $128 million annually. We understand the financial impact this could have on the DMEPOS community. However, we note that we anticipate over $660 million in annual savings to the Medicare Trust Funds and the taxpayers due primarily to the removal of non-compliant DMEPOS suppliers from the Medicare program. Of no less importance, we believe that more frequent surveys, ad-hoc surveys, and stricter requirements for AOs will encourage DMEPOS suppliers and AOs to be much more vigilant in maintaining and verifying compliance with the quality standards. To illustrate, with ad-hoc surveys, a DMEPOS supplier will not know whether or when it will be selected for such a survey, meaning that the supplier could believe that it is compelled to never allow itself to fall out of compliance with the quality standards, even for an extremely brief period. With the quality standards being designed in large part to protect beneficiaries, we believe that greater compliance therewith will reduce risks to patients' health safety from, for example, substandard DMEPOS items, inadequate equipment instructions, and poor customer service.

Hence, we concluded that notwithstanding the burden associated with these requirements, the saving of potentially billions of taxpayer dollars and the preservation of beneficiary safety justify it.

16. Comments Received

a. Annual Surveys and Reaccreditations (Revised § 424.57(c)(24))

Comment: Many commenters opposed our annual survey and reaccreditation proposal. These commenters believe that this would impose significant operational, administrative, and financial burdens on DMEPOS suppliers due primarily to: (1) more frequent accreditation fees; (2) more reaccreditation paperwork; and (3) having to devote more staff time and resources to surveys and reaccreditations and the supplier's preparations for them. Numerous commenters stated that these burdens could be especially difficult for smaller and community-based

DMEPOS suppliers, some of which are financially struggling, operate on small profit margins and, with our proposal, could be compelled to close. These commenters added that while larger supplier organizations have the financial and personnel resources to handle annual reaccreditations, smaller companies do not. This could mean that the DMEPOS industry might eventually be limited to large supplier organizations as smaller suppliers drop out or no longer take Medicare; many patients would be unable to purchase these supplies out-of-pocket. With fewer suppliers, the commenters concluded: (1) patient choice and access to care would be restricted; and (2) longer patient wait times could result because the remaining suppliers would have to service more patients.

Response: We appreciate these comments and understand the concerns expressed. We recognized in the proposed rule the financial impact our requirements could have on suppliers. Yet we note several things.

First, as already noted, the proposed rule calculated an annual savings to the Medicare program via this requirement of more than $660 million. We believe these savings will benefit all Americans, including DMEPOS suppliers, by helping to limit inappropriate payments to non-compliant suppliers. While we acknowledge the potential direct financial burden on otherwise compliant DMEPOS suppliers, we believe these suppliers will accrue indirect benefits via: (1) savings to the Trust Funds; and (2) the Medicare revocation of suppliers that are not as committed to adhering to the quality standards as compliant suppliers are. Indeed, we received comments from the latter group of suppliers expressing frustration that fraudulent and non-compliant suppliers are harming the DMEPOS arena. We fully concur, and we believe their removal from Medicare – which, in our view, our annual reaccreditation requirement will help facilitate via the closer analysis of supplier operations – will assist in addressing said frustrations.

Second, and in a similar though broader vein, we have an obligation to the American people at large to ensure the accurate spending of taxpayer dollars for Medicare services and items. If a DMEPOS supplier is non-compliant with the quality standards – which, we

emphasize, can only be ascertained via a survey and accreditation – Americans' tax monies are threatened if payment is made to a supplier that is not qualified to participate in Medicare. We must do everything possible to fulfill our role as the financial steward of the Medicare program. Given this, the greater the frequency of surveys, the better we can ensure that taxpayer dollars are not improperly paid.

Third, in January 2, 2009, **Federal Register** (74 FR 166), we published a final rule in the titled "Medicare Program; Surety Bond Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)". This final rule required non-exempt suppliers to acquire and maintain a surety bond in the amount of at least $50,000 as a condition of enrollment. The preamble of the January 2009 final rule noted that commenters had expressed concern about the monetary impact of the bond requirement on small businesses, specifically the bond's annual cost (74 FR 171). They believed that many of these suppliers would have to depart the Medicare program due to an inability to sustain the bond's costs. However, we did not experience such an exodus, and the vast preponderance of small suppliers were able to purchase and maintain the bond. We also did not see from our surety bond requirement: (1) larger suppliers taking over the DMEPOS arena from smaller suppliers; or (2) patient access to care problems. Accordingly, based on this past experience, we believe smaller suppliers will generally be able to afford annual reaccreditations to the extent they did with bonds, with no material decrease in their overall participation in Medicare or in beneficiary access to care.

In sum, although we understand commenters' concerns about revised § 424.57(c)(24), we reiterate our responsibility to safeguard the expenditure of Americans' tax dollars for Medicare services and items. Failing to ensure that DMEPOS suppliers are always adherent to the quality standards (rather than merely compliant once every 3 years) is directly antithetical to this.

Comment: Multiple commenters stated that CMS should offset the financial burden of additional fees, surveys, etc., with increased reimbursement to DMEPOS suppliers; this would

lessen the monetary impact of our proposal. Without said raise in reimbursement, the commenters stated, CMS should not finalize this provision.

Response: We most respectfully disagree. We certainly understand the commenters' concerns, but we are unable to make our program integrity efforts dependent upon whether the affected providers or suppliers receive an offsetting increase in reimbursement, for such increase may not be possible regardless. To illustrate, assume there have been numerous payment safeguard problems involving Provider Type X, whereby millions of dollars have been paid to fraudulent providers. We believe a particular initiative, though imposing some burden on providers of Type X, could significantly alleviate this fraud. Under the commenters' suggestion, we could not undertake this initiative unless Type X providers receive additional payments. Since higher reimbursement might not occur, Type X fraud would continue unbated and place tens or even hundreds of millions of dollars at risk. CMS' payment safeguard efforts across the board would be obstructed if they had to be tied to a concomitant rise in provider/supplier payments.

Comment: Several commenters believed that revised § 424.57(c)(24) was unnecessary because DMEPOS suppliers already undergo extensive screening and review, such as via: (1) accreditation every 3 years; (2) enrollment site visits; (3) enrollment criminal background checks of the supplier's owners; and (4) the surety bond process. They added that the current 3-year cycle already adequately ensures supplier compliance and protects beneficiaries.

Response: As we explained at length in the proposed rule and this final rule, these and other screening mechanisms -- important and beneficial though they have been -- have not by themselves adequately halted DMEPOS supplier non-compliance or the problem of payments to such suppliers. More is needed, and we believe increasingly frequent examinations of quality standard compliance could assist in this regard.

Comment: Numerous commenters stated the current 3-year cycle is sufficient because it strikes a good balance between the need for oversight of suppliers and the importance of

reducing supplier burden and enabling suppliers to focus on patient care and business sustainability.

Response: We respectfully disagree that the existing 3-year timeframe is adequate. We noted in the proposed rule and this final rule that some suppliers fall out of compliance with the quality standards during this very lengthy period and remain non-compliant for an extended timeframe. As an example, suppose Supplier Y, a high-volume biller, no longer complies with the quality standards beginning 6 months after its most recent accreditation. With a 3-year cycle, millions of Medicare dollars might be paid to a supplier that was non-compliant for up to 2.5 years (until its next reaccreditation). Under an annual cycle, though, the non-adherence could have been detected much sooner, thus saving considerable taxpayer monies. Furthermore, we reiterate that the quality standards are designed to protect the health and well-being of beneficiaries by ensuring that the supplier meets strict guidelines involving product safety and consumer services. With the possibility that a supplier's non-adherence to the quality standards could result in beneficiary harm, there might be a greater chance for such harm the longer the period of non-compliance. Yet this risk would be minimized with more frequent surveys. Accordingly, for purposes of both patient safety and program integrity, we believe revised § 424.57(c)(24) is needed.

Comment: Several commenters stated that more paperwork and administrative burden does not correlate to increased quality of care, adding that said burden would divert supplier time and resources from patient care. They further stated that: (1) a sizable portion of DMEPOS suppliers' daily functions involve paperwork, documentation, etc., which cuts into their available time to spend on beneficiary care; (2) some suppliers are already short-staffed, with employees having to perform multiple roles and being unable to take on additional burden. They believed that revised § 424.57(a)(24) would exacerbate these issues, particularly since some suppliers cannot afford to hire additional staff. Other commenters stated that suppliers that can afford to hire personnel would undoubtedly have to do so to accommodate our requirement, hence costing

the supplier additional funds that the supplier could otherwise use to invest in and improve its business.

Response: We appreciate and understand these concerns. Yet we most respectfully believe that DMEPOS suppliers should not view the requirement strictly as increased paperwork but instead as a means of protecting patients and taxpayer dollars, both of which can benefit DMEPOS suppliers. For instance, when an accreditation organization finds a supplier non-compliant with the quality standards and the supplier is accordingly revoked from the Medicare program, this helps protect the tax dollars of DMEPOS suppliers and their personnel no less than those of other Americans. Moreover, while again recognizing the additional burden of revised § 424.57(c)(24), we stress that this provision would only require a survey and reaccreditation at least once every 12 months and would not involve, for example, a tri-annual burden. Even acknowledging the time and effort a supplier may expend in preparing for and undergoing more frequent surveys, we do not believe it would be so extensive as to materially impact (from a time perspective) the supplier's patient care or other services over the course of a given year.

Comment: Numerous commenters expressed concern that AOs will increase their fees to cover the additional costs associated with having to perform more surveys (for example, hotel and travel costs).

Response: Although we respectfully cannot predict this requirement's impact on AOs' per-supplier fees, it is possible that they may increase. It is also possible, though, that they will not change because the AOs' costs may be covered by the greater number of fees that DMEPOS suppliers will pay under revised § 424.57(c)(24).

Comment: Several commenters stated that revised § 424.57(c)(24) would be inconsistent with the 3-year survey cycle for hospitals, HHAs, and certain other providers. Since hospitals and HHAs have a 3-year cycle, DMEPOS suppliers should, too.

Response: We respectfully disagree. All provider and supplier types are different, including with respect to the program integrity risks they pose. Simply because a particular

provider type has a certain survey cycle does not mean all other provider and supplier types must have the same. We noted in the proposed rule and this final rule the very serious and longstanding payment safeguard issues involving DMEPOS suppliers. Thus, we believe it is appropriate to tailor the DMEPOS survey cycle to the risk these suppliers present, hence the proposed shorter period.

Comment: A number of commenters requested that CMS permit sampling as a standard practice, especially for State-licensed and chain pharmacies. Several commenters recommended using criteria such as size, geographic locations, product codes, and past accreditation performances. Another commenter recommended that CMS establish a uniform sampling approach that all AOs must follow. An additional commenter stated that CMS should explicitly permit sampling via rulemaking and not have CMS personnel making sampling decisions.

Response: We appreciate this feedback. As we indicated in the proposed rule, we cannot commit to permitting sampling due to the need to ensure that all DMEPOS suppliers (regardless of sub-type) are compliant with the quality standards. However, we also recognized that there could be isolated instances where it might be warranted, hence our proposal in § 424.58(c)(1)(iii)(G) to have AOs discuss their suggested sampling methodology. Whether we will allow sampling at a later time will depend on circumstances, but we will attempt to ensure consistency and take into account several factors (potentially, for instance, geographic locations) should it be permitted. Regarding the final commenter's feedback, we reiterate our role in preserving the Trust Funds from inappropriate payments and safeguarding patient safety. Therefore, we must have the discretion to identify if or when sampling should be undertaken.

Comment: A commenter expressed concern about the impact on smaller suppliers and stated that some of the fraud and non-compliance examples cited in the proposed rule seem limited to larger suppliers with extensive billing events and do not involve small businesses. Other commenters stated that revised § 424.57(c)(24) should be restricted to larger suppliers (perhaps those with at least 10 locations), since they are financially the best equipped to absorb

the extra costs. A commenter contended that our proposed requirement seems to be one-size-fits-all in nature, treats all suppliers the same, and ignores resource disparities between large and small suppliers. The commenter stated that: (1) some small, minority-owned businesses do not have compliance teams or legal departments; and (2) a uniform approach harms small, local suppliers in underserved communities.

Response: Although we appreciate the commenters' concerns, neither the examples in the proposed rule nor the other cases we have seen are limited to larger suppliers. Indeed, non-compliance with the quality standards can occur with smaller suppliers as frequently as with larger ones. Accordingly, we cannot restrict our requirement to large supplier organizations.

Comment: A commenter stated that many of the fraud and abuse examples in the proposed rule were for new suppliers located in high-risk areas.

Response: We respectfully disagree. Some cases: (1) were in states not traditionally considered to pose very high risks of fraud; and (2) involved suppliers that had been enrolled in Medicare for some time. DMEPOS non-compliance can occur in any area of the country and involve suppliers enrolled for any length of time.

Comment: Numerous commenters expressed uncertainty as to how accreditating organizations will secure the staff and resources to perform the new surveys and reaccreditations. Several commenters stated that because the AOs would now have to perform so many surveys and employ numerous additional surveyors, the AOs might: (1) hire whatever staff they can – including unqualified surveyors – to cover the additional surveys and reaccreditations; and (2) conduct rushed and substandard surveys to ensure it can perform the extra work under this requirement, which, in turn, could harm the integrity of the survey process. They added that the current 3-year cycle gives AOs adequate time to perform thorough surveys and reaccreditation reviews. A commenter stated that the AOs would be unable to acquire enough staff to perform the surveys. Other commenters contended that AO survey delays that currently exist due to lack of staff would only get worse with an annual survey requirement. Too, a commenter stated that

CMS has not demonstrated how the AOs would expand their infrastructure to meet demand without impairing survey quality or causing accreditation delays. Additional commenters did not believe the AOs would have the resources to perform annual surveys and reaccreditations.

Response: We appreciate these comments. CMS is not positioned to publicly outline in minute detail how each AO will expand their operations to carry out this requirement; we believe this is a matter largely internal to the AOs. Nonetheless, and as a general view, we are confident that the AOs will have the ability to perform more frequent surveys and reaccreditations in a timely and thorough manner for two principal reasons. First, we believe the additional fees the AOs will receive will enable them to hire additional surveyors and other personnel to implement and effectively carry out revised § 424.57(c)(24); in other words, the increased income from fees will cover the increased workload. Second, the significant enhancement of our oversight of AOs – both initially and on an ongoing basis – will allow us to closely review and monitor AOs to ensure they have the capacity to timely and satisfactorily conduct these activities with qualified personnel. Should significant delays occur or survey quality decreases, though, we will work to alleviate these issues.

Comment: Several commenters stated that if revised § 424.57(c)(24) overwhelms the AOs' operations and leads to survey delays, some suppliers may be forced to suspend operations until the survey is performed, which could harm patient access to care.

Response: For reasons stated in our prior response, we believe the AOs will be able to effectively and timely handle the required surveys and reaccreditations; this will reduce the potential for temporary cessations of supplier operations.

Comment: A commenter stated that our proposed requirement appears to stem from the recent fraud activity of large DMEPOS suppliers – not small suppliers -- established during the pandemic that were not required to go through the normal verification process. The commenter questioned which DMEPOS AOs were responsible for accrediting those suppliers recently found guilty of fraud and whether there was a common denominator involved.

Response: While we are not in a position to publicly identify AOs that may have accredited fraudulent suppliers, we stress two things. First, and as previously stated, the disconcerting DMEPOS supplier activities we have seen are not restricted to large suppliers but also involve smaller suppliers; these cases, furthermore, did not necessarily result from relaxed verification procedures during the pandemic. Second, our proposals stem predominantly from concerns about suppliers not meeting the quality standards – irrespective of whether any fraud is involved. We have already emphasized that non-compliance with the quality standards can lead to: (1) hundreds of millions of dollars in improper payments; and (2) beneficiary harm.

Comment: A number of commenters stated that revised § 424.57(c)(24) could be especially difficult on suppliers with multiple locations, since each site would be impacted (for example, accreditation fees paid for each location); large chain pharmacies, in particular, might have to pay tens of thousands of dollars in fees to have all of their sites surveyed.

Response: We thank the stakeholders for these comments but reiterate that § 424.57(c)(24) requires all DMEPOS locations to meet the quality standards and be separately accredited in order to bill Medicare. There is no exception for suppliers with multiple locations, meaning, in our view, that the cycle for such suppliers should mirror that for single-site suppliers. Furthermore, our obligation to protect the Trust Funds and beneficiaries from non-compliant suppliers is the same regardless of the supplier's organizational status. While we understand the commenters' concerns, we also note that larger supplier organizations will likely have a greater financial capacity to bear the costs of an annual survey for their various locations.

Comment: Several commenters stated that annual surveys of all locations of national suppliers is redundant and unnecessary because these suppliers already operate under standard national policies and procedures.

Response: Although we appreciate this comment, individual sites of nationwide suppliers can lose compliance with the quality standards no differently than other supplier subtypes, even if the national organization has centralized and uniform policies and procedures.

Comment: Numerous commenters stated that revised § 424.57(c)(24) would not stop fraud or improve patient outcomes or safety, and there is no data to suggest it would. Several commenters stated that surveys are not intended to assess adherence to the False Claims Act, the Anti-Kickback Statute, other anti-fraud federal laws, or Medicare billing requirements. Other commenters contended that it appears CMS is attempting to turn AOs and their staffs into legal experts, law enforcement officials, anti-fraud investigative entities, and billing specialists. Another commenter stated that nefarious individuals will simply seek new and different means of continuing their fraudulent conduct notwithstanding revised § 424.57(c)(24); this could even include finding gaps within the annual accreditation process itself. Several commenters stated that there is no evidence that accredited orthotic and prosthetic facilities have committed fraud.

These and other commenters contended that there are more effective means for CMS to combat DMEPOS supplier fraud, waste, and abuse than revised § 424.57(c)(24). Among the commenters' suggestions were: (1) data analytics; (2) focusing on billing claims; (3) random audits; (4) digital compliance; (5) enhanced reporting; (6) increased and unannounced site visits; (7) concentrating on higher-volume billers or higher-risk suppliers (for example, those under foreign ownership); (8) more severe penalties for supplier fraud; (9) requiring that DMEPOS suppliers have compliance programs; (10) increased use of pre-payment and post-payment audits; (11) taking action against suppliers with a history of beneficiary complaints; (12) requiring increased document submission requirements by suppliers (for example, copies of policies and equipment records, photos, etc.); (13) requiring AOs to report all suspected fraud to CMS for investigation; (14) requiring annual document submissions, attestations, and provider enrollment revalidation; (15) greater beneficiary participation in CMS' program integrity efforts; (16) requiring suppliers to maintain and submit logs of annual fraud, waste, and abuse training completions and to submit a full documentation packet to their AO, with annual updates limited to any changes in policies or procedures; (17) virtual surveys (rather than in-person) and virtual

review of patient and personnel files; (18) interviewing supplier staff; and (19) increased supplier education and training.

Response: We respectfully believe there may be a misunderstanding regarding the purpose of our proposal. It is true that we cited numerous instances of DMEPOS fraud in the proposed rule to highlight the persistent program integrity problems involving this supplier type. In addition: (1) several quality standards at least indirectly touch upon the issue of fraud (for example, having practices to prevent fraud, waste, and abuse and to ensure accurate billing); and (2) we proposed that AOs establish policies for detecting and addressing potential fraud, waste, and abuse. Yet as we indicated in the proposed rule, the core aim of this requirement is to better ensure suppliers' consistent compliance with the quality standards, which would, in turn, reduce inappropriate payments to non-adherent suppliers and help protect beneficiaries. In other words, the issue is non-compliance as a whole, regardless of whether this non-compliance also rose to the level of knowing fraudulent conduct. The AOs are not (and have never been) expected to actively investigate the supplier's operations for fraudulent conduct beyond what they might ordinarily uncover during the standard survey processes they have historically used. Indeed, we recognize that the AOs are not fraud examiners and note that we have instead primarily used a number of the commenters' suggested program integrity measures (as well as others) to detect fraud; this includes, for instance, enhanced focus on certain high-risk DMEPOS supplier types and geographic areas. Notwithstanding all of this, though, it is possible that an AO could uncover a supplier's potential fraud, waste, and abuse during a particular survey (for example, while reviewing patient records), perhaps even as part of a larger fraud scheme.

We hope the foregoing clarifies for stakeholders the principal goal of this requirement.

Comment: Several commenters stated that our proposal is merely: (1) a sudden reaction to a few problematic parties in the DMEPOS supplier and AO communities; and (2) an attempt to compensate for the failures of CMS' contractors, auditors, oversight systems, etc., to halt

improper DMEPOS activity. They urged CMS to correct these issues instead of burdening DMEPOS suppliers and the AOs.

Response: We respectfully disagree with these comments. We reiterate that the purpose of accreditation is to confirm quality standard compliance and not to detect fraud; these are two entirely separate activities that do not necessarily overlap. Accordingly, we are not using tightened accreditation standards as a substitute for any lack of anti-fraud enforcement success; indeed, we have worked extremely hard over the years via many vehicles to stem DMEPOS supplier fraud. In addition, while we were determined to take prompt action to address issues in the DMEPOS accreditation arena and facilitate quality standard compliance, this does not mean it was devised without any forethought or careful consideration. We diligently examined the potential benefits and drawbacks of more frequent accreditations and, after lengthy consideration, determined that this was the soundest approach.

Comment: A commenter stated that CMS should ensure that outreach and training regarding these requirements are available in Spanish; this should include technical assistance to suppliers in Puerto Rico.

Response: We appreciate this comment and intend to undertake educational efforts regarding this requirement towards DMEPOS suppliers throughout the United States and its territories.

Comment: Commenters stated that many suppliers have always remained fully adherent to the quality standards as evidenced by their successful surveys and reaccreditations. They believed that our proposal would only harm these suppliers, and that it is unfair to punish them for the actions of a few unscrupulous suppliers.

Response: We thank the commenters for their views. We certainly understand that there are numerous DMEPOS suppliers that have routinely passed their surveys every 3 years. However, absent a survey and reaccreditation, we have no means of confirming whether a DMEPOS supplier has fallen out of quality standard compliance at some point during this

lengthy period; in addition, merely because a DMEPOS supplier passed its previous surveys does not automatically mean that it will remain compliant with the quality standards for another 3 years. As we explained in the proposed rule and this final rule, non-compliance for any period of time can lead to millions of dollars in inappropriate payments and the potential for patient harm. This is a particular concern regarding DMEPOS suppliers given, as already noted, the high program integrity risk this supplier type has historically posed in comparison to other provider and supplier types. While we appreciate DMEPOS suppliers' concerns about burden, we again stress our obligation to beneficiaries and the taxpayers to ensure that DMEPOS suppliers are constantly adherent to all Medicare requirements, hence the need for our provisions. Too, and as noted previously, the prevention of potentially billions of dollars in inappropriate payments and the protection of beneficiaries benefits all Americans, including DMEPOS suppliers and their personnel.

Comment: Several commenters stated that the accreditation process is designed to determine compliance with the quality standards and is not a regulatory compliance process.

Response: The commenters are correct regarding the accreditation process's central purpose of verifying quality standard adherence. However, it is a regulatory compliance process as well because quality standard adherence is required per regulations at § 424.57(c)(22).

Comment: Numerous commenters expressed particular concern about the impact this requirement could have on: (1) rural suppliers; (2) underserved areas; and (3) suppliers that furnish very specialized services and items and, consequently, may be the only supplier within a wide geographic region. The commenters stated that if these suppliers were forced to close due to the burden of revised § 424.57(c)(24), many beneficiaries could be left without any reasonably proximate access to services and items. Several commenters added more generally that some communities have only one supplier, which could be compelled to cease operations under our proposal.

Response: We respectfully do not anticipate a material reduction in the number of DMEPOS suppliers – whether rural or urban, in underserved regions, etc. – resulting from the additional costs of revised § 424.57(c)(24). In implementing provider enrollment-related initiatives over many years that imposed costs on DMEPOS suppliers (for instance, surety bonds, fingerprint-based criminal background checks, stringent enrollment requirements, etc.), we did not see access to care problems arising for DMEPOS beneficiaries. We believe the same will occur under our proposal, though we will closely observe this matter during and after the implementation of our requirement.

Comment: A commenter stated that, for multi-location supplier organizations, patients serviced by a particular location could lose access to care if said site fails the survey.

Response: We appreciate this comment but reiterate that all DMEPOS suppliers must meet the quality standards to enroll in and bill Medicare, even if this unfortunately means a particular location may be found non-compliant and revoked from Medicare, thus potentially removing a beneficiary's preferred supplier site. While, as stated, we will monitor the implementation of our requirement for any resulting patient access issues, we do not expect them to occur. We note that over the years we have revoked DMEPOS suppliers without beneficiaries losing the ability to obtain care from other suppliers.

Comment: A commenter questioned the need for more frequent surveys and reaccreditations when, according to the commenter, CMS does not effectively utilize the information that AOs already furnish to CMS.

Response: We respectfully disagree. We indeed review the data the AOs provide to us; in fact, this assisted us in the development of our proposals. We also do not believe that our examination of AO-submitted information is related to the matter of accreditation frequency. The latter should not be predicated on the former; for reasons already stated, we must enhance the AOs' oversight of DMEPOS suppliers irrespective of the level of our review of AO data.

Comment: Several commenters stated that the current 3-year cycle allows: (1) DMEPOS owners, practitioners, technicians, and billing staff to learn and improve over an extended period; and (2) DMEPOS owners to build their business based on auditor observations, which would help ensure compliance with DMEPOS requirements. Another commenter stated that the value of the accreditation process is when it is consultative in nature.

Response: We sincerely thank the stakeholders for this feedback but disagree for two reasons. First, while the survey process can help suppliers better understand the quality standards and improve supplier performance, surveys for purposes of our DMEPOS accreditation program are not principally intended to serve as educational mechanisms. They instead are designed to verify the supplier's compliance with the quality standards. Most respectfully, we are unable to tailor aspects of its accreditation requirement (for example, contents of the supplier standards, length of the reaccreditation cycle) to accommodate suppliers' wishes for guidance from AOs. It is ultimately the supplier's responsibility to familiarize itself with the quality standards and the means of complying therewith. Second, even if one acknowledges the potential educational aspects of a survey, we believe that annual surveys would provide more frequent guidance to suppliers than would surveys occurring every 3 years.

Comment: Multiple commenters requested that CMS exempt suppliers of post-mastectomy services from revised § 424.57(c)(24). The commenters stated that these suppliers often service large geographic areas because there are few suppliers. The costs of additional surveys and accreditations, the commenter stated, could force these suppliers to shut down, leaving beneficiaries unable to access these services. Another commenter urged retention of the 3-year cycle for lymphedema specialties.

Response: We appreciate the commenters' concerns but respectfully are unable to exempt such suppliers or, for that matter, other types of DMEPOS suppliers. Quality standard non-compliance, which our requirement seeks to halt, can occur among any and all supplier types, and exempting certain types could lead to non-adherent suppliers receiving millions of dollars in

inappropriate payments or to patient harm. We also restate our view that we do not foresee an exodus of suppliers (including suppliers of post-mastectomy services) from the Medicare program due to our requirement.

Comment: Several commenters did not believe that our proposal would make suppliers more apt to be compliant with the quality standards because: (1) many suppliers constantly strive to ensure adherence thereto; and (2) the current 3-year timeframe already gives suppliers an incentive to remain compliant.

Response: We respectfully disagree. We believe DMEPOS suppliers may be more inclined to constantly comply with the quality standards if their next survey and reaccreditation will occur much sooner than every 3 years – a critical consideration in light of DMEPOS suppliers' uniquely heightened program integrity risk. Mirroring a prior example we have cited, a DMEPOS supplier that passed a survey on June 1, 2026, might believe it is unnecessary to retain compliance with the quality standards for the next 2 or 2.5 years, knowing it could wait to remedy its non-adherence until immediately before its next survey at the 3-year mark. More frequent surveys will give suppliers much less time and opportunity to become or remain non-compliant.

Comment: Many commenters suggested that instead of revised § 424.57(c)(24), CMS should base the frequency of surveys on the general and historical performance of suppliers and the risk the supplier poses. To illustrate, suppliers that have had difficulty meeting the quality standards should be reviewed more frequently, while those that routinely pass surveys (or show consistent improvement on surveys) should be reviewed less frequently or, as present, every 3 years. A commenter suggested that if a supplier passes its surveys in 3-4 consecutive cycles, another re-survey should not be required for another 5 years. Other commenters suggested an approach that required new suppliers to undergo surveys and reaccreditations in their first 3 years of enrollment; if the supplier passed these, a 3-year cycle would apply.

While supporting a more risk-based survey approach (rather than an across-the-board requirement), another commenter stated that CMS should focus especially on the billing patterns of new suppliers, with another commenter recommending that the number of complaints against the supplier be a consideration in survey frequency. Other commenters suggested exempting pharmacies (particularly state licensed ones or those involving immediate time-sensitive pharmacy DMEPOS codes, such as nebulizers) or lower-risk suppliers from revised § 424.57(c)(24). Additional commenters that supported a risk-based approach recommended that CMS consider factors such as the supplier's: (1) past level of compliance or non-compliance; (2) governance structure; (3) financial wherewithal and billing revenue; (4) location; (5) subtype (and the relative program integrity risk of that subtype); (6) number of employees; and (7) recent history of immediate jeopardy deficiencies, if any. Another commenter recommended that the purview of § 424.57(c)(24) be limited to suppliers with a material failure to comply with billing, enrollment, and accreditation requirements, with materiality being determined by factors such as, but not limited to. continued non-compliance with fraud, waste, and abuse-related requirements.

Response: We sincerely appreciate all of these suggestions. Yet we reemphasize that passage of a survey – or even multiple consecutive surveys – does not guarantee that a supplier is or will remain compliant for the entirety of each of their 3-year cycles. Too, although some suppliers may pose less risk than others, the former can still lose compliance with the quality standards for a lengthy period, placing taxpayer dollars at serious risk. In our view, only via more frequent surveys can CMS better confirm that there are no lapses in the supplier's compliance and that DMEPOS beneficiaries are protected.

Comment: A commenter stated that the burden of our requirement on AOs may become so significant that they no longer accredit DMEPOS suppliers, thus possibly compelling smaller suppliers to seek accreditation from larger or remaining organizations at a higher cost.

Response: We appreciate this concern but believe that: (1) the additional fees these organizations would receive would alleviate the burden on them; and (2) these entities would seek to continue their roles in the CMS DMEPOS accreditation program.

Comment: A commenter suggested that in lieu of revised § 424.57(c)(24), CMS should focus on operational and compliance issues among the AOs.

Response: We agree that the latter is critical, hence our proposed revisions to § 424.58 to enhance our oversight of AOs. Yet we do not see this as an "either/or" situation where we must choose between more frequent reaccreditation and AO oversight. They are not mutually exclusive, and both can and should be pursued for reasons described in the proposed rule and this final rule.

Comment: A commenter stated that there is no indication that DMEPOS suppliers are failing to meet the quality standards in a greater proportion than other providers and suppliers that are subject to a 3-year reaccreditation cycle.

Response: We appreciate this comment. However, as indicated previously and further discussed in this final rule, DMEPOS suppliers are entirely different from certified providers and certified suppliers in terms of, among many other things: (1) the types of services furnished; (2) requirements and standards that must be met; (3) extent of state oversight and regulation; and (4) qualifications of personnel. We cite two examples:

- Various certified provider/supplier types (such as hospitals and skilled nursing facilities (SNFs)) tend to be subject to substantially stricter state requirements than DMEPOS suppliers. In fact, some states do not even license certain suppliers of DMEPOS.

- Notwithstanding DMEPOS suppliers' provision of medical equipment, there is no requirement in § 424.57 that the supplier have medical professionals on staff. Individuals with little if any medical knowledge can open and operate a DMEPOS supplier. Certified providers such as hospices and SNFs, on the other hand, are required to have medical directors and other qualified personnel.

With, in many cases, less state oversight of DMEPOS suppliers and the relative ease of starting up a supplier when compared to certified providers/suppliers, DMEPOS accreditation is a uniquely critical means of protecting Medicare beneficiaries – particularly so given the aforementioned lack of required medical personnel; indeed, the lack of health care background of some suppliers could make them especially susceptible to quality standard violations. When combined with the almost unprecedented program integrity risk that DMEPOS suppliers present, the respective accreditation processes of DMEPOS suppliers and certified providers/suppliers must be different. This means that rates of certified provider/supplier compliance cannot dictate the frequency or requirements of DMEPOS supplier accreditation. The aforementioned DMEPOS supplier characteristics necessitate, in our view, more frequent surveys and reaccreditations ;

Comment: Several commenters stated that large chain (and other) pharmacies should be exempt from revised § 424.57(c)(24) because: (1) the overwhelming preponderance of pharmacies are compliant with the quality standards and there is no evidence to indicate otherwise; and (2) pharmacies are already very heavily regulated at the federal and state level. They noted that CMS has exempted these suppliers from surveys in the past. A commenter suggested that for national providers with 25 or more locations, a sample of no more than 33 percent of locations surveyed every 3 years is appropriate if they have been inspected by either a state agency or Medicaid agency. Another commenter stated that none of the examples of criminal activity identified in the proposed rule involved pharmacies. An additional commenter stated that our proposal could lead to a dramatic reduction in the number of pharmacies, resulting in reduced beneficiary access to care.

Response: We sincerely appreciate these comments and reiterate that there could be limited instances where sampling would be warranted. As previously explained, though, a supplier can lose compliance with the quality standards irrespective of their subtype, historical extent of adherence, and degree of regulation. Consequently, and as with other DMEPOS

supplier types that have made similar requests, we most respectfully must decline to establish an across-the-board exemption from § 424.57(c)(24) for pharmacies.

Comment: A commenter stated that CMS should establish a recovery-focused accreditation pathway recognizing the unique operational requirements of suppliers serving patients with substance use disorders, mental health conditions, or complex rehabilitation needs.

Response: While we sincerely appreciate this feedback, we are most respectfully uncertain as to the commenter's recommendation. If, as it appears, the commenter is requesting an exception from revised § 424.57(c)(24) for DMEPOS suppliers serving the indicated beneficiaries, we refer the commenter to our prior explanations of the need for revised § 424.57(c)(24). We believe these reasons apply here, too.

Comment: A commenter stated that CMS should adopt the position that DMEPOS suppliers will not be penalized if their AO is unable to conduct an annual survey and reaccreditation through no fault of the supplier.

Response: We thank the commenter for this suggestion and fully appreciate the views expressed. Respectfully, though, we cannot in this rule establish such a broad, blanket, and absolute exemption in every case regardless of the facts of the particular situation. This is because each situation may have slightly different circumstances that, in our view, warrant individual consideration on our part. Nonetheless, and as with other aspects of our proposal, we will very closely monitor its implementation and take action as needed to address issues that arise.

Comment: A commenter recommended that in lieu of revised § 424.57(c)(24), CMS should establish a short form or checklist whereby a supplier can report any material changes to its business.

Response: While we appreciate this suggestion, a checklist would not be an adequate substitute for an on-site survey. Given the tremendous importance of the quality standards in helping to ensure that the supplier is legitimate, we believe that a thorough, comprehensive

review by an independent organization – rather than relying solely upon the supplier's checklist assertions - is the best means of ensuring compliance.

Comment: A commenter stated that CMS appears to be placing the burden on AOs to ensure program integrity and compliance instead of performing this function itself. The commenter added that this is unfair given that CMS' performance of surveys and site visits is often delayed; the AOs, the commenter stated, should not be compelled to perform CMS functions in this regard.

Response: We respectfully disagree that CMS is effectively delegating its DMEPOS payment safeguard activities to the AOs. On-site verification of suppliers' compliance with the quality standards via the survey process has always been an AO function, not a CMS one; indeed, section 1834(e)(20)(F)(i) of the Act is clear that DMEPOS suppliers must be accredited by an independent organization to participate in Medicare. CMS is therefore not passing any such role to the AOs because CMS has never had this role. Rather, the core change involves the frequency of surveys and reaccreditations, which we believe should be consistent with revised § 424.57(c)(24) for reasons already described. We will continue to perform all other DMEPOS program integrity and anti-fraud activities.

Comment: Several commenters expressed concern about the proposal's potentially disproportionate burden on orthotic and prosthetic (O & P) suppliers. A comment er stated that these are often small practices serving rural or underserved areas that already meet rigorous accreditation standards. Citing various data, the commenter stated that: (1) the proposed change would impose $6.2 to 9.3 million in addition to direct accreditation costs on O & P suppliers before factoring in indirect costs (for example, lost clinical time); and (2) improper payments and relative risks for O & P suppliers are comparatively low compared to other DMEPOS supplier types, a position that other stakeholders shared. Moreover, the commenter stated that these suppliers pose less of a risk than hospitals but that the latter have a 3-year cycle while O & P suppliers would have to undergo much more frequent reaccreditations. The commenter

concluded that: (1) the burden of this requirement on O & P suppliers could exceed the potential net savings; and (2) O & P suppliers should be exempt from revised § 424.57(c)(24). Sharing the previously discussed views regarding O & P suppliers, another commenter stated that CMS should track all fraud, waste, and abuse within the DMEPOS community by sub-supplier type and then publish the results.

Response: We thank the commenters for this feedback. However, for reasons similar to our aforementioned position regarding a blanket exemption for pharmacies and other DMEPOS supplier subtypes, we must respectfully decline to adopt an O & P supplier exemption as well. We also reiterate that while certain DMEPOS supplier sub-types might present less program integrity risk than others, the risk for the DMEPOS supplier type as a whole is (and has always been) very high. Hence, as we have with other DMEPOS payment safeguard initiatives, we believe we must view the DMEPOS supplier type in its entirety within the context of accreditation requirements.

Comment: Several commenters suggested that instead of more frequent surveys for all suppliers, CMS should retain the 3-year period but make greater use of ad-hoc surveys, with a commenter stating that the latter should focus on certain quality standards rather than all of them; the commenter believed this would reduce the burden on suppliers and the AOs.

Response: We appreciate these recommendations. We concur that greater use of ad-hoc surveys could prove beneficial in certain circumstances (for example, the AO or CMS receives information that a supplier has lost adherence to the quality standards). Yet we do not believe these surveys would be an adequate substitute for revised § 424.57(c)(24), which would facilitate stricter and more frequent oversight of DMEPOS suppliers.

In terms of the scope of ad-hoc surveys, we respectfully cannot commit to having all surveys be partial in nature, for there may be circumstances where a full survey addressing all quality standards is necessary.

Comment: Several commenters suggested that if CMS believes the current 3-year cycle is too lengthy, it should change it to every 2 years, rather than annually (or, perhaps, 2 years for low-risk suppliers),

Response: We appreciate this suggestion. Again, though, we believe an annual timeframe (instead of every 2 years) will be more effective in halting inappropriate payments and protecting the quality and safety of services and items provided to beneficiaries due to the greater frequency of AO reviews.

Comment: Several commenters stated that to avoid our proposed requirement, some multi-location DMEPOS suppliers might transition their sites from servicing locations to warehouses, repair centers, or call centers that do not require accreditation. They might also consolidate their locations so as to limit the number of surveys the DMEPOS organization must undergo. This could decrease beneficiary access to services and potentially result in program integrity issues due to the lack of a survey. Another commenter expressed concern that if suppliers elected to depart Medicare due to our proposal, this could impact Medicaid services because many states require a valid Medicare Provider Transaction Access Number (PTAN) for Medicaid participation.

Response: We thank the commenters for this feedback. We cannot exclude the possibility that some DMEPOS suppliers may: (1) transition their sites as the commenters noted; or (2) depart Medicare. Yet we also cannot allow this prospect to deter us from undertaking critical program integrity and quality of care measures such as annual surveys and reaccreditations. Moreover, and as previously stated, we respectfully do not anticipate significant numbers of suppliers exiting Medicare or beneficiaries having access to care problems; we further do not believe large numbers of suppliers will transition to entities that do not require accreditation as DMEPOS suppliers. Still, we recognize the importance of these issues and will carefully monitor our enhanced requirements to ensure that patient access to care remains sufficient.

Comment: A commenter stated that the implementation of our proposal would place a large burden on CMS employees, which appears to contradict the aim of streamlining regulatory agencies.

Response: While we appreciate this feedback, accreditation surveys are performed by the AOs, not CMS or Medicare NPEC staff. To the extent that our requirement would increase CMS or NPEC workload, CMS and the NPECs will be able to accommodate this.

Comment: Several commenters stated that instead of our proposal, CMS should establish a formal process that allows NPECs and AOs to promptly share information when there is suspicion of fraud, waste or abuse. Other commenters recommended closer collaboration with the NPECs, DME MACs, AOs, and other stakeholders on fraud, waste, and abuse matters.

Response: CMS regularly coordinates with the NPECs on fraud, waste, and abuse matters, and we believe our updates to § 424.58 will strengthen communication with the AOs on such issues, too. Again, though, the purpose of accreditation is to validate quality standard adherence, which is not necessarily the same thing as fraud detection. For this reason, we respectfully cannot adopt the commenter's suggestion (appreciated though it is) in lieu of revised § 424.57(c)(24).

Comment: Although urging the retention of the 3-year cycle, numerous commenters requested that CMS delay enforcement of revised § 424.57(c)(24). A commenter requested that this requirement be grandfathered in; this would give the AOs and suppliers time to incrementally implement the annual survey and reaccreditation process over the next 2 years. An additional commenter stated that because CMS must have a clear plan for implementing this requirement, CMS should postpone implementation until: (1) the AOs demonstrate the capacity to do the required activities without compromising the quality of the surveys; and (2) CMS has implemented mechanisms to ensure consistent training and surveyor knowledge across all AOs. Another commenter requested a delay: (1) for at least 12 months; and (2) until support systems and robust technical assistance are ready and a transition grace period has been provided.

Response: We sincerely appreciate these recommendations but do not believe these requirements can be postponed. As noted, the problem of inappropriate payments and the potential for patient harm is very real, and we must implement these requirements as soon as possible, hence the January 1, 2026, effective date.

b. Temporary Accreditation (§ 424.57(c)(23))

Comment: Numerous commenters expressed concern that our proposal to eliminate temporary accreditation would prevent new locations from operating until a survey is performed – and said survey could be delayed due to the AOs' need to perform many other surveys. This could, they contended, decrease or delay beneficiaries' access to and continuity of care, impair the supplier's financial situation, and prevent the supplier's expansion of its operations via the establishment of new locations; some commenters stated that this could be particularly problematic for beneficiaries in underserved areas. Another commenter stated that our proposed change could also delay the enrollment process, since the site could not be enrolled until the survey is performed. An additional commenter stated that the current temporary accreditation allowance enables suppliers to hire staff, obtain equipment, and establish proper workflows before an accreditation review. Removing this allowance would require suppliers to undergo a survey before they were ready, increasing the likelihood of non-compliance. Another commenter stated that the 90-day allowance should be retained for newly-enrolling O & P suppliers.

Response: We appreciate the commenters' concerns. We recognize that removal of this provision could delay the ability of certain locations to enroll in and bill Medicare. However, we reiterate that a supplier must meet the quality standards and be accredited before it can become Medicare-enrolled. We have no way of knowing whether the quality standards are met unless a survey is performed. It is very possible that the 90-day temporary accreditation provision over the years has resulted in many millions of dollars in inappropriate payments because the supplier – despite its temporary accreditation – did not, in fact, meet the quality standards. We do not

believe accreditation is appropriate without confirmation via a detailed and thorough on-site inspection of quality standard adherence. We have an obligation to the American people to ensure that Medicare dollars are only paid to demonstrably compliant DMEPOS suppliers.

We also do not believe this change will cause access to care issues. As stated, there are roughly 75,000 enrolled DMEPOS suppliers. Given this substantial number, we are unaware of beneficiaries experiencing significant difficulty securing DMEPOS due to a lack of suppliers. Too, this revision will in no way prevent new locations from enrolling in areas where there may be a need for an additional site. It will merely delay enrollment until we are certain that the supplier meets all qualifications.

Comment: Several commenters stated that the current 90-day provision strikes a sound balance between quality oversight and timely access to care and should be retained.

Response: For reasons outlined in our previous response, we most respectfully disagree with these commenters. We believe the current provision, rather than ensuring quality oversight, does the exact opposite. It permits accreditation (albeit temporary) without any review as to whether the quality standards are met. Considering the historical payment safeguard risks that DMEPOS suppliers have posed, the maximum feasible oversight is necessary; the 90-day accreditation provision is directly contrary to this.

Comment: A commenter indicated that temporary accreditation should remain available for suppliers being acquired by an entity that is already accredited.

Response: Although we appreciate this recommendation, merely because an accredited and enrolled supplier is purchasing an existing supplier does not guarantee that the latter under its new ownership is or will be compliant with the quality standards. As stated, each supplier site must be separately accredited, enrolled, and adherent to the quality standards. Most respectfully, the accreditation of one supplier (in the commenter's scenario, the purchasing supplier) cannot be used to influence the degree to which another supplier (the purchased supplier) is reviewed for quality standard compliance.

Comment: Several commenters stated that temporary accreditation should remain available for supplier organizations with a history of compliance.

Response: We appreciate this request but refer the commenters to our previous response. Again, we most respectfully believe that each location must be assessed on its own credentials regardless of any prior compliance of the controlling organization at large.

Comment: A commenter stated: (1) how CMS defines a "new" location in the context of the removal of the temporary accreditation provision (for example, whether it includes location updates); and (2) why CMS believes that a supplier that is compliant in one location will not be compliant at another one. Concerning the former, the commenter stated that it should not apply to location updates. If CMS nevertheless chooses to apply it in this manner, the commenter urged that: (1) CMS exclude suppliers that are in good standing at their other location; and (2) CMS require AOs to complete the new location survey within 20 days of the supplier's request. The commenter further suggested that the temporary accreditation allowance only apply to new suppliers that have no other locations.

Response: Strictly for purposes of temporary accreditation, a "new" location is one that is, simply put, newly established and newly opening. Depending on the circumstances, this could include situations where a supplier is closing operations at one location and moving them to a new site.

We are respectfully unclear as to the term "location updates." If the commenter is referencing the scenario at the end of the previous paragraph, we note two things. First, if the location shift involves the establishment of a new location, the new site must independently meet the quality standards. It cannot rely upon its compliance at the prior site. Second, considering the volume of their other DMEPOS accreditation responsibilities (for example, performing additional reaccreditation surveys and complaint surveys), we do not believe the AOs should be required to survey the site within 20 days.

Comment: A commenter recommended that if CMS removes the temporary accreditation allowance, surveys should occur 6 months after the approval, so: (1) services and records are available to review; and (2) compliance can be better assessed.

Response: While we are most respectfully uncertain as to the commenter's specific suggestion and its context, the comment appears to describe a variation of the existing temporary accreditation allowance. For reasons we have previously cited, the site cannot be approved and enrolled until the survey is performed and the location becomes accredited.

c. Unannounced Surveys

Comment: Several commenters stated that unannounced site surveys: (1) unnecessarily waste surveyor resources; (2) unduly strain the supplier's staff and resources, perhaps making accreditation-related activities a year-round process for supplier; (3) do not protect consumers; and (4) particularly harm smaller DMEPOS suppliers attempting to expand their business. They added that scheduled surveys could equally achieve CMS' goals.

Response: We note two things. First, unannounced DMEPOS supplier surveys are and have been common. Accordingly, our proposal would not necessarily constitute a new requirement or a dramatic change from present practice. Second, we reemphasize our obligation to protect beneficiaries and the Trust Funds by ensuring that DMEPOS suppliers are compliant with the quality standards. Given this, and as explained in the proposed rule and this final rule, we believe DMEPOS supplier surveys should be unannounced so that a non-compliant supplier cannot use prior notice of a survey to remedy its deficiencies solely to pass the survey (after which it may resume its non-adherence). In this context, we also believe that unannounced surveys will encourage suppliers to remain compliant on a consistent basis since they will not know when surveyors may arrive. (We note that the aforementioned February 15, 2024, proposed rule also recognized the importance of unannounced surveys for certified providers and certified suppliers.)

Regarding the commenters' specific assertions, we respectfully disagree that unannounced surveys waste surveyor resources, fail to protect consumers, or unduly strain supplier staff and resources, especially those of smaller suppliers. In the first case, we in fact believe it preserves surveyor resources. This is because it helps ensure that the surveyor's review is an accurate assessment of the supplier's compliance, rather than one where an otherwise non-adherent supplier can, upon advance notice of the survey, temporarily become compliant to pass the survey and then restart its prior non-compliance. For this reason, we also believe that unannounced surveys would better protect beneficiaries and the taxpayers from non-compliant suppliers. As for supplier resources, we emphasize that while suppliers would be surveyed considerably more frequently under our requirement, reaccreditation would still only be as prescribed under revised § 424.57(c)(24). It would not be an ongoing, constant, year-long process. We accordingly but respectfully maintain that while a burden would be involved, it would not be so significant, frequent, or time-consuming as to strain the resources of large or small suppliers to a material degree.

Comment: Numerous commenters stated that unannounced DMEPOS surveys would not align with all business models, particularly those operating across multiple offices or serving specialized patient populations. Some expressed concern that a supplier with a very small staff but several sites would lose their accreditation if: (1) critical staff on a particular day were at one location (Location X); (2) surveyors appeared unannounced at another site (Location Y); and (3) they were unable to perform the survey due to lack of available supplier personnel. The problem of the unavailability of supplier personnel could also occur, other commenters noted, when said individuals visit and furnish items to patients in their homes, if they serve patients strictly on an appointment-only basis, or they furnish mobile services in rural areas. These commenters stated that CMS must be flexible with unannounced surveys, adding that unannounced surveys do not allow the surveyor to confirm whether the supplier will have staff on-site when the surveyor arrives.

Response: We reiterate the importance of unannounced surveys and intend to finalize this proposal. Yet we acknowledge that DMEPOS supplier types vary with respect to the services and items they furnish and their business operations; as the commenters note, certain suppliers may, for instance, do frequent home visits. Accordingly, we will closely follow this issue as we implement this requirement, though we reiterate that unannounced surveys presently do occur.

Comment: Multiple commenters stated that if surveyors appeared unannounced at a supplier location, the location's staff might be in the middle of treating a patient (for example, fitting an orthotic). This would interrupt and perhaps terminate the patient's service that day and be embarrassing for the supplier. It also could require the rescheduling of that patient's appointments as well as others scheduled for that day, hence further delaying patient care.

Response: Although we understand and appreciate that a beneficiary's service could be interrupted or postponed due to an unannounced survey, we reemphasize our overriding obligation to tens of millions of Medicare beneficiaries to ensure that the suppliers they use are compliant with the qualified standards, which, again, can be best confirmed via unannounced surveys.

Comment: Several commenters stated that unannounced surveys could greatly restrict the supplier's flexibility to, for instance, perform public/community health fairs or meetings, since supplier staff must always be on-site in case surveyors appear unexpectedly. This could be particularly challenging if only one or two employees are typically tasked with working with surveyors during an on-site review; these individuals would have to constantly remain at the location, further restricting staff flexibility. Other commenters stated that staff unavailability due to vacations and "black-out" dates could incorrectly give unannounced surveyors a negative impression of the supplier's operations. They added that if the survey cannot be performed, the supplier may have to pay another fee and go through the survey and reaccreditation process all over again, further increasing supplier costs; too, some suppliers will lack the financial means to hire more staff to ensure that personnel is always on-site.

Response: We appreciate these concerns but again stress that revised § 424.57(c)(24) would only require surveys and reaccreditations at least once every 12 months. It would not be a year-round extended burden. Thus, we respectfully believe that unannounced surveys would not substantially impair a supplier's ability to perform outreach or other activities.

Comment: A number of commenters suggested exceptions to the unannounced survey requirement for situations such as, but not limited to, extreme weather, public health emergencies, and similarly atypical situations. A commenter stated that unannounced surveys should be limited to problematic suppliers. Others recommended that CMS ensure that suppliers receive advance notice of a forthcoming survey, with a commenter suggesting a 2-week notice and another recommending 3 days. Additional stakeholders suggested: (1) 24-hour advance notice for suppliers that are appointment-only or that mostly furnish services in patients' homes; and (2) a 2-week 'window' for a survey that allows 'black out dates' for religious holidays or other reasons such as jury duty. Commenters also stated that CMS should establish a different method of ensuring supplier compliance.

Response: We appreciate these recommendations but believe, for reasons already noted, that unannounced surveys are the best means of ensuring quality standard compliance.

Comment: A commenter stated that an unannounced survey would not necessarily weed out "bad actors."

Response: While we appreciate this comment, we believe that unannounced surveys would be more effective than announced surveys in detecting non-compliant suppliers because, again, said suppliers would have no time to attempt to restore compliance before the survey.

Comment: A commenter: (1) questioned how AOs should conduct unannounced surveys for O & P suppliers that are appointment only; and (2) recommended that AOs be permitted to contact the supplier on the morning of the survey or the prior business day or, as an alternative, exclude "by appointment only" suppliers from the unannounced survey requirement.

Response: We most respectfully must decline the commenter's recommendation regarding prior notice for reasons already outlined. Concerning the first comment, we expect that suppliers would likely make themselves and their staff available within a reasonable period of time if they were not already onsite.

d. AO Requirements and Related Provisions in §§ 424.57 and 424.58

Comment: A commenter generally supported the proposed rule's efforts to achieve greater consistency with certain provisions in 42 CFR part 488. Yet the commenter emphasized that DMEPOS suppliers differ significantly from institutional providers, nothing that many operate without fixed facilities, clinical personnel, or centralized infrastructure. As such, the commenter stated that certain part 488 procedures may require adaptation to reflect the operational realities of the DMEPOS sector.

Response: We appreciate the commenter's support and agree with the thoughts expressed. As previously discussed, DMEPOS suppliers and DMEPOS accreditation are very different from certified providers, certified suppliers, and the accreditation thereof. Accordingly, it is not possible to incorporate many aspects of existing part 488 certified provider/supplier accreditation procedures into § 424.58.

Comment: Several commenters opposed aspects of our conflict of interest and consulting provisions. Multiple commenters stated that CMS should not restrict an AO from providing education and training at any time before the organization's initial survey and during the 6-month period prior to each organization's reaccreditation survey; they explained that this is when education is most needed and that such training can be invaluable.

Response: We thank the commenters for this feedback. However, we remain very concerned about the potential for partiality in DMEPOS accreditation surveys. As we explained in the proposed rule and this final rule, these surveys are meant to objectively ascertain the supplier's adherence to the quality standards. We believe that the surveying AO's prior aid (or "coaching") in helping the supplier achieve such compliance is antithetical to this. The supplier

must always meet the quality standards on its own merits. We believe our proposed conflict of interest provisions will assist in ensuring impartial surveys.

Comment: A commenter opposed requiring a review of patient records instead of mock records, adding that it is unclear which patient records would be reviewed.

Response: We thank the commenter for this comment. Yet as we explained in the proposed rule and this final rule, we have seen instances where multiple suppliers within a larger organization have similar patient records. In our view, records of other suppliers' patients should not be considered in the survey; this is because they do not reflect the items and services that the surveyed supplier itself is furnishing. More basically, the review of patient of records is already part of an AO's process for assessing quality standard compliance; for this reason, we respectfully do not believe additional guidance on this topic is needed.

Comment: While agreeing that consulting could create a conflict of interest, a commenter believed our definition of "consulting" was too broad and seems to limit an AO's ability to answer a supplier's questions. Another commenter stated that our conflict of interest and consulting provisions should: (1) have a narrower, more targeted approach that preserves access to experienced AO personal and surveyors; and (2) clarify the distinction between educational and consulting services. Regarding the latter, another commenter stated that supplier education (for instance, workshops, workbooks, webinars, conferences, and other tools) is critical in the months before a survey and strengthens compliance. The types of education an AO offers also helps distinguish one AO from another; restricting the provision of education diminishes such competition. Also, AOs are well-positioned to furnish supplier education, and the commenter added that education and consulting are different concepts. The commenter, as well as several others, urged that the former be permitted, with a commenter adding that prohibiting education could require the supplier to hire a non-AO consultant, which the supplier may not be able to afford.

Response: We appreciate these comments. While we recognize the AOs' expertise and the value of supplier education, we reiterate that the concept of AO survey impartiality is imperative. As noted in the previous response, we believe our provisions in proposed § 424.58(m) and (n) will be important means of ensuring this. Should the AOs seek elucidation on the scope of these provisions (for instance, whether forms of education fall within § 424.58(m) and (n)), we will consider issuing guidance.

Comment: Stating that the SOM contains guidance and instructions to state survey agencies and AOs for conducting certified provider/supplier surveys and certifications, a commenter expressed concern that the proposed rule: (1) did not reference the SOM in § 424.58; and (2) contains provisions that conflict with the SOM or otherwise disregard certain SOM procedures. Another commenter stated that § 424.58(e)(3)(A), (B), and (C) do not align with procedures in Chapter 5 of the SOM or those for any other deemed program. The commenter noted that Chapter 5 reads in part: "All the procedures in this chapter are followed when complaints and reported incidents, including referrals from public entities, involve Medicare-certified providers/suppliers, Medicaid-certified providers/suppliers, or CLIA-certified laboratories." The commenter thus contended that CMS should: (1) adopt the Chapter 5 complaint procedures and definitions in lieu of the process in proposed § 424.58(e)(3)(A), (B), and (C) so that all AOs handle complaints consistently; and (2) permit administrative reviews/offsite investigations instead of surveys for Non-IJ Medium and No-IJ Low situations, which would expedite the investigation and resolution.

Response: We appreciate this feedback but refer the commenters to our previous responses regarding the distinction between DMEPOS suppliers and certified providers/suppliers. We further emphasize that the SOM has never applied to DMEPOS suppliers or their accreditation. We believe it is more important to establish accreditation procedures that are best suited to address the unique characteristics and risks of DMEPOS

suppliers than to mirror procedures (such as onsite surveys for Non-IJ Medium and No-IJ Low situations) in guidance that, again, is inapplicable to said suppliers.

Comment: A commenter noted proposed § 424.58(c)(1)(xxiii)(D), which would require an AO to notify CMS within 3 business days of the revocation or revision of a supplier's accreditation status). The commenter stated that this provision should be changed to read: "The accrediting organization must agree to provide this notification in writing to CMS of the accrediting organization's action to revoke or revise the accreditation status of a supplier within 30 days allowing for an appeal, a review of presented materials, and a decision." The commenter explained that state agencies and AOs permit providers and suppliers to appeal a decision and indicated that CMS should only require the notification previously discussed after the appeal has been completed. For the same reason, the commenter recommended that the 5 calendar-day reported period in § 424.58(e)(5)(i) be revised to reflect the suggested change to § 424.58(c)(1)(xxiii)(D); another commenter recommended changing the 5-calendar day period to 5 business days.

Response: We appreciate this comment but respectfully disagree with the suggested changes. The appeals process is a different issue than that of reporting data to CMS about a supplier's status. Considering the rule's emphasis on enhanced CMS oversight of the AOs, the overall DMEPOS accreditation process, and DMEPOS suppliers, we believe we must receive prompt notification of an accreditation revocation, revision, denial, etc., all the while recognizing that the AO action might be reversed on appeal.

Comment: Several commenters requested that the 2-calendar-day timeframe for notifying CMS of an immediate jeopardy situation be changed to 2 business days.

Response: We agree with this suggestion and have incorporated it into our final regulatory text.

Comment: A commenter stated that the term "law enforcement" in § 424.58(c)(1)(xxii) should be changed to "the Office of Inspector General."

Response: We must respectfully decline this recommendation because there are other law enforcement bodies besides the OIG that might be involved in assessing allegations of fraud, waste, and abuse.

Comment: A commenter questioned whether the 10-day period in § 424.58(c)(1)(xxiii)(E) for notifying CMS of CAPs begins on the date when the AO makes its determination to apply a CAP or the date on which the AO requests the CAP.

Response: Section 424.58(c)(1)(xxiii)(E) requires the notification to be made within 10 days of the AO's decision, which, for purposes of this paragraph, we equate to the date the determination is made.

Comment: A commenter questioned whether the AO should send proposed changes to its accreditation standards, requirements, or survey process only when there is a change.

Response: We are respectfully unclear as to the commenter's query. If the commenter is asking for clarification regarding when and how the aforementioned changes must be reported to CMS, we address this in proposed § 424.58(e)(2).

Comment: A commenter requested that CMS change the term "corrective action plan" in § 424.58 to "plan of correction" to better align with the terminology in part 488 and the SOM.

Response: We appreciate this request. Yet we wish to retain "corrective action plan" because we have used this term for many years in the DMEPOS accreditation arena.

Comment: Several commenters expressed concern regarding the requirement in § 424.58(c)(1)(xxiii)(D) that the AO notify CMS within 3 business days of any decision to terminate, revoke, withdraw or amend a particular supplier's accreditation status. The commenters suggested that we change the reporting timeframe to 10 business days or longer.

Response: We appreciate this suggestion but must respectfully decline to accept it. If an AO terminates a supplier's accreditation, the supplier is out of compliance with § 424.57(c)(22) and its enrollment should be revoked. If we extended the reporting period from 3 business days to 10 business days, this could result in 7 additional days of inappropriate payments to a non-

compliant supplier. Therefore, we must be made aware of such AO actions as promptly as possible.

Comment: With respect to our proposal in new § 424.58(i)(4) that affected suppliers must be notified of their AO's suspension and the status of their existing accreditation, several commenters suggested that the accreditations of such suppliers remain effective: (1) for 1 year; (2) until their next scheduled reaccreditation; or (3) until the AO's suspension is lifted. A commenter stated that it could be difficult for another AO to immediately reaccredit the supplier, noting that said AO may not have: (1) a relationship with the supplier, which could complicate communication; and (2) adequate experience in accrediting suppliers that furnish the specific types of items that the supplier does. Other commenters stated that CMS should: (1) stipulate a minimum timeframe for suppliers to reconcile with a new AO if their current one is revoked; and (2) grant extensions to suppliers who are forced to switch accreditation organizations due to delays outside of their control.

Response: We appreciate these comments, which appear to generally recommend that the supplier's accreditation remain in effect for a period following the AO's suspension and not be immediately terminated upon said suspension. If this is indeed the commenters' suggestion, we refer them to proposed § 424.58(i)(4) wherein we stated that, with certain exceptions, the supplier's accreditation would remain effective through the length of the suspension. Although we recognize the commenter's concern about having to obtain accreditation from a different AO, we reiterate our obligation to protect the Trust Funds and beneficiaries through, in part, ensuring that the AOs are performing effectively. We most respectfully believe this must take precedence. Concerning the final set of comments, we respectfully are uncertain as to the commenters' meaning of "reconcile" and "delays outside of their control" in the context of our proposal. Regardless, we believe that proposed § 424.58(i)(4) gives DMEPOS suppliers enough time to be accredited by another AO if that is required under paragraph (i)(3).

Comment: Several commenters opposed proposed new § 424.58(e)(3). They stated that the 21-day period identified therein may not be appropriate or feasible in all circumstances. They added that the reporting timeframes should account for the complaint's materiality and seriousness. Additional commenters contended that not all complaints are of the same importance or urgency, with some too immaterial to report to CMS lest the AO and CMS burden for disclosing and reviewing these complaints become overwhelming. A commenter recommended that CMS, in partnership with the AOs, establish a tiered response level to complaints.

Response: We thank the commenters for this feedback. Considering the historically high program integrity risk that DMEPOS suppliers have posed and our aforementioned need for much greater oversight of the DMEPOS accreditation program, we believe that complaints should: (1) be carefully reviewed and reported to us regardless of materiality; and (2) promptly result in a survey if the review concludes that non-compliance may exist. Survey delays in the second instance could lead to thousands of dollars in additional payments to non-adherent suppliers. Still, we recognize the commenters concerns about the relative importance of certain complaints and will keep this in mind as we implement § 424.58(e)(3).

Comment: Multiple commenters stated that CMS should: (1) send notices of actions against AOs via e-mail; and (2) have all AO probation, suspension, and termination notices publicly available on the CMS website.

Response: We appreciate these suggestions. All AO suspensions and terminations will indeed be posted our CMS website. Probations will not because, as previously stated, an AO on probation would normally be able to continue its activities without interruption. Regarding the first recommendation, we are respectfully unclear whether the commenter is referencing a CMS e-mail notification to all suppliers. If the commenter is, we respectfully believe the CMS website posting constitutes sufficient notice. However, we may in the future consider supplemental notification measures if deemed appropriate.

Comment: Regarding the AO data reporting requirements in § 424.58, a commenter stated that CMS should ensure that: (1) the timeframes are reasonable and feasible; and (2) it shares data and feedback with the AOs as well (perhaps establishing a data exchange process between CMS, the AOs, and the NPECs). The commenter also suggested that CMS establish a working group and closer CMS collaboration with AOs to develop and facilitate clear guidelines, performance standards, and best practices.

Response: We appreciate these recommendations. We believe the proposed timeframes are indeed reasonable and feasible, and, as previously noted, we regularly meet and exchange information with the AOs and NPECs on various matters. We anticipate even more frequent communications and close collaboration with the AOs as we implement our accreditation proposals.

Comment: A commenter questioned whether the surveys and reviews addressed in 424.58(f)(2) and (f)(4) would be announced or scheduled.

Response: We thank the commenter for this query, a matter on which CMS will issue guidance to the AOs during the implementation of our DMEPOS accreditation provisions.

Comment: A commenter stated that our proposed consulting requirements in § 424.58(m)(4)(i), (ii), (iii), and (iv) could be impossible to meet for two reasons. First, firewalls prevent this information from being shared, and the AO's education area does not possess this data. (For example, the list of attendees is not shared between the educational division and the accreditation division.) The commenter stated that this requirement would force the two separate divisions to share provider information that is prohibited, hence removing the integrity of the separation because the accrediting division should never know which suppliers have received education. Second, these provisions require unobtainable information, such as the names and billing numbers of all suppliers that receive fee-based consulting or general education from the AO.

Response: For reasons already discussed in the proposed rule and this final rule, we believe our conflict-of-interest provisions are necessary. However, we appreciate the commenter's concerns and will monitor these matters during and after these provisions' implementation.

Comment: A commenter stated that "lookback surveys" addressed in proposed § 424.58(f)(2), are not a reliable or meaningful method of validation. The commenter stated that conditions within the supplier's operations are likely to change after an accreditation survey (for example, implementing corrective action). Given this different environment, it could be difficult to draw accurate conclusions about the original survey's findings. Sharing this commenter's views, other commenters recommended a direct observation model instead of "look-behind surveys."

Response: Although we appreciate these comments, these surveys have been included within § 424.58 since 2006. We continue to believe they can be beneficial since they enable CMS itself to perform a survey.

Comment: Regarding proposed § 424.58(c)(1)(xxii), a commenter recommended that CMS define the terms "fraud", "waste", and abuse".

Response: We appreciate this comment. However, we respectfully believe that for purposes of § 424.58(c)(1)(xxii), the meanings of these three terms are plain on their face.

Comment: A commenter questioned whether § 424.58(e)(1)(i) was intended to establish a new monthly reporting requirement.

Response: AOs are presently required to submit data to CMS each month per existing § 424.58(c)(1). Section 424.58(e)(1)(i) merely modifies the types of information to be reported. From that standpoint, therefore, it does not create a new reporting requirement.

Comment: A commenter expressed concern regarding CMS' reapplication procedures in § 424.58(c) and (d), that: (1) CMS was requiring AOs to reapply annually; (2) reapplication could create instability among the AOs, hence creating a vulnerability that unscrupulous parties

would exploit; and (3) the proposed rule lacked clear criteria/scoring metrics for evaluating AOs and a clear process for appealing.

Response: We appreciate the commenters' views and note the following. First, we did not propose to require annual AO reapprovals. Second, we do not see our reapproval proposals as risking AO instability or creating loopholes. We instead believe they will strengthen the accreditation process by enabling CMS to ensure that its AOs are fully qualified. Third, we are not positioned to outline in this final rule an extensive, detailed scoring system for our reapproval application assessments because: (1) we did not propose one; and (2) we must have the flexibility to make our application assessments based on each AO's individual and unique credentials. Fourth, we outlined reasons in §§ 424.58(c) and (d) for which, after our application review, we can deny AO reapproval, and we also explained the AO's appeal rights.

Comment: While supporting our proposal that AOs must review complaints against accredited facilities thoroughly, consistently, and diligently, a commenter raised two matters. First, the commenter requested that CMS specify the term "other applicable CMS requirements" in its "complaint" definition in § 424.58(b). Second, the commenter requested that CMS amend this definition to exclude a complaint against a supplier related to customer service on a non-DMEPOS item or matter (for example, the price of a particular medication was too high).

Response: We appreciate these comments. We will furnish clarification regarding the "other applicable CMS requirement" language prior to the implementation of our requirements. Regarding the second comment, we do not believe the suggested amendment is necessary; this is because non-DMEPOS issues are unrelated to the quality standards and thus would not fall within our revised "complaint" definition.

Comment: Several commenters questioned whether the AO's authorized official attestation in § 424.58(c)(1)(xxiii) must be submitted annually or only with initial and reapproval applications. Another commenter questioned whether the attestation's provision regarding patient records is a one-time requirement or will be on a cycle.

Response: We thank the commenters for these queries. The attestation (which references the use of patient records) need only be furnished when submitting an initial application or reapproval application under, respectively, § 424.58(c) and (d). However, the agreements contained therein remain in effect so long as the organization is a DMEPOS AO.

Comment: A commenter supported the requirement that an AO's application define "deficiency." Yet the commenter also urged CMS and the AOs to be more visible about this definition (and all levels thereof) to help suppliers understand the term's meaning and scope. Another commenter recommended that CMS define the term "deficiency" (and levels thereof) in future rulemaking to ensure consistency among the AOs. Another commenter suggested that in defining "deficiency" and striving for more consistent AO determinations, CMS should adopt the same language and process it utilizes for the ambulatory surgical center (ASC) accreditations process explained in 42 CFR 488.26 and the SOM. An additional commenter suggested that CMS adopt the same definition of "deficiency" (and its levels) that exists in § 488.705.

Response: We appreciate the first commenter's support and will, as needed, issue guidance regarding this definition. We may consider defining "deficiency" in future rulemaking, but we believe at this time that we must have the flexibility to do so via sub-regulatory guidance. This would enable us to receive detailed and ongoing feedback from the AOs on this definition as well as on setting deficiency levels; it is for these reasons that we also must respectfully decline the suggestions of the final two commenters.

Comment: Concerning § 424.58(e)(10), a commenter requested that CMS to identify the system into which the AO would have to enter data.

Response: CMS has not determined whether this will be a requirement or, if it is, what system will be involved. CMS would notify the AOs ahead of time should this guidance be adopted, as well as the relevant system.

Comment: Several commenters supported our conflict of interest (COI) and consulting proposals, stating that robust COI procedures for AOs were necessary.

Response: We appreciate the commenters' support.

Comment: A commenter stated that CMS should not have the complete discretion to define "deficiency" but should instead seek feedback from experts at the AOs, suppliers, and associations. The commenter added that any proposed updates to the quality standards should first be reviewed by these same experts.

Response: Although, as previously indicated, CMS intends to define "deficiency", we recognize the expertise of the DMEPOS AOs, which is partly why AOs in their initial and reapproval applications would be required to define this term as well as identify deficiency levels. We believe this feedback would assist us in formulating an appropriate definition.

While we appreciate the stakeholder's comment regarding the quality standards, we believe it is outside the scope of this final rule.

Comment: A commenter stated, regarding proposed § 424.58(e)(8)(i)(A), that requiring a survey is unnecessary for codes that do not need additional licensing or qualified personnel. (For example, an accredited supplier furnishes basic DME like a walker and wants to add canes and crutches.) More limited means of review would be equally effective.

Response: While we appreciate this comment: (1) the quality standards must be met irrespective of whether the new codes require additional licensing or qualified personnel; and (2) a survey would be the most effective means of determining quality standard compliance.

Comment: A commenter stated that AO reapproval should be for a maximum of 6 years to mirror current approval standards for home health and hospice.

Response: We concur with the commenter and note that this is what we proposed in § 424.58(d).

Comment: A commenter expressed concern with respect to CAPs about the volume of CAP data that must be reported (which the commenter stated goes beyond what AOs must report for other Medicare providers and suppliers). The commenter questioned whether CMS would have the capacity to review all the CAPs the AOs submitted and sought our assurance that CMS

would use all the data submitted. The commenter further contended that our CAP submission requirements: (1) could incentivize AOs to avoid CAPs and the need to report them (and the burden involved in doing so) for minor deficiencies; and (2) would place an excessive burden on AOs that properly use CAPs, thus punishing their diligence. Another commenter stated that CMS appears to be: (1) requesting that AOs defend each CAP they apply; (2) asserting that CAPs should focus on minor deficiencies; and (3) assuming that accreditation denials and CAPs are mutually exclusive (with the commenter stating that CAPs can be useful in enhancing compliance). This commenter stated that CMS should identify in rulemaking any deficiencies it believes are so serious that they should not be resolved via a CAP. An additional commenter, meanwhile, stated that CMS should define the term "corrective action plan".

Response: We thank the commenters for this feedback and respond as follows:

First, and as with complaints, we believe CAPs should be reported to us, considering the very high payment safeguard risk that DMEPOS suppliers have presented and our consequent need for significantly greater oversight of the DMEPOS accreditation program and the AOs. CMS will have the capacity to review all CAPs submitted.

Second, while we again acknowledge the AO burden involved, we reiterate our previous statements that certified provider/supplier accreditation is different from DMEPOS supplier accreditation; consequently, the policies for the latter cannot be dictated by the former. We also emphasize that the CAP reporting requirement is not intended to punish AOs, to have AOs defend every CAP, or to focus on minor deficiencies. It is to help us exercise closer monitoring of DMEPOS accreditation, the importance of which we have already discussed.

Third, CMS recognizes the distinction between CAPs and accreditation denials, and our proposals are not designed to blur it or to greatly restrict the AOs' ability to impose a CAP.

Fourth, we did not propose to: (1) identify which deficiencies should result in a CAP; or (2) define "corrective action plan." We will, though, consider these matters as we implement our proposed requirements and, if need be, formulate guidance.

Comment: A commenter supported our 36-month rule proposal in new § 424.551, though recommended that the 36-month clock not be triggered when a multi-location supplier sells one or more of its sites. Another commenter stated that with respect to the exception concerning parent company restructurings, CMS should expand the interpretation of "parent" to include any entity that is a wholly-owned direct or indirect owner of the DMEPOS supplier.

Response: We thank the commenters for their feedback. As each DMEPOS supplier must individually enroll as a separate supplier and meet all CMS requirements, we respectfully do not believe an exception should be given to sites within multi-location entities. (We note that no such exemption exists for HHAs and hospices under § 424.550(b).) Regarding parent companies, CMS will consider issuing guidance to clarify this term.

Comment: Several commenters expressed concern that: (1) there are too few AOs for certain types of DMEPOS suppliers (such as those providing mastectomy and lymphedema services); (2) the removal of one or more AOs could be harmful to the accreditation process; and (3) the metrics that CMS will use to take action against an AO (and what those actions might be) are unclear.

Response: We appreciate these comments. We will likely require existing AOs to undergo the reapproval process very soon after the final rule's publication. We cannot predict the number of AOs that: (1) will remain after this process is completed; or (2) may be added in the future (if any) to accredit different types of suppliers. We can, though, assure the commenter that all such reviews of AOs will be comprehensive and thorough. Insofar as removals of (and CMS action against) AOs, we outline the grounds for such action in proposed § 424.58(h), (i), and (j). While we recognize the commenter's concern that an AO's removal could be harmful to DMEPOS accreditation, we most respectfully believe the opposite. To ensure the integrity of the accreditation process, we must confirm that the AOs are performing their DMEPOS accreditation activities effectively, competently, and consistent with CMS requirements; if an

AO is not, we believe it could be more harmful to DMEPOS accreditation to retain that AO than to remove it.

Comment: Several commenters expressed concern about proposed § 424.58(e)(5)(ii), under which CMS could direct an AO to deny or terminate a supplier's accreditation. They believed this provision: (1) could impact the supplier's involvement with state licensing bodies and non-Medicare plans that require or rely upon the supplier's accreditation; (2) appears to be a punitive enforcement tool; and (3) could unfairly revoke accreditation for minor matters, such as non-compliance with merely one quality standard. The commenter recommended that CMS limit its enforcement mechanisms to enrollment revocation and payment suspensions; should CMS finalize this proposal, the commenter urged a robust appeals process, during which any termination would be stayed. Another commenter stated that the proposed provision could reduce the AO's independence and lead to arbitrary CMS decisions if CMS is unaware of the full circumstances of the supplier's case.

Response: We thank the commenters for sharing their concerns. We stress that any such CMS direction would occur extremely rarely (if ever) and only in the most exigent of circumstances, in part because we do not wish to hinder the AO's independence. It would not be used as a punitive enforcement mechanism for minor matters, or in instances where CMS did not have a complete understanding of the facts of the case. The supplier's appeal rights regarding the accreditation (and whether the denial or termination would be stayed) would be consistent with the AO's existing procedures.

Comment: Concerning our proposed definition of "immediate family member", a commenter stated that: (1) U.S. federal government standard practice does not restrict immediate family members from working in different facets of the government or as a contractor to the government; and (2) the conflict of interest process restricts said family members from participating in any activities with each other (for example, program decision-making or outcome reviews that involve both parties). The commenter thus concluded that employment in

either organization itself does not reflect a conflict of interest. The commenter recommended that CMS: (1) align the DMEPOS conflict of interest requirements with those in the SOM; (2) clarify if the proposed provisions preclude an AO surveyor from consulting outside of their AO position with a DMEPOS supplier; and (3) clarify whether a surveyor could disclose their consulting relationship to the AO, so the individual is not assigned to survey that specific supplier. If our definition is finalized, the commenter stated that CMS should provide AOs with standardized conflict of interest disclosure forms or questionnaires that outlines the scenarios and relationships that CMS considers problematic.

Response: We appreciate the stakeholder's comments. We respectfully do not believe that the first two scenarios the commenter mentions are applicable to the conflict-of-interest situation addressed in the proposed rule. The latter is narrower and focuses on AO consulting practices. Also, our proposed "immediate family member" definition and conflict of interest requirements are similar to those in the aforementioned February 15, 2024, proposed rule.

Comment: Several commenters stated that CMS must provide definitions and guidance to the AOs on CAPs and deficiencies before implementing its proposed changes regarding potential disciplinary action against AOs for survey finding disparities

Response: We thank the stakeholders for these comments. For reasons previously stated, we must respectfully decline to delay the implementation of our provisions (or to make their commencement dependent upon the previously discussed definitions and guidance being issued). Nonetheless, we expect to issue the commenters' requested sub-regulatory guidance to the AOs as promptly as possible.

Comment: Regarding our proposal that AOs must submit conflict of interest data to CMS at any time outside the initial approval and reapproval processes, a commenter urged CMS to provide a reasonable timeframe for AOs to assemble and organize data requested.

Response: We agree and will do so when making such requests.

Comment: Several commenters opposed our proposed 36-month rule expansion to include DMEPOS suppliers. Multiple commenters stated that CMS has not demonstrated that: (1) DMEPOS suppliers are establishing new businesses and then selling them after accreditation; or (2) requiring the new owner to reenroll could prevent fraud, waste, and abuse. Another commenter stated that the delays involved in reenrolling as a new supplier (as well as becoming accredited again) could prove very burdensome and delay patient care. The commenter added that there is already a process for notifying CMS of a change in majority ownership. The commenter recommended that CMS withdraw the 36-month proposal and instead impose stricter requirements on the new supplier, such as annual accreditations. An additional commenter stated that with the requirement to obtain a new accreditation as well as the need for suppliers to alert other health care plans of both the change in ownership and the accreditation change, this could delay the processing of the changes by said plans. Another commenter stated that this provision would essentially shut down the supplier's operations for a period of time, potentially harming patient access.

Response: We appreciate these comments and respond as follows. First, we noted in the proposed rule that we indeed have seen situations where suppliers were sold after accreditation. Second, the reenrollment/reaccreditation requirement is less geared towards preventing fraud, waste, and abuse (though this is always a critical consideration in our DMEPOS program integrity efforts) and more towards confirming that the supplier's new ownership is fully committed to quality standard compliance. Third, while we recognize the burden involved and the potential for delays in application processing and patient care, we reiterate the need to ensure that taxpayer dollars are only paid to compliant suppliers. We further do not believe patient access to care will be harmed given: (1) the vast number of other DMEPOS suppliers from which beneficiaries can receive services and items; and (2) that we have not seen HHA and hospice patient access issues resulting from § 424.550(b).

Comment: Multiple commenters stated that the proposed 36-month rule expansion is impractical because DMEPOS suppliers cannot provide services to beneficiaries without a PTAN. Another commenter suggested that instead of a new survey and reaccreditation, the new owner's credentials could be examined via other means (for example, through staff interviews).

Response: We appreciate these comments. We respectfully disagree with the first assertion. Akin to our robust and longstanding provider enrollment requirements, our DMEPOS accreditation provisions are intended to ensure that the supplier meets the quality standards before enrolling and receiving a PTAN. If an unvetted supplier was enrolled with a PTAN and began billing prior to any enrollment or accreditation reviews, millions of dollars in improper payments could ensue. Insofar as the second assertion, we already carefully screen new provider and supplier owners via the enrollment process. Section 424.551 as finalized will involve a more thorough analysis of the new owner's commitment to quality standard compliance.

Comment: A commenter questioned whether the reviews identified in § 424.58(f)(4)(i)(A), would be announced or scheduled.

Response: We appreciate this comment. We will issue guidance on this matter upon the implementation of our accreditation requirements.

Comment: With respect to existing § 424.58(b)(3) (proposed as redesignated § 424.58(f)(2)(ii)), several commenters believed that AOs should not be held responsible for future non-compliance by a supplier. They stated that no other enforcement entity, licensing board, etc., is responsible for future provider/supplier performance. A commenter contended that if a supplier becomes non-compliant and a survey is needed, it should be at the supplier's expense and not the AO's.

Response: After reviewing these comments, we have decided not to finalize this provision at this time. We may reconsider this issue in future rulemaking. Proposed § 424.58(f)(2)(iii), (iv), and (v) will be finalized and redesignated as § 424.58(f)(2)(ii), (iii), and (iv).

Comment: A commenter stated that to alleviate burden on CMS staff in reviewing AO reports, CMS should only require AOs to maintain documentation and supply it to CMS upon request when a supplier is under review.

Response: We respectfully disagree. To ensure proper oversight of the DMEPOS accreditation program, we believe we must have regular and detailed information from the AOs, which we are confident that CMS staff will have the capacity to review.

Comment: A commenter suggested that CMS integrate PECOS and the National Plan and Provider Enumeration System into AO reviews of suppliers to ensure real-time verification of supplier compliance.

Response: We appreciate this recommendation but believe it is outside the scope of this final rule.

e. General/Miscellaneous Comments

Comment: Several commenters supported our proposed DMEPOS accreditation provisions. A commenter stated that these proposals strengthen oversight and patient access, with another stating that CMS is rightly concerned that some AOs may be accrediting suppliers that do not meet the quality standards. An additional commenter stated that there have been significant instances of DMEPOS fraud in recent and past years, increasing expenditures for the Medicare program and beneficiaries. The commenter believed our changes, including revised § 424.57(c)(24), would: (1) help ensure that AOs serve their expected role; (2) give CMS additional tools to ensure the integrity of the Medicare DMEPOS benefit and to protect the interests of beneficiaries and taxpayers; (3) address vulnerabilities that CMS has identified; (4) increase the utility of AOs and accreditation for Medicare; and (5) improve consistency among the AOs. Another commenter agreed that there should be repercussions for AOs that are underperforming or that use unscrupulous individuals to perform inspections. Too, a commenter expressed support for our revisions to § 424.57(c)(22). An additional commenter supported unannounced and more frequent surveys.

Response: We appreciate the commenters' support.

Comment: A commenter stated that the cost of "rolling out" these proposed changes would be better spent in increasing reimbursement to DMEPOS suppliers.

Response: While we appreciate the commenter's feedback, we have articulated the reasons for our proposals and most respectfully maintain that they are necessary irrespective of existing or future levels of supplier reimbursement.

Comment: A commenter stated that a supplier's accreditation should not be terminated or revoked until the appeals process has expired.

Response: Though we appreciate this comment, we did not propose provisions pertaining to the: (1) appeals process for terminations or revocations of DMEPOS supplier accreditations; or (2) the effective dates of such actions. We thus believe this comment is outside the scope of this final rule.

Comment: A commenter stated that: (1) our proposed requirements would disincentivize companies from entering the DMEPOS field; and (2) Medicare should instead create a program that rewards people who enter said field.

Response: We thank the commenter for this feedback. We cannot exclude the possibility that our accreditation requirements may make certain prospective suppliers more reluctant to enroll in Medicare. As indicated previously, though, we have implemented DMEPOS supplier enrollment requirements in prior years (for instance, surety bonds, high-risk screening, etc.). These did not end the enrollment of new DMEPOS suppliers into the program. To the contrary, we regularly enroll new suppliers, including over 1,500 within a recent 12-month period; thus, while a reduction in new suppliers is possible, we do not believe it will be substantial, based on our past experience. In addition, although we sincerely appreciate the services that compliant DMEPOS suppliers furnish, we most respectfully cannot tailor our DMEPOS payment safeguard measures to ensure that DMEPOS suppliers: (1) can enroll in significant numbers; and (2) be rewarded for their entry (as the commenter appears to recommend). They must instead be geared

towards protecting the quality of DMEPOS services as well as the Trust Funds, the taxpayers, and beneficiaries, particularly given the program integrity problems that DMEPOS suppliers have long presented.

Comment: Several commenters stated that instead of proceeding with its DMEPOS accreditation proposals, CMS should engage with stakeholders (such as hospice-based suppliers) to develop a framework that balances: (1) the need for supplier accountability; and (2) the importance of ensuring patient access to care and limiting supplier burden.

Response: CMS regularly interacts with DMEPOS suppliers, DMEPOS representatives, the AOs, and other stakeholders on a wide variety of DMEPOS enrollment and accreditation matters. These communications help CMS remain abreast of any issues within the supplier community, and we keep these in mind when developing DMEPOS enrollment or accreditation-related initiatives. In developing our accreditation proposals, we remained cognizant of the potential burden on suppliers but concluded that our obligation to prevent improper payments to non-compliant suppliers and to protect beneficiaries warrants annual surveys and reaccreditations. Although, as previously explained, we do not anticipate access to care problems arising from this requirement, we will monitor the matter as our requirements are implemented.

Comment: A commenter recommended that CMS: (1) further examine Stark Laws; and (2) revise rules regarding physician prescribing of DMEPOS and the fitting of the physician's patients at the physician's practice location.

Response: We appreciate this comment but believe it is outside the scope of this rule.

Comment: A commenter stated that AOs do not consistently: (1) verify whether each supplier site has its own NPI, PTAN, surety bond, and Medicare enrollment; and (2) hold suppliers accountable for meeting all DMEPOS quality standards. The commenter stated that along with ensuring consistency in the AOs' accreditation process, CMS should require AOs to confirm that each DMEPOS location has its own NPI, PTAN, surety bond, and enrollment

record as part of the accreditation process. The commenter added that CMS should enhance training and oversight of AOs to ensure consistent enforcement of all DMEPOS supplier and quality standards.

Response: We appreciate and will contemplate these recommendations as we continue our efforts to strengthen our oversight of the DMEPOS accreditation program and the AOs.

Comment: Several commenters stated that instead of our DMEPOS accreditation proposals, CMS should focus on investigating: (1) companies that improperly obtain Medicare beneficiary information; (2) physician and physical therapy offices that prescribe and provide orthopedic devices: (3) DMEPOS dealers that solicit by television, radio, or telephone; and (4) aggressive telemarketing and patient targeting (for which, a commenter stated, CMS could establish a centralized CMS-managed watchlist to report suspected marketing-related fraud).

Response: We appreciate these comments. CMS has undertaken many DMEPOS program integrity measures over the years. For instance, we strive to protect DMEPOS beneficiary data and work closely with law enforcement in cases where such data has been improperly obtained; we take the security of beneficiary information and the inappropriate access thereof with great seriousness. However, we respectfully do not believe that our program integrity actions in this and other areas requires us to eschew other necessary initiatives, such as strengthening the DMEPOS accreditation process. That is, program integrity is a wide-ranging effort encompassing many components addressing many areas, and merely because one measure is taken does not mean we must disregard addressing other vulnerabilities. While safeguarding beneficiary data and preventing improper payments via more frequent surveys are two distinct matters, both are needed.

Comment: A commenter requested several changes in how AOs conduct surveys. First, if the supplier does not furnish rental items, the AO should not require the supplier to produce a rental policy. Second, the AO should not require the supplier to post an emergency exit map on the supplier's wall if the local fire inspector does not require it and the supplier passed its annual

fire inspection. Third, AOs should permit financial and employee information to be submitted via fax or email rather than on demand at a site inspection. Fourth, AOs should have to complete surveys within 45 calendar days of the supplier's paperwork submission; this would better enable supplier staff to perform other activities since they will not need to wait indefinitely for the survey's performance.

Response: We respectfully believe that the commenters' first three requests are outside the scope of this final rule. As for the fourth, we did not propose a general timeframe by which AOs must complete all surveys and, given the extent of their other DMEPOS accreditation responsibilities, do not at this time believe one should be established.

Comment: Several commenters stated that the best option for combating fraud, waste, and abuse in the O & P field would be to implement: (1) section 427 of the Benefits Improvement and Protection Act of 2000; and (2) elements of the "Medicare Orthotics and Prosthetics Patient-Centered Care Act" bills before the Congress, S. 2329 and H.R. 4475.

Response: We appreciate these suggestions but believe they are outside the scope of this final rule.

Comment: A commenter stated that CMS' requirement that DMEPOS suppliers have in-office hours is outdated.

Response: We respectfully disagree. Consistent with § 424.510, all provider and supplier locations (including DMEPOS supplier sites) must be "operational" as defined in § 424.502. Per this definition, the practice must be "open to the public for the purpose of providing health care related services." This requirement has been effective for many years, helps confirm the DMEPOS location is legitimate, and is no less necessary than before.

Comment: A commenter stated that AOs should not go beyond verification of the quality standards or supplier standards in their reviews. To guard against such situations, improve AO consistency, and prevent arbitrary findings, the commenter suggested that CMS require AOs to: (1) map each survey element to the specific standard it intends to verify; (2) publish the

minimum evidence of compliance expected for each element; (3) reserve termination for core, non-remediable violations (fraud, licensure, phantom locations); (4) use CAPs for remediable issues like signage, hours, or maintenance documentation; (5) ensure that surveyors meet published minimum qualifications, including continuing education); (6) publish surveyor qualification and training standards so suppliers have visibility into the process; and (7) align reviewer expertise with subject matters (for instance, clinical reviewers for clinical standards, operations reviewers for facility/administrative checks).

Response: We appreciate these comments. Elements of the comments regarding the survey process will, as deemed appropriate, be taken into consideration for future sub-regulatory guidance.

Comment: A commenter stated that DMEPOS suppliers are still recovering from the economic effects of the pandemic, inflation, shipping delays, and workforce shortages. The commenter stated that implementing our DMEPOS provisions without transition support would be unsustainable and risk forcing suppliers - especially those in rural or underserved areas—out of the Medicare program.

Response: We appreciate this comment. While we respectfully are uncertain as to the type of support the commenter is referencing, we plan to conduct extensive outreach and provide guidance to DMEPOS suppliers. We believe this will help them understand and transition to our new requirements.

Comment: While supporting the strengthening of the DMEPOS accreditation program, a commenter expressed concern that some of the AO-specific proposals — such as mandatory preapproval for AO procedural changes, expanded data submission requirements, and undefined deficiency categories—could inadvertently delay accreditation processes and hinder responsiveness to urgent patient needs. The commenter: (1) stated that clear requirements for AOs (for example, defined timelines and streamlined documentation requirements) would help preserve accountability and efficiency; and (2) urged CMS to work collaboratively with AOs and

suppliers to refine these proposals, so they enhance quality without compromising suppliers' ability to serve patients effectively.

Response: We appreciate these comments. We respectfully believe our proposed requirements: (1) are necessary, adequately detailed, and clear on their face; and (2) will not lead to material delays or patient access to care problems. Although, except as otherwise noted in this final rule, we do not believe our proposals require revisions, we will, as already stated, monitor their implementation and address any issues that arise.

Comment: A commenter questioned whether CMS could pay suppliers' accreditation fees or set the amount of AO fees.

Response: While we appreciate this request, DMEPOS AO fees have always been paid by suppliers (including certified providers and certified suppliers). Too, since the AOs are independent entities, they have the discretion to establish their own fee amounts.

Comment: A commenter stated that CMS should work with the OIG to update DMEPOS supplier corporate compliance guidance.

Response: We appreciate this suggestion but believe it is outside the scope of this final rule.

Comment: A commenter stated that if an AO disregards the quality standards during a survey and instead focuses on other regulations, the supplier should be able to report the AO to CMS.

Response: We appreciate this suggestion and will take it under advisement as we continue our efforts to strengthen CMS' DMEPOS accreditation program.

Comment: A commenter recommended that CMS tailor its accreditation oversight activities and regulatory provisions to those in part 488 regarding home infusion therapy suppliers.

Response: Though we appreciate this recommendation, we reemphasize that all provider and supplier types are different and that accreditation processes for one type may be unsuitable

for another. It is more important that we establish DMEPOS accreditation requirements that address the specific characteristics of DMEPOS than to ensure that they match all those of another provider or supplier type. Nonetheless, and as previously noted, we considered the procedures outlined 42 CFR part 488 in developing our revisions to § 424.58.

Comment: A commenter contended that some DMEPOS suppliers do not obtain their own NPI, surety bond, or accreditation for each practice location. Instead, they often submit claims using the NPI and PTAN of the supplier's main office or other supplier locations. The commenter stated that this: (1) undermines CMS's goal of ensuring that each location is independently accountable and compliant with Medicare standards; and (2) should result in stronger penalties against suppliers that submit claims using credentials from other locations.

Response: While we respectfully believe this comment is outside the scope of this rule, we appreciate the commenter's concerns and will take them under advisement.

Comment: Regarding proposed § 424.58(e)(8), a commenter: (1) requested that CMS define "all supplier locations" (for instance, whether it include service locations only, warehouses, etc.); and (2) questioned whether this change eliminates the 90-day extension of accreditation for a new location added to an already accredited supplier organization.

Response: For purposes of § 424.58(e)(8), the term "all supplier locations" means locations for which: (1) the supplier seeks accreditation or reaccreditation with the AO; and (2) the AO is required to perform a survey under §§ 424.57 or 424.58. As noted previously, we are removing the 90-day temporary accreditation allowance from § 424.57(c)(23).

Comment: A commenter supported our proposals to reduce inconsistencies between certain AOs.

Response: We appreciate the commenter's support.

Comment: A commenter specifically recommended that accreditation standards cover: (1) software change management; (2) security baselines; (3) incident/recall procedures that

incorporate Unique Device Identifiers; and (4) verification that electronic user instructions provided to beneficiaries are accessible.

Response: We appreciate this comment. However, as we did not address revisions to the quality standards in the proposed rule, we believe the comment is outside the scope of this final rule.

Comment: To enhance insight into the proposed rule's DMEPOS provisions, a commenter requested that CMS share DMEPOS data on issues such as targeted states, supplier newness, accreditation organizations, supplier size, multi locations, poor survey outcomes, etc.

Response: We appreciate this suggestion. While we are respectfully uncertain as to context and extent of the requested data, we note that CMS regularly posts DMEPOS accreditation-related information and guidance at https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/durable-medical-equipment-prosthetics-orthotics-supplies-dmepos). We will continue to do so as we implement our requirements.

Comment: A commenter stated that O & P suppliers should: (1) be certified by two particular AOs specified by the commenter; and (2) have its personnel meet certain education requirements. The commenter believed, in part, that this could prevent call centers from fraudulently billing Medicare.

Response: We appreciate this comment but believe it is outside the scope of this final rule.

Comment: A commenter stated that CMS did not furnish evidence that: (1) DMEPOS AOs are failing in their functions; (2) the current system lacks safeguards against DMEPOS AO conflicts of interest, quality lapses, or improper supplier accreditation; (3) there are widespread deficiencies among existing AOs; and (4) current AO vetting and oversight practices are inadequate. The commenter added that our revisions to § 424.58 (and our other provisions) did not account for patient access and supplier burden (including in rural or underserved areas). The

commenter accordingly urged CMS to withdraw its changes to § 424.58 and engage with stakeholders to identify targeted, evidence-based improvements that might be needed.

Response: We appreciate these comments but respectfully disagree. We indeed have seen deficiencies among the AOs, and, as previously explained, § 424.58 contains numerous gaps that we believe hinder our AO oversight. (For example, there are no provisions regarding conflicts of interest.) We also discussed in the proposed rule: (1) the matter of patient access; and (2) the estimated supplier burden in the collection of information and regulatory impact analysis sections. As already noted, we believe our § 424.58 proposals are necessary, though we will continue our communications with stakeholders as they are implemented.

Comment: A commenter stated that: (1) physicians should not be permitted to fit off-the-shelf devices; and (2) mailing orthotics to patients should be prohibited.

Response: We appreciate this comment but believe it is outside the scope of this final rule.

Comment: A commenter requested that Post-Mastectomy Products/Facilities be given their own prosthetic category, such as "Mastectomy Prosthetics and Products" as a unique specialty.

Response: We appreciate this comment but believe it is outside the scope of this final rule.

Comment: A commenter stated that CMS should adopt a personnel standard requiring each supplier location to employ at least one individual holding the Certified Durable Medical Equipment Specialist (CDME) credential.

Response: We appreciate this comment but believe it is outside the scope of this final rule.

Comment: A commenter stated that CMS should develop a specific list of issues that pose a serious risk of fraud, waste and abuse (such as prior instances of noncompliance) to identify requirements for annual reaccreditation.

Response: We appreciate this comment but believe it is outside the scope of this final rule.

Comment: A commenter stated that in lieu of some of our DMEPOS accreditation proposals, CMS could adopt the same monitoring system it uses to oversee hospices and HHAs.

Response: We appreciate this comment but are respectfully unclear as to the monitoring system to which the first commenter refers. We also restate that while our proposals mirror certain provisions in 42 CFR part 488, DMEPOS suppliers are entirely different from HHAs, hospices and must, accordingly, have unique accreditation requirements.

17. Final Provisions

After reviewing the comments received, we are finalizing all of our proposals without modification except as follows:

- The proposed 2 calendar day timeframe for reporting immediately jeopardy situations to CMS will be changed to 2 business days.

- We are not finalizing proposed § 424.58(f)(2)(ii). Proposed § 424.58(f)(2)(iii), (iv), and (v) will be redesignated and finalized as § 424.58(f)(2)(ii), (iii), and (iv).

Although we did not receive comments on the matter, we also have decided not to finalize the proposed language in § 424.58(e)(1)(i) that reads "no later than the last day of each month." We will instead retain the language in the opening paragraph of § 424.58(c)(1) (which we are redesignating as new paragraph (e)(1)(i)) that states "on a monthly basis". This is because the monthly reports currently required under existing paragraph (c)(1) are not necessarily due at the end of each month.

C. Exemption Process for Prior Authorization of Certain DMEPOS Items (§ 414.234(c)(1) and (c)(1)(ii))

1. Background

The Comprehensive Error Rate Testing (CERT) program measures improper payments in the Medicare Fee-For-Service (FFS) program. CERT is designed to comply with the Payment Integrity Information Act of 2019 (Pub. L. 116-117). As stated in the CERT 2024 Medicare FFS Supplemental Improper Payment Data report, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) claims had an improper payment rate of 21.4 percent, accounting for approximately 6.1 percent of the overall Medicare FFS improper payment rate.[54] Over the years we have implemented conditions of payment and other requirements to decrease the improper payment rate for DMEPOS.

Currently, the scope of payment for medical supplies, appliances, and devices, including prosthetics and orthotics, are defined at 42 CFR 410.36(a) and the scope and certain conditions for payment of durable medical equipment (DME) are described at § 410.38. Medicare pays for DMEPOS items only if the beneficiary's medical record contains sufficient documentation of the beneficiary's medical condition to support the need for the type and quantity of items ordered. In addition, other conditions of payment must be satisfied for the claim to be paid. Conditions of payment vary by item but are specified in statute and in our regulations. These conditions are further detailed in our manuals and in local and national coverage determinations. Additionally, for certain DMEPOS items we require suppliers to follow a prior authorization process through which a request for provisional affirmation of coverage is submitted for review before a DMEPOS item is furnished to a beneficiary and before a claim is submitted for payment[55]. Prior authorization plays an important role in ensuring Medicare's coverage, coding, and payment requirements are met, allowing suppliers a provisional assurance of claim coverage.

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54 https://www.cms.gov/files/document/2024-medicare-fee-service-supplemental-improper-payment-data.pdf

55 https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicare-ffs-compliance-programs/dmepos/downloads/dmepos_pa_required-prior-authorization-list.pdf

On December 30, 2015, we published a final rule in the **Federal Register** titled ‘‘Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies’’ (80 FR 81674), hereinafter referred to as the ‘‘December 2015 final rule,’’ that established a permanent prior authorization program nationally. The December 2015 final rule was based on the authority outlined in section 1834(a)(15) of the Act, which permits the Secretary to develop and periodically update a list of DMEPOS items that the Secretary determines, based on prior payment experience, are frequently subject to unnecessary utilization and to develop a prior authorization process for these items. Specifically, the December 2015 final rule established a new provision at § 414.234 that specified a process for prior authorization of DMEPOS items frequently subject to unnecessary utilization.

In addition, § 414.234(b) details criteria needed for inclusion on the Master List of Items Potentially Subject to Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements (“Master List”). Placement on the Master List makes an item eligible for CMS to require prior authorization as a condition of payment. CMS selects items from the Master List that will require prior authorization as a condition of payment, and we publish notice of such items in the **Federal Register**.

Prior authorization supports ongoing efforts to safeguard beneficiaries’ access to medically necessary items and services, while reducing improper Medicare billing and payments. This is important because documentation of practitioner involvement, including their orders for DMEPOS items and documented medical necessity (as assessed under prior authorization), is all used to support proper Medicare payment for DMEPOS items.

In the November 8, 2019, **Federal Register**, we published a final rule titled ‘‘Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Proposed Amendments,

Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements'' (84 FR 60648), hereinafter referred to as the "2019 ESRD PPS & DMEPOS final rule."

In the 2019 ESRD PPS & DMEPOS final rule, we finalized technical corrections; updates to definitions and documentation requirements; standard elements of a DMEPOS order; established one harmonized Master List; revised factors for placing an item on the Required Prior Authorization List; and established the authority to exempt compliant suppliers from the prior authorization process. We noted that we believe this exemption process meets our fiduciary obligation to protect the Medicare Trust Funds while remaining cognizant of contractor resource limitations and supplier burden. Specifically, § 414.234(c)(1)(ii) clarifies that CMS may elect to exempt suppliers from prior authorization upon demonstration of compliance with Medicare coverage, coding, and payment rules through such prior authorization process. We did not provide specifics on this exemption process in the regulatory text. However, we received comments suggesting that prior authorization be reserved for aberrant billers and suggesting that CMS consider compliance incentives to waive prior authorization for suppliers that are compliant with billing requirements. We stated that we would consider these suggestions in future rulemaking.

2. Provisions of the Proposed Rule

Prior authorization for certain DMEPOS items ensures that Medicare beneficiaries continue to receive medically necessary items while protecting the Medicare Trust Funds from improper payments, and at the same timekeeping the medical necessity documentation requirements unchanged for suppliers. We proposed to add language to § 414.234(c)(1) that provides additional specificity for the exemption process in § 414.234(c)(1)(ii).

To reduce supplier burden and effectively utilize contractor resources, we proposed to clarify circumstances under which CMS would exempt a supplier from the prior authorization

process (see § 414.234(c)(1)(ii)(A)) upon demonstration of compliance with Medicare coverage, coding, and payment rules and that this exemption would remain in effect until CMS withdraws the exemption. We will exempt suppliers that achieve a prior authorization provisional affirmation threshold of at least 90 percent during an initial or periodic assessment. We believe that, by achieving this percentage, the supplier will be demonstrating an understanding of the requirements for submitting accurate claims. We do not believe it is necessary for a supplier to achieve 100 percent compliance to qualify for an exemption because unintentional and sporadic errors could occur that are not deliberate or systematic attempts to submit claims that are not payable. In addition, we proposed that we would withdraw an exemption if evidence becomes available, based on a review of claims, that the supplier has begun to submit claims that are not payable based on Medicare's billing, coding or payment requirements. If the rate of non-payable claims submitted becomes higher than 10 percent during a periodic assessment, we would withdraw the exemption.

In proposed § 414.234(c)(1)(ii)(B), we proposed to provide 60-day notice of an exemption from mandatory prior authorization requirements. Similarly, we proposed to provide 60-day notice if an exemption is withdrawn, to give the supplier time to begin submission of prior authorization requests, in compliance with mandatory requirements. We solicited comments on these proposals and received a small number of comments. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported the proposed prior authorization exemption process.

Response: We appreciate the commenters' support.

Comment: A commenter recommended that suppliers should be provided with a choice to be exempt from prior authorization, as some suppliers may want to continue to obtain prior authorization to ensure claims meet Medicare medical need requirements.

Response: We thank the commenter for the suggestion and respond by clarifying that suppliers that find value in the prior authorization program may decline the exemption.

Comment: A commenter suggested that we modify the analyses on compliance approval ratings for national suppliers with more than 10 locations by using the organization's tax identification numbers or legal entity, inclusive of all locations, versus individual PTAN or individual location to ensure an accurate sample size. The commenter stated that this will allow for more manageable implementation and reduce the potential volume of audits.

Response: We appreciate the suggestion and will continue to assess methodologies and adjust in the future, if needed; however, at this time we believe our current methodology provides us with the information needed to make the most accurate determination of compliance.

Comment: A commenter suggested we set a minimum number of surveys, such as 20, to ensure sufficient sample size occurs.

Response: We appreciate the suggestion and agree that sample sizes are important when assessing data; however, because we have suppliers that may not meet this minimum threshold, we are unable to incorporate this suggestion.

Comment: A few commenters urged CMS to apply exemptions equitably and transparently, requesting that CMS develop criteria that would avoid creating a two-tiered system favoring larger suppliers. Another commenter supported a more formal and transparent process for granting and rescinding prior authorization exemptions.

Response: We agree that there should be equity and transparency in the exemption process and believe we have achieved that by providing our metrics in this rule and by applying it consistently to all suppliers. We do not believe this creates a two-tiered system favoring larger suppliers.

Comment: A commenter recommended we include contingency mechanisms for extraordinary circumstances in situations where electronic communication with plans and CMS may be disrupted, such as a natural disaster.

Response: We appreciate the commenter's suggestion; however, without more information or details on why this may be needed or how this may benefit suppliers that may or may not qualify for an exemption, we are unable to incorporate this suggestion.

Comment: Some commenters, while supportive, stated that prior authorization creates excessive administrative burden, penalizes clerical errors, and greatly impairs beneficiary access to medically necessary care.

Response: This rule focuses exclusively on the prior authorization exemption process, which will reduce burden, and not the required prior authorization program in its entirety. Therefore, this comment is outside of the scope of this rule.

After consideration of public comments, we are finalizing all of our proposals to clarify circumstances under which CMS would exempt a DMEPOS supplier from the prior authorization process, including our proposal to provide notice of the exemption, or the withdrawal of the exemption, from prior authorization requirements.

VII. DMEPOS Competitive Bidding Program

A. Background

Section 1847(a) of the Act, as amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), requires the Secretary of the Department of Health and Human Services (the Secretary) to establish and implement competitive bidding programs (CBPs) in competitive bidding areas (CBAs) throughout the United States for contract award purposes for the furnishing of competitively priced DMEPOS items and services, including:

- Certain DME and medical supplies (as defined in section 1834(a)(13) of the Act) for which payment would otherwise be made under section 1834(a) of the Act.
- Enteral nutrients, equipment, and supplies (enteral nutrition) described in section 1842(s)(2)(D) of the Act.
- Off-the-shelf (OTS) orthotics for which payment would otherwise be made under section 1834(h) of the Act.
- Lymphedema compression treatment items (as defined in section 1861(mmm) of the Act) for which payment would otherwise be made under section 1834(z) of the Act.

1. Benefits of the DMEPOS CBP

The DMEPOS CBP utilizes bids submitted by DMEPOS suppliers to establish applicable payment amounts under Medicare Part B for certain DMEPOS items and services.

The primary goal of the DMEPOS CBP is to reduce excessive Medicare payments for DMEPOS items and services by awarding contracts to a group of suppliers with the lowest bid amounts that have the capacity to furnish the items and services needed in each CBA. In accordance with section 1847(b)(2)(A)(iii) of the Act, contracts cannot be awarded if the total amounts to be paid to contract suppliers in the area are not expected to be less than the total amounts that would otherwise be paid under the DMEPOS fee schedules. Another goal is to provide the best value DMEPOS to achieve positive health outcomes for Medicare beneficiaries.

In accordance with section 1847(b)(2)(A)(i) of the Act, contracts cannot be awarded to any supplier that does not meet the quality standards established in accordance with section 1834(a)(20) of the Act. From 2011 through 2018, both of these goals were successfully accomplished for many categories of DMEPOS items and services mandated for inclusion under the program that had the highest volume in terms of total allowed charges. The DMEPOS CBP provides additional benefits that are arguably just as important as lowering excessive payment rates. In general, when the DMEPOS CBP lowers the allowed amounts paid for items and services, it decreases the incentive for committing fraud. Limiting the number of contracts awarded in a competition also reduces the number of suppliers with which a contract supplier must compete for Medicare business. The lower the number of contracts awarded, the greater the chance a supplier receiving a contract has to maintain a steady stream of business and potentially increase their volume of business. The lower the number of contract awards, the more valuable the contracts become, creating a greater incentive for bidding entities to bid more competitively.

Another important benefit of the DMEPOS CBP is that it ensures access to covered DMEPOS items and services. Pursuant to section 1847(b)(3)(A) of the Act and 42 CFR 414.422, the terms of an awarded contract require that a contract supplier must agree to furnish items under its contract to any beneficiary who maintains a permanent residence in, or who visits, the CBA and who requests those items from that contract supplier. For example, a supplier with a contract to furnish oxygen and oxygen equipment, a product category that includes highly profitable items like oxygen concentrators, and less profitable items like liquid oxygen, must provide access to liquid oxygen as a term of their contract. Contract suppliers may not elect to only furnish the more profitable items and services included in a product category under their contract or to only furnish the items and services to beneficiaries who are less costly to serve (due to, for example, lower shipping or delivery costs for those that live in close proximity to the contract supplier's location). In contrast, suppliers of items not included under the DMEPOS CBP are not mandated to furnish any item or service to any beneficiary. They may elect not to

serve beneficiaries in hard-to-reach places or not to furnish items such as liquid oxygen and oxygen equipment that are not as profitable as other items such as stationary oxygen concentrators.

2. Standard Payment Rules for DMEPOS Items and Services and Competitive Bidding Demonstrations

Medicare began paying for DME and orthotics (leg, arm, back, and neck braces) on a fee schedule basis beginning January 1, 1989, in accordance with section 1834(a) of the Act. The fee schedule payment rules for orthotics were subsequently relocated under new section 1834(h) of the Act. In 2001, payment on a fee schedule basis was implemented for enteral nutrition covered under the prosthetic device benefit defined under section 1861(s)(8) of the Act based on the authority provided by section 1842(s)(2) of the Act. The Medicare allowed payment amounts for these DMEPOS items and services are based on the lower of the supplier's actual charge on the claim or the fee schedule amount for the item. Prior to implementation of the fee schedules, payment for these items and services was made in accordance with the reasonable charge payment methodology mandated by section 1842(b)(3) of the Act, which based the Medicare allowed payments for these items in a given calendar year based on what suppliers charged for furnishing the items and services in the preceding calendar year. The reasonable charge payments began in 1966 and increased each year without any limit on inflation until October 1986.

The statute mandates a very specific methodology for calculating the fee schedule amounts. The fee schedule amounts for DME, which were first implemented in 1989, are based on the average of the reasonable charges paid for the item during 1986 and 1987 in each State, increased on an annual basis by covered item update factors in accordance with section 1834(a)(14) of the Act. The statewide fee schedule amounts for the contiguous United States are limited by a national ceiling and floor based on the median of the statewide fee schedule amounts (ceiling) and 85 percent of the median of the statewide fee schedule amounts (floor). The fee

schedule amounts for orthotics are based on the average of the reasonable charges paid for the item during 1986 and 1987 and are increased on an annual basis by covered item update factors in accordance with section 1834(h)(4) of the Act. For areas within the contiguous United States, the fee schedule amounts are based on the average reasonable charges in ten regions of the United States. The regional fee schedule amounts are limited by a national ceiling and floor based on 120 percent of the average of the regional fee schedule amounts across all States (ceiling) and 90 percent of the average of the regional fee schedule amounts across all States (floor). The fee schedule amounts for enteral nutrition were the nationwide fee schedule amounts from 2002 through 2015. The nationwide fee schedule amounts were based on the lower of the average of the reasonable charges paid for the item in 1995 or 2002, increased on an annual basis by update factors in accordance with section 1842(s)(1)(B) of the Act. In 2016, the fee schedule amounts for enteral nutrition were adjusted based on information from the DMEPOS CBP and converted to statewide fee schedule amounts. For items of DME and orthotics that were not paid for under Medicare during 1986 and 1987, the fee schedule amounts for the items are established using the fee schedule amounts for comparable items or supplier price lists in accordance with regulations at 42 CFR 414.238. For items of enteral nutrition that were not paid for under Medicare in either 1995 or 2002, the fee schedule amounts for the items are established using the fee schedule amounts for comparable items or supplier price lists in accordance with regulations at 42 CFR 414.112.

Complaints and reports about excessive rental payments for DME began in the 1960s and early 1970s. As early as May 1972, the idea of using competitive bidding to reduce reasonable payments was presented in a report by the Government Accountability Office (GAO), then referred to as the General Accounting Office.[56] In response to rapidly growing expenditures for DME in the early 1980s, CMS, then referred to as the Health Care Financing Administration,

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56 "Need for Legislation to Authorize More Economical Ways of Providing Durable Medical Equipment Under Medicare," B-164031 (4), May 12, 1972

contracted with Abt Associates, Inc., to design Medicare competitive bidding demonstrations for DME, which were planned to go into effect in 1987 in nine metropolitan statistical areas (MSAs). However, Congress imposed a funding moratorium on the demonstrations before they could be implemented. Throughout the 1980s and 1990s, excessive Medicare payments for DME continued to be the focus of reports by the Department of Health and Human Services, Office of Inspector General (OIG) and the GAO, as well as media outlets and Congressional Hearings. Section 4319 of the Balanced Budget Act (BBA) of 1997 (Pub. L. 105-33) mandated demonstration projects for competitive bidding for oxygen and oxygen equipment and other Part B items and services, other than physician services. CMS contracted with Abt Associates, Inc., to design the competitive bidding demonstrations mandated by the BBA of 1997, and many aspects of the demonstrations designed in the 1980s were incorporated into the demonstrations held in Polk County, Florida, for oxygen equipment and supplies, hospital beds and accessories, enteral nutrition, urological supplies, and surgical dressings from October 1, 1999 through September 30, 2002, and in San Antonio, Texas, for oxygen equipment and supplies, hospital beds and accessories, wheelchairs and accessories, general orthotics, and nebulizer drugs from February 1, 2001, through December 31, 2002. The Medicare payment amounts under the demonstrations were lowered by approximately 19 percent. Statistical and qualitative data indicate that beneficiary access and quality of services were essentially unchanged.

The DMEPOS CBP was modeled after the successful demonstration programs from the late 1990s and early 2000s. For more information about the demonstrations, refer to the proposed rule titled, "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues," published in the **Federal Register** on May 1, 2006 (hereafter referred to as the "2006 proposed rule") (71 FR 25654). During the initial development of the DMEPOS CBP, we received substantial feedback from the Program Advisory and Oversight Committee (PAOC), mandated by section 1847(c) of

the Act, as amended by section 302(b)(1) of the MMA, to provide advice to the Secretary with respect to the following functions:

- The implementation of the Medicare DMEPOS CBP.
- The establishment of financial standards for entities seeking contracts under the Medicare DMEPOS CBP, taking into account the needs of small providers.
- The establishment of requirements for collection of data for the efficient management of the Medicare DMEPOS CBP.
- The development of proposals for efficient interaction among manufacturers, providers of services, suppliers (as defined in section 1861(d) of the Act), and individuals.
- The establishment of quality standards for DMEPOS suppliers under section 1834(a)(20) of the Act.

The DMEPOS CBP was initially implemented using the final rule titled, "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues," published in the **Federal Register** on April 10, 2007 (72 FR 17992), hereafter referred to as the "2007 final rule." Additional changes were made to the DMEPOS CBP in subsequent rulemaking.

3. Phased In Implementation of the DMEPOS CBP

As discussed previously, section 1847(a) of the Act provides discretion to phase in items into the DMEPOS CBP. Section 1847(a)(1)(B) and (D) of the Act mandate the phase-in of the DMEPOS CBP in nine of the largest MSAs (known as "Round 1", implemented on January 1, 2011), followed by 91 additional large MSAs (known as "Round 2", implemented on July 1, 2013), and finally in additional areas, which do not necessarily need to be tied to MSAs. Although the DMEPOS CBP is mandated to be expanded into areas throughout the United States, no timeframe is provided for when all areas must be phased in under the DMEPOS CBP. In accordance with section 1847(a) of the Act, rural areas and areas with low population density within urban areas that are not competitive may be excluded from the DMEPOS CBP, unless

there is a significant national market through mail order for a particular item or service. Section 1847(b)(3)(B) of the Act mandates that the contracts awarded to suppliers under the CBP must be recompeted not less often than once every 3 years. In accordance with these directives, we initiated several rounds of the DMEPOS CBP, as summarized in table FF-25:

TABLE FF-25: COMPETITIVE BIDDING ROUNDS AND CONTRACT PERIODS

<table>
<tr><th>Calendar Year</th><th>Round 1 Areas (9 Metropolitan Statistical Areas (MSAs))</th><th>Round 2 Areas (90 MSAs) and National Mail Order</th></tr>
<tr><td>2011</td><td rowspan="3">Round 1
1/11/2011 - 12/31/2013</td><td rowspan="2">--</td></tr>
<tr><td>2012</td></tr>
<tr><td>2013</td><td rowspan="3">Round 2 & National Mail Order
7/1/2013 - 6/30/2016</td></tr>
<tr><td>2014</td><td rowspan="3">Round 1 Recompete
1/1/2014 - 12/31/2016</td></tr>
<tr><td>2015</td></tr>
<tr><td>2016</td><td rowspan="2">Round 2 & National Mail Order Recompetes
7/1/2016 - 12/31/2018</td></tr>
<tr><td>2017</td><td rowspan="2">Round 1 2017 (recompete)
1/1/2017 - 12/31/2018</td></tr>
<tr><td>2018</td></tr>
<tr><td>2019</td><td colspan="2" rowspan="2">Temporary Gap Period</td></tr>
<tr><td>2020</td></tr>
<tr><td>2021</td><td colspan="2" rowspan="3">Round 2021 (recompetes for Round 1 and Round 2)
1/1/2021 - 12/31/2023</td></tr>
<tr><td>2022</td></tr>
<tr><td>2023</td></tr>
<tr><td>2024</td><td colspan="2" rowspan="2">Temporary Gap Period</td></tr>
<tr><td>2025</td></tr>
</table>

For competitions under the DMEPOS CBP prior to July 1, 2016, there were some CBAs that included MSAs that spanned multiple states. However, starting on July 1, 2016 (Round 2 Recompete), those CBAs were sub-divided so that there are no multi-state CBAs. This has resulted in the DMEPOS CBP operating in 130 CBAs throughout the nation, and those CBAs contain approximately half of the enrolled Medicare Part B population. The other half of the Medicare Part B population resides in areas where the DMEPOS CBP has not yet been phased-in, including approximately 275 MSAs, which we refer to as non-competitive bidding areas (non-CBAs).

In competitions under the DMEPOS CBP prior to Round 2021, bidding entities bid for contracts for furnishing multiple items and services, identified by Healthcare Common Procedure Coding System (HCPCS) Level II codes, under several different product categories. The product categories included in the CBPs prior to and including Round 2021 are as follows:

- National Mail Order CBA: Diabetes testing supplies.

- Round 1 2017 and Round 2 Recompete: Enteral Nutrients, Equipment and Supplies; General Home Equipment and Related Supplies and Accessories (including hospital beds, pressure reducing support surfaces, commode chairs, patient lifts, and seat lifts); Nebulizers and Related Supplies; Negative Pressure Wound Therapy (NPWT) Pumps and Related Supplies and Accessories; Respiratory Equipment and Related Supplies and Accessories (including oxygen and oxygen equipment, continuous positive airway pressure (CPAP) devices, and respiratory assist devices (RADs)); Standard Mobility Equipment and Related Accessories (including walkers, standard manual wheelchairs, and standard power wheelchairs); and Transcutaneous Electrical Nerve Stimulation (TENS) Devices and Supplies.
- Round 2021: OTS Back Braces and OTS Knee Braces.

In past rounds of competition, CMS allowed a 60-day bidding window for bidding entities to prepare and submit bids. Our regulation at § 414.412 specifies the rules for submission of bids under the DMEPOS CBP. Each bid submission is evaluated, and contracts are awarded to qualified bidding entities in accordance with the requirements of section 1847(b)(2) of the Act and the regulation at § 414.414, which specifies conditions for awarding contacts, including a financial standard evaluation of each bidding entity that submits a bid. This process included a review of tax records, credit reports, and other financial data, which led to the calculation of a financial score, similar to processes used by lenders when evaluating the viability of a company. All bidding entities must meet the financial standards established for the program to be offered a contract. Applying financial standards to bidding entities is needed to assess the expected financial health and quality of bidding entities, and to ensure that the selected bidding entities are able to continue to serve market demand throughout the duration of the contract period.

4. Bid Surety Bonds

Section 522(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114-10) (MACRA) requires bid surety bonds and State licensure for entities submitting bids under the DMEPOS CBP and was implemented as part of the final rule titled, “Medicare

Program; End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model," published in the **Federal Register** on November 4, 2016 (81 FR 77834) (hereinafter referred to as the "2016 ESRD PPS & DMEPOS final rule"). Section 522(a) of MACRA added section 1847(a)(1)(G) of the Act to require bidders to submit a bid surety bond by the deadline for bid submission. We implemented section 522(a) of MACRA during the next round of competitive bidding following enactment of MACRA, which was Round 2021, even though Round 2021 began after the time period specified in the statute. Section 1847(a)(1)(H)(i) of the Act provides that in the event that a bidder is offered a contract for any product category for a CBA, and its composite bid for such product category and area was at or below the median composite bid rate for all bidders included in the calculation of the single payment amount (SPA) for the product category and CBA, and the entity does not accept the contract offered, the bid surety bond(s) for the applicable CBAs will be forfeited and the Secretary will collect on the bid surety bond(s). In instances where a bidder does not meet the bid surety bond forfeiture conditions for any product category for a CBA as specified in section 1847(a)(1)(H)(i) of the Act, then the bid surety bond liability submitted by the entity for the CBA will be returned to the bidder within 90 days of the public announcement of the contract suppliers for such product category and area. Detailed conditions of the bid surety bonds were implemented in the 2016 ESRD PPS & DMEPOS final rule (81 FR 77931). The regulation (subsequently redesignated from § 414.412(h) to § 414.412(g) (see 83 FR 56922)) requires bidders to obtain bid surety bonds, and if an entity is offered a contract for any product category for a CBA, its composite bid for such product

category and area is at or below the median composite bid rate for all bidders included in the calculation of the SPA(s) for the product category/CBA combination, and the entity does not accept the contract offered, the bid surety bond for the applicable CBA will be forfeited and CMS will collect on the bid surety bond via Electronic Funds Transfer from the respective bonding company. We believe the bid surety bond requirement encourages all bidding entities to submit substantiated bid amounts – that is, to further prevent bidding entities from submitting a low bid amount to have a better opportunity in being offered a DMEPOS Contract.

On June 30, 2025, CMS issued a proposed rule with a 60-day comment period on the issues related to the provisions of this final rule.

B. Determining Payment Amounts and the Number of Contracts Awarded for the DMEPOS CBP

In order to incentivize bidding entities to submit competitive bids and in order to ensure that the amounts to be paid to contract suppliers for an item under a competitive bidding program are expected to be less than the amounts that would otherwise be paid for the same item under subpart C or subpart D, we proposed to make modifications to the process for selecting the number of contract suppliers sufficient to furnish items and services in a competition and the methodology for establishing SPAs for lead and non-lead items. We also proposed, in lieu of self-reported supplier capacity, to estimate supplier capacity in accordance with 42 CFR 414.414(e)(2) using data on actual contract supplier capacity from previous rounds of the DMEPOS CBP.

We solicited comments on these proposals.

1. Background

The DMEPOS CBP is a program in which Medicare-enrolled DMEPOS suppliers submit bids and compete to receive a limited number of contract(s) to furnish DMEPOS items and services, identified by HCPCS codes, within different product categories in different CBAs throughout the nation. The bids from contract suppliers under the program are used to calculate SPAs to pay the contract suppliers in lieu of the payment amounts they would otherwise receive

under the standard payment rules under sections 1834(a)(2) through (7), 1834(h), 1834(z), and 1842(s) of the Act. Section 1847(b)(5) of the Act provides that Medicare payment for competitively bid items and services is equal to 80 percent of the applicable SPA, less any unmet Part B deductible described in section 1833(b) of the Act. The contract supplier collects a coinsurance payment from the beneficiary equal to 20 percent of the applicable SPA as well as any unmet Part B deductible. The total payment made to the contract supplier by Medicare and the beneficiary cannot exceed the SPA. For DMEPOS items and services that are not paid for under the DMEPOS CBP, a non-participating supplier has the option to collect more than the Medicare allowed amount from the beneficiary, a practice referred to as balance billing. Balance billing is not allowed under the DMEPOS CBP.

a. Rules in Effect Prior to Round 2021 of the DMEPOS CBP

In accordance with the 2007 final rule (72 FR 17992), prior to Round 2021, bidding entities submitted a bid amount for each item in a product category. These bid amounts were combined into one composite bid for each bidding entity, aggregating their bids for all items in a product category. To compute a composite bid, historical DMEPOS utilization data was used to assign weights to each item in each product category based on the national volume of the item in proportion to the national volume of all items in the product category. The composite bid for a bidding entity equaled the item's weight multiplied by the item's bid amount and summed across all items in the product category, which was used to determine the expected costs for all items in the product category based upon expected volume. Once a composite bid was calculated for each entity that submitted a bid in the competition, the composite bids were arrayed in order from lowest to highest. CMS began the contract award process by awarding a contract to the supplier with the lowest composite bid and then awarding contracts to the next supplier in the array. This process was repeated until there were enough suppliers to meet the projected demand[57] in the

[57] As explained in the 2007 DMEPOS final rule (72 FR 18039), demand for items and services was projected using Medicare claims data for allowed services during the previous 2 years, trended forward to the contract period.

CBA for the items in the product category. The composite bid for the bidding entity where the cumulative capacity of the bidding entities for furnishing the items and services meets or exceeds projected demand is referred to as the pivotal bid. The array of bidding entities with bids at or below the pivotal bid are referred to as the winning contract suppliers or the winning array of suppliers. The bids for these contract suppliers are used to establish the SPAs for the items and services in the product category for each CBA.

Prior to Round 2021, the SPA for each item in the product category was calculated based on the median of the winning contract suppliers' bids for each item. As explained in the 2007 final rule, we believed that setting the SPA based on the median of the contract suppliers' bids satisfies the statutory requirement that SPAs are to be based on bids submitted and accepted. This resulted in a single payment for an item under a DMEPOS CBP that was representative of all acceptable bids, not just the highest or the lowest of the winning bids for that item (72 FR 18045). Using the median of the winning bids as opposed to the lowest or highest bids is consistent with how Medicare has established allowed payment amounts for DMEPOS items since the beginning of the Medicare program. Under the reasonable charge payment methodology in place from 1966 through 1988, payment was based on the lower of the supplier's customary charge (the 50th percentile of charges from the supplier), or the prevailing charge for the item (the 75th percentile of customary charges for the item from suppliers in a given locality). The fee schedule amounts used to pay claims for DMEPOS beginning in 1989 are based on average reasonable charges for the items. The lowest or highest charges for an item were never used to establish the Medicare allowed payment amount for the DMEPOS item.

At the start of the DMEPOS CBP in 2011, CMS inflated demand for items and services in the CBAs so that more contracts would be awarded than needed to better ensure access to items and services under the new program. Prior to the finalization of the median of winning bids methodology, CMS explained to the PAOC that although a number of suppliers will be paid

below what they bid, an approximately equal number of suppliers will be paid more than what they bid.[58]

From the inception of the DMEPOS CBP in 2011 and implementation of subsequent rounds through 2018, CMS implemented a very successful program using item weights, composite bids, and SPAs that were based on the median of the winning contract suppliers' bids for each item. Using the median of the winning bids resulted in 40 to 80 percent reductions in payment amounts under the program, even though more contracts were awarded than needed to meet an inflated demand target for items and services, because use of the median of winning bids reduces the impact of "outlier" bids at the top and bottom of the array of winning bids on the payment amount established for all contract suppliers. Suppliers accepted their contract offers at the median of the winning supplier bids approximately 92 percent of the time consistently from round to round, Medicare and taxpayers saved money, and access to quality items and service was preserved. Section 1834(a)(1)(F) of the Act requires CMS to adjust fee schedule amounts for DME items and services furnished in non-CBAs based on the SPA pricing. Sections 1834(h)(1)(H)(ii) and 1842(s)(3)(B) of the Act provide discretion to adjust fee schedule amounts for OTS orthotics and enteral nutrition, respectively, furnished in non-CBAs based on SPA pricing. Adjustments to the fee schedule amounts have been in place for these items and services for several years and contract suppliers have accepted payment at the adjusted rates as payment in full for approximately 99 percent of all claims with no significant downward trends in utilization, and no negative changes in beneficiary health outcomes, as determined by CMS's health outcome claims monitoring.

b. Changes Implemented with Round 2021 of the DMEPOS CBP

[58] As required by section 1847(c) of the Act, the Secretary of Health and Human Services established the PAOC, which advised the Secretary on a range of implementation topics for the DMEPOS CBP. The PAOC was comprised of a broad mix of relevant industry, consumer, and government parties. Specifically, the membership included beneficiary/consumer representatives, manufacturer representatives, supplier representatives, certification/standard representatives, Federal and State program representatives, a physician and a pharmacist.

To improve the competitiveness and sustainability of the program, significant changes to the DMEPOS CBP were made as part of the "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments To Correct Existing Regulations Related to the CBP for Certain DMEPOS," published in the **Federal Register** on November 14, 2018, (83 FR 56922) (hereinafter referred to as (2018 ESRD & DMEPOS final rule). Effective January 1, 2019, and beginning with Round 2021, a "lead item" pricing methodology was established for submitting bids, calculating composite bids for bidding entities, determining pivotal bids, and calculating SPAs. The methodology for calculating SPAs was changed from the median of the winning contract suppliers' bid amounts for each item in the product category to the maximum winning contract supplier bid amount for a "lead item" in the product category, which is used to calculate the SPAs for all items in the product category. Under these rules, instead of submitting bid amounts for each item in the product category, the bidding entity submits a single bid amount for a "lead item" in the product category and this bid amount represents the bidding entity's "composite bid" for furnishing all items in the product category. The "lead item" in each product category is defined in our regulations at § 414.402 to mean the item, in a product category with multiple items, with the highest total nationwide Medicare allowed charges of any item in the product category prior to each competition. The bids for the lead item are used to establish the SPAs for both the lead item and all other items (non-lead items) in the product category. In accordance with § 414.416(b)(1), the SPA for a lead item furnished under a CBP is equal to the maximum bid amount submitted for that item by bidding entities whose composite bids for the product category that includes the item are equal to or below the pivotal bid for that product category. Additionally, under § 414.416(b)(2), the SPA for a lead item must be less than or equal to the amount that would otherwise be paid for the

same item under the DMEPOS fee schedule. The SPAs for the non-lead items within the product category are determined by multiplying the lead item SPA by a relative ratio. The ratios are based on the historic differences in the fee schedule amounts for the lead item and non-lead items. In accordance with § 414.416(b)(3), the SPA for a non-lead item in a product category furnished under a CBP is equal to the SPA for the lead item in the same product category multiplied by the ratio of the average of the 2015 fee schedule amounts for all areas (that is, all states, the District of Columbia, Puerto Rico, and the United States Virgin Islands) for the non-lead item to the average of the 2015 fee schedule amounts for all areas for the lead item.[59]

The lead item pricing methodology was adopted to prevent a phenomenon that had been occurring under the DMEPOS CBP known as "unbalanced bidding," where bidding entities submitted low bid amounts for higher volume items under the product category because these bid amounts had a greater impact on their composite bid, and higher bid amounts for lower volume items under the product category because these bid amounts had a lesser impact on their composite bid. This resulted in skewed pricing results where SPAs for lower cost items with fewer features such as a manual hospital bed without side rails were higher than SPAs for higher cost items with more features such as a semi-electric hospital bed with side rails. Lead item pricing maintains the historic differences in prices for these items, while streamlining the bidding process and significantly decreasing the burden for bidding entities since they only have to submit one bid amount for each competition (product category and CBA). Previously, the bidding entity had to submit bid amounts for every item in the product category, which for some product categories such as standard power wheelchairs and standard manual wheelchairs was over a hundred separate bid amounts.

c. Projecting Demand for Items and Services and Estimating Supplier Capacity for Furnishing Items and Services

59 Calendar year 2015 is the last year the fee schedule amounts were not adjusted based on information from the CBP.

In determining the number of contract suppliers for a competition, we aim to limit the number of contract suppliers to ensure they are incentivized to submit a competitive bid. As discussed in section B.1.d. of this final rule, awarding too many contracts decreases the incentive for a bidding entity to submit a competitive bid—given that bidding entities would be more likely to be awarded a contract regardless of the submitted bid amount. At the same time, in determining the number of contracts to award in a competition, we balance a number of other considerations set forth at sections 1847(b)(2)(A)(iv) and (b)(4)(B) of the Act. Section 1847(b)(4)(A) of the Act, allows the Secretary to limit the number of contract suppliers in a CBA to the number needed to meet projected demand for items and services covered under the contracts and also directs the Secretary to consider whether the bidders can furnish enough items or services to meet the anticipated needs of individuals within the contract's geographic area on a timely basis. Section 1847(b)(4)(B) of the Act also specifies that the Secretary shall award contracts to multiple entities submitting bids in each area for an item or service and section 1847(b)(2)(A)(iv) of the Act specifies that individuals must have access to multiple contract suppliers in the CBA or else contracts may not be awarded in that area. In balancing these considerations, we codified in current regulations at 42 CFR 414.414(e) our process for selecting the number of contract suppliers to be awarded a contract for a competition.

From 2011 through 2023, the methodologies and procedures used for projecting demand for items and services and estimating a supplier's capacity for furnishing items and services as a contract supplier remained virtually unchanged. These methodologies were designed to overestimate demand and underestimate capacity to ensure access under the program when it began. These methodologies inflated the projected demand target for items and services, awarded no capacity for contract suppliers new to an area or product category, and limited a contract supplier's estimated capacity to their historic levels if they did not meet certain financial standards. Soon after the program was implemented in 2011, it was apparent that more contracts were being awarded under the program than needed to meet demand for items and services;

however, CMS decided to continue using these methodologies during each round of competition up to and including Round 2021. While more contracts were awarded than needed to meet demand, this was balanced by establishing SPAs using the median of winning bids rather than a higher amount such as the maximum winning bid, thus still achieving the goal of lowering payment amounts and achieving savings under the DMEPOS CBP.

Under current regulations at 42 CFR 414.414(e)(1), which were revised as part of the 2018 ESRD & DMEPOS final rule (83 FR 57018), we first calculate the expected beneficiary demand in the CBA for the lead item in the product category. This methodology accounts for actual historic beneficiary utilization of the lead item in the product category prior to each round of the DMEPOS CBP, while also considering the expected growth in the number of Medicare beneficiaries in the CBA as well as the expected growth in utilization of the lead item in the product category in the CBA. Specifically, under this methodology, CMS calculates the projected beneficiary demand for the lead item by multiplying the actual historic beneficiary utilization by a percent increase that is derived from increasing historic utilization by both the expected increase in number of beneficiaries and the expected increase in utilization, in general. If either the change in number of beneficiaries or the change in utilization in the CBA is expected to be negative, the negative trend is not included in the projection of demand and is instead set equal to one. In addition, the projected beneficiary demand is not reduced based on the number of items that would likely be furnished by grandfathered suppliers, which typically furnish approximately 15 percent of rented durable medical equipment items and related accessories (83 FR 57024). In accordance with section 1847(a)(4) of the Act and regulations at 42 CFR 414.408(j), suppliers of rented DME and oxygen and oxygen equipment can become "grandfathered suppliers" and continue furnishing these items under the DMEPOS CBP if the rental agreement or supply arrangement with the beneficiary began prior to the start of the contract period. CMS has thus inflated the demand target in order to provide more contract suppliers for beneficiaries to choose from by using historic utilization, trending this forward by

both the expected increase in number of beneficiaries and the expected increase in utilization and by not decreasing the number to account for fraudulent claims, decreases in the number of beneficiaries, or the percentage of demand that is accounted for by grandfathered suppliers or other non-contract suppliers under the exceptions at 42 CFR 414.404(b) for physicians, hospital outpatient departments, physical therapists, and occupational therapists. In the past, this did not compromise savings under the program when the median of winning bids was used to establish SPAs rather than a higher payment such as the maximum winning bids.

After determining the projected beneficiary demand, pursuant to 42 CFR 414.414(e)(2), we then calculate the total supplier capacity that would be sufficient to meet the expected beneficiary demand in the CBA for the lead item in the product category. The capacity is currently based on the bidding entity's self-reported projection of how many items they could furnish at the amounts they bid. If a bidding entity reported a capacity that was less than their historic capacity, the capacity for the bidding entity was adjusted up to the level of their historic capacity; however, the capacity was never increased above their historic capacity.

Pursuant to 42 CFR 414.414(e)(5), CMS then analyzes each eligible bidder's financial health to assess its ability to furnish its estimated capacity against the projected beneficiary demand in each competition.

- If a bidder's financial score[60] meets the minimum financial threshold required by CMS for a bidder to receive additional capacity beyond its historical amount, CMS accepts the bidder's capacity at the greater of its estimated or historical capacity (based on claims data). However, if a bidder's financial score does not meet this threshold, the bidder is a new supplier (does not have 12 months of actual financial statements and submits at least one month of pro

[60] CMS uses the required tax return extract and the required financial documents to calculate standard accounting ratios for each bidder. These ratios, along with the credit report and numerical credit score or rating, are used to compute the bidder's financial score. The methodology for computing bidders' financial scores has remained consistent throughout all rounds of the DMEPOS CBP.

forma statements), or the bidder is a specialty supplier, CMS only accepts its capacity at its historical amount.

- If a bidder's accepted capacity is greater than 20 percent of projected beneficiary demand in the CBA, CMS adjusts the bidder's capacity to 20 percent of projected beneficiary demand to ensure at least five contracts are awarded for each competition, in accordance with 42 CFR 414.414(h).

Pursuant to 42 CFR 414.414(e)(3) and (4), we then array the composite bids from the lowest composite bid price to the highest composite bid price and calculate the pivotal bid for the product category using the projected beneficiary demand and supplier demand calculated in accordance with 42 CFR 414.414(e)(1) and (2), as discussed previously. The pivotal bid, as defined under 42 CFR 414.402, is the lowest composite bid based on bids submitted by bidding entities for a product category that includes a sufficient number of suppliers to meet beneficiary demand for the items in that product category. In accordance with 42 CFR 414.414(e)(5), contracts are awarded to all suppliers and networks whose composite bids are less than or equal to the pivotal bid for that product category (and that meet the supplier eligibility requirements specified in the regulations and the Request for Bids Instructions).

To ensure that the number of contract suppliers selected will meet beneficiary demand, CMS conducts a secondary analysis to determine if additional contract suppliers should be awarded contracts. Part of this analysis examines if bidding entities awarded contracts need (and are planning) to expand operations and need time to ramp up to meet projected beneficiary demand. To do so, CMS analyzes the most recent 12 months of claims data that was not available when we first conducted this analysis for all contract suppliers that should be awarded contracts under the initial analysis. Using this data allows CMS to account for any unforeseen increases in utilization as almost a year has passed since the original calculation of the projected beneficiary demand. This secondary analysis further scrutinizes bidders' capacity to confirm that they are capable of furnishing items at levels exceeding their historical capacity in the

competition prior to calculating the final SPAs. This is performed by separating bidders into three groups that factor in each bidder's financial health, experience furnishing the lead item, and ramp-up revenue percentage.[61] Expansion plans were required in rounds prior to Round 2021 for suppliers that were new to an area, new to a product category, or submitted an estimated capacity that represented substantial growth over current levels. Beginning with Round 2021, bidders were no longer required to submit expansion plans as part of this process in accordance with the 2018 ESRD & DMEPOS final rule (83 FR 57052).

Group 1:

- Meets the minimum financial threshold required by CMS for a bidder to receive additional capacity beyond its historical amount; and
- Has experience furnishing the lead item in the CBA; and
- Has sufficient ramp-up revenue.

CMS accepts the higher of the estimated or historical capacity for Group 1 bidders.

Group 2:

- Meets the minimum financial threshold required by CMS for a bidder to receive additional capacity beyond its historical amount; and
- Does not have experience furnishing the lead item in the CBA, but has experience furnishing the lead item in other CBAs for which the bidder has submitted a bid; and
- Has sufficient ramp-up revenue.

CMS uses an experience factor to determine the capacity for Group 2 bidders by dividing the CBAs in which a bid was submitted where the bidder has experience furnishing the lead item by the total CBAs in which a bid was submitted for the lead item.

[61] Ramp-up revenue is determined by multiplying a bidder's projected growth (that is, taking the bidder's estimated capacity minus its historical capacity) by the preliminary SPA for the lead item. To determine if a bidder has sufficient ramp-up revenue to support its estimated capacity, its ramp-up revenue is divided by the bidder's actual revenue to produce a percentage. The purpose of this process is to act as a safeguard to ensure bidders are not over-estimating their ability to expand.

Group 2 bidders will have their capacity adjusted by multiplying the bidder's estimated capacity, in each of the competitions where they do not have experience, by the experience factor. For example, if a bidder submitted 10 bids for enteral nutrition and only had experience in half of those competitions, the bidder would have its estimated capacity lowered by 50 percent for the competitions where it does not have experience.

Group 3:

- Does not meet the minimum financial threshold required by CMS for a bidder to receive additional capacity beyond its historical amount; or
- Is a new supplier or a specialty supplier; or
- Does not have experience furnishing the lead item in any CBA for which the bidder has submitted a bid; or
- Does not have sufficient ramp-up revenue.

CMS accepts the historical capacity for Group 3 bidders, which is zero for bidders with no experience furnishing the lead item.

As initially stated, it is important to note that this secondary analysis is only used as a method for offering additional contracts and will not remove any bidding entities from the initial winning array (that is, bidding entities whose bids were at or below the pivotal bid). That is, the pivotal bid amount set during the initial capacity analysis is never lowered, even if this secondary analysis determines that beneficiary demand can be met with fewer suppliers. As a result, this secondary analysis removes the 20 percent of projected beneficiary demand limit (explained in the second bullet in Step 1 noted previously) because Step 1 already ensures that at least five contracts are awarded for each competition in accordance with § 414.414(h).

If the secondary analysis determines that no additional bidders are needed to meet beneficiary demand, the preliminary SPAs established under the initial analysis are set as the final SPAs for the competition as explained in the next section. However, if the secondary analysis determines that additional bidders are needed to meet beneficiary demand, CMS

continues through the array (bidders that are eligible for a contract offer are arranged by lowest to highest lead item bid amount) until bidder capacity meets or exceeds beneficiary demand for the competition. Once CMS adds enough bidders to where the cumulative accepted capacity of the bidders selected in the array meets beneficiary demand, the pivotal bid is increased accordingly, and the resulting SPAs are set as the final SPAs for the competition.

As established at 42 CFR 414.416(b)(1), the SPA for a lead item furnished under a competitive bidding program is equal to the maximum bid submitted for that item by suppliers whose composite bids for the product category that includes the item are equal to or below the pivotal bid for that product category. Once the pivotal bid is determined and the selection of winning contract suppliers is finalized, the SPAs are calculated based on the maximum submitted bid amount of contract suppliers in the winning array.

In order to ensure that small suppliers, meaning a supplier that generates gross revenue of $3.5 million or less in annual receipts including Medicare and non-Medicare revenue, have an opportunity to be considered for participation under the CBP in accordance with section 1847(b)(6)(D) of the Act, the special rules at § 414.414(g) establish a goal of awarding at least 30 percent of the total number of contracts to small suppliers. CMS first determines which percentage of bidders in the winning array of bids are small suppliers. If less than 30 percent, CMS will offer a contract to the next eligible small supplier(s) until the 30 percent small supplier target is reached or there are no more eligible small suppliers for the competition. Additional contracts may be awarded when a bid disqualification is overturned. Additional contracts may also be awarded if needed to meet demand when a contract offer is declined. Finally, in accordance with § 414.414(i), additional contracts may be awarded after CMS initially awards contracts, if necessary, to meet demand.

d. Problems Associated with Awarding More Contracts than Needed to Meet Demand for Items and Services

The current process for calculating total supplier capacity in accordance with 42 CFR 414.414(e)(2), which is calculated based upon the supplier's estimated capacity levels once awarded a contract, and for projecting beneficiary demand in accordance with 42 CFR 414.414(e)(1), which, as described previously is inflated above historic levels even in situations where the Medicare fee-for-service beneficiary population is declining in the CBA, results in the awarding of significantly more contracts than needed to meet actual demand for items and services in the CBA. Although access to multiple suppliers is mandated by section 1847 (b)(2)(A)(iv) of the Act, awarding an excess number of contracts can reduce the competitiveness of the program, which results in higher payment amounts – hurting potential savings. Large suppliers especially have limited to no incentive to submit competitive bids in such an environment (where excessive numbers of contracts are awarded). To highlight this issue, take for example if there were only two or three very large national chain suppliers that were all awarded contracts in most of the CBAs from 2011 through 2018. It is possible that any one of these suppliers alone would have been able to meet most of the actual demand for the particular item or service in many of the CBAs. If two chain suppliers become contract suppliers for a competition round after round regardless of what bid amount they submit, they would learn that they could submit a bid amount that is higher than they would be willing to accept and still be added as a contract supplier for the competition, which in turn would have a negative impact on savings under the competition. We observed this issue in the Round 2 Recompete (2016). We found that on average, 13 contracts were awarded per competition, but typically 4 contract suppliers were sufficient to meet the beneficiary demand in the CBA for the lead item in the product category. In general, 4 of the selected contract suppliers had no utilization and 5 of the contract suppliers had low utilization (that is, furnishing items and services to less than 5 percent of the applicable beneficiary population). Most DMEPOS product categories have historically been dominated by a few large national chain suppliers, and we have seen a downward trend in the total number of suppliers and more concentration among the large suppliers in terms of

volume and market share. From 2022 to 2024, the number of medical supply companies enrolled as DMEPOS suppliers decreased by 7 percent from 6,438 to 5,973. Over this same 2-year period, Medicare Part B enrollment also decreased by 5 percent from 35.3 million to 33.4 million, while the number of allowed services attributed to enrolled DMEPOS suppliers grew from 1.97 billion to 2.11 billion. While savings were generally favorable under this approach, this evidence indicates that future competitions would have been increasingly strained to recompete items and services.

2. Current Issues

The lead item pricing and maximum winning bid amount SPA methodologies were implemented under Round 2021 of the DMEPOS CBP (refer to table FF-25 for an explanation of the CBP rounds). CMS competed 16 product categories in 130 CBAs in Round 2021, although the product category for non-invasive ventilators was removed in April 2020 following the exercise of the Defense Production Act due to the coronavirus disease 2019 (COVID-19) PHE. Of the remaining 15 product categories, 13 were included in previous rounds of the CBP, while OTS back and knee braces were competed for the first time. Within the 130 CBAs, there were over 2,000 competitions and CMS received and reviewed over 49,000 bids. The Round 2021 contracts went into effect in 127 CBAs for the OTS back braces and OTS knee braces product categories, resulting in estimated Medicare savings of $934 million. Pursuant to 42 CFR 414.414(f), CMS announced that it would not award competitive bidding contracts for 13 product categories for Round 2021 that were previously competed because the payment amounts did not achieve expected savings.[62]

The competitions for contracts in Round 2021 were largely unsuccessful in achieving savings because the methodology for calculating SPAs was changed from the median of winning bid amounts used in previous rounds to the maximum winning bid amount, but CMS made no changes to how the number of contracts awarded in a competition is calculated. As discussed, the

[62] https://www.cms.gov/files/document/round-2021-dmepos-cbp-single-payment-amts-fact-sheet.pdf

current process for selecting the number of contracts to award results in significantly more contracts than needed to meet actual demand for items and services in the CBA and this process has resulted in higher payment amounts than the payment amounts that would have been established if the number of contracts was limited to the number needed to meet actual demand for items and services in the CBA. By calculating SPAs based on the maximum bid amount submitted for that item by suppliers whose composite bids for the product category that includes the item are equal to or below the pivotal bid for that product category, CMS began setting payments based on the highest of the bid amounts from suppliers not needed to meet the demand for items and services in the CBA. In addition, these maximum winning bid amounts were often an outlier price (a bid amount from a single bidding entity that is significantly higher than the bid amounts from other bidding entities). Consequently, adjusting the methodology for setting the SPA without adjusting the number of contracts awarded eliminated the ability of the program to achieve savings because the SPAs that would have been used to pay contract suppliers would have resulted in total payments to contract suppliers that greatly exceeded the total amounts that would otherwise be paid. When the maximum winning bid amount is used to establish the SPA rather than a bid amount from lower in the winning array of bidders, it is more likely that an outlier bid amount will be selected as the SPA, which is not optimal.

Table FF-26 shows the actual bid amounts submitted for a Round 2021 competition (the competition is not identified to protect the confidentiality of the bidding entities). The bid amounts are for the bidding entities that would have been awarded contracts based on the current methodologies for projecting demand and determining supplier capacity for meeting demand.

TABLE FF-26: BID AMOUNTS FOR BIDDING ENTITIES IN "WINNING RANGE" FOR SAMPLE ROUND 2021 COMPETITION

Number in Array	Bid Amount	Note
36	$189.00	Maximum winning bid amount
35	$150.00	
34	$135.00	
33	$131.66	
32	$124.00	
31	$120.00	
30	$120.00	
29	$114.95	

Number in Array	Bid Amount	Note
28	$110.00	
27	$105.00	
26	$99.88	
25	$99.00	
24	$98.00	
23	$97.97	
22	$94.64	
21	$89.95	
20	$89.00	
19	$83.78	
18	$81.75	Median – $82.76
17	$78.90	
16	$77.64	
15	$77.62	
14	$72.07	$74.25 = 2021 Amount Otherwise Paid
13	$69.50	
12	$68.00	
11	$65.52	
10	$65.00	
9	$62.99	
8	$62.37	
7	$62.00	
6	$61.88	
5	$60.00	
4	$60.00	
3	$59.90	
2	$53.29	
1	$41.00	

Pursuant to 42 CFR 414.414(f), contracts were not awarded for this product category and CBA because the total payments that would have been made to contract suppliers based on the maximum winning bid amount of $189.00 would have greatly exceeded the payment amounts that would have otherwise been made at $74.25, the adjusted fee schedule amount calculated in accordance with 42 CFR 414.210(g)(10) using bid amounts from previous rounds of competition. This table shows the impact of outlier pricing on the SPA that results when using the maximum winning bid method. The maximum winning bid of $189 is $39 (26 percent) higher than the next highest bid of $150. This real-life scenario demonstrates that just adding one additional bidding entity has a significant impact on the amount that all the contract suppliers would be paid, particularly when their bids do not include capacity numbers above their historical norms. In contrast, the median of winning bids is right in the middle of the array of bids and is not affected greatly by the outlier bid of $189. Removing the bidding entity with the $189 bid from the array only decreases the median by one dollar from $82.76 to $81.75. In this specific example, had the number of contracts awarded been limited to 14 rather than 36, then

the payment amount would have been lower than the amount that would otherwise have been paid and contracts could have been awarded (assuming no other proposals in this rule were otherwise adopted and only the median bid methodology was in effect). Of the 36 bidding entities in this example, 9 were new bidding entities and the policy for new bidding entities is to count their capacity as zero, meaning they were not needed to meet demand. An additional 13 bidding entities did not indicate that they could expand their capacity beyond historic levels if awarded a contract. Removing 22 bidding entities from the list of winning range suppliers (the nine new bidding entities and the 13 bidding entities that indicated they could not expand their capacity) coincidentally leaves 14 bidding entities in the winning range. In order to have successful competitions in the future, the number of contracts awarded and the methodology used to establish the payment amounts made to the contract suppliers must result in total payments to contract suppliers that do not exceed the amounts that would otherwise be paid, after also factoring in the impact of the CBP in reducing fraud, waste, and abuse as discussed in greater detail in section VII.D., titled "Bid Limits and Conditions for Awarding Contracts if Savings are Not Expected."

The goal in this final rule is to find the right mix in terms of the number of contracts awarded and how to establish the SPAs using the bid amounts so that contracts are awarded to multiple suppliers but no more than needed to meet beneficiary demand for items and services, and to ensure the DMEPOS CBP will generate total payments to contract suppliers that are less than the total amounts that would otherwise be paid under the standard payment rules under sections 1834(a)(2) through (7), 1834(h), 1834(z), and 1842(s) of the Act. As noted previously, CMS must be cognizant of how the SPA methodology, and the methodology to select the number of awarded contracts can impact whether total payments to contract suppliers are less than the total amounts that would otherwise be paid under standard payment rules.

As explained in more detail later in this section, we believe certain changes to how CMS determines the number of awarded contracts and changes to the SPA methodology can increase

the likelihood that the DMEPOS CBP program will generate savings. Regarding changes to how CMS determines the number of awarded contracts, we believe data on actual contract supplier capacity from previous rounds of the DMEPOS CBP should be used in lieu of self-reported supplier capacity , to determine the number of contracts needed to meet demand for items and services in a CBA in accordance with 42 CFR 414.414(e)(2).

Three options for determining SPAs are discussed later in this section and address how the number of contract suppliers would need to be limited in order to achieve savings at the median bid level if bid amounts higher than the median bid amounts are used to establish the SPA. These options include using the median of winning bid amounts, using the maximum winning bid amount but limiting the number of contract suppliers so that the maximum winning bid amount is approximately equal to the median of winning bid amounts, or using the 75th percentile of winning bid amounts but limiting the number of contract suppliers so that a maximum winning bid amount is approximately equal to the median of winning bid amounts. In addition to the change described previously, we evaluate how complementary changes to the methodology for calculating number of awarded contracts may or may not affect the competitiveness of the program. One option is to use the median of winning bids (median bid option). The second option is to continue using the maximum winning bid (maximum bid option) and limit the number of contracts awarded so that the maximum winning bid is approximately equal to where the median of winning bids would be under the median bid option. The third option, which we believe is the best approach, is to establish SPAs based on the 75th percentile of winning bids (75th percentile option) and limit the number of contracts awarded so that the 75th percentile of winning bids is approximately equal to where the median of winning bids would be under the median bid option. Using the 75th percentile approach pays more contract suppliers above their bid amount than below their bid amount, which was a criticism of the median bid option, and is less susceptible to outlier pricing than the maximum bid option.

Conceptually, where the SPA is based on the maximum winning bid rather than the median of winning bids, many contract suppliers are paid using a SPA that is significantly higher than the bid amount they submitted, therefore providing more money for them to furnish additional items and services (that is, to increase their capacity) and resulting in the need for fewer contract suppliers.

Round 2021 was not successful for the 13 product categories included under the CBP. In the previous competitions from 2011 through 2018, these product categories were paid with SPAs calculated based on the median of winning bids. However, CMS did not change the methodology for determining the number of contracts to award, continuing the practice of awarding more contracts than needed to meet demand, even though the bid amount used for calculating SPAs was changed from the median of winning bids to the maximum winning bid. If, in addition to adjusting the SPA methodology, CMS had revised the methodology for determining the number of contracts to award so that less contracts were awarded, it would have been more likely that that the maximum winning bid amounts would have been closer to the median of winning bid amounts in prior rounds. This is important because the fee schedule amounts for items included in prior competitions had already been adjusted in accordance with section 1834(a)(1)(F) of the Act based on the SPAs calculated using the median of winning bids, becoming the payment amounts that would otherwise be paid in the absence of implementation of the DMEPOS CBP. Under the requirements for awarding contracts under section 1847(b)(2)(A)(iii) of the Act, total payments to contract suppliers based on SPAs must not be expected to exceed the total amount that would otherwise be paid. Contracts could not be awarded under Round 2021 if the SPAs based on the maximum winning bids were significantly higher than the SPAs previously established for the items and services based on the median of winning bids, as this would have resulted in total payments to contract suppliers being greater than the adjusted fee schedule amounts that would otherwise be paid. As explained later in this section, this problem was further compounded by bidding entities submitting lower capacity

estimates than in previous rounds of competition, with very few bidding entities providing estimates that they could increase their volume of business and market share if awarded a contract.

Prior to the opening of the bid window for Round 2021, CMS published a "Capacity and Demand" Fact Sheet to increase transparency regarding the DMEPOS CBP by explaining the methodology that CMS would utilize to calculate projected beneficiary demand for Round 2021, as well as how CMS would determine a bidder's capacity to meet projected demand. CMS also provided increased transparency by publishing a "Financial Scoring Methodology" Fact Sheet that explained how bidding entities would be evaluated to determine if they met the financial standards mandated by section 1847(b)(2)(A)(ii) of the Act. After receiving this detailed information, some industry consultants created and distributed information encouraging bidding entities to submit very low estimates of their capacity to furnish items if awarded a contract in order to significantly overinflate the total number of contracts awarded and drive up the maximum winning bids and SPAs. For example, when bidding to become contract suppliers for oxygen and oxygen equipment, 56 percent of the bidding entities "estimated" they could furnish less than one percent of the projected first year demand target and 1,496 out of 3,192 (47 percent) bidding entities submitting oxygen bids in Round 2021 "estimated" that they would not be able to provide one additional oxygen concentrator a month beyond what they have historically furnished. Also, 261 out of 3,192 (8 percent) bidding entities submitted an estimated capacity of one concentrator a month. This is the lowest possible capacity number a bidding entity could provide as their estimated capacity because the DMEPOS Bidding System would not allow an estimated capacity entry of zero.

After the Round 2021 bid evaluation processes concluded, we estimated that if payments had been made using SPAs based on the maximum winning bids, this would have resulted in an increase of $1.2 billion in total payments to contract suppliers above the total amounts that would otherwise have been made over the 3-year contract performance period for Round 2021. As a

result, CMS was prohibited from awarding contracts, per section 1847(b)(2)(A)(iii) of the Act, in all product categories except OTS back braces and OTS knee braces, which saved an estimated $934 million. The OTS back braces and OTS knee braces product categories were new, and payment using the SPAs based on maximum winning bid amounts did result in lower payments to contract suppliers than would otherwise be made in most of the 130 CBAs. We found as a result of this effort that the practice of providing very low-capacity estimates as part of the bid in order to increase SPAs affects the calculation of the SPA regardless of whether the SPA is based on the maximum winning bid amount or the median of winning bid amounts, but the effect is much more pronounced and subject to outlier bids when the SPA is based on the maximum winning bid. A median is calculated using all bids (low and high), whereas the maximum winning bid is based on one bid amount (the highest) and can change dramatically from one bidding entity to the next as shown in table FF-26.

Very low bidding entity-reported estimates of their capacity for furnishing items would have resulted in the award of more contracts than needed to meet demand. The combination of the awarding of more contracts than needed to meet demand and the change in determining SPAs to use of the maximum winning bid in Round 2021 resulted in an inability to award contracts for almost all items and services because total payments to contract suppliers would have greatly exceeded payments that would have otherwise been made. It is therefore important to establish a more accurate methodology for determining the number of contract suppliers needed to incentivize competitive bids and meet projected demand for items and services, and to select a methodology for determining SPAs that does not result in situations where total payments to contract suppliers would exceed payments that would otherwise be made. Furthermore, CMS does not have a mechanism to address situations where bidding entities submit capacity estimates that do not accurately reflect their ability to increase their volume of business if awarded a contract. As seen in the bids for Round 2021, this resulted in capacity estimates that were arbitrary and would have resulted in an increase in the number of contracts awarded and

thereby drive up the prices paid under the program. In order for pricing to be competitive, especially as markets consolidate and small suppliers may not be expanding their businesses, the number of contracts awarded has to be limited to the degree that large suppliers face the risk of not being awarded a contract, thereby creating an incentive to bid more competitively. Only a small number of bidders were excluded in past rounds of competition, greatly reducing the incentive for suppliers to bid competitively. Thus, we believe the methodology for determining the number of contracts to award for future rounds of the DMEPOS CBP cannot rely on self-reported capacity estimates from bidding entities as this methodology is not effective in limiting the number of contracts awarded to the number needed to meet projected demand for items and services in accordance with section 1847(b)(4)(A) of the Act.

In order to successfully recompete contracts for product categories previously bid under the methodology that established SPAs based on the median of winning bid amounts in accordance with section 1847(b)(2)(A)(iii) of the Act, there must be an expectation that total payments to contract suppliers will be less than the total amounts that would otherwise be paid. We have explored and summarized three options, which have been informed by simulations we conducted using bid and contracting information from previous rounds of the DMEPOS CBP. We explain additional details about these simulations in a later discussion.

The first possible option of accomplishing this is to implement the methodology for determining SPAs used under competitions prior to Round 2021 that established SPAs based on the median of winning bid amounts, and award the same number of contracts awarded under those pre-Round 2021 competitions, adjusted based on the percentage change in Medicare Part B enrollment in the CBAs. We refer to this as the "median bid" option.

A second option would be to maintain the current methodology that establishes SPAs based on the maximum winning bid amount. Based on our analysis of past bidding rounds, we believe that to meet the requirements of section 1847(b)(2)(A)(iii) of the Act and maintain the current methodology for determining SPAs based on maximum winning bid amounts, we would

need to better ensure that the maximum winning bid amount is closer to the median winning bid amount that would be selected under the first option. We believe this could be achieved by reducing the number of contracts awarded under future competitions by approximately 50 percent below the number of contracts awarded in past bidding rounds. This would reduce the likelihood of basing the SPA on an outlier bid amount and could increase the likelihood that the SPAs established under this option would be roughly equivalent to the SPAs that would be established under the median bid option. We refer to this as the "maximum bid" option.

A third option would be to implement a methodology that uses the 75th percentile of winning bid amounts to establish a SPA, which is halfway between the median or 50th percentile of winning bid amounts and the maximum winning bid amount or 100th percentile of winning bid amounts. Similar to the process discussed for the second option, based on our analysis of past bidding rounds, we believe that to meet the requirements of section 1847(b)(2)(A)(iii) of the Act we would need to implement a process to better ensure that the selected bid amount is not influenced by outlier bid amounts and remains closer in value to the amount that would be selected under option one. We believe this could be achieved by reducing the number of contracts awarded under future competitions by approximately 25 percent below the number of contracts awarded in past bidding rounds. This would reduce the likelihood of basing the SPA on an outlier bid amount and better increase the likelihood that the SPAs established under this option would be roughly equivalent to the SPAs that would be established under the median bid option. We refer to this as the "75th percentile" option.

Reducing the number of contracts awarded in proportion to the position in the array of winning contract suppliers used to establish the SPA is necessary in order to comply with the requirements of the statute. Section 1847(b)(3)(B) of the Act requires that contracts be recompeted not less often than once every 3 years, while section 1847(b)(2)(A)(iii) of the Act prohibits the awarding of contracts under these competitions unless the total amounts to be paid to contract suppliers in a CBA are expected to be less that the total amounts that would otherwise

be paid. Establishing SPAs using bid amounts from suppliers higher in the array of winning contract suppliers than the median of bid amounts increases the chances that the SPA will be based on an outlier price (a bid amount that is significantly higher than other bid amounts for contract suppliers in the winning array), and therefore increases the chances that the competitions will not be successful in generating payments that are less than the amounts that would otherwise be paid for the items and services. These risks must be considered to implement future competitions under the DMEPOS CBP that are successful in generating program savings for competitively priced DMEPOS items and services. Table FF-27 lists the three options discussed previously and the tradeoffs associated with each option.

TABLE FF-27: THREE OPTIONS FOR DETERMINING SPAS

SPA	Tradeoffs
Median Bid	• Highest number of winners and choice of contract suppliers and lowest risk of outlier prices • Approximately half of winning contract suppliers with bid amounts below SPA
75th Percentile	• Lower number of winners and greater risk of outlier prices than median bid option • More contract suppliers paid at or above their bid amount than median bid option
Maximum Bid	• Lowest number of winners and greatest risk of outlier prices • All contract suppliers paid at or above their bid amount

The median bid option offers the highest number of contracts for suppliers, and, therefore, the greatest degree of choice for beneficiaries. Even though this option results in payment amounts that are higher than the bid amounts for approximately half of the suppliers in the winning array of bidding entities, much criticism has been provided by DMEPOS suppliers, manufacturers, and certain economists about the fact that this option results in payment amounts that are lower than the bid amounts for approximately half of the suppliers in the winning array of bidding entities. Despite that criticism, suppliers accepted the contracts at the median SPA rates 92 percent of the time, and as noted previously, beneficiary access was not compromised, suppliers in non-CBAs adjusted to using these rates, assignment rates remained high, and beneficiary health outcomes remained stable. Nevertheless, as noted previously, we were seeing some pressures in downward trends in regard to suppliers' willingness to expand capacity, indicating that the current structure might not have been sustainable for the long term.

The maximum bid option, which would base SPAs on the maximum winning bid amounts coupled with an approximate 50 percent reduction in the number of contracts awarded below past bidding rounds, offers the lowest number of contracts for suppliers, and, therefore, the smallest degree of choice for beneficiaries. While this option results in payment amounts that are equal to or higher than the bid amounts for all of the suppliers in the winning array of bidding entities, even with a reduction in the number of contract suppliers, it also presents the highest risk of establishing a SPA based on an outlier bid, resulting in a SPA that might not meet the statutory requirement for total payments to contract suppliers that are lower than the total amounts that would otherwise be made for the items and services in the CBA. We observed this in Round 2021. We believe the risk of additional unsuccessful competitions using this option is too great.

The 75th percentile option uses the bid amount in the array of winning bid amounts that is halfway between the median of the winning bid amounts (50th percentile) and maximum winning bid amount (100th percentile) to establish the SPA, and, therefore, serves a "middle ground" option. This option would be coupled with an approximate 25 percent reduction in the number of contracts awarded below past bidding rounds. It therefore results in more contracts and less risk of outlier prices than the maximum winning bid option, but fewer contracts and more risk of outlier prices than the median bid option. It is also an option that has never been attempted under the DMEPOS CBP. This option partly addresses the criticism provided by DMEPOS suppliers, manufacturers, and certain economists about paying contract suppliers less than their bid amount. However, as noted previously, the fact that 92 percent of suppliers accepted contracts at the median bid rates, and these amounts were proven to be adequate for items and services to be furnished with no negative impact on health outcomes, indicates that this criticism may be unfounded. While there is still a greater risk of outlier prices associated with this option than the median bid option, we believe this option would result in successful competitions, and we solicited comments on a proposal that this methodology replace the current maximum bid

methodology in the regulations for calculating the SPAs for items and services under the CBP. In order for this option to enable the DMEPOS CBP to meet its statutory objectives, the number of contracts awarded must be reduced by approximately 25 percent from the current methodology so that total payments to contract suppliers based on SPAs equal to the 75th percentile of winning bid amounts are no greater than total payments to contract suppliers based on SPAs equal to the median (or 50th percentile) of winning bid amounts. We continue to maintain that, "One of the purposes of the program is to create a competitive bidding payment structure that is more reflective of a competitive market" (72 FR 18036).

We analyzed the performance of contract suppliers under the previous Round 2 Recompete and Round 1 2017 competitions and identified the number of contract suppliers in each competition that provided at least 5 percent of total contract supplier utilization during these rounds of competition. We believe these numbers represent the number of contract suppliers that made a meaningful contribution toward meeting demand for the items and services in each competition. Under the previous Round 2 Recompete and Round 1 2017 competitions, on average, only 28 percent of contract suppliers furnished at least 5 percent of the total number of items and services furnished by contract suppliers in each competition. This indicates that the vast majority of contracts awarded under these previous rounds were not necessary to ensure access and that there is sufficient experience and rationale for reducing the number of contracts offered under the DMEPOS CBP to determine a competitive price while maintaining access as mandated by section 1847(b)(4)(A) of the Act.

If under future competitions, the number of contracts awarded for each competition was limited to the number of contract suppliers that furnished at least 5 percent of the total number of items and services for the competition, this would reduce the number of contract suppliers in the winning array and increase the likelihood that total payments to contract suppliers under future rounds of competition would be lower than the amounts that would otherwise be paid. If we continue awarding the same number of contracts as in past rounds of competition and use the

75th percentile of winning bid amounts rather than the 50th percentile (median) of winning bid amounts to establish the SPAs, the SPAs would be prohibitively higher than they would otherwise be if we had used the median of winning bid amounts to establish SPAs. To counter this, we can reduce the number of contracts awarded so that the 75th percentile of winning bid amounts are more closely aligned to where the median of winning bid amounts would have fallen. Using the competition example under table FF-26, the 75th percentile of the 36 bid amounts is $105.00, which is much higher than the median of winning bid amounts of $82.76. Under this competition, if the number of suppliers in the winning array is reduced by 25 percent from 36 to 27, the 75th percentile of the 27 bid amount amounts is $89.95, which is only 9 percent higher than the median of winning bid amounts of $82.76. However, there is no way to know for sure if the contract suppliers in the winning array under future competitions with this type of cap on the number of contracts awarded would have the capacity to furnish all of the items and services needed in the competition. Although larger suppliers should have economies of scale that would allow them to bid lower than smaller suppliers, it is possible that all large suppliers could be outbid by small suppliers that collectively do not have the capacity to meet demand for the items and service covered under their contracts. We therefore solicited comments on a proposal to increase the number of contracts awarded to double the number of contract suppliers that previously furnished at least 5 percent of the items and services needed in the competition. This would mitigate the risk of awarding too few contracts such that the total supplier capacity would not be sufficient to meet the expected beneficiary demand, but would also increase the risk of awarding too many contracts, resulting in situations where total payments to contract suppliers at the 75th percentile of winning bid amounts could be greater than the payments that would otherwise be made based on fee schedule amounts adjusted using information from past rounds of the CBP where SPAs were established based on the median (or 50th percentile) of winning bid amounts rather than the 75th percentile of winning bid amounts.

CMS contracted with the Research Triangle Institute (RTI) to evaluate how the changes in Round 2021 impacted the DMEPOS CBP, and to consider ways in which the DMEPOS CBP can address the issues that occurred in Round 2021. RTI conducted a simulation of the 75th percentile option using bid and contracting information from previous rounds of the DMEPOS CBP. Specifically, RTI used the number of Round 2 Recompete and Round 1 2017 contracts in each of these successful competitions, as well as Round 2 Recompete and Round 1 2017 contract supplier utilization, to determine the number of contract suppliers that furnished at least 5 percent of total contract supplier utilization under each under these previous rounds. These numbers were then doubled to generate the target number of suppliers to include in the winning array in each competition under the simulation. The SPAs for the lead item in each competition were calculated based on the 75th percentile of bid amounts for suppliers in the winning array. If the 75th percentile fell directly on one of the suppliers in the winning array, that bidding entity's bid amount became the SPA for the competition under the simulation. Table FF-27 provides an example of this calculation. If the 75th percentile fell between 2 bidding entities (that is, there was an odd number of bids in the winning array), the SPA was determined using the amount that is 75 percent between the two bid amounts, rounded to the nearest cent. An example of this calculation is provided in Table FF-28.

TABLE FF-27: EXAMPLE OF CALCULATING THE 75TH PERCENTILE WHEN FALLING ON ONE SUPPLIER

Winning Contract Suppliers	Bid Amount
1	$4.00
2	$5.00
3	$5.25
4	$5.50
5	$6.00
6	$6.50
7	$7.00
8	$7.50

The 75th percentile falls directly on the sixth winning supplier (8 X 75 percent = 6), resulting in the SPA of $6.50.

TABLE FF-28: EXAMPLE OF CALCULATING THE 75TH PERCENTILE WHEN FALLING BETWEEN TWO SUPPLIERS

Winning Contract Suppliers	Bid Amount
1	$4.00
2	$5.00
3	$5.25
4	$5.50
5	$6.00
6	$6.50
7	$7.00
8	$7.50
9	$8.00

The 75th percentile falls between the 6th and 7th winning supplier with bid amounts of $6.50 and $7.00, respectively. The SPA is calculated using the amount that is 75 percent of the way between $6.50 and $7.00, rounded to the nearest cent, which is $6.88 ([($7.00 - $6.50) * 75 percent] + $6.50).

After the SPAs were calculated, additional contracts were added for small suppliers, if necessary, to meet the 30 percent small supplier target in each competition.

The last step of the simulation involved a review of the utilization for the suppliers that would be awarded contracts in each competition under the simulation to determine if their combined historic capacity totaled at least 5 percent of the overall utilization for the lead item in the competition. If the suppliers that would be awarded contracts did not collectively provide at least 5 percent of the overall utilization for the lead item in the competition, one additional bidding entity that met all eligibility requirements as stated in the request for bids for the competition and furnished at least 5 percent of the overall utilization in the competition for the lead item, was awarded, if available. If bidding entities met these criteria, the bidding entity with the lowest bid amount was awarded a contract under the simulation.

The resulting SPAs and total number of contracts awarded under the simulation were then compared to the SPAs and total number of contracts awarded under the previous Round 2 Recompete and Round 1 2017 competitions. In 91 percent of the simulated competitions (1,539 of 1,690), both the SPAs and number of contracts awarded were lower than the SPAs and

number of contracts awarded under Round 2 Recompete and Round 1 2017. Of the remaining 151 simulated competitions, 10 competitions resulted in the same number of contracts being awarded under Round 2 Recompete and Round 1 2017 competitions, while three competitions resulted in more contracts being awarded. Additionally, of the 151 simulated competitions, 105 competitions had higher SPAs than the Round 2 Recompete and Round 1 2017 competitions, while 41 competitions had SPAs that were the same as the Round 2 Recompete and Round 1 2017 competitions. Please note that there is overlap in how the simulation data for the remaining 151 competitions is presented. For example, a simulated competition that resulted in more contracts and a higher SPA compared to a Round 2 Recompete and Round 1 2017 competition could be counted in both the contract and SPA data mentioned previously.

In order to ensure beneficiary access to items and services under the simulation, a floor on the total number of contracts awarded was established, so that the number of contracts awarded under the simulation would be no less than 50 percent of the number of contracts awarded under the previous rounds, rounded up to the nearest whole number. Also, in order to ensure savings under the simulation, a ceiling on the total number of contracts awarded was established, so that the number of contracts awarded under the simulation would be no more than 75 percent of the number of contracts awarded under the previous rounds, rounded down to the nearest whole number. Note that modifications to the methodology for determining the number of contracts to award for product categories that have never been included under the CBP, as well as the product categories for OTS back braces and OTS knee braces included in Round 2021, are discussed later in this section. The simulation was run again using the floor and ceiling, and the results were analyzed. The simulated SPAs were mostly lower than the SPAs under the previous Round 2 Recompete and Round 1 2017 competitions. For all product categories and CBAs for both the Round 2 Recompete and Round 1 2017 competitions, the percentage reduction in the number of contracts awarded ranged from 33 percent for enteral nutrients, equipment, and supplies, to 41 percent for standard manual wheelchairs. In addition,

the percentage reduction in SPAs ranged from 2.6 percent for hospital beds to 13.8 percent for group 2 support surfaces. To illustrate the results of the simulation, the simulation SPAs and number of contract suppliers is compared to the number of contracts and SPAs for Round 1 2017 for oxygen and oxygen equipment (lead item, HCPCS Level II code E1390) in table FF-29.

TABLE 29: ROUND 2017 RESULTS COMPARED WITH SIMULATION RESULTS FOR OXYGEN AND OXYGEN EQUIPMENT (LEAD ITEM HCPCS LEVEL II CODE E1390)

CBA	2017 # of Contracts	2017 SPA	75th # of Contracts	75th SPA	Reduction in # of Contracts	Reduction in SPA
Charlotte-Concord-Gastonia, NC	21	$79.00	14	$72.33	33%	8%
Chester, Lancaster & York Counties, SC	15	$70.04	11	$70.00	27%	0%
Cincinnati, OH	21	$79.00	12	$76.21	43%	4%
Cleveland-Elyria, OH	25	$78.00	16	$77.42	36%	1%
Covington-Florence-Newport, KY	18	$72.45	11	$69.81	39%	4%
Dallas-Fort Worth-Arlington, TX	31	$76.48	22	$72.90	29%	5%
Dearborn, Franklin, Ohio & Union Counties, IN	15	$74.92	9	$70.09	40%	6%
Kansas City-Overland Park-Ottawa, KS	18	$79.23	12	$73.91	33%	7%
Kansas City, MO	19	$78.53	13	$73.91	32%	6%
Miami-Fort Lauderdale-West Palm Beach, FL	29	$90.01	16	$82.99	45%	8%
Orlando-Kissimmee-Sanford, FL	23	$79.20	12	$72.00	48%	9%
Pittsburgh, PA	28	$77.50	20	$70.71	29%	9%
Riverside-San Bernardino-Ontario, CA	21	$79.22	13	$70.77	38%	11%

Under the simulation, there was a 36 percent average reduction in the number of contracts awarded for oxygen and oxygen equipment in the Round 1 2017 CBAs under the simulation and a 6 percent average reduction in the SPAs. For comparison, the percentage of contract suppliers in each Round 2 Recompete and Round 1 2017 competition that furnished 5 percent or more of total contract supplier utilization was, on average, only 28 percent suggesting that the number of contracts awarded but not needed in a competition in the previous rounds was as high as 72 percent. Thus, we believe a reduction in the number of contracts awarded under the DMEPOS CBP of approximately 36 percent would not result in a shortage of contract suppliers.

We acknowledge the simulation uses supplier bids from past competitions and does not reflect how suppliers may actually bid in future competitions. However, we believe the balance of achieving savings while ensuring access to items and services under the program would be preserved if these changes are implemented. The suppliers competing for contracts would know that only a limited number of contracts would be offered, and we believe this would increase the

level of competition under the program in terms of lower bid amounts that also result in adequate payment for all contract suppliers, while also mitigating some of the concerns of the supplier community associated with using the median winning bid.

If the maximum bid option were used, the reduction in the number of contracts awarded would need to be even greater, such as no more than 50 percent of the number of contracts awarded in the previous rounds of competition. Using the maximum bid option would mean fewer suppliers would be awarded contracts than under the other two options, providing less choice for beneficiaries and increasing the chances that the amount paid is an outlier price that is significantly higher than the bid amounts of other winning contract suppliers. Using the median bid option would minimize or eliminate the impact of outlier prices but would result in more contract suppliers being paid less than the amount they bid. We did not propose either of these options, but we solicited comments on these two options in addition to the proposed 75th percentile option. A summary of how the number of contracts to award in the next competition for items included in Round 2 Recompete, Round 1 2017, and Round 2021 of the DMEPOS CBP would be determined under the three options is summarized in Table F-30.

TABLE FF-30: THREE OPTIONS FOR DETERMINING SPAS AND NUMBER OF CONTRACTS TO AWARD FOR PRODUCT CATEGORIES AND CBAS INCLUDED IN ROUND 2 RECOMPETE, ROUND 1 2017, AND ROUND 2021 OF THE DMEPOS CBP

SPA	Number of Winning Contract Suppliers for Next Competition
Median Bid Alternative	The number of winning contract suppliers is equal to the total number of contract suppliers from the last successful competition (regardless of the quantity of items furnished by each contract supplier), adjusted up or down based on the percentage change in Part B enrollment in the CBA since 2018 or 2023 for OTS back braces and OTS knee braces.
75th Percentile Proposal	The number of winning contract suppliers is equal to double the number of Round 2 Recompete, Round 1 2017, or Round 2021 contract suppliers that furnished at least 5 percent of the total utilization for the lead item in the competition, adjusted up or down based on the percentage change in Part B enrollment in the CBA since 2018 or 2023 for OTS back braces and OTS knee braces. The total number of contracts awarded would be no less than 50 percent of the number of contracts in Round 2 Recompete, Round 1 2017, or Round 2021 rounded up to the nearest whole number and no more than 75 percent of the number of contracts in Round 2 Recompete, Round 1 2017, or Round 2021 rounded down to the nearest whole number.
Maximum Bid Alternative	The number of winning contract suppliers is equal to 50 percent of the total number of contract suppliers in Round 2 Recompete, Round 1 2017, or Round 2021 (regardless of quantity of items furnished by each contract supplier), adjusted up or down based on the percentage change in Part B enrollment in the CBA since 2018 or 2023 for OTS back braces and OTS knee braces.

As an example of how this would work for the 75th Percentile Proposal, in 2018, CMS had 29 contract suppliers to furnish continuous positive airway pressure (CPAP) items in the Miami, FL competitive bidding area, but only 9 contract suppliers furnished at least 5 percent of

the total utilization for CPAP in the Miami, FL CBA. If Part B enrollment for the area has decreased by 5 percent since 2018, the CMS would do the following:

- Double the number of contract suppliers furnishing at least 5% in 2018:

  9 x 2 = 18

- Adjust the result by the 5 percent decrease in Part B enrollment since 2018:

  18 x 0.95 = 17.1 rounded to the nearest whole number, 17.

- Determine the fewest number of contracts to award:

  29 x 0.50 = 14.5 rounded up to the nearest whole number, 15.

- Determine the highest number of contracts to award:

  29 x 0.75 = 21.75 rounded down to the nearest whole number, 21.

- Compare the result in Step 2 to the fewest and highest number of contracts and adjust up or down, if necessary:

No change needed as 17 is greater than 15 and less than 21.

Result: CMS would award 17 contracts for CPAP in the Miami, FL CBA.

In addition, as explained earlier, we did not propose any changes to the method of using the lead item to establish pricing under current regulations at 42 CFR 414.416, but did propose to change the methodology used for determining SPAs for lead items under § 414.416(b)(1) to replace "maximum bid" with "75th percentile of bids".

We also solicited comments on our proposal to change the way the SPAs are calculated for the non-lead items in a product category. Currently, to calculate the non-lead item, CMS multiplies the lead item SPA by a relative ratio, which is based on the average of the 2015 fee schedule amounts for all areas (that is, all states, the District of Columbia, Puerto Rico, the United States Virgin Islands) for the non-lead item divided by the average of the 2015 fee schedule amounts for all areas for the lead item. This formula uses average fee schedule amounts, which in some cases results in SPAs for non-lead items being higher than the fee schedule amount that would otherwise be paid because the 2015 fee schedule amounts for some

areas are lower than the average of the 2015 fee schedule amounts for all areas. To address this situation for CBAs other than a nationwide or regional CBA, we solicited comments on a proposal to calculate the ratio based on the 2015 fee schedule amounts for each specific area rather than the average of the 2015 fee schedule amounts for all areas. For example, in the Miami/CPAP competition, the lead item SPA for the CPAP product category will be multiplied by a relative ratio, which will be based on the 2015 fee schedule amount for the CPAP non-lead item in Miami divided by the 2015 fee schedule amount for the CPAP lead item in Miami. For nationwide or regional CBAs, we would still need to use the average of the fee schedule amounts since these CBAs would include multiple areas with different fee schedule amounts.

For all three options, the number of winning contract suppliers for all subsequent competitions would be provided to bidders prior to bidding. For example, based on the Miami/CPAP 75th percentile option example noted previously, we would let bidding entities know that for the initial competition for these items last furnished by contract suppliers in 2018, a total of 17 contracts would be awarded for this competition. The SPA for the lead item would be based on the 75th percentile of the bids for the 17 lowest bidding entities for the CPAP product category in Miami. For subsequent rounds of competition, the number of contracts awarded would be based on the number of winning contract suppliers from the initial competition under the new rules (17 in this example), trended up or down based on the percentage change in Part B enrollment in the CBA since the first year (12-month period) of the last contract period.

We solicited comments on a proposal to slightly modify versions of the methodology discussed previously for determining the number of contracts to award for product categories that have not previously been included under the DMEPOS CBP. For product categories or CBAs that were not included in Round 2 Recompete, Round 1 2017, or Round 2021 of the DMEPOS CBP, the proposed methodology for determining the number of winning contract

suppliers in the next competition under the 75th percentile option, as well as the alternative options, are described in table FF-31.

TABLE FF-31: DETERMINING SPAS AND NUMBER OF CONTRACTS TO AWARD FOR NEW PRODUCT CATEGORIES AND CBAs PHASED IN TO THE DMEPOS CBP

SPA	Number of Winning Contract Suppliers for Next Competition
Median Bid Alternative	The number of winning contract suppliers is equal to 150 percent of the number of suppliers that furnished at least 3 percent of total utilization for the lead item in the product category and CBA during the most recent calendar year, rounded up to the nearest whole number.
75th Percentile Proposal	The number of winning contract suppliers is equal to 125 percent of the number of suppliers that furnished at least 3 percent of total utilization for the lead item in the product category and CBA during the most recent calendar year, rounded up to the nearest whole number.
Maximum Bid Alternative	The number of winning contract suppliers is equal to the number of suppliers that furnished at least 3 percent of total utilization for the lead item in the product category and CBA during the most recent calendar year, rounded up to the nearest whole number.

The number of winners for the 75th percentile option would be 25 percent lower than the median option and 25 percent higher than the maximum option, which is in proportion to the percentage increase in the position in the winning array of bid amounts where the SPA would be set using the median option (50th percentile) and the percentage decrease in the position in the winning array of bid amounts where the SPA would be set using the maximum option (100th percentile). The number of winning contract suppliers for competitions following the initial competition under the new rules would be based on the number of winning contract suppliers from the initial competition under the new rules, trended up or down based on the percentage change in Part B enrollment in the CBA since the first year (12-month period) of the last contract period. For new product categories and CBAs, we use 3 percent of total utilization for the lead item rather than 5 percent as the measure of a contract supplier that made a meaningful contribution toward meeting total demand for the lead item. We believe the measure of meaningful supplier performance should be different for product categories and areas that have never been included under the CBP because there is no limit on the number of suppliers that can furnish items and services; therefore, overall utilization of the items and services is spread out over more contract suppliers. As noted previously, under the previous Round 2 Recompete and Round 1 2017 competitions, on average, only 28 percent of contract suppliers furnished at least 5 percent of the total number of items and services furnished by contract suppliers in each

competition. For new product categories there is no limit on the number of suppliers furnishing items like there is under the DMEPOS CBP and therefore our claims data shows less concentration and a lower average volume of items furnished per supplier. However, data indicates that generally, there have been the same dominant, local suppliers in the competitive bidding areas providing the majority of DMEPOS, even prior to the implementation of the DMEPOS CBP.

We can illustrate how we would determine the number of contracts to award for new product categories being phased into the DMEPOS CBP using 2023 Medicare claims data. If competitions were held today for a nationwide remote item delivery (RID) CBP as proposed under section F using the 75th percentile methodology, then based on 2023 Medicare claims data for the lead items for the examples of potential future product categories in Table F-9 titled "Categories of Items Furnished from Remote Supplier Locations", we would award the following numbers of RID CBP contracts: 7 for urological supplies; 8 for ostomy supplies; nine for class II continuous glucose monitors (CGMs); 9 for OTS upper extremity braces; 9 for OTS back braces; and 10 for OTS knee braces. By comparison, 11 contracts were awarded for the Round 2 Recompete national mail order CBP for diabetes testing supplies. Five contract suppliers furnished at least 3 percent of total contract supplier utilization (allowed services) for diabetes testing supplies. These 5 suppliers accounted for 92 percent of total contract supplier utilization (allowed services) from July 1, 2016, through December 31, 2018.

There could be situations where CMS is not able to award enough contracts to meet the target number of contracts in a competition, if for example, the target number of contracts for the competition is 10, but only 5 entities submitted a bid. In these instances, CMS plans to move forward with awarding contracts to all eligible bidding entities in the competition, as long as there are at least 2 or more eligible bidding entities to award contracts to, and we do not otherwise have data indicating that the bidding entities that would be awarded contracts would not be able to meet beneficiary demand. Once the competition is implemented, CMS will

monitor for any potential access concerns, as it has done continually since 2011 (even during temporary gap periods in the DMEPOS CBP).

Finally, current regulations at 42 CFR 414.414(h) indicate that contracts are generally awarded to at least five suppliers satisfying the conditions for awarding contracts under § 414.414(b) through (f). As the program is implemented in additional areas throughout the United States, we believe that five contract suppliers would be excessive for some areas and product categories. Therefore, in addition to proposing to revise the regulations to include the methodologies described previously for determining the number of contract suppliers needed for each competition, we proposed to indicate at § 414.414(h)(1)(i)(C) that this number can be no lower than 2 for any competition as the statute mandates multiple contract suppliers (at least 2), per section 1847(b)(4)(B) of the Act. We solicited comments on these proposals.

3. Provisions of the Regulation

In the previous section, we discussed three options to calculate the SPAs for items and services under the CBP (the current maximum bid methodology, the median bid methodology used in prior rounds of the CBP, and a 75th percentile methodology). Based on that discussion we solicited comments on our proposal to:

- Change the methodology used for determining SPAs for lead items under the program by revising § 414.416(b)(1) to replace "maximum bid" with "75th percentile of bids," so that the SPA for the lead item in the product category would be based on the 75th percentile of bid amounts for the lead item that are equal to or below the pivotal bid for the product category. The pivotal bid is the bid amount of the last bidder selected when CMS arrays the bidders from the lowest bid to the highest bid, and beginning from the lowest bidder, selects bidders equal to the number of contracts determined in proposed paragraph (h) of § 414.414.

- Revise § 414.416(b)(1) to indicate that in cases where there is an odd number of winning contract suppliers and the 75th percentile falls between 2 suppliers, the SPA for the lead

item would be determined by going 75 percent of the way between the 2 bid amounts, rounded to the nearest cent.

- Change the way the SPAs are calculated for the non-lead items in a product category in CBAs other than a nationwide or regional CBA by revising § 414.416(b)(2). Specifically, the calculation would involve multiplying the lead item SPA by a relative ratio, which would be based on the 2015 fee schedule amount for the non-lead items in the applicable state divided by the 2015 fee schedule amounts for the lead item in the applicable state.

- Change the methodology for calculating the number of contract suppliers sufficient to furnish items and services in a competition by revising § 414.414(h). Specifically, for competitions included in the DMEPOS CBP in 2018 or 2023, the first time a competition is recompeted after 2023, the number of contract suppliers selected to furnish items and services is double the number of contract suppliers that furnished at least 5 percent of total allowed services for the lead item furnished by contract suppliers to the applicable beneficiary population during 2018 or 2023, adjusted up or down based on the percentage change in Part B enrollment in the CBA since 2018 or 2023, unless there would be less than 2 contract suppliers, in which case the number of contract suppliers will be 2. The number of suppliers awarded contracts would not be less than 50 percent of the total number of contract suppliers in 2018 or 2023 rounded up to the nearest whole number, or more than 75 percent of the total number of contract suppliers in 2018 or 2023 rounded down to the nearest whole number. After the first time a competition is recompeted after 2023, the number of contract suppliers selected to furnish items and services would be equal to the number of contract suppliers selected the first time a competition is recompeted after 2023, trended up or down based on the percentage change in Part B enrollment in the CBA since the first year (12-month period) of the most recent contract period.

For competitions not included in the DMEPOS CBP in 2018 or 2023, the first time a competition is conducted after 2023, the number of contract suppliers needed to furnish items and services would be 125 percent of the number of contract suppliers that furnished at least 3

percent of total utilization for the lead item in the product category and CBA during the most recent calendar year at the time of bidding, unless there would be less than 2 contract suppliers, in which case the number of contract suppliers will be 2.

For all subsequent recompetes for the competition, the number of contract suppliers needed to furnish items and services would be equal to the number of contracts awarded the first time a competition is held after 2023, trended up or down based on the percentage change in Part B enrollment in the CBA since the first year (12-month period) of the most recent contract period.

In previous sections we proposed using contract supplier capacity data from previous rounds of the DMEPOS CBP, as opposed to using supplier-reported capacity, to determine the number of contract suppliers needed to meet demand for items and services in a CBA. Therefore, we proposed to change the methodology for evaluating bids by revising § 414.414(e). Specifically, CMS proposed to evaluate composite bids submitted for a lead item within a product category by: 1) calculating the number of contract suppliers selected to furnish the items and services in the competition based on the methodology described previously, 2) arraying the composite bids from the lowest composite bid price to the highest composite bid price, and 3) selecting the number of contract suppliers and networks that were calculated in #1 that meet basic supplier eligibility, quality standards and accreditation, and financial standards. We solicited comments on these proposals.

The following is a summary of the comments we received regarding establishing SPAs under the DMEPOS CBP and our responses.

Comment: Many commenters supported the current methodology for establishing SPAs based on maximum winning bid amounts and were opposed to significantly reducing the number of contracts awarded but provided no recommendations for changes that would keep total amounts paid to contract suppliers using maximum winning bid amounts less than total amounts that would otherwise be paid under the fee schedule to make this methodology viable in terms of generating or maintaining program savings in accordance with section 1847(b)(2)(A)(iii) of the

Act. Some commenters suggested using other methodologies such as the 90th percentile of winning bid amounts. Many commenters believed use of the 75th percentile of winning bid amounts combined with the bid limits proposed at § 414.412(b) and a reduction in the number of contract suppliers to achieve prices comparable to median bid amounts would result in payment amounts that are too low and are not sustainable.

Response: As discussed in the proposed rule, use of the maximum bid methodology does not reliably result in total payments to contract suppliers that are less than the total amounts that would otherwise be paid under the DMEPOS fee schedule. As discussed in the proposed rule, CMS did not award DMEPOS CBP supplier contracts for a Round 2021 competition because the SPA, under the current methodology, would have resulted in the CBP greatly exceeding the payment amounts that would have otherwise been made under the DMEPOS fee schedule (90 FR 29239). While use of the maximum bid methodology could, with more reliability, result in total payments to contract suppliers that are less than the total amounts that would otherwise be paid under the DMEPOS fee schedule if CMS reduced the number of awarded contracts, we do not believe this is an appropriate solution because it would still be susceptible to outlier pricing. For example, one small, inefficient supplier that has no purchasing power could have the maximum winning bid and this supplier's bid amount could be much higher than bids from other, larger, more efficient suppliers with greater purchasing power. Using the maximum winning bid in this case would result in an SPA that is not representative of the bids from the suppliers as a whole. We believe that use of the 90th percentile of winning bids as the methodology for establishing SPAs would still include a high risk of outlier pricing and would also not be representative of the bids from the suppliers as a whole. Based on our research and the models run by RTI, we found that use of the 75th percentile of winning bids is less susceptible to outlier pricing, In addition, use of the 75th percentile of winning bids would better represent the bids from the suppliers as a whole, and would result in a majority of winning suppliers being paid more than their bid amounts. We do not believe prices comparable to updated median bid amounts from past rounds

of competition would result in payment amounts that are too low and are not sustainable. The most recent median bid-based SPAs for DME and enteral nutrition used to make adjustments to the fee schedule amounts for these items in all areas including former CBAs have been in place since 2019 and there have been no access problems or negative health outcomes associated with the items and services furnished and paid for using these rates during these past seven years, including the years of the Covid-19 public health emergency.

Comment: A commenter supported the goal of creating a payment methodology that avoids outlier pricing, promotes sustainable supplier participation, and preserves beneficiary access. This commenter encouraged CMS to conduct impact analysis across a range of product categories, commit to ongoing analyses, and engage in stakeholder engagement. A few commenters stated that CMS did not provide sufficient rationale for setting the SPA at the 75th percentile of winning bids. A commenter was concerned that reliance on this untested pricing approach created significant risk for suppliers and beneficiaries. Several commenters urged CMS to increase transparency and allow for stakeholder and patient input before implementing changes to the DMEPOS CBP. A commenter requested comprehensive and transparent evaluation of patient outcomes, focusing on consequences for vulnerable populations.

Response: We thank the commenters for their comments. The DMEPOS CBP is a statutorily mandated program that we believe must be restored as soon as possible. We are confident that the proposed provisions will result in successful competitions under the DMEPOS CBP. We do not agree that sufficient rationale for use of the 75th percentile of winning bids has not been provided. As discussed in the proposed rule, we proposed setting the SPA at the 75th percentile of winning bids in part based on a careful evaluation with the Research Triangle Institute (90 FR 29243). We plan to continue closely monitoring health outcomes for beneficiaries under the DMEPOS CBP, as we have done for previous rounds of the DMEPOS CBP. We will continue to be transparent in implementing the DMEPOS CBP and welcome

stakeholder input on all aspects of the DMEPOS CBP during all stages of implementation of the program.

Comment: Several commenters recommended paying each supplier based on their individual bid amount.

Response: The statute mandates we determine a single payment amount for each item or service in each competitive acquisition area. The statute therefore does not provide authority for paying each supplier based on their individual bid amount.

After consideration of the public comments, we are finalizing the changes to § 414.416(b) as proposed, with a technical change in the proposed regulation text for § 414.416(b)(1). The proposed rule's regulation text for § 414.416(b)(1) incorrectly stated "(1) Notwithstanding paragraphs (b)(2) through (4) of this section, s single payment…" and should instead state "(1) Notwithstanding paragraphs (b)(2) through (3) of this section, a single payment…".

The following is a summary of the comments we received regarding determining the number of contract suppliers under the DMEPOS CBP under proposed § 414.414(h) and our responses.

Comment: Several commenters opposed the proposed method for determining the number of contract suppliers needed to meet demand for items and services in a CBA. A commenter stated that placing a limit on the number of contracts awarded without providing any basis as to how the limited number of contracts would meet demand for items and services in a competition or how CMS would address situations where contract suppliers are not able to meet demand for items and services in a competition is arbitrary and capricious. These commenters were concerned that CMS did not address concerns about contract suppliers being able to meet projected demand for items and services in a competition, or how CMS would deal with situations where contract suppliers fail to meet demand for items and services after

implementation of contracts. A commenter stated that CMS must ensure that contracted suppliers have clearly demonstrated the capacity to supply needed volumes.

Response: We do not agree that the proposed methodology is arbitrary and capricious. The proposed methodology for previously bid product categories and areas relies on actual contract supplier capacity from previous rounds of competition to inform the program on the number of contract suppliers needed to meet demand for items and services in the same areas for the same product categories in subsequent rounds of competition. The number of contract suppliers from previous rounds of competition was greater than the number needed to meet demand by design. Setting payment based on the median of winning bids in previous rounds created savings while allowing for a surplus number of contract suppliers and more options for beneficiaries and referral agents. We believe that approximately half of the number of contracts awarded in past competitions were not needed to meet actual demand for items and services. We believe that a floor on the number of contract suppliers equal to 50 percent of the number from the previous round of competition provides an adequate safeguard for assuring enough contract suppliers to meet demand for items and services. Even if the proposed methodology for determining the number of contract suppliers needed based on past supplier performance and a decrease in beneficiary population in the CBA suggests less than 50 percent of the number of contract suppliers from the previous round of competition is needed to meet demand for items and services in a competition, we believe it is important to award contracts to no less than half the number of contracts awarded in the previous competition to better ensure access to items and services. Basing the number of contract suppliers on the number needed to meet demand in previous rounds, namely, the number of contract suppliers furnishing 5 percent or more of total contract supplier capacity, is directly linked to supplier capacity for meeting demand for the specific items in an area and is not arbitrary. This number is doubled under the proposed methodology to provide another safeguard for assuring enough contract suppliers to meet demand for items and services. Doubling the number of contract suppliers needed to meet

demand for items and services in the previous competition round means that winning suppliers in the next competition for items previously bid, on average, only need to be able to produce half the average capacity of the suppliers that met demand for items and services in the previous competition to meet demand for items and services in the new competition. We believe this provides sufficient assurance that the winning suppliers will be up to the task of furnishing the number of items and services needed. We believe the likelihood of the scenario occurring where winning suppliers will not be able to meet projected demand for items and services is low. We recognize that some commenters may be concerned about suppliers with demonstrated capacity of supplying the required items and services to beneficiaries being excluded from a competition. We believe such a scenario would be unlikely. In accordance with 42 CFR 414.414(b)(4), before awarding contracts, each bid is screened and evaluated to ensure that it is bona fide so that CMS can verify that the supplier can provide the product to the beneficiary for the bid amount, and those that fail are excluded from the competition (83 FR 57018). Suppliers must also meet various other financial standards. Based on our review of prior bid data, we believe the suppliers furnishing larger volumes of items and services under a product category in an area have a much greater chance to submit lower bid amounts that are bona fide due to their current purchasing power than suppliers furnishing smaller volumes of items and services under the same product category and area. In the event that CMS determines that additional contract suppliers are needed to meet beneficiary demand for items under a competitive bidding program, we remind commentors that under 42 CFR 414.414(i), CMS may award contracts to additional suppliers. The additional contract offers are made using the existing SPAs. For new product categories, the threshold for suppliers that provide a meaningful contribution towards meeting demand for items in an area is 3 percent rather than 5 percent to account for the greater pool of suppliers competing for business in a non-competitive bidding environment. Using national claims for the monthly supplies for a class II non-adjunctive CGM (HCPCS Level II code A4239) for a hypothetical nationwide remote item delivery CBP, eight suppliers furnished at least 3 percent of the total

national allowed services for this code in 2024. Under the proposed methodology, this would result in an initial winning range of ten contract suppliers. The top ten suppliers for class II claims for code A4239 accounted for 67 percent of total national class II claims for code A4239. It is likely that many of these top suppliers could provide competitive bids and be strong candidates for contracts because of their ability to receive discounted rates for the volume of products they are already purchasing.

Comment: Some commenters were concerned about the change in the minimum number of contract suppliers from five to two and access to items and services with such a low number of contract suppliers. A commenter questioned how it is possible to meet the 30 percent small supplier target required by the statute with only two contract suppliers. A commenter recommended that CMS not include small suppliers in meeting the minimum number of winning contractors and that the addition of small suppliers should be beyond the two contract winners' threshold.

Response: The 30 percent small supplier target is not a specific statutory requirement. It is one of the rules established to address the mandate under section 1847(b)(6)(D) of the Act to take appropriate steps when developing procedures relating to bids and the awarding of contracts under the DMEPOS CBP to ensure that small suppliers of items and services have an opportunity to be considered for participation in the DMEPOS CBP. If there are only two winning suppliers for a competition and one of them is a small supplier, then the 30 percent small supplier target is met. If neither supplier is small, then the steps under current regulations at 42 CFR 414.414(g) would be followed and potentially more contracts offered in an attempt to meet the 30 percent small supplier target.

Section 1847(b)(4)(B) of the Act mandates that contracts must be awarded to multiple entities submitting bids in each area for an item or service, and mathematically, this would be two or more if the proposed methodology for determining the number of contract suppliers needed to meet demand for items and services in a competition produces a number this low. We

believe that if the program is phased in for CBAs for lower volume product categories where two contract suppliers are all that is needed to meet demand for items and services in a competition, then awarding contracts to five suppliers under such a competition would be excessive.

After consideration of the public comments, we are finalizing the proposed changes with a few corrections to technical errors in the regulation text. First, the proposed section 414.414(h)(1) indicates that "…for competitions included in the DMEPOS CBP in 2018 or 2023, the first time a competition is recompeted after 2023, the number of contract suppliers selected to furnish items and services in the competition is no more than double the number of contract suppliers that furnished at least 5 percent of total allowed services for the lead item furnished by contract suppliers to the applicable beneficiary population during 2018 or 2023, adjusted up or down based on the percentage change in Part B enrollment in the CBA since 2018 or 2023, and rounded to the nearest whole number." We are removing the words "no more than" prior to the word "double" since the proposed methodology as discussed in the preamble of the proposed rule is to use double the number in all cases during this step of the methodology for determining a sufficient number of contract suppliers (90 FR 29243). Second, the proposed § 414.414 (h)(1)(i)(B) states "More than 75 percent of the total number of contract suppliers that furnished the lead in 2018 or 2023 rounded down to the nearest whole number; and". We are adding the word "Not" prior to the word "more" since the proposed methodology as discussed in the preamble of the proposed rule is to limit the number of contract suppliers during this step of the methodology to no more than 75 percent of the total number of contract suppliers that furnished the lead item in 2018 or 2023 rounded down to the nearest whole number (90 FR 29244). In addition, we are adding the word "item" following the word "lead" as the defined term is "lead item". Third, the proposed § 414.414(h)(3)(i) stated that "for competitions not included in the DMEPOS CBP in 2018 or 2023, the first time a competition is conducted after 2023, the number of contract suppliers selected is at least 2, but no more than 125 percent of the number of suppliers that furnished at least 3 percent of total utilization for the lead item in the product

category and CBA during the most recent calendar year, and rounded to the nearest whole number." We are removing the words "at least 2, but no more than" prior to the phrase "125 percent" and at the end adding the phrase "unless there would be less than 2 contract suppliers, in which case the number of contract suppliers will be 2" since the proposed methodology, as discussed in the preamble of the proposed rule, is to use 125 percent of the number in all cases during this step of the methodology for determining a sufficient number of contract suppliers, unless there would be less than 2 contract suppliers, in which case the number of contract suppliers will be 2 (90 FR 29247).

C. Adjustments to SPAs

CMS recognizes the increased challenge future price increases may present for a supplier when formulating its bids. We solicited comments on our proposal to apply an annual update factor to SPAs as we believe it would give bidding entities more certainty and confidence in formulating their bids based on their costs at the time of bidding and would help ensure beneficiary access in the event that costs do increase significantly during a contract performance period.

1. Background

The fee schedule amounts for DME, orthotics, and enteral nutrition are updated by annual update factors specified in sections 1834(a)(14), 1834(h)(4)(A), and 1842(s)(1)(B) of the Act, respectively. The payment amounts for lymphedema compression treatment items are updated on an annual basis in accordance with regulations at 42 CFR 414.1650(c). In general, the annual update factors are established based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI–U) calculated by the Bureau of Labor Statistics for the 12-month period ending with June of the previous year, although for certain years, the statute has mandated a "freeze" or zero percent update, or other percentage below the percentage change in the CPI-U, for DME, orthotics, and enteral nutrition. In addition, for 2011 and subsequent years, the update factors for DME, orthotics, and enteral nutrition are reduced by a productivity adjustment, which

in some years can result in a negative percentage change or reduction in the fee schedule amounts.

In the 2006 proposed rule (71 FR 25663), we proposed to apply an annual inflation update to the SPAs established for a CBP (proposed 42 CFR 414.408(b)). Specifically, beginning with the second year of a contract entered into under a CBP, we proposed to update the SPAs by the percentage increase in the CPI–U for the 12-month period ending with June of the preceding calendar year. We stated that using the CPI–U index would be consistent with Medicare using this index to update the DME fee schedule and would obviate the need for the bidding entity to consider inflation in the cost of business when submitting its bids for furnishing competitively bid items under a multiyear contract. We did not finalize the proposal to apply an annual inflation update to SPAs. In the 2007 final rule (72 FR 18005), we stated that we believed it is more appropriate for bidding entities to address the possible effects of inflation or price increases when they formulate their bids because automatic payment adjustments to competitively bid items may result in higher payment amounts than would occur under the DMEPOS fee schedule payment amounts if these amounts are subject to legislative freezes or payment reductions.

2. Current Issues

As a result of the COVID-19 PHE, supply chain disruptions, and recent years' higher than normal inflation, we believe it would improve the CBP to add an annual inflation update to the SPAs as long as the updates are the same as the updates to the DMEPOS fee schedule amounts, which would prevent the SPAs from becoming higher than the fee schedule amounts during a contract period of 2 or 3 years in length. CMS has recognized the increased challenge future price increases may present for a supplier when formulating its bids. We believe that adding an annual update factor would address unforeseen changes and inflation, as described previously, giving bidding entities more certainty and confidence in formulating their bids based on their costs at the time of bidding. We believe this would reduce burden for bidding entities since they would no longer need to factor standard inflationary cost increases into their bid

calculation. We also believe it would help to better ensure access to items and services under the program in the event that costs do increase significantly during the contract period.

3. Provisions of the Regulation

We proposed to amend 42 CFR 414.408 by revising paragraph (b) and its title to adjust the SPAs for the second and third years of a DMEPOS CBP supplier contract performance period by an inflation update equal to the percentage change in the CPI-U for the 12-month period ending 6 months prior to the beginning of the respective second or third year of the DMEPOS CBP supplier contract performance period. We proposed that in no case could the updated SPA for an item in the applicable CBA be greater than the unadjusted fee schedule amount for the item in such area or 110 percent of the adjusted fee schedule amount for the item in such area. We solicited comments on this proposal.

The following is a summary of the comments we received regarding applying an annual update factor to SPAs and our response to the comments.

Comment: Many commenters supported the proposal to apply an annual update factor to SPAs.

Response: We thank commenters for their support of the proposed change to apply an annual update factor to SPAs.

After consideration of the public comments, we are finalizing the proposed changes to § 414.408(b).

D. Bid Limits and Conditions for Awarding Contracts if Savings are Not Expected

Recognizing that the DMEPOS CBP generates additional savings for Medicare beyond reducing the payment amounts for DMEPOS items and services, we proposed that in determining whether the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid, in accordance with section 1847(b)(2)(A)(iii) of the Act, that CMS would not award a contract under the DMEPOS CBP if CMS determines the total amount paid under the DMEPOS CBP would be greater than all

payments that would otherwise be made—inclusive of payments made pursuant to improper billing and any other expenses paid under the DMEPOS fee schedules. Accompanying this proposal, we proposed to modify under what circumstances CMS would not award a contract for a competition under 42 CFR 414.414(f) and modify the maximum bid amounts allowed for bids under 42 CFR 414.412.

We solicited comments on these proposals.

1. Background

Section 1847(b)(2)(A)(iii) of the Act prohibits the awarding of contracts to any entity unless the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid under the methodologies set forth in sections 1834 and 1842 of the Act. We emphasize that the language in the statute refers to "total amounts paid" and not to individual payment amounts. Other factors other than the specific dollar amount paid per item can impact the total amounts paid.

In the 2007 final rule (72 FR 18084) CMS implemented the DMEPOS CBP and established that bids submitted for each item in a product category could not exceed the payment that would otherwise be made under the existing fee schedule methodology (42 CFR 414.412(b)(2)). We stated that we would not accept any bid for an item that is higher than the current fee schedule amount for that item. This approach would ensure that the SPA for each item in a product category is equal to or less than our current fee schedule amount for that item. As noted in the rule, we implemented this policy in part out of concern that if contracts were awarded that allowed higher prices for some items while lower prices for others, this could incentivize improperly shifting utilization to the higher-priced items, defeating the intent that the CBP create savings.

Section 1834(a)(1)(F)(ii) and (iii) of the Act requires the Secretary to use information on the payment determined under a DMEPOS competitive bidding program to adjust the DMEPOS fee schedule amounts in areas where competitive bidding is not in effect. Authority for adjusting

payment amounts in a similar manner for OTS orthotics, lymphedema compression treatment items, and enteral nutrition is provided by sections 1834(h)(1)(H)(ii), 1834(z)(3)(B), and 1842(s)(3)(B) of the Act, respectively. In the final rule implementing these provisions, published in the **Federal Register** on November 6, 2014, and titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies", we noted that these adjusted fee schedule amounts would serve as the bid limit for future competitive bidding (79 FR 66120).

In the November 2016 final rule, we established an alternative ''lead item'' bidding method for submitting bids and determining SPAs for certain groupings of similar items (for example, walkers) with different features (wheels, folding, etc.) under the DMEPOS CBP (81 FR 77834). To conform with this change, the bid limit language at 42 CFR 414.412(b)(2) was updated to refer to "lead items." Along with this change, the rule also changed the bid limit from the adjusted fee schedule amount to the unadjusted fee schedule amount. As the preamble to the rule noted, this change to bid limits was made to address concerns that use of adjusted fees as the bid limit may make the DMEPOS CBP unviable as cost pressures evolve over time (81 FR 77950).

2. Current Issues

As discussed previously, CMS announced that it would not award competitive bidding contracts for 13 product categories for Round 2021 that were previously competed because the payment amounts did not achieve expected savings. In addition to the changes proposed elsewhere in this rule, we believe that further changes to the bid limit provisions at § 414.412(b)(2) through (5) and (9) through (12) and conditions for awarding contracts at § 414.414(f) are needed to ensure both the continued viability of the DMEPOS CBP and adherence to the requirement for savings laid out in 1847(b)(2)(A)(iii) of the Act. We also believe that differing approaches to bid limits are needed for items that have been included in a previous round of competitive bidding and those that have not because the specific amounts that would

otherwise be paid for the former are adjusted based on rates established under previous rounds of the DMEPOS CBP while the specific amounts that would otherwise be paid for the later have not yet been adjusted based on rates established under the DMEPOS CBP.

The expectation of savings has been at the heart of the DMEPOS CBP since its inception for good reason. In examining the first two rounds of bidding, the GAO found that among the products that had been part of the Round 1 Rebid, the Round 1 Recompete, and Round 2, the SPA continued to decrease with each competition for all products except for standard power wheelchairs (which decreased with the first round and remained below the pre CBP payment amount in subsequent rounds). The largest price decrease occurred with the initial round of bidding, with savings ranging from 20 to 50 percent as compared to the previous Medicare fee schedule payment amounts (https://www.gao.gov/assets/gao-15-63.pdf). With the Round 2 expansion of the program, SPAs were, on average, 45 percent less than the fee schedule amounts, and SPAs for the national mail order program for diabetes supplies were, on average, 72 percent less than the previous fee schedule amounts.

However, as explained in section VII.A.1 of this final rule, in addition to the price savings, there are two important benefits of the DMEPOS CBP that must be taken into consideration: guaranteed access for beneficiaries and reductions in improper utilization. Outside of the DMEPOS CBP, Medicare functions as an open network. Suppliers may choose which items to provide, and there is understandable market pressure to focus on more profitable or higher-volume items. Also, despite successful efforts to target waste, fraud, and abuse, it is often difficult to identify bad actors until claims patterns have demonstrated areas of concern. Within the DMEPOS CBP, instances of waste, fraud, and abuse are less likely to occur for two reasons: lower payment amounts reduce the profit to be made from improper payments, and the reduction in the number of suppliers and heightened scrutiny and monitoring of contract suppliers makes it more difficult for entities, particularly new entrants, intending to commit fraud to gain access to the program.

While it is difficult to put a dollar amount on the benefit of guaranteed access for beneficiaries, it is possible to quantify the impact the DMEPOS CBP has had on reducing improper utilization. In its study of the DMEPOS CBP Round 1 Rebid, the GAO found that the number of beneficiaries furnished DME items covered by the CBP decreased more in the competitive bidding areas than in non-competitive bidding areas (https://www.gao.gov/assets/gao-14-156.pdf), even as monitoring of medical outcomes and beneficiary complaints did not suggest any difficulties in beneficiary access. Although the specific decrease in utilization varied across product categories, this study found decreases of 10 to 20 percent attributable to the CBP. The GAO study of Round 2 found a 17 percent decrease in the number of beneficiaries receiving items covered by the DMEPOS CBP as compared to 6 percent in non-CBP areas (in the context of a broader enforcement program that saw over 580,000 providers lose billing privileges). Similar to Round 1, this decrease was not accompanied by any evidence that beneficiaries were unable to access needed equipment, and the competitive bidding areas experiencing the largest decreases in utilization were in states with historically high rates of fraud and abuse (https://www.gao.gov/assets/gao-16-570.pdf).

Given these findings, it is clear that the historic savings generated by the DMEPOS CBP come from two sources: the reduction in price that comes from the competitive bidding process and a reduction in improper utilization. Because the evidence suggests a 10 to 20 percent reduction in waste, fraud, and abuse is associated with the DMEPOS CBP, we believe that it is appropriate and consistent with 1847(b)(2)(A)(iii) of the Act to award contracts in a CBA even if the SPA is 10 percent higher than the adjusted fee schedule payment amount that would otherwise be paid for items included under previous rounds of the DMEPOS CBP, as long as the SPA does not exceed the unadjusted fee schedule amounts for the items and services or the fee schedule amounts in effect prior to the application of the fee schedule adjustments using the methodologies under 42 CFR 414.210(g).

(a) Limits on SPAs

We solicited comments on a proposal to modify 42 CFR 414.414(f) to specify that a contract would not be awarded for a competition if the SPA for the lead item would be greater than the lesser of 110 percent of the adjusted fee schedule amount for the lead item, if applicable, or 100 percent of the unadjusted fee schedule amount for the lead item.

(b) Submission of Bids

For similar reasons, we solicited comments on a proposal for several modifications to 42 CFR 414.412 regarding the bid amounts submitted for competitions under a DMEPOS CBP to better ensure that total payments to contract suppliers would be no higher than the total payments that would otherwise be made for the items and services in the CBA.

We also solicited comments on a proposal to modify 42 CFR 414.412(b)(2) to expressly specify that the bid submitted for each lead item and product category included under the DMEPOS CBP for the first time must not exceed the unadjusted fee schedule amount for the lead item.

For items included in a prior competition, we solicited comments on a proposal to modify 42 CFR 414.412(b) to require that the bid submitted for each lead item and product category must not exceed, for the same CBA, the lesser of the most recent SPA for the item plus 10 percent or the unadjusted fee schedule amount for the item. If it has been more than one year since the most recent SPA was last paid due to a temporary gap in the CBP, we proposed that the bid for the lead item must not exceed the lesser of the most recent SPA for the item, adjusted by an inflation factor, plus 10 percent or the unadjusted fee schedule amount for the item. Updating the most recent SPA in this manner allows for the bid limit to address the possible effects of inflation since the most recent SPA was last paid.

We also solicited comments on a proposal that the inflation adjustment factor would be based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI-U) from the mid-point of the 12-month period that the most recent SPA was in effect to the date that

is 6 months prior to the date CMS announces the dates suppliers may register and submit bids under the applicable round of competition.

We solicited comments on a proposal that the bid submitted for each lead item and product category included in a prior competition but made under a bid for a new CBA must not exceed the lesser of the adjusted fee schedule amount for the lead item plus 10 percent or the unadjusted fee schedule amount for the lead item. For the same reasons noted previously for adding 10 percent to the SPA for the lead item from a previous competition in the same CBA, we proposed to add 10 percent to the adjusted fee schedule amount for the lead item in this case since the adjusted fee schedule amounts are the amounts that would otherwise be paid and are based on SPAs from previous competitions.

Bidding entities would be educated that they would not be allowed to enter bids that are higher than these proposed limits. The SPAs going from one round to the next would not be able to exceed the 10 percent increase in payments that, as discussed previously, we believe would still allow contracts to be awarded in accordance with section 1847(b)(2)(A)(iii) of the Act.

We note that these proposals are different than the limits on SPAs described under "(a) Limits on SPAs" because adjusted fee schedule amounts may be calculated using multiple CBAs in the same region of the country or CBAs from across the country. As a result, the amount that would otherwise be paid in a CBA at the adjusted fee schedule rates could be higher than the previous SPAs from individual CBAs. Therefore, it is necessary to separately limit both the bids for individual CBAs as described here in addition to the overall SPAs as described in "(a) Limits of SPAs."

As discussed in section VII.F.3 of this final rule, OTS back braces and OTS knee braces are currently delivered to beneficiaries from remote supplier locations that on average are hundreds of miles from the beneficiary's residence. We therefore solicited comments on a proposal to establish a nationwide or regional CBA(s) for items such as OTS back braces and OTS knee braces to be phased in at some point in the future. We solicited comments on a

proposal to amend 42 CFR 414.412(b) to establish bid limits for OTS back braces and OTS knee braces for the first time they are phased in as the lead item in a product category under a nationwide or regional CBA(s). OTS back braces and OTS knee braces were included under the DMEPOS CBP in over 100 CBAs from 2021 through 2023 with SPAs calculated using maximum winning bid amounts. The fee schedule amounts for OTS back braces and OTS knee braces are adjusted based on the prices established under this round of the DMEPOS CBP. In accordance with regulations at 42 CFR 414.210(g)(1), the fee schedule amounts for nonrural areas within the contiguous United States are adjusted based on regional average SPAs limited by a national ceiling and floor. The average of the 2025 fee schedule amounts for nonrural areas for HCPCS level II code L0450 for example is $124.53. By comparison, the average of the 2025 adjusted fee schedule amounts for these items when furnished to beneficiaries in rural areas within the contiguous United States and areas outside the contiguous United States for HCPCS level II code L0450 is $184.76. The higher fee schedule amounts established for these areas in accordance with regulations at 42 CFR 414.210(g)(2)(ii) and (iii) account for higher costs of suppliers furnishing items in these areas. However, these items are being furnished mostly by mail to beneficiaries across the nation from remote supplier locations. The cost of shipping an item from a remote location to a beneficiary residing in a rural area is typically no higher than the cost of shipping an item from a remote location to a beneficiary residing in a nonrural area. Additional shipping and handling costs may be incurred in some cases for items that are shipped to an area outside the contiguous United States such as Alaska, Hawaii, or Puerto Rico, but there are very few beneficiaries living in these areas compared to areas within the contiguous United States. We solicited comments on a proposal that the bids submitted for an OTS back brace or an OTS knee brace included as a lead item in a product category in a nationwide or regional RID CBP for the first time cannot exceed the average of the nonrural fee schedule amounts that would otherwise apply to the item under subpart D of this part for the areas included in the nationwide or regional CBP.

While we believe this bid limit for items that have previously been part of competitive bidding is important in terms of balancing the benefits of the DMEPOS CBP with the statutory requirement for savings, we also recognize that it may be possible in the long term that the bid limit as previously described may, in fact, exceed the unadjusted fee schedule amounts for certain items. For this reason, we proposed a "fail-safe" to ensure that the bid limit would never exceed the unadjusted fee schedule amount.

3. Provisions of the Regulation

We proposed to amend 42 CFR 414.412 to amend paragraph (b)(2) to specify that this paragraph would apply to items included under the DMEPOS CBP for the first time, and to streamline the text by deleting the references to the application of §§ 414.210(g), 414.105, and 414.1690. We proposed to renumber paragraphs (b)(3) through (b)(5) as (b)(6) through (b)(8), respectively. We proposed to add a new paragraph (b)(3) to set the bid limit for items that have been previously included under a competition for the same CBA with a SPA used to pay contract suppliers as the lesser of the most recent SPA for the item plus 10 percent or the unadjusted fee schedule amount for the item. We proposed to add a new paragraph (b)(4) to specify that if it has been more than one year since the most recent SPA was last paid, the amount under (b)(3) would be adjusted by the percentage change in the CPI-U from the mid-point of the most recent 12-month period the SPA was in effect to the date that is 6 months prior to the date CMS announces the dates suppliers may register and submit bids under the current round of competition, plus 10 percent. Should either the most recent SPA plus 10 percent or the most recent SPA plus 10 percent and the increases for inflation for SPAs that have not been used for payment for more than one year exceed the unadjusted fee schedule amount for the lead item, the bid submitted would be limited to the unadjusted fee schedule amount. We proposed to add new paragraph (b)(5) to set the bid limit for items that have been previously included under the DMEPOS CBP but are being phased into a CBA where the items have never been bid as the adjusted fee schedule amount for the lead item plus 10 percent. If the adjusted fee schedule amount for the

lead item plus 10 percent exceeds the unadjusted fee schedule amount for the lead item, the bid submitted would be limited to the unadjusted fee schedule amount for the lead item. We proposed to specify under new paragraph (b)(9) that the bid amounts submitted for rental of class II continuous glucose monitors included as a lead item in a product category in a RID CBP for the first time must not exceed the payment amount that would otherwise apply to the monthly fee schedule amount for the supplies for the class II continuous glucose monitor under subpart D of this part plus the average of the purchase fee schedule amounts that would otherwise apply to the class II continuous glucose monitor for the areas included in the RID CBP divided by 60. We proposed to specify under new paragraph (b)(10) that the bid amounts submitted for rental of insulin infusion pumps included as a lead item in a product category in a RID CBP for the first time must not exceed the nonrural adjusted fee schedule amount that would otherwise apply to the supplies and accessories for the insulin infusion pump under subpart D of this part for a 1-month period plus the total nonrural adjusted rental fee schedule amounts that would otherwise apply to the rental of the insulin pump for 13 months of continuous use under subpart D of this part divided by 60. We proposed to specify under new paragraph (b)(11) that the bid amounts submitted for an OTS back brace or OTS knee brace included as a lead item in a product category in a RID CBP for the first time cannot exceed the average nonrural payment amount that would otherwise apply to the item under subpart D of this part, with the application of § 414.210(g), for the areas included in the RID CBP. We proposed to specify under new paragraph (b)(12) that the bid amounts submitted for all other items included as a lead item in a product category in a RID CBP for the first time must not exceed the average payment amount that would otherwise apply to the item under subpart C, D, or Q of this part for the areas included in the RID CBP.

We proposed to amend 42 CFR 414.414(f) to state that contracts cannot be awarded for a competition unless CMS determines the SPA to be paid to contract suppliers for the lead item

would be no greater than the lesser of 110 percent of the adjusted fee schedule amount for the item, if applicable, or the unadjusted fee schedule amount for the lead item.

We solicited comments on these proposals to amend the regulations at § 414.412(b)(2) through (5) and (9) through (12) to establish limits on bids submitted to better ensure savings under the DMEPOS CBP and at § 414.414(f) for the purpose of implementing section 1847(b)(2)(A)(iii) of the Act and how we would make a determination that the total amounts to be paid to contract suppliers in a CBA are expected to be less than the total amounts that would otherwise be paid. We received 107 comments from individuals, manufacturers, suppliers, and industry associations. The following is a summary of the comments we received and our responses.

Comment: Many commenters expressed concern that the bid limit would force prices in the DMEPOS CBP to continue to decrease with each successive round to unsustainably low levels. Some of these commenters believe that there should be no bid limit at all.

Response: The bid limit helps to ensure that the DMEPOS CBP fulfills the statutory requirement for savings. Where items have been previously bid, the bid limit would allow prices to increase over time by as much as ten percent from the previous round, so long as they do not exceed the amount CMS would otherwise pay.

Comment: Many commenters believe that savings should be measured based off the unadjusted fee schedule amounts, rather than fee schedule amounts that have been adjusted for previous competitive bidding results. Many commenters believe that bid limits should be similarly tied to the unadjusted fee schedule amounts and that SPAs should be allowed to increase under the DMEPOS CBP. A commenter further proposed that savings be considered at a national level instead of being considered at the level of each competitive bidding area.

Response: We do not agree. We proposed that in determining whether the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid, in accordance with section 1847(b)(2)(A)(iii) of the Act, that CMS would not

award a contract under the DMEPOS CBP if CMS determines the total amount paid under the DMEPOS CBP would be greater than all payments that would otherwise be made—inclusive of payments made pursuant to improper billing and any other expenses paid under the DMEPOS fee schedules (90 FR 29249). We believe it is important to take a look at savings holistically because reductions in improper billing are a key benefit of the DMEPOS CBP that could result in total amounts paid to contract suppliers in a CBA being less than the total amounts that would otherwise be paid even if the SPAs are higher than the fee schedule amounts that would otherwise be paid. This is because a certain number of suppliers who would engage in improper billing would not be awarded contracts under the DMEPOS CBP, which has a direct impact on the total amounts paid. By taking this holistic approach, SPAs would be allowed to increase under the DMEPOS CBP by more than the normal inflation adjustments. However, we do not believe that it would be consistent with the statute to expand this approach to a national level, as section 1847(b)(A)(iii) of the Act specifically refers to payments in a competitive acquisition area in defining the requirement for savings. Finally, section 1834(a)(1)(F) of the Act requires that the Medicare fee schedule amounts for DME be adjusted based on the results of the DMEPOS CBP; therefore, in the absence of future rounds of competitive bidding, the amounts that would otherwise be paid would be the adjusted fee schedule amounts. As was experienced under Round 2021 of the DMEPOS CBP, if the unadjusted fee schedule amount is used as the upper limit on the bids submitted for an item, the bid amounts could be significantly higher than the adjusted fee schedule amount for the item and could result in contracts not being awarded due to a failure to achieve savings.

Comment: A commenter believes that the 10 percent margin was arbitrary and does not reflect market forces that would otherwise lead to higher prices. The commenter also claimed the reduction in utilization in previous rounds of the DMEPOS CBP was due to problems with patient access instead of a reduction in fraud associated with implementation of the DMEPOS CBP.

Response: The 10 percent margin for the bid limit and conditions for awarding contracts is based on the cited GAO reports that showed substantial reductions in utilization without any indication that beneficiaries were unable to access prescribed DMEPOS items. This is also supported by our own very frequent, thorough, and ongoing monitoring of health outcomes for beneficiaries in CBAs using the bid items or with conditions supporting the need for the bid items. As such, this percentage is meant to approximate the reduction in inappropriate use of DMEPOS associated with implementation of the DMEPOS CBP and help determine the total amounts expected to be paid to contract suppliers in a CBA for the purpose of implementing section 1847(b)(2)(A)(iii) of the Act.

Comment: A few commenters expressed concern that tying bid limits to the adjusted fee schedule amount with only a 10 percent margin does not reflect the true cost pressures suppliers have faced in recent years. Several commenters further expressed concern that the proposed bid limit would lead to beneficiary access problems due to either supplier bankruptcies or Medicare payment amounts below cost.

Response: Medicare fee schedule amounts are adjusted for annual inflation either by the CPI-U or the covered item update, as provided in the statute and regulations. We have proposed a further 10 percent margin for the bid limit as well as an annual inflation update for SPAs. We note that acceptance of contracts is voluntary, and in accordance with 42 CFR 414.412(g)(3)(ii), any supplier whose bid is above the median bid faces no penalty for refusing a contract. In addition, we have proposed adding a termination clause to the contracts for suppliers that would allow us to terminate the contracts if needed due to problems with beneficiary access to items and services due to a public health emergency (PHE) declared under Section 319 of the Public Health Services Act.

After consideration of the public comments, we are finalizing the proposed changes to § 414.412(b) and § 414.414(f). In determining whether the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that would otherwise be paid, in

accordance with section 1847(b)(2)(A)(iii) of the Act, CMS will not award a contract under the DMEPOS CBP if CMS determines the total amount paid under the DMEPOS CBP is greater than all payments that would otherwise be made—inclusive of payments made pursuant to improper billing and any other expenses paid under the DMEPOS fee schedules.

E. Revising the Definition of "Item" Related to Medical Supplies

Section 1847(a)(1) of the Act requires that the Secretary implement competitive bidding programs under which CBAs are established throughout the United States for contract award purposes for the furnishing under Medicare Part B of competitively priced DMEPOS items and services described in section 1847(a)(2) of the Act, including durable medical equipment and medical supplies described in section 1847(a)(2)(A). We proposed to revise the definition of "item" under § 414.402 to include the medical supplies described in section 1847(a)(2)(A). We solicited comments on this proposal.

1. Background

Section 1847(a)(1)(B) of the Act authorizes the Secretary to phase in CBPs first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential.

In the 2007 final rule we stated we would rely on several variables in determining the savings potential for specific items or categories of items. Those variables include annual allowed charges, annual growth in expenditures, number of suppliers, savings under the demonstrations, and various reports and studies conducted by CMS and other Federal agencies (72 FR 18025).

We received several comments in the 2007 final rule from commenters who believed that ostomy products and supplies do not meet the definition of DME and, therefore, are not part of the items and services subject to the CBPs described in section 1847(a)(2)(A) of the Act (72 FR 18023). We responded that we believe that section 1847(a)(2)(A) of the Act is ambiguous regarding whether ostomy products and supplies are to be included in the Medicare DMEPOS

CBP because the term “medical supplies” in the section heading could be interpreted either to modify the term “durable medical equipment” (meaning that the medical supplies would have to be associated with the DME to be included), or to be a separate category of items that are not associated with DME. In addition, although the definition of “covered item” in section 1834(a)(13) of the Act means “durable medical equipment (as defined in section 1861(n) [of the Act]), including such equipment described in section 1861(m)(5) [of the Act] ...,” the term “such equipment” in section 1861(m)(5) of the Act could be interpreted to refer either to the term “durable medical equipment” or to the term “medical supplies” (which would include ostomy supplies) in that section. In light of these ambiguities, we stated that we believe we have discretion to interpret section 1847(a)(2)(A) of the Act to include or exclude ostomy products and supplies in the competitive bidding programs. We did not exercise our authority to include these items at that time and stated we would continue to review this issue.

Prior to enactment of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Pub. L. 108–173, section 4319 of the Balanced Budget Act of 1997 (BBA), Pub. L. 105–33, authorized implementation of up to five demonstration projects of competitive bidding for Medicare Part B items, except physician services. In accordance with section 4319 of the BBA, we planned and implemented the DMEPOS Competitive Bidding Demonstration to test the feasibility and program impacts of using competitive bidding to set prices for DMEPOS. The demonstration was implemented at two sites: Polk County, Florida, and in the San Antonio, Texas, Metropolitan Statistical Area (MSA). The competitive bidding demonstrations, authorized under the BBA, were implemented successfully in both demonstration sites from 1999 to 2002, resulted in a substantial savings to the program, and offered beneficiaries sufficient access and quality products.

At the first site, Polk County, Florida, we conducted the first of two rounds of bidding in 1999. Five categories of DMEPOS were put up for bidding: oxygen equipment and supplies (required by statute); hospital beds and accessories; enteral nutrition formulas and equipment;

urological supplies; and surgical dressings. A total of 16 contract suppliers began providing demonstration products in Polk County on October 1, 1999, and continued for 2 years. The second and final round of bidding in Polk County was conducted in 2001 for the same product categories minus enteral nutrition (Enteral nutrition was dropped to retain only product categories that are overwhelmingly used in private homes). The second set of competitively bid payment amounts took effect in October 2001. As in round one, 16 suppliers were selected, of whom half had participated as winners previously. The new fee schedules developed from the bids in each round replaced the Statewide Medicare DMEPOS fees. The second round of the demonstration in Polk County ended in September 2002. Texas was the second site for the demonstration. In Bexar, Comal, and Guadalupe counties in the San Antonio MSA, we conducted bidding in 2000 for five kinds of DMEPOS: oxygen equipment and supplies; hospital beds and accessories; wheelchairs and accessories; general orthotics; and nebulizer drugs. Fifty-one suppliers were selected and began serving Medicare beneficiaries under the new fees in February 2001. The San Antonio site ended operations in December 2002, the statutorily required termination date in the BBA.

In each area of evaluation, the data indicated mostly favorable results for the Medicare program. The demonstration led to lower Medicare fees for almost every item in almost every product category in each round of bidding. Fee reductions varied by product category and item, resulting in a nearly 20 percent overall savings at each site. Statistical and qualitative data indicate that beneficiary access and quality of services were essentially unchanged. For urological supplies, the estimated savings rate for the first round of the demonstration in Polk County were $36,169, which were 18 percent, and Round 2 bidding in Polk County resulted in 9 percent savings (72 FR 18078). In the proposed rule, we stated the estimated savings rate for the first round of the demonstration in Polk County for urological supplies was $16,409 (90 FR 29252). To clarify, this was an annual estimated savings rate, from a 2002 report.[63] The 2007

63 https://www.cms.gov/files/document/2rtcappendixpdf

final rule provided an updated number of $36,169 (72 FR 18078), which included the savings rate from years 1 and 2 of Round 1 of the Polk County demonstration. The 2002 report noted that beneficiary surveys in Polk County did not indicate that beneficiaries using urological supplies experienced any negative impact on the quality of their equipment.

Multiple winners were selected in each product category in each round of bidding. In Polk County, non-demonstration suppliers in Round 1 bid successfully in Round 2. However, the falling number of bidders for urological supplies raised questions about the feasibility of bidding for products with low allowed charges. At the time, this product category did not have a single dominant product code, with the items with the highest allowed charges accounting for only 28 percent of total Medicare allowed charges for urological supplies.

2. Current Issues

There have been several reports detailing Medicare's excessive payment rates for items not included in the DMEPOS CBP. In 2018, the Medicare Payment Advisory Commission (MedPAC) released a report describing how Medicare expenditures for DMEPOS products excluded from the CBP have continued to grow.[64] MedPAC discussed how "…some non-CBP DMEPOS products continue to generate high rates of improper payments, experience high utilization growth, and exhibit patterns of potential fraud and abuse." In this report, MedPAC looked at ostomy, tracheostomy, and urological supplies (for example, catheters), and found two products for which Medicare's payment rates were 45 percent and 57 percent higher than private-payer rates. Specifically, intermittent urinary curved tip catheters under HCPCS Level II code A4352 were 57 percent more, whereby Medicare could save $37 million dollars if Medicare paid the median private-payer rate. Intermittent urinary straight tip catheters (HCPCS Level II code A4351) were 45 percent more, whereby Medicare could save $41 million dollars if Medicare paid the median private-payer rate.

64 https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun18_ch6_medpacreport_sec.pdf

In August 2022, the HHS Office of Inspector General (OIG) released a report titled, "Reducing Medicare's Payment Rates for Intermittent Urinary Catheters Can Save the Program and Beneficiaries Millions of Dollars Each Year" (OEI-04-20-00620).[65] The report found that, "Medicare and its beneficiaries paid suppliers $407 million for intermittent urinary catheters in fiscal year 2020, more than 3 times the suppliers' estimated acquisition costs of $121 million." Based on these findings, OIG recommended that CMS lower Medicare's payment rates for intermittent urinary catheters. OIG noted that CMS could incorporate such items into the DMEPOS CBP.

We have also seen significant growth in allowed charges for ostomy, tracheostomy, and urological supplies. In 2001, the second year of the demonstration in Polk County, total allowed charges for intermittent urinary curved tip catheter HCPCS Level II code A4352 were $1,779,928 while total allowed charges for intermittent urinary straight tip catheters HCPCS Level II code A4351 were $5,753,184. Total allowed charges have increased significantly for these items in 2022, to $344,012,449 for HCPCS Level II code A4352 and $153,606,517 for HCPCS Level II code A4351. Medicare allowed charges for ostomy supplies have also grown significantly. For instance, total allowed charges for HCPCS Level II code A4407 for ostomy skin barriers increased from $12,990,011 in 2003 to $37,478,467 in 2022. Additionally, reviews performed by OIG and CMS contractors have identified high improper payment rates for urological supplies (including intermittent urinary catheters) that did not meet Medicare requirements.[66] We also published in the **Federal Register** on September 27, 2024 a Medicare Shared Savings Program final rule (89 FR 79152), in which we discussed significant, anomalous, and highly suspect (SAHS) billing activity for certain intermittent urinary catheters on Medicare DMEPOS claims in CY 2023. We finalized several proposals as a result of this SAHS billing activity, one of which was to specify in the Shared Savings Program regulations at 42 CFR

65 https://oig.hhs.gov/oei/reports/OEI-04-20-00620.pdf
66 https://oig.hhs.gov/documents/audit/10169/A-09-22-03019.pdf

425.670(b) that CMS has determined that the billing of HCPCS codes A4352 (Intermittent urinary catheter; Coude (curved) tip, with or without coating (Teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each) and A4353 (Intermittent urinary catheter, with insertion supplies) represents SAHS billing activity for CY 2023 that would have caused significantly inaccurate and inequitable payments and repayment obligations in the Shared Savings Program if not addressed (89 FR 79158).

Further information about this urinary catheter fraud that CMS identified in 2023 can be found in a CMS case study titled "Urinary Catheter Case Study: CMS' Swift Action Saves Billions".[67] In sum, CMS identified a concerning rise in urinary catheter billings attributed to a small group of 15 DMEPOS supply companies that had recently changed ownership. Through investigative work, CMS determined that people with Medicare did not receive catheters from these DMEPOS companies and were not billed directly, physicians did not order these supplies, and the supplies were not needed. While CMS took swift action to protect people with Medicare and the Medicare program in this situation[68], including ostomy, tracheostomy, and urological supplies in the DMEPOS CBP may mitigate such situations in the future.

3. Provisions of the Regulation

We solicited comments on our proposal that the medical equipment set forth at section 1861(m)(5) of the Act, namely home health medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care, and certain covered osteoporosis drugs) be included in the list of items CMS may subject to the DMEPOS CBP. In general, section 1847(a)(1)(A) of the Act states the Secretary must establish and implement competitive bidding for covered items. In identifying the scope of covered items subject to the DMEPOS

67 https://www.cms.gov/files/document/cpi-urinary-catheter-case-study.pdf

68 Using fraud prevention tools, CMS stopped over 99% of the payments to the small group of potential bad actors before they went out the door. There was no impact to legitimate suppliers providing medically necessary services to people with Medicare. CMS revoked enrollment of the 15 potential bad actors from Medicare between late 2023 and 2024, meaning they are no longer able to bill Medicare for services and cannot re-enroll for up to 10 years. CMS also replaced hundreds of thousands of Medicare Beneficiary Identifiers (MBIs) that were used to file the suspicious claims, changed the MBIs of the most at-risk people with Medicare, and completed changing all impacted MBIs in March 2024.

CBP, section 1847(a)(2) of the Act relies on section 1834(a)(13) of the Act, which defines covered items as durable medical equipment, as defined at section 1861(n) of the Act (including supplies used in conjunction with durable medical equipment), and certain equipment described in section 1861(m)(5) of the Act used to furnish home health services, such as catheters, catheter supplies, ostomy bags, and supplies related to ostomy care, and certain covered osteoporosis drugs. Consequently, we believe that ostomy, tracheostomy, and urological supplies are included within the scope of section 1847(a)(2)(A) of the Act that CMS may select for competitive bidding. We no longer believe that section 1847(a)(2)(A) of the Act is ambiguous regarding whether ostomy products and supplies are to be included in the Medicare DMEPOS CBP.

Additionally, the Conference Report for the MMA of 2003 (H. Rept. 108-391) says, "The Secretary would be required to establish and implement competitive acquisition programs for durable medical equipment, medical supplies, items used in infusion, drugs and supplies used in conjunction with durable medical equipment, medical supplies, home dialysis supplies, blood products, parental nutrition, and off the-shelf orthotics (requiring minimal self-adjustment for appropriate use) that would replace the Medicare fee schedule payments."[69] Here, "medical supplies", twice mentioned, is a distinct category from "durable medical equipment" and from "drugs and supplies used in conjunction with durable medical equipment".

We solicited comments on a proposal to add equipment described in section 1861(m)(5) of the Act, including ostomy, tracheostomy, and urological supplies to the definition of "Item" as § 414.402(6). We also solicited comments on a proposal to add § 414.408(g)(6) to specify medical equipment, including ostomy, tracheostomy, and urological supplies are purchased items for which the SPA is calculated based on the bids submitted and accepted. We received comments on this proposal.

69 https://www.congress.gov/108/crpt/hrpt391/CRPT-108hrpt391.pdf

Comment: Many commenters raised legal concerns regarding the proposed revision to the definition of item under 42 CFR 414.402 and inclusion of ostomy, tracheostomy, and urological supplies in the DMEPOS CBP.

Response: We appreciate the comments. Section 1847(a)(1)(A) of the Act requires the Secretary to establish competitive bidding for items and services, including covered items (as defined in section 1834(a)(13) of the Act), for which payment would otherwise be made under section 1834(a) of the Act. Section 1834(a)(13) of the Act defines a covered item as durable medical equipment (as defined in section 1861(n) of the Act), including such equipment described in section 1861(m)(5) of the Act, but not including implantable items that may be paid as part of hospital outpatient department services. Section 1861(m)(5) of the Act includes "medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care…)[.]" Section 1834(h)(1)(E) of the Act provides that payment for ostomy supplies, tracheostomy supplies, and urologicals shall be made under Section 1834(a) of the Act. Therefore, we believe the competitively priced items and services described in section 1847(a)(2)(A) of the Act include these medical supplies in addition to DME.

Comment: Many commenters expressed support for the proposal of revising the definition of item to include medical supplies such as urological supplies, highlighting concerns about high costs and the need for equitable pricing. These commenters noted disparities in charges between private insurance and Medicare and see competitive bidding as a way to reduce costs for taxpayers by lowering Medicare payment amounts for these items and services. A commenter emphasized the significance of ensuring a consistent supply and fair pricing, especially for individuals on fixed incomes who depend on these essential products. Several commenters recognized the importance of competitive bidding and cost containment efforts by Medicare/HHS, but noted it is crucial that any bidding process does not restrict product selection or the availability or quality of necessary products. Another commenter expressed support for phasing in ostomy, tracheostomy, and urological supplies under the DMEPOS CBP, indicating

that such an action could lead to lower Medicare costs and improved efficiency, citing prior reports from the HHS Office of the Inspector General that noted these payments were significantly higher than private payer rates. A commenter stated that overpaying for these and the other proposed items unnecessarily increases both Medicare spending and beneficiary cost sharing. The commenter also stated that CMS should implement the proposed change and review other items currently excluded from CBP as potential candidates for the program.

Response: We agree that phasing in these items and services under the DMEPOS CBP could lead to lower costs for Medicare beneficiaries and the program. We recognize the critical importance of ensuring that contract suppliers furnish the items prescribed by a physician or treating practitioner and will continue to evaluate, as part of our monitoring system, health outcomes data and beneficiary access to competitively bid items. Regarding the quality of competitively bid items, the competitive bidding nondiscrimination provision at 42 CFR 414.422(c) establishes clear standards for contract suppliers. This regulation requires that the items contract suppliers furnish to beneficiaries under the DMEPOS CBP are the same items that they furnish to their other customers, ensuring consistent quality across all patient populations.

Comment: Multiple commenters voiced concerns that including ostomy, tracheostomy, and urological supplies in the DMEPOS CBP could limit patient choice of brands and access to these essential medical supplies. A commenter emphasized that restricting beneficiaries to specific suppliers would create barriers to accessing the products needed for effective condition management, noting that many ostomy products are similar but not identical, with variations in chemical composition and features critical for individual use. Several commenters cited the prior competitive bidding demonstrations in Polk County, Florida as proof that urological supplies are not well-suited for competitive bidding, contending that the demonstrations led to problems obtaining access to supplies, and safety and quality issues for beneficiaries. These commenters referenced the 2001 report Evaluation of Medicare's Competitive Bidding Demonstration for

DMEPOS contracted by CMS (Contract Number 500-95-0061/T.O. #3)[70], as well as the 2004 Final Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies.[71] These commenters stressed that patient preferences and individualized needs for specific brands are essential to ensuring quality care.

Several commenters underscored the consequences of reduced supplier choice and diminished patient support. Multiple commenters noted that the DMEPOS CBP could disrupt long-standing patient-supplier relationships and incentivize suppliers to stock only the lowest-cost products. They cautioned that such changes may undermine critical services like product fitting, insurance paperwork, and emergency replacements, while limiting access to clinically optimal items.

Response: We recognize the concerns of the commenters and believe that the existing requirements under the DMEPOS CBP, along with other requirements under the Medicare Part B program, will ensure that beneficiaries have access to the most appropriate ostomy, tracheostomy, and urological supplies for their medical condition. Per regulations at 42 CFR 414.422(e)(1), a contract supplier cannot refuse to furnish items and services to a beneficiary residing in a CBA if they request those items from the contract supplier. The DMEPOS CBP also has a safeguard that is part of the supplier's contract and regulations at 42 CFR 414.420, that ensures that beneficiaries have access to specific brands of items under the program. Further, the nondiscrimination clause at 42 CFR 414.422(c) requires that the contract supplier furnish the same choice of items to Medicare beneficiaries that they provide to other customers. Medicare beneficiaries who are dual eligibles in Medicaid-funded Home and Community-Based Services programs who receive items from contract suppliers under the DMEPOS CBP must also be offered the same choice in supplies.

70 https://www.cms.gov/priorities/innovation/files/migrated-medicare-demonstration-x/karon_2001_1.pdf
71 https://www.cms.gov/priorities/innovation/files/migrated-medicare-demonstration-x/cms_rtc.pdf

We also note that under the DMEPOS Quality Standards with which, per 42 CFR 414.414(c), suppliers must comply in order to participate in the DMEPOS CBP, the supplier is charged with obtaining and providing appropriate quality items to beneficiaries as well as implementing a program that promotes the safe use of these items. The supplier also must provide comprehensive training, information and instructions to beneficiaries on use, maintenance and safety, with materials tailored to individual needs and abilities for safe and effective use of all provided items.

We do not agree with the commenters that prior competitive bidding demonstrations for urological supplies provide evidence that ostomy, tracheostomy and urologicals are not well suited for inclusion in a competitive bidding program. The Final Report to Congress: Evaluation of Medicare's Competitive Bidding Demonstration for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (2004) found that beneficiary access and quality of services were essentially unchanged because of the new demonstration payment system.[72] The 2004 report noted that the urological category in Polk County, Florida had relatively low allowed charges and a small number of suppliers even before the demonstration began. The report observed that unless "designs to bolster participation can be developed, such small-volume DMEPOS categories may represent lower-priority areas for conducting competitive bidding, not only in terms of the limited savings potential on a small dollar base but also in terms of a category's competitive potential." The Report's evaluation of whether product categories, including the urological category, were "not as well suited" for bidding as other demonstration product categories was based on the items having relatively low allowed charges and a low number of suppliers. The Report also cautioned that its evaluations on the suitability of particular product categories "should not be taken as definitive for guiding future bidding initiatives." As referenced in Table 45 of the proposed rule, the 2024 Medicare allowed charges for the

72 https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/reports/downloads/rtc_dmepos.pdf

urological supplies category furnished from remote supplier areas was $1,214 million, demonstrating significant growth in this category since the demonstrations. In addition, urological supplies are typically furnished to beneficiaries from remote supplier locations or locations that are hundreds of miles on average from the beneficiary residence where items are delivered, suggesting a significant change in delivery method since the demonstrations. As with previous competitive bid Rounds, CMS will continue to closely monitor access to competitively bid items in real time.

After consideration of the public comments, we are finalizing the proposed changes to paragraph (6) of the definition of "item" in 42 CFR 414.402 and 414.408(g)(6). We are making one technical change to the regulation text in paragraph (6) of the definition of "item" at § 414.402. Tracheostomy supplies are "supplies related to ostomy care" as described under section 1861(m)(5) of the Act. We are changing the language in paragraph (6) of the definition of "item" at § 414.402 from "Other medical equipment described in section 1861(m)(5) of the Act, including ostomy, tracheostomy, and urological supplies" to "Other medical equipment described in section 1861(m)(5) of the Act, including supplies related to ostomy care and urological supplies" to align with the language under section 1861(m)(5) of the Act.

F. Remote Item Delivery (RID) CBP

We solicited comments on a proposal to establish definitions for "remote item delivery CBP" and "remote item delivery item." A remote item delivery CBP is similar to a mail order CBP except that items furnished on a non-mail basis would not be excluded from the remote item delivery CBP as they are under a mail order CBP.

1. Background

In a September 2004 report (GAO–04–765), GAO recommended that we consider using mail delivery for items that can be provided directly to beneficiaries in the home as a way to implement a DMEPOS competitive bidding strategy. The report stated that "Because MMA authorizes CMS to designate the geographic areas for competition for different items,

designating the entire country as the competitive area for selected items is a possibility." The GAO noted that demonstration suppliers provided surgical dressings, urological supplies, and inhalation drugs to beneficiaries by mail.[73] Additionally, the GAO noted that the MMA states that areas within metropolitan statistical areas (MSAs) that have low population density should not be excluded from competition if a significant national market exists through mail order for a particular item or service. The GAO went on to say that "in contrast to conducting competitive bidding on a piecemeal basis in multiple geographic areas, a consolidated nationwide approach would allow CMS to more quickly implement competitive bidding on a large scale." The GAO also stated that "this approach would enable companies that provide, or demonstrate the ability to provide, nationwide mail-order service to compete for Medicare beneficiaries' business." In the report we stated that CMS would explore the feasibility of GAO's recommendation to consider using mail-order delivery for items that could be provided directly to beneficiaries in the home, as a way to implement a national competitive bidding strategy.

In response, we have continued to review and evaluate avenues to expand mail delivery for items under the DMEPOS CBP. In the 2006 proposed rule (71 FR 25669), we stated that our data shows that a significant percentage of certain items such as diabetes testing supplies (blood glucose test strips and lancets) are furnished to beneficiaries by national mail order supplier and proposed to establish a nationwide or regional competitive bidding program, effective for items furnished on or after January 1, 2010, for the purpose of awarding contracts to suppliers to furnish these items across the nation or region to beneficiaries who elect to obtain them through the mail order outlet. Specifically, we proposed in § 414.410(d)(2) and § 414.412(f) and (g) to establish a nationwide competitive bidding program or regional competitive bidding programs for the purpose of awarding contracts to suppliers to furnish these items across the nation or region to beneficiaries who elect to obtain them through the mail. We proposed that the national or regional CBAs under the Medicare DMEPOS CBP would be phased in after CY 2009, and

73 https://www.gao.gov/assets/gao-04-765.pdf

payment would be based on the bids submitted and accepted for the furnishing of items through mail order throughout the nation or region. Suppliers that furnish these items through mail order on either a national or regional basis would be required to submit bids to participate in any CBP implemented for the furnishing of mail order items.

In the 2007 final rule (72 FR 18018), we finalized these proposals and specified that our data indicated that over 60 percent of Medicare expenditures for diabetes supplies are for items furnished by nationwide mail order suppliers. In the 2007 final rule (72 FR 18018), we stated that any national or regional mail order CBP that we might choose to implement starting in CY 2010 would be limited to the furnishing of items "through the mail." The 2007 final rule included the addition of definitions under § 414.402 related to nationwide or regional CBPs.

A national mail order CBP was implemented for diabetes testing supplies (supplies for blood glucose monitors) from July 1, 2013, through December 31, 2018. Prior to implementing this national mail order program, as part of a final rule published in the **Federal Register** on November 29, 2010, titled "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011" (75 FR 73567), we established definitions for "mail order item" and "non-mail order item" in § 414.402. These definitions were established to clarify that a mail order item is not limited to an item that is literally furnished through the mail (United States Postal Service) and includes any item delivered to the beneficiary, whereas a non-mail order item was an item the beneficiary picked up in person at a local pharmacy or other supplier storefront. The definition for "mail order item" is "any item (for example, diabetes testing supplies) shipped or delivered to the beneficiary's home, regardless of the method of delivery." The definition for "non-mail order item" is "any item (for example, diabetes testing supplies) that a beneficiary or caregiver picks up in person at a local pharmacy or supplier storefront." Non-mail order diabetes testing supplies were not included under the national mail order program. However, the fee schedule amounts for these items are established based on the

payment amounts determined for the items under the national mail order program in accordance with section 1834(a)(1)(H) of the Act.

2. Current Issues

Medicare claims data shows that several high-volume categories of items subject to the DMEPOS CBP are furnished to beneficiaries throughout the nation from remote supplier locations. As shown in table FF-32, the national average distance between the beneficiary address and supplier location is several hundred miles for the lead items in seven, high volume categories of items. The average delivery distance was measured based on the distance between the beneficiary residence and supplier location for all claims with dates of service in calendar year 2024 for the "lead item" in the category of items, or the item with the highest total nationwide Medicare allowed charges in 2024 of any item in the category.

TABLE FF-32: CATEGORIES OF ITEMS FURNISHED FROM REMOTE SUPPLIER LOCATIONS

Category	2024 Allowed Charges for the Category	Lead Item	Average Distance[74] (Lead Item)
Class II Continuous Glucose Monitors	$1,945 million	A4239	813 miles
Urological Supplies[1]	$1,214 million	A4353	784 miles
Ostomy Supplies[1]	$436 million	A5057	758 miles
Insulin Pumps	$151 million	E0784	679 miles
Off-the-shelf Knee Braces	$138 million	L1852	1047 miles
Off-the-shelf Upper Extremity Braces	$127 million	L3916	1049 miles
Off-the-shelf Back Braces	$126 million	L0651	976 miles

[1] Urological supplies and ostomy supplies categories have 9 overlapping HCPCS codes totaling $16 million.

We solicited comments on a proposal that items like those listed in table FF-32 that are generally furnished from remote supplier locations should be included under a remote item delivery CBP that does not exclude non-mail order items as is the case under a mail order CBP.

[74] Average distance is the distance (miles) between the supplier's practice address and the beneficiary's mailing address, totaled across all claims, divided by the total number of claims. The supplier's address is identified by matching the Supplier Number (billing number assigned by the Medicare Enrollment Contractor) in claims data (variable name SUPLRNUM) to the corresponding identifier in PECOS data and selecting the latest address associated with the supplier from PECOS. For OTS knee and back brace average distance, average distance is the distance (miles) between the supplier's practice address and the beneficiary's mailing address, totaled across all non-CBA claims, divided by the total number of non-CBA claims. CBA claims are excluded when calculating OTS knee and back average distance because in certain areas of the country these items were included under Round 2021. As these CBAs were limited to MSA boundaries, contract suppliers for these areas might have focused on serving only these areas and including these CBA claims could have skewed the national average distance.

Rather than implementing hundreds of local CBPs and CBAs and placing unnecessary burden on the bidding program and suppliers, we believe the easiest and best way to implement CBPs for remotely delivered items such as these is to include them under product categories in one nationwide "RID" CBP or several large regional "RID" CBPs, which would consist of all areas where a beneficiary resides or receives covered items under the product categories, with limited exceptions as explained later in this section. This is consistent with the findings of a report from the GAO from September 2004[75] that discussed the use of national CBAs as a way to streamline the implementation of the CBP. Listed in table FF-33 are the current HCPCS Level II codes for several product categories we believe should be included under a future RID CBP(s) because they are typically furnished to beneficiaries from remote supplier locations, or locations that are hundreds of miles on average from the beneficiary residence where the items are delivered. This table is for illustration purposes only. The actual product categories to be phased in under a RID CBP(s) would be designated through program instructions or by other means in accordance with existing regulations at § 414.406(d).

TABLE FF-33: EXAMPLES OF RID CBP PRODUCT CATEGORIES AND HCPCS CODES

Product Category	HCPCS Level II Code	Short Description
Class II CGMs and Insulin Pumps	A4224	Supply insulin inf cath/wk
Class II CGMs and Insulin Pumps	A4225	Sup/ext insulin inf pump syr
Class II CGMs and Insulin Pumps	A4239	Non-adju cgm supply allow
Class II CGMs and Insulin Pumps	E0784	Ext amb infusn pump insulin
Class II CGMs and Insulin Pumps	E2103	Non-adju cgm receiver/mon
OTS Back Brace	L0450	Tlso flex trunk/thor pre ots
OTS Back Brace	L0455	Tlso flex trnk sj-t9 pre ots
OTS Back Brace	L0457	Tlso flex trnk sj-ss pre ots
OTS Back Brace	L0467	Tlso r fram soft pre ots
OTS Back Brace	L0469	Tlso rig fram pelvic pre ots
OTS Back Brace	L0621	Sio flex pelvic/sacr pre ots
OTS Back Brace	L0623	Sio rig pnl pelv/sac pre ots
OTS Back Brace	L0625	Lo flex l1-below l5 pre ots
OTS Back Brace	L0628	Lso flex no ri stays pre ots
OTS Back Brace	L0641	Lo rig pos pnl l1-l5 pre ots
OTS Back Brace	L0642	Lo sag ri an/pos pnl pre ots
OTS Back Brace	L0643	Lso sag ctr rigi pos pre ots
OTS Back Brace	L0648	Lso sag r an/pos pnl pre ots
OTS Back Brace	L0649	Lso sc r pos/lat pnl pre ots
OTS Back Brace	L0650	Lso sc r ant/pos pnl pre ots

75 https://www.gao.gov/assets/gao-04-765.pdf

Product Category	HCPCS Level II Code	Short Description
OTS Back Brace	L0651	Lso sag-co shell pnl pre ots
OTS Knee Brace	L1812	Ko elastic w/joints pre ots
OTS Knee Brace	L1830	Ko immob canvas long pre ots
OTS Knee Brace	L1833	Ko adj jnt pos r sup pre ots
OTS Knee Brace	L1836	Ko rigid w/o joints pre ots
OTS Knee Brace	L1850	Ko swedish type pre ots
OTS Knee Brace	L1851	Ko single upright prefab ots
OTS Knee Brace	L1852	Ko double upright prefab ots
OTS Upper Extremity Brace	L3650	So 8 abd restraint pre ots
OTS Upper Extremity Brace	L3660	So 8 ab restr can/web pre ots
OTS Upper Extremity Brace	L3670	So acro/clav can web pre ots
OTS Upper Extremity Brace	L3675	So vest canvas/web pre ots
OTS Upper Extremity Brace	L3678	So hard plas stabili pre ots
OTS Upper Extremity Brace	L3710	Eo elas w/ metal jnts pre ots
OTS Upper Extremity Brace	L3761	Eo, adj lock joint prefab ot
OTS Upper Extremity Brace	L3762	Eo rigid w/o joints pre ots
OTS Upper Extremity Brace	L3809	Whfo w/o joints pre ots
OTS Upper Extremity Brace	L3908	Who cock-up nonmolde pre ots
OTS Upper Extremity Brace	L3912	Hfo flexion glove pre ots
OTS Upper Extremity Brace	L3916	Who nontorsion jnts pre ots
OTS Upper Extremity Brace	L3918	Metacarp fx orthosis pre ots
OTS Upper Extremity Brace	L3924	Hfo without joints pre ots
OTS Upper Extremity Brace	L3925	Fo pip dip jnt/springs pre ots
OTS Upper Extremity Brace	L3927	Fo pip dip no jt spr pre ots
OTS Upper Extremity Brace	L3930	Hfo nontorsion jnts pre ots
Ostomy Supplies	A4331*	Extension drainage tubing
Ostomy Supplies	A4357*	Bedside drainage bag
Ostomy Supplies	A4361	Ostomy face plate
Ostomy Supplies	A4362	Solid skin barrier
Ostomy Supplies	A4363	Ostomy clamp, replacement
Ostomy Supplies	A4364	Adhesive, liquid or equal
Ostomy Supplies	A4366	Ostomy vent
Ostomy Supplies	A4367	Ostomy belt
Ostomy Supplies	A4368	Ostomy filter
Ostomy Supplies	A4369	Skin barrier liquid per oz
Ostomy Supplies	A4371	Skin barrier powder per oz
Ostomy Supplies	A4372	Skin barrier solid 4x4 equiv
Ostomy Supplies	A4373	Skin barrier with flange
Ostomy Supplies	A4375	Drainable plastic pch w fcpl
Ostomy Supplies	A4376	Drainable rubber pch w fcplt
Ostomy Supplies	A4377	Drainable plstic pch w/o fp
Ostomy Supplies	A4378	Drainable rubber pch w/o fp
Ostomy Supplies	A4379	Urinary plastic pouch w fcpl
Ostomy Supplies	A4380	Urinary rubber pouch w fcplt
Ostomy Supplies	A4381	Urinary plastic pouch w/o fp
Ostomy Supplies	A4382	Urinary hvy plstc pch w/o fp
Ostomy Supplies	A4383	Urinary rubber pouch w/o fp
Ostomy Supplies	A4384	Ostomy faceplt/silicone ring
Ostomy Supplies	A4385	Ost skn barrier sld ext wear
Ostomy Supplies	A4387	Ost clsd pouch w att st barr
Ostomy Supplies	A4388	Drainable pch w ex wear barr
Ostomy Supplies	A4389	Drainable pch w st wear barr
Ostomy Supplies	A4390	Drainable pch ex wear convex
Ostomy Supplies	A4391	Urinary pouch w ex wear barr
Ostomy Supplies	A4392	Urinary pouch w st wear barr

Product Category	HCPCS Level II Code	Short Description
Ostomy Supplies	A4393	Urine pch w ex wear bar conv
Ostomy Supplies	A4394	Ostomy pouch liq deodorant
Ostomy Supplies	A4395	Ostomy pouch solid deodorant
Ostomy Supplies	A4396	Peristomal hernia supprt blt
Ostomy Supplies	A4398	Ostomy irrigation bag
Ostomy Supplies	A4399	Ostomy irrig cone/cath w brs
Ostomy Supplies	A4402*	Lubricant per ounce
Ostomy Supplies	A4404	Ostomy ring each
Ostomy Supplies	A4405	Nonpectin based ostomy paste
Ostomy Supplies	A4406	Pectin based ostomy paste
Ostomy Supplies	A4407	Ext wear ost skn barr <=4sq"
Ostomy Supplies	A4408	Ext wear ost skn barr >4sq”
Ostomy Supplies	A4409	Ost skn barr convex <=4 sq i
Ostomy Supplies	A4410	Ost skn barr extnd >4 sq
Ostomy Supplies	A4411	Ost skn barr extnd =4sq
Ostomy Supplies	A4412	Ost pouch drain high output
Ostomy Supplies	A4413	2 pc drainable ost pouch
Ostomy Supplies	A4414	Ost sknbar w/o conv<=4 sq in
Ostomy Supplies	A4415	Ost skn barr w/o conv >4 sqi
Ostomy Supplies	A4416	Ost pch clsd w barrier/filtr
Ostomy Supplies	A4417	Ost pch w bar/bltinconv/fltr
Ostomy Supplies	A4418	Ost pch clsd w/o bar w filtr
Ostomy Supplies	A4419	Ost pch for bar w flange/flt
Ostomy Supplies	A4420	Ost pch clsd for bar w lk fl
Ostomy Supplies	A4422	Ost pouch absorbent material
Ostomy Supplies	A4423	Ost pch for bar w lk fl/fltr
Ostomy Supplies	A4424	Ost pch drain w bar & filter
Ostomy Supplies	A4425	Ost pch drain for barrier fl
Ostomy Supplies	A4426	Ost pch drain 2 piece system
Ostomy Supplies	A4427	Ost pch drain/barr lk flng/f
Ostomy Supplies	A4428	Urine ost pouch w faucet/tap
Ostomy Supplies	A4429	Urine ost pouch w bltinconv
Ostomy Supplies	A4430	Ost urine pch w b/bltin conv
Ostomy Supplies	A4431	Ost pch urine w barrier/tapv
Ostomy Supplies	A4432	Os pch urine w bar/fange/tap
Ostomy Supplies	A4433	Urine ost pch bar w lock fln
Ostomy Supplies	A4434	Ost pch urine w lock flng/ft
Ostomy Supplies	A4435	1pc ost pch drain hgh output
Ostomy Supplies	A4436	Irr supply sleev reus per mo
Ostomy Supplies	A4437	Irr supply sleev disp per mo
Ostomy Supplies	A4450*	Non-waterproof tape
Ostomy Supplies	A4452*	Waterproof tape
Ostomy Supplies	A4455*	Adhesive remover per ounce
Ostomy Supplies	A4456*	Adhesive remover, wipes
Ostomy Supplies	A5051	Pouch clsd w barr attached
Ostomy Supplies	A5052	Clsd ostomy pouch w/o barr
Ostomy Supplies	A5053	Clsd ostomy pouch faceplate
Ostomy Supplies	A5054	Clsd ostomy pouch w/flange
Ostomy Supplies	A5055	Stoma cap
Ostomy Supplies	A5056	1 pc ost pouch w filter
Ostomy Supplies	A5057	1 pc ost pou w built-in conv
Ostomy Supplies	A5061	Pouch drainable w barrier at
Ostomy Supplies	A5062	Drnble ostomy pouch w/o barr
Ostomy Supplies	A5063	Drain ostomy pouch w/flange
Ostomy Supplies	A5071	Urinary pouch w/barrier
Ostomy Supplies	A5072	Urinary pouch w/o barrier
Ostomy Supplies	A5073	Urinary pouch on barr w/flng
Ostomy Supplies	A5081	Stoma plug or seal, any type

Product Category	HCPCS Level II Code	Short Description
Ostomy Supplies	A5082	Continent stoma catheter
Ostomy Supplies	A5083	Stoma absorptive cover
Ostomy Supplies	A5093	Ostomy accessory convex inse
Ostomy Supplies	A5102*	Bedside drain btl w/wo tube
Ostomy Supplies	A5120	Skin barrier, wipe or swab
Ostomy Supplies	A5121	Solid skin barrier 6x6
Ostomy Supplies	A5122	Solid skin barrier 8x8
Ostomy Supplies	A5126	Disk/foam pad +or- adhesive
Ostomy Supplies	A5131*	Appliance cleaner
Urological Supplies	A4217	Sterile water/saline, 500 ml
Urological Supplies	A4295	Straigh tip hydrophilic cath
Urological Supplies	A4296	Coude tip hydrophilic cath
Urological Supplies	A4297	Hydrophilic coat insert sup
Urological Supplies	A4310	Insert tray w/o bag/cath
Urological Supplies	A4311	Catheter w/o bag 2-way latex
Urological Supplies	A4312	Cath w/o bag 2-way silicone
Urological Supplies	A4313	Catheter w/bag 3-way
Urological Supplies	A4314	Cath w/drainage 2-way latex
Urological Supplies	A4315	Cath w/drainage 2-way silcne
Urological Supplies	A4316	Cath w/drainage 3-way
Urological Supplies	A4320	Irrigation tray
Urological Supplies	A4322	Irrigation syringe
Urological Supplies	A4326	Male external catheter
Urological Supplies	A4327	Fem urinary collect dev cup
Urological Supplies	A4328	Fem urinary collect pouch
Urological Supplies	A4331*	Extension drainage tubing
Urological Supplies	A4332	Lube sterile packet
Urological Supplies	A4333	Urinary cath anchor device
Urological Supplies	A4334	Urinary cath leg strap
Urological Supplies	A4336	Urethral insert
Urological Supplies	A4338	Indwelling catheter latex
Urological Supplies	A4340	Indwelling catheter special
Urological Supplies	A4344	Cath indw foley 2 way silicn
Urological Supplies	A4346	Cath indw foley 3 way
Urological Supplies	A4349	Disposable male external cat
Urological Supplies	A4351	Straight tip urine catheter
Urological Supplies	A4352	Coude tip urinary catheter
Urological Supplies	A4353	Intermittent urinary cath
Urological Supplies	A4354	Cath insertion tray w/bag
Urological Supplies	A4355	Bladder irrigation tubing
Urological Supplies	A4356	Ext ureth clmp or compr dvc
Urological Supplies	A4357*	Bedside drainage bag
Urological Supplies	A4358	Urinary leg or abdomen bag
Urological Supplies	A4360	Disposable ext urethral dev
Urological Supplies	A4402*	Lubricant per ounce
Urological Supplies	A4450*	Non-waterproof tape
Urological Supplies	A4452*	Waterproof tape
Urological Supplies	A4455*	Adhesive remover per ounce
Urological Supplies	A4456*	Adhesive remover, wipes
Urological Supplies	A5102*	Bedside drain btl w/wo tube
Urological Supplies	A5105	Urinary suspensory
Urological Supplies	A5112	Urinary leg bag
Urological Supplies	A5113	Latex leg strap
Urological Supplies	A5114	Foam/fabric leg strap
Urological Supplies	A5131*	Appliance cleaner
Urological Supplies	A5200	Percutaneous catheter anchor

* HCPCS Level II codes included in product categories for ostomy supplies and urological supplies

Specifically with regard to certain codes for lower volume items under the OTS Upper Extremity Braces and OTS Back Braces product categories, the average delivery distances were less than 100 miles as shown in tables FF-11 and 12. Although it does not appear that the braces falling under these codes are currently being delivered from remote locations, we still believe that they could be furnished by nationwide or regional contract suppliers. However, we solicited comments on whether there is any reason that these codes should not be furnished on a mail order basis from remote supplier locations and instead should only be furnished on a non-mail order basis. The alternative would be to exclude codes that have a national average delivery distance of less than 100 miles and include them in future nationwide or regional competitions if the delivery distance for these codes increases to more than 100 miles. Excluding the items would mean that contract suppliers would not be required to furnish these braces, and we are concerned that this could potentially affect access to these items. However, contract suppliers would have discretion to furnish the items to beneficiaries on a non-mail order basis in addition to furnishing the items on a mail order basis, but contract suppliers would not be required to furnish the items on a non-mail order basis.

TABLE FF-34: NATIONAL AVERAGE DELIVERY DISTANCE FOR OTS UPPER EXTREMITY BRACES (2024)

HCPCS Level II Code	Average Distance	Allowed Charges
L3650	111	$248,236
L3660	489	$6,072,706
L3670	403	$15,405591
L3675	194	$178,258
L3678	13	$974
L3710	32	$50,676
L3761	813	$11,742340
L3762	129	$468,633
L3809	356	$15,210,077
L3908	275	$13,311,651
L3912	59	$21,253
L3916	1,049	$59,578,443
L3918	160	$12,113
L3924	263	$3,989,591
L3925	41	$100,324
L3927	52	$112,892
L3930	84	$10,240

TABLE FF-35: NATIONAL AVERAGE DELIVERY DISTANCE FOR OTS BACK BRACES (2024)

HCPCS Level II Code	Average Distance	Allowed Charges
L0450	16	$10,903
L0455	12	$5,570
L0457	832	$20,199,134
L0467	4	$1,911
L0469	4	$1,629
L0621	221	$117,797
L0623	1,055	$13,417
L0625	57	$46,479
L0628	39	$11.732
L0641	292	$131,336
L0642	157	$3,799,823
L0643	13	$3,341
L0648	252	$4,563,082
L0649	146	$4,401
L0650	179	$18,004,560
L0651	976	$79,147,145

In the case of a RID CBP, the bid items would be delivered by the contract supplier to the beneficiary from a remote location, for example, through the mail. Items may be furnished to beneficiaries who come into the local storefront of a contract supplier, but we believe that most contract suppliers would have a limited number of local storefronts and therefore these occurrences would be rare. Again, contract suppliers would have discretion to furnish the items to beneficiaries on a non-mail order basis in addition to furnishing the items on a mail order basis, but contract suppliers would not be required to furnish the items on a non-mail order basis.

We believe that situations where a beneficiary loses or is temporarily without supplies that Medicare has already paid for are rare. Claims for replacement supplies furnished from a supplier in these situations would be denied because Medicare has already paid for supplies for the time when the replacement supplies are needed. The supplier of the replacement supplies would likely have the beneficiary sign an Advance Beneficiary Notice of Noncoverage (ABN), form CMS-R-131, making the beneficiary liable for the cost of the replacement supplies in the event the claim is denied. The beneficiary can appeal the denial of the claim for the replacement supplies, indicating the reason why the replacement supplies were needed, and the claim denial could potentially be overturned on appeal. We solicited comments on our proposal that for

supplies included under a RID CBP, these situations would continue to be handled the way they are now, through the claim appeals process. We also solicited comments on our proposal that obtaining replacement supplies from a local storefront owned by a non-contract supplier in these rare situations would not be a reason to deny a claim if it is determined that paying the claim for the replacement supplies would otherwise be reasonable.

3. Provisions of the Regulation

We solicited comments on our proposal to phase in a nationwide RID CBP or regional RID CBPs, to be defined under § 414.402, for product categories including items such as those listed in table FF-32 that typically are furnished to beneficiaries from remote supplier locations or locations that are hundreds of miles on average from the beneficiary residence under a future round of the DMEPOS CBP. The term "Remote item delivery competitive bidding program" would be defined under § 414.402 to mean "a competitive bidding program wherein contract suppliers are responsible for furnishing remote item delivery items under a product category to all Medicare beneficiaries regardless of where they live in the CBA. The CBA could be one nationwide CBA that includes all areas (all States, territories, and the District of Columbia) or a CBA covering a specific region of the country." The term "Remote item delivery item" would be defined under § 414.402 to mean "an item falling under a remote item delivery competitive bidding program that may be shipped or delivered to a beneficiary's home, regardless of the method of delivery, or picked up at a local pharmacy or supplier storefront if the beneficiary or caregiver for the beneficiary chooses to pick the item up in person." The product categories to be phased in under a RID CBP(s) would be designated through program instructions or by other means in accordance with existing regulations at 42 CFR 414.406(d). Contract suppliers serving a nationwide or regional RID CBP would be responsible for furnishing the items on either a mail order or non-mail order basis under the product category to all Medicare beneficiaries, regardless of where they live in the CBA. If a beneficiary who resides in a CBA receives an item in person at a local supplier storefront, that supplier would need to be a contract supplier for the item.

Items furnished to beneficiaries from remote supplier locations, such as those listed in table FF-33 would be furnished in a nationwide RID CBP or regional RID CBPs that include both mail order and non-mail order items, and not under a "mail order" program that only includes mail order items.

We solicited comments on these provisions.

Comment: A commenter supported the proposal but included some recommendations for monitoring the program, such as geographic analysis and beneficiary complaint data to monitor supplier performance in the RID CBP. The commenter also suggested using partnerships (for example, UPS, Amazon, USPS) to test delivery in rural/underserved regions and flagging suppliers overusing the RID CBP in ways inconsistent with patient demographics.

Response: We appreciate the support and agree about the need for monitoring. We have an established monitoring system and analyze reports regularly. We discuss some of this monitoring work in prior rules, such as in the final rule entitled "Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues, and Level II of the Healthcare Common Procedure Coding System (HCPCS); DME Interim Pricing in the CARES Act; Durable Medical Equipment Fee Schedule Adjustments To Resume the Transitional 50/50 Blended Rates To Provide Relief in Rural Areas and Non-Contiguous Areas," published on December 28, 2021 (86 FR 73871). Additional information about our DMEPOS CBP health status monitoring work can also be found on the CMS website: https://www.cms.gov/medicare/payment/fee-schedules/dmepos-competitive-bidding/health-status-monitoring. As we have noted, the items listed in table FF-32 are being delivered from remote supplier locations and suppliers are able to use the means of delivery that works best for their company (for example, U.S. Postal Service, Federal Express, United Parcel Service). We have not received information that beneficiaries have not received orders due to use of specific delivery methods or couriers. Finally, as with all parts of the Medicare program, we will monitor contract suppliers to detect instances of waste, fraud, and abuse under the DMEPOS CBP.

Comment: Several commenters were concerned the proposal would cause small DME suppliers to close, change long-standing supplier relationships, and make it difficult for suppliers to meet beneficiary demand at lower prices. These commenters were also concerned about the quality of items and services provided under a RID CBP, and what action beneficiaries can take if they are unsatisfied with the quality of the items and services provided. Some commenters were concerned that if the quality of items were to decrease or there were delays in receiving the equipment, it would lead to more out of pocket expenses for beneficiaries who choose to purchase products from non-DMEPOS CBP suppliers, or cause more hospitalizations for those who choose to go without the lower quality items offered by the contract suppliers. Many commenters stated beneficiaries would lose access to effective, timely local support. Some commenters stated this proposal may also present issues after a natural disaster when time-sensitive support is critical.

Response: We appreciate the concerns and share the goal of ensuring beneficiary access to quality DMEPOS items and services under the DMEPOS CBP. The DMEPOS CBP helps ensure access to medically necessary items by requiring contract suppliers to furnish items to any beneficiary who maintains a permanent residence in, or who visits, the CBA and who requests those items from that contract supplier, as required by 42 CFR 414.422(e)(1). This will allow beneficiaries to have additional information about the product they will be obtaining and utilizing. Additionally, as directed under section 1847(b)(6)(D) of the Act, CMS will continue to ensure that small suppliers, meaning a supplier generates gross revenue of $3.5 million or less in annual receipts including Medicare and non-Medicare revenue, have the opportunity to participate in a competitive bidding program. The special rules at § 414.414(g) establish a goal of awarding at least 30 percent of the total number of contracts to small suppliers.

Regarding the concern about the RID CBP making it difficult for suppliers to meet beneficiary demand for beneficiaries at lower prices, it is up to the supplier to submit bids based on their own cost analysis and operational capacity. Each supplier determines the price point at

which they believe they can sustainably furnish items and services. As a reminder, in accordance with 42 CFR 414.414(b)(4), before awarding contracts, each bid is screened and evaluated to ensure that it is bona fide so that CMS can verify that the supplier can provide the product to the beneficiary for the bid amount. Additionally, the proposed provisions under 42 CFR 414.414(h) and (i) help ensure there are a sufficient number of suppliers to meet beneficiary demand. Regarding the concern about the quality of items and services furnished under a RID CBP, suppliers participating in the RID CBP must continue to follow the DMEPOS Quality Standards. These standards not only require suppliers to obtain and provide appropriate quality equipment, item(s), and service(s), but also require suppliers to deliver and set-up, or coordinate set-up with another supplier, all equipment and item(s) in a timely manner.[76] We plan to continue closely monitoring health outcomes for beneficiaries under the DMEPOS CBP. We also will continue the use of our monitoring and complaint system under the DMEPOS CBP, which we finalized in the 2007 final rule (72 FR 18061). If a beneficiary has a problem getting needed DMEPOS items or services or is concerned about the quality of the items and services, they can reach out to their supplier, contact 1-800-MEDICARE, or contact the Competitive Acquisition Ombudsman (CAO) by asking the 1-800-MEDICARE representative to submit your complaint or inquiry to the CAO. The supplier standards under 42 CFR 424.57(c) address the requirements suppliers must follow with regards to complaints. For example, suppliers must answer questions and respond to complaints a beneficiary has about the Medicare-covered item that was sold or rented, maintain documentation of contacts with beneficiaries regarding complaints or questions, and have a complaint resolution protocol to address beneficiary complaints that relate to these supplier standards.

Finally, regarding concerns about access to local support, we note a RID CBP would be established for items already furnished primarily by suppliers from remote locations.

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76 https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Downloads/Final-DMEPOS-Quality-Standards-Eff-01-09-2018.pdf

Additionally, regarding the concerns about how a RID CBP may affect time-sensitive support after a natural disaster, the DMEPOS Quality Standards require that suppliers have a contingency plan that enables them to respond to emergencies and disasters or to have arrangements with alternative suppliers in the event that the supplier cannot service its own customers as the result of an emergency or disaster. We also note our proposal in § 414.422, whereby if CMS determines that due to a PHE contract suppliers are unable to furnish certain items and services to beneficiaries in certain areas impacted by a PHE (PHE-impacted area) as required under their respective DMEPOS CBP supplier contracts, CMS would have the option to unilaterally terminate or modify each applicable DMEPOS CBP supplier contract to allow any Medicare enrolled DMEPOS supplier to furnish the applicable items and services to Medicare beneficiaries in the PHE-impacted area. *Comment:* Several commenters expressed concerns about potential negative effects the remote method of delivery under the RID CBP may have on local suppliers and beneficiaries in rural and underserved areas. A commenter stated it is unclear if reimbursement will reflect the cost and responsibilities of hybrid delivery requirements (mail and in person). A few commenters noted that in a prior CBP demonstration, CMS found that beneficiaries wanted the choice to come to a storefront to obtain urological supplies, and this proposal would eliminate patient choice. Many commenters stated the RID CBP may hurt beneficiaries who rely on in-person fittings or education on proper usage, including beneficiaries who use off-the-shelf (OTS) orthotics, intermittent catheters, or ostomy items. A few commenters also stated this proposal would be especially concerning for older or vulnerable populations, who may lack resources or care to manage care remotely. Some commenters noted that many braces are dispensed immediately following surgery, and shifting to mail order delivery may disrupt and delay patient care. A commenter asked if contract suppliers would be required to maintain local storefronts and furnish the items on a non-mail order basis in addition to furnishing the items on a mail order basis.

Response: Thank you for the comments. As discussed in the proposed rule, a RID CBP would be established for items already furnished primarily by suppliers from remote locations (90 FR 29254). As we indicated in the proposed rule, we anticipate limiting RID CBPs to product categories that are typically furnished to beneficiaries from remote supplier locations, or locations that are hundreds of miles on average from the beneficiary residence where the items are delivered. Under a RID CBP, contract suppliers would not be required to furnish the items in local storefronts in addition to furnishing them from remote locations, but they can voluntarily maintain local storefronts to furnish these items as well as furnishing them from remote locations to beneficiaries in all parts of the country. We stated that we believe most contract suppliers would have a limited number of local storefronts and therefore these occurrences would be rare (90 FR 29260). If a supplier chooses to furnish items and services via mail and in person, it is up to them to factor in the costs of doing so in their bid amount. We do not believe it is necessary to furnish these items in local storefronts and believe that beneficiaries in all areas would have access to the items furnished from remote supplier locations as is currently being done in a majority of cases now. Education will be provided for all beneficiaries, including those who are not adept at using mail order, on how to contact suppliers to arrange for delivery of items and services. The RID CBP is therefore a way to ensure access for all beneficiaries, including beneficiaries located in rural areas, and requires less government resources than the alternative of implementing thousands of local CBAs throughout the nation since the statute does not allow any areas to be excluded from the DMEPOS CBP for these items. We plan to closely monitor access and health outcomes under the RID CBP.

Regarding orthotics, while local DMEPOS suppliers certainly play a valuable role in the delivery of orthotic care, it is important to distinguish between custom-fitted and custom-fabricated orthotics, which require clinical expertise and in-person fitting, and OTS orthotics under section 1847(a)(2)(C) of the Act, which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit

the beneficiary. The RID CBP proposal is limited only to OTS orthotics that are appropriate for remote delivery. We agree that patient education is important, even for items furnished OTS. However, many OTS orthotics come with manufacturer-provided instructions, and per the DMEPOS Quality Standards, suppliers must provide clear, written or pictorial, and oral instructions related to the use, maintenance, infection control practices for, and potential hazards of equipment and/or item(s) as appropriate. In-person instruction, while beneficial, is not always necessary to achieve appropriate outcomes for these devices particularly when the devices are low-risk, low-complexity, and clearly indicated by diagnosis. In accordance with section 1847(a)(7)(A) of the Act and regulations at 42 CFR 414.404(b)(1), physicians, treating practitioners, and hospitals may furnish competitively bid OTS orthotics without submitting a bid and being awarded a contract under the DMEPOS CBP, provided that certain conditions are satisfied. This applies when the items are furnished by the physician or treating practitioner to their own patients as part of their professional service or by a hospital to its own patients during an admission or on the date of discharge, and if the items are billed under a billing number assigned to the hospital, physician, the treating practitioner (if possible), or a group practice to which the physician or treating practitioner has reassigned the right to receive Medicare payment.

Comment: A commenter questioned if there will be a continuity-of-care exemption during the transition period to prevent abrupt disruptions in access.

Response: Thank you for the question about continuity-of-care protections during the transition period. Pursuant to section 1847(a)(4) of the Act, CMS intends, in the case of a covered item for which payment is made on a rental basis under section 1834(a) of the Act and in the case of payment for oxygen under section 1834(a)(5) of the Act, to allow rental agreements for the covered items and supply arrangements with oxygen suppliers entered into before the application of DMEPOS CBP for the item to be continued. In the case of any such continuation, the supplier involved would continue to provide for appropriate servicing and replacement.

Comment: A commenter stated the proposal did not define what "regional" means. Another commenter stated that a regional RID CBP should be no larger than a State.

Response: Thank you for the comment. As discussed in the proposed rule, the term "Remote item delivery competitive bidding program" would be defined under § 414.402 to mean "a competitive bidding program wherein contract suppliers are responsible for furnishing remote item delivery items under the product category to all Medicare beneficiaries regardless of where they live in the CBA. The CBA could be one nationwide CBA that includes all areas (all States, territories, and the District of Columbia) or a CBA covering a specific region of the country." Per 42 CFR 414.406(b), CMS designates through program instructions or by other means, each CBA in which a competitive bidding program may be implemented. We are not proposing in this rule which specific areas would be included under a RID CBP, but if regional RID CBPs are established, they could cover smaller regions such as a State, territory, or the District of Columbia, or they could cover larger areas such as a group or combination of States, territories, and/or the District of Columbia.

Comment: Several commenters responded to CMS' solicitation of comments on whether there is any reason that certain codes for lower volume items under the product categories for OTS upper extremity braces and OTS back braces should not be furnished on a mail order basis from remote supplier locations and instead should only be furnished on a non-mail order basis. A commenter stated the proposed OTS upper extremity braces were not previously included in competitive bidding, and new products should not be incorporated into an untested RID CBP. This commenter also stated that any RID CBP should at a minimum be limited to items delivered from remote locations with an average delivery distance of 100 miles or more. Another commenter recommended excluding all orthotics from the DMEPOS CBP and any RID CBP due to low volume and the necessity of in-person fitting.

Response: Thank you for the responses to our solicitation of comments. We note that while some OTS items under the upper extremity and back brace categories are considered low

volume, low utilization alone should not be the basis for excluding them from a CBP. Contract suppliers must furnish all items in a product category regardless of how often they are needed, and so beneficiaries are guaranteed access to low volume items as well as high volume items under a CBP. It is important to clarify that the remote delivery model under consideration for orthotics is intended solely for OTS orthotics, products that do not require clinical customization, in-person fitting, or direct patient assessment. These items are standardized and designed to be used with minimal self-adjustment, making them suitable for secure and efficient remote fulfillment. As explained previously, OTS orthotics do not need to be furnished in person. While certain braces may not currently be furnished primarily through the mail, this does not mean that they cannot be furnished through the mail if they do not require in-person services. Some of the lower volume braces that also have average delivery distances of less than 100 miles may not be furnished often or at all by national mail order suppliers because they are not as profitable or are not as commonly needed as other braces. This does not mean they are not items that can be furnished on a mail order basis and by including them in the CBP contract suppliers would need to furnish them when they are needed. Additionally, we believe it is unnecessary to exclude items such as OTS upper extremity braces from the RID CBP just because they have not been included in any prior CBP. These are items that are typically furnished to beneficiaries from remote supplier locations and so we believe it makes the most sense to include them in a RID CBP as opposed to a local CBP. The RID CBP may be a new regulatory definition, but we have implemented a national CBA before through the national mail order DMEPOS competitive bidding program, and we have implemented numerous local CBPs throughout the country. A RID CBP would simply allow both forms of delivery under one CBP. We will keep these comments in mind as we decide whether to include these items in a future RID CBP.

Comment: Some commenters stated that mail-order distribution increases the risk of billing fraud.

Response: Thank you for the comments. As always, all future CBPs will be closely monitored for fraudulent activities or other abuses of the Medicare program.

Comment: Several commenters opposed the proposal because they believe that there will be mail order complications. Many commenters noted that the RID CBP could complicate or delay mail ordering, potentially creating a safety risk for patients. These commenters noted mail delays due to weather events or transit delays could have serious consequences to beneficiaries' health, including for patients with certain health conditions such as diabetes, sleep apnea, or urological needs. Another commenter noted the post office can also close for non-emergency reasons. A commenter stated the proposal would also complicate ordering, returns, and urgent replacements. A commenter suggested product recalls could also present a challenge if a supplier does not have alternate options readily available. Some commenters stated patients frequently come into their store because their supplies have been lost or delayed in the mail and that suppliers with local storefronts may be reluctant to serve beneficiaries whose supplies were delayed in being delivered by a mail order supplier**.** Another commenter stated CMS's assumptions about delivery equivalency between rural and urban areas are not accurate in all cases – while the cost of shipping is comparable, the reliability and timeliness of delivery are not. The commenter stated that individuals in rural or underserved regions may face longer wait times, limited availability of preferred carriers, or difficulties resolving delivery issues without in-person assistance.

Response: Thank you for the comments. While there can be challenges with mail order delivery, it is also a very efficient, cost-effective and convenient means of delivery and we believe these benefits outweigh its challenges. Additionally, the items that would be included in the RID CBP are those items that are already furnished from remote supplier locations, and so mail order delivery of these items would not be new. Mail order also allows for items to reach rural or underserved regions that may not have any nearby in-person assistance to begin with. The DMEPOS Quality Standards, including timely delivery standards, require suppliers to

deliver and set-up, or coordinate set-up with another supplier, all equipment and item(s) in a timely manner as agreed upon by the beneficiary and/or caregiver, supplier, and prescribing physician. If a beneficiary has a problem getting needed DMEPOS items or services or is concerned about the quality of the items and services, they can reach out to their supplier, contact 1-800-MEDICARE, or contact the Competitive Acquisition Ombudsman (CAO) by asking the 1-800-MEDICARE representative to submit your complaint or inquiry to the CAO. The terms of the contracts under the DMEPOS CBP at 42 CFR 414.422(e)(1) require suppliers to serve all beneficiaries within the CBA. Suppliers must factor these geographic challenges into their service delivery plans and bid submissions. We will continue to monitor any effects on access as we implement future CBPs.

Comment: Many commenters commented on our proposal regarding situations where a beneficiary loses or is temporarily without supplies that Medicare has already paid for. Many commenters noted that this shifts liability to the beneficiary for delays outside of their control. Some commenters requested that beneficiaries should retain the freedom and ability to choose to obtain items either from a mail order supplier or from a non-mail order supplier. A commenter recommended adding provisions to allow beneficiaries to obtain items from local non-contract suppliers in urgent or emergent situations.

Response: Thank you for the comments. We will closely monitor the contract suppliers to ensure they are furnishing replacement supplies on a timely basis. We believe many situations where a beneficiary is without supplies would likely be due to lost or misplaced supplies. For example, when a beneficiary gets on a flight and forgets to bring their supplies. As we stated in the proposed rule, these types of situations are rare and are currently handled through the claims appeals process. We believe these situations are rare and can continue to be handled adequately through the claims appeals process under a RID CBP.

Comment: A commenter stated the RID CBP is duplicative of existing regional and national mail-order provisions because the CBP already includes provisions for regional and national mail order competitions. The commenter believed this would confuse beneficiaries.

Response: Thank you for the comment. We believe it is necessary to define a RID CBP as what we are proposing would include both mail order and non-mail order delivery. The current definition of national mail order DMEPOS competitive bidding program under 42 CFR 414.402 is only for mail order.

Comment: Several commenters opposed the proposal because of concerns with licensing. A few commenters stated the proposed bidding process would require state licenses and bid bonds to be obtained prior to submitting a bid, which would put more financial burden on small suppliers. Similarly, another commenter stated that state licensing requirements vary from state to state, and could impact a supplier's ability to serve beneficiaries in specific states. Another commenter noted most suppliers only maintain state licenses in areas where they operate, but under a national RID CBP, these DME suppliers would either need to take on the costs of obtaining and maintaining nationwide licensure or decline to participate in the program. A commenter noted that some states require a brick and mortar location to be owned by a supplier within that state before dispensing DME items within that state, and many suppliers will not acquire brick and mortar locations unless they know they are actually going to be dispensing DME in those states. A commenter noted that individual state orthotic licensing rules and regulations may limit the reasonable implementation of an orthotic RID CBP by prohibiting suppliers outside of the state from delivering orthoses in the state. A commenter requested that before implementing a RID CBP, CMS should identify state licensing requirements for bidders, provide advance notice to apply for these licenses, and eliminate any bids that do not meet licensing requirements. This commenter suggested that CMS should also work with state Boards of Pharmacy and DME (where applicable) to identify licensing requirements for drop shipping as a non-resident facility, since many suppliers will not have locations in every state.

Response: Thank you for the comments. Just like any other DMEPOS CBP, the RID CBP has the same statutory requirements regarding bid bonds and licensure. A bidding entity may not submit a bid(s) and be awarded a contract for a competition unless it obtains a bid surety bond for the CBA from an authorized surety on the Department of the Treasury's Listing of Certified Companies and provides proof of having obtained the bond by submitting a copy to CMS by the deadline for bid submission. The bid surety bond requirement discourages bidding entities from submitting unrealistic and non-serious bids that they cannot support, leading to more accurate bids. Additionally, this requirement helps ensure that bidding entities continue to accept contract offers as their bid surety bond will be forfeited if certain criteria are met. The bid surety bond requirement also contains a level of financial assurance as the approved surety company will typically conduct an underwriting process to evaluate a bidding entity's financial health, experience, and business practices prior to issuing a bid surety bond(s) to a bidding entity. Section 1847(b)(2)(A) of the Act, as implemented under 42 CFR 414.414, states CMS may not award a DMEPOS CBP supplier contract unless CMS finds that the bidding entity meets applicable State licensure requirements. Pursuant to the DMEPOS supplier standards at 42 CFR 424.57(c), a supplier must operate its business and furnish Medicare covered items in compliance with all applicable Federal and State licensure and regulatory requirements. To be eligible for a contract, a supplier must possess the applicable licenses by the close of the bid window. We have implemented a national CBA before through the national mail order DMEPOS competitive bidding program, and under this program suppliers had to have the applicable licenses for all 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, and American Samoa. Not all states required a license for mail-order diabetic supplies, but it was up to the supplier to confirm which states required a license to mail diabetic testing supplies, obtain those licenses, and submit them to what was then the National Supplier Clearinghouse (now called the National Provider Enrollment contractor). We also note that items that would be included in a RID CBP are items that are already furnished by national mail order suppliers and

for States that have a requirement that the supplier maintain a physical location within or close to the State, regional RID CBPs can be established, if necessary, to address this situation if the national suppliers furnishing the items do not already have locations in or near these States.

Comment: A commenter noted HCPCS codes proposed for RID CBP inclusion may be subject to additional federal, state, and local regulatory policies, processes, and/or procedures. For example, in an RID CBP environment, meeting CMS prior-authorization requirements would be extremely challenging and further delay urgent orthotic needs.

Response: Thank you for the comment. Each HCPCS code has its own applicable policies, and it is up to the supplier to follow those policies and bill each HCPCS code appropriately. Without knowing which specific HCPCS codes or policies the commenter is referring to, we cannot predict what effect the RID CBP would have on those unspecified policies. Regarding prior-authorization, we are also unsure what part of the RID CBP environment would make prior-authorization challenging. Prior authorization has occurred under prior rounds of the CBP, including the most recent round for certain off-the-shelf back and knee braces. If the commenter is referring to how a potential national RID CBP may make prior authorization more challenging, as discussed in the proposed rule and above CMS envisions that a RID CBP would be for items and services that are generally furnished from remote supplier locations. In determining which items may fall under a nationwide RID CBP, we will consider whether suppliers typically furnish the item around the country or if they are typically furnished on a regional basis.

Comment: A commenter stated that the previous national mail order CBP for diabetic supplies failed.

Response: We do not agree. The national mail order CBP for diabetic testing supplies was successful in lowering excessive payment amounts and fraud while access to diabetic supplies and health outcomes remained stable or improved. The MedPAC has also found that the program dramatically reduced Medicare and beneficiary spending on diabetes testing supplies,

while beneficiaries maintained broad access to test strips, health outcomes remained stable, and further found that program likely reduced abusive billing practices for test strips.[77]

Comment: Several commenters recommended testing or implementing various demonstration of a RID CBP before implementing a national RID CBP. A commenter suggested delaying the implementation of the RID CBP by 2 years, allowing suppliers, manufacturers, and patients time to adapt to the new framework and give CMS the opportunity to conduct further impact assessments and stakeholder engagement. Some commenters also suggested engaging with the patient community, including stakeholders in niche categories before implementing a RID CBP.

Response: Thank you for the comments and recommendations. We will consider these as we work towards implementing a RID CBP in the future.

After consideration of the public comments received, we are finalizing our proposals to establish definitions for "remote item delivery competitive bidding program" and "remote item delivery item." We are also finalizing our policy to continue using the claims appeals process to determine whether payment can be made for replacement of supplies by non-contract suppliers in cases where replacement of supplies is needed and the supplies cannot be delivered on a timely basis by a contract supplier.

G. Payment for Continuous Glucose Monitors and Insulin Infusion Pumps

Because CGMs and insulin infusion pumps are subject to rapid technological change, requiring frequent and substantial servicing, we proposed to reclassify all CGMs and infusion pumps under the frequent and substantial servicing payment category at section 1834(a)(3) of the Act, as implemented under § 414.222(a). CMS would pay for all CGMs and insulin infusion pumps on a monthly rental basis under both the DMEPOS CBP, and in non-CBAs under the fee

77 https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/default-document-library/dmepos-slide-deck-(final-9-3-19)f8ad12adfa9c665e80adff00009edf9c.pdf

schedule payments. The monthly rental payments would include payment for any necessary supplies and accessories. As further discussed later in this section, this would be a departure from how these items are currently paid under the Medicare DMEPOS fee schedule. Under the Medicare DMEPOS fee schedule, we typically pay for the purchase of CGMs, which are classified as routinely purchased equipment. Payment for insulin pumps is made on a capped rental basis, with beneficiaries taking over ownership of the pump after rental payments are made for 13 months of continuous use. In addition, we proposed to allow contract suppliers to bill for up to 3 months of rental for these items in advance.

Class III devices are statutorily excluded from the DMEPOS CBP per section 1847(a)(2)(A) of the Act. Because certain brands of insulin infusion pumps are used in conjunction with class III CGMs, we proposed that insulin infusion pumps used in conjunction with class III CGMs would also be excluded from the DMEPOS CBP. We want to avoid a situation where Medicare payments for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs are grossly excessive compared to Medicare payments for class II CGMs and insulin pumps that are not used in conjunction with class III CGMs. To avoid this, we proposed that once class II CGMs and insulin infusion pumps are phased into the DMEPOS CBP, if the rental fee schedule amounts for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs are more than 15 percent higher than the SPAs established for class II CGMs and insulin infusion pumps under the DMEPOS CBP, then we proposed that we would adjust the fee schedule amounts for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs to be equal to the SPAs established for class II CGMs and insulin infusion pumps under the DMEPOS CBP in accordance with the process described in 42 CFR 405.502.

We solicited comments on these proposals.

1. Background

The Medicare Part B benefit for DME is primarily a benefit for rental of durable medical equipment such as wheelchairs, hospital beds, oxygen equipment, and ventilators for use in the beneficiary's home, including certain institutions used as the beneficiary's home. Various statutory payment provisions that added an option to purchase certain DME in lieu of rental or that cap total rental payments after a certain number of months or when total payments equal the purchase price for the equipment were phased in beginning in 1968. These statutory rules were intended to save money for the beneficiary and the Medicare program in cases where DME is needed on a long-term basis. However, we are concerned that two types of DME — CGMs and insulin infusion pumps — are classified under statutory provisions that limit beneficiary choice and access to newer technology, thereby limiting options for beneficiaries to improve their health and not accounting for the frequent and substantial servicing these devices require.

Medicare payment for CGM receivers can be made on a lump sum purchase basis or a monthly rental basis, although most Medicare beneficiaries receive the items on a purchase basis. Medicare pays for CGM receivers classified by the Food and Drug Administration (FDA) as class II or class III devices under the Federal Food, Drug, and Cosmetic Act. CGM systems can only be classified under class II if they can meet the requirements to be an integrated CGM system in accordance with Federal regulations at 21 CFR § 862.1355. Class III CGMs are not accurate enough to be classified as an integrated CGM system.

The 2025 average Medicare fee schedule amount for purchase of a new, class II CGM receiver is $286.03. In addition to receiving payment for the purchase of the CGM receiver, suppliers are allowed to bill for replacement supplies necessary for the operation of the CGM every 90 days for a payment of $803.76 for supplies used with class II CGMs, with total payments for the ongoing replacement of supplies accounting for over 98 percent of the total CGM costs over 5 years. CMS issued program instructions on October 19, 2023 (Transmittal 12303; Change Request 13397) instructing Medicare Administrative Contractors (MAC) to allow CGM supplies to be billed in 90 day increments to align with longstanding practices in

place for blood glucose monitors. In addition, the DME MAC Local Coverage Determinations for external infusion pumps allow suppliers to dispense up to 3 months of supplies at a time: *https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33794*.

Medicare payment for insulin infusion pumps is made on a capped rental basis, with beneficiaries taking ownership of the pump after rental payments are made for 13 months of continuous use. The rental payments over 13 months add up to $5,702.34 for insulin pumps furnished in nonrural areas (metropolitan statistical areas) and $5,926.87 for insulin pumps furnished in other, rural areas and non-contiguous areas of the United States (Alaska, Hawaii, Puerto Rico, etc.). In addition to receiving payment for rental of the insulin pump, suppliers are allowed to bill for replacement supplies necessary for the operation of the insulin pump every 90 days for a payment of approximately $403.68 for nonrural areas and $447.06 for rural and non-contiguous areas, with total payments for the ongoing replacement of supplies accounting for 60 percent of the total insulin pump costs, not including the cost of insulin, over 5 years.

In accordance with the payment rules for DME under section 1834(a) of the Act, DME items are classified under six different payment classes with different payment rules under section 1834(a)(2) through (7)of the Act, added by section 4062(b) of the Omnibus Budget Reconciliation Act (OBRA) of 1987 (Public Law 100-203). In accordance with section 1834(a)(2)(A)(ii) of the Act and regulations at 42 CFR 414.220(a)(2), equipment that was acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987 is considered routinely purchased equipment and can be paid on a rental or lump-sum purchase basis in accordance with the rules at section 1834(a)(2) of the Act and regulations at 42 CFR 414.220, but total payments for the equipment cannot exceed the purchase price for the item. Therefore, if the equipment is rented, the rental payments would cap at the point where total rental payments equal the Medicare fee schedule amount for purchase of the item. Although Medicare did not start covering CGMs until 2017, blood glucose monitors, predecessors to the CGM, were acquired by purchase on a national basis more than 90 percent of

the time during the period July 1986 through June 1987. As part of the final rule entitled "Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues, and Level II of the Healthcare Common Procedure Coding System (HCPCS); DME Interim Pricing in the CARES Act; Durable Medical Equipment Fee Schedule Adjustments To Resume the Transitional 50/50 Blended Rates To Provide Relief in Rural Areas and Non-Contiguous Areas," published on December 28, 2021, CGMs were classified as routinely purchased equipment (86 FR 73900).

Since Medicare did not start covering insulin infusion pumps until 1994, they also were not acquired by purchase on a national basis at least 75 percent of the time during the period July 1986 through June 1987. Other types of external infusion pumps that were covered as DME during the period July 1986 through June 1987 were not acquired by purchase on a national basis at least 75 percent of the time. Therefore, insulin infusion pumps are not classified as routinely purchased equipment in accordance with the statute and regulations and are not inexpensive equipment which can be paid in accordance with the rules at section 1834(a)(2) of the Act and regulations at 42 CFR 414.220. As such, insulin infusion pumps are classified as other covered items of DME and paid for in accordance with the capped rental payment rules at sections 1834(a)(7) and (8) of the Act and regulations at 42 CFR 414.229. Medicare pays a monthly rental amount for capped rental items for a period not to exceed 13 months of continuous use. "Continuous use" is defined in regulations at 42 CFR 414.230. After the 13-month capped rental period is over, the title to the equipment transfers to the beneficiary. In the case of both CGMs and insulin infusion pumps, Medicare makes separate payments on a purchase basis for supplies necessary for the effective use of the CGM or insulin infusion pump using fee schedule amounts calculated in accordance with section 1834(a)(6) and (8) of the Act.

Other than customized items of DME paid for in accordance with section 1834(a)(4) of the Act and regulations at 42 CFR 414.224 and oxygen and oxygen equipment paid for in accordance with section 1834(a)(5) and (9) of the Act and regulations at 42 CFR 414.226, CMS

may classify an item as DME requiring frequent and substantial servicing paid for in accordance with section 1834(a)(3) of the Act and regulations at 42 CFR 414.222 if the item requires frequent and substantial servicing in order to avoid risk to the patient's health. Payment for items falling under this class are made on a monthly rental basis, with rental payments continuing as long as coverage of the equipment under Part B continues and the equipment is being used in the home. The monthly rental amount includes payment for rental of the equipment, including maintenance and servicing of the equipment, and replacement of supplies and accessories necessary for the effective use of the DME. Separate payment is not allowed for supplies and accessories for items falling under this payment class.

We believe payment for CGMs and insulin infusion pumps should be on a continuous rental basis like other DME items requiring frequent and substantial servicing. The class of DME items requiring frequent and substantial servicing is described on page 392 of the House of Representatives Committee on the Budget Report 100-391 that accompanied OBRA 87 as items "that are technologically sophisticated and require frequent monitoring or adjustment in order to make sure they are functioning properly or being properly utilized by the patient. They are also typically quite expensive to purchase and often subject to relatively rapid technological change." As we discuss in greater detail later in this section, CGMs and insulin infusion pumps are subject to rapid technological change and require frequent servicing by the supplier.

2. Current Issues

While Medicare beneficiaries enrolled under Part B who use CGM equipment generally use it on a long-term basis, making purchase of the equipment seem more practical than rental, the ongoing need to purchase replacement supplies for the equipment continues, and, in accordance with current regulations at 42 CFR 414.210(f)(1), the beneficiary is not able to obtain new, replacement CGMs or insulin pumps for 5 years unless the equipment is lost, stolen, or irreparably damaged. The technology for CGMs and insulin infusion pumps is rapidly evolving to be more accurate and to work in tandem, with combination CGM/insulin pump systems that

regulate the administration of insulin based on patient need and even in anticipation of a patient's need. The American Diabetes Association (ADA) has also noted that diabetes technology is rapidly changing, but there is no "one-size-fits-all" approach to technology use in people with diabetes. Per the ADA, insurance coverage can lag behind device availability, patient interest in devices and willingness to change can vary, and providers may have trouble keeping up with newly released technology.[78]

We believe that the technology for CGMs and insulin infusion pumps, which are often used in conjunction with CGMs, will continue to change very rapidly in future years. In the CY 2022 DMEPOS final rule, commenters noted the rapid pace in changes in technology for CGMs and diabetes equipment in general. We discussed how glucose monitoring technology is changing rapidly, and the Medicare fee schedule amounts for this equipment should not be limited solely to the technology that is currently on the market (86 FR 73901). Rickson et al. (2023) have noted that 17 new CGM devices have been introduced to the market during the past decade.[79] Rickson et al. (2023) have also noted that the time between innovation and market launch for diabetes technologies is relatively short. New models with new features come onto the market often and physicians who treat patients with diabetes are frequently monitoring the patient's needs and whether they are properly utilizing their glucose monitoring and insulin infusion equipment. CGMs are used to alert the patient about dangerous glucose levels and to set insulin delivery rates or shut off insulin delivery via their infusion pumps, if necessary. Thus, it is vital that patients are using equipment with the latest features and technology to ensure that the measuring and displaying of glucose levels is as accurate as possible, so that the best information is available for both patient activated and equipment activated changes in diet and insulin.

Both CGMs and insulin pumps require software updates to ensure they are functioning properly and are protected from hacking or cyberattacks. Klonoff (2019) has noted the need for

78 https://diabetes.org/sites/default/files/2023-09/dc22s007.pdf
79 https://pubmed.ncbi.nlm.nih.gov/37306447/

diabetes devices to meet established, sound security baselines in design and throughout the product's lifecycle.[80] Klonoff (2015) also notes that everything about the importance of robust cybersecurity that is true for medical devices in general is particularly true for diabetes devices. Thus, software updates are often necessary to ensure the cybersecurity of diabetes devices and prevent adverse events.[81] The FDA, for instance, in 2019 warned patients and health care providers that certain insulin pumps were being recalled due to potential cybersecurity risks, and recommended that patients using these models switch their insulin pump to models better equipped to protect against these potential risks.[82] The FDA noted that the cybersecurity vulnerabilities could allow a person to over deliver insulin to a patient, leading to low blood sugar (hypoglycemia), or to stop insulin delivery, leading to high blood sugar and diabetic ketoacidosis (a buildup of acids in the blood). For this recall, the manufacturer did not update the software, and instead opted to replace the device. However, Klonoff (2019) noted in response to this recall that insulin pump manufacturers should carefully review the cybersecurity of their products already on the market and provide software patches or updates when possible. Klonoff (2015) notes that patients with diabetes have a special need for impeccable data fidelity when they access their current glucose levels, glucose trend data, predictive data, insulin dosing records, hypoglycemia alerts, hyperglycemia alerts, blood pressure records, calorie information exercise records, and various reminders and timely notifications.

If beneficiaries are using rented CGM and/or insulin pump equipment, then the supplier of the rented equipment is responsible for making sure the equipment has the latest software updates and that the beneficiary is educated on how to use any updated software or features on the rented equipment. As the technology for these devices is rapidly changing and becoming more complex, beneficiaries may require more technical support from their supplier for any

80 https://pmc.ncbi.nlm.nih.gov/articles/PMC6955451/
81 https://pmc.ncbi.nlm.nih.gov/articles/PMC4667325/
82 https://www.fda.gov/news-events/press-announcements/fda-warns-patients-and-health-care-providers-about-potential-cybersecurity-concerns-certain

hardware or software issues. If either a CGM or insulin pump were to malfunction, for example provide inaccurate glucose measurements or insulin dosage, it would present an immediate health risk requiring urgent intervention. Suppliers of CGMs and insulin pumps must also adhere to frequent supply delivery schedules, as the supplies for these devices require frequent replacement so beneficiaries can maintain proper use of their equipment. Thus, we believe it is in the best interest of the beneficiary to classify CGMs and insulin pumps as items requiring frequent and substantial servicing.

We also believe that classifying CGMs and insulin pumps as items requiring frequent and substantial servicing, which would pay on a monthly rental basis in accordance with section 1834(a)(3) of the Act under the fee schedule payment rules and under the DMEPOS CBP in accordance with regulations at 42 CFR 414.408(h)(8) and (j)(2)(iii), would have the additional benefit of allowing greater access to the latest technology equipment. This would eliminate beneficiary-ownership of the CGMs or insulin pumps for new patients but allow flexibility to switch to newer technology equipment and supplies more often than once every 5 years. The beneficiary would no longer be locked into the same CGM device or insulin pump technology for 5 years. Moreover, this would prevent the concerning scenario where beneficiaries rely on CGM or insulin pump technology that has lost manufacturer support, resulting in reduced software updates, discontinued security patches, or obsolete components. Such outdated technology poses significant risks to patient safety, data security, and therapeutic efficacy. By reclassifying these devices under the frequent and substantial servicing payment class, Medicare would ensure beneficiaries maintain access to current, fully supported technology that meets evolving safety and performance standards, which could ultimately reduce the potential for outdated device complications. The contract supplier of the rented equipment would be responsible for updating the software (including supporting the beneficiary with appropriately updating the software) and performing any other necessary maintenance and servicing of the equipment. The contract supplier would also be responsible for addressing recalls of the rented

equipment and furnishing replacement equipment as necessary. As evidenced previously, the risk of recalls for this technology is real and serious if it were to occur. Under the DMEPOS CBP, the contract supplier would be required to furnish the CGM receiver or insulin pump ordered by the beneficiary's physician for use in treating diabetes, with the physician now being able to order changes in the equipment more frequently so that the beneficiary is able to take advantage of the latest equipment features and technology for managing diabetes. Over 98 percent of the cost of the CGM over 5 years is attributed to the frequent replacement of supplies and over 70 percent of the cost of the insulin pump over 5 years is attributed to the frequent replacement of supplies.

As discussed in section VII.F. of the preamble of this final rule, these items are currently delivered to beneficiaries from remote supplier locations that on average are hundreds of miles from the beneficiary's residence. In this section of the preamble of this final rule, we proposed to establish a nationwide or regional CBP(s) for items such as CGMs and insulin pumps that may be phased in under future competitions. We proposed to phase in payment on a monthly rental basis for CGMs and insulin pumps and all related supplies and accessories under the DMEPOS CBP. The monthly rental payments would continue as long as Medicare Part B coverage for the items continue. We proposed to amend 42 CFR 414.412(b) to establish bid limits for CGMs and insulin infusion pumps for the first time they are phased in as the lead item in a product category under a nationwide or regional CBA(s). For CGMs, we proposed that the bids submitted for rental of CGMs included as a lead item in a product category in a RID CBP for the first time cannot exceed the payment amount that would otherwise apply to the supplies for the CGM under subpart D of this part plus the average of the purchase fee schedule amounts that would otherwise apply to the CGM for the areas included in the RID CBP divided by 60 for the number of months over a 5-year period because the purchase fee schedule amount for the CGM receiver would cover use of the device for 5 years. Using 2025 fee schedule amounts to demonstrate how the bid limits would be calculated, for a nationwide CBP, the monthly fee schedule amount for

the supplies for a non-adjunctive CGM (HCPCS level II code A4239) is $267.92. The average of the 2025 fee schedule amounts for the purchase of a new, non-adjunctive CGM (HCPCS level II code E2103) with a reasonable useful lifetime of 5 years is $286.03, which when divided by 60 generates a monthly payment of $4.77. The 2025 bid limit for the bundled nationwide monthly rental payment for non-adjunctive, class II CGMs would therefore be $272.69 ($267.92 + $4.77). Bidding entities competing to be a nationwide contract supplier for these items and other items in the same product category would need to submit bids that are lower than the bid limit ($272.69 in this example) to be considered. Not factoring in reduced pricing under the DMEPOS CBP, beneficiary coinsurance payments would be the same as they are now for the CGM receiver and monthly supplies, but the coinsurance payments for the CGM receiver would now be lower and spread out over 60 months rather than paid all at once in one lump sum.

Insulin infusion pumps were included under the DMEPOS CBP in nine CBAs from 2014 through 2016 as part of the product category for external infusion pumps. The fee schedule amounts for insulin infusion pumps and related supplies and accessories are adjusted based on the prices established under this round of the DMEPOS CBP. In accordance with current regulations at 42 CFR 414.210(g)(3), the fee schedule amounts for nonrural areas within the contiguous United States are adjusted based on 110 percent of the unweighted average of the nine SPAs in effect in 2016, which are updated on an annual basis in accordance with inflation update factors specified under 42 CFR 414.210(g)(4). The current nonrural 2025 fee schedule amount for rental of an insulin infusion pump (HCPCS level II code E0784) is $543.08. The current nonrural 2025 fee schedule amount for the weekly supplies for an insulin infusion pump (HCPCS level II code A4224) is $25.19, and the current nonrural 2025 fee schedule amount for one sterile syringe type cartridge supply for an insulin infusion pump (HCPCS level II code A4225) is $3.38. By comparison, the 2025 adjusted fee schedule amounts for these items when furnished to beneficiaries in rural areas within the contiguous United States and areas outside the contiguous United States are much higher. The average of the 2025 fee schedule amounts for

these areas is $565.51 for HCPCS level II code E0784, $28.50 for HCPCS level II code A4224, and $3.54 for HCPCS level II code A4225. The higher fee schedule amounts established for these areas in accordance with regulations at 42 CFR 414.210(g)(2)(ii) and (iii) account for higher costs of suppliers furnishing items in these areas. However, these items are being furnished mostly by mail to beneficiaries across the nation from remote supplier locations. The cost of shipping an item from a remote location to a beneficiary residing in a rural area is typically no higher than the cost of shipping an item from a remote location to a beneficiary residing in a nonrural area. Additional shipping and handling costs may be incurred in some cases for items that are shipped to an area outside the contiguous United States such as Alaska, Hawaii, or Puerto Rico, but there are very few beneficiaries living in these areas compared to areas within the contiguous United States.

For insulin pumps, we solicited comments on our proposal that the bids submitted for rental of insulin infusion pumps included as a lead item in a product category under the DMEPOS CBP for the first time cannot exceed the payment amount that would otherwise apply to the supplies and accessories for the equipment under subpart D of this part for nonrural areas for a one month period plus the total rental fee schedule amounts that would otherwise apply to rental of the insulin pump for 13 months of continuous use under subpart D of this part for nonrural areas divided by 60. The payment amount that would otherwise apply to the supplies and accessories for insulin pumps would be calculated using the nonrural weekly fee schedule amount for supplies paid using HCPCS level II code A4224 multiplied by four plus the nonrural fee schedule amount for nine sterile, syringe type cartridges paid using HCPCS level II code A4225. In 2024, Medicare paid for seven to nine units of A4225 per month on average for beneficiaries using insulin infusion pumps (HCPCS code E0784). We solicited comments on our proposal to use nine units for the one-month supply calculation as this represents the upper range currently being paid for by Medicare on a monthly basis and therefore builds in sufficient payment to ensure this quantity of supplies can continue to be furnished. Using 2025 fee

schedule amounts to demonstrate how the bid limits would be calculated, for a nationwide CBP, the weekly nonrural 2025 fee schedule amount for the supplies for an insulin infusion pump (HCPCS level II code A4224) is $25.19 and the monthly allowance is $100.76 ($25.19 multiplied by 4). The nonrural 2025 fee schedule amount for one sterile syringe type cartridge for an insulin infusion pump (HCPCS level II code A4225) is $3.38 and the monthly allowance is $30.42 ($3.38 multiplied by nine). The total nonrural 2025 rental payments for the insulin infusion pump over 13 months is $5,702.34 and the monthly allowance is $95.04 ($5,702.34 divided by 60 for the number of months over 5 years). The 2025 bid limit for the bundled nationwide monthly rental payment for insulin pumps would therefore be $226.22 ($100.76 + $30.42 + $95.04). Bidding entities competing to be a nationwide contract supplier for these items and other items in the same product category would need to submit bids that are lower than the bid limit ($226.22 in this example) to be considered. Not factoring in reduced pricing under the DMEPOS CBP, for beneficiaries that begin using insulin pumps once the new rules would take effect, coinsurance payments would be approximately the same as they are now for the insulin pumps and monthly supplies and accessories, but the coinsurance payments for the insulin pump would now be lower and spread out over 60 months rather than over 13 months. For beneficiaries who own their insulin infusion pump, coinsurance payments would remain approximately the same unless they elect to obtain a new insulin pump, which would result in new monthly coinsurance payments that include payment for the pump as well as the supplies and accessories for the pump. For beneficiaries who are in the middle of the 13-month capped rental period at the time the pumps are phased into the DMEPOS CBP and the new rules would take effect, their coinsurance payments would increase since they would transition to the new monthly payments with coinsurance payments which would not be reduced by the amounts attributed to the monthly rental payments already made under the capped rental rules. However, the payments made overall should be reduced under the DMEPOS CBP and therefore the net

change in beneficiary coinsurance after factoring in the competitive bidding price reductions should be a reduction in cost sharing across the board.

We solicited comments on our proposal to make corresponding changes to the regulations for determining competitive bidding payment amounts for non-lead items at 42 CFR 414.416(b) to reflect how to use the bid amounts to calculate the monthly payments for the non-lead items. We solicited comments on our proposal that the SPAs for the rental of a non-lead item in a product category including CGMs and insulin infusion pumps would be established in a manner that is consistent with how SPAs are established currently for non-lead items in accordance with § 414.416(b). Currently the SPA for a non-lead item is equal to the SPA for the lead item multiplied by the ratio of the 2015 fee schedule amount for the non-lead item for each area to the 2015 fee schedule amount for the lead item for the same area. Our methodology for calculating SPAs for non-lead items is based on the difference in the unadjusted fee schedule amounts for the lead item compared to the non-lead item. We use the 2015 fee schedule amounts for this purpose as this was the last year the DMEPOS fee schedule amounts were not adjusted based on pricing from the DMEPOS CBP. The fee schedule amounts for insulin pumps were adjusted using pricing from the DMEPOS CBP. Given the possibility that CGMs and insulin pumps would be included in the same product category (with CGMs being the lead item), we proposed to calculate what the unadjusted fee schedule amounts for CGMs would have been in 2015 so we can compare that to the unadjusted fee schedule amounts for insulin pumps from 2015 for the purpose of calculating the non-lead item SPAs for the insulin pumps. We solicited comments on our proposal that the 2015 fee schedule amounts for the monthly rental of a class II CGM would be calculated using the 2025 fee schedule amounts and removing the fee schedule update factors from 2016 through 2025 to convert the 2025 fee schedule amounts to 2015 fee schedule amounts. We also solicited comments on our proposal to then add the 2015 fee schedule amount for the monthly supplies for a class II CGM to the average of the 2015 fee schedule amounts for the purchase of a new class II CGM divided by 60 for the areas included in the CBA. The

conversion of the fee schedule amounts to 2015 fee schedule amounts is necessary because the methodology under § 414.416(b) uses the ratio of unadjusted fee schedule amounts from 2015 (the year before the DMEPOS CBP was implemented) between the non-lead item and the lead item multiplied by the SPA for the lead item to establish the SPA for the non-lead item and because Medicare did not start paying for class II CGMs until after 2015.

We solicited comments on our proposal that the 2015 fee schedule amounts for the monthly rental of an insulin infusion pump would be calculated using the average 2015 fee schedule amounts for the insulin infusion pump multiplied by 10.5 and divided by 60 for the nonrural areas included in the RID CBP, and then adding the average 2015 fee schedule amounts for the sterile syringe type cartridge for the insulin infusion pump multiplied by nine for the nonrural areas included in the RID CBP plus the average 2015 fee schedule amounts for the weekly insulin pump supplies multiplied by 4 for the nonrural areas included in the RID CBP. The average 2015 fee schedule amounts for the insulin infusion pump multiplied by 10.5 equals the total rental payments made over the 13-month capped rental period.

DME items that are class III devices under the Federal Food, Drug, and Cosmetic Act are excluded from the DMEPOS CBP by section 1847(a)(2)(A) of the Act. Federal Food, Drug, and Cosmetic Act classifies medical devices into three classes based on the level of control needed to ensure their safety and effectiveness. Class I devices are considered low risk and are subject to general controls. Class II devices are considered moderate risk and are subject to general controls and special, device-specific controls. Class III devices are considered high risk and are subject to general controls and premarket approval, the most stringent device marketing application required by the FDA. Class III CGMs are excluded from the DMEPOS CBP by section 1847(a)(2)(A) of the Act. In addition, there are some insulin infusion pumps that are approved by the FDA for use in conjunction with a class III CGM. In instances where an insulin infusion pump that has been approved by the FDA for use in conjunction with a class III CGM is being used in conjunction with a class III CGM, we believe the insulin pumps should be excluded from

the DMEPOS CBP as well. We solicited comments on this proposal to exclude insulin pumps used in conjunction with a class III CGM from the DMEPOS CBP under these circumstances.

a. Medicare Part B Payment for Class III CGMs and Insulin Pumps Used in Conjunction with Class III CGMs

Because class III CGMs are excluded from the DMEPOS CBP by statute and we proposed that insulin infusion pumps used in conjunction with class III CGMs would also be excluded from the DMEPOS CBP, we believe it is necessary to use the authority at section 1842(b)(8) of the Act to limit the payment amounts for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs to the level established for class II CGMs and insulin infusion pumps that are used alone or in conjunction with a class II CGM under the CBP.

As discussed previously, class III CGMs are statutorily excluded from the DMEPOS CBP and are less accurate than class II CGMs. We believe that lowering the Medicare payment amounts for class II CGMs and class II insulin infusion pumps under the DMEPOS CBP and maintaining higher payments for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs under the Medicare fee schedule for DME would encourage a shift from more accurate class II CGMs and insulin pumps to less accurate class III CGMs and insulin pumps. To prevent this from happening, we therefore proposed to adjust the fee schedule amounts for class III CGMs and insulin pumps used in conjunction with class III CGM to equal the payment amounts established for class II CGMs and insulin pumps under the DMEPOS CBP.

In order to make proposals to use the authority at section 1842(b)(8) of the Act to adjust the fee schedule payment amounts for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs, the process mandated by section 1842(b)(9) of the Act and its implementing regulations at 42 CFR 405.502(g) and (h) apply. We expect that reductions in the payment amounts for class II CGMs and insulin pumps under the DMEPOS CBP would result in payment amounts for these items that are more than 15 percent below the fee schedule amounts for class III CGMs and insulin pumps used in conjunction with class III CGMs. We proposed

that in situations where the Medicare bundled monthly rental payment amounts for class II CGMs and/or insulin pumps under the DMEPOS CBP are more than 15 percent lower than the Medicare bundled monthly rental fee schedule amounts for class III CGMs and insulin pumps used in conjunction with class III CGMs, that the Medicare bundled monthly rental fee schedule amounts for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs would be adjusted so that they are equal to the bundled monthly rental payment amounts established under the DMEPOS CBP for the class II CGMs and insulin pumps.

b. Medicare Part B Fee Schedule Payments for Class II CGMs and Insulin Pumps

We did not propose to utilize the inherent reasonableness authority at 42 CFR 405.502(g) and (h) to adjust the prices of class II CGMs or insulin infusion pumps paid under Medicare Part B. In accordance with section 1834(a)(1)(F)(i) of the Act, the payment basis for class II CGMs and insulin infusion pumps furnished in a CBA is the payment basis determined under the CBP. In accordance with section 1834(a)(1)(F)(ii) and (iii) of the Act, we solicited comments on our proposal that the fee schedule amounts for class II CGMs or insulin infusion pumps would be adjusted based on information on the payment determined under the CBP for the rental of the equipment using the methodology established in regulations at 42 CFR 414.210(g). For the same reasons discussed previously for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs, in any situation where payment for class II CGMs or insulin infusion pumps not used in conjunction with class III CGMs are paid for in accordance with the fee schedule payment basis at section 1834(a)(1)(B) of the Act in an areas that is not a CBA following the phase in of these items under the DMEPOS CBP, these items would be classified as items requiring frequent and substantial servicing under section 1834(a)(3) of the Act.

3. Provisions of the Regulation

a. Payment for CGMs and Insulin Pumps Furnished by Contract Suppliers Under the DMEPOS CBP and by Grandfathered Suppliers

We solicited comments on our proposal to make payment on a monthly rental basis for CGMs and insulin pumps furnished by contract suppliers under the DMEPOS CBP and by non-contract, grandfathered suppliers in accordance with section 1847(a)(4) of the Act, which allows rental agreements for covered CGMs and insulin pumps entered into before the application of the DMEPOS CBP to be continued once the items are phased in under the program, on a bundled monthly rental basis in accordance with regulations at 42 CFR 414.408(h)(8) and (J)(2)(iii), respectively. Payment would be based on SPAs for the bundled, monthly rental of the items for both the contract suppliers and non-contract grandfathered suppliers. Separate payment for supplies and accessories for the equipment would no longer be made and contract suppliers would retain ownership of the rental equipment.

b. Bids Submitted for Class II CGMs or Insulin Pumps Included as a Lead Item in a Product Category for the First Time

We solicited comments on our proposal to amend the regulations at 42 CFR 414.412 to specify that the bids submitted for rental of CGMs included as a lead item in a product category under the DMEPOS CBP for the first time cannot exceed the payment amount that would otherwise apply to the supplies for the equipment under subpart D plus the average of the purchase fee schedule amounts that would otherwise apply to the CGM (HCPCS level II code E2103) for the areas included in the CBA divided by 60.

We also solicited comments on our proposal to amend the regulations at 42 CFR 414.412 to specify that the bids submitted for rental of insulin infusion pumps included as a lead item in a product category under the DMEPOS CBP for the first time cannot exceed the payment amount that would otherwise apply to the supplies and accessories for the equipment under subpart D of this part for nonrural areas for a one month period plus the total rental fee schedule amounts that would otherwise apply to rental of the insulin pump for 13 months of continuous use under subpart D of this part for nonrural areas divided by 60. The payment amount that would otherwise apply to the supplies and accessories for insulin pumps would be calculated using the

nonrural weekly fee schedule amount for supplies paid using HCPCS level II code A4224 multiplied by 4 plus the nonrural fee schedule amount for nine sterile, syringe type cartridges paid using HCPCS level II code A4225.

c. Separate Payment for Replacement of Supplies and Accessories for Class II CGMs and Insulin Pumps Owned by the Beneficiary at the Time These Items are Phased in Under the DMEPOS CBP for the First Time in a CBA

We solicited comments on our proposal that separate payment can continue to be made under the DMEPOS CBP for replacement of supplies and accessories necessary for the effective use of a CGM or insulin pump owned by the beneficiary at the time these items are phased in under the DMEPOS CBP for the first time in a CBA. The beneficiary would continue to own the CGM or insulin pump and would receive replacement supplies and accessories for the CGM or insulin pump from a contract supplier for the CBA where they reside. This is a temporary transition rule that would phase out once all beneficiary-owned CGMs or insulin pumps are replaced by rented equipment after they are lost, stolen, irreparably damaged, have been in use for the equipment's 5-year reasonable useful lifetime. During this transition period, SPAs for the monthly supplies and accessories for a beneficiary-owned CGM or insulin pump would be established in accordance with the payment rules for non-lead items under proposed regulations at 42 CFR 414.416(b)(4) summarized in section VII.G. As noted previously, we proposed that the beneficiary would have the option to transition from the use of the equipment they own to use of a rented CGM and/or insulin pump from a contract supplier at any time.

d. Calculating SPAs for Class II CGMs, Insulin Pumps, and Supplies and Accessories for Beneficiary-Owned Class II CGMs and Insulin Pumps Furnished as Non-Lead Items in a Remote Item Delivery CBP

We solicited comments on our proposal to amend existing regulations at 42 CFR 414.416(b) by adding paragraph (3) to establish the methodologies for calculating the SPAs for items furnished as non-lead items under product categories in a RID CBP for the monthly rental

of class II CGMs, the monthly rental of insulin infusion pumps, the monthly supplies for a beneficiary-owned class II CGM, and the monthly supplies and accessories for a beneficiary-owned insulin infusion pump in a manner consistent with existing regulations at 42 CFR 414.416 which bases the SPAs for the lead item in a product category and CBA on the bids submitted and the SPAs for each non-lead item in the same product category and CBA based on the 2015 fee schedule amount for the non-lead item divided by the 2015 fee schedule amount for the lead item multiplied by the SPA for the lead item.

We also solicited comments on our proposed methodologies for calculating the 2015 fee schedule amounts for the monthly rental of class II CGMs, the monthly rental of insulin infusion pumps, the monthly supplies for a beneficiary-owned class II CGM, and the monthly supplies and accessories for a beneficiary-owned insulin infusion pump under paragraphs (i) through (iv) of § 414.416(b)(3) as follows:

- The 2015 fee schedule amounts for the monthly bundle that includes a CGM and supplies are calculated using the 2025 fee schedule amounts and removing the fee schedule update factors from 2016 through 2025, and then adding the 2015 fee schedule amount for the supplies to the average of the 2015 fee schedule amounts for the purchase of a new CGM divided by 60 for the areas included in the RID CBP.

- The 2015 fee schedule amount for the monthly supplies for a CGM owned by a beneficiary is calculated using the 2025 fee schedule amount and removing the fee schedule update factors from 2016 through 2025.

- The 2015 fee schedule amounts for the monthly bundle that includes an insulin infusion pump and supplies and accessories are calculated using the average 2015 nonrural fee schedule amounts for the insulin infusion pump multiplied by 10.5 and divided by 60 for the areas included in the RID CBP, and then adding the average 2015 nonrural fee schedule amounts for the sterile syringe type cartridge for the insulin infusion pump multiplied by nine for the areas

included in the RID CBP plus the average 2015 nonrural fee schedule amounts for the weekly insulin pump supplies multiplied by 4 for the areas included in the RID CBP.

- The 2015 fee schedule amounts for the monthly bundle that includes the supplies and accessories for an insulin infusion pump owned by a beneficiary is calculated using the average 2015 nonrural fee schedule amounts for the sterile syringe type cartridge for the insulin infusion pump multiplied by nine for the areas included in the RID CBP plus the average 2015 nonrural fee schedule amounts for the weekly insulin pump supplies multiplied by 4 for the areas included in the RID CBP.

e. Insulin Infusion Pumps Used in Conjunction with Class III CGM

We solicited comments on our proposal that in instances where an insulin infusion pump that has been approved by the FDA for use in conjunction with a class III CGM is being used in conjunction with a class III CGM, both the insulin pump and the class III CGM would be excluded from the DMEPOS CBP.

f. Payment Reclassification of CGMs and Insulin Infusion Pumps

We solicited comments on our proposal to reclassify all CGMs and insulin infusion pumps paid for in accordance with the rules at section 1834(a) of the Act as items requiring frequent and substantial servicing under section 1834(a)(3) of the Act and regulations at 42 CFR 414.222 for the reasons highlighted in section VII.A.

g. Special Payment Limits for Class III CGMs and Insulin Infusion Pumps Used in Conjunction with Class III CGMs.

With regard to class III CGMs excluded from the DMEPOS CBP by section 1847(a)(2)(A) of the Act and insulin infusion pumps used in conjunction with class III CGMs, we solicited comments on our proposal to use the authority at section 1842(b)(8) of the Act to establish special payment limits for these items if the bundled monthly rental amounts for class II CGMs and/or insulin infusion pumps established under the DMEPOS CBP are at least 15 percent below the bundled monthly rental fee schedule amounts for the class III CGMs and related

supplies and insulin infusion pumps and related supplies established in accordance with section 1834(a)(3) of the Act. In accordance with § 405.502(g)(1)(ii), a payment amount can be considered grossly excessive and can be adjusted using the authority under section 1842(b)(8) of the Act and process outlined in section 1842(b)(9) of the Act and regulations at § 405.502(g) if it is determined that an overall payment adjustment of 15 percent or more is necessary to produce a realistic and equitable payment amount. We believe it is realistic to conclude that suppliers of class III CGMs and insulin pumps used in conjunction with class III CGMs would be able to furnish class III CGMs and insulin pumps at the payment amounts established for class II CGMs and insulin pumps under the DMEPOS CBP. We believe the bids obtained for class II CGMs and insulin pumps under the DMEPOS CBP that are determined to be bona fide is valid and reliable data for use in establishing realistic payment amounts for class III CGMs and insulin pumps used in conjunction with class III CGMs. We believe it would not be equitable to pay more for a class III CGM and/or insulin pump than a class II CGM and/or insulin pump because class III CGMs are less accurate than class II CGMs. We believe that a reduction in payment for class II CGMs and/or insulin pumps under the DMEPOS CBP of greater than 15 percent indicates that the fee schedule amounts for these items were grossly excessive. We believe that if the fee schedule amounts for class III CGMs and/or insulin pumps used in conjunction with class III CGMs are more than 15 percent higher than the payment amounts established for class II CGMs and/or insulin pumps under the DMEPOS CBP, that the fee schedule amounts for class III CGMs and/or insulin pumps used in conjunction with class III CGMs are grossly excessive. We believe that similar conclusions can be made regarding supplies and accessories used in conjunction with class III CGMs and insulin pumps used in conjunction with class III CGMs owned by the beneficiary at the time class II CGMs and insulin pumps are phased in under the DMEPOS CBP. We believe it is realistic and equitable to establish the payment amounts for these supplies and accessories based on the payment amounts established under the DMEPOS CBP for supplies and accessories used in conjunction with beneficiary-owned class II CGMs and

insulin pumps. Separate payment for supplies and accessories for beneficiary-owned class III CGMs and insulin pumps used in conjunction with class III CGMs would no longer be made once the 5-year reasonable useful lifetime for the beneficiary-owned equipment has expired. Medicare payment for class II CGMs and insulin pumps would be established under the DMEPOS CBP and therefore the fee schedule amounts for these items would not be adjusted using the authority under section 1842(b)(8) of the Act. We also solicited comments on our proposal that the monthly rental fee schedule payment amounts for class III CGMs would be limited to the monthly rental SPAs established for class II CGMs under the DMEPOS CBP. We proposed that the monthly rental fee schedule payment amounts for insulin pumps used in conjunction with class III CGMs would be limited to the monthly rental SPAs established for insulin pumps under the DMEPOS CBP. We solicited comments on our proposal that the monthly fee schedule payment amounts for supplies used in conjunction with beneficiary-owned class III CGMs would be limited to the monthly SPAs established for supplies used in conjunction with beneficiary-owned class II CGMs under the DMEPOS CBP. We also solicited comments on our proposal that the monthly fee schedule payment amounts for supplies and accessories used in conjunction with beneficiary-owned insulin pumps that are used in conjunction with class III CGMs would be limited to the monthly SPAs established for supplies and accessories used in conjunction with beneficiary-owned insulin pumps under the DMEPOS CBP.

In accordance with section 1842(b)(8)(C)(ii) of the Act, we believe that the payment amounts for class III CGMs, insulin pumps used in conjunction with class III CGMs, and supplies and accessories used in conjunction with beneficiary-owned class III CGMs and insulin pumps used in conjunction with class III CGMs do not reflect changing technology, increased facility with that technology, or reductions in acquisition or production costs. If the fee schedule payment amounts for class II CGMs and insulin pumps are reduced by more than 15 percent under the DMEPOS CBP, then this is an indication that the cost of furnishing these items is

significantly lower than the fee schedule amounts for these items. We believe the same would also be true for class III CGMs and insulin pumps used in conjunction with class III CGMs as we believe the acquisition and production costs of class III CGMs and insulin pumps used in conjunction with class III CGMs are similar to the acquisition and production costs of class II CGMs and insulin pumps that are not used in conjunction with class III CGMs. The equipment is used for the same purpose and includes the same covered features of continuous glucose monitoring and pumping of insulin. In the case of CGMs, manufacturers of class II CGMs have invested in making the equipment more accurate and therefore the acquisition and production costs of class II CGMs may be higher than the acquisition and production costs of class III CGMs. Insulin pumps used in conjunction with class III CGMs perform the same covered function as insulin pumps that are not used in conjunction with class III CGMs. We believe it is therefore realistic and equitable to pay no more for a class III CGM or insulin pump used in conjunction with a class III CGM than the payment amount established under the DMEPOS CBP for a class II CGM or insulin pump.

In accordance with section 1842(b)(9)(A) of the Act, the Secretary shall consult with representatives of suppliers or other individuals who furnish an item or service before making a determination under section 1842(b)(8)(B) of the Act to reduce payment for the item or service by more than 15 percent for a year. The corresponding regulations at 42 CFR 405.502(g)(3) require CMS to publish in the **Federal Register** proposed and final notices announcing a special payment limit before it adopts the limit. Regarding special payment limit adjustments greater than 15 percent of the payment amount, 42 CFR 405.502(h)(3) requires that before making a determination that a payment amount for a category of items or services is not inherently reasonable by reason of its grossly excessive or deficient amount, CMS consult with representatives of the supplier industry likely to be affected by the change in the payment amount. CMS must publish in the **Federal Register** the proposed and final notices of a special payment limit before it adopts the limit. Therefore, as part of this final rule, we solicited

comments from representatives of suppliers or other individuals who furnish class III CGMs, insulin pumps used in conjunction with class III CGMs, and supplies and accessories used in conjunction with beneficiary-owned class III CGMs or beneficiary-owned insulin pumps used in conjunction with class III CGMs on the proposed payment reductions for these items and services.

In accordance with section 1842(b)(9)(B)(iii) of the Act and the corresponding regulations at 42 CFR 405.502(h), when the proposed special payment limit adjustments are greater than 15 percent of the payment amount within a year, CMS must consider in a proposed and final notice the potential impacts of the proposed payment reductions on quality, access, and beneficiary liability, including the likely effects on assignment rates and participation rates. We proposed that the payment amounts for class III CGM suppliers and manufacturers would be reduced, but at the same rate as class II CGM suppliers and manufacturers, avoiding the potential impact of providing a financial incentive to increase access to less accurate class III CGMs and decrease access to more accurate class II CGMs. We solicited comments on the proposed reductions in payment and believe they would level the playing field and avoid providing class III CGM suppliers and manufacturers with an unfair advantage. The quality of CGMs in general would not be impacted and if anything would be preserved since contract suppliers would not have a financial incentive to furnish class III CGMs in place of class II CGMs. Class III CGMs currently make up about 25 percent of total allowed charges for CGMs under Medicare and so any impact resulting from the proposed reductions in payment for class III CGMs would be significantly less than any impact resulting from payment reductions for class II CGMs under the DMEPOS CBP. We therefore believe the proposed payment special payment limits and special payment method for class III CGMs and insulin pumps would have a minimal impact on the CGM and insulin pump industry in general. The impact on access to CGMs in general as a result of the special payment limit and method of payment would also therefore be minimal. Beneficiary cost-sharing for class III CGMs, insulin pumps used in conjunction with class III

CGMs, and supplies and accessories used with beneficiary-owned class III CGMs and insulin pumps would be reduced as a result of the special payment limit and method. Program savings would also be achieved for these items. Assignment rates and participation rates would likely not be affected as a result of the proposed special payment limits and payment method as payment for the cost of furnishing class III CGMs and insulin pumps on assignment-related basis would be based on the payment established under the DMEPOS CBP based on bids submitted by bidding entities for furnishing class II CGMs and insulin pumps on an assignment-related basis for all beneficiaries under the DMEPOS CBP. Under the DMEPOS CBP, contract suppliers of class II CGMs and insulin pumps are required to accept assignment of all claims for furnishing these items by section 1847(b)(5)(C) of the Act. Suppliers of class III CGMs know that if they do not accept assignment of the claims for the class III CGMs or insulin pumps used in conjunction with class III CGMs, their customers could switch to a class II CGM supplier or supplier of an insulin pump that is not used in conjunction with a class III CGM to avoid the financial liability associated with unassigned claims.

h. Advance Billing for Three Months of Rental

Payment for supplies and accessories used with a beneficiary-owned class II or class III CGM or a beneficiary-owned insulin infusion pump is currently made for these items in quantities necessary for a 90-day period. We solicited comments on a proposal to allow contract suppliers to bill for up to 3 months of rental for CGMs and insulin infusion pumps in advance to be consistent with this policy.

i. Summary of Provisions

The following is a summary list of the provisions under this section for which we solicited comments:

Payment Rules for Class II CGMs and Insulin Infusion Pumps that are not used in Conjunction with Class III CGMs and are Furnished under the DMEPOS CBP

- Payment would be on a continuous rental basis with payment for use of the equipment and all necessary supplies and accessories included in monthly rental payments made for up to 3 months in advance. Contract suppliers retain ownership of the rented equipment.
- Payment for replacement of supplies and accessories only for beneficiary-owned equipment at the start of the program in a CBA would continue to be made as separate items under the product category until the beneficiary-owned equipment is

replaced because it is lost, stolen, irreparably damaged, has exceeded the reasonable useful lifetime (as defined at 42 CFR 414.210(f)(1)), or in cases where the beneficiary elects to obtain newer equipment. Beneficiaries who own their equipment and want to replace the equipment with new equipment would have the option to obtain new rented equipment from a contract supplier at any time.

- Rental agreements for equipment in place at the time the new rules are phased in under a CBA may be continued under the existing grandfathering rules for items requiring frequent and substantial servicing. Payment to grandfathered suppliers would be based on the monthly rental payment amounts established under the DMEPOS CBP.
- If the class II CGM is the lead item in the product category the first time the new payment rules are implemented in a CBA, the bid limit would be established based on the monthly fee schedule amount for the replacement supplies plus the average purchase new fee schedule amount for the CGM for the areas included in the CBA divided by 60.
- If the insulin pump is the lead item in the product category the first time the new payment rules are implemented in a CBA, the bid limit would be established based on the average weekly fee schedule amount for the replacement supplies and accessories for the areas included in the CBA multiplied by 4, plus the average fee schedule amount for the syringe type cartridge for the areas included in the CBA multiplied by nine, plus the average of the total rental fee schedule amounts over 13 months for the insulin pump for the areas included in the CBA divided by 60.

Payment Rules for Class III CGMs and Insulin Infusion Pumps used in Conjunction with Class III CGMs (to be effective on the date the new rules for Class II CGMs and Insulin Pumps are Implemented)

- All CGM and insulin pump equipment would be classified as items requiring frequent and substantial servicing for the purposes of implementing the payment rules under section 1834(a) of the Act. Payment would be on a continuous rental basis with payment for use of the equipment and all necessary supplies and accessories included in monthly rental payments made for up to 3 months in advance. Contract suppliers retain ownership of the rented equipment.
- Special payment limits would be established in accordance with regulations at 42 CFR 405.502(g) and sections 1842(b)(8) and (9) of the Act to limit payment for class III CGMs and insulin infusion pumps used in conjunction with class III CGMs as well as supplies and accessories for beneficiary owned class III CGMs and insulin infusion pumps used in conjunction with class III CGMs to the payment amounts established for class II CGMs and insulin infusion pumps as well as supplies and accessories for beneficiary owned class II CGMs and insulin infusion pumps under the DMEPOS CBP.
- Payment for replacement of supplies and accessories only for beneficiary-owned equipment would continue to be made as separate items after the implementation date of the CBP until the beneficiary-owned equipment is replaced because it is lost, stolen, irreparably damaged, is more than 5 years old, or in cases where the beneficiary elects to obtain newer equipment.

We solicited comments on these provisions as well as on the proposed provisions for determining SPAs for non-lead items under a product category including class II CGMs and/or insulin infusion pumps.

Comment: A number of commenters expressed concern over the implications of the proposals on patient access to care and associated outcomes, emphasizing the complications and side effects that occur due to unmanaged diabetes, such as diabetic ketoacidosis, kidney failure, heart disease, neuropathy, amputation, and vision loss. Many commenters referred back to the recommendations established by the American Diabetes Association's 2025 Standards of Care in Diabetes emphasizing the need for access to appropriate technology and medication, including the consistent use of CGMs for people with diabetes who use any form or frequency of insulin, as well as those who do not use insulin but use at least one non-insulin, glucose-lowering medication. Many commenters also stated that there is a documented decrease in health

expenditures and hospitalizations after the integration of CGMs and pumps for insulin therapy. Positive health outcomes are associated with the use of these devices, including lower A1c (HbA1c) levels, increased glycemic control, and reduced time managing the disease.

Response: We agree with the comments and believe beneficiaries should be able to use the latest CGM and/or insulin pump technologies. We proposed to change the current rules to prevent beneficiaries from being locked into a device for five years. As discussed in the proposed rule, the technology for CGMs and insulin infusion pumps is rapidly evolving to be more accurate and to work in tandem, with combination CGM/insulin pump systems that regulate the administration of insulin based on patient need and even in anticipation of a patient's need. It is vital that patients are using equipment with the latest features and technology to ensure that the measuring and displaying of glucose levels is as accurate as possible, so that the best information is available for both patient activated and equipment activated changes in diet and insulin.

Comment: A commenter stated that suppliers are not obligated to carry or provide all brands of CGMs and insulin pumps at this time, and creating the bundled category of CGMs and insulin pumps has the potential to eliminate suppliers who have a strong history of supplying specific types of diabetes technologies. The commenter stated that suppliers would need to revise their approach (for example, acquiring and providing certain diabetes technologies that they have never offered previously and may be unfamiliar with) or limit beneficiary access to a few, specific diabetes technologies such as one type of CGM and/or one type of insulin pump. If CGMs and insulin pumps are bundled, this will present even greater challenges for beneficiary access to their preferred technologies as there will be no obligation or clear mechanism for suppliers to stock and offer the multiple combinations of CGMs and insulin pumps that beneficiaries currently use and to which they have access today.

Response: Under the physician authorization process at 42 CFR 414.420, a contract supplier must furnish the specific brand of CGM and/or insulin pump prescribed by the physician or treating practitioner if the physician or treating practitioner believes the specific brand is

needed to avoid adverse health outcomes. Once folded into the DMEPOS CBP, contract suppliers are required to furnish any brand of class II CGM or insulin pump included under the product category if the beneficiary requests the item from the contract supplier and the physician authorizes use of a specific brand CGM or insulin pump as part of their order. We are confident that manufacturers of CGMs and insulin pumps will work closely with the contract suppliers to make the products available and educate and train contract suppliers to make them familiar with the brands of class II CGMs or insulin pumps they have not carried in the past. This is not unlike any situation today where a supplier starts furnishing a new brand of CGM or insulin pump that has just been introduced onto the market and needs to become familiar with the new product.

Comment: Many commenters do not believe CGMs and insulin pumps can be furnished on a rental basis, stating that suppliers lack the expertise to furnish CGMs and insulin pumps on a rental basis, including repairing and servicing equipment, managing returns and replacements of equipment, including recalls, refurbishing equipment for reuse, and providing technical support, software updates, and device training that manufacturers are currently providing for this equipment. Commenters stated that certain CGMs and insulin pumps are single patient use devices and cannot be reused. Many commenters do not believe suppliers can absorb the upfront costs of purchasing equipment that may quickly be replaced and will not be able to recoup their investments in the equipment from payments over 5 years.

Response: We note that all DME items are required to be able to withstand repeated use in accordance with regulations at 42 CFR 414.202, including CGMs, and can be rented to another patient once one patient is finished renting the item. The DMEPOS supplier standards at 42 CFR 424.57(c) require suppliers to answer questions and respond to complaints a beneficiary has about any DMEPOS item that is sold or rented. The supplier may not pass this responsibility off to the manufacturer of the equipment. Suppliers may subcontract with manufacturers to perform repairs or maintenance and servicing of rented CGMs and insulin pumps. Insulin infusion pumps are currently paid for on a rental basis for a period of continuous use of 13

months, during which time suppliers must maintain and repair the equipment as needed and provide all services necessary for the equipment to function properly. While we acknowledge not all suppliers have experiencing repairing and servicing equipment, managing returns and replacements of equipment, including recalls, refurbishing equipment for reuse, and providing technical support, software updates, and device training that manufacturers are currently providing for this equipment, we believe current evidence demonstrates the need for suppliers to provide frequent and substantial servicing in order to reduce complications with the use of such technology. We believe that the assistance and services currently provided by manufacturers to owners of CGMs who are Medicare beneficiaries can be redirected to the suppliers or owners of the rented CGMs. Regarding the ability of suppliers to absorb the upfront cost of rented CGM receivers, we believe this is an expense that can easily be borne by suppliers that would also be receiving payment for the supplies for these items. In 2024, Medicare allowed charges for CGMs receivers and supplies totaled $1,989 million, or almost $2 billion, and 96 percent of these payments ($1,905 million) were for the supplies for the CGM. We believe suppliers will be able to absorb the upfront cost of purchasing CGMs they rent from the money they receive for the supplies for the rented CGMs. Suppliers will consider all of their costs, including the upfront cost of purchasing and servicing CGMs they will rent, into the bid amounts they submit for these items under the DMEPOS CBP. Based on our experience with blood glucose monitors and the widespread rebates offered by manufacturers, which often brought the cost of the glucose monitor down to $0, we are confident that manufacturers will help suppliers bear the cost of the upfront purchase of stand-alone CGMs that suppliers will now be furnishing on a rental basis to beneficiaries under Medicare Part B. CGMs are similar to blood glucose monitors in that most of the money made is for the ongoing replacement of the supplies for the monitor. Manufacturers of blood glucose monitors were very willing to significantly reduce the cost of purchasing blood glucose monitors to reap profits from the ongoing supplies for their brand of blood glucose monitors. We believe manufacturers of CGMs, some of which are also manufacturers of blood

glucose monitors, will have a similar incentive to reduce the cost of their brand of CGM receiver, thereby reducing the cost for the supplier.

Comment: Some commenters stated that CMS does not have the authority to change the payment methodology for CGMs and insulin pumps because CMS does not have the authority to classify the items as items requiring frequent and substantial servicing.

Response: We do not agree. Section 1834 of the Act directs CMS to make payment determinations for DME items and services, which includes a determination regarding which of the paragraphs (2) through (7) of subsection (a) of section 1834 of the Act the items and services are classified under, as well as how the fee schedule amounts for the items and services are established, so that they are in compliance with the exclusive payment rules under sections 1834(a) and 1847(a) and (b) of the Act.

Comment: A commenter agreed with the change in payment methodology for class II CGMs, but believed that the change in payment methodology should be implemented before the items are phased in under the DMEPOS CBP.

Response: We do not agree. We continue to believe that payment on a continuous monthly rental basis for these items should be phased in at the same time that class II CGMs and insulin pumps are phased in under the DMEPOS CBP to give suppliers time to prepare for the transition to the new monthly rental business model. Given the fact that class II CGMs and insulin pumps are currently the highest volume category of items and services subject to the mandate for competitive bidding under section 1847(a) of the Act, and given the emphasis under section 1847(a)(1)(B)(ii) of the Act to prioritiz the highest volume items and service first under the DMEPOS CBP, we believe class II CGMs and insulin pumps are the highest priority category of items and services for phase in next under the DMEPOS CBP. As such, both suppliers and manufacturers should begin preparing for the phase in of class II CGMs and insulin pumps under the DMEPOS CBP and the concurrent classification of CGMs and insulin pumps paid for on a fee schedule basis as items requiring frequent and substantial servicing. We will

announce the effective date of this payment classification through program instructions in accordance with regulations at 42 CFR 414.210(b)(2).

Comment: A commenter requested that the monthly payment for the equipment be based on a 3-year lifetime rather than a 5-year lifetime to account for the cost of replacing equipment more often when beneficiaries elect to upgrade their rented equipment. Another commenter stated that CMS did not provide a rationale for why the equipment costs should be amortized over 5 years when calculating the monthly equipment rental payment and that the payment for the equipment acquisition costs should not be spread over 5 years so that the supplier can be fully paid for the equipment if a beneficiary decides to upgrade to newer technology equipment before the 5 year period is over. Some commenters suggested as an alternative to the proposed rule that CMS lower the reasonable useful lifetime for CGMs and insulin pumps from 5 years to 3 years so that beneficiaries could obtain new technology items every 3 years instead of every 5 years.

Response: We do not agree with these comments. The Medicare payment for DME is based on payment for new items expected to last for 5 years. Pursuant to 42 CFR 414.210(f), the reasonable useful lifetime of DME or prosthetic and orthotic devices is determined through program instructions. In the absence of program instructions, carriers may determine the reasonable useful lifetime of equipment but in no case can it be less than 5 years. A reasonable useful lifetime of 3 years has not been established for any DME item. The equipment lifetime is 5 years and so the equipment acquisition costs can be recouped over 5 years by renting the equipment to multiple patients. If the reasonable useful lifetime of the equipment was changed from 5 years to 3 years, a corresponding reduction in the fee schedule amounts for the equipment of 40 percent would be necessary to make the change budget neutral and would defeat the purpose of the commenters' suggestion. In addition, manufacturers often provide trade-in promotions to reduce the cost of upgrading equipment to newer products. CMS may determine the reasonable useful lifetime of DME or prosthetic or orthotic devices through program

instructions. In the absence of program instructions, the reasonable useful lifetime must not be less than 5 years. If interested parties believe a reasonable, useful lifetime of 5 years is not appropriate for CGMs and/or insulin pumps, we welcome additional information supporting consideration of an alternative to the 5-year useful lifetime for such equipment. Adjusting the reasonable useful lifetime of an item solely to facilitate beneficiary access to newer technology is inconsistent with the reasonable useful lifetime requirement for capped rental DME established under section 1834(a)(7)(C)(iii) of the Act, which provides that the Secretary may establish an alternative reasonable useful lifetime for an item if, based on prior payment experience for such item, the Secretary determines that a five-year reasonable useful lifetime is not appropriate for that particular item.

As discussed in the proposed rule, technology for CGMs and insulin pump equipment is rapidly evolving and becoming increasingly complex (90 FR 29263). These devices often require regular software updates to ensure proper functionality and protection against hacking or other cybersecurity threats. In addition, beneficiaries may require more extensive technical support from their suppliers to address hardware and software issues. Taken together, these characteristics indicate that such devices are items requiring frequent and substantial servicing and, therefore, should be paid in accordance with 42 CFR 414.222.

Comment: Some commenters did not agree that the monthly cost of insulin pump supplies should be calculated by multiplying the currently weekly (7-day) allowance for the supplies (HCPCS level II code A4224) by 4 since there are often more than 28 days in a month.

Response: We do not agree. Although the current allowance for code A4224 is for a one-week supply and there are often more than 28 days in a month, not all beneficiaries will use the supplies for a full 4 weeks or a full 30, 31, or even 28 days. The monthly payment should cover the average cost of the supplies and not the maximum cost (the cost in a scenario that does not exist where all beneficiaries use the supplies for the full month each month). Based on Medicare

claims data for 2024, the average number of paid units per month per beneficiary for HCPCS level II code A4224 was 3.49 (the average usage is three and a half weeks or approximately 24 days). Multiplying the fee schedule amount for HCPCS level II code A4224 by 4 for payment for supplies for 28 days more than covers the average monthly Medicare payment for these supplies as currently billed.

Comment: Some commenters did not agree that the monthly cost of insulin pump syringes (HCPCS level II code A4225) should be calculated by multiplying the fee schedule amount for level II code A4225 by nine and believe the monthly usage is 10 or more.

Response: We do not agree. Based on Medicare claims data for 2024, the average number of paid units per month per beneficiary for HCPCS level II code A4225 was 8.63. Multiplying the fee schedule amount for HCPCS level II code A4225 by nine more than covers the average monthly Medicare payment for these supplies as currently billed.

Comment: Many commenters did not agree that the inherent reasonableness authority and process for adjusting grossly excessive fee schedule amounts under section 1842(b)(8) and (9) of the Act and regulations at 42 CFR 405.502(g) and (h) should be used to limit the monthly rental fee schedule amounts for class III CGMs and insulin pumps used in conjunction with class III CGMs to the monthly rental payment amounts established for class II CGMs and insulin pumps not used in conjunction with class III CGMs under the DMEPOS CBP. Some commenters pointed out that class III CGMs pose a higher risk to patients than class II CGMs.

Response: We do not agree with commenters that the inherent reasonableness authority should not be used to keep payments for class III CGMs and insulin pumps used in conjunction with class III CGMs in line with payments for class II CGMs and other insulin pumps. We believe that the equipment is very comparable and that the cost of the class III CGMs and insulin pumps used in conjunction with class III CGMs are no higher than or less than the cost of comparable class II CGMs and insulin pumps. We agree that certain class III CGMs cannot be used to make diabetes treatment decisions without verification by blood glucose monitors and

therefore pose a higher risk to patients than other CGMs because they are less accurate. As a result, we do not believe it would be inherently reasonable for Medicare payment amounts for less accurate and less expensive CGMs to be higher than the Medicare payment amounts for other CGMs that are more accurate. We are therefore finalizing the proposed special payment limits for class III CGMs and insulin pumps used in conjunction with class III CGMs.

Regulations at 42 CFR 405.502(h)(3)(ii) require that the final notice of a special payment limit must include an explanation of the factors and data considered in establishing the special payment limit and include the economic justification for any uniform fee or payment limit established. As explained in the paragraph previously, class III CGMs and insulin pumps used in conjunction with class III CGMs are very comparable to class II CGMs and other insulin pumps, and in some cases, class III CGMs, unlike class II CGMs, cannot be used to make diabetes treatment decisions without verification of the results by a blood glucose monitor. Based on these factors, we conclude that it would not be inherently reasonable to pay more for a class III CGM or insulin pump used in conjunction with a class III CGM than a class II CGM or insulin pump that is not used in conjunction with a class III CGM. In cases where the fee schedule amounts for class III CGMs and insulin pumps used in conjunction with class III CGMs are at least 15 percent higher than the Medicare payment amounts established for class II CGMs and insulin pumps under the DMEPOS CBP in the same area(s), the fee schedule amounts for class III CGMs and insulin pumps used in conjunction with class III CGMs are considered grossly excessive and are adjusted so as not to exceed the payment amounts established for class II CGMs and insulin pumps under the DMEPOS CBP for the same area(s). CGMs and insulin pumps are mainly furnished on a mail order basis from remote supplier locations. If one uniform, national payment amount is established for class II CGMs and insulin pumps under the DMEPOS CBP, the economic justification for establishing a uniform special payment limit for class III CGMs and insulin pumps used in conjunction with class III CGMs equal to the uniform, national payment amount established for class II CGMs and insulin pumps under the DMEPOS

CBP is that the cost of furnishing the items does not vary based on where the item is shipped and it is therefore reasonable to have one national uniform rate for the items.

Comment: Some commenters believe that since class III DME items are excluded from the DMEPOS CBP that pricing from the DMEPOS CBP cannot be used to establish the payment amounts for items excluded from the DMEPOS CBP.

Response: We do not agree. The Medicare payment rules for CGMs and insulin pumps are located at section 1834(a) of the Act, which is the exclusive provision for payment for these DME items under Part B and under Part A to a home health agency. Section 1834(a)(10)(B) of the Act authorizes use of the inherent reasonableness authority to make adjustments in the payment for DME items under section 1834(a) of the Act if the payment amount is determined to be grossly excessive or deficient and is therefore, not inherently reasonable. Regulations implementing this provision at 42 CFR 405.502(g) and (h) specify factors that result in grossly deficient or excessive payment amounts that include, but are not limited to, whether the payment amounts for a category of items or services are grossly higher or lower than the payments made for the same category of items or services by other purchasers in the same locality. As explained previously, we believe that class III CGMs and insulin pumps used in conjunction with class III CGMs are comparable to class II CGMs and insulin pumps used in conjunction with class II CGMS. As explained previously, we believe that class III CGMs and insulin pumps used in conjunction with class III CGMs are comparable to class II CGMs and insulin pumps used in conjunction with class II CGMs. The cost of the class III CGMs and insulin pumps used in conjunction with class III CGMs are no higher than or less than the cost of comparable class II CGMs and insulin pumps. In some cases, class III CGMs, unlike class II CGMs, cannot be used to make diabetes treatment decisions without verification of the results by a blood glucose monitor. It would not be inherently reasonable to pay more for a class III CGM or insulin pump used in conjunction with a class III CGM than a class II CGM or insulin pump that is not used in conjunction with a class III CGM. .

Comment: Some commenters believe the process outlined in the statute and regulations for establishing special payment amounts using the inherent reasonableness authority has not been followed and others believe the requirements for use of valid and reliable data in determining an appropriate payment amount for class III CGMs and insulin pumps used in conjunction with class III CGMs have not been met.

Response: We do not agree with the comments. We are following the process outlined in the statute and regulations for establishing special payment amounts using the inherent reasonableness process. We are consulting with representatives of suppliers or other individuals who furnish class III CGMs and insulin pumps used in conjunction with class III CGMs via the proposed rule and the comments that we received on the proposed rule from representatives of suppliers or other individuals who furnish class III CGMs and insulin pumps used in conjunction with class III CGMs. We published notice of the proposed determination in the Federal Register on July 2, 2025 (90 FR 29266), specifying the proposed special method to be used in determining the payment amount for class III CGMs and insulin pumps used in conjunction with class III CGMs in accordance with regulations at 42 CFR 405.502(g)(1)(v), explaining the factors and data we took into account in determining the payment amount, and explaining the potential impacts of the determination on quality, access, and beneficiary liability, including the likely effects on assignment rates and participation rates. We clarified that in accordance with regulations at 42 CFR 405.502(g)(1)(ii) the fee schedule amounts for class III CGMs and insulin infusion pumps would not be considered grossly excessive and would not be adjusted if it is determined that an overall payment adjustment of less than 15 percent is necessary to produce a realistic and equitable payment amount. This was all discussed in the July 2, 2025, edition of the Federal Register (90 FR 29267), which went on display on June 30, 2025. We allowed 60 days for public comment on the proposed determination. The factors and data we took into consideration in making the final determination are explained in the response to public comments (and also summarized later in the section), which also explains why we believe the

factors and data considered are valid and reliable. Regarding the specific requirements for use of valid and reliable data at §405.502(g)(4), the criteria listed under (i) through (xi) are applicable when conducting a pricing survey, which was not done in this case. As explained in response to comments received on the proposed special payment limits noted previously, our determination is based on other factors other than prices obtained from a pricing survey; therefore, the criteria listed under §405.502(g)(4) are not applicable. We are now publishing this document in the Federal Register with notice of the final determination.

The following is an explanation of the factors and data we considered in making the inherent reasonableness determinations, including the economic justification for a uniform fee/payment limit:

As explained in the response to comments noted previously, class III CGMs and insulin pumps used in conjunction with class III CGMs are very comparable to class II CGMs and other insulin pumps, and in some cases, class III CGMs, unlike class II CGMs, cannot be used to make diabetes treatment decisions without verification of the results by a blood glucose monitor. Based on these factors, we conclude that it would not be inherently reasonable to pay more for a class III CGM or insulin pump used in conjunction with a class III CGM than a class II CGM or insulin pump that is not used in conjunction with a class III CGM. In cases where the fee schedule amounts for class III CGMs and insulin pumps used in conjunction with class III CGMs are at least 15 percent higher than the Medicare payment amounts established for class II CGMs and insulin pumps under the DMEPOS CBP in the same area(s), the fee schedule amounts for class III CGMs and insulin pumps used in conjunction with class III CGMs are considered grossly excessive and are adjusted so as not to exceed the payment amounts established for class II CGMs and insulin pumps under the DMEPOS CBP for the same area(s). CGMs and insulin pumps are mainly furnished on a mail order basis from remote supplier locations. If one uniform, national payment amount is established for class II CGMs and insulin pumps under the DMEPOS CBP, the economic justification for establishing a uniform special payment limit for

class III CGMs and insulin pumps used in conjunction with class III CGMs equal to the uniform, national payment amount established for class II CGMs and insulin pumps under the DMEPOS CBP is that the cost of furnishing the items does not vary based on where the item is shipped and it is therefore reasonable to have one national uniform rate for the item We also note that the OIG recently issued a report titled "Medicare Payments for Continuous Glucose Monitors and Supplies Exceeded Supplier Costs and Retail Market Prices, Indicating Medicare Can Save At Least Tens of Millions of Dollars in One Year" (OEI-04-23-00430) showing that the average supplier acquisition cost for supplies for a class III CGM are lower than the average supplier acquisition cost for supplies for a class II CGM, further supporting the need to ensure that Medicare payment amounts for class III CGMs and CGM supplies do not exceed the amounts paid for class II CGMs and CGM supplies.

After consideration of the public comments received, we are finalizing the proposal with one technical change in the regulation text. In the proposed rule, the proposed regulation text under 42 CFR 414.416(b)(3)(iv) incorrectly used the acronym "CBR" for competitive bidding program instead of "CBP". We are finalizing that portion of the regulation text to instead say "CBP" under 42 CFR 414.416(b)(3)(iii). We are finalizing the rest of the proposal without changes including the following:

- Class II CGMs and insulin pumps phased in under the DMEPOS CBP will be paid for on a monthly rental basis in accordance with § 414.408(h)(8) as DME items requiring frequent and substantial servicing. Noncontract suppliers with grandfathered rental agreements in place at the time the new rules are phased in under a CBA may be continued under the existing grandfathering rules for items requiring frequent and substantial servicing, and will be paid based on the monthly rental amounts established under the DMEPOS CBP. Suppliers may bill for up to three months of rental in advance.● Payment for replacement supplies and accessories for beneficiary-owned class II CGMs and insulin infusion pumps will be paid for under the

DMEPOS CBP in accordance with the special temporary transition rules at § 414.408(m) until the beneficiary-owned equipment is replaced.

- All CGMs and insulin pumps paid for in accordance with section 1834(a) of the Act will be classified as items requiring frequent and substantial servicing under section 1834(a)(3) of the Act beginning on the date class II CGMs and insulin pumps are first phased in under the DMEPOS CBP, which we expect will occur in the near future.

- Payment for class III CGMs and insulin pumps used in conjunction with class III CGMs will be limited to the amounts established for class II CGMs and insulin pumps under the DMEPOS CBP if these amounts are at least 15 percent lower than the fee schedule amounts for class III CGMs and insulin pumps used in conjunction with class III CGMs.
- Suppliers may bill for up to three months of rental in advance for all CGMs and insulin pumps regardless of whether payment is made under a DMEPOS CBP or under the fee schedule.

- Payment for replacement supplies and accessories for beneficiary-owned class III CGMs and insulin pumps used in conjunction with class III CGMs will be paid for under the fee schedule in the same amounts established for these items under the DMEPOS CBP until the equipment is replaced or the beneficiary elects to obtain new equipment from a contract supplier under the DMEPOS CBP.

H. Revising the Submission of Financial Document Requirements for the DMEPOS CBP

1. Background

Section 1847(b)(2) of the Social Security Act (Act) outlines the conditions for awarding a DMEPOS CBP supplier contract. Section 1847(b)(2)(A)(ii) of the Act specifies that CMS may not award a contract to any entity under the competition conducted in a competitive acquisition area unless the Secretary finds that the entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers.

Section 1847(a)(1)(F) of the Act applies to supplier feedback on missing financial documentation. Section 1847(a)(1)(F)(iv) of the Act defines a covered document as "a financial, tax, or other document required to be submitted by a bidder as part of an original bid submission under a competitive acquisition program in order to meet required financial standards. Such term does not include other documents, such as the bid itself or accreditation documentation." If a covered document is submitted to CMS by the covered document review date (CDRD) and one or more covered documents is missing, per section 1847(a)(1)(F)(i)(I) of the Act, the Secretary is required to provide notice no later than 45 days (in the first round of competition acquisition program as described in subparagraph (B)(i)(I)) or 90 days (in subsequent rounds of such programs) after the CDRD. Per section 1847(a)(1)(F)(ii)(I) and (II) of the Act, the CDRD is the date that is the later of 30 days before the final date specified by the Secretary for submission of bids under the program or the date that is 30 days after the first date specified by the Secretary for submission of bids under the program.

Section 1847(a)(1)(F)(i)(II) of the Act specifies that the Secretary may not reject the bid submission on the basis that any covered document is missing or has not been submitted on a timely basis, if all such missing documents identified in the notice provided to the bidding entity is submitted to the Secretary no later than 10 business days after the date of such notice. Per the limitations of this process in section 1847(a)(1)(F)(iii)(I)-(IV) of the Act, it applies only to the timely submission of covered documents, does not apply to any determination as to the accuracy or completeness of covered documents submitted or whether the documents meet applicable requirements, shall not prevent the Secretary from rejecting a bid based on any basis not described in clause (i)(II) of section 1847(a)(1)(F) of the Act, and shall not be construed as permitting a bidding entity to change bidding amounts or to make other changes in a bid submission.

In the 2006 proposed rule (71 FR 25675), CMS proposed that, as part of the bid selection process, the Request for Bids (RFB) will identify the specific information CMS requires to

evaluate bidding entities, which may include: a bidding entity's bank reference that reports general financial condition, credit history, insurance documentation, business capacity and line of credit to successfully fulfill the contract, net worth, and solvency.

In the 2007 final rule (72 FR 18037), CMS agreed with comments that the proposed financial documentation would be too burdensome, particularly for small suppliers. Additionally, the final rule (72 FR 18037) stated that in order to obtain a sufficient amount of information about each bidding entity, while minimizing the burden on both bidding entities and the bid evaluation process, CMS would require, for the initial round of competition (what is referred to as the Original Round 1), bidding entities to submit certain schedules from their tax returns, a copy of the 10K filing report from the immediate 3 years immediately prior to the date on which the bid is submitted (if the supplier is publicly traded), certain specified financial statement reports such as cash flow statements, and a copy of its current credit report, which must have been completed within 90 days prior to the date in which the supplier submits its bid and must have been prepared by one of the following: Experian, Equifax, or TransUnion. The RFB has required a numerical credit score and/or rating being included with the credit report.

The covered documents described in the 2007 final rule were also outlined in the Original Round 1 RFB in accordance with 42 CFR 414.414(d), which states that each bidding entity must submit along with its bid[83] the applicable covered documents specified in the RFB. For all subsequent rounds after the Original Round 1 (Round 1 Rebid through Round 2021), the covered documents were specified in the RFB for each applicable round, which included the tax return, income statement, balance sheet, statement of cash flows, and a credit report with a numerical credit score and/or rating.

On January 16, 2009 we published in the **Federal Register** an interim final rule titled "Medicare Program; Changes to the Competitive Acquisition of Certain Durable Medical

[83] Bid means an offer to furnish an item or items for a particular price and time period that includes, where appropriate, any services that are directly related to the furnishing of the item or items.

Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) by Certain Provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)" (hereafter referred to as the "2009 interim final rule") (74 FR 2876) that codified the aforementioned process for reviewing covered documents in § 414.414(d)(2).

Additionally, the 2006 proposed rule (71 FR 25675) and the 2007 final rule (72 FR 18037) stated that applying financial standards would assist CMS in assessing the expected quality of bidding entities, estimating the total potential capacity of winning contract suppliers, and ensuring that winning contract suppliers are able to continue to serve market demand for the duration of their contracts. We also stated that we would generally require that bidding entities submit the same types of information for subsequent competitions, but we might choose to add or delete specific document requests as we gather experience on what financial information most accurately predicts whether a suppler is financially stable enough to participate in the Medicare DMEPOS CBP (72 FR 18037).

2. Current Issues

CMS solicited comments on a proposal to reduce the number of covered documents that bidding entities are required to submit during the bid window and modify how CMS will evaluate and determine the financial standards for each bidding entity, while still ensuring that a bidder offered a contract is financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract performance period. We believe a bidding entity's credit score is an up-to-date, reliable, and sufficient measure of the entity's ability to serve market demand for the duration of the contract performance period because data from Round 2021 shows that only 1.7 percent of bidding entities' Tax Identification Numbers (TINs) had a lower credit score, and 21.1 percent of those bidding entities' TINs no longer had an active location (otherwise known as a Provider Transaction Access Number (PTAN)) as of December 28, 2023 – the specifics for how these percentages were calculated are described later in this section. This proposal would also align with CMS's focus on continuous process improvement and increase

operational and policy efficiency and effectiveness for all aspects of the DMEPOS CBP, while ensuring the integrity of the program is not compromised.

Specifically, CMS solicited comments on a proposal to reduce the burden of submitting financial documentation from bidding entities by no longer requiring the submission of a tax return extract, income statement, balance sheet, and statement of cash flows. However, CMS would still require bidding entities to submit a credit report with a numerical credit score or rating from one of the approved credit reporting agencies during the bid window. This proposal will significantly reduce the burden on bidding entities as they will only be required to submit a credit report with a numerical credit score or rating.

To further clarify, CMS solicited comments on a proposal to require a bidding entity submit a business credit report with a numerical credit score or rating. However, there may be instances where the bidding entity does not have a business credit report with a numerical credit score or rating if the entity has not been in operation long enough to generate a numerical score or rating. Bidding entities that are unable to generate a credit report with a numerical credit score or rating would be required to submit a business credit report showing no data or insufficient information to generate a credit score, in addition to a personal credit report with a numerical credit score or rating from the supplier's Authorized Official or Delegated Official listed in CMS' PECOS. If the individual's name on the credit report is not an Authorized Official or Delegated Official listed in PECOS, CMS will deem the personal credit report with a numerical credit score or rating unacceptable, and the supplier will not be eligible for a DMEPOS CBP supplier contract.

Commonly owned and/or commonly controlled bidding entities are prohibited from competing against themselves when submitting bids in the same competition. Therefore, when registration opens, commonly owned and/or commonly controlled bidding entities must register one time with a primary Provider Transaction Access Number (PTAN) which designates the primary location in the bidding system and identifies the entity responsible party for all

contractual requirements (that is, the bidding entity). When the bid window opens, the bidding entity must submit one bid that includes all commonly owned and/or commonly controlled locations that would furnish the lead item and all non-lead items in the same competition. The legal business name (LBN) for the primary location will auto-populate in the bidding system on the Business Organization section of Form A. This LBN must be the same LBN on your bid surety bond(s). If awarded a contract, CMS will contract with the legal business entity identified by the LBN for the primary location.

Given the longstanding policy as specified in the Request for Bid Instructions, commonly owned and/or commonly controlled supplier organizations that submit separate bids for the same competition will have their bids for the competition disqualified.

Similarly, as specified in the Request for Bid Instructions, the bidding entity must attest in the bidding system that it is submitting one bid that includes all commonly owned and/or commonly controlled locations, and that it will furnish the lead item and all non-lead items in the same competition.

The bidding entity must upload a copy of its business' credit report showing the approved crediting agency, the numerical credit score or rating, the entity’s name, and the date that the credit report was prepared not earlier than 90 calendar days prior to the opening of the bid window in a form and manner specified by CMS. If the numerical credit score or rating is generated separately from the credit report, the bidding entity’s name and the date it was prepared must be shown on both the credit report and the numerical credit score or rating.

Bidding entities that are unable to generate either a credit report with a numerical credit score or rating would be required to submit a business credit report showing no data or insufficient information to generate a credit score or rating, and would be further required to submit a personal credit report with a numerical credit score or rating from the supplier’s Authorized Official or Delegated Official listed in CMS’ PECOS.

This proposal would also reduce the resources needed to review the submissions of covered documents and will streamline the evaluation of financial standards, while ensuring that the entities that are awarded a contract are financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract performance period. In addition, bidding entities may have improved opportunity to receive a contract offer because they will no longer be disqualified due to errors in their submitted financial statements and tax return extracts, which would disqualify a bidding entity in previous rounds.

CMS analyzed all credit reports with a numerical credit score or rating from bidding entities that submitted a complete bid[84] in the most recent round of the DMEPOS CBP (Round 2021), as well as Medicare supplier enrollment data, to evaluate if a bidding entity's credit report with a numerical credit score or rating is sufficient in determining the financial stability of a bidding entity and if they can fulfill its contractual obligations for the duration of the contract performance period. Specifically, CMS first determined which bidding entities submitted a complete bid for all product categories competed in Round 2021 (the analysis was not limited to the bidding entities that submitted a complete bid for the OTS Back Brace and OTS Knee Brace product categories that were included in Round 2021) to determine how many bidding entities (identified by TIN) were included on the submission of a complete bid. CMS identified 1,153 bidding entities' TINs and first determined how many of them were still in business as of December 28, 2023, by utilizing data from PECOS.

CMS found that 88.2 percent (1,017 of 1,153) of bidding entities' TINs still had at least one PTAN as of December 28, 2023. Because the Round 2021 bid window was open from July 16, 2019, through September 18, 2019, this means that 88.2 percent of the 1,153 Round 2021 bidding entities had at least one PTAN that was still active/enrolled as a Medicare-enrolled supplier more than 4 years later, supporting the fact that most DMEPOS CBP suppliers are able

[84] A complete bid is defined as a supplier submitting an approved Form A and a certified Form B in the DMEPOS Bidding System, as well as uploading at least one bid surety bond and at least one of the required financial documents in the DMEPOS CBP's secure portal, by the close of the window.

to stay in business for the duration of a DMEPOS CBP supplier contract performance period which cannot exceed 3 years. CMS would like to note that this timeframe was during the COVID-19 pandemic indicating that companies that submit a bid to participate in the DMEPOS CBP appear to typically be financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract performance period as most were able to stay in business during/after the pandemic.

Additionally, CMS analyzed the numerical credit score and/or rating on the credit report for each bidding entity's TIN to determine where the majority of bidding entities fell within CMS' 5-tier credit scoring system. Table FF-36 outlines the 5-tier credit scoring system, and table FF-37 provides a description of each business credit report, which were both included in the Round 2021 Financial Scoring Methodology Fact Sheet. Table FF-36 (Credit Report Scoring List) contains a list of credit reports and credit scores or ratings, as well as the associated tiers and scoring. All bidding entities were required to submit a credit report with a numerical credit score and/or rating on the Credit Report Scoring List and depending on the bidding entity's credit score or rating, the bidding entity fell within a specific tier and received a correlating score of either 4, 8, 12, 16, or 20 points, where a score of 4 is the worst and 20 is the best. Historically, a bidding entity could receive a maximum score of 20 points from its credit report with a numerical credit score or rating and the remaining 80 points (equating to 100 total points) from its tax return extract, income statement, balance sheet, and statement of cash flows, which will no longer be applicable in future rounds of the DMEPOS CBP per this proposal. Specifically, the remaining 80 points were determined by computing each standard accounting ratio for each bidding entity and arraying the bidding entities from the best to worst ratio. Bidding entities in the bottom 10 percent of the array for a specific ratio received a score of 1 (worst) and suppliers in the top 10 percent of the array for a specific ratio received a score of 7.6 or 9.6 (best). The remaining bidding entities' (that is, those falling in between the top and bottom 10 percent) scores were prorated between 1 and 7.6/9.6. Of the 10 standard accounting ratios, 8 have a

maximum score of 7.6, while two have a maximum score of 9.6. This information was contained in the Round 2021 Financial Scoring Methodology Fact Sheet.

Table FF-36 includes a detailed description of each business credit report to help suppliers understand the difference between the business credit reports.

TABLE FF-36: CREDIT REPORT SCORING LIST

Credit Report Name	Tiers and Scoring				
	20	**16**	**12**	**8**	**4**
Business Credit Reports					
Equifax - Business Payment Index	100-90	89-80	79-60	59-40	39-1
Equifax - Business Credit Risk Score	992-697	696-649	648-575	574-492	491-101
Equifax - Business Delinquency Score	662-477	476-446	445-400	399-347	346-101
Equifax - Business Failure Risk Score	1610-1488	1487-1366	1365-1244	1243-1122	1121-1000
Experian - Intelliscore Credit Ranking Score/Business Credit Score	100-76	75-51	50-26	25-11	10-1
Experian - Financial Stability Risk Class	1	2	3	4	5
Dun & Bradstreet - Delinquency Predictor Risk Class	1	2	3	4	5
Dun & Bradstreet - Commercial Credit Score	670-580	579-530	529-481	480-453	452-101
Dun & Bradstreet - Supplier Evaluation Risk Rating	1-2	3-4	5-6	7-8	9
Dun & Bradstreet – Paydex	100-80	79-62	61-46	45-32	31-1
Dun & Bradstreet - Financial Stress Class	1	2	3	4	5
Standard & Poor's	AAA	A	BBB	BB	CC
	AA			B	C
				CCC	D
Personal Credit Reports					
Experian - Plus Score	830-721	720-681	680-630	629-480	479-330
Equifax – Score	850-760	759-725	724-660	659-560	559-280
Transunion – Score	850-781	780-661	660-601	600-501	500-300
FICO SCORE - Experian, Equifax, TransUnion	850-781	780-661	660-601	600-501	500-300
Vantage	850-781	780-661	660-601	600-501	500-300

TABLE FF-37: BUSINESS CREDIT REPORTS WITH DETAILED INFORMATION ON SCORING OR RATING

Approved Credit Reporting Agency	Acceptable Credit Score or Rating	Detailed Description of the Credit Score or Rating
Equifax	**Business Payment Index**	The Payment Index is a dollar-weighted indicator of a business's payment performance based on the most recently reported financial and non-financial payment experiences.
Equifax	**Business Credit Risk Score**	The Business Credit Risk Score predicts the likelihood of a business incurring greater than 90 days severe delinquency or charge-off within a 12-month period.
Equifax	**Business Delinquency Score**	The Business Delinquency Score predicts the likelihood of severe delinquency (91 days or greater), charge-off or bankruptcy within the next 12 months.
Equifax	**Business Failure Risk Score**	The Business Failure Score predicts the likelihood of business failure through either formal or informal bankruptcy within the next 12 months.
Source: www.equifax.com		
Experian	**Intelliscore Credit Ranking Score/Business Credit Score**	The Intelliscore Credit Ranking Score predicts the likelihood of delinquency within the next 12 months. Predicts seriously derogatory payment behavior.
Experian	**Financial Stability Risk Class**	The Financial Stability Risk Class quickly identifies the highest risk businesses and avoid bankruptcy risk and accounts likely to default.
Source: www.experian.com		
Dun & Bradstreet	**Delinquency Predicator Risk Class**	The Delinquency Predictor Risk Class predicts the likelihood that a company will pay its bills late or on time over the next 12 months.
Dun & Bradstreet	**Commercial Credit Score**	The Commercial Credit Score predicts the likelihood of an account becoming severely delinquent within the next 12 months.
Dun & Bradstreet	**Supplier Evaluation Risk Rating**	The Supplier Evaluation Risk Rating predicts the likelihood that a supplier will cease business operations or become inactive over the next 12 months-predicts whether the business will deliver goods and services as promised.
Dun & Bradstreet	**Paydex**	The Paydex score indicates how quickly a company pays its bills based on the payment experiences in the D&B credit file.
Dun & Bradstreet	**Financial Stress Class**	The Financial Stress Class predicts the likelihood that a business will experience financial distress or failure over the next 12 months.
Source: www.dnb.com		
Standard & Poor's	**S&P Ratings**	An S&P credit rating is a forward looking opinion on the creditworthiness of an obligor to meet its overall financial commitments, or financial commitments with respect to specific issues/programs.
Source: www.standardandpoors.com		

The Round 2021 data showed that only 1.7 percent (19 out of 1,133) of suppliers' TINs received a credit score or rating of 8 or lower. Please note that CMS was not able to calculate a score for 20 bidding entity TINs (1,153 - 1,133), mainly due to the following reasons:

- The credit report submitted was not for the entity that submitted the bid.
- There was no date on the credit report indicating when it was generated (credit reports were required to be generated no earlier than 90 calendar days prior to the opening of the bid window).
- A bidding entity that filed a tax return (Form 1120) as a regular "C" corporation submitted a personal credit report instead of a business credit report.

All of these requirements were outlined in the Round 2021 RFB.

CMS analyzed the 19 suppliers' TINs that received a score of 8 or lower aforementioned and found that 21.1 percent (4 of the 19) of those bidding entities' TINs did not have an active PTAN as of December 28, 2023, supporting our experience that there is a strong correlation between a bidding entity that has a poor credit score and a supplier no longer being enrolled with Medicare.

CMS solicited comments on a proposal to continue requiring each bidding entity to submit a credit report with a numerical credit score or rating that is on the CMS Credit Report Scoring List. This list cannot be finalized until closer to when the bid window opens as credit reporting agencies occasionally update the names of their credit reports, as well as the credit score or rating ranges, so CMS also solicited comments on a proposal to include the list that is applicable for each round in the round-specific RFB or a Financial Scoring Methodology Fact Sheet, so bidding entities have plenty of time to obtain the applicable information and submit it prior to the close of the bid window.

CMS also solicited comments on a proposal to continue using the same 5-tier scoring system, so bidding entities will continue to receive a score of 4, 8, 12, 16, or 20 for their credit report with a numerical credit score or rating as it was successful in Round 2021 per the aforementioned data. Because the credit report with a numerical credit score or rating will be the only covered document submitted, CMS solicited comments on a proposal to deem a bidding entity that receives a minimum score of 12 or higher as passing – meets financial sustainability threshold and be financially eligible for a potential contract offer. We believe that a score of 12 or above would be indicative of the bidding entity being financially stable enough to furnish DMEPOS items during the contract performance period. If deemed as "passing," the bidding entity will continue to be evaluated for a potential contract offer. Because the Credit Report Scoring List as well as the tier and scoring information will be published prior to the bid window opening, bidding entities will be able to determine if they meet CMS's financial standards prior to submitting its bid(s).

Furthermore, CMS solicited comments on a proposal to no longer use a bidding entity's financial score to assist in determining the capacity to assign to each contract supplier to meet projected beneficiary demand. Specifically, CMS has historically used the bidding entity's financial score, as well as a few other factors, to determine if it can provide more than what it has historically provided to beneficiaries – the details of this process are outlined in the "Determining Payment Amounts and the Number of Contracts Awarded for the DMEPOS CBP" proposal where CMS proposed to use a methodology to establish the target number of contracts to award in each competition, so the financial score is no longer applicable for this process.

Lastly, CMS has historically utilized a bidding entity's tax return extract to determine if the entity is a small supplier and has attempted to have at least 30 percent of contract suppliers be small suppliers in each competition to align with section 1847(b)(6)(D) of the Act. For competitive bidding purposes, a small supplier is a supplier that generates gross revenue of $3.5 million or less in annual receipts including Medicare and non-Medicare revenue. However, because CMS proposed to no longer require the submission of the tax return extract and the gross revenue is typically not shown on a credit report, CMS solicited comments on a proposal to add a field in the bidding system requiring the bidding entity included on the bid have a gross revenue that is under the small supplier threshold. Additionally, before a bidding entity submits its bid(s) in the bidding system, the entity will be required to attest in the bidding system that the information entered into the bidding system is true, correct, and complete – just as bidding entities have done in prior rounds. All bidding entities will also continue to be presented with the "Penalties for Falsifying Information" in the bidding system prior to submitting bid(s).

CMS intends to review Medicare fee-for-service claims data for bidding entities that indicate in the DMEPOS Bidding System that they are a small supplier to confirm accuracy. Bidding entities that falsify the small supplier status in the bidding system may be prohibited from participating in the DMEPOS CBP for both the current and the next round of the program in accordance with 42 CFR 414.412(g)(4)(i). Additionally, bidding entities that falsify the small

supplier status will be referred to the Office of Inspector General and Department of Justice for further investigation.

3. Provisions of the Regulation

a. Required Covered Documents:

CMS proposed that each bidding entity submit a business credit report with a numerical credit score or rating, unless the bidding entity does not have a business credit report with a numerical credit score or rating because the entity has not been in operation long enough to generate a numerical score or rating. Bidding entities that are unable to generate a credit report with a numerical credit score or rating would be required to submit a business credit report showing no data or insufficient information to generate a credit score or rating, in addition to a personal credit report with a numerical credit score or rating from the bidding entity's Authorized Official or Delegated Official listed in CMS' PECOS.

The bidding entity must upload a copy of its business' credit report showing the approved crediting agency, a numerical credit score or rating, the bidding entity's name, and the date that the credit report was prepared, which must be within 90 calendar days prior to the opening of the bid window. If the numerical credit score or rating is generated separately from the credit report, the bidding entity's name and the date it was prepared must be shown on the credit report and included with the numerical credit score or rating.

b. Financial Scoring Methodology:

CMS proposed to continue publishing a Credit Report Scoring List and utilize the same 5-tier credit report scoring system used in prior rounds of the DMEPOS CBP. The report will be published in the round specific RFB and/or a fact sheet prior to the opening of the bid window, and will contain the same credit reports with numerical scores or ratings, unless: a credit reporting agency discontinues, changes the name of a credit report, and/or revises the numerical score/rating ranges.

CMS proposed to continue using the 4, 8, 12, 16, or 20 scoring system when evaluating a bidding entity's credit report with a numerical credit score or rating. CMS proposed to deem a bidding entity that receives a minimum score of 12 or higher as passing – meets financial sustainability threshold. If deemed as passing, the bidding entity will continue to be evaluated for a potential contract offer.

CMS proposed to no longer use a bidding entity's financial score to assist in determining the capacity to assign to each contract supplier to meet projected beneficiary demand.

CMS proposed to add a field in the bidding system requiring the bidding entity to verify that all the bidding entities included on the bid has a gross revenue that is under the small supplier threshold. We solicited comments on this proposal. The following is a summary of the comments we received regarding the submission of covered documents and the financial scoring methodology, as well as our responses.

Comment: A commenter supported no longer requiring a tax return extract, income statement, balance sheet, and statement of cash flows and only requiring the credit report with a numerical credit score and/or rating. A few commenters stated that they support the reduction in the tax return extract and corresponding financial statements for all suppliers except for small suppliers. A few commenters suggested that CMS should increase, not decrease, financial oversight to ensure that only qualified, capable suppliers participate, but did not provide any recommendations. Other commenters stated that while streamlining the bid submission process is a worthwhile goal, eliminating the tax return, income statement, balance sheet, and statement of cash flows documentation in favor of a single credit report and credit score with a numerical score and/or rating is inadequate. Commenters further stated that a reduction in financial documentation is dangerous as it invites inexperienced suppliers to submit low bid amounts and, if awarded a contract, may fail to serve beneficiaries.

Response: We thank the commenters for their comments. CMS believes that the data from past rounds (outlined previously in this proposal) supports the decision to require a credit

report with a numerical credit score and/or rating to determine if a bidding entity is financially stable enough to participate in the program for the duration of the contract performance period. In addition to the financial requirements, all bidding entities must be compliant with the DMEPOS supplier and quality standards, which includes being properly licensed and accredited, to be awarded a DMEPOS CBP contract to provide competitively bid items. Additionally, CMS believes that the bid surety bond requirement, per Section 522(a) of the Medicare Access and CHIP Reauthorization Act of 2015, will continue to deter bidding entities from submitting unrealistic bid amounts.

Comment: A commenter requested clarification about whether the credit evaluation will be based solely on the most recent year, or if it will include a multi-year look back.

Response: A bidding entity must upload a copy of its business' credit report showing the approved crediting agency, a numerical credit score or rating, the bidding entity's name, and the date that the credit report was prepared no earlier than 90 calendar days prior to the opening of the bid window.

Comment: Commenters requested that CMS issue clearer guidance on the financial documentation requirements based on the structure of the business (that is, sole proprietorship, partnership, limited liability company, C or S-corporation) to limit errors, inadvertent omissions, and inaccurate disqualifications.

Response: CMS will provide detailed information regarding the credit report and numerical credit score and/or rating requirements for entity types in the Request for Bids Instructions, which will be published prior to the opening of the bid window for each round of the DMEPOS CBP.

Comment: Many commenters had concerns that a credit report and credit score and/or rating would not be sufficient in determining if a supplier could increase their capacity to meet beneficiary demand. Commenters stated that financial documentation is critical to assessing a supplier's ability to scale operations and meet demand. Another commenter suggested that this

proposal would undermine program integrity and invites abuse as suppliers can manipulate credit scores to secure contracts, only to not be able to meet beneficiary demand. Other commenters both agreed and disagreed to no longer use a bidder's financial score to determine capacity. Other commenters stated that data such as supplier-reported capacity, a DME supplier's historical capacity, and additional financial documentation (tax return extracts and financial statements, including an income statement, balance sheet, and statement of cash flows) must be provided to assess a supplier's potential to successfully increase its capacity. A commenter agreed that using a supplier's reported capacity is not reliable.

Response: We thank the commenters for their comments. Bidding entities that manipulate credit scores may be prohibited from participating in the DMEPOS CBP for both the current and the next round of the program in accordance with 42 CFR 414.412(g)(4)(i). Additionally, bidding entities that manipulate credit scores will be referred to the Office of Inspector General and Department of Justice for further investigation. Furthermore, CMS will not rely on supplier-reported capacity because suppliers that bid in Round 2021 did not submit realistic capacity estimates. CMS believes that using the finalized methodology in the "Determining Payment Amounts and the Number of Contracts Awarded for the DMEPOS CBP" proposal will be sufficient in determining the number of contract suppliers that will be needed to collectively meet the projected beneficiary demand in each competition. Additionally, CMS anticipates that most, if not all, suppliers awarded contracts in a competition will have prior experience providing the items in the product category and may also have experience providing the items in the area(s) in which the supplier received a contract. Also, CMS has further confidence that the finalized methodology in the "Determining Payment Amounts and the Number of Contracts Awarded for the DMEPOS CBP" proposal is sufficient because CMS' grandfathering policies will allow rental agreements for DMEPOS items and services entered into before the application of the DMEPOS CBP to be continued once items are phased in under the program in accordance with regulations at 42 CFR 414.408(J), enabling continuity of care for beneficiaries already

receiving items included in the DMEPOS CBP. For the product categories that include purchased items, CMS believes that they are easier to furnish and will most likely be able to be provided by mail. Additionally, at least 75 percent of the contract suppliers will be reimbursed at their bid amount (most will receive more than their bid amount), allowing for increased supplier profit and the ability to provide at a higher capacity. However, in the event CMS determines that beneficiaries are having difficulty obtaining competitively bid DMEPOS in a particular competition, CMS can award additional contracts to suppliers who were not initially offered a contract but were included in the winning array.

Comment: Commenters stated that CMS should continue requiring small suppliers to submit a tax return extract, instead of accepting a bidder's attestation, so CMS can confirm that the definition of a small supplier is being met, preventing bad actors from having the ability to receive a DMEPOS CBP contract by abusing the honor system.

Response: As noted in this proposal, CMS intends to review Medicare FFS claims data for bidding entities that indicate in the DMEPOS Bidding System that they are a small supplier to confirm accuracy. Bidding entities that falsify the small supplier status in the bidding system may be prohibited from participating in the DMEPOS CBP for both the current and the next round of the program in accordance with 42 CFR 414.412(g)(4)(i). Additionally, bidding entities that falsify the small supplier status will be referred to the Office of Inspector General and Department of Justice for further investigation.

Comment: A commenter recommended that all locations/billing numbers that are part of a single corporate entity should count as a single supplier.

Response: We agree that all locations/billing numbers that are part of a single corporate entity for a DMEPOS supplier should count as a single supplier for the purposes of the competition. As discussed previously, we proposed a new financial standards requirement requiring a bidding entity to attest in the bidding system that it is submitting one bid that includes

all commonly owned or commonly controlled locations, and that it will furnish the lead item and all non-lead items in the same competition.

Comments: A commenter suggested that CMS should apply artificial intelligence (AI) enhanced risk scoring to submitted financial data to detect inconsistencies, anomalies, or patterns linked to fraud cases.

Response: CMS will continue to assess ways in which AI can be incorporated into the DMEPOS CBP.

We are finalizing as proposed to revise our regulations at 42 CFR 414.414(d)(1), with the exception of certain technical changes. In the proposed rule, the proposed regulation text for 42 CFR 414.414(d)(1) incorrectly labeled the subparagraphs as (A) through (D) instead of (i) through (iv). We will be finalizing the regulation text by redesignating paragraphs (1)(A) through (1)(D) as (1)(i) through (iv). As part of this same change, we will also be finalizing a change that revises (1)(iii) to refer to documentation described in paragraphs (d)(1)(i) and (ii) rather than (d)(1)(A) and (B). We also provided technical edits in 42 CFR 414.414(d)(1)(i). Technical edits were also provided in 42 CFR 414.414(d)(1)(ii) as well as clarification that the documentation would need to be submitted by the close of the bid window. Additionally, CMS provided clarification in 42 CFR 414.414(d)(1)(iii) to specify the items that must be contained on the documentation outlined in in 42 CFR 414.414(d)(1)(i) and (ii).

We are finalizing as proposed to revise our regulations at 42 CFR 414.414(d)(2) as this will allow CMS to obtain the most updated credit report and numerical credit score and/or rating information to assess if a supplier is financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract performance period, with the exception of certain clarifying edits.

We are providing clarification to 42 CFR 414.414(d)(2)(i) to state that bidding entities that must obtain both a business and personal credit report with a numerical credit score or rating

do not have to utilize the same approved credit agency for both. CMS has also provided technical edits in 42 CFR 414.414(d)(2)(ii) and (iii).

We received no comments on the proposal to continue publishing a Credit Report Scoring List and utilize the same five-tier credit report scoring system, and we are finalizing this proposal without modification.

We are finalizing the proposal to no longer use a bidding entity's financial score to assist in determining the capacity to assign to each contract supplier to meet projected beneficiary demand as the tax return extract and financial statements will no longer be required covered documents in future rounds and CMS is finalizing the "Determining Payment Amounts and the Number of Contracts Awarded for the DMEPOS CBP" proposal which contains a methodology that is sufficient in determining the number of contract suppliers needed to collectively meet the projected beneficiary demand in each competition.

We are finalizing the proposal requiring a bidding entity attest that they are small supplier in the DMEPOS bidding system if the bidding entity meets the small supplier threshold as CMS intends to review Medicare FFS claims data, bidding entities that falsify the small supplier status in the bidding system may be prohibited from participating in the DMEPOS CBP for both the current and the next round of the program in accordance with 42 CFR 414.412(g)(4)(i), and bidding entities that falsify the small supplier status will be referred to the Office of Inspector General and Department of Justice for further investigation.

We received no comments on the requirement for commonly owned and/or commonly controlled bidding entities being prohibited from competing against themselves when submitting bids in the same competition, and we are finalizing this proposal without modification.

We are finalizing the rest of the proposal without changes, including those that did not receive comments.

I. Revising the CDRD Evaluation and Notification Process for the DMEPOS CBP

1. Background

If a bidding entity submits at least one covered document by the CDRD and one or more covered documents are missing, per section 1847(a)(1)(F)(i)(I) of the Act the Secretary is required to notify the bidding entity no later than 45 days (in the first round of competition acquisition program as described in subparagraph (B)(i)(I)) or 90 days (in subsequent rounds of such programs) after the CDRD of any missing covered document(s).

Section 1847(a)(1)(F)(i)(II) of the Act specifies that the Secretary may not reject the bid submission on the basis that any covered document is missing or has not been submitted on a timely basis, if all such missing documents identified in the notice provided to the bidding entity are submitted to the Secretary no later than 10 business days after the date of such notice. Per the limitations of this process in section 1847(a)(1)(F)(iii)(I) through (IV) of the Act, section 1847(a)(1)(F)(i)(I) and (II) of the Act-- (1) applies only to the timely submission of covered documents; (2) does not apply to any determination as to the accuracy or completeness of covered documents submitted or whether the documents meet applicable requirements; (3) shall not prevent the Secretary from rejecting a bid based on any basis not described in clause (i)(II) of section 1847(a)(1)(F) of the Act; and (4) shall not be construed as permitting a bidding entity to change bidding amounts or to make other changes in a bid submission.

Per section 1847(a)(1)(F)(ii)(I) and (II) of the Act, the CDRD is the later of the date that is 30 days before the final date specified by the Secretary for submission of bids under the program or the date that is 30 days after the first date specified by the Secretary for submission of bids under the program.

The 2009 interim final rule codified the CDRD process, which is outlined in 42 CFR 414.414(d)(2) (74 FR 2876 through 2877).

2. Current Issues

Since the inception of the DMEPOS CBP, within either 45 (for Round 1 bids) or 90 days (for subsequent round bids) after the CDRD, CMS has notified bidding entities that submitted at least one covered document by the CDRD, if a covered document was missing by the CDRD and

by the close of the bid window. The first step has been identifying the universe of bidding entities that submitted a covered document by the CDRD. The next step has been to determine if each bidding entity with a complete bid has any missing documents covered by the CDRD and the closing of the bid window. If a covered document is identified as missing by the CDRD, CMS then determines if the covered document was received or not by the close of the bid window. Once the analysis is completed, CMS has communicated its findings to the applicable bidding entity within 45 or 90 days after the CDRD, as applicable. CMS specifies in each bidding entity's notification, to the extent applicable, if: 1) a covered document(s) was missing by the CDRD and was still missing by the close of the bid window, 2) a covered document(s) was missing by the CDRD date but was received by the close of the bid window, 3) covered documents were missing by the CDRD but at least one of the missing covered documents was received by the close of the bid window while the other covered document(s) was still missing by the close of the bid window, or 4) no covered document(s) was missing by the CDRD.

CMS proposed to streamline the evaluation and notification processes by only informing bidding entities if a covered document was missing by the close of the bid window. Each bidding entity would receive a notification stating if: (1) a covered document(s) was missing by the close of the bid window; or (2) no covered document(s) was missing by the close of the bid window. CMS believes that this proposal aligns with the intent of statute as bidding entities would continue to be notified of any missing covered documents (as long as they submit at least one covered document by the CDRD) and would continue to be able to submit any missing covered documents within 10 business days of receiving the notification.

This proposal would also reduce CMS workload in determining if/when a covered document is missing for bidding entities that submitted at least one covered document by the CDRD. Specifically, CMS proposed to identify the universe of bidding entities that submitted at least one covered document by the CDRD and then determines if they have a missing covered document(s) by the close of the bid window. CMS would notify bidding entities if they have

missing covered documents or if all covered documents were submitted, so CMS will only have to send two different types of notifications compared to the four different notifications previously mentioned. Additionally, due to the simplification of the notifications, bidding entities would have an easier time understanding which covered documents they may need to submit in response to their notification. We solicited comments on this proposal.

3. Provisions of the Regulation

CMS proposed to streamline the evaluation and notification processes for missing covered document(s). Under this proposal, CMS will no longer evaluate if a bidding entity was missing a covered document(s) by the CDRD and by the close of the bid window, and will only determine if a bidding entity had a missing covered document by the close of the bid window. Once the evaluation is completed, CMS proposed to continue notifying bidding entities, within 90 days of the CDRD, of the specific covered document(s) that was missing or provide confirmation that all applicable covered documents had been received by the close of the bid window. Bidding entities will continue to have 10 business days from receiving their notification to submit the missing covered document(s). We solicited comments on this proposal.

Comments: Commenters supported the proposal.

Response: We are finalizing our proposal as proposed with the exception of technical changes made to the regulation text. In the proposed rule, the proposed regulation text cited 42 CFR 414.414(d)(2) incorrectly. We are finalizing the regulation text by redesignating paragraphs (d)(2) to (d)(3) and will finalize the rest of the proposal without changes, which is reflected in 42 CFR 414.414(d)(3)(ii)(B).

J. Bid Surety Bond Review Process

1. Background

Section 1847(a)(1)(G) of the Act, as added by section 522(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10) (MACRA), requires a bid surety bond for bidders. We believe that a bid surety bond would help address the fact that the bids submitted

under the DMEPOS CBP are not binding, which can encourage the practice of bidders submitting "low-ball" bids. Requiring a bid surety bond was also believed to reduce the number of bad actors submitting bids in the DMEPOS CBP, while imposing a penalty for a bidder that does not accept a contract that they won.

If a bidder is offered a contract for a competition and its bid is at or below the median composite bid rate for all bidders included in the calculation of the SPA, and it does not accept the contract offer, the bidder's bid surety bond would be forfeited for that CBA. Bidders that accepted the contract offer, or those bids that are above the median composite bid rate, would have the bid surety bond liability returned.

The 2016 ESRD & DMEPOS final rule (81 FR 77966 and 77967) finalized the regulations at 42 CFR 414.412(g) for setting the requirements for bid surety bonds. Additionally, CMS proposed to correct a technical error in 42 CFR 414.412(g) that happened as a result of a previous paragraph redesignation in the 2018 ESRD & DMEPOS final rule (83 FR 57072).

2. Current Issues

This proposal codifies how CMS handles situations where at least one of the bid surety bond requirements outlined in 42 CFR 414.412(g)(2)(i) and (ii) is not properly met after a bidder submits its bid surety bond(s) during the bid window. Specifically, if CMS determines that a bid surety bond requirement is not met, the bidder would be notified by CMS and would be provided with an opportunity to correct the deficiency on the bid surety bond via a bid surety bond rider. A bid surety bond rider is a change or amendment to the original bid surety bond. It is the only legal way of modifying or updating information on a bid surety bond which is still in effect, and it can only be issued by the authorized surety agency that issued the original bid surety bond. Allowing bidders to submit a bid surety bond rider would provide bidders that have a bid surety bond deficiency(s) an opportunity to correct the deficiency(s) instead of the bid(s) for the applicable CBA(s) being disqualified in the early stages of the bid evaluation process. Bids that

are disqualified for a bid surety bond deficiency are not included in other bid evaluation processes that are necessary to determine if a bid is eligible for a contract offer.

CMS applied the bid surety bond rider process during bid evaluation for Round 2021 of the DMEPOS CBP and now proposed to codify this process in regulation. Additionally, CMS proposed correcting a technical error in 42 CFR 414.412(g) that happened as a result of a paragraph redesignation in 83 FR 57072.

3. Provisions of the Regulation

CMS proposed to correct a technical error created 2018 ESRD & DMEPOS final rule (83 FR 57072) where CMS redesignated paragraphs (e) through (h) as paragraphs (d) through (g), respectively. The redesignated paragraph (g)(3)(ii) still contained a reference to the paragraph (h)(3)(i), which, with the redesignation, was deleted in its entirety. The proposed correction would revise existing paragraph (g)(3)(ii) by removing the reference to "(h)(3)(i)" and replacing it with "(g)(3)(i)". All other parts of paragraph (g)(3)(ii) remain unchanged with this proposal. We solicited comments on this proposal.

In 2015, Congress passed section 522(a) of MACRA, which required a bid surety bond for bidders. The 2016 ESRD & DMEPOS final rule (81 FR 77966 and 77967) finalized the regulations at 42 CFR 414.412(g) for setting the requirements for bid surety bonds. Round 2021 of the DMEPOS CBP was the first round that required bid surety bonds. As a result, CMS reviewed all bids to ensure a bid surety bond was uploaded to the DMEPOS CBP's secure portal by the deadline for bid submission for each CBA in which a bid was submitted, and that it met all bid surety bond requirements outlined in 42 CFR 414.412(g)(2)(i) and (ii). During the Round 2021 bid evaluation, CMS was able to identify bid surety bonds that had deficiencies with the bid surety bond requirements and allowed certain deficiencies to be corrected via a bid surety bond rider.

Round 2021 had 1,338 bidders and 43 were identified as having at least one bid surety bond with a minimum of one deficiency that was able to be corrected via a bid surety bond rider.

These 43 bidders were provided with the opportunity to submit a bid surety bond rider from its surety within a 10-business day timeframe rectifying all deficiencies. Of the 43 bidders, 40 responded within the allotted timeframe; however, only 36 out of the 40 bidders submitted a bid surety bond rider that properly corrected the deficiencies. After successful implementation of the process for Round 2021, CMS proposed to include this process in all future rounds of the program.

Each bid surety bond requirement, described in 42 CFR 414.412(g)(2)(i) and (ii), is listed later in this section followed by an example(s) of the type of deficiency that could be corrected by a bid surety bond rider, which is a change or amendment to the original bid surety bond, that can only be issued by the authorized surety, at its discretion, that issued the original bid surety bond:

- The name of the bidder as the principal/obligor: If a bidder submits a bid surety bond that contains a name of a different entity other than the Legal Business Name entered in the Business Organization section of Form A in the DMEPOS Bidding System, for example using its "doing business as" name or the name is missing the "LLC" at the end, then the error can be corrected by a bid surety bond rider.

- The name and the National Association of Insurance Commissioners (NAIC) number of the authorized surety: If a bidder submits a bid surety bond with a missing or illegible name or NAIC number, or the NAIC number does not match the name on the Treasury Department's list of authorized sureties, these issues can be corrected with a bid surety bond rider.

- CMS as the named obligee: If a bidder submits a bid surety bond without naming CMS as obligee or names another agency or department as obligee, this error can be corrected by a bid surety bond rider.

- The conditions of the bid surety bond as specified in § 414.412(g)(3), which is forfeiture of the bid surety bond language; If a bidder submits a bid surety bond that is missing

part or all of the pertinent language on forfeiture of the bid surety bond, then the omission of bid surety bond forfeiture language can be corrected by a bid surety bond rider.

- The CBA covered by the bid surety bond: If a bidder submits a bid surety bond with an incorrect or missing CBA name, then the CBA name can be corrected by a bid surety bond rider.

- The bid surety bond number: If a bidder submits a bid surety bond with a missing or illegible bid surety bond number, then the bid surety bond number can be corrected by a bid surety bond rider.

- The date of issuance: If a bidder submits a bid surety bond with a missing or illegible date of issuance, then the date of issuance can be corrected by a bid surety bond rider.

- The bid surety bond value of $50,000.00 If a bidder submits a bid surety bond for a value other $50,000.00, then the bid surety bond value can be corrected by a bid surety bond rider.

The following are examples of the type of deficiencies that a bidder may have on its bid surety bonds that cannot be corrected by a bid surety bond rider:

- Late Bid Submissions: CMS will not review any bid surety bonds that are submitted after the deadline for bid submission. The Social Security Act clearly states that bidders must provide "proof of having obtained" a bid surety bond by the "deadline for bid submission." Submission of a bid surety bond rider will not rectify a bid(s) from a bidder that is disqualified for having a bid surety bond failure, if the failure was for not submitting a bid surety bond prior to the deadline for bid submission. This would also include a bidder that submitted a document other than a bid surety bond (for example, a Medicare enrollment bond, or a Certificate of Liability Insurance). No notice would be provided to a bidder in this situation.

- Missing Bid Surety Bonds: If a bidder submitted bids in two different CBAs, but the bidder uploaded the same bid surety bond for both CBAs, then the bidder will not be notified that there is a deficiency for the bid for the CBA in which the bid surety bond that was never

uploaded, as a bid surety bond rider cannot correct the issue of a missing bid surety bond, and the bidder did not provide proof of having a bid surety bond for the one CBA by the deadline for bid submission. For example, this could occur by error, where the bidder accidentally uploaded the same bid surety bond for both CBAs, despite having two bid surety bonds; or this could occur by a mistaken understanding of the bidder that one bid surety bond should be sufficient for both CBAs.

Bidders would be notified by CMS of the deficiency (that is, the incorrect, incomplete, or missing requirement) and would be permitted to obtain the bid surety bond rider within a certain timeframe to submit to CMS in order for its bid(s) to remain eligible for further review during bid evaluation. CMS proposed sending the notification to bidders and having bidders provide the bid surety bond riders via the DMEPOS CBP's secure portal. CMS will not notify bidders of deficiencies that are not correctable with a bid surety bond rider during this review process.

CMS proposed to provide bidders with a single, 10-business day timeframe to obtain and submit a bid surety bond rider correcting the deficiencies on the bid surety bond. A 10-business day timeframe was utilized for Round 2021, which provided bidders ample time to obtain a bid surety bond rider from the authorized surety that issued the original bid surety bond and submit the bid surety bond rider via the DMEPOS CBP's secure portal. Additionally, we anticipate the 10-business day timeframe will run concurrent with other bid evaluation processes, and extending this timeframe would result in some bid evaluation processes being delayed until the bid surety bond rider review process is complete, impacting CMS's ability to continue evaluating all bids submitted and ultimately awarding contracts in a timely manner. Lastly, CMS believes that bidders have the resources (for example, fact sheets, bid surety bond template) available, and that it is the responsibly of the bidder to submit a bid surety bond that meets all bid surety bond requirements outlined in 42 CFR 414.412(g)(2)(i) and (ii). For these reasons, CMS believes a single, 10-business day opportunity to rectify the deficiency is sufficient. We solicited comments on this proposal.

The following is a summary of the comments we received regarding the bid surety bond review process and our responses.

Comment: Commenters supported the proposal of allowing bidders with a single, 10-business day timeframe to submit a bid surety bond rider correcting certain deficiencies on their bid surety bond(s). Other commenters stated that the 10-business day timeframe is too short and recommended a 30-business day timeframe.

Response: CMS utilized a 10-business day timeframe in Round 2021 and did not receive complaints from bidders about having difficulty obtaining a bid surety bond rider from its surety agency within this timeframe.

Comment: Commenters suggested CMS clarify when a supplier can decline a contract offer(s) without forfeiting its bid surety bond with the application of setting the single payment amounts at the 75th percentile.

Response: Per 42 CFR 414.412(g)(3)(i), when a bidding entity is offered a contract for a competition and its composite bid (the bid submitted by the supplier for the lead item in the product category) for the competition is at or below the median composite bid rate for all bidding entities included in the calculation of the single payment amounts within the competition and the bidding entity does not accept the contract offer, its bid surety bond submitted for that CBA will be forfeited and CMS will collect on the bond.

Comment: A commenter suggested that CMS consider reimbursement of bid surety bond premiums or credits toward future rounds of the DMEPOS Competitive Bidding Program in the event the current program is not implemented. Another commentor indicated that requiring upfront financial cost with no protection or refund mechanism if CMS does not implement the program represents an unfair burden on small businesses and mid-sized suppliers that already operate on tight margins.

Response: CMS believes that bidding suppliers should discuss any refund mechanism with the authorized surety that issued the bond(s).

We are finalizing all provisions outlined in 42 CFR 414.412(g)(5) as proposed. CMS is also finalizing revisions in 42 CFR 414.412(g)(1) to clarify that, for each round of the DMEPOS CBP, a bidding entity must obtain a bid surety bond for each CBA included on a bid(s) from an authorized surety on the Department of the Treasury's Listing of Certified Companies and provide proof of having obtained the bond by submitting a copy to CMS by the deadline for bid submission. Additionally, CMS is finalizing the proposal to correct a technical error created 2018 ESRD & DMEPOS final rule (83 FR 57072) where CMS redesignated paragraphs (e) through (h) as paragraphs (d) through (g), respectively. The redesignated paragraph (g)(3)(ii) still contained a reference to the paragraph (h)(3)(i), which, with the redesignation, was deleted in its entirety. The finalization of this correction will revise existing paragraph (g)(3)(ii) by removing the reference to "(h)(3)(i)" and replacing it with "(g)(3)(i)". All other parts of paragraph (g)(3)(ii) will remain unchanged. We will be finalizing the rest of the proposal without changes.

K. Tribal Exemption from Participating in the DMEPOS CBP

1. Background

There is a special government-to-government relationship between the federal government and federally recognized tribes based on U.S. treaties, laws, Supreme Court decisions, Executive Orders, and the U.S. Constitution. This government-to-government relationship forms the basis for federal health services to American Indians/Alaska Natives (AI/AN) in the U.S. In 1976, the Indian Health Care Improvement Act (IHCIA) (Pub. L. 94-437, September 30, 1976) amended the Act to permit payment by Medicare and Medicaid for services provided to AI/ANs in Indian Health Service (IHS) and Tribal health care facilities that meet the applicable requirements. Under this authority, Medicare services may be furnished by IHS operated facilities and programs, and Tribally operated facilities and programs, under Title I or Title V of the Indian Self Determination Education Assistance Act, as amended (ISDEAA) (Pub. L. 93–638, January 4, 1975) to AI/ANs. As of October 10, 2025, the IHS healthcare delivery system currently consists of 44 hospitals, with 20 of those hospitals operated by the IHS

and 24 of them operated by Tribes under the ISDEAA, as well as 391 health centers, 51 operated by IHS and 340 operated by Tribes under the ISDEAA.

The Act prohibits Medicare payment to non-contract suppliers under the DMEPOS CBP. Specifically, section 1847(b)(6) of the Act states that, "payment shall not be made for items and services described in section 1847(a)(2) furnished by a contractor and for which competition is conducted under this section unless: (i) the contractor has submitted a bid for such items and services under this section; and (ii) the Secretary has awarded a contract to the contractor for such items and services under this section."

However, section 1862(a)(17) of the Act carves out an exception to this rule. Section 1862(a)(17) of the Act states, "Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services where the expenses are for an item or service furnished in a competitive acquisition area (as established by the Secretary under section 1847(a) of the Act) by an entity other than an entity with which the Secretary has entered into a contract under section 1847(b) of the Act for the furnishing of such an item or service in that area, unless the Secretary finds that the expenses were incurred in a case of urgent need, or in other circumstances specified by the Secretary."

2. Current Issues

Tribes that operate health facilities or suppliers under the ISDEAA have approached CMS requesting an exception from the DMEPOS CBP to allow Medicare payment for competitively bid items provided to AI/AN Medicare beneficiaries, who reside in a CBA, but who receive services from an IHS or Tribally operated facility or supplier, which can be located 60 or 90 minutes outside the CBA. Many of these AI/AN Medicare beneficiaries receive primary care services at a Tribally operated facility, and, as a result of this visit, might be provided DMEPOS by the facility or a Tribally operated supplier. Without an exception, the IHS or Tribally operated facility or supplier would not be paid by Medicare when providing

competitively bid DMEPOS to eligible AI/AN Medicare beneficiaries during an active round of the DMEPOS CBP.

In addition, under the Indian Health Care Improvement Act (IHCIA), AI/ANs who are eligible for services from the IHS, in general do not pay coinsurance for DMEPOS they receive from an IHS supplier or facility. However, under an active round of the DMEPOS CBP, AI/AN Medicare beneficiaries residing in a CBA must receive DMEPOS from a competitive bidding contract supplier in their CBA and pay a 20 percent coinsurance, even in cases where they receive care at a Tribally operated facility outside their CBA. This creates added expenses for AI/AN Medicare beneficiaries.

3. Provisions of the Regulation

CMS proposed to use the authority at section 1862(a)(17) of the Act to add an exception to § 414.408(e)(2) that would allow Medicare payment to IHS or Tribally operated facilities and suppliers that furnish competitively bid items and services to AI/AN Medicare beneficiaries who reside in a CBA so that the AI/AN Medicare beneficiaries can retain the benefits described previously when receiving DMEPOS items and services from a Tribal supplier. We solicited comments on this proposal.

Comment: CMS received comments that were in support of this proposal.

Response: We are finalizing all provisions outlined in 42 CFR 414.408(e)(2)(v) as proposed. We will be finalizing the rest of the proposal without changes.

L. Addition of a Termination Clause for the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) Supplier Contracts

1. Background

As previously discussed, an important benefit of the DMEPOS CBP is that it ensures access to covered DMEPOS items and services. Current regulations at 42 CFR 414.422 establishing the terms of each DMEPOS CBP contract state that contract suppliers must agree to furnish items under its contract to any beneficiary who maintains a permanent residence in, or

who visits, the CBA and who requests those items from that contract supplier. CMS implemented these regulations pursuant to section 1847(b)(3)(A) of the Act, which states that the Secretary may specify the terms and conditions of a DMEPOS CBP contract. In the 2006 proposed rule (71 FR 25682), CMS proposed adding a unilateral contract termination for convenience clause to the DMEPOS CBP supplier contracts. After receiving multiple public comments challenging the termination for convenience clause, per the 2007 final rule (72 FR 18054 and 18055), CMS decided not to finalize the proposal.

2. Current Issues

Since the inception of the DMEPOS CBP, CMS has never verified an instance where all contract suppliers for a competition were not able to meet beneficiary demand for the competition, even during a PHE. For example, after the Secretary of HHS declared PHEs after major hurricanes, contract suppliers were able to replace damaged DMEPOS and furnish competitively bid DMEPOS items to beneficiaries without any access concerns. CMS believes this can be attributed to the fact that not all contract suppliers for a CBA are physically located within the impacted CBA. Also, Medicare requires Medicare-enrolled DMEPOS suppliers to "have a contingency plan that enables it to respond to emergencies and disasters or to have arrangements with alternative suppliers in the event that the supplier cannot service its own customers as a result of an emergency or disaster" (see section 1.F of the CMS DMEPOS Quality Standards). CMS has experienced that contract suppliers are prepared to promptly resume operations and remain in compliance with the terms of the DMEPOS CBP supplier contract, without a need for any contract action by CMS. Additionally, there is an already established network of agencies and organizations at the federal, state, and local levels that are integral in responding to the immediate needs, including DMEPOS needs, during a PHE. For instance, CMS works closely with HHS's Administration for Strategic Preparedness and Response (ASPR) that leads the nation's medical and public health preparedness for, response to, and recovery from disasters and other PHEs.

Nevertheless, we are concerned that, in the event of a PHE, contract suppliers may be unable to fulfill their obligations under DMEPOS CBP supplier contracts to furnish certain required items and services to beneficiaries in CBAs or defined area(s) within CBAs specified in the contracts and affected by the PHE (the PHE-impacted area). In the event that CMS determines that, due to a PHE, contract suppliers are unable to furnish items and services to beneficiaries in a PHE-impacted area specified in their DMEPOS CBP contracts, we believe it is prudent for CMS to have the authority to unilaterally terminate or modify each applicable contract to exclude the requirement to furnish such items and services in the PHE-impacted area from the scope of the DMEPOS CBP. If the items and services in the PHE-impacted area to be removed from the DMEPOS CBP encompasses all competitions referenced in a DMEPOS CBP contract, CMS would unilaterally terminate the contract supplier's entire contract. If the items and services in the PHE-impacted area to be removed from the DMEPOS CBP encompass only a portion of the items and services and areas referenced in a DMEPOS CBP supplier contract, CMS would unilaterally modify the contract to exclude the requirement to furnish the applicable items and services in the PHE-impacted area. Upon modification, the contract supplier would no longer be obligated under the terms of the contract to furnish the specified items and services in the PHE-impacted area, and CMS would no longer provide payment under the contract for furnishing those items and services in that area. Depending on the PHE, such area may be a specific CBA or a defined area within a CBA. A DMEPOS CBP supplier contract modified to exclude the requirement to furnish certain items and services in the PHE-impacted area would continue to remain in effect for all other items and services and all other geographic areas that are within the scope of the contract. Upon the termination and/or modification of each DMEPOS CBP supplier contract impacted by the PHE, any Medicare enrolled DMEPOS supplier would be able to furnish the applicable items and services to Medicare beneficiaries in the PHE-impacted area.

CMS would reserve the right to unilaterally terminate or modify every DMEPOS CBP supplier contract impacted by a PHE in accordance noted previously if the following conditions are met: (1) the Secretary of HHS declares a PHE; (2) CMS determines the PHE has created an access concern for beneficiaries receiving items and services under the DMEPOS CBP in certain CBAs or defined area(s) within CBAs; (3) CMS determines that awarding additional CBP contracts, per 42 CFR 414.414(i), would not address the access concerns; and (4) CMS determines terminating or modifying each impacted DMEPOS CBP supplier contract to exclude those specific areas from the DMEPOS CBP would alleviate access concerns.

To determine whether or not a PHE has created an access concern, CMS would review information obtained directly from the contract supplier(s) impacted by a PHE, along with data obtained through CMS's monitoring system (complaints, claims data, beneficiary health outcomes, assignment rates, etc.) and from other agencies and organizations at the federal, state, and local levels. CMS would continue to remain in communication with affected contract suppliers throughout a PHE. CMS would share all relevant information from contract suppliers with applicable emergency response partners to aid in the response efforts. We would also be analyzing the information to determine the scope and length of the challenges being experienced to assess whether it is necessary to terminate an entire DMEPOS CBP supplier contract, terminate a competition(s), or terminate a defined area(s) within a CBA. For example, if the Secretary of HHS declares a PHE due to a pandemic and the President of the United States enacts the Defense Production Act to assist with furnishing essential medical supplies, CMS would communicate with contract suppliers to determine if they are able to continue furnishing the competitively bid DMEPOS item to beneficiaries in the CBA under existing conditions. The information and data obtained from contract suppliers would be combined with relevant information gathered from other agencies and organizations at the federal, state, and local levels that are integral in responding to the PHE. We solicited comments on this proposal.

In a form and manner to be determined by CMS, CMS would announce the exclusion of the PHE-impacted area from the scope of the DMEPOS CBP to all applicable contract suppliers and would further notify each applicable contract supplier if the DMEPOS CBP supplier's contract, based on this announcement, will be terminated or unilaterally modified.

Any termination or modification made in accordance with this proposal would remain in effect for the remainder of the DMEPOS CBP supplier contract term, even if the PHE ends before the contract's expiration date.

CMS would apply a high degree of prudence when making an informed decision to terminate and/or modify a DMEPOS CBP supplier contract to exclude areas impacted by a PHE. CMS would not consider a situation that does not meet the qualifying criteria previously mentioned. Even if a PHE meets the qualifying criteria, CMS would not terminate and/or modify a DMEPOS CBP supplier contract if the body of evidence and information determines that there is sufficient capacity from remaining contract suppliers, or if CMS is able to award additional contracts to meet the existing market demands for the competition(s) or defined area(s) within a CBA. For example, if most contract suppliers for a competition say that they are unable to furnish an item to beneficiaries, but there are at least two contract suppliers that provide evidence that they can meet the demand for the competition, CMS may decide that there is sufficient capacity remaining from a contract supplier. We solicited comments on this proposal.

3. Provisions of the Regulation

If CMS determines that due to a PHE, contract suppliers are unable to furnish certain items and services to beneficiaries in certain areas impacted by a PHE (PHE-impacted area) as required under their respective DMEPOS CBP supplier contracts, CMS proposed in § 414.422 to have the option to unilaterally terminate or modify each applicable DMEPOS CBP supplier contract to allow any Medicare enrolled DMEPOS supplier to furnish the applicable items and services to Medicare beneficiaries in the PHE-impacted area. Depending on the geographic

extent of the PHE, a PHE-impacted area may refer to entire CBA(s) or only certain areas within a CBA.

If the items and services in the PHE-impacted area identified encompass all competitions referenced a DMEPOS CBP supplier contract, CMS proposed in § 414.422 to unilaterally terminate the DMEPOS CBP supplier contract.

If the items and services in the PHE-impacted area identified encompass only a portion of the items and services and geographic areas referenced in a DMEPOS CBP supplier contract, CMS proposed in § 414.422 to unilaterally modify the DMEPOS CBP supplier contract to remove the contract supplier's obligation to furnish specified items and services in the PHE_impacted area, as well as CMS's obligation to pay for those items and services under the DMEPOS CBP supplier contract.

After termination and/or modification of all applicable DMEPOS CBP supplier contracts, CMS proposed in § 414.422 to revert back to the general fee-for-service program requirements set forth in 42 CFR Part 414 Subpart D for the applicable competition(s) or defined area(s) within a CBA. As a reminder, fee-for-service (Medicare enrolled) DMEPOS suppliers are not required to furnish DMEPOS to beneficiaries in the CBA, nor are they required to accept assignment, unless they are already participating suppliers with Medicare. We solicited comments on this proposal.

CMS proposed in § 414.422 to have the option to remove items and services furnished in a PHE-impacted areas from the DMEPOS CBP when all of the following qualifying criteria are met: (1) the Secretary declares a PHE; (2) CMS determines that verifiable evidence exists of a DMEPOS access problem for beneficiaries for a certain competition or defined area(s) within the competition's CBA; (3) CMS determines that awarding additional DMEPOS CBP supplier contracts, per § 414.414(i), would not address the access concerns; and (4) CMS determines terminating or modifying each impacted DMEPOS CBP supplier contract to exclude certain

competition(s) or defined area(s) within the competition's CBA from the DMEPOS CBP would alleviate access concerns. We solicited comments on this proposal.

Comment: Commenters supported this proposal. A commenter stated that while the proposal allows CMS to terminate contracts during a public health emergency, that does not solve the risk of over-consolidation and indicated that replacement providers will not be staffed or stocked to absorb a sudden surge, leaving patients vulnerable.

Response: CMS wants to clarify that this proposal has no impact on DMEPOS supplier consolidation and that any enrolled DMEPOS supplier will be permitted to provide services to Medicare beneficiaries who live in a competitive bidding area if DMEPOS CBP contracts are terminated during a Public Health Emergency. We are finalizing the addition of 42 CFR 414.422(h) as proposed.

M. Technical Change to § 414.408(h)(8)

In the 2007 final rule we added § 414.408(h)(7), which set the payment amounts for rented DME requiring frequent and substantial servicing (72 FR 18032). We added § 414.408(h)(7)(i), which referred to paragraph (h)(7)(ii) of this section. Subsequently, we published in the **Federal Register** a final rule in 2011 titled "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011" (75 FR 73170). In this rule, we added § 414.408(h)(2). As a result of this addition, what used to be § 414.408(h)(7), became § 414.408(h)(8). However, § 414.408(h)(8)(i) was inadvertently not updated to refer to paragraph (h)(8)(ii), and it still refers to paragraph (h)(7)(ii). We are therefore making a technical change to the regulation text at § 414.408(h)(8)(i) so that it will refer to paragraph (h)(8)(ii) instead of paragraph (h)(7)(ii).

We solicited comments on this proposal and received no comments, and therefore, we are finalizing as proposed.

N. Definitions of "Competition" and "Adjusted Fee Schedule Amount" and "Unadjusted Fee Schedule Amount" under § 414.402

The Medicare fee schedule amounts for enteral nutrition furnished in non-CBAs are adjusted using information from the DMEPOS CBP in accordance with § 414.105. The Medicare fee schedule amounts for DME and medical supplies and OTS orthotics furnished in non-CBAs are adjusted using information from the DMEPOS CBP in accordance with § 414.210(g). The Medicare payment amounts for lymphedema compression treatment items are adjusted using information from the DMEPOS CBP in accordance with § 414.1690. For the purposes of streamlining the language under this subpart, we proposed to add definitions for "Adjusted fee schedule amount" and "Unadjusted fee schedule amount" under § 414.402. We proposed that *Adjusted fee schedule amount* means the payment amount established for the item under Subpart C of this part, with the application of § 414.105; Subpart D of this part, with the application of § 414.210(g); or Subpart Q of this part, with the application of § 414.1690. We proposed that *Unadjusted payment amount* means the payment amount established for the item under- Subpart C of this part, without the application of § 414.105; Subpart D of this part, without the application of § 414.210(g); or Subpart Q of this part, without the application of § 414.1690.

Similarly, for the purpose of streamlining regulation text, rather than continuing to write out "competitive bidding area and product category combination," we proposed to add a definition for "Competition" under § 414.402 to read *Competition* means a competitive bidding area and product category combination for which a bidding entity submits a bid and for which a supplier enters into a DMEPOS supplier contract to furnish items and services within the product category to beneficiaries residing within the competitive bidding area.

We solicited comments on this proposal. We did not receive public comments on these issues, and therefore, we are finalizing as proposed.

VIII. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 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.

B. Information Collection Requirements (ICRs)

In the CY 2026 HH PPS proposed rule, we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

1. ICRs for HH QRP

a. Data Reporting Requirements

Failure to submit HH QRP data required under section 1895(b)(3)(B)(v) of the Act with respect to a program year would result in the reduction of the annual home health market basket percentage increase otherwise applicable to an HHA for the corresponding calendar year by 2 percentage points. As we noted in the CY 2018 HH PPS final rule (82 FR 52738 through 51740), we believe the reconsideration requirements, and the associated burden would be incurred subsequent to an administrative action. In accordance with the implementing regulations for the

PRA (5 CFR 1320.4(a)(2) and (c)), the burden associated with any information collected subsequent to the administrative action is exempt from the requirements of the PRA. We have, however, provided detailed cost estimates in section VIII. of the proposed rule. We welcomed public comments on the accuracy of the cost estimate assigned to this administrative burden.

b. Removal of Standardized Patient Assessment Data Elements

As discussed in section III.D.3. of the proposed rule, we proposed to remove four items as standardized patient assessment data elements beginning with the CY 2026 HH QRP. The four assessment items proposed for collection are (1) Living Situation; (2) Food Runs Out; (3) Food Doesn't Last; and (4) Utilities as outlined in section III.D.5. of the proposed rule. All elements discussed will be collected at the start of care and resumption of care timepoints. To clarify, home health episodes begin with either a start of care or a resumption of care, corresponding to admission in other PAC settings. We assumed the Living Situation and Utilities data elements require 0.3 minutes each of clinician time to complete. We assume the Food Runs Out and Food Doesn't Last data elements require 0.15 minutes each of clinician time to complete. Therefore, we estimated that there will be a decrease in clinician burden per OASIS assessment of 0.9 minutes at the start of care and resumption of care. We also proposed to remove the patient COVID-19 vaccination item beginning with the CY 2026 HH QRP. This item is collected at the transfer of care, death at home, and discharge assessment timepoints of the OASIS and requires 0.3 minutes of clinician time to complete at each of these time points.

The net effect of these proposals is a decrease in four data elements collected at the start of care and one data element at transfer of care, death at home, and discharge for the OASIS implemented on April 1, 2026.

For purposes of calculating the costs associated with the information collection requirements, we obtained median hourly wages for these from the U.S. Bureau of Labor Statistics' May 2024 National Occupational Employment and Wage Estimates (https://www.bls.gov/oes/current/oes_nat.htm). To account for other indirect costs such as

overhead and fringe benefits (100 percent), we have doubled the hourly wage. These amounts are detailed in table 38.

TABLE 38: U.S. BUREAU OF LABOR STATISTICS' MAY 2024 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Median Hourly Wage ($/hr)	Fringe Benefit (100%) ($/hr)	Adjusted Hourly Wage ($/hr)
Administrative Services Manager	11-3012	$52.11	$52.11	104.22
Registered Nurse (RN)	29-1141	$45.00	$45.00	$90.00
Physical therapists (PT)	29-1123	$48.57	$48.57	$97.14
Speech-Language Pathologists (SLP)	29-1127	$45.87	$45.87	$91.74
Occupational Therapists (OT)	29-1122	$47.28	$47.28	$94.56
Miscellaneous Health Technologists and Technicians	29-2090	$23.84	$23.84	$47.68

The OASIS is completed by RNs or PTs, or very occasionally by occupational therapists (OT) or speech language pathologists (SLP/ST). Data from 2023 show that the SOC/ROC OASIS is completed by RNs (approximately 75.42 percent of the time), PTs (approximately 23.71 percent of the time), and other therapists, including OTs and SLP/STs (approximately 0.87 percent of the time). Based on this analysis, we estimated a weighted clinician average hourly wage of $ 91.72, inclusive of fringe benefits, using the hourly wage data in table G2 (0.7542×$90.00+0.2371×$97.14+0.0087×$93.15= $91.72. Individual providers determine the staffing resources necessary.

For purposes of estimating burden, we compare item-level burden estimates for the OASIS to be released on April 1, 2026 that removes the SDOH and COVID-19 data elements, to the originally planned OASIS update for January 1, 2027 release finalized in CY 2024 HH PPS final rule (88 FR 77763 through 77768) that included the collection of four SDOH items and a COVID 19 data element. This comparison of the intended release of OASIS in **January 1,2027** with the **April 1, 2026** being finalized with this rule will outline the extent of the reduction in burden.

A first step in calculating a change in burden based on removal of the SDOH and COVID-19 items is to estimate the total increase in the number OASIS assessments expected to be collected in CY 2027 with implementation of all payer OASIS data submissions. In the CY 2023 HH PPS

Final Rule, we estimated that all payer OASIS data submission would increase overall annual OASIS assessments by 30 percent. Table G2 shows the total number of OASIS assessments at each OASIS time point in CY 2023 before implementation of all payer OASIS data submissions. Table 2 also shows the total expected assessments in CY 2027 based on our estimates that implementing all payer submission in will increase the number of assessments at each timepoint by 30 percent. (CY 2023 assessment total + CY 2023 assessment total *0.3= Estimated CY 2027 Assessment total based on all payer data collection). This estimated total for CY 2027 will be used to calculate the CY 2027 OASIS burden with the planned additions of the SDOH and COVID-19 items and the April 1, 2026 OASIS being finalized with the collection of these items removed.

TABLE 39. OASIS SUBMISSIONS BY TIMEPOINT BASED ON CY 2023 & CY 2027 ESTIMATED OASIS DATA

Time Point	CY 2023 OASIS Assessments Completed	Estimated CY 2027 OASIS Assessments Based on All-Payer Data Collection
Start of Care	6,627,912	8,616,286
Resumption of Care	911,245	1,184,618
Transfer of Care	1,818,914	2,364,588
Death at Home	48,398	62,917
Discharge	5,389,311	7,006,104
Total Assessments	14,795,780	19,234,513

The totals from table 39 are used to calculate the hourly burden estimates in table 40 based on the following calculations:

- **START OF CARE**		
- Estimated time spent per each **2027** OASIS SOC Assessment/Patient = 57.3 clinician minutes		
- 204 data elements x (range of 0.15 to 0.3) minutes per data element = 57.3 minutes of clinical time spent to complete data entry for the OASIS SOC assessment.		
- ● 23 data elements counted as 0.15 minutes/data element (3.45 minutes).	- ● 9 data elements counted as 0.25 minutes/ data element (2.25 minutes).	- ● 172 data elements counted as 0.30 minutes/ data element (51.6 minutes).
- Clinician Estimated hourly burden for all HHAs (11,904) for **2027** OASIS SOC assessments = 8,228,553 hours		
- 57.3 clinician minutes per SOC assessment x 8,616,286 assessments = 493,713,188 minutes/60 minutes per hour = 8,228,553 hours for all HHAs		
- Clinician Estimated hourly burden for all HHAs (11,904) for **2027** OASIS SOC assessments = 8,228,553 hours		
-		
- Estimated time spent per each **2026** OASIS SOC Assessment/Patient = 56.4 clinician minutes.		
- 200 data elements x (range of 0.15 to 0.3) minutes per data element = 56.4 minutes of clinical time spent to complete data entry for the OASIS-E1 SOC assessment.		

- ● 21 data elements counted as 0.15 minutes/data element (3.15 minutes).	- ● 9 data elements counted as 0.25 minutes/data element (2.25 minutes).	- ● 170 data elements counted as 0.30 minutes/data element (51 minutes).
-		
- Clinician Estimated hourly burden for all HHAs (11,904) for **2026** OASIS SOC assessments = 8,099,309 hours		
- 56.4 clinician minutes per SOC assessment x 8,616,286 assessments =485,958,530 minutes/60 minutes per hour = 8,099,309 hours for all HHAs.		

- **RESUMPTION OF CARE**		
- Estimated time spent per each **2027** OASIS ROC Assessment/Patient = 48 minutes		
- 172 data elements x (range of 0.15 to 0.3) minutes per data element = 48 minutes of clinical time spent to complete data entry for the OASIS ROC assessment		
- ● 21 data elements counted as 0.15 minute/data element (3.15 minutes)	- ● 9 data elements counted as 0.25 minute/data element (2.25 minutes)	- ● 142 data elements counted as 0.30 minute/data element (42.6 minutes)
-	-	-
- Clinician Estimated Hourly Burden for all HHAs for **2027** OASIS ROC assessments = 947,694 hours		
- 48 clinician minutes per ROC assessment x 1,184,618 ROC assessments = 56,861,664 minutes/60 minutes = 947,694 hours for all HHAs		
-		
- Estimated time spent per each **2026** OASIS-E1 ROC Assessment/Patient = 47.1 minutes		
- 168 data elements x (range of 0.15 to 0.3) minutes per data element = 47.1 minutes of clinical time spent to complete data entry for the OASIS-E1 ROC assessment		
- ● 19 data elements counted as 0.15 minute/data element (2.85 minutes)	- ● 9 data elements counted as 0.25 minute/data element (2.25 minutes)	- ● 140 data elements counted as 0.30 minute/data element (42 minutes)
-		
- Clinician Estimated Hourly Burden for all HHAs for **2026** OASIS-E1 ROC assessments =823,310 hours		
- 47.1 clinician minutes per ROC assessment x 1,184,618 ROC assessments = 55,795,508 minutes/60 minutes = 929,925 hours for all HHAs		

- **TRANSFER OF CARE**		
- Estimated time spent per each **2027** OASIS TOC Assessment/Patient = 6.9 minutes		
- 23 data elements x 0.3 minutes per data element = 6.9 minutes of clinical time spent to complete data entry for the OASIS TOC assessment		
- ● 23 data elements counted as 0.3 minutes/ data element (6.9 minutes)	-	-
-		
- Clinician Estimated Hourly Burden for all HHAs for **2027** OASIS TOC assessments = 271,927 hours		
- 6.9 clinician minutes per TOC assessment x 2,364,588 TOC assessments = 16,315,657 minutes/60 minutes = 271,927 hours for all HHAs		
-		
- Estimated time spent per each **2026** OASIS TOC Assessment/Patient = 6.6 minutes		
- 22 data elements x 0.3 minutes per data element = 6.6		
- ● 22 data elements counted as 0.3 minutes/data element (6.6 minutes)	-	-
-		
- Clinician Estimated Hourly Burden for all HHAs for **2026** OASIS TOC assessments = 260,105 hours		

- 6.6 clinician minutes per TOC assessment x 2,364,588 TOC assessments = 15,606,281 minutes/60 minutes=260,105 hours for all HHAs

- **DEATH AT HOME**		
- Estimated time spent per each **2027** OASIS-E1 DAH Assessment/Patient = 3 minutes		
- 10 data elements x 0.3 minutes per data element = 3 minutes of clinical time spent to complete data entry for the OASIS DAH assessment		
- ● 10 data elements counted as 0.3 minutes/data element (3 minutes)	-	-
-		
- Clinician Estimated Hourly Burden for all HHAs for **2027** OASIS DAH assessments = 3,146 hours		
- 3 clinician minutes per DAH assessment x 62,917 DAH assessments = 188,751 minutes/60 minutes=3,146 hours for all HHAs.	-	-
-		
- Estimated time spent per each **2026** OASIS-E1 DAH Assessment/Patient = 2.7 minutes		
- ● 9 data elements counted as 0.3 minutes/data element (2.7 minutes)	-	-
-		
- Clinician Estimated Hourly Burden for all HHAs for **2026** OASIS DAH assessments = 2,831 hours		
- 2.7 clinician minutes per DAH assessment x 62,917 DAH assessments = 169,876 minutes/60 minutes=2,831 hours for all HHAs		

- **DISCHARGE**		
- Estimated time spent per each **2027** OASIS DC Assessment/Patient = 40.2 minutes		
- 146 data elements x (range of 0.15 to 0.3) minutes per data element = 40.2 minutes of clinical time spent to complete data entry for the OASIS-E1 DC assessment		
- ● 21 data elements counted as 0.15 minutes/data element (3.15 minutes)	- ● 9 data elements counted as 0.25 minutes/data element (2.25 minutes)	- ● 116 data elements counted as 0.30 minutes/data element (34.8 minutes)
-		
- Clinician Estimated Hourly Burden for all HHAs for **2027** OASIS DC assessments = 4,694,090 hours		
- 40.2 clinician minutes per DC assessment x 7,006,104 DC assessments = 281,645,381minutes/60 minutes =4,694,090 hours for all HHAs		
-		
- Estimated time spent per each **2026** OASIS DC Assessment/Patient = 39.9 minutes		
- 145 data elements x (range of 0.15 to 0.3) minutes per data element = 39.9 minutes of clinical time spent to complete data entry for the OASIS DC assessment		
- ● 21 data elements counted as 0.15 minute/data element (3.15 minutes)	- ● 9 data elements counted as 0.25 minute/data element (2.25 minutes)	- ● 115 data elements counted as 0.30 minute/data element (34.5 minutes)
-		
- Clinician Estimated Hourly Burden for all HHAs for **2026** OASIS DC assessments = 4,659,059 hours		
- 39.9 clinician minutes per DC assessment x 7,006,104 DC assessments = 279,543,550 minutes/60 minutes = 4,659,059 hours for all HHAs		

Table 40 summarizes the estimated clinician hourly burden for the OASIS that will be implemented in 2026 with the finalized changes of a decrease in four data elements at start of care and resumption of care and a decrease in a data element at transfer of care, death at home, and discharge compared to the originally scheduled 2027 OASIS burden if these reductions were not implemented. This is calculated by multiplying the total number of assessments by the decrease in assessment time required. We calculate the 2027 and 2026 burden estimates in minutes and then calculate hourly burden estimates shown in Table 40. We estimated a net decrease of 194,181 hours of clinician burden across all HHAs or 16.31 hours (194,181/11,904) for each of the 11,904 active HHAs.

TABLE 40. SUMMARY OF ESTIMATED CLINICIAN HOURLY BURDEN FOR CY 2027 AND CY 2026 OASIS

OASIS Assessment Type	Clinician Estimated SOC/ROC Hourly Burden – OASIS 2027	Clinician Estimated SOC/ROC Hourly Burden – OASIS 2026	Total Decrease in Hours
Start of Care	8,228,553	8,099,309	-129,244
Resumption of Care	947,694	929,925	-17,769
Transfer of Care	271,927	260,105	-11,822
Death at Home	,146	32,831	-315
Discharge	4,694,090	4,659,059	-35,031
Totals	14,145,410	13,951,229	-194,181

Table 41 summarizes the estimated clinician costs for the 2027 OASIS and the 2026 OASIS with the net reduction of four data elements at start of care and resumption of care and one data element removed from transfer of care, death at home, and discharge using CY 2024 BLS wage inputs. Total clinician costs for 2027 and 2026 are estimated by multiplying total hourly burden for each year as reported in table 40 by the weighted clinician average hourly wage of $91.72. We then calculate the difference in clinician-estimated costs between 2027 and 2026. This calculates the estimated decrease in costs associated with adding the four data elements at the start of care and resumption of care and removing a data element at transfer of care, death at home, and discharge. For the COVID-19 items collected at transfer of care, death at home, and discharge, we estimate a decrease in clinician cost of $4,326,249 or $363 ($4,326,249/11,904) for each of the 11,904 active HHAs. For the four SDOH data elements

removed at the start of care or resumption of care, we estimate a decrease in clinician cost of $13,484,033 or $1,133 ($13,484,033/11,904) for each of the 11,904 active HHAs. For all proposals, we estimate a decrease in clinician costs of $17,786,980 between 2027 and 2026 related to the implementation of the proposals outlined in the proposed rule across all HHAs or a $1,494 decrease (-$17,786,980/11,904) for each of the 11,904 active HHAs. This decrease in burden will begin with the April 1, 2026, OASIS assessments. The burden estimates detailed in this section have been submitted for OMB review and approval as part of revision of the information collection request currently approved under OMB control number 0938-1279[85]...

TABLE 41. SUMMARY OF ESTIMATED CLINICIAN COSTS FOR CYs 2027 AND 2026

OASIS Assessment Type	Clinician Estimated Cost – OASIS 2027	Clinician Estimated Cost – OASIS-E1 2026	Total Cost
Start of Care	$754,722,881	$742,868,621	-$11,854,260
Resumption of Care	$86,922,494	$85,292,721	-$1,629,773
Transfer of Care	$24,941,144	$23,856,831	-$1,084,313
Death at Home	$288,551	$259,659	-$28,892
Discharge	$430,541,935	$427,328,891	-$3,213,044
Totals	$1,297,417,005	$1,279,606,723	-$17,810,282

(1) COVID-19 Data Element Burden

Comment: A majority of commenters supported the CMS recommendation to remove the COVID-19 Vaccine: Percent of Patients Who Are Up to Date measure from the HHQRP with most citing the collection burden associated with the measure. Many commenters highlighted the many other sources that can provide national COVID-19 vaccination rates.

Response: We thank commenters for their support. We agree that the burden associated with this measure, including the resources spent by HH staff in trying to ascertain patients' vaccination status, outweigh the benefit of its continued use in the program, given the end of the PHE, the decrease in COVID cases as well as the availability of treatments. After consideration of the public comments, we are finalizing our proposal to remove the COVID-19 Vaccine:

85 The currently approved OASIS information collection request expires 12/31/2027. https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202406-0938-007

Percent of Patients/Residents Who Are Up to Date measure from the HH QRP beginning with the CY 2026 HH QRP. Beginning with patients discharged on or after April 1, 2026, HHAs would not be required to collect and submit the Patient/Resident COVID-19 Vaccine measure data to CMS. Until that time and with the posting of this final rule, HHAs may submit any valid response (0 – No, 1-Yes or dash) on a Transfer, Death at home, or Discharge OASIS assessment, without any future quality measure implications.

(2) SDOH Data Elements Burden

Comment: A slight majority of commenters supported the proposal to remove the four standardized patient assessment data elements focused on collecting information related to SDOH. These commenters often acknowledged the importance of better understanding of SDOH in addressing healthcare challenges but noted that there may be less burdensome methods to obtaining the required SDOH data.

Response: We thank commenters for their support for our proposal to remove these four SDOH items from the standardized patient assessment data elements collected and submitted using the OASIS. We continue to monitor the HH QRP data collection requirements to look for ways to reduce administrative burden, where appropriate, while maintaining a high standard of quality care. We agree that removing these items at this time will alleviate some of the burden on HH providers associated with HH QRP data collection and submission requirements. We intend to align the HH QRP more closely with our overarching goal for improved health care delivery through health IT advances and low-burden interoperable electronic systems. As we stated in the CY 2026 HH PPS proposed rule (90 FR 2908), we plan to refocus efforts on how data elements can improve care coordination, efficiency, reduction in errors, and patient experience.

Final Decision: After consideration of the public comments, we are finalizing our proposal to remove four standardized patient assessment data elements (one item for Living Situation (R0310); two items for Food (R0320A and R0320B); and one item for Utilities

(R0330)) collected under the SDOH category from the HH QRP beginning with the CY 2026 HH QRP without modification.

c. ICRs for the Modification of the HHCAHPS Survey

Beginning with the CY 2027 Public Reporting Period/CY 2028 Payment Determination as described in section III.H. of the proposed rule, we proposed to modify the HHCAHPS Survey measure beginning in April 2026. Specifically, the updated measures include updates to the Care of Patients and Communication between Providers and Patients measures, and removal of Specific Care Issues measure and replacing this measure with three single-item measures related to reviewing home safety, reviewing medications and discussing side effects of medications. As part of these changes, the HHCAHPS Survey is being reduced by 8 survey items. Under OMB control number 0938-1066[86], we estimated the time to complete the current HHCAHPS Survey to be approximately 12 minutes per respondent and approximately 1,043,447 respondents would complete and submit the HHCAHPS Survey as part of the Home Health Quality Reporting Program annually. We estimated the combination of survey removals and additions would result in a decrease of 3 minutes (.05 hour) per respondent to complete the updated version of the HHCAHPS Survey. Therefore, we estimated the updated time to complete the shorter HHCAHPS Survey would be 9 minutes per respondent (0.15 hour) at $32.66 per hour.[87] Our estimate is based on the written length of the survey and CMS's experience with the revised survey during the mode experiment (CMS 10784, OMB control number 0938-1404). In aggregate, we estimated a burden of 153,884 hours (1,025,894 patients (updated estimated of number of patients) x 0.15 hr.) at a cost of $5,025,851 (153,884 hr. x $32.66/hr.) or $4.90 per survey ($5,025,851 /1,025,894 patients). The burden estimates detailed in this section will be

86 The currently approved HHCAHPS information collection request expires July 31, 2026.

87 To derive the average costs for individuals, we used data from the U.S. Bureau of Labor Statistics' May 2024 National Occupational Employment and Wage Estimates for our salary estimate (www.bls.gov/oes/current/oes_nat.htm). We believe that the burden will be addressed under All Occupations (occupation code 00-0000) at $32.66/hr. since the group of individual respondents varies widely from working and nonworking individuals and by respondent age, location, years of employment, and educational attainment, etc. Unlike our private sector adjustment to the respondent hourly wage (see below), we are not adjusting this figure for fringe benefits and overhead since the individuals' activities would occur outside the scope of their employment.

submitted for OMB review and approval as part of revision of the information collection request currently approved under OMB control number 0938-1066.

2. ICRs for the Expanded HHVBP Model

a. ICRs for the Changes to the Measure Removal Factors and HHVBP Model Applicable Measure Set

The changes to the measure removal factors, changes to the HHVBP applicable measure set, and the RFI for the expanded HHVBP Model included in section IV. of the proposed rule do not result in an increase in costs to HHAs. Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the expanded HHVBP Model, from the provisions of the PRA. Specifically, this section provides that the provisions of the PRA do not apply to the testing and evaluation of Innovation Center models or to the expansion of such models.

3. ICRs for Updates to the Home Health Agency Conditions of Participation (CoPs) to Align with the OASIS All-Payer Submission Requirements

As discussed in section V. of the final rule, we proposed technical revisions to the HHA CoPs to further clarify that the existing requirement for reporting OASIS information applies to all HHA patients receiving skilled services. This technical change sought to provide clarity by creating alignment between the terminology used in the CoPs and requirements for data collection and submission to OASIS for purposes of the HH QRP. CMS did not propose to introduce any new required OASIS items with the implementation of the all payer proposal that would require a change to OASIS submission processes nor did CMS propose to require any change to HHA electronic medical record systems. HHAs will continue to have access to technical support relative to submission of OASIS data via the QIES Technical Support Office website https://qtso.cms.gov/ and iQIES team at CMS. For a review of the burden and operational costs associated with the transition to the OASIS all-payer submission requirements we refer readers to the CY 2023 HH PPS final rule “Collection of Information” section (87 FR

66877 through 66879) and to the CY 2024 HH PPS final rule for the latest burden estimates (88 FR 77850 through 77855).

Comment: A commenter requested additional clarification regarding the OASIS all-payer requirements. The commenter noted that the proposed policy shift would be a significant operations change for HHAs and the electronic medical record (EMR) systems they utilize. The commenter suggested CMS update the OASIS validation rules and engage EMR vendors in pilot testing.

Response: While the commenter noted the operational change that this policy requires, HHAs have had substantial time to prepare for the transition to the OASIS all-payer requirement as this policy was initially finalized in 2022 in the CY 2023 HH PPS final rule (87 FR 66862). This requirement does not revise the previously-finalized requirements for submitting data to OASIS and does change the data required to be collected that was finalized in the CY 2023 HH PPS final rule. Therefore, we do not believe this technical change would result in an increase in burden for HHAs. After consideration of public comment, we are finalizing the technical changes to the CoPs as proposed. These technical changes to update terminology further clarify that the requirement for reporting OASIS information applies to all HHA patients receiving skilled services and align the language in the CoPs with the requirements finalized in the CY 2023 and CY 2025 HH PPS final rules.

4. Medicare and Medicaid Provider Enrollment

As discussed in section VI.A. of this final rule, we proposed and are finalizing several changes to our Medicare provider enrollment regulations, with one minor revision to a Medicaid provider enrollment provision in 42 CFR part 455, subpart E. Except as otherwise explained in this section VIII. of this final rule, we do not believe that any of our provider enrollment provisions implicate an ICR burden.

a. Submission of Additional Documentation

We proposed to add new paragraph (C) to § 424.510(d)(2)(iii) such that CMS could require a provider or supplier to submit any documentation (that is, documentation beyond that currently required under § 424.510(d)(1)) to verify and confirm the information furnished on the enrollment application; this includes, but is not limited to, documentation regarding the provider's or supplier's ownership or management. We cannot predict the number or types of providers and suppliers that would be requested to provide such documentation or the specific documentation involved; this is because it would vary widely by provider and supplier. Nonetheless, we believe a general estimate, solely for purposes of this ICR section, is possible.

In terms of cost, it has been our experience that Form CMS-855 applications are completed by the provider's or supplier's office staff. Accordingly, we will use the following wage category and hourly rate from the U.S. Bureau of Labor Statistics' (BLS) May 2024 National Occupational Employment and Wage Estimates for all salary estimates (https://data.bls.gov/oes/#/industry/000000).

TABLE 42: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES – PROVIDER ENROLLMENT

Occupation Title	Occupation Code	Median Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Office and Administrative Support Workers, All Other	43-9199	22.14	22.14	44.28

We anticipated that: (1) most of the requested documentation would be that which helps validate the provider's or supplier's ownership and management; (2) 5,000 providers and suppliers per year would have to secure and submit it; and (3) it would take the provider or supplier 15 minutes (0.25 hr) to do so. This results in an annual burden of 1,250 hours and $55,350 ($44.28 x 5,000 x 0.25).

b. DMEPOS Liability Insurance

To enroll and maintain enrollment in the Medicare program, DMEPOS suppliers under §424.57(c)(10) must have a comprehensive liability insurance policy of at least $300,000 that

covers the supplier's place of business, customers, and employees. We proposed to revise § 424.57(c)(10) such that an "authorized official" of the DMEPOS supplier (as that term is defined in §424.502) must sign the liability insurance policy. We do not have data indicating the number of DMEPOS suppliers whose liability insurance policies are signed by: (1) an authorized official; or (2) someone of equivalent status within the organization who nonetheless may not be listed as an authorized official on the supplier's application. Therefore, we are unable to project any ICR burden associated with this change. However, we solicited comment from the DMEPOS supplier community on the possible burden.

c. Miscellaneous

We also proposed in § 424.516 to reduce the timeframe in which a provider or supplier must report an adverse legal action to CMS from 90 days to 30 days. We do not believe this would result in a change in provider burden. This is because regardless of the reporting timeframe involved, the change must be reported; that is, only the timeframe for disclosure is changing, not the burden.

We received no comments on our provider enrollment ICR burden estimates and are therefore finalizing them as proposed.

5. DMEPOS Supplier Accreditation Organizations (AOs)

Section 424.57 requires that DMEPOS suppliers be accredited by a CMS-approved AO to enroll in and bill the Medicare program. The main purpose of accreditation is to confirm -- typically via a survey of the DMEPOS supplier's location -- that the supplier meets detailed quality standards involving, for example, its administration, financial management, customer service, and DMEPOS product safety. Section 424.58, which was promulgated in 2006, outlines some of the components and requirements of the DMEPOS accreditation program, which CMS oversees but the AOs largely operate. These components include but are not limited to: (1) the process via which an organization can apply to become an AO; and (2) AO submission of accreditation data to CMS.

T wo core concerns have arisen regarding aspects of the DMEPOS accreditation program. First, non-compliance with the quality standards among DMEPOS suppliers has continued notwithstanding the accreditation requirement. Second, we believe that the current provisions in § 424.58 must be strengthened to help ensure that AOs are adequately executing their DMEPOS accreditation activities. In our view, and as explained in section VI.B. of the proposed rule, we believe additional requirements are needed and proposed (and are finalizing) a number of them.

This section VIII of the this final outlines the estimated ICR burden associated with several of these data categories. Other costs are addressed in the regulatory impact analysis (RIA) of this final rule. We note that only those categories that involve a new burden – that is, above and beyond the current provisions of § 424.58 – are addressed.

a. Submission of Data During AO Initial Application and Reapproval Application

Current §424.58(b) (which would become new paragraphs (c) and (d)) outlines information that organizations must submit when applying or reapplying to become a DMEPOS AO. We proposed additional data that must be provided in these situations. These data elements are outlined in Table 43, which also lists our estimated hour burden of compiling, preparing, drafting, and submitting this information.

TABLE 43: NEW DATA SUBMISSION ELEMENTS IN PROPOSED § 424.58(c) AND (d)

Regulatory Citation in Revised § 424.58(c)	Data Element	Estimated Hour Burden Per Submission
(c)(1)(iii)	Description of survey and other accreditation processes	4
(c)(1)(iii)(G)	How AO determines whether to perform survey (including sampling methodology)	2
(c)(1)(vii)(D)	Policies/procedures for avoiding conflicts of interest (including consulting firewall policies)	2
(c)(1)(vii)(E)	Policies/procedures for ensuring adequate number of surveyors	2
(c)(1)(viii)	Process for identifying/addressing deficiencies within its accreditation program	3
(c)(1)(ix)	How AO uses data to ensure compliance with Medicare program requirements	3
(c)(1)(x)(A) and (B)	Outline of steps AO would take in reviewing complaints and determining compliance	3
(c)(xvi)	Information demonstrating AO's DMEPOS knowledge/expertise/experience	2
(c)(xvii)	Information on AO's ability to conduct timely application reviews	2
(c)(xviii)	Description of decision-making process (including approving/denying/terminating a DMEPOS supplier's accreditation and the reasons for denial or termination)	4
(c)(xix)	Policies/procedures for determining whether/when survey is performed and ensuring unannounced surveys	2
(c)(xx)	Policies/procedures for when CAP applied	4
(c)(xxi)	Explanation of what AO deems and defines as deficiency and levels thereof	2

Regulatory Citation in Revised § 424.58(c)	Data Element	Estimated Hour Burden Per Submission
(c)(xxii)	Processes for detecting/reporting fraud, waste, and abuse	3
(c)(xxiii)	Signed statement/agreement	6
(c)(2)	Submission of additional application information per CMS request	8
	Total Hour Burden Per Application Submission	52

As we believe that clinicians (such as nurses) and AO managers would be most likely to prepare and submit the application, we would use the following May 2024 BLS median wage categories:

TABLE 44: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Median Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Registered Nurses	29-1141	45.00	45.00	90.00
Medical and Health Services Managers	11-9111	56.71	56.71	113.42
Office and Administrative Support Workers, All Other	43-9199	22.14	22.14	44.28
General and Operations Managers	11-1201	49.50	49.50	99.00

The aforementioned statement in § 424.58(c)(1)(xxiii) must be signed by the AO's chief executive officer (CEO) or someone with equivalent authority within the AO. To account for this task, we would also use May 2024 BLS median wage category of "Chief Executives" (Occupation Code 11-1011). The wage amount is $99.24; with fringe benefits and overhead, it is $198.48.

There are currently 8 CMS-approved DMEPOS AOs. For purposes of this ICR estimate only, we assume that all 8 would apply for reapproval sometime within the next 3-year timeframe (which is the standard OMB approval period) and that 2 organizations would initially apply for AO approval. This would result in a total hour burden for this period of 520 hours (52 hours x 10 organizations). Of these 520 hours, 10 hours (or 1 hour for each of the 10 AOs) would involve the CEO's review and signature of the statement, resulting in a cost of $1,985 (10 x $198.48). As for the remaining 510 hours, we believe that nurses and the aforementioned managers would be equally involved in preparing the application. We would hence use a

midpoint wage estimate of $101.71 (($90.00 + $113.42)/2). This results in a total 3-year cost of $53,857 (($101.71 x 510 hours) + $1,985), with an annual burden of 173 hours and $17,952.

Except as otherwise noted, we will use the $101.71 wage figure for the remainder of our DMEPOS accreditation ICR estimates.

b. Monthly Submission of Data

Existing § 424.58(c)(1) (new paragraph (e)(1)(i)) requires AOs to submit certain data to CMS on a monthly basis (for example, notice of accreditation decisions). We proposed in new paragraph (e)(1) that each AO must also – as part of its monthly submission to CMS -- furnish notice of: (1) the instances where the AO had the discretion to perform a survey but decided not to (including the reason for the AO's decision); and (2) all currently resolved deficiencies among its DMEPOS suppliers.

Although we cannot determine how many DMEPOS AOs there would be over the next 3 years, we will - for purposes of this ICR only - use the current number of 8 AOs.

We estimate it would take an AO a total of 6 hours each month to compile and submit the data in (1) and (2). (That is, about 3 hours for each task.) This would result in an ICR burden over 3 years of 1,728 hours (6 hours x 8 AOs x 12 months x 3 years) at a cost of $175,755 (1,728 hours x $101.71), with the annual burden being 576 hours and $58,585.

c. CMS Ad-Hoc Data Requests

We noted that new paragraph (e)(1)(ii) would state that CMS may at any time request the AO to submit any of the information described in paragraph (e)(1)(i); this data must be furnished to CMS within 3 business days of the request. We cannot predict the number of instances where CMS would request this data or the specific information that would be solicited. However, solely for purposes of this ICR, we estimate that we would request paragraph (e)(1)(i) data from each AO 3 times per year and that it would take the AO 3 hours to accumulate data for each request. This would result in a 3-year burden of 216 hours (3 hours x 3 requests x 8 AOs x 3 years) and $21,969 (216 x $101.71). The annual burden would be 72 hours and $7,323.

d. Notice to CMS of Changes to the AO's Accreditation Standards, Requirements, or Survey Process

Among the monthly data the AO must submit under current paragraph (c)(1)(v) is notice of any changes to the AO's accreditation standards, requirements, or survey process. We proposed to remove this provision from the monthly reporting requirement and instead in new paragraph (e)(2) require the AO to: (1) report such changes to us 60 days before the planned effective date; and (2) submit detailed information about the changes, the rationale for them, and an accompanying crosswalk. We do not expect the 60-day requirement to impose an additional burden since the changes would still be reported to us, but we believe the additional information in (2) that must be furnished would.

Per our experience, each AO undertakes and reports these program revisions to us about twice per year. We estimate that the additional details that must be submitted would take 2 hours for the AO to compile. The resulting 3-year burden would thus be 96 hours (2 per year x 2 hours x 8 AOs x 3 years) and $9,764 (96 x $101.71), with the annual burden being 32 hours and $3,255.

e. Submission of Complaint Data

AOs under existing § 424.58(c)(1)(iii) must report to CMS each month all complaints related to DMEPOS suppliers. We proposed to remove this requirement from § 424.58(c)(1)(iii) and establish a new paragraph (e)(3) devoted exclusively to complaints. There are two new ICR-related provisions therein. Specifically--

- Upon receipt of a complaint, the AO must notify CMS in writing of the complaint within 5 calendar days of receiving it; and
- Notify CMS in writing of the result of its review of the complaint, the result of the survey, or of any action the AO took against the supplier.

The more frequent reporting of complaints to CMS -- as well as notice of the results of the AO's investigation – would constitute an additional ICR burden. Given the number of

complaints currently reported to us on a monthly basis, we estimate that each AO would annually report 50 complaints to us and, in turn, submit 50 investigation reports to us. We project that the former would take 1 hour to complete and submit and the latter 3 hours, for an average of 2 hours. This results in a 3-year burden of 4,800 hours ((50 complaint reports + 50 investigation reports)) x 2 hours x 8 AOs x 3 years) at a cost of $488,208 (4,800 x $101.71), with the annual burden being 1,600 hours and $162,736.

f. Corrective Action Plans (CAPs)

New paragraph (e)(4) would require AOs to notify CMS in writing of any decision to apply a CAP to a specific supplier within 10 calendar days of the decision. The notice must include: (1) the reason for the decision; (2) a detailed explanation and justification as to why the AO applied a CAP instead of revoking the supplier's accreditation; and (3) the details of the supplier's CAP. We believe that each AO would submit approximately 75 such notices to CMS per year and that each notice would take 2 hours to complete. The 3-year burden would therefore be 3,600 hours (75 submissions x 2 hours x 8 AOs x 3 years) and $366,156 (3,600 x $101.71). The annual burden would be 1,200 hours and $122,052.

g. Denials and Terminations of DMEPOS Supplier's Accreditation

Under proposed §424.58(e)(5)(i), the AO must notify CMS in writing of any decision to deny accreditation to (or terminate the accreditation of) a DMEPOS supplier within 5 calendar days of the decision; the notification must include the reason for the denial or termination. While AOs are currently required under §424.58(c)(1)(iv) to report DMEPOS supplier terminations to CMS on a monthly basis, new paragraph (e)(5) would increase the frequency with which this information must be provided. We project that each AO would submit approximately 100 such reports to CMS each year. Each report would take 2 hours to prepare and submit. This would result in a 3-year burden of 4,800 hours (100 reports x 8 AOs x 3 years x 2 hours) and $488,208 (4,800 x $101.71) and an annual burden of 1,600 hours and $162,736.

Proposed §424.58(e)(5)(ii)(A)*(5)* would require an AO to deny or terminate a DMEPOS supplier's accreditation if directed by CMS. The AO under §424.58(e)(5)(ii)(B)(*2*) would also have to notify CMS in writing that it has taken the directed action. We estimate that each year an AO would submit roughly 20 notices to CMS and that it would take 0.5 hours for the AO to do so each time. The total 3-year burden would thus be 240 hours (20 reports x 0.5 x 8 AOs x 3 years) and $24,410 (240 hours x $101.71). The annual burden would be 80 hours and $8,137.

h. Voluntary Terminations

New §424.58(g) would outline procedures via which an AO can voluntarily withdraw from the DMEPOS accreditation program. Part of this process involves: (1) notifying CMS in writing of its decision; and (2) providing written notice to each of its accredited DMEPOS suppliers. For purposes of this ICR only, we estimate that 1 DMEPOS AO over a 3-year period would voluntarily terminate its accreditation and that the tasks in (1) and (2) would take the AO 6 hours combined to complete (mostly involving the second task, which we believe would be done via a listserv message to all suppliers) at a cost of $610 (1 x 6 hours x $101.71). The annual burden would be 2 hours and $203.

i. Involuntary Terminations

New §424.58(h)(4) would require a terminated AO to provide written notice of the termination to each of its accredited DMEPOS suppliers. As with voluntary terminations, we estimate that 1 DMEPOS AO over a 3-year period would have its CMS approval terminated. We estimate it would take the AO 6 hours to notify its DMEPOS suppliers of the termination via a list-serv message. This would result in a 3-year burden of 6 hours at a cost of $610. The annual burden would be 2 hours and $203.

j. Acknowledgement of Suspension and Lifting Thereof

New §424.58(i) states that if CMS notifies the AO that its accreditation program has been suspended, the AO must send CMS a written acknowledgment of CMS' notice. Likewise, the AO must notify CMS in writing of its acknowledgment of a CMS notification that the

suspension has been lifted. We project that 1 AO over a 3-year period would be suspended and that each of the two acknowledgments would take 1 hour to complete and submit. The 3-year burden would hence be 2 hours (1 hour x 2 acknowledgments) at a cost of $203. The annual burden would be 0.667 hours and $68.

k. Conflicts of Interest and Consulting

New §424.58(m) and (n) would establish requirements regarding AO consulting services and conflicts of interest, respectively. There are two principal ICR aspects of these requirements:

- The AO's submission of a report upon CMS request regarding any consulting activities it has engaged or is engaging in (paragraph (m)(4)).
- Preparation and submission to CMS (upon the latter's request) of the AO's written consulting firewall polices (paragraph (m)(5)).

(These documents must also be submitted with an AO's request for initial approval or reapproval of its DMEPOS accreditation program, though the burden associated with this is included in the ICR calculations for AO initial and reapproval applications.)

We project that the report in paragraph (m)(4) would take an AO 2 hours to complete and submit and that CMS would request it twice per year. This would result in a 3-year burden of 96 hours (2 reports per year x 2 hours x 8 AOs x 3 years) and $9,764 (96 x $101.71), or 32 hours and $3,255 annually. Regarding the firewall policies and procedures, we estimate that it would take the AO 2 hours to prepare and submit these policies and that CMS would request them once a year. The 3-year burden of this activity would be 48 hours (2 hours x 1 request per year x 8 AOs x 3 years) and $4,882, or 16 hours and $1,627 per year. The combined annual ICR burden of the requirements of paragraph (m) are 48 hours (32 + 16) and $4,882 ($3,255 + $1,627).

l. AO Changes of Ownership

We proposed in new §424.58(o) procedures for which a DMEPOS AO can undergo a change of ownership. Said procedures would be those outlined in § 488.5(f). The latter section contains several actions that we believe would have ICR implications for an AO changing its

ownership. Table 45 outlines these actions and the estimated time burden of completing each of them:

TABLE 45: NEW DATA SUBMISSION ELEMENTS IN PROPOSED § 424.58(o)

Regulatory Citation in § 488.5(f)	Action	Estimated Hour Burden Per Action
(f)(1)	DMEPOS AO contemplating or negotiating a change of ownership must notify CMS in writing.	2
(f)(2)(iii)	Prospective AO buyer must submit detailed data in its request for approval of transfer of AO's current approval to the buyer (that is, identifying information, financial statements, transition plan, policies to avoid conflicts of interest).	135
(f)(3) and (4)(ii)	Prospective AO buyer's submission of written acknowledgments to CMS.	2
(f)(4)(i) *	All parties to the transaction must notify all affected DMEPOS suppliers of any CMS approval of the transfer.	12
(f)(5)	Prospective AO buyer notifies CMS in writing that the change of ownership has occurred.	1
TOTAL		152

* Takes into account the aforementioned 6-hour supplier notification burden for voluntary and involuntary terminations.

Regarding the 135-hour burden for § 488.5(f)(2)(iii), we note that we published a final rule in the April 29, 2022, **Federal Register** titled "Medicare Program; Accrediting Organizations—Changes of Ownership" (87 FR 25413). This final rule added new requirements and processes for AO changes of ownership. The estimated burden therein for the activity in § 488.5(f)(2)(iii) was 135 hours, and the material to be submitted would be prepared by individuals in the BLS wage categories of Registered Nurse, Medical or Health Services Manager, and Accountant or Auditor (Occupation Code 13-2011). Therefore, we would use this hour burden for paragraph (f)(2)(iii) (as applied to DMEPOS AO ownership changes) and a combined average wage for these three BLS categories. We previously mentioned the wages for the first two categories, $90.00 and $113.42. For accountants and auditors, the median wage with fringe benefits and overhead is $78.54. The average of these three figures is $93.99.

We assume for purposes of this ICR that 1 DMEPOS AO over a 3-year period would undergo a change of ownership. Using our total hour burden from table 45G8, this would result in a 3-year burden of 152 hours and $14,286. The annual burden would be 51 hours and $4,762.

m. DMEPOS Supplier Change in Majority Ownership

We proposed in new §424.551 that a DMEPOS supplier that undergoes a change in majority ownership (CIMO) (as that term is defined in § 424.551) that does not qualify for an exception under that section must enroll in Medicare as an initial DMEPOS supplier, obtain a new accreditation, and receive an accreditation survey. This would require completion of an initial Form CMS-855S Medicare Enrollment Application - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers[88]., OMB No.: 0938-1056).

We projected in section IX. of the proposed rule that an average of 3,768 DMEPOS suppliers each year have a CIMO. We currently require any DMEPOS supplier undergoing a change of ownership involving a new tax identification number to enroll in Medicare as a new supplier. Since these suppliers already have to complete a new enrollment application, there would be no change in their Form CMS-855S information collection burden. Although we do not have concrete estimates as to what portion of the 3,768 suppliers fall into this category, we believe it is roughly 400-500. We will therefore base our Form CMS-855S burden projections on an estimated 3,300 affected suppliers.

Per previous projections, completion of an initial Form CMS-855S application takes approximately 4 hours, resulting in an annual time burden of 13,200 hours (3,300 hours x 4). In terms of costs, office and administrative support workers (BLS median wage of $44.28) complete the application for a 3.5-hour burden, and a general and operations manager ($99.00 wage) spends 0.5 hours reviewing and signing the form. This results in an annual cost burden of $674,784 ((3.5 hours x 3,300 x $44.28) + (0.5 hours x 3,300 x $99.00)).

n. Totals

Table 46 outlines the annual ICR burdens associated with our proposed DMEPOS accreditation provisions:

TABLE 46: ANNUAL ICR BURDEN ESTIMATES FOR DMEPOS AO REQUIREMENTS

88 The currently approved CMS-855S information collection request expires 12/31/2025.

	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($) (includes 100% fringe benefits)	Total Cost ($)
Submission of Additional Initial Application and Reapproval Application Data	0938-New	4	4	Varies	173	101.71	17,596
Submission of Additional Monthly Data	0938-New	8	96	6	576	101.71	58,585
Ad-Hoc CMS Data Requests	0938-New	8	24	3	72	101.71	7,323
Notice of Changes in AO's Standards/Requirements	0938-New	8	16	2	32	101.71	3,255
Complaint Reports	0938-New	8	800	2 (average)	1,600	101.71	162,736
CAPs	0938-New	8	600	2	1,200	101.71	122,052
Denials/Terminations of Supplier's Accreditation Reports to CMS	0938-New	8	800	2	1,600	101.71	162,736
Notice to CMS that AO Denied/Terminated Supplier's Accreditation Per CMS Direction	0938-New	8	160	0.5	80	101.71	8,137
Voluntary Terminations – Notice to CMS and Suppliers	0938-New	0.333	0.333	6	2	101.71	203
Involuntary Termination – Notice to Suppliers	0938-New	0.333	0.333	6	2	101.71	203
Acknowledgment of Suspension and Lifting Thereof	0938-New	0.333	0.333	1	0.333	101.71	34
Consulting Data	0938-New	8	24	Varies	48	101.71	4,882
AO Changes of Ownership	0938-New	0.333	0.333	Varies	51	93.99	4,793
Completion of Initial Form CMS-855S	0938-1056	3,300	3,300	4	13,200	Varies	674,784
TOTALS (Rounded to Nearest Whole Dollar)	**N/A**	**3,369**	**5,825**	**Varies**	**18,636**	**Varies**	**1,227,319**

The costs of our DMEPOS accreditation provisions to DMEPOS suppliers – as well as additional costs to DMEPOS AOs – are addressed in section IX.C.6. of the proposed rule.

We solicited comment from stakeholders regarding any potential DMEPOS accreditation ICR burdens that may not have been addressed in this section VIII.B.5. of the proposed rule. The burden estimates detailed in this section will be submitted for OMB review and approval as part of new information collection request, (That is, a request for a new OMB control number.)

We did not receive any comments on our ICR estimates for our proposed DMEPOS accreditation provisions. We are thus finalizing them as proposed.

6. ICRs for the Exemption Process for Prior Authorization of Certain DMEPOS Items (§414.234(c)(1) and (c)(1)(ii))

We proposed to add technical language to § 414.234(c)(1) that provides for the exemption process in §414.234 (c)(1)(ii). We also proposed to exempt a supplier from the mandatory prior authorization process (OMB Control No. 0938-1293) in newly proposed § 414.234(c)(1)(ii)(A) upon demonstration of compliance with Medicare coverage, coding, and payment rules and that this exemption would remain in effect until CMS withdraws the exemption. In proposed § 414.234 (c)(1)(ii)(B), we would provide 60-day notice of an exemption from mandatory prior authorization requirements. Similarly, we proposed to provide 60-day

notice if an exemption is withdrawn. We would exempt suppliers that achieved a prior authorization provisional affirmation threshold of at least 90 percent during a periodic assessment. If the rate of prior authorizations with non-affirmations submitted becomes higher than 10 percent during an annual assessment, we would consider withdrawing exemption for the specific noncompliant supplier, until the following periodic assessment.

We estimated there would be savings for compliant suppliers who meet the 90 percent affirmation threshold. We based our savings estimates on presumptions, which we would discuss herein, and internal data obtained from the DME MACs. Compliant suppliers would not have to submit prior authorization requests (PARs). The burden associated with submitting prior authorization requests is the time and effort necessary for the submitter to locate and obtain the supporting documentation for the prior authorization request and to forward the materials to the MAC for review. CMS expects that this information would generally be maintained by suppliers as a normal course of business and that this information would be readily available. The documentation submitted must support medical necessity for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, Medicare benefit eligibility, and meet all other applicable Medicare statutory and regulatory requirements.

a. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (May 2024 Occupational Employment Statistics report) to find the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage. Based on the Bureau of Labor Statistics report (Healthcare Support Occupations), we estimate an average hourly rate of $19.06 with a loaded rate of $38.12.

The process of submitting, and unit cost of reviewing expedited prior authorization requests is the same for standard review. Items on the Required Prior Authorization List are rarely used in emergent situations, consequently, we expect the request for expedited reviews to remain low.

In addition to mail, suppliers can submit documentation through fax, electronic portals, and esMD, so supplier burden should not be affected by the method of submission. CMS estimates that the average time for office clerical activities associated with this task to be 30 minutes. Average labor costs (including 100 percent fringe benefits) used to estimate the costs are calculated using data available from the BLS.

We based the estimated number of responses for Year 1 on the number of prior authorization requests for the DMEPOS items currently on the Required Prior Authorization List for Calendar Year 2024. We estimate a 3 percent increase in the number of PARs received in CYs 2024, 2025, and 2026. In Year One (CY 2026) we anticipate that there would be 232,836 initial requests and 57,017 resubmissions.

We estimated around 30,000 initial prior authorization requests for DMEPOS items that could potentially be added to the Required Prior Authorization List in the future. Of these, we estimated only 80 percent would submit an initial prior authorization request, resulting in 24,000 additional initial requests, plus the estimated CY 2026 initial requests of 232,836, for a total of 256,836 initial requests in CY 2026.

We assumed that 20 percent of the estimated initial prior authorization requests received (256,836) would receive a non-affirmative decision and would resubmit their request, for a total of 51,367 level one resubmissions. We assumed that subsequent resubmissions would be 10 percent of the previous level resubmission, totaling 5,137 for level 2 resubmissions, and 514 for level 3 resubmissions. In sum, we estimated the total number of submissions for Year 1 to be 256,836 initial requests plus 57,017 resubmissions for a total of 313,852 submissions. We estimated the cost of mailing medical records to be $6,275 in Year 1. The total estimated burden for Year 1 is $5,988,332, which includes the time associated with submitting prior authorization requests multiplied by the loaded rate of $38.12 an hour, plus the cost of mailing records and documents.

b. Prior Authorization Process for Certain DMEPOS Items

TABLE 47: DMEPOS PRIOR AUTHORIZATION SUBMISSION BURDEN FOR YEAR 1

Activity	Estimated Responses Per Year (number of prior authorization requests submitted)	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs Per Year Using Loaded Rate
Fax and Electronic Initial Submissions	255,808	0.5	127,904	$4,875,700
Fax and Electronic Resubmissions	56,789	0.5	28,395	$1,082,417
Mail Initials	1,027	0.5	514	$19,594
Mail Resubmissions	228	0.5	114	$4,346
Mail Cost	N/A	$5 (1,255)	N/A	$6,275
Total	313,852	N/A	156,927	$5,988,332

We expect an annual growth rate of 3 percent for the number of requests based on more people aging into the program and qualifying for coverage. Accordingly, in Year 2 we estimated that there would be 264,541 initial prior authorization requests from Year 1 plus and an additional 24,000 initial requests from codes that would potentially be added to the Required Prior Authorization List in Year 2 for a total of 288,541 initial requests. Using the same rates of resubmissions described in Year 1, we estimated 64,056 resubmission requests for the total number of submissions in Year 2 of 352,597. We assumed 20 percent of initial requests will be resubmitted for a level one total of 57,708. Subsequent resubmissions would be 10 percent of the previous level resubmission, totaling 5,771 for level 2 resubmissions, and 577 for level 3 resubmissions. Accordingly, we estimated a total burden of $6,727,543 for Year 2.

TABLE 48: TOTAL ANNUAL BURDEN

Year One	Year Two	Average Annual Burden
$5,988,332	$6,727,543	$6,357,938

The annual burden for Year 1 is $5,988,332, the annual burden for Year 2 is $6,727,543 for an average annual burden of $6,357,938.

The provisions permit CMS to exempt suppliers that achieve a prior authorization provisional affirmation threshold of at least 90 percent during a periodic assessment. If the rate

of non-payable claims submitted becomes higher than 10 percent during an assessment, we would withdraw exemption for the specific noncompliant supplier. We assessed data from previous years to determine the number of suppliers that would have met the 90 percent compliance rate.

To assess the reduction in burden for compliant suppliers, we started by looking at the total number of provider transaction access numbers (PTANs), a unique identification number assigned by Medicare to providers and suppliers that bill Medicare for services, submitting claims for payment and mandatory prior authorization requests. That total number for 2024 was 9,298. Of the total number of PTANs, 6 percent of those PTANs met the criteria for an exemption from mandatory prior authorization requirements, or 558 total PTANs. We were unable to determine the number of compliant suppliers in future years. However, if we average the data from previous years, the average percentage of compliant suppliers or PTANs is 4 percent.

TABLE 49: AVERAGE EXEMPT SUPPLIERS BY YEAR

CY	Total PTAN	PTAN Who Meet Criteria	Percentage of Exempt PTAN
2022	7,049	148	2%
2023	8,048	249	3%
2024	9,298	558	6%

The total burden is assessed in Table 49. By reducing the total average annual burden ($6,357,938) by the average number of suppliers (represented by PTANs) *not* submitting prior authorization requests by 4 percent, we have an average savings of $254,318 per year.

We did not receive comments on this proposal and therefore are finalizing this provision without modification.

7. DMEPOS Competitive Bidding Program

a. ICRs for the Submission of Financial Documents (§414.402)

The following changes will be submitted to OMB for reinstatement under control number 0938-1016 (CMS-10169). CMS notes that we let the previously approved requirements and

burden lapse as the requirements/burden were no longer relevant at the time of the December 31, 2021, expiration date, and we wanted to avoid creating unnecessary confusion and soliciting comment on such outdated requirements/burden.

As discussed in section VII of this final rule, we are streamlining the DMEPOS CBP financial standards requirements and evaluation, while still ensuring that suppliers offered contracts are financially stable enough to participate in the Medicare DMEPOS CBP for the duration of the contract performance period. Specifically, CMS is finalizing that it will only require suppliers to submit a credit report with a numerical credit score or rating during the bid window. The submission of a tax return extract, income statement, balance sheet, and statement of cash flows would no longer be required, which would significantly reduce the time it takes a supplier's Administrative Services Manager to assemble and upload financial documents during the bidding process by minus 5 hours and 15 minutes (from 8 hr and 21 min to 3 hr and 6 min). We anticipate that an Administrative Services Manager has the requisite knowledge, access to information, and decision-making authority related to a bidder's business operations necessary to formulate a bid.

As a result of this revised requirement, CMS will no longer utilize revenue data from the bidder's tax return to determine if a bidder meets the definition of a "small supplier" in the DMEPOS CBP (that is, a supplier that generates gross revenue of $3.5 million or less in annual receipts including Medicare and non-Medicare revenue). In its place, CMS is adding a question to Form A that requires a bidder to attest whether it meets the definition of a small supplier.

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While we do not know the exact number of bidders that would bid in the next round, for the purpose of scoring the PRA-related impact of this rule, we assume that the number of bidders would increase by approximately 1,000 bidders (from 1,500 to 2,500 bidders) as a result of the proposals discussed in sections VII.B, C, and F. of this rule. As a result, we estimate there would

be approximately 833.33 bidders annually over 3 years (2,500 bidders/3 yr) in the next round and each bidder would complete Form A. This is an increase of 333.33 bidders/yr (1,000 bidders/3 yr).

We expect the estimated burden associated with this new attestation to be minimal, as suppliers should already be aware of their current revenue levels. Specifically, we estimate that the average amount of time to complete the attestation question would be 6 minutes (0.1 hr).

In aggregate, we estimate an annual savings of minus 1,717 hours (333.33 bids/yr x [0.1 hr increase - 5.25 hr reduction]) and minus $178,946 (1,717 hr x $104.22/hr).

Our July 2, 2025, NPRM did not receive PRA-related comments from the public. Therefore, CMS is finalizing the proposed provision and burden.

b. ICRs for Adjustments to Single Payment Amounts (SPAs) (§414.408(b))

The following changes will be submitted to OMB for reinstatement under control number 0938-1016 (CMS-10169). CMS notes that we let the previously approved requirements and burden lapse as the requirements/burden were no longer relevant at the time of the December 31, 2021, expiration date and we wanted to avoid creating unnecessary confusion and soliciting comment on such outdated requirements/burden.

As discussed in section VII of this final rule, we are adding an annual update factor to adjust the SPAs for the second and third year of a DMEPOS CBP contract performance period by the same annual covered item update factors applied to the fee schedule amounts for the items in non-CBAs. Therefore, a bidder will no longer need to account for the potential future effects of price increases when formulating its bid amounts at the time of bidding and entering it on Form B.

We estimate this change will reduce the amount of time for an Administrative Services Manager to complete Form B by minus 24 minutes (0.4 hr) (from 3 hrs to 2.6 hrs). We anticipate that an Administrative Services Manager has the requisite knowledge, access to information, and decision-making authority related to a bidder's business operations necessary to formulate a bid.

While we do not know the exact number of bidders that would bid in the next round, for the purpose of scoring the PRA-related impact of this rule, we assume that the average bidder will bid in 22 competitions. While we previously estimated that the average bidder will complete 35 Form Bs, we believe that the additional 1,000 bidders (from 1,500 to 2,500 bidders as noted in VIII.B.7.a.of this final rule) will only submit, on average, bids for approximately two competitions in the next round of the DMEPOS CBP, thereby reducing the average number of Form B submissions by minus 13 competitions/bidder (35 current – 22 revised).

However, when considering the decrease in the number of competitions each bidder will submit a bid(s), on average, along with the number of additional bidders, we estimate a reduction of minus 97,000 hours ([Current: 1,500 bidders x 35 competitions/bidder x 3 hrs)] - [Revised: 2,500 bidders x 22 competitions/bidder x 1.1 hr)] and minus $10,109,340 (97,000 hr x $104.22/hr).

The finalizing of adding an annual update factor to adjust the SPAs for the second and third year of a DMEPOS CBP contract performance period was a result of internal review and response to industry feedback.

Our July 2, 2025, the proposed rule did not receive PRA-related comments from the public. Therefore, CMS is finalizing the proposed provision and burden.

c. ICRs for Determining the Number of Contracts Awarded (§ 414.414(h))

The following changes will be submitted to OMB for reinstatement under control number 0938-1016 (CMS-10169). CMS notes that we let the previously approved requirements and burden lapse as the requirements/burden were no longer relevant at the time of the December 31, 2021, expiration date and we wanted to avoid creating unnecessary confusion and soliciting comment on such outdated requirements/burden.

As discussed in section VII.B of this rule, we revised how CMS determines the number of DMEPOS CBP contracts to award to DMEPOS suppliers by using contract supplier utilization information from previous rounds of the DMEPOS CBP for product categories previously

included in the DMEPOS CBP as well as information on current supplier utilization for new product categories. With this change, bidders will no longer have to determine the capacity that they could furnish in each competitive bidding area and product category combination (competition) and enter the applicable capacity estimate(s) on Form B of their bid submission. We believe it took a supplier's Administrative Services Manager approximately 90 minutes (1.5 hr) to determine their estimated capacity for each Form B so the removal of the requirement to determine an estimated capacity in each competition and entering it on each Form B will result in an estimated reduction in burden of minus 1.5 hours per form.

As previously mentioned, while we do not know the exact number of bidders that will bid in the next round, for purposes of scoring the PRA-related impact of this rule, we assume that the average bidder would bid in 22 competitions. While we previously estimated that the average bidder would complete 35 Form B's, we believe that the additional 1,000 bidders (from 1,500 to 2,500 bidders as noted in section VIII.B.7.a. of this final rule) would only submit, on average, bids for approximately two competitions in the next round of the DMEPOS CBP, reducing the average number of Form B submissions by minus 13 competitions/bidder (35 current – 22 revised).

We anticipate that an Administrative Services Manager has the requisite knowledge, access to information, and decision-making authority related to a bidder's business operations necessary to formulate a bid.

However, when considering the decrease in the number of competitions each bidder will submit a bid(s), on average, along with the number of additional bidders, we estimate a reduction of minus 97,000 hours ([Current: 1,500 bidders x 35 competitions/bidder x 3 hrs)] - [Revised: 2,500 bidders x 22 competitions/bidder x 1.1 hr)] and minus $10,109,340 (97,000 hr x $104.22/hr).The finalizing of no longer requiring capacity estimates and use of contract supplier utilization information from previous rounds of the DMEPOS CBP for product categories

previously included in the DMEPOS CBP, as well as information on current supplier utilization for new product categories, was a result of internal review.

Our July 2, 2025, the proposed rule did not receive PRA-related comments from the public. Therefore, CMS is finalizing the proposed provision and burden.

d. ICRs for the Remote Item Delivery (RID)CBA and Revising the Definition of Item Related to Medical Supplies (§414.402)

The following changes will be submitted to OMB for reinstatement under control number 0938-1016 (CMS-10169). CMS notes that we let the previously approved requirements and burden lapse as the requirements/burden were no longer relevant at the time of the December 31, 2021, expiration date and we wanted to avoid creating unnecessary confusion and soliciting comment on such outdated requirements/burden.

As discussed in section VII.F of this rule, we are finalizing the creation of a new definition under § 414.402 for the purpose of establishing one or more RID CBAs wherein contract suppliers would be responsible for furnishing the items and services under the product category primarily on a mail order basis to all Medicare beneficiaries regardless of where they live in the CBA, but could also furnish the items on a non-mail order basis.

As discussed in section VII.E of this rule, we are also finalizing that ostomy and urological supplies are medical supplies mandated for inclusion under the DMEPOS CBP by section 1847(a)(2)(A) of the Act.

We assume that both changes will result in an increase in burden as suppliers will potentially have additional CBAs and product categories in which they could bid. However, while we do not know the exact number of bidders that would bid in the next round, for purposes scoring the PRA-related impact of this rule we assume that the average bidder would bid in 22 competitions. We previously estimated that the average bidder would complete 35 Form Bs, we believe that the additional 1,000 bidders (from 1,500 to 2,500 bidders as noted in section VII.B.7.a. of this final rule) would only submit, on average, bids for approximately two

competitions in the next round of the DMEPOS CBP, reducing the average number of Form B submissions by minus 13 competitions/bidder (35 current – 22 revised).

We estimate that it will take 1 hour at $104.22/hr for a supplier's Administrative Services Manager to develop its bid amount for each product category that they bid and 6 minutes (0.1 hr) to complete Form B.

We anticipate that an Administrative Services Manager has the requisite knowledge, access to information, and decision-making authority related to a bidder's business operations necessary to formulate a bid.

When considering the decrease in the number of competitions each bidder will submit a bid(s), on average, along with the number of additional bidders, we estimate a reduction of minus 97,000 hours ([Current: 1,500 bidders x 35 competitions/bidder x 3 hrs)] - [Revised: 2,500 bidders x 22 competitions/bidder x 1.1 hr)] and minus $10,109,340 (97,000 hr x $104.22/hr).

Our July 2, 2025, NPRM did not receive PRA-related comments from the public. As a result, CMS is finalizing the proposed provision and burden.

e. Summary of Annual Burden Estimates for DMEPOS CBP Finalized Requirements

TABLE 50: DMEPOS CBP ANNUAL BURDEN ESTIMATES

OMB CONTROL NUMBER 0938-1016 (CMS-10169)

Regulation Section(s) under Title 42 of the CFR	Respondents	Total Responses	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)
Form A						
§414.402 (Submission of Financial Documents)	2,500	333.33	(5.15)	(1,717)	104.22	(178,946)
Subtotal: Form A	*2,500*	*333.33*	*(5.15)*	*(1,717)*	*104.22*	*(178,946)*
Form B						
§414.408(b) (Adjustments to SPAs)	2,500	333.33	(1.9)	(97,000)	104.22	(10,109,340)
§414.414(h) (Determining the Number of Contracts Awarded)	2,500	333.33	(1.9)	(97,000)	104.22	(10,109,340)
§414.402 (RID CBA and Revising the Definition of Item Related to Medical Supplies)	2,500	333.33	(1.9)	(97,000)	104.22	(10,109,340)
Subtotal: Form B	*2,500*	*1,000*	*(1.9)*	*(291,000)*	*104.22*	*(30,328,020)*
TOTAL	**2,500**	**1,333**	**varies**	**(292,717)**	**104.22**	**(30,506,966)**

VIII. Waiver of Delay in Effective Date

In the absence of an appropriation for FY 2026 or a Continuing Resolution, the federal government shut down on October 1, 2025. During the funding lapse, which lasted from October 1, 2025 through November 12, 2025, only excepted operations continued, which largely excluded work on this final rule. Accordingly, most of the work on this final rule was not completed in accordance with our usual schedule for final calendar-year-based 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 generally required by Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), 5 U.S.C. 801(a)(3), can be waived, however, if the agency finds for good cause that notice and public procedure thereon are 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 impracticable and contrary to the public interest to delay the effective date of the HH PPS, HH PPS Grouper refinements, recalibration of the case-mix weights, updates to the functional impairment levels and comorbidity subgroups, and quality reporting portions of this final rule. The HH PPS is a calendar-year payment system, and we typically issue the final rule by November 1 of each year to ensure that the payment policies for the system, associated HH PPS Grouper, and quality reporting requirements 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 were to be delayed by 60 days, the policies adopted in this final rule would not be effective until after January 1, 2026which would result in HHAs receiving 2025 payment rates, instead of receiving 2026 payment rates. This would be contrary to the public's interest in ensuring that home health agencies and state survey agencies receive appropriate payments in a timely manner. For these reasons we find that the delayed effective date is both impracticable and

contrary to the public interest, and we are waiving such delay in the effective date of this final rule.

IX. Regulatory Impact Analysis

A. Statement of Need

1. HH PPS

Section 1895(b)(1) of the Act requires the Secretary to establish an HH PPS for all costs of home health services paid under Medicare. In addition, section 1895(b) of the Act requires: (1) the computation of a standard prospective payment amount include all costs for home health services covered and paid for on a reasonable cost basis and that such amount be initially based on the most recent audited cost report data available to the Secretary; (2) the prospective payment amount under the HH PPS to be an appropriate unit of service based on the number, type, and duration of visits provided within that unit; and (3) the standard prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs. Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the home health applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act requires the standard prospective payment amount be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of appropriate case-mix adjustment factors for significant variation in costs among different units of services. Lastly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area compared to the applicable national average level.

Section 1895(b)(3)(B)(iv) of the Act provides the Secretary with the authority to implement adjustments to the standard prospective payment amount (or amounts) for subsequent years to eliminate the effect of changes in aggregate payments during a previous year or years that were the result of changes in the coding or classification of different units of services that do

not reflect real changes in case-mix. Section 1895(b)(5) of the Act provides the Secretary with the option to make changes to the payment amount otherwise paid in the case of outliers because of unusual variations in the type or amount of medically necessary care. Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit data for purposes of measuring health care quality and links the quality data submission to the annual applicable percentage increase.

Sections 1895(b)(2) and 1895(b)(3)(A) of the Act, as amended by sections 51001(a)(1) and 51001(a)(2) of the BBA of 2018 respectively, required the Secretary to implement a 30-day unit of payment, for 30-day periods beginning on and after January 1, 2020. Section 1895(b)(3)(D)(i) of the Act, as added by section 51001(a)(2)(B) of the BBA of 2018, requires the Secretary to annually determine the impact of differences between assumed behavior changes, as described in section 1895(b)(3)(A)(iv) of the Act, and actual behavior changes on estimated aggregate expenditures under the HH PPS with respect to years beginning with 2020 and ending with 2026. Section 1895(b)(3)(D)(ii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more permanent increases or decreases to the standard prospective payment amount (or amounts) for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. Additionally, 1895(b)(3)(D)(iii) of the Act requires the Secretary, at a time and in a manner determined appropriate, through notice and comment rulemaking, to provide for one or more temporary increases or decreases to the payment amount for a unit of home health services for applicable years, on a prospective basis, to offset for such increases or decreases in estimated aggregate expenditures, as determined under section 1895(b)(3)(D)(i) of the Act. The HH PPS wage index utilizes the wage adjustment factors used by the Secretary for purposes of sections 1895(b)(4)(A)(ii) and (b)(4)(C) of the Act for hospital wage adjustments.

2. HH QRP

Section 1895(b)(3)(B)(v) of the Act authorizes the HH QRP, which requires HHAs to

submit data in accordance with the requirements specified by CMS. Failure to submit data required under section 1895(b)(3)(B)(v) of the Act with respect to a program year would result in the reduction of the annual home health market basket percentage increase otherwise applicable to an HHA for the corresponding calendar year by 2 percentage points.

3. Expanded HHVBP Model

In the CY 2022 HH PPS final rule (86 FR 62292 through 62336) and codified at 42 CFR part 484, subpart F, we finalized our policy to expand the HHVBP Model to all Medicare certified HHAs in the 50 States, territories, and District of Columbia beginning January 1, 2022. CY 2022 was a pre-implementation year. CY 2023 was the first performance year in which HHAs individual performance on the applicable measures affects their Medicare payments in CY 2025. In this final rule, we include changes to the expanded HHVBP Model applicable measure set and measure weights, a new measure removal factor, and summarize comments received in response to a request for information (RFI) related to potential future measure concepts that was included in the proposed rule.

4. Updates to the Home Health Agency CoPs to Align with the OASIS All-Payer Submission Requirements

This final rule updates the CoPs to clarify that the OASIS all-payer submission requirement applies to all HHA patients receiving skilled services. beneficiaries.

5. Provider Enrollment

Consistent with section 1866(j) of the Act, we proposed several Medicare provider enrollment provisions to strengthen and clarify certain aspects of the provider enrollment process. These include but are not limited to: (1) adding and modifying grounds for denying, revoking, or deactivating a provider's or supplier's Medicare enrollment; and (2) expanding the reasons for which CMS can apply a retroactive effective date for provider and supplier enrollment revocations. These changes are necessary to help ensure that payments are made only to qualified providers and suppliers, which we believe would assist in protecting the Trust

Funds and Medicare beneficiaries.

6. DMEPOS Supplier Accreditation Organizations

Section 1834(a)(20) of the Act and 42 CFR 424.57 require DMEPOS suppliers to be accredited by a CMS-approved AO to enroll in and bill the Medicare program. The main purpose of accreditation is to confirm -- typically via a survey of the DMEPOS supplier's location -- that the supplier meets detailed quality standards involving, for example, its administration, financial management, customer service, and DMEPOS product safety. Section 424.58 outlines some of the components and requirements of the DMEPOS accreditation program. However, this regulatory section has not been updated since its promulgation in 2006. Given the ongoing problem of non-compliant DMEPOS suppliers – as well as the regulatory gaps that exist in § 424.58 – we believe it is necessary via this final rule to strengthen our oversight of DMEOS accreditation by enhancing the regulatory requirements of § 424.58.

7. DMEPOS Prior Authorization

Consistent with provisions in section 1834(a)(15) of the Act and existing authority at §414.234 (c)(1)(ii) that permits exemption from prior authorization for certain compliant suppliers, we proposed and are finalizing guidelines for establishing an exemption and withdrawal of an exemption. Furthermore, we are finalizing the proposed notification requirements to put suppliers on notice that the exemption has either been granted or withdrawn.

8. DMEPOS Competitive Bidding Program

This rule revises the DMEPOS CBP to enhance its effectiveness in achieving the objectives of the program as mandated by section 1847(a) of the Act. This rule revises how SPAs mandated by section 1847(b)(5)(A) of the Act will be calculated and how CMS determines the number of contracts it would award in each CBA for every product category, taking into account the ability of bidding entities (bidders) to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the CBA on a timely basis as mandated by section 1847(b)(4)(A) of the Act. This rule will also apply annual

inflation update factors to the SPAs. Additionally, this final rule would establish special payment rules for class II continuous glucose monitors and insulin infusion pumps to pay for these items and all related supplies and accessories on a 90-day rental basis under the DMEPOS CBP. This rule classifies class III continuous glucose monitors and insulin infusion pumps used in conjunction with class III continuous glucose monitors as items that require frequent and substantial servicing and make payment for the items using the same 90-day rental method and payment amounts established for class II continuous glucose monitors and insulin infusion pumps under the DMEPOS CBP. This rule also establishes the definition of "remote item delivery competitive bidding area" under the DMEPOS CBP. In addition, this final rule revises the methodology used to establish bid limits and addresses the conditions for determining when contracts cannot be awarded in accordance with section 1847(b)(2)(A)(iii) of the Act because the total amounts to be paid to contractors in a CBA are expected to be less than the total amounts that will otherwise be paid. This proposed rule also revises the definition of "item" to clarify that items that may be included in a CBP include medical supplies, including ostomy, tracheostomy, and urological supplies in accordance with section 1847(a)(2)(A) of the Act. Also, this proposed rule streamlines the requirements and evaluation of the DMEPOS CBP financial standards as well as the processes for evaluating and notifying a bidder of any applicable covered document(s) not submitted by the CDRD. In addition, this rule codifies the DMEPOS CBP bid surety bond rider process. This rule also adds a Tribal exception to the DMEPOS CBP. This rule adds a termination clause to the DMEPOS CBP supplier contracts that could be utilized during a public health emergency.

B. Overall Impact

We have examined the impacts of this final rule as required by E.O. 12866, "Regulatory Planning and Review"; E.O. 13132, "Federalism ; E. O. 13563, "Improving Regulation and Regulatory Review"; E.O. 14192, "Unleashing Prosperity Through Deregulation"; and the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 through 612; section 1102(b) of the Social

Security Act; section 202 of the Unfunded Mandates Reform Act of 1995."; and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; and distributive impacts). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the Executive Order itself.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of Executive Order 12866. Based on our analysis, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant pursuant to section 3(f)(1) of Executive Order 12866. Furthermore, in accordance with Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), OIRA has determined that this rule meets the criteria for a major rule as defined in 5 U.S.C. 804(2). Accordingly, we have prepared a regulatory impact analysis that presents, to the best of our ability, the estimated costs and benefits associated with this rulemaking.

C. Detailed Economic Analysis

1. Effects of the Changes for the CY 2026 HH PPS

This final rule updates Medicare payments under the HH PPS for CY 2026. The net transfer impact related to the changes in payments under the HH PPS for CY 2026 is estimated to be -$220 million (-1.3 percent). The $220 million decrease in estimated payments for CY 2026 reflects the effects of the proposed CY 2026 home health payment update percentage of 2.4 percent ($405 million increase), an estimated -0.9 percent decrease that reflects the effects of the permanent adjustment ($150 million decrease), an estimated -2.7 percent decrease that reflects the effects of the temporary adjustment ($460 million decrease) and an estimated -0.1 percent decrease that reflects the updated FDL ($15 million decrease).

We use the latest data and analysis available. However, we do not adjust for future changes in such variables as number of visits or case-mix. This analysis incorporates the latest estimates of growth in service use and payments under the Medicare home health benefit, based primarily on Medicare claims data for periods that ended on or before December 31, 2024. We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to errors resulting from other changes in the impact time period assessed. Some examples of such possible events are newly-legislated general Medicare program funding changes made by the Congress or changes specifically related to HHAs. In addition, changes to the Medicare program may continue to be made as a result of new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that overall changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon HHAs.

Table 51 represents how HHA revenues are likely to be affected by the final policy changes for CY 2026. For this analysis, we used an analytic file with linked CY 2024 OASIS assessments and home health claims data for dates of service that ended on or before December 31, 2024. The first column of table 51 classifies HHAs according to several characteristics including provider type, geographic region, and urban and rural locations. The

second column shows the number of facilities in the impact analysis. The third column shows the payment effects of the permanent adjustment on all payments. The aggregate impact of the permanent adjustment reflected in the third column does not equal the final -1.023 percent permanent adjustment because the adjustment only applies to the national, standardized 30-day period payments and does not impact payments for 30-day periods which are LUPAs. The fourth column shows the payment effects of the recalibration of the case-mix weights offset by the case-mix weight budget neutrality factor. The fifth column shows the payment effects of updating the CY 2026 wage index (that is, the FY 2026 hospital pre-floor, pre-reclassified wage index for hospital cost reporting periods beginning on or after October 1, 2021, and before October 1, 2022 (FY 2022 cost report data)) with a 5 percent cap on wage index decreases. The aggregate impact of the changes in the fifth column is zero percent, due to the wage index budget neutrality factor. The sixth column shows the payment effects of the final CY 2026 home health payment update percentage. The seventh column shows the payment effects of the final FDL. The eighth column shows the payment effects of the temporary adjustment on all payments. The aggregate impact of the temporary adjustment reflected in the eighth column does not equal the -3.0 percent temporary adjustment because the adjustment only applies to the national, standardized 30-day period payments and does not impact payments for 30-day periods which are LUPAs. The last column shows the combined effects of all the final provisions.

Overall, it is projected that aggregate payments in CY 2026 would decrease by 1.3 percent which reflects the -0.9 percent decrease from the permanent adjustment, the -2.7 percent decrease from the temporary adjustment, the -0.1 percent decrease from the updated FDL and the 2.4 percent home health payment update. As illustrated in table 51, the combined effects of all changes vary by specific types of providers and by location. We note that some individual HHAs within the same group may experience different impacts on payments than others due to the distributional impact of the CY 2026 wage index, the percentage of total HH PPS payments that were subject to the LUPA or paid as outlier payments, and the degree of Medicare utilization.

TABLE 51: CY 2026 HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY

	Number of Agencies	Permanent Adjustment	CY 2026 Case-Mix Weights Recalibration Neutrality Factor	CY 2026 Updated Wage Index (with 5% cap)	CY 2026 Final HH Payment Update Percentage	CY 2026 Fixed-Dollar Loss (FDL) Update	Temporary Adjustment	Total
All Agencies	**9,851**	**-0.9%**	**0.0%**	**0.0%**	**2.4%**	**-0.1%**	**-2.7%**	**-1.3%**
Facility Type and Control								
Free-Standing/Other Vol/NP	718	-0.9%	0.1%	0.5%	2.4%	-0.1%	-2.7%	-0.7%
Free-Standing/Other Proprietary	8,140	-0.9%	0.0%	-0.2%	2.4%	-0.1%	-2.8%	-1.6%
Free-Standing/Other Government	101	-0.9%	-0.1%	0.3%	2.4%	-0.1%	-2.6%	-1.0%
Facility-Based Vol/NP	388	-0.9%	0.1%	0.3%	2.4%	-0.1%	-2.6%	-0.8%
Facility-Based Proprietary	24	-0.9%	0.1%	-0.9%	2.4%	-0.1%	-2.7%	-2.1%
Facility-Based Government	167	-0.9%	0.2%	0.4%	2.4%	-0.1%	-2.7%	-0.7%
Subtotal: Freestanding	9,033	-0.9%	0.0%	0.0%	2.4%	-0.1%	-2.7%	-1.3%
Subtotal: Facility-based	580	-0.9%	0.1%	0.3%	2.4%	-0.1%	-2.6%	-0.8%
Subtotal: Vol/NP	1,106	-0.9%	0.1%	0.5%	2.4%	-0.1%	-2.6%	-0.6%
Subtotal: Proprietary	8,164	-0.9%	0.0%	-0.2%	2.4%	-0.1%	-2.8%	-1.6%
Subtotal: Government	268	-0.9%	0.1%	0.4%	2.4%	-0.1%	-2.6%	-0.7%
Facility Type and Control: Rural								
Free-Standing/Other Vol/NP	166	-0.9%	0.1%	0.8%	2.4%	-0.1%	-2.7%	-0.4%
Free-Standing/Other Proprietary	796	-1.0%	0.0%	0.0%	2.4%	-0.1%	-2.8%	-1.5%
Free-Standing/Other Government	62	-0.9%	-0.2%	1.2%	2.4%	-0.1%	-2.6%	-0.2%
Facility-Based Vol/NP	153	-0.9%	0.2%	1.2%	2.4%	-0.1%	-2.6%	0.2%
Facility-Based Proprietary	8	-0.9%	0.4%	0.7%	2.4%	-0.1%	-2.7%	-0.2%
Facility-Based Government	120	-0.9%	0.1%	0.6%	2.4%	-0.1%	-2.6%	-0.5%
Facility Type and Control: Urban								
Free-Standing/Other Vol/NP	552	-0.9%	0.1%	0.5%	2.4%	-0.1%	-2.7%	-0.7%
Free-Standing/Other Proprietary	7,342	-0.9%	0.0%	-0.2%	2.4%	-0.1%	-2.8%	-1.6%
Free-Standing/Other Government	39	-0.9%	0.0%	-0.1%	2.4%	-0.1%	-2.6%	-1.3%
Facility-Based Vol/NP	235	-0.9%	0.1%	0.2%	2.4%	-0.1%	-2.5%	-0.8%
Facility-Based Proprietary	16	-0.9%	-0.1%	-1.5%	2.4%	-0.1%	-2.7%	-2.9%

Facility-Based Government	47	-0.9%	0.3%	0.2%	2.4%	-0.1%	-2.7%	-0.8%
Facility Location: Urban or Rural								
Rural	1,362	-0.9%	0.0%	0.3%	2.4%	-0.1%	-2.8%	-1.1%
Urban	8,459	-0.9%	0.0%	-0.1%	2.4%	-0.1%	-2.7%	-1.4%
Facility Location: Region of the Country (Census Region)								
New England	302	-0.9%	-0.1%	1.6%	2.4%	-0.1%	-2.7%	0.2%
Mid Atlantic	370	-0.9%	0.2%	-0.3%	2.4%	-0.1%	-2.7%	-1.4%
East North Central	1,372	-0.9%	0.0%	0.6%	2.4%	-0.1%	-2.8%	-0.8%
West North Central	548	-0.9%	0.0%	0.9%	2.4%	-0.1%	-2.7%	-0.4%
South Atlantic	1,573	-0.9%	0.0%	0.6%	2.4%	-0.1%	-2.8%	-0.8%
East South Central	357	-1.0%	0.0%	0.1%	2.4%	-0.1%	-2.8%	-1.4%
West South Central	1,961	-0.9%	-0.1%	-0.5%	2.4%	-0.1%	-2.8%	-2.0%
Mountain	699	-0.9%	0.0%	0.2%	2.4%	-0.1%	-2.7%	-1.1%
Pacific	2,627	-0.9%	0.0%	-1.1%	2.4%	-0.1%	-2.7%	-2.4%
Outlying	42	-0.9%	1.1%	-0.1%	2.4%	-0.1%	-2.7%	-0.3%
Facility Size (Number of 30-day Periods)								
< 100 periods	2,285	-0.9%	-0.2%	-0.5%	2.4%	-0.1%	-2.7%	-2.0%
100 to 249	1,573	-0.9%	-0.2%	-0.5%	2.4%	-0.1%	-2.7%	-2.0%
250 to 499	1,767	-0.9%	-0.1%	-0.4%	2.4%	-0.1%	-2.7%	-1.8%
500 to 999	1,920	-0.9%	-0.1%	-0.3%	2.4%	-0.1%	-2.7%	-1.7%
1,000 or More	2,306	-0.9%	0.1%	0.1%	2.4%	-0.1%	-2.7%	-1.1%

Source: CY 2024 Medicare claims data for periods with matched OASIS records ending in CY2024 (as of July 11, 2025).

Notes: The estimated 0.9 percent decrease related to the final permanent adjustment includes all payments, while the -1.023 percent permanent adjustment only applies to the national, standardized 30-day period payments and does not impact payments for 30-day periods which are LUPAs. Similarly, the estimated 2.7 percent decrease related to the final temporary adjustment includes all payments, while the -3.000 percent temporary adjustment only applies to the national, standardized 30-day period payments and does not impact payments for 30-day periods which are LUPAs. The “CY 2026 Updated Wage Index (with 5% cap)” column reflects a 5-percent cap on wage index decreases. The "Fixed Dollar Loss (FDL) Update" column reflects a change in the FDL from 0.35 to 0.37. Due to missing Provider of Services file information (from which home health agency characteristics are obtained), some subcategories in the impact tables have fewer agencies represented than the overall total (of 9,851): totals involving facility type (only) add up to 9,613, totals involving control type add up to 9,538, and totals involving urban/rural location add up to 9,821.

REGION KEY:
New England=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Middle Atlantic=Pennsylvania, New Jersey, New York
South Atlantic=Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia

East North Central=Illinois, Indiana, Michigan, Ohio, Wisconsin
East South Central-Alabama, Kentucky, Mississippi, Tennessee
West North Central=Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota
West South Central=Arkansas, Louisiana, Oklahoma, Texas
Mountain=Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming
Pacific=Alaska, California, Hawaii, Oregon, Washington
Other=Guam, Puerto Rico, Virgin Islands

2. Effects of the Changes for the HH QRP for CY 2027

Failure to submit HH QRP data required under section 1895(b)(3)(B)(v) of the Act with respect to a program year will result in the reduction of the annual home health market basket percentage increase otherwise applicable to an HHA for the corresponding calendar year by 2 percentage points. For the CY 2023 program year, 820 of the 11,549 active Medicare-certified HHAs, or approximately 7.1 percent, did not receive the full annual percentage increase because they did not meet assessment submission requirements. The 820 HHAs that did not satisfy the reporting requirements of the HH QRP for the CY 2023 program year represent $149 million in home health claims payment dollars after APU penalty during the reporting period out of a total $16.4 billion for all HHAs.

We proposed to remove four items as standardized patient assessment data elements beginning with the CY 2026 HH QRP. The four assessment items proposed for collection are (1) Living Situation, (2) Food Runs Out, (3) Food Doesn't Last, and (4) Utilities. We also proposed to remove the COVID-19 Vaccine: Percent of Patients Who Are Up to Date measure and the item related to the measure and corresponding data element. The net effect of these proposals is a decrease of four data elements at the start of care and resumption of care time points and a decrease in one data element at the transfer of care, death at home and discharge time points for a net decrease in burden.

Section VIII.B.1. of this final rule provides a detailed description of the net decrease in burdens associated with the proposed changes that are being finalized. We proposed that removal of data elements associated with the HH QRP would begin with assessments as of April 1, 2026. The cost impact of these proposed changes was estimated to be a net decrease of $17,810,282 in annualized cost to HHAs, discounted at 2 percent relative to year 2023, over a perpetual time horizon beginning in CY 2026. We described the estimated burden and cost reductions for these measures in section VIII. of this final rule. In summary, the implementation of provisions

outlined in this final rule for the HH QRP is estimated to decrease the burden on HHAs by $1,496 per HHA annually, or $17,810,282 for all HHAs annually.

In section III.E. of this final rule, we proposed to amend the data non-compliance reconsideration request policy and process. For HHAs that seek to file an extension to file a request for reconsideration of a noncompliance determination, we estimated that this request will take HHAs approximately 15 minutes to complete. We believe that this data will be entered by the medical records specialists. However, HHAs determine the staffing resources necessary. For the purposes of calculating the costs we obtained median hourly wages from the U.S. Bureau of Labor Statistics' (BLS) May 2024 National Occupational Employment and Wage Estimates.[89] To account for overhead and fringe benefits, we have doubled the hourly wage. These amounts are detailed in Table 52.

TABLE 52: U.S. BUREAU OF LABOR AND STATISTICS' MAY 2024 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Median Hourly Wage ($/hr)	Other Indirect Costs and Fringe Benefits ($/hr)	Adjusted Hourly Wage ($/hr)
Medical Records Specialists	29-2072	$24.16	$24.16	$48.32

We estimated that the collection of this request would result in an additional 15 minutes, or 0.25 hours, per request. Based on the number of reconsiderations requests we have received in the previous 3 years, we estimate an average of 85 requests per year, for an additional 21 hours per year (0.25 hours x 85 forms per year) for all HHAs. Given an estimated $48.32 hourly wage, we estimate an increase of $1015 (21 hours x $48.32) for all HHAs annually or $11.94 per HHA that request reconsiderations.

Section VIII. of this final rule provides a detailed description of the net decrease associated with the changes. For the COVID-19 items collected at transfer of care, death at home, and discharge, we estimated a decrease in clinician cost of $4,326,249 or $363

[89] U.S. Bureau of Labor Statistics' (BLS) May 2024 National Occupational Employment and Wage Estimates. https://www.bls.gov/oes/current/oes_nat.htm

(-$4,326,249/11,904) for each of the 11,904 active HHAs. For the four SDOH data elements removed at start of care or resumption of care, we estimated a decrease in clinician cost of $13,484,033 or $1,132 (-$13,484,033/11,904) for each of the 11,904 active HHAs. For all provisions, we estimated a decrease in clinician costs of -$17,810,282 between 2027 and 2026 related to the implementation of the provisions outlined in this final rule across all HHAs or a $1,496 decrease (-$17,810,282/11,904).

a. COVID-19 Data Element Burden

Comment: A majority of commenters supported the CMS recommendation to remove the COVID-19 Vaccine: Percent of Patients Who Are Up to Date measure from the HHQRP with most citing the collection burden associated with the measure. Many commenters highlighted the many other sources that can provide national COVID-19 vaccination rates.

Response: We thank commenters for their support. We acknowledge commenters' difficulty with assessing patients' vaccination status in the HHA. We agree that the burden associated with this measure, including the resources spent by HH staff in trying to ascertain patients' vaccination status, outweighs the benefit of its continued use in the program, given the end of the PHE, the decrease in COVID cases, as well as the availability of treatments. After consideration of the public comments, we are finalizing our proposal to remove the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure from the HH QRP beginning with the CY 2026 HH QRP. Beginning with patients discharged on or after April 1, 2026, HHAs would not be required to collect and submit the Patient/Resident COVID-19 Vaccine measure data to CMS. Until that time and with the posting of this final rule, HHAs may submit any valid response (0 – No, 1-Yes or dash) on a Transfer, Death at home, or Discharge OASIS assessment, without any future quality measure implications.

b. SDOH Data Elements Burden

Comment: A slight majority of commenters supported the proposal to remove the four standardized patient assessment data elements focused on collecting information related to

SDOH. These commenters often acknowledged the importance of better understanding of SDOH in addressing healthcare challenges but noted that there may be less burdensome methods to obtaining the required SDOH data.

Response: We thank commenters for their support for our proposal to remove these four SDOH items from the standardized patient assessment data elements collected and submitted using the OASIS. We continue to monitor the HH QRP data collection requirements to look for ways to reduce administrative burden, where appropriate, while maintaining a high standard of quality care. We agree that removing these items at this time will alleviate some of the burden on HH providers associated with HH QRP data collection and submission requirements. We intend to align the HH QRP more closely with our overarching goal for improved health care delivery through health IT advances and low-burden interoperable electronic systems. As we stated in the CY 2026 HH PPS proposed rule (90 FR 2908), we plan to refocus efforts on how data elements can improve care coordination, efficiency, reduction in errors, and patient experience.

Final Decision: After consideration of the public comments, we are finalizing our proposal to remove four standardized patient assessment data elements (one item for Living Situation (R0310); two items for Food (R0320A and R0320B); and one item for Utilities (R0330)) collected under the SDOH category from the HH QRP beginning with the CY 2026 HH QRP without modification.

3. Effects of the Expanded HH VBP Model

In the CY 2022 HH PPS final rule (88 FR 77676), we estimated that the expanded HHVBP Model would generate a total projected 5-year gross FFS savings of $3,376,000,000. The changes to the applicable measure set proposed in this rule would not change those estimates because they do not change the number of HHAs in the Model or the payment methodology.

Based on policies discussed in this final rule, Tables 69 and 70 display the distribution of possible unweighted payment adjustments[90] using CY 2023 as the performance year and CY

90 Payment adjustments calculated for all HHAs with Medicare certification dates prior to January 1, 2021.

2022 as the baseline year for all 1-year measures. For 2-year measures (such as DTC and MSPB-PAC), payment adjustments were calculated using CYs 2022 and 2023 as the performance period and CYs 2021 and 2022 as the baseline period. Note that payment adjustments in the expanded Model are made in a budget-neutral manner.

Tables 52 and 53 show the value-based incentive payment adjustments for the estimated 7,061 HHAs that would qualify to compete in the expanded Model based on CY 2023 performance data stratified by volume-based cohort, as defined in section III.F. of the CY 2022 HH PPS final rule (86 FR 62312). Using CY 2023 performance year data and the 5 percent payment adjustment, based on the 11 proposed quality measures, the 6,391 HHAs in the larger-volume cohort would have an average payment adjustment of positive 0.004 percent (+0.004 percent). Overall, smaller-volume HHAs would have an average payment adjustment of positive 0.006 percent (+0.006 percent). Eighteen states/territories do not have any HHAs in the smaller-volume cohort. The remaining states/territories have HHAs in both volume-based cohorts. Florida, for example, has 556 HHAs in the larger-volume cohort with an average payment adjustment of positive 0.289 percent (+0.289 percent) and 50 HHAs in the smaller-volume cohort with an average payment adjustment of negative 0.003 percent (-0.003 percent).

The next columns provide the distribution of payment adjustment by percentile. For example, 10 percent of HHAs in the larger-volume cohort would receive downward payment adjustments of more than negative 2.252 percent (-2.252 percent). The median (50^{th} percentile) payment adjustment for the larger-volume cohort is negative 0.086 percent (-0.086 percent). Among smaller-volume HHAs, 10 percent of HHAs would receive downward payment adjustments of more than negative 2.513 percent (-2.513 percent). The median (50^{th} percentile) payment adjustment for the smaller-volume cohort is negative 0.094 percent (-0.094 percent). As an example of the range of payment adjustments in a given state, payment adjustments for larger-volume HHAs in Florida range from negative 2.284 percent (-2.284 percent) at the 10^{th}

percentile to positive 2.945 percent (+2.945 percent) at the 90th percentile, while the median (50th percentile) payment adjustment is positive 0.211 percent (+0.211 percent).

Table 54 provides the payment adjustment distribution based on the proportion of dual-eligible beneficiaries, average case mix using Hierarchical Condition Category (HCC) scores, proportion of beneficiaries that reside in rural areas, and HHA organizational status. To define cutoffs for the "percentage of dual eligible beneficiaries," low through high percentage dual-eligible are based on the 20th, 40th, 60th, and 80th percentiles of percent dual eligible beneficiaries, respectively, across HHAs in CY 2021. To define case mix cutoffs, low, medium, or high acuity are based on less than the 25th percentile, between the 25th and 75th percentiles, and greater than the 75th percentile of average HCC scores, respectively, across HHAs in CY 2021. To define cutoffs for percentage of rural beneficiaries, all non-rural, up to 50 percent rural, and over 50 percent rural are based on the home health beneficiaries' core-based statistical area (CBSA) urban versus rural designation. Based on CY 2021 data, HHAs with the highest proportion of dual-eligible beneficiaries served have the highest average payment adjustment (+0.228 percent). In addition, a higher proportion of rural beneficiaries served is associated with better performance. Specifically, HHAs serving over 50 percent rural beneficiaries have an average payment adjustment of positive 0.167 percent (+0.167 percent), compared to a slightly negative average payment adjustment for HHAs serving only non-rural beneficiaries or HHAs serving up to 50 percent rural beneficiaries. Among organizational types, proprietary HHAs have a slightly negative average payment adjustment of 0.047 (-0.047 percent), whereas HHAs in other organizational type categories have a positive average payment adjustment.

TABLE 52: PAYMENT ADJUSTMENT DISTRIBUTION BY VOLUME-BASED COHORT: LARGE-VOLUME COHORT

Larger-volume Cohort											
			Payment Adjustment Percentile Distribution (%)								
State	# of HHAs	Average Payment Adjustment (%)	10%	20%	30%	40%	50%	60%	70%	80%	90%
AK	10	(0.692)	(2.830)	(2.112)	(1.518)	(0.908)	(0.515)	(0.378)	0.252	0.793	1.152
AL	111	0.418	(1.536)	(0.798)	(0.195)	0.189	0.406	0.827	1.259	1.609	2.008
AR	88	0.265	(2.237)	(0.893)	(0.484)	(0.079)	0.327	0.648	1.063	1.473	2.495
AZ	116	(0.503)	(2.731)	(1.966)	(1.350)	(0.993)	(0.392)	(0.098)	0.309	0.721	1.863
CA	1070	0.207	(2.411)	(1.636)	(1.116)	(0.507)	0.054	0.601	1.308	2.042	3.073

Larger-volume Cohort											
			Payment Adjustment Percentile Distribution (%)								
State	# of HHAs	Average Payment Adjustment (%)	10%	20%	30%	40%	50%	60%	70%	80%	90%
CO	99	(0.219)	(2.294)	(1.669)	(1.232)	(0.810)	(0.387)	0.194	0.655	1.185	2.408
CT	62	(0.240)	(2.822)	(1.892)	(1.063)	(0.446)	0.051	0.291	0.566	1.253	2.044
DC	9	(0.759)	(2.201)	(2.067)	(1.806)	(1.315)	(1.106)	(0.800)	(0.234)	0.244	2.452
DE	12	(0.160)	(1.285)	(1.176)	(1.076)	(0.868)	(0.776)	(0.564)	0.341	0.364	1.394
FL	566	0.289	(2.284)	(1.366)	(0.898)	(0.300)	0.211	0.699	1.358	2.088	2.945
GA	95	(0.650)	(2.314)	(1.934)	(1.363)	(0.921)	(0.555)	(0.314)	(0.030)	0.354	0.998
GU	3	(2.536)	(3.294)	(3.294)	(3.294)	(2.830)	(2.830)	(2.830)	(1.485)	(1.485)	(1.485)
HI	11	(1.012)	(3.015)	(2.250)	(1.995)	(1.191)	(0.969)	(0.550)	(0.384)	0.019	0.187
IA	85	0.463	(1.554)	(1.143)	(0.672)	0.066	0.516	0.880	1.464	1.872	2.544
ID	44	0.072	(1.840)	(1.126)	(0.881)	(0.078)	0.146	0.358	0.713	1.723	1.839
IL	338	(0.010)	(2.199)	(1.601)	(1.018)	(0.519)	(0.099)	0.421	0.857	1.395	2.364
IN	116	0.071	(2.039)	(1.552)	(0.875)	(0.529)	0.007	0.525	0.900	1.400	2.435
KS	77	0.032	(2.205)	(1.524)	(0.903)	(0.438)	0.105	0.640	1.018	1.522	2.056
KY	85	0.563	(1.154)	(0.775)	(0.239)	0.090	0.605	0.930	1.244	1.727	2.411
LA	160	0.174	(1.994)	(1.319)	(0.658)	(0.127)	0.207	0.674	0.981	1.527	2.072
MA	105	0.079	(2.389)	(1.538)	(1.075)	(0.544)	(0.042)	0.381	1.058	1.506	2.705
MD	49	0.264	(1.965)	(1.442)	(0.913)	(0.074)	0.303	0.592	0.972	1.829	2.529
ME	18	0.792	(0.686)	(0.232)	(0.012)	0.374	0.771	1.050	1.536	1.592	2.568
MI	230	0.270	(1.912)	(1.273)	(0.806)	(0.384)	0.153	0.603	1.107	1.625	2.702
MN	85	(0.154)	(2.277)	(1.788)	(1.267)	(0.547)	(0.104)	0.278	0.742	1.000	2.059
MO	101	0.340	(2.003)	(1.005)	(0.592)	(0.238)	0.082	0.666	1.132	2.066	2.900
MS	42	0.245	(1.056)	(0.580)	(0.165)	0.293	0.530	0.599	0.950	1.038	1.389
MT	17	(1.066)	(2.883)	(2.610)	(2.231)	(1.929)	(1.562)	(0.684)	(0.457)	0.521	1.327
NC	146	(0.246)	(1.950)	(1.255)	(0.849)	(0.561)	(0.320)	(0.124)	0.384	0.695	1.380
ND	13	(0.186)	(2.271)	(1.868)	(1.384)	(0.467)	(0.257)	0.014	1.027	1.193	1.971
NE	44	0.185	(1.775)	(1.357)	(0.757)	(0.470)	(0.053)	0.879	1.221	1.712	2.152
NH	19	0.037	(1.689)	(0.986)	(0.807)	(0.383)	0.200	0.602	0.730	0.888	1.617
NJ	39	0.559	(0.674)	(0.269)	(0.206)	0.089	0.566	0.904	1.057	1.423	1.969
NM	58	(0.432)	(2.325)	(1.425)	(1.188)	(0.875)	(0.522)	(0.027)	0.331	0.510	1.577
NV	101	(0.092)	(2.513)	(1.895)	(1.400)	(1.090)	(0.445)	0.212	0.769	1.791	2.853
NY	94	0.193	(1.671)	(1.253)	(0.850)	(0.533)	0.010	0.454	0.736	1.660	2.713
OH	226	(0.170)	(2.424)	(1.838)	(1.367)	(0.765)	(0.368)	0.233	0.801	1.377	2.538
OK	175	(0.379)	(2.310)	(1.782)	(1.263)	(0.821)	(0.487)	(0.110)	0.414	0.945	1.622
OR	41	(0.540)	(2.079)	(1.839)	(1.386)	(1.041)	(0.831)	(0.243)	(0.029)	0.329	1.889
PA	179	0.041	(1.835)	(1.200)	(0.665)	(0.266)	(0.031)	0.376	0.666	1.317	1.719
PR	35	(1.647)	(3.394)	(2.891)	(2.693)	(2.425)	(2.226)	(1.937)	(1.697)	(0.392)	0.575
RI	18	0.575	(1.414)	(0.614)	(0.042)	0.198	0.413	0.761	1.321	1.973	2.648
SC	65	0.162	(1.555)	(1.064)	(0.526)	(0.109)	0.097	0.399	0.679	1.087	1.674
SD	19	1.458	(0.332)	(0.169)	0.018	0.445	0.942	1.564	2.535	3.668	4.333
TN	109	0.146	(1.941)	(1.115)	(0.537)	(0.072)	0.167	0.432	0.860	1.280	2.055
TX	778	(0.425)	(2.500)	(1.981)	(1.505)	(1.084)	(0.549)	(0.130)	0.409	1.106	1.864
UT	61	0.985	(1.701)	(1.015)	(0.219)	0.237	0.928	1.553	2.001	2.769	4.004
VA	168	(0.329)	(2.303)	(1.760)	(1.290)	(0.899)	(0.378)	(0.118)	0.377	1.075	2.034
VI	1	0.182	0.182	0.182	0.182	0.182	0.182	0.182	0.182	0.182	0.182
VT	10	(1.084)	(2.084)	(1.698)	(1.569)	(1.343)	(1.182)	(1.076)	(0.807)	(0.207)	0.223
WA	58	(0.369)	(2.245)	(1.661)	(1.477)	(1.078)	(0.379)	(0.125)	0.256	1.119	2.144
WI	66	0.327	(1.450)	(1.145)	(0.649)	(0.376)	0.303	1.133	1.369	1.698	2.560
WV	45	0.025	(2.400)	(1.470)	(0.610)	(0.127)	0.246	0.502	0.819	1.080	1.660
WY	19	(0.217)	(2.396)	(1.363)	(1.155)	(0.688)	(0.404)	0.156	0.727	0.951	2.180
ALL	**6,391**	**0.004**	**(2.252)**	**(1.570)**	**(1.058)**	**(0.539)**	**(0.086)**	**0.364**	**0.862**	**1.509**	**2.414**

TABLE 53: PAYMENT ADJUSTMENT DISTRIBUTION BY VOLUME-BASED COHORT: SMALL-VOLUME COHORT

Smaller-volume Cohort											
			Payment Adjustment Percentile Distribution (%)								
State	# of HHAs	Average Payment Adjustment (%)	10%	20%	30%	40%	50%	60%	70%	80%	90%
AK	1	(1.089)	(1.089)	(1.089)	(1.089)	(1.089)	(1.089)	(1.089)	(1.089)	(1.089)	(1.089)
AL	1	(2.729)	(2.729)	(2.729)	(2.729)	(2.729)	(2.729)	(2.729)	(2.729)	(2.729)	(2.729)

Smaller-volume Cohort											
State	# of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
AR	2	1.219	1.162	1.162	1.162	1.162	1.219	1.275	1.275	1.275	1.275
AZ	4	(0.800)	(2.776)	(2.776)	(2.345)	(2.345)	(2.158)	(1.970)	(1.970)	3.890	3.890
CA	209	0.244	(2.430)	(1.712)	(0.956)	(0.360)	0.139	0.639	1.355	2.205	2.921
CO	7	(0.565)	(4.699)	(3.813)	(0.908)	(0.908)	(0.383)	1.234	1.234	1.369	3.243
CT	0	-	-	-	-	-	-	-	-	-	-
DC	0	-	-	-	-	-	-	-	-	-	-
DE	1	(4.272)	(4.272)	(4.272)	(4.272)	(4.272)	(4.272)	(4.272)	(4.272)	(4.272)	(4.272)
FL	50	(0.003)	(2.685)	(2.229)	(1.601)	(0.944)	0.029	0.468	1.141	2.231	2.836
GA	0	-	-	-	-	-	-	-	-	-	-
GU	0	-	-	-	-	-	-	-	-	-	-
HI	0	-	-	-	-	-	-	-	-	-	-
IA	11	1.412	(0.843)	(0.264)	0.565	1.200	1.766	2.082	2.176	2.771	3.237
ID	0	-	-	-	-	-	-	-	-	-	-
IL	60	0.361	(2.255)	(1.486)	(0.957)	(0.597)	(0.019)	0.788	1.287	2.089	3.443
IN	12	(0.606)	(2.826)	(2.608)	(1.733)	(1.256)	(0.579)	(0.025)	0.283	0.410	1.829
KS	3	2.566	2.257	2.257	2.257	2.456	2.456	2.456	2.984	2.984	2.984
KY	0	-	-	-	-	-	-	-	-	-	-
LA	2	(1.843)	(2.945)	(2.945)	(2.945)	(2.945)	(1.843)	(0.741)	(0.741)	(0.741)	(0.741)
MA	5	(0.883)	(3.391)	(2.247)	(1.103)	(1.059)	(1.014)	(0.613)	(0.212)	0.547	1.305
MD	0	-	-	-	-	-	-	-	-	-	-
ME	0	-	-	-	-	-	-	-	-	-	-
MI	41	0.692	(1.816)	(0.776)	(0.039)	0.208	0.696	1.088	2.103	2.371	2.934
MN	5	0.241	(2.098)	(1.511)	(0.924)	(0.847)	(0.770)	0.804	2.377	2.500	2.622
MO	4	0.695	0.132	0.132	0.467	0.467	0.663	0.858	0.858	1.323	1.323
MP	1	(1.072)	(1.072)	(1.072)	(1.072)	(1.072)	(1.072)	(1.072)	(1.072)	(1.072)	(1.072)
MS	0	-	-	-	-	-	-	-	-	-	-
MT	2	(0.810)	(0.913)	(0.913)	(0.913)	(0.913)	(0.810)	(0.707)	(0.707)	(0.707)	(0.707)
NC	3	(0.260)	(1.583)	(1.583)	(1.583)	(0.060)	(0.060)	(0.060)	0.864	0.864	0.864
ND	0	-	-	-	-	-	-	-	-	-	-
NE	6	(1.046)	(3.063)	(2.555)	(2.555)	(1.707)	(1.569)	(1.430)	0.075	0.075	2.405
NH	2	(0.654)	(1.636)	(1.636)	(1.636)	(1.636)	(0.654)	0.328	0.328	0.328	0.328
NJ	0	-	-	-	-	-	-	-	-	-	-
NM	1	(0.927)	(0.927)	(0.927)	(0.927)	(0.927)	(0.927)	(0.927)	(0.927)	(0.927)	(0.927)
NV	15	(0.214)	(1.985)	(1.959)	(1.067)	(0.510)	(0.242)	(0.075)	0.462	0.842	1.914
NY	3	0.150	(2.442)	(2.442)	(2.442)	0.309	0.309	0.309	2.582	2.582	2.582
OH	12	(0.069)	(2.573)	(1.741)	(0.555)	(0.190)	(0.064)	0.276	0.349	1.571	1.632
OK	12	(0.852)	(2.373)	(1.560)	(1.451)	(1.331)	(1.197)	(0.661)	(0.466)	(0.424)	(0.307)
OR	1	(0.191)	(0.191)	(0.191)	(0.191)	(0.191)	(0.191)	(0.191)	(0.191)	(0.191)	(0.191)
PA	12	(0.380)	(2.461)	(2.016)	(1.845)	(0.706)	(0.559)	(0.349)	0.343	1.879	1.892
PR	0	-	-	-	-	-	-	-	-	-	-
RI	0	-	-	-	-	-	-	-	-	-	-
SC	0	-	-	-	-	-	-	-	-	-	-
SD	1	3.442	3.442	3.442	3.442	3.442	3.442	3.442	3.442	3.442	3.442
TN	1	(0.925)	(0.925)	(0.925)	(0.925)	(0.925)	(0.925)	(0.925)	(0.925)	(0.925)	(0.925)
TX	150	(0.536)	(2.795)	(2.250)	(1.827)	(1.221)	(0.741)	0.063	0.661	1.203	1.810
UT	8	0.487	(2.776)	(1.032)	(0.454)	0.047	0.355	0.662	0.775	3.169	3.503
VA	14	0.207	(2.286)	(1.428)	(0.724)	(0.670)	(0.104)	0.827	1.007	1.915	2.840
VI	0	-	-	-	-	-	-	-	-	-	-
VT	0	-	-	-	-	-	-	-	-	-	-
WA	0	-	-	-	-	-	-	-	-	-	-
WI	2	2.769	1.757	1.757	1.757	1.757	2.769	3.780	3.780	3.780	3.780
WV	3	0.353	(0.286)	(0.286)	(0.286)	0.023	0.023	0.023	1.322	1.322	1.322
WY	3	(0.229)	(1.022)	(1.022)	(1.022)	(0.734)	(0.734)	(0.734)	1.070	1.070	1.070
ALL	**670**	**0.006**	**(2.513)**	**(1.938)**	**(1.177)**	**(0.684)**	**(0.094)**	**0.504**	**1.083**	**1.874**	**2.772**

TABLE 54: HHVBP PAYMENT ADJUSTMENT DISTRIBUTION BY HHA CHARACTERISTICS

HHA Characteristics	# of HHAs	Average Payment Adjustment (%)	Payment Adjustment Percentile Distribution (%)								
			10%	20%	30%	40%	50%	60%	70%	80%	90%
Percentage Dual-eligible											
1st Quintile: % Dual-eligible	1,407	0.122	(2.221)	(1.523)	(1.026)	(0.431)	0.040	0.520	1.058	1.668	2.611
2nd Quintile: % Dual-eligible	1,407	0.033	(2.064)	(1.368)	(0.805)	(0.380)	0.014	0.412	0.840	1.354	2.122
3rd Quintile: % Dual-eligible	1,407	(0.060)	(2.089)	(1.442)	(0.955)	(0.519)	(0.104)	0.330	0.733	1.331	2.028
4th Quintile: % Dual-eligible	1,407	(0.317)	(2.459)	(1.932)	(1.398)	(0.938)	(0.466)	0.032	0.579	1.198	2.038
5th Quintile: % Dual-eligible	1,407	0.228	(2.525)	(1.733)	(1.101)	(0.507)	0.057	0.602	1.355	2.228	3.319
Acuity (HCC)											
1-Lowest Acuity	1,750	0.286	(2.430)	(1.675)	(1.038)	(0.415)	0.160	0.739	1.406	2.193	3.304
2-Medium Acuity	3,498	(0.062)	(2.234)	(1.555)	(1.063)	(0.554)	(0.103)	0.329	0.781	1.367	2.138
3-Highest Acuity	1,749	(0.130)	(2.232)	(1.572)	(1.076)	(0.628)	(0.237)	0.195	0.654	1.266	2.135
% Rural Beneficiaries											
1-All non-rural	3,804	(0.018)	(2.459)	(1.791)	(1.205)	(0.691)	(0.178)	0.349	0.899	1.666	2.698
2-Up to 50% rural	1,991	(0.059)	(2.151)	(1.481)	(0.979)	(0.503)	(0.102)	0.305	0.727	1.281	2.009
3-Over 50% rural	1,228	0.167	(1.920)	(1.261)	(0.755)	(0.304)	0.087	0.583	1.070	1.584	2.330
Organizational Type											
1-Vol Non-Profit-Religious	258	0.508	(1.767)	(1.034)	(0.301)	0.087	0.513	0.858	1.467	2.008	2.811
2-Vol Non-Profit-Private	521	0.089	(1.952)	(1.374)	(0.913)	(0.479)	(0.042)	0.436	0.893	1.500	2.455
3-Vol Non-Profit-Other	417	0.105	(1.929)	(1.247)	(0.768)	(0.273)	0.050	0.484	1.059	1.443	2.058
4-Proprietary	5,601	(0.047)	(2.350)	(1.700)	(1.150)	(0.632)	(0.156)	0.320	0.838	1.503	2.480
5-Govt-State/County	146	0.259	(1.674)	(1.211)	(0.688)	(0.259)	0.099	0.599	1.070	1.580	2.435
6-Govt-Govt & Voluntary	11	0.497	(0.735)	(0.357)	(0.279)	(0.055)	0.075	0.269	0.314	1.589	2.392
7-Govt-Local	91	0.270	(1.770)	(1.071)	(0.647)	(0.314)	0.491	0.669	1.038	1.748	2.308

Notes:

- Dual: low, medium, high are based on 25th and 75th percentiles of the percent of Medicare fee-for-service beneficiaries with any dual indicated across all HHAs in 2021.
- HCC Score Acuity: low, medium, high are based on 25th and 75th percentiles of the average HCC of Medicare fee-for-service beneficiaries across all HHAs in 2021.
- Percentage rural Medicare fee-for-service beneficiaries: based on CBSA of beneficiaries' ZIP code aggregated to the HHA level in 2021.

The total number of HHAs differ by category due to missing HHAs in some data sources.

4. Updates to the Home Health Agency Conditions of Participation (CoPs) to Align with the OASIS All-Payer Submission Requirements

As discussed in section V. of this final rule, we proposed technical revisions to the HHA CoPs to further clarify that the existing requirement for reporting OASIS information applies to all HHA patients receiving skilled services. This technical change sought to provide clarity by creating alignment between the terminology used in the CoPs and requirements for data collection and submission to OASIS for purposes of the HH QRP. CMS did not propose any revisions to the specific requirements for submitting data to OASIS or expand the data required to be collected that was finalized in the CY 2023 HH PPS final rule (87 FR 66862). For a review of the burden and operational costs associated with the transition to the OASIS all-payer submission requirements, we refer readers to the CY 2023 HH PPS final rule "Collection of Information" section (87 FR 66877 through 66879) and to the CY 2024 HH PPS final rule for the latest burden estimates (88 FR 77850 through 77855).

We received no comments on the regulatory impact analysis for this proposal and believe there is no additional burden..

5. Provider Enrollment

As previously noted, we proposed several provider enrollment provisions to strengthen and clarify certain aspects of the provider enrollment process. This RIA addresses provisions that: (1) we believe would have a financial impact; and (2) would not, in our view, have such an impact but which require explanation.

a. Retroactive Revocations

Section 424.535(g)(1) states that except as described in § 424.535(g)(2) and (3), a revocation becomes effective 30 days after CMS or its contractor mails notice of its determination to the provider. Under existing § 424.535(g)(2)(i) through (viii), there are grounds for which CMS can revoke a provider's enrollment retroactively to the date the provider's non-compliance commenced. Retroactive revocation allows CMS to collect monies that have been

paid to the provider since the beginning of its non-compliance. We explained in section VI.A. of this final rule that we proposed to increase significantly the number of grounds for a retroactive revocation in new § 424.535(a)(8)(iii) and (g)(2)(viii) through (xiv). These nine situations and our proposed revocation effective dates (listed in parentheses) are as follows:

- An independent diagnostic testing facility's (IDTF's) liability insurance lapsed (date the insurance lapsed).
- The provider submitted false or misleading information on its enrollment application (date the provider signed the application's certification statement).
- The provider failed to timely report a change of ownership, an adverse legal action, or addition, deletion, or change of a practice location (day after the date by which the provider was required to report the change, addition, or deletion).
- The provider's Drug Enforcement Administration (DEA) certificate of registration was surrendered in response to a show cause order (date the certificate was surrendered).
- The individual's ability to prescribe one or more drugs has been suspended or revoked by any state in which the physician or non-physician practitioner practices (date of the state's suspension or revocation).
- Under § 424.535(i), if we revoke a provider's enrollment, we can revoke all of the provider's other enrollments. The effective dates of these other revocations would be the effective date of the triggering revocation.
- A DMEPOS supplier was revoked for non-compliance with a condition or standard in § 424.57(b) or (c), such as the requirement to meet the DMEPOS quality standards (date on which the non-compliance began).
- Under § 424.535(a)(8)(i), the provider or supplier submits a claim or claims for services that could not have been furnished to a specific individual on the date of service (the earliest date of service on the claim or claims that is or are triggering the revocation).

- Under § 424.535(a)(8)(ii), CMS determines that the provider or supplier has a pattern or practice of submitting claims that fail to meet Medicare requirements (the last date of service on the claims in question).

Table 72 contains several data categories. One is the average annual number of revocations that occur in each of the previous scenarios. Another is the average length of time between when the non-compliance begins in these situations and 30 days after the revocation letter is sent to the provider in question. For instance, suppose a provider undergoes a change of ownership effective May 1 but fails to report it to CMS. The revocation letter is mailed to the provider on June 1, meaning the effective date is July 1. The period between the date of non-compliance and the effective date under paragraph (g)(1) is thus 60 days. However, under our proposal the provider would be ineligible for payments for services furnished during this 60-day period because its revocation would now be retroactive.

An additional category addresses the amount of savings that would accrue to the Medicare program from our proposal. Based on internal CMS data, we calculated in the fourth column in Table 72 the average amount of actual payments made to each of the providers in each of the table's nine revocation reasons in Table 72 during the estimated time period in the table's third column. We then multiplied this figure by the numbers in the second column (average annual number of revocations). The fifth and final column outlines the total annual savings that would result. To illustrate--

- There are 11 revocations per year for lapses in IDTF liability insurance.
- As shown in the fourth column of the table, each of these 11 IDTFs received an average of $19,423 during the 3-month period identified in the third column of the chart.
- Multiplying 11 by $19,423 results in $213,653 in total, combined annual savings for that category of revoked providers.

We recognized that in certain prior provider enrollment regulations, we have used a standard $50,000 average annual payment amount when calculating savings figures. However,

the totals in the third column of the table reflect the actual amounts the revoked providers were paid. They are accordingly much more accurate than a base $50,000 figure.

TABLE 55: ANNUAL SAVINGS FROM RETROACTIVE REVOCATION GROUNDS

New Retro Revocation Basis	Number of Revocations Per Year	Estimated Length of Time Between When the Non-Compliance Occurs and 30 Days After the Revocation Letter is Sent	Based Average Payments Made to Revoked Enrollment During Estimated Non-Compliance Time Period	Estimated Total Annual Savings (Number of Revocations x Average Payments)
IDTF's liability insurance lapsed	11	3 months (0.25 years)	19,423	213,653
Provider submits false/misleading information on application	31	6 months (0.5 years)	225,824	7,000,544
Provider failed to timely report change of ownership, adverse action or practice location	461	6 months (0.5 years)	1,321,736	609,320,296
Provider's DEA certificate is suspended, revoked, or surrendered in response to show cause order OR State suspends or revokes individual's ability to prescribe	7	60 days (0.164 years)	79,227	554,589
Revocation resulting in other revocations under § 424.535(i).	3	60 days (0.164 years)	281,756	845,268
DMEPOS supplier revoked for non-compliance with condition or standard in 424.57(b) or (c).	790	3 months (0.25 years)	488,328	385,779,120
§ 424.535(a)(8)(i)	9	1 year	18,371,237	165,341,133
§ 424.535(a)(8)(ii)	130	60 days (0.164 years)	7,910,366	1,028,347,580
TOTALS & AVERAGES	**1,442 Per Year**	**Varies**	**28,697,897**	**2,197,402,183**

We accordingly project annual savings of $2,197,402,183 stemming from our retroactive revocation proposals.

b. Expanded and Clarified Revocation Reasons

In accordance with existing § 424.535(a)(14), CMS can revoke a physician's or practitioner's enrollment if the individual has a pattern or practice of prescribing Part B or D drugs that is abusive, threatens the health and safety or Medicare beneficiaries, or fails to meet Medicare requirements. We proposed to expand this authority to include drugs associated with services covered under Part A. We are unable to establish a savings estimate for this revision, for we cannot predict the number of instances in which we would utilize § 424.535(a)(14) for Part A prescribing patterns or practices.

We also proposed in new § 424.535(a)(8)(i)(D) to clarify that our revocation authority under paragraph (a)(8)(i) includes situations where beneficiary attestations state that the service(s) or item(s) the provider claims were furnished to the beneficiary were, in fact, not. As

this is merely an elucidation of our existing authority to revoke in such situations, we do not anticipate additional savings therefrom.

c. Additional Deactivation Reason

We proposed under new § 424.547 that CMS may deactivate a physician's or non-physician's practitioner's ability to order, certify, or refer the Medicare services and items identified in § 424.507(a) and (b) if the individual--

- Is enrolled in Medicare solely to order, certify, or refers beneficiaries for Medicare Part A or B services or items; *and*
- The individual has not been listed as the ordering, certifying, or referring individual on a Medicare Part A or B claim received in the previous 12 consecutive calendar months.

As with our proposed expansion of § 424.535(a)(14), we are unable to establish a savings or burden estimate for new § 424.547 because we cannot predict the number of instances in which we would apply this authority.

d. Comments Received and Conclusion

We received no comments on our regulatory impact estimates for the provider enrollment proposals addressed in this section IX.C.45. Accordingly, we are finalizing these projections as proposed.

6. DMEPOS Supplier Accreditation Organizations

Section VI.B. of this final rule outlines our revisions to §§ 424.57 and 424.58 and the reasons for them. Most of our changes would involve: (1) additional requirements an organization must meet to become and remain a CMS-approved DMEPOS AO; and (2) additional surveys that must be performed. The ICR component of these requirements was addressed in section VII. of this final rule. This RIA discusses the principal non-ICR costs and potential savings associated with our provisions. Our proposed estimates are below followed by the comments we received and our responses thereto.

a. Costs

For purposes of our cost calculations, we would use the following median wage categories and hourly rates from the BLS May 2024 National Occupational Employment and Wage Estimates for all salary estimates. We believe these occupational classifications, some of which were used in the February 15, 2024, proposed rule referenced in section VI.B. of the subject rule, would be most applicable to our cost impact analysis:

TABLE 56: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Median Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Registered Nurses	29-1141	45.00	45.00	90.00
Medical and Health Services Managers (MHSM)	11-9111	56.71	56.71	113.42
Other Healthcare Practitioners and Technical Occupations (OHPTO)	29-9000	30.20	30.20	60.40
Office and Administrative Support Workers, All Other	43-9199	22.14	22.14	44.28

There are generally two types of surveys that will form the bases of our calculations: (1) initial and reaccreditation surveys (which include the survey and the accreditation); and (2) "off-cycle" surveys, or ad-hoc surveys performed outside of the initial and reaccreditation process to reconfirm compliance with the quality standards. Ad-hoc surveys-- which, except perhaps in cases where the supplier is adding a new product, typically does not involve the accreditation process itself but only the survey – can occur in response to, for instance, a complaint or a CMS request that a survey be performed. The hour burdens and fees associated with (1) and (2) vary widely among AOs. However, based on our information, we estimated the following, emphasizing that: (1) the hour burdens could involve multiple individuals (for example, a 6-hour burden could have two individuals contributing 3 hours each); (2) the survey costs to the AO include travel and other expenses; and (3) both the hour and cost burdens could include incidental tasks (for example, the AO contacts the supplier for additional data regarding its reaccreditation application):

- Initial and Reaccreditation Processes and Surveys

++ Burden to Supplier for Initial Accreditation and Survey - 24 hours and $5,000 fee the supplier pays to the AO.

++ Burden to Supplier for Reaccreditation and Survey - 14 hours and $3,000 fee.

(Note that the two preceding burdens include the supplier's preparation and submission to the AO of its accreditation or reaccreditation materials.)

++ Burden to AO for Survey, Review/Decision, and Accreditation (Initials and Reaccreditation) – 20 hours

- Off-Cycle Surveys

++ Burden to Supplier for Survey – 6 hours and $2,000 cost of the survey

++ Burden to AO for Survey and Review/Decision – 14 hours (cost addressed below).

These figures will be used as inputs for the succeeding estimates.

There is also variance among the DMEPOS AOs regarding the staff that performs the surveys and accreditation reviews. We recognized that many DMEPOS AOs hire contractors to conduct surveys and that non-medical personnel at the AO might make final accreditation decisions. Yet we also wish to remain as consistent as possible with wage categories in other CMS accreditation rulemaking efforts. For purposes of this RIA and our burden calculations only, therefore, we assumed that: (1) contractor personnel (under the OHPTO wage category) would perform the surveys; and (2) nurses and MHSMs would perform initial reviews and make final determinations regarding the supplier's accreditation. As for the suppliers themselves, we believe that administrative personnel would work with the AO in the survey and be involved in the accreditation process (for example, preparing the application, as they do with Form CMS-855 enrollment applications).

There are five categories of surveys, reviews, and accreditations that form the bases of our accreditation cost estimates: (1) complaint investigations and surveys; (2) additional initial surveys; (3) annual reaccreditations and surveys; (4) CMS-directed ad-hoc surveys; and (5) change of ownership surveys. These are addressed in the succeeding subsections.

(1) Complaint Investigations and Surveys

Proposed new § 424.58(e)(3)(i)(B) and (C), state, respectively, that after receiving a complaint, an AO must--

- Perform an initial review of the complaint to determine whether, based on the complaint and any other information, the supplier may be non-compliant with one or more DMEPOS quality standards; and
- Conduct a survey of the accredited facility if the AO's initial review concludes that such non-compliance may exist and a survey is deemed necessary.

In assessing potential ICR costs to the AO, we estimated that each year an AO would report 50 complaints to us. With 8 AOs, this would result in 400 complaints annually. We further assumed the following:

- It would take an average of 4 hours for an AO to perform its initial review of potential non-compliance. The hourly rate of this task would be split between nurses and MHSMs, resulting in a wage of $101.71 ($90.00 + $113.42)/2).
- Roughly 20 percent of initial reviews would result in an off-cycle survey, which would take the OHPTO 8 hours to perform; this would also result in 80 complaint surveys being performed each year (400 x 0.2).
- It would take the AO 6 hours to render a decision on the survey and whether the supplier should remain accredited (as well as to notify the supplier of the decision). We will apply the aforementioned combined $101.71 hourly rate for this task.
- The supplier would incur a burden of 6 hours during the survey. The hourly rate would be $44.28.
- The cost of the complaint survey would be $2,000, which the supplier would pay to the AO.

Given these assumptions, we project the following annual figures for complaint surveys:

- Initial Review Burden to AOs – 1,600 hours and $162,736 (400 complaints x 4 hours x $101.71)

- Survey Cost Burden to AOs – 640 hours and $38,656 (80 surveys x 8 hours x $60.40)

- Post-Survey Decision Burden to AOs – 480 hours and $48,821 (80 x 6 hours x $94.59)

- Burden to Suppliers During Survey – 480 hours and $21,254 (80 x 6 x $44.28)

- Supplier Survey Fees Paid to AO - $160,000 (80 x $2,000)

Table 57 outlines the annual burden impact of § 424.57(e)(3)(i)(B) and (C).

TABLE 57: ANNUAL BURDEN OF COMPLAINT INVESTIGATIONS AND SURVEYS

BURDEN TO AO				
Task	**Hour Burden Per Task**	**Total Hours**	**Wage ($)**	**Total Cost ($)**
AO Burden - Initial Review of Complaint	4	1,600	101.71	162,736
AO Burden – Survey	8	640	60.40	38,656
AO Burden - Post-Survey Review/Decision	6	480	101.71	48,821
Survey Fee Collections	N/A	N/A	N/A	(160,000)
TOTAL	18	2,720	Varies	90,213
BURDEN TO SUPPLIER				
Burden to Supplier During Survey	6	480	44.28	21,254
Survey Fee	N/A	N/A	N/A	160,000
TOTAL	6	480	N/A	181,254
COMBINED NET BURDEN	**24**	**3,200**	**N/A**	**271,467**

(2) Additional Surveys and Reaccreditations

Several other provisions would increase the frequency of surveys to be performed and/or reaccreditations to be undertaken:

- Proposed § 424.58(e)(8)(i)(A) states that except as otherwise directed or permitted by CMS, the AO must perform a survey of all suppliers and their locations seeking initial accreditation or reaccreditation with the AO.

- Proposed § 424.57(c)(24) states that supplier locations must be resurveyed and reaccredited at least once every 12 months (rather than the current 3-year period).

- Proposed § 424.58(e)(8)(ii) states that CMS may, at any time, direct the AO to perform a survey of an accredited supplier or group thereof.

● Proposed § 424.551 states that a DMEPOS supplier must enroll as a new supplier, receive a survey, and be reaccredited if it undergoes a non-exempted change in majority ownership.

There presently are approximately 46,500 accredited and enrolled DMEPOS suppliers, and about 1,780 accredited DMEPOS suppliers enroll in Medicare each year.

We currently permit a limited amount of sampling, which allows a DMEPOS AO to forgo performing a survey for certain supplier types, such as large chain suppliers in areas without high rates of fraud, waste, and abuse. While we do not have exact figures regarding the number of supplier locations that are not surveyed due to sampling, we estimate – solely for purposes of this RIA -- the amount to be roughly 50 percent of all chain suppliers.

(a) Initial Accreditation

The only additional initial accreditation burden associated with §§ 424.58(e)(8)(i)(A) would involve surveys of 50 percent of 1,780 of the aforementioned DMEPOS suppliers (or 890) at a cost to each supplier of $2,000 per survey. Using our previous calculations, Table 58 outlines the annual hour and cost burdens.

TABLE 58: ADDITIONAL ANNUAL BURDEN OF INITIAL SURVEYS

BURDEN TO AO				
Task	**Hour Burden Per Task**	**Total Hours**	**Wage ($)**	**Total Cost ($)**
AO Burden — Survey	8	7,120 (8 x 890)	60.40	430,048
Survey Fee Collections	N/A	N/A	N/A	(1,780,000) (or $2,000 cost x 890 surveys)
TOTAL	8	7,120	N/A	(1,349,952)
BURDEN TO SUPPLIER				
Burden to Supplier During Survey	6	5,340 (6 x 890)	44.28	236,455
Survey Fee	N/A	N/A	N/A	1,780,000
TOTAL	6	5,340	N/A	2,016,455
COMBINED NET BURDEN	**14**	**12,460**	**N/A**	**666,503**

(b) Reaccreditation

The additional burden associated with reaccreditation would involve 46,500 suppliers being surveyed and reaccredited twice more than they currently are within a 3-year period. This means that approximately 93,000 new re-surveys and reaccreditations would occur within the

first 3 years of this rule, or 46,500 per year. Added to this will be the 3,560 new suppliers that would become initially accredited and enrolled during this period (1,780 x 2 years), thus totaling an annual average of 48,280 (46,500 + 1,780) suppliers over this period. We will use the following baselines for our estimates:

- As previously noted, we project the time burden for a survey and reaccreditation to be 14 hours for the supplier and 20 hours for the AO.
- The fee will be $3,000.
- The survey hour and wage estimates will remain the same (for example, 8 hours per survey for the AO).
- The following wage rates will be used:

++ Suppliers - $44.28 (administrative personnel).

++ AO application review - $101.71 (same as the AO post-survey wage).

++ AO surveyors - $60.40.

- The supplier accreditation application process will take 8 hours (14 hours – 6 hours for the survey), and the AO application review process will take 6 hours (20 hours – 8 hours for the survey – 6 hours for the final review/decision).

Table 59 accordingly outlines the burden associated with our annual resurvey and reaccreditation proposals:

TABLE 59: ESTIMATED ANNUAL NEW BURDEN OF RESURVEYS AND REACCREDITATIONS

BURDEN TO AO				
Task	**Hour Burden Per Task**	**Total Hours**	**Wage ($)**	**Total Cost ($)**
AO Burden – Application Review	6	289,680 (6 x 48,280)	101.71	29,463,353
AO Burden – Survey	8	386,240 (8 x 48,280)	60.40	23,328,896
AO Burden – Application/Post-Survey Review/Decision	6	289,680 (6 x 48,280)	101.71	29,463,353
Accreditation Fee Collections	N/A	N/A	N/A	(144,840,000) (or $3,000 x 48,280)
TOTAL	20	965,600	N/A	(62,584,398)
BURDEN TO SUPPLIER				
Supplier Burden – Application Process	8	386,240 (8 x 48,280)	44.28	17,102,707
Burden to Supplier During Survey	6	289,680 (6 x 48,280)	44.28	12,827,030
Accreditation Fee	N/A	N/A	N/A	144,840,000
TOTAL	14	675,920	N/A	174,769,737
COMBINED NET BURDEN	**N/A**	**1,641,520**	**N/A**	**112,185,339**

(c) CMS-Directed Off-Cycle/Ad-Hoc Surveys

We projected that CMS each year would direct the performance of 100 surveys outside of the proposed annual reaccreditation surveys and the complaint surveys. We noted that per proposed § 424.58(c)(1)(xxiii)(L), the AO must have a binding written agreement with its DMEPOS suppliers regarding whether the AO, the supplier in question, or both will assume the costs of a CMS-directed survey. Solely for purposes of this impact analysis, we projected that the supplier would pay the survey cost. Table 59 outlines our estimated net costs of ad-hoc/CMS-directed surveys:

TABLE 6059: ANNUAL BURDEN OF CMS-DIRECTED OFF-CYCLE/AD-HOC SURVEYS

BURDEN TO AO				
Task	**Hour Burden Per Task**	**Total Hours**	**Wage ($)**	**Total Cost ($)**
AO Burden – Survey	8	800 (8 x 100)	60.40	48,320
AO Burden - Post-Survey Review/Decision	6	600 (6 x 100)	101.71	61,026
Survey Fee Collections	N/A	N/A	N/A	(200,000) (or 100 x $2,000)
TOTAL	N/A	1,400	Varies	(90,654)
BURDEN TO SUPPLIER				
Burden to Supplier During Survey	6	600 (6 x 100)	44.28	26,568
Survey Fee	N/A	N/A	N/A	200,000
TOTAL	N/A	600	N/A	226,568
COMBINED NET BURDEN	**N/A**	**2,000**	**N/A**	**135,914**

(d) Change in Majority Ownership

Our data indicates that, on average, approximately 3,768 DMEPOS suppliers each year undergo an ownership change involving a new owner of 50.0 percent or more of the supplier. These surveys would be conducted outside the reaccreditation, complaint, and CMS-directed survey processes. Table 61 outlines the following annual non-ICR burden estimates.

TABLE 61: ANNUAL BURDEN OF OWNERSHIP CHANGE SURVEYS

BURDEN TO AO				
Task	**Hour Burden Per Task**	**Total Hours**	**Wage ($)**	**Total Cost ($)**
AO Burden – Application Review	6	22,608 (6 x 3,768)	101.71	2,299,460
AO Burden - Survey	8	30,144 (8 x 3,768)	60.40	1,820,698
AO Burden – Application/Post-Survey Review/Decision	6	22.608 (6 x 3,768)	101.71	2,299,460
Accreditation Fee Collections	N/A	N/A	N/A	(18,840,000) (or $5,000 fee x 3,768 surveys)
TOTAL	20	75,360	Varies	(12,420,382)
BURDEN TO SUPPLIER				
Burden to Supplier – Application Process	8	30,144 (8 x 3,768)	44.28	1,334,776
Burden to Supplier During Survey	6	22,608 (6 x 3,768)	44.28	1,001,082
Accreditation Fee	N/A	N/A	N/A	18,840,000

TOTAL	14	52,752	N/A	21,175,858
COMBINED NET BURDEN	**N./A**	**128,112**	**N/A**	**8,755,476**

(3) Additional Costs

(a) Conflicts of Interest

We proposed new § 424.58(n) several prohibitions against AO conflicts of interest. For instance, proposed paragraph (n)(1) would state that if a DMEPOS AO's owner, surveyor, or employee has or had an interest in or relationship with a DMEPOS supplier the AO has accredited, the AO owner, surveyor, or other employee cannot participate in the survey of that supplier. We estimated in section VII. of this final rule the AO's ICR burden of explaining in its initial and reapproval applications its policies/procedures for avoiding conflicts of interest. Beyond this, though, we are unable to establish a burden estimate for this provision. The reason is that – aside from the recent criminal case cited in section VI.B. of this final rule -- we do not know the extent to which conflicts of interest exist among our 8 DMEPOS AOs. We requested feedback from stakeholders that could help us prepare such a projection.

(b) Consulting

We proposed in new § 424.58(m) to prohibit consulting services – as that term will be defined in that paragraph (m) -- by an AO and its associated consulting divisions or companies to any DMEPOS supplier to which the AO provides accreditation services: (1) prior to an initial accreditation survey; or (2) within 6 months of the next scheduled re-accreditation survey. We do not know the degree to which such services – which, for purposes of our proposal, focus mostly on simulated surveys -- are furnished by DMEPOS AOs to DMEPOS suppliers; nor do we have data regarding potential DMEPOS AO lost revenue (if any) resulting from new § 424.58(m). Therefore, we solicited comments from AOs and suppliers for the purpose of establishing an estimate regarding the financial impact of this proposal.

(c) Additional Staff

We recognized that our proposal for annual DMEPOS supplier surveys and reaccreditations would require DMEPOS AOs to hire additional personnel. Regarding surveys, we mentioned earlier that AOs often have contracted staff perform them. Although we estimated the hour and cost burden associated with the additional surveys -- using a $60.40 wage and an 8-hour burden for each contracted surveyor -- we have no means of calculating any precise increase in the AO's contract costs (such as additional payments to the contractor, costs of contract revisions, or securing a new contractor); this is because we are not privy to the terms of each AO's individual contract. Accordingly, we solicited comments from stakeholders regarding potential costs beyond those relating to the surveyor hour burden. As for AO personnel who review accreditation applications, make final decisions thereon, and perform other related tasks, we would project that the eight AOs combined would hire 12 nurses and 12 MHSMs to handle this additional work. In calculating the burden, we will utilize our previously noted $90.00 and $113.42 wages (for nurses and MHSMs, respectively), which results in a $101.71 average wage. We will also assume a 2,080-hour work year. This results in an hour burden of 49,920 ((12 + 12) x 2,080) and a cost of $5,077,363, which would include training costs. We welcomed comments on this projection, particularly regarding the number of individuals AOs may have to hire.

(d) AO Ownership Changes

We proposed in new § 424.58(o) to mirror the policies and procedures in 42 CFR 488.5(f) for situations where an AO undergoes a change of ownership. We are not including a burden estimate for this proposal because we do not anticipate a DMEPOS AO undergoing an ownership change in the coming years,

(e) Rebates

We proposed in new § 424.58(h) and (i) that if CMS terminates or suspends a DMEPOS AO's approved status, the AO must refund to a DMEPOS supplier all payments the supplier made to the organization:

- As part of the DMEPOS supplier's request for accreditation or reaccreditation; and

- Prior to the organization's notification to the DMEPOS supplier of its final decision regarding the supplier's request.

We estimated in the ICR section of this final rule that one AO will be terminated over the next 3 years and one AO suspended over this same period. We cannot project how many suppliers' applications (and surveys) would be in process at the time of termination or suspension. However, if we assumed that 46,500 suppliers will be annually reaccredited and there are eight AOs, each AO on average will have 5,813 reaccreditations each year (46,500/8), or 484 (5,813/12) per month. If we further assume that an accreditation takes 4 months to complete, approximately 1,936 accreditations (484 x 4 months) could be in process with the AO at any given time. With a $3,000 reaccreditation fee that will be refunded and 0.66 AOs being terminated or suspended each year ((one termination + one suspension)/3 years), this results in an annual total refund amount of $3,833,280 ($3,000 x 1,936 x 0.66).

(f) Form CMS-855S Initial Application – Required Fee

DMEPOS suppliers that are initially enrolling in Medicare due to a change in majority ownership under proposed § 424.551 would have to pay an application fee in accordance with § 424.514. The application fees for each of the past 3 calendar years were or are $730 (CY 2025), $709 (CY 2024), and $688 (CY 2023). Consistent with § 424.514, the differing provider application fee amounts were predicated on changes/increases in the CPI for all urban consumers (all items; United States city average, CPI-U) for the 12-month period ending on June 30 of the previous year. While we cannot predict future changes to the CPI, the application fee amounts between 2023 and 2025 increased by an average of $14 per year. We believe this is a reasonable barometer with which to establish estimates (strictly for purposes of this proposed rule) of the provider enrollment application fee amounts in the first 3 calendar years of the final provision (that is, 2026, 2027, and 2028). Thus, we project a fee amount of $744 in 2026, $758 for 2027, and $772 for 2028.

Applying these prospective fee amounts to the annual number of projected DMEPOS suppliers impacted by our change in majority ownership proposal – specifically, 3,300 suppliers -- this results in a figure of $2,455,200 (or 3,300 x $744) in the first year, $2,501,400 in the second year, and $2,547,600 in the third year. Averaged over this 3-year period, the amount would be $2,501,400, though there is ambiguity about whether this effect would be classified as a transfer rather than a cost.

(4) Total Costs

Table 62 outlines the proposed total annual net costs of our changes to §§ 424.57 and 424.58. Two things must be mentioned regarding these figures. First, and as already noted, some costs could not be calculated due to a lack of available data. Second, accreditation fees and refunds are not included in the following table because they are considered transfers rather than costs. This is reflected in the accounting statement.

TABLE 62: TOTAL ANNUAL PROJECTED NET BURDEN OF CHANGES TO §§ 424.57 AND 424.58

Task	Total Hours	Net Financial Burden ($)
Submission of Additional Data by AO or DMEPOS Supplier (ICR Burden)	18,636	1,227,319
Complaint Surveys	3,200	271,467
Additional Initial Accreditation Surveys	12,460	666,503
Annual Reaccreditations and Resurveys	1,641,520	112,185,339
CMS-Directed Surveys	2,000	136,004
Change in Majority Ownership Surveys	128,112	8,755,476
Additional Employees	49,920	5,077,363
TOTAL	**1,855,808**	**128,319,471**

(5) Comments Received and Responses

We solicited comments on the following specific matters concerning our DMEPOS accreditation cost projections:

- Whether there are any other costs that we should consider in our analysis and, if so, what those costs are. This could include costs to parties other than DMEPOS suppliers and DMEPOS AOs.

- Whether our hour estimates for each noted task (for example, initial AO review of a reaccreditation application) are reasonable and, if not, what the revised estimate(s) should be.

We received the following comments on our proposed estimates:

Comment: Several commenters believed that our proposed burden estimates were too low, including the projection regarding the number of employees the AOs may have to hire.

Response: While we appreciate these comments, we believe our projections are reasonable and are therefore finalizing them.

Comment: Multiple commenters stated that our DMEPOS accreditation proposals conflict with Executive Orders 14192 and 14267, which direct agencies to reduce burdens and expand—not restrict—competition.

Response: We appreciate these comments. Regarding Executive Order 14192, we refer stakeholders to section IX.J. of this final rule for a discussion of the rule's interaction with this order. As for Executive Order 14267, we do not believe our DMEPOS proposals restrict competition; they merely aim to help us exercise greater oversight of the DMEPOS accreditation process to ensure that DMEPOS payments are only made to compliant DMEPOS suppliers.

Comment: Several commenters requested detailed financial analyses of the impact of our DMEPOS accreditation proposals on: (1) hospice-based suppliers; and (2) small and medium suppliers, especially those in Puerto Rico.

Response: While we thank the commenters for their requests, we believe establishing general estimates applicable to all DMEPOS supplier types and geographical regions is the most appropriate means of helping stakeholders understand the burden associated with our DMEPOS accreditation proposals.

(b) Savings

We stated in the proposed rule that we anticipate considerable savings to the Trust Funds and the taxpayers resulting from our DMEPOS AO provisions. This will stem from what we believe will be dramatic reductions in inappropriate payments to DMEPOS suppliers due to non-

compliance with the DMEPOS quality standards. More frequent surveys and reaccreditations will allow us to closely monitor suppliers for non-compliance. Indeed, we noted our concern that DMEPOS suppliers fall out of compliance with the quality standards between their initial accreditation and their reaccreditation 3 years later.

Per our internal data, we project that an average of 339 DMEPOS suppliers are revoked each year based on a termination of their accreditation under § 424.57(c)(24). We noted in Table 72 that the average supplier of the 790 that were revoked for violation of a condition or standard in § 424.57(b) or (c) received $488,328 over a 3-month period. Although we are unable to ascertain the number of these 790 suppliers that were revoked for violating § 424.57(c)(24), we believe it is appropriate to apply the $488,328 figure to those revoked for a loss of accreditation.

Each supplier would be reaccredited three times more frequently than it presently is. Therefore, we will use a figure of 339 revocations occurring 2 years sooner than they otherwise would have and 339 occurring 1 year sooner than they otherwise would have. This results in a 3-year total of $497 million (= (2 x 339 x $488,328) + (339 x $488,328)), or a yearly average estimate of $166 million (= $497 million ÷ 3). As this is only a 3-month total, we must multiply it by 4 to achieve an annual savings (3 months x 4 = 12 months), which we projected to be $664 million. (It should be noted that there will be double-counting if the estimate resulting from this calculation were added to the $386 million estimate in Table 72—because for the overlap that exists between the estimated 790 and 1,017 suppliers, either the retroactive collection brings in reimbursements equal to three months' worth of improper payments, leaving only 9 months' worth to be affected by the reaccreditation, or reaccreditation brings in 12 months' worth, leaving none to be affected by retroactive collection.)

We received no comments on our DMEPOS accreditation savings estimates and are therefore finalizing them as proposed.

7. DMEPOS Prior Authorization

We proposed adding technical language to § 414.234 (c)(1) that provides for the exemption process in § 414.234 (c)(1)(ii). We also proposed to exempt a supplier from the mandatory prior authorization process (OMB Control No. 0938-1293) in § 414.234 (c)(1)(ii)(A) upon demonstration of compliance with Medicare coverage, coding, and payment rules and that this exemption will remain in effect until CMS withdraws the exemption. In proposed § 414.234(c)(1)(ii)(B), we proposed to provide 60-day notice of an exemption from mandatory prior authorization requirements. Similarly, we proposed to provide 60-day notice if an exemption is withdrawn. We will exempt suppliers that achieved a prior authorization provisional affirmation threshold of at least 90 percent during a periodic assessment. If the rate of prior authorizations with non-affirmations submitted becomes higher than 10 percent during a periodic assessment, we would withdraw the exemption for the specific noncompliant supplier, until the following periodic assessment.

a. MAC Workload Reduction

Based upon our internal data for CY 2024, looking across the 4 Durable Medical Equipment Medicare Administrative Contractor (DME MAC) jurisdictions, we assessed the number of suppliers that would have met the 90 percent threshold needed to qualify for an exemption from mandatory prior authorization each year. Based upon contractual costs to complete mandatory prior authorization, the total cost for all 4 DME MACs' workload was $13,194,555. We assessed the reduction in workload, accounting for compliant suppliers that met the 90 percent threshold, to be an average of 17 percent reduction, or $2,243,074 in savings in 1 year had this process been in place for CY 2024. We note that the number of compliant suppliers (for example: 6 percent in 2024) does not directly reflect the number of PARs submitted or the workload required by the MACs. In our assessment, we found that suppliers submit PARs for multiple items and multiple beneficiaries, and the most compliant suppliers submit more PARs than the noncompliant suppliers.

b. Supplier Burden Reduction

A detailed analysis of the supplier burden reduction is found in the ICR section of this rule; however, an overview of the totals is found herein.

TABLE 63: TOTAL ANNUAL BURDEN

Year One	Year Two	Average Annual Burden
$5,988,332	$6,727,543	$6,357,938

We were unable to determine the number of compliant suppliers in future years. However, if we average the data from previous years, the average percentage of compliant suppliers or PTANs is 4 percent.

TABLE 64: AVERAGE EXEMPT SUPPLIERS BY YEAR

CY	Total PTAN	PTAN Who Meet Criteria	Percentage of Exempt PTAN
2022	7,049	148	2%
2023	8,048	249	3%
2024	9,298	543	6%

The total burden is assessed in Table 80. By reducing the total average annual burden ($6,357,938) by the average number of suppliers (represented by PTANs) *not* submitting prior authorization requests by 4 percent, we have an average savings of $254,318 per year.

c. Total Burden Reduction

We estimated the reduction of burden for suppliers to be $254,318 per year. We estimated the reduction in workload for the MACS to be $2,243,074 per year. Combined, we estimated these savings to equal a total sum of $2,497,392 per year.

We received no comments on this section of the proposal and therefore are finalizing this provision without modification.

8. DMEPOS Competitive Bidding Program

We believe that the provisions of this regulation related to the DMEPOS CBP and payment for CGMs have no net impact. The DMEPOS CBP is required to be implemented by the Act and impacts associated with its implementation have already been accounted for.

a. Changes to the Calculation of SPAs and Number of Contracts to be Awarded

From 2011 to 2018, the competitive bidding program calculated SPAs based on the median (50th percentile) of winning bids but targeted a large number of contracts to award. Current regulations set the SPA as the maximum (100th percentile) of the winning bids, but did not generate the savings required to award contracts under the Act. We expect that the combination of setting the SPA as the 75th percentile and reducing the number of contracts to be awarded will result in SPAs broadly similar to those seen in previous, successful rounds of competitive bidding, and therefore result in zero net expenditure.

b. Application of Annual Inflation Update Factors to SPA

In previous rounds of competitive bidding, bidders were expected to account for expected inflation over the contract period when making their bids and thus bid higher to account for these costs. With this change, we expect that bidders will bid lower prices, based on current year costs, with the understanding that these will be escalated by inflation in future years. Over the course of the contract, there should be no net impact from this change.

c. Revision of Payment for CGMs

The change in payment category for CGMs will have no net impact because the Medicare payment amount calculated as the bundled rental payment under the classification as items that require frequent and substantial servicing will equal the expected payments that Medicare would have made under the current payment category.

d. Other Provisions

The other provisions of this rule are purely an administrative effort with no impact on Medicare coverage or expenditure, and, for this reason, have no cost or transfers associated with them.

D. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with the 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 year's proposed rule will be the number of reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's proposed rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of commenters would be a fair estimate of the number of reviewers of this rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $113.42 per hour, 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 8.05 hours for the staff to review half of this final rule. For each entity that reviews the rule, the estimated cost is $913.03 (8.05 hours × $113.42). Therefore, we estimate that the total cost of reviewing this regulation is $14,379,309 ($913.03 × 15,749) [15,749 is the number of estimated reviewers, which is based on the total number of unique commenters from this year's proposed rule].

E. Alternatives Considered

1. HH PPS

We described in section II.C.1.e. of this final rule, to achieve budget neutrality as required by law, we calculated a permanent adjustment by determining what the 30-day base payment amount should have been in CYs 2020, 2021, 2022, 2023, and 2024 in order to achieve the same estimated aggregate expenditures as obtained from the simulated 60-day episodes. One alternative to the finalized -1.023 percent permanent adjustment included finalizing the calculated permanent adjustment of -4.162 percent. Another alternative would be to calculate and only finalize the remaining permanent adjustment needed to account for behavior change

attributable to the implementation of the PDGM for CYs 2020 through 2021 claims, rather than through 2022 claims. Another alternative would be to not finalize an adjustment and delay the permanent adjustment to a future year. However, we believe it is most appropriate to finalize only applying the remaining adjustment to CYs 2020 through 2022 claims, as there are several factors that make it difficult to separate the effects of PDGM and non-PDGM-related behaviors on estimated aggregate expenditures, such as changes to the OASIS assessment which started in CY 2023. Moreover, the utilization trends provide evidence that most of the effects related to the implementation of PDGM occurred by the end of CY 2022.

Finally, we proposed to implement a temporary adjustment to begin reconciling retrospective overpayments from CYs 2020, 2021, 2022, 2023, and 2024, as discussed in section II.C.1.f. of this final rule. Section 1895(b)(3)(D)(iii) of the Act gives CMS the authority to make a temporary adjustment in a time and manner deemed appropriate though notice and comment rulemaking.

We considered not finalizing a temporary adjustment, as in prior rules. Another alternative would be to either finalize the -5.0 temporary adjustment as proposed or finalize a different percentage to begin to recoup the calculated temporary adjustment dollar amount. However, due to the growing temporary adjustment amount calculated from CYs 2020 through 2024, to delay the implementation of a temporary adjustment would lead to many more years of reductions to the payment rate to reach budget neutrality. We did, however, consider commenters' concerns about the magnitude of a -5.0 percent temporary adjustment in tandem with any finalized permanent adjustment. As such, we believe it is most appropriate to finalize implementing a 3.0 percent reduction in CY 2026, that is equivalent to a 0.9700 temporary adjustment factor, to the CY 2026 national, 30-day payment rate. By implementing a -3.0 percent temporary adjustment, we can begin recoupment of retrospective overpayments. Postponing the collection of this large dollar amount would lead to an extended duration of temporary adjustments or larger reductions to the payment rates in future years to reach budget neutrality

sooner.

Therefore, we believe it was best to finalize the implementation of the permanent adjustment of -1.023 percent and a temporary adjustment of -3.0 percent to the CY 2026 base payment rate.

2. HH QRP

Regarding our proposal to remove the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure, we considered keeping the measure, but determined the cost and burden associated with maintaining these measures outweigh the benefit of their continued collection and are proposing to remove them.

Regarding our proposal to remove four standardized patient assessment data elements we are removing these in an effort to reduce burden. We considered keeping these but believe that removing will help reduce burden.

Finally, regarding proposals to amend the reconsideration request policy and process, we considered the alternative of leaving the policy language unchanged. However, we have noted some areas in our policy where HHAs may benefit from clearly demarcated deadlines regarding requests for reconsideration.

3. Provider Enrollment

There were two principal alternatives we considered. First, we contemplated proposing more than the nine retroactive revocation grounds addressed in § 424.535(a)(8) and (g)(2)(viii) through (xiv). However, we decided to only include these nine and to address potential other grounds via future rulemaking. Second, we considered a 6-month period (instead our proposed 12-month timeframe) for our proposal in new § 424.547 regarding ordering, certifying, and referring physicians and non-physician practitioners. Given that this would be a new provision and that a 12-month timeframe would be consistent with that which had applied to non-billing providers and suppliers for many years, we decided that a 12-month period would be most appropriate.

We received no comments on the provider enrollment alternatives section of this RIA and are therefore finalizing this section without modification.

4. DMEPOS Supplier Accreditation Organizations

There are several alternatives we contemplated in preparing our proposed revisions to §§ 424.57 and 424.58.

First, we considered retaining the current 3-year cycle for resurveys and reaccreditations. However, as explained in section VI. of this final rule, we are concerned that unqualified suppliers are becoming accredited and that existing accredited suppliers are falling out of compliance with the quality standards between their 3-year reaccreditation periods. This has potentially resulted in many millions of dollars being inappropriately paid to non-adherent suppliers. Only through closer vetting of suppliers via more frequent surveys can we be better assured that Medicare is only paying legitimate suppliers.

Second, existing § 424.58(b)(1) lists detailed information that DMEPOS AOs must submit with their initial approval and reapproval applications. We considered retaining this list as is and even eliminating several items therefrom so as to ease the application burden on AOs. However, as we noted in section VI.B. of this final rule, we have not re-approved any existing AOs since 2006. Considering this long passage of time, we believe it is critical to have as much data as possible about our AOs. Therefore, we proposed to increase the scope of information that AOs must submit with their applications. This will help ensure that: (i) we have all the data needed to make informed application decisions; and (ii) only qualified organizations perform DMEPOS accreditation activities.

Third, we contemplated duplicating the requirements that initial AO application submissions, initial AO application decisions, and AO terminations be published in the **Federal Register**. We ultimately declined this approach and instead proposed to make these pronouncements – including those for suspensions – on our CMS website. We believe this will facilitate faster communication with interested stakeholders.

Fourth, and in a broader context, we considered the extent to which our proposed provisions should parallel those in part 488. We contemplated having practically all of provisions be distinct from part 488, meaning there would be little duplication. This was primarily because of the excessive program integrity risk that DMEPOS suppliers have traditionally posed to Medicare and the consequent need to tailor our provisions to effectively address it. While we indeed proposed a significant number of provisions that are either modifications of those in part 488 or are not included in part 488 at all, we decided to mirror certain provisions in part 488. As explained in section VI.B. of this final rule, we believe this will create precedent for some of our provisions and take advantage of existing, well-established procedures regarding certified provider and supplier accreditation.

We received no comments on the DMEPOS accreditation alternatives section of this RIA and are therefore finalizing this section without modification.

5. Prior Authorization of Certain DMEPOS Items

Regarding our proposal to clarify circumstances under which CMS would exempt a supplier from the prior authorization process in proposed § 414.234(c)(1)(ii)(A) upon demonstration of compliance with Medicare coverage, coding, and payment rules, we did not consider the alternative of *not* providing prior authorization exemptions to certain suppliers, as we believe the benefits of the exemption program provides savings to both the Trust Funds, as well as eligible suppliers.

We did not consider alternatives to the 90 percent provisional affirmation threshold. We believe that by achieving this percentage, the supplier would be demonstrating an understanding of the requirements for submitting accurate claims. We do not believe it is necessary for a supplier to achieve 100 percent compliance to qualify for an exemption because unintentional and sporadic errors could occur that are not deliberate or systemic attempts to submit claims that are not payable. We use a 90 percent threshold for exempting hospital OPD providers from the prior authorization process upon a provider's demonstration of compliance with Medicare

coverage, coding, and payment rules. Additionally, we use a 90 percent affirmation rate threshold in our Review Choice Demonstration for Home Health Services for home health agencies demonstrating compliance with Medicare requirements. In that program, home health agencies select from different initial review choices, such as pre-claim review (which is similar to prior authorization) and postpayment review of all home health billing periods. After a 6-month review period, agencies are evaluated to determine their review approval rate. If the agency meets the 90 percent threshold, they have additional review options open to them, including relief from most reviews. This threshold represents the best balance between the need to review PARs, while reducing burden on suppliers and effectively utilizing contractor resources, creating savings to the Trust Funds.

We received no comments on this section of the proposal and therefore are finalizing this provision without modification.

6. DMEPOS Competitive Bidding Program

Alternative possibilities for setting the SPA were considered. However, the current method of using the maximum bid did not result in savings while the previous method of using the median, definitionally, forced half the suppliers to accept a SPA below their bid. We believe the 75th percentile represented the best balance of the need to reduce the impact of outlier bids while paying most suppliers at or above their bid amount.

Similarly, while we considered other methods to determine the number of contracts to offer in each CBA, we concluded that the chosen methodology results in the best method of balancing the need to ensure a sufficient number of bidders to meet the anticipated needs of beneficiaries, while ensuring an adequate level of business for winning bidders.

We did not consider alternatives to the other proposed changes as we believe these specific changes were needed to ensure the efficient operation of the CBP.

F. Accounting Statements and Tables

Consistent with OMB Circular A-4 (available at https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf), we have prepared an accounting statement in Table 65 showing the classification of the impacts associated with the provisions of this final rule.

TABLE 65: ACCOUNTING STATEMENT:

HH PPS (FROM CY 2025 TO CY 2026)	
Category	**Primary Estimate**
Annualized Monetized Transfers	-$220 million
From Whom To Whom	Federal Government To Medicare HHAs
PROVIDER ENROLLMENT PROVISIONS (CY 2026)	
Category	**Primary Estimate**
Annualized Monetized Transfers	-$2.2 billion
From Whom To Whom	Federal Government To Medicare Providers and Suppliers
DMEPOS ACCREDITATION PROVISIONS (CY 2026)	
Accreditation/Survey Fees	
Category	**Primary Estimate**
Annualized Monetized Transfers	$162 million
From Whom To Whom	DMEPOS Suppliers To DMEPOS AOs
Category	**Primary Estimate**
Annualized Monetized Transfers	-$664 million
From Whom To Whom	Federal Government To Medicare Providers and Suppliers
Category	**Primary Estimate**
Annualized Monetized Costs	$128.3 million
DMEPOS Prior Authorization	
Category	**Primary Estimate**
Annualized Monetized Costs	-$2.5 million
HH QRP COSTS (CY 2026)	
Category	**Primary Estimate**
Annualized Monetized Costs	-$17.8 million

G. Regulatory Flexibility Act (RFA)

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. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. In addition, HHAs are small entities, as that is the term used in the RFA. Individuals and States are not included in the definition of a small entity.

The North American Industry Classification System (NAICS) was adopted in 1997 and is the current standard used by the Federal statistical agencies related to the U.S. business economy. We utilized the NAICS U.S. industry title "Home Health Care Services" and corresponding NAICS code 621610 in determining impacts for small entities. The NAICS code 621610 has a size standard of 19 million[91] and approximately 96 percent of HHAs are considered small entities. Table 66 shows the number of firms, revenue, and average revenue per firm for the home health care services category (NAICS 621610).

TABLE 66: NUMBER OF FIRMS, REVENUE, AND AVERAGE REVENUE PER FIRM OF HOME HEALTH CARE SERVICES FOR NAICS CODE 621610

NAICS	NAICS Description	Enterprise Size ($1,000)	Number of Firms	Receipts ($1,000)	Average Receipts Per Firm ($1,000)
621610	Home Health Care Services	<100	6,361	232,967	$36.62
621610	Home Health Care Services	100-499	7,099	1,869,713	$263.38
621610	Home Health Care Services	500-999	3,866	2,829,374	$731.86
621610	Home Health Care Services	1,000-2,499	5,218	8,370,496	$1,604.16
621610	Home Health Care Services	2,500-4,999	2,560	8,833,076	$3,450.42
621610	Home Health Care Services	5,000-7,499	885	5,275,636	$5,961.17
621610	Home Health Care Services	7,500-9,999	450	3,789,016	$8,420.04
621610	Home Health Care Services	10,000-14,999	466	5,256,982	$11,281.08
621610	Home Health Care Services	15,000-19,999	235	3,621,448	$15,410.42
621610	Home Health Care Services	>20,000	1,058	73,271,709	$69,254.92
621610	Home Health Care Services	Total	28,198	113,350,417	$4,019.80

Source: Data obtained from United States Census Bureau table "us_6digitnaics_rcptsize_2022" (SOURCE: 2022 SUSB Annual Data Tables by Establishment Industry) Release Date: 4/10/2025: https://www2.census.gov/programs-surveys/susb/tables/2022/us_6digitnaics_rcptsize_2022.xlsx

Notes: The 'Average Receipts Per Firm' column is calculated as the Receipts ($1,000)/Number of firms. The 'Total' row represents all the home health care services firms under NAICS 621610. Overall receipts (revenue) for the 28,198 firms (NAICS 621610) are approximately $113 billion.

The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The majority of HHAs' visits are Medicare paid visits and therefore the majority of HHAs' revenue consists of Medicare payments. Based on our analysis, we conclude that the policies finalized in this rule would result in an estimated total impact of 3 to 5 percent

[91] https://www.sba.gov/sites/sbagov/files/2023-03/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023.xlsx

or more on Medicare revenue for greater than 5 percent of HHAs. Therefore, the Secretary has determined that the HH PPS final rule would have a significant economic impact on a substantial number of small entities.

Specifically, we estimate that the net impact of the payment policies in this final rule would be a -1.3 percent impact in the aggregate for CY 2026 or approximately -$220 million. Table 66 details the total percentage payment reduction by number of 30-day periods. We estimate that smaller HHAs (those with less than 100 periods of care and thereby lower overall revenues) would receive a -2.0 percent payment impact in CY 2026. Also, we estimate that larger HHAs (those with more than 1,000 periods of care and thereby higher overall revenues) would receive a -1.1 percent payment impact in CY 2026. Furthermore, table 51 details the total percentage payment impact by facility location. We estimate that HHAs located in the Pacific region would receive the largest impact reflecting a -2.4 percent payment impact. As discussed in the preamble, the net decrease in CY 2026 is mostly driven by the impact of the permanent and temporary adjustments which are reflected in the third and eighth columns of table 51. We solicited comments on this RFA analysis on small entities and did not receive any comments.

Regarding options for regulatory relief, we note that section 1895(b)(3)(D)(i) of the Act requires CMS to annually determine the impact of differences between the assumed behavior changes, which were finalized in the CY 2019 HH PPS final rule with comment period (83 FR 56461), and actual behavior changes on estimated aggregate expenditures under the HH PPS with respect to years beginning with 2020 and ending with 2026. Additionally, section 1895(b)(3)(D)(ii) and (iii) of the Act requires us to make permanent and temporary adjustments to the payment rate to offset for such increases or decreases in estimated aggregate expenditures through notice and comment rulemaking. While we find that the -1.023 percent permanent adjustment, described in section II.C.1.g. of this final rule, is necessary to offset the increase in estimated aggregate expenditures for CYs 2020 through 2022 based on the impact of the differences between assumed behavior changes and actual behavior changes, we would also

continue to reprice claims, per the finalized methodology, and make any additional adjustments to account for behavior change related to the implementation of the PDGM and the change to a 30-day unit of payment at a time and manner deemed appropriate in future rulemaking.

As discussed previously in the Alternatives Considered section of this final rule, we explored alternatives to the finalized -1.023 percent permanent adjustment including finalizing the remaining permanent adjustment needed to account for behavior change attributable to the implementation of the PDGM for CYs 2020-2021, rather than through 2022 claims. However, we believe that our data supports finalizing the remaining permanent adjustment to account for behavior changes only for claims in CYs 2020 through 2022. Another alternative would be to delay the permanent adjustment to a future year. We do not believe delaying the permanent adjustment is an appropriate alternative as it would continue to defer application of a permanent adjustment to prevent future overpayments and would allow for continued accrual of the temporary adjustment. Furthermore, we agree with commenters who highlighted multiple other factors which likely have contributed to behavior change that is outside of the statutory scope to make permanent and temporary adjustments related to the effects of actual behavior change resulting from the implementation of the PDGM and the change to a 30-day unit of payment. We agree that these factors make it difficult to separate the effects of PDGM and non-PDGM-related behaviors on estimated aggregate expenditures. As such, we believe the finalized policies offer the most regulatory relief to HHAs.

In addition, we explored alternatives to the finalized -3.0 percent temporary adjustment to reconcile retrospective overpayments in CYs 2020 through 2024. However, as stated previously in this final rule, we believe that delaying the implementation of a temporary adjustment would lead to many more years of reductions to the payment rate to reach budget neutrality. We also recognized commenters' concerns about the magnitude of finalizing the proposed -5.0 percent temporary adjustment in tandem with any finalized permanent adjustment. Postponing the collection of this large dollar amount would lead to an extended duration of temporary

adjustments or larger reductions to the payment rates in future years to reach budget neutrality sooner. We solicited comments on the overall HH PPS RFA analysis and did not receive any comments.

Among the over 7,000 HHAs that are estimated to qualify to compete in the expanded HHVBP Model, we estimate that the percent payment adjustment resulting from this final rule would be larger than ±3 percent, in magnitude, for about 660 competing HHAs (9 percent) (estimated by applying the 5 percent maximum payment adjustment under the expanded Model to CY 2023 data). As a result, more than the RFA threshold of 5 percent of HHAs nationally would be significantly impacted.

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 RFA provisions at 5 U.S.C. 604. 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 and has fewer than 100 beds. This final rule is not applicable to hospitals. Therefore, the Secretary has certified that this final rule will not have a significant economic impact on the operations of small rural hospitals.

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 and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $8.0 million to $41.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. This final rule primarily affects pharmacies and drug stores and home health equipment rental suppliers.

TABLE 67: DMEPOS SUPPLIERS SIZE STANDARDS

NAICS (6-digit)	Industry Subsector Description	SBA Size Standard/Small Entity Threshold	Total Small Businesses
446110	Pharmacies and Drug Stores	$37.5 million	18,952
532283	Home Health Equipment Rental	$41 million	553

Source: SUSB 2017 Country Business Patterns and Economic Census

Since we are uncertain of the DMEPOS suppliers' composition, we asked the public for aid in understanding the various industries that supply DMEPOS products. So far, we have identified only the two industries in table 68.

TABLE 68: DMEPOS SUPPLIERS' CONCENTRATION RATIOS (PHARMACIES AND DRUG STORES AND HOME HEALTH EQUIPMENT RENTAL)

Firm Size (by Receipts)	Firm Count	% of Small Firms	Total Average Revenue
SMALL FIRMS	**19,505**	**100.0%**	**$3,374,384**
<100,000	706	3.6%	$51,647
100,000-499,999	2,139	11.0%	$290,675
500,000-999,999	2,065	10.6%	$744,226
1,000,000-2,499,999	5,693	29.2%	$1,745,060
2,500,000-4,999,999	5,255	26.9%	$3,559,904
5,000,000-7,499,999	1,839	9.4%	$6,032,844
7,500,000-9,999,999	709	3.6%	$8,506,154
10,000,000-14,999,999	573	2.9%	$11,926,209
15,000,000-19,999,999	226	1.2%	$16,037,279
20,000,000-24,999,999	103	0.5%	$18,479,010
25,000,000-29,999,999	65	0.3%	$25,465,123
30,000,000-34,999,999	49	0.3%	$27,426,041
35,000,000-39,999,999	37	0.2%	$28,005,054
40,000,000-49,999,999	46	0.2%	$31,703,478
LARGE FIRMS			
Receipts ≥50 million	318	NA	**$690,720,449.69**

SOURCE: 2017 County Business Patterns and Economic Census.
Note: Home Health Equipment Rental includes firms earning up to $49.9 million, which is greater than the $41 million SBA size standard, and Pharmacies and Drug Stores include includes firms earning up to $39.9 million, which is greater than the $37.5 million SBA size standard.

As can be seen in table 68, almost all DMEPOS suppliers are small entities as that term is used in the RFA[92]. Additionally, table 68 shows the disproportionate impacts among firms, and between small and large firms. In table 68, both industries, Pharmacies and Drug Stores and Home Health Equipment Rental firm size (by receipts), firm count, percentage of small firms, and total average revenue were aggregated to determine the DMEPOS concentration ratios.

[92] Note, the entire population of DMEPOS suppliers is not known at this time. However, based on our experience, the majority of DMEPOS suppliers are covered in the two industries identified.

For purposes of the RFA, approximately 98.4 percent of pharmacies and drugs stores and home health equipment rental industries are considered small businesses according to the SBA's size standards with total revenues of $49.9 million or less in any 1 year. Individuals and states are not included in the definition of a small entity.

This rule does not affect health care enterprises operated by small government entities such as counties or towns with populations 50,000 or less. HHS generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. The RFA threshold analysis, therefore, indicates that there is not a significant economic impact on a substantial number of small entities. Furthermore, the regulation review costs mentioned previously, is de minimis and would not impose any additional burden on these small businesses. Therefore, the Secretary certifies that this final rule would not have a significant economic impact on a substantial number of small government 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. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates 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 regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

H. Unfunded Mandates Reform Act (UMRA)

Section 202 of UMRA of 1995 UMRA also requires that agencies assess anticipated costs and benefits 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 final rule will not impose a mandate that will result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of more than $187 million in any one year.

I. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates 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. We have reviewed this proposed rule under these criteria of Executive Order 13132 and have determined that it would not impose substantial direct costs on State or local governments.

J. 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."

K. Conclusion

In conclusion, we estimate that the provisions in this final rule will result in an estimated net decrease in home health payments of -1.3 percent for CY 2026 ($220 million). The $220 million decrease in estimated payments for CY 2026 reflects the effects of the finalized CY 2026 home health payment update percentage increase of 2.4 percent ($405 million increase), an estimated -2.7 percent decrease that reflects the effects of the temporary adjustment ($460 million) and an estimated -0.1 percent decrease that reflects the effects of an updated FDL ($15

million). Lastly, the implementation of the HH QRP policy is estimated to increase the costs to HHAs by $1,058.88 per HHA annually, or $12,604,894.62 in the aggregate for HHAs annually..

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on November 28, 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, 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 455

Fraud, Grant programs—health, Health facilities, Health professions, Investigations, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 484

Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

1. The authority 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 405.800 is amended by revising paragraph (b)(2) to read as follows:

§ 405.800 Appeals of CMS or a CMS contractor.

* * * * *

(b) * * *

(2) *Effective date of revocation*. The effective date of a revocation is as specified in § 424.535 of this chapter.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

3. The authority for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

4. Section 414.234 is amended by revising paragraph (c)(1) introductory text and adding paragraphs (c)(1)(ii)(A) and (B) to read as follows:

§ 414.234 Prior authorization for items frequently subject to unnecessary utilization.

* * * * *

(c) * * *

(1) *Items requiring prior authorization.* CMS publishes in the **Federal Register** and posts on the CMS Prior Authorization website a list of items, the Required Prior Authorization List, that require prior authorization as a condition of payment, unless otherwise exempt under paragraph (c)(1)(ii) of this section.

* * * * *

(ii) * * *

(A) An exemption is provided for a supplier that achieves a rate of payable claims submitted, based on Medicare's billing, coding or payment requirements, of at least 90 percent during an initial or periodic review and remains in effect until CMS withdraws the exemption. An exemption of a supplier is withdrawn if the rate of non-payable claims submitted, based on Medicare's billing, coding or payment requirements, becomes higher than 10 percent, based upon a periodic assessment.

(B) CMS provides a notice of an exemption or withdrawal of an exemption to the supplier at least 60 days before the effective date.

* * * * *

5. Section 414.402 is amended by—

a. Adding the definitions of "Adjusted fee schedule amount" and "Competition" in alphabetical order;

b. Removing the phrase "Competitive bidding program" in the definition of "Competitive bidding program" and adding in its place "Competitive bidding program (CBP)";

c. Adding paragraph (6) to the definition of "Item"; and

d. Adding the definitions of "Remote item delivery competitive bidding program", "Remote item delivery item", and "Unadjusted fee schedule amount" in alphabetical order.

The additions read as follows:

§ 414.402 Definitions.

* * * * *

Adjusted fee schedule amount means the payment amount established for the item under one of the following:

(1) Subpart C of this part, with the application of § 414.105.

(2) Subpart D of this part, with the application of § 414.210(g).

(3) Subpart Q of this part, with the application of § 414.1690.

* * * * *

Competition means a competitive bidding area and product category combination for which a bidding entity submits a bid and for which a supplier enters into a DMEPOS CBP supplier contract to furnish items and services within the product category to beneficiaries residing within the competitive bidding area.

* * * * *

Item * * *

(6) Other medical equipment described in section 1861(m)(5) of the Act, including supplies related to ostomy care and urological supplies.

* * * * *

Remote item delivery competitive bidding program means a competitive bidding program wherein contract suppliers are responsible for furnishing remote item delivery items under a product category to all Medicare beneficiaries regardless of where they live in the CBA. The CBA could be one nationwide CBA that includes all areas (all States, territories, and the District of Columbia) or a CBA covering a specific region of the country.

Remote item delivery item means an item falling under a remote item delivery competitive bidding program that may be shipped or delivered to a beneficiary's home, regardless of the method of delivery, or picked up at a local pharmacy or supplier storefront if the beneficiary or caregiver for the beneficiary chooses to pick the item up in person.

* * * * *

Unadjusted fee schedule amount means the payment amount established for the item under one of the following:

(1) Subpart C of this part, without the application of § 414.105.

(2) Subpart D of this part, without the application of § 414.210(g).

(3) Subpart Q of this part, without the application of § 414.1690.

* * * * *

6. Section 414.408 is amended by--

a. Revising paragraph (b); and

b. Adding paragraphs (e)(2)(v), (g)(6), and (m).

The revision and additions read as follows:

§ 414.408 Payment rules.

* * * * *

(b) *Changes to the single payment amount*. (1) For the second year (12-month period) of a DMEPOS CBP supplier contract period, the single payment amount for each item under each competitive bidding program is updated based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI-U) for the 12-month period ending 6 months prior to the start of the second year of the applicable DMEPOS CBP supplier contract period.

(2) For the third year (12-month period) of a DMEPOS CBP supplier contract period, if applicable, the single payment amount for each item under each competitive bidding program is updated based on the percentage change in the Consumer Price Index for all Urban Consumers (CPI-U) for the 12-month period ending 6 months prior to the start of the third year of the applicable DMEPOS CBP supplier contract period.

(3) In no case can the updated single payment amount for an item in the applicable CBA be greater than the unadjusted fee schedule amount for the item in such area or 110 percent of the adjusted fee schedule amount for the item in such area.

* * * * *

(e) * * *

(2) * * *

(v) A Medicare enrolled provider or supplier, as the terms are defined under § 400.202 of this chapter, that is operated by the Indian Health Service (IHS) or a Tribe or Tribal organization in accordance with the Indian Self-Determination and Education Assistance Act (25 U.S.C.

5301, *et seq*.) may furnish an item to an AI/AN Medicare beneficiary who is eligible for services from the IHS.

* * * * *

(g) * * *

(6) Other medical equipment described in section 1861(m)(5) of the Act, including supplies related to ostomy care and urological supplies.

* * * * *

(m) *Special temporary transition rules for payment for supplies and accessories necessary for the effective use of beneficiary-owned continuous glucose monitors and insulin infusion pumps.* CMS continues, as applicable, to make separate payments under the DMEPOS competitive bidding program for supplies and accessories for class II continuous glucose monitors or insulin infusion pumps owned by the beneficiary at the time a competitive bidding program is phased in for class II continuous glucose monitors or insulin infusion pumps for the first time in a CBA where the beneficiary resides until coverage for the beneficiary-owned equipment ends, the equipment is no longer used, or at any point when the equipment has been replaced with rented equipment under the DMEPOS CBP.

7. Section 414.412 is amended by—

a. Revising paragraph (b)(2);

b. Redesignating paragraphs (b)(3) through (5) as paragraphs (b)(6) through (8);

c. Adding new paragraphs (b)(3) through (5);

d. Adding paragraphs (b)(9) through (12);

e. Revising paragraphs (g)(1) and (g)(3)(ii); and

f. Adding paragraph (g)(5).

The revisions and additions read as follows:

§ 414.412 Submission of bids under a competitive bidding program.

* * * * *

(b) * * *

(2) The bid amount for each lead item in a product category included under the DMEPOS CBP for the first time must not exceed the unadjusted fee schedule amount for the lead item.

(3) The bid amount for each lead item in a product category included in a prior competition, if it has been 1 year or less since a SPA was paid for the item in the prior competition, must not exceed, for the same CBA, the lesser of--

(i) The most recent SPA for the item plus 10 percent; or

(ii) The unadjusted fee schedule amount for the item.

(4) The bid amount for each lead item in a product category included in a prior competition, if it has been more than 1 year since a SPA was paid for the item in the prior competition, must not exceed the lesser of the--

(i) Most recent SPA made for the item, as adjusted by the percentage change in the Consumer Price Index for all Urban Consumers (CPI-U) from the mid-point of the most recent 12-month period the SPA was in effect to the date that is 6 months prior to the date CMS announces the dates suppliers may register and submit bids under the current round of competition, plus 10 percent; or

(ii) The unadjusted fee schedule amount for the item.

(5) The bid amount for each lead item in a product category included in a prior competition but made under a bid for a new CBA, must not exceed the lesser of the--

(i) Adjusted fee schedule amount for the item plus 10 percent; or

(ii) Unadjusted fee schedule amount for the item.

* * * * *

(9) The bid amount submitted for rental of class II continuous glucose monitors included as a lead item in a product category in a remote item delivery competitive bidding program for the first time must not exceed the payment amount that would otherwise apply to the monthly fee schedule amount for the supplies for the class II continuous glucose monitor under subpart D of

this part plus the average of the purchase fee schedule amounts that would otherwise apply to the class II continuous glucose monitor for the areas included in the remote item delivery competitive bidding program divided by 60.

(10) The bids amount submitted for rental of insulin infusion pumps included as a lead item in a product category in a remote item delivery competitive bidding program for the first time must not exceed the nonrural payment amount that would otherwise apply to the supplies and accessories for the insulin infusion pump under subpart D of this part, with the application of §414.210(g), for a 1-month period plus the total nonrural rental fee schedule amounts that would otherwise apply to rental of the insulin pump for 13 months of continuous use under subpart D of this part, with the application of §414.210(g), divided by 60.

(11) The bid amounts submitted for an OTS back brace or OTS knee brace included as a lead item in a product category in a remote item delivery competitive bidding program for the first time cannot exceed the average nonrural payment amount that would otherwise apply to the item under subpart D of this part, with the application of §414.210(g), for the areas included in the remote item delivery competitive bidding program.

(12) Notwithstanding paragraphs (b)(9) through (11) of this section, the bid amount for each lead item in a product category in a remote item delivery competitive bidding program for the first time must not exceed the average payment amount that would otherwise apply to the item under subpart C, D, or Q of this part for the areas included in the remote item delivery competitive bidding program.

* * * * *

(g) * * *

(1) *Bidding requirements*. A bidding entity may not submit a bid(s) and be awarded a contract for a competition unless it obtains a bid surety bond for the CBA from an authorized surety on the Department of the Treasury's Listing of Certified Companies and provides proof of having obtained the bond by submitting a copy to CMS by the deadline for bid submission.

* * * * *

(3) * * *

(ii) Where the bid(s) does not meet the specified forfeiture conditions in paragraph (g)(3)(i) of this section, the bid surety bond liability will be returned within 90 days of the public announcement of contract suppliers for the CBA. CMS will notify the bidding entity that it did not meet the specified forfeiture requirements and the bid surety bond will not be collected by CMS.

* * * * *

(5) *Bid surety bond riders*. (i) Bid surety bonds submitted prior to the deadline for bid submission are reviewed to determine if they contain any deficiencies that would make the applicable bid(s) ineligible to receive a DMEPOS CBP supplier contract offer. If any deficiency is found that can be rectified under paragraph (g)(5)(ii) of this section, CMS will notify the bidder of the deficiency(ies) and allow the bidder to submit a bid surety bond rider to rectify the deficiency(ies).

(ii) Bidding entities can submit a bid surety bond rider to correct the identified deficiency(ies) applicable to any of the bid surety bond requirements outlined in paragraphs (g)(2)(i) and (ii) of this section. No other deficiency(ies) can be rectified by a bid surety bond rider.

(iii) Bidding entities notified of a bid surety bond deficiency have 10-business days after the date of the notice to submit a bid surety bond rider. The bidder must receive the bid surety bond rider from the authorized surety that issued the original bid surety bond.

8. Section 414.414 is amended by revising paragraphs (d), (e), (f), and (h) to read as follows:

§ 414.414 Conditions for awarding contracts.

* * * * *

(d) *Financial standards*--(1) *Financial document requirements.* (i) By the close of the bid window, the bidding entity must, in accordance with paragraph (d)(2) of this section, submit a business credit report with a numerical credit score or rating, unless the bidding entity is unable to generate a business credit report with a numerical credit score or rating because the bidding entity has not been in operation long enough to generate a numerical score or rating.

(ii) By the close of the bid window, a bidding entity that is unable to generate a business credit report with a numerical credit score or rating is required to submit both a business credit report showing no data or insufficient information to generate a credit score and a personal credit report with a numerical credit score or rating from the bidding entity's Authorized Official or Delegated Official listed in CMS' PECOS.

(iii) The bidding entity must submit the documentation described in paragraphs (d)(1)(i) and (ii) of this section containing the approved crediting agency, an approved numerical credit score or rating, the name of the bidding entity or authorized official or delegated official, as applicable, and the date that the credit report was prepared, which must be generated within the 90 calendar days prior to the opening of the bid window in a form and manner specified by CMS. If the numerical credit score or rating is generated separately from the credit report, the bidding entity's name and the date it was prepared must be shown on the credit report and included with the numerical credit score or rating.

(iv) The bidding entity must attest in the bidding system that it is submitting one bid that includes all commonly owned or commonly controlled locations, and that it will furnish the lead item and all non-lead items in the same competition.

(2) *Financial scoring methodology.* A credit report scoring list is published before the opening of the bid window in the round specific Request for Bids Instructions or a fact sheet or both which includes all of the following:

(i) The approved credit agencies from which a bidding entity must obtain business and personal credit reports as applicable with a numerical credit score or rating. Bidding entities that

must obtain both a business and personal credit report with a numerical credit score or rating do not have to utilize the same approved credit agency for both.

(ii) The approved business and personal credit reports as applicable and associated numerical credit scores or ratings that must be submitted.

(iii) The scoring system that will be utilized to determine if a bidding entity meets the financial sustainability threshold.

(e) *Evaluation of bids*. CMS evaluates composite bids submitted for a lead item within a product category by doing all of the following:

(1) Calculating the number of suppliers selected to furnish the items and services in the competition in accordance with paragraph (h) of this section.

(2) Arraying the composite bids from the lowest composite bid price to the highest composite bid price.

(3) Selecting the number of suppliers and networks calculated under paragraph (e)(1) of this section that meet the requirements in paragraphs (b) through (d) of this section with the lowest composite bids.

(f) *Expected savings*. A DMEPOS CBP supplier contract is not awarded for a competition under this subpart unless CMS determines that the SPA to be paid to contract suppliers for the lead item would be no greater than the lesser of--

(1) 110 percent of the adjusted fee schedule amount for the item, if applicable; or

(2) The unadjusted fee schedule amount for the item.

* * * * *

(h) *Sufficient number of contract suppliers.* (1) Notwithstanding paragraph (h)(1)(ii) of this section, for competitions included in the DMEPOS CBP in 2018 or 2023, the first time a competition is recompeted after 2023, the number of contract suppliers selected to furnish items and services in the competition is double the number of contract suppliers that furnished at least 5 percent of total allowed services for the lead item furnished by contract suppliers to the applicable beneficiary population during 2018 or 2023, adjusted up or down based on the

percentage change in Part B enrollment in the CBA since 2018 or 2023, and rounded to the nearest whole number.

(i) CMS adjusts the number of contract suppliers selected in accordance with paragraph (h)(1) of this section for a competition to ensure the number selected is —

(A) Not less than 50 percent of the total number of contract suppliers that furnished the lead item in 2018 or 2023 rounded up to the nearest whole number;

(B) Not more than 75 percent of the total number of contract suppliers that furnished the lead in 2018 or 2023 rounded down to the nearest whole number; and

(C) At least 2.

(ii) [Reserved]

(2) For competitions included in the DMEPOS CBP in 2018 or 2023, the first time a competition is recompeted after 2023 in accordance with paragraph (h)(1) of this section, the number of contract suppliers selected to furnish items and services in the competition is equal to the number of contract suppliers CMS selected the first time the competition was recompeted after 2023 in accordance with paragraph (h)(1) of this section, trended up or down based on the percentage change in Part B enrollment in the CBA since the first year (12-month period) of the most recent DMEPOS CBP supplier contract period, and rounded to the nearest whole number.

(3) For competitions not included in the DMEPOS CBP in 2018 or 2023--

(i) The first time a competition is conducted after 2023, the number of contract suppliers selected to furnish items and services is 125 percent of the number of suppliers that furnished at least 3 percent of total utilization for the lead item in the product category and CBA during the most recent calendar year, and rounded to the nearest whole number, unless there would be less than 2 contract suppliers, in which case the number of contract suppliers will be 2.

(ii) For all subsequent recompetes for the competition, the number of suppliers selected to furnish items and services is equal to the number of contract suppliers selected in the prior competition or recompete, as applicable, trended up or down based on the percentage change in

Part B enrollment in the CBA since the first year (12-month period) of the most recent DMEPOS CBP supplier contract period, and rounded to the nearest whole number.

* * * * *

9. Section 414.416 is amended by revising paragraph (b) to read as follows:

§ 414.416 Determination of competitive bidding payment amounts.

* * * * *

(b) *Methodology for setting payment amount*. (1) Notwithstanding paragraphs (b)(2) and (3) of this section, a single payment amount for a lead item furnished under a competitive bidding program is equal to the 75th percentile of bid amounts submitted for that item by suppliers whose composite bids for the product category that includes the item are equal to or below the pivotal bid for that product category. If the 75th percentile of bid amounts falls between 2 bidding entities, the SPA is determined by using the amount that is 75 percent between the two bid amounts, rounded to the nearest cent.

(2) The single payment amount for an item in a product category furnished under a competitive bidding program that is not a lead item for that product category (non-lead item) is equal to the single payment amount for the lead item in the same product category multiplied by the ratio of the 2015 fee schedule amount for the non-lead item for the applicable area to which the fee schedule amount applies (State, District of Columbia, Puerto Rico, or United States Virgin Islands) to the 2015 fee schedule amount for the lead item for the same area.

(3) The single payment amount for an item included in a product category in a remote item delivery competitive bidding program furnished under a competitive bidding program that is not a lead item for that product category (non-lead item) is equal to the single payment amount for the lead item in the same product category multiplied by the ratio of the average 2015 fee schedule amount for the non-lead item for the applicable area to which the fee schedule amount applies (State, District of Columbia, Puerto Rico, or United States Virgin Islands, a combination

thereof, or nationwide) to the average 2015 fee schedule amount for the lead item for the same area.

(i)(A) The 2015 fee schedule amounts for a continuous glucose monitor and supplies are calculated using the 2025 fee schedule amounts and removing the covered items update factors for years 2016 through 2025 specified under section 1834(a)(14) of the Act.

(B) The 2015 fee schedule amounts for the bundled monthly rental of a continuous glucose monitor are calculated by adding the 2015 fee schedule amount for the supplies to the average of the 2015 fee schedule amounts for the purchase of a new continuous glucose monitor divided by 60 for the areas included in the remote item delivery CBP.

(ii) The 2015 fee schedule amount for the monthly supplies for a continuous glucose monitor owned by a beneficiary is calculated using the 2025 fee schedule amount and removing the covered item update factors for years 2016 through 2025 specified under section 1834(a)(14) of the Act.

(iii) The 2015 fee schedule amounts for the bundled monthly rental of an insulin infusion pump and supplies and accessories are calculated using the average 2015 fee schedule amounts for the insulin infusion pump multiplied by 10.5 and divided by 60 for the nonrural areas included in the remote item delivery CBP, and then adding the average 2015 fee schedule amounts for the sterile syringe type cartridge for the insulin infusion pump multiplied by 9 for the nonrural areas included in the remote item delivery CBP plus the average 2015 fee schedule amounts for the weekly insulin pump supplies multiplied by 4 for the areas included in the remote item delivery CBP.

(iv) The 2015 fee schedule amounts for the monthly supplies and accessories for an insulin infusion pump owned by a beneficiary is calculated using the average 2015 fee schedule amounts for the sterile syringe type cartridge for the insulin infusion pump multiplied by 9 for the areas included in the remote item delivery CBP plus the average 2015 fee schedule amounts

for the weekly insulin pump supplies multiplied by 4 for the areas included in the remote item delivery CBP.

10. Section 414.422 is amended by adding paragraph (h) to read as follows:

§ 414.422 Terms of contracts.

* * * * *

(h) *Contract termination during a public health emergency (PHE) under section 319 of the Public Health Service Act*. (1) If CMS determines in accordance with paragraph (h)(2) of this section, that due to a public health emergency (PHE) declared by the Secretary under section 319 of the Public Health Services Act, contract suppliers are unable to furnish certain items and services to beneficiaries in certain areas impacted by a PHE (PHE-impacted area) as required under their respective DMEPOS CBP supplier contracts, CMS may unilaterally terminate or modify each applicable DMEPOS CBP supplier contract to allow any Medicare enrolled DMEPOS supplier to furnish the applicable items and services to Medicare beneficiaries in the PHE-impacted area. Depending on the geographic extent of the PHE, a PHE-impacted area may refer to entire CBA(s) or only certain areas within a CBA.

(i) If the items and services in the PHE-impacted area identified in accordance with paragraph (h)(2) of this section encompass all competitions referenced in a DMEPOS CBP supplier contract, CMS will unilaterally terminate the DMEPOS CBP supplier contract.

(ii) If the items and services in the PHE-impacted area identified in accordance with paragraph (h)(2) of this section encompass only a portion of the competitions referenced in a DMEPOS CBP supplier contract, CMS will unilaterally modify the DMEPOS CBP supplier contract to remove the contract supplier's obligation to furnish specified items and services in the PHE- impacted area, as well as CMS's obligation to pay for those items and services under the DMEPOS CBP supplier contract.

(iii) After termination or modification of all applicable DMEPOS CBP supplier contracts, CMS reverts back to the general fee-for-service program requirements set forth in subpart D of this part for the applicable competition(s) or defined area(s) within a CBA.

(2) CMS may remove items and services furnished in a PHE-impacted area from the DMEPOS CBP when all of the following qualifying criteria are met:

(i) The Secretary declares a PHE under section 319 of the Public Health Services Act.

(ii) CMS determines that verifiable evidence exists of a DMEPOS access problem for beneficiaries for a certain competition or defined area(s) within the competition's CBA.

(iii) CMS determines that awarding additional DMEPOS CBP supplier contracts, per § 414.414(i), would not address the access concerns.

(iv) CMS determines terminating or modifying each impacted DMEPOS CBP supplier contract to exclude certain competition(s) or defined area(s) within the competition's CBA from the DMEPOS CBP would alleviate access concerns.

PART 424--CONDITIONS FOR MEDICARE PAYMENT

11. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

12. Section 424.22 is amended by:

a. Revising paragraph (a)(1)(v)(A); and

b. Removing paragraph (a)(1)(v)(C).

The revision reads as follows:

§ 424.22 Requirements for home health services.

* * * * *

(a) * *

(1) * * *

(v) * * *

(A) The face-to-face encounter must be performed by one of the following:

(*1*) A physician (as defined at § 484.2 of this chapter).

(*2*) A nurse practitioner (as defined at § 484.2 of this chapter).

(*3*) A clinical nurse specialist (as defined at § 484.2 of this chapter).

(*4*) A physician assistant (as defined at § 484.2 of this chapter).

(*5*) A certified nurse-midwife (as defined in section 1861(gg) of the Act) as authorized by State law.

* * * * *

13. Section 424.57 is amended by--

a. Revising paragraphs (c)(10), (22), (23), and (24) and (e)(1); and

b. Adding paragraph (h).

The revisions and addition read as follows:

§ 424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.

* * * * *

(c) * * *

(10) Has a comprehensive liability insurance policy in the amount of at least $300,000 that covers both the supplier's place of business and all customers and employees of the supplier.

(i) In the case of a supplier that manufactures its own items, this insurance must also cover product liability and completed operations.

(ii) Failure to maintain required insurance at all times results in revocation of the supplier's billing privileges retroactive to the date the insurance lapsed.

(iii) An authorized official of the supplier (as that term is defined in § 424.502) must sign the liability insurance policy.

* * * * *

(22)(i) All suppliers of DMEPOS and other items and services, and all of their locations whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited to enroll in and bill Medicare.

(ii) The accreditation must indicate the specific products and services for which the DMEPOS supplier is accredited in order for the supplier to receive payment for those specific products and services.

(iii) An accredited DMEPOS supplier may be denied enrollment, or its enrollment may be revoked, if CMS determines that it is not compliant with the DMEPOS quality standards.

(23) All DMEPOS suppliers must notify their DMEPOS accrediting organization when a new DMEPOS location is opened.

(24) All accredited DMEPOS suppliers must be surveyed and reaccredited at least once every 12 months.

* * * * *

(e) * * *

(1) *Revocation*. CMS revokes a supplier's billing privileges if it is found not to meet the conditions or standards in paragraphs (b) and (c) of this section. Except as otherwise provided in this section, the revocation effective date is as specified in § 424.535.

* * * * *

(h) *Change in majority ownership*. A supplier must comply with the provisions of § 424.551 if it undergoes a change in majority ownership.

14. Section 424.58 is amended by revising paragraphs (b) through (e) and adding paragraphs (f) through (o) to read as follows:

§ 424.58 Accreditation.

* * * * *

(b) *Definitions*. The following definitions apply to the provisions in this section:

Complaint means an allegation from any party and via any format that one of the DMEPOS accrediting organization's accredited DMEPOS suppliers may be non-compliant with one or more DMEPOS quality standards or other applicable CMS requirement. The complaint need not involve actual or potential beneficiary harm.

Immediate family member means any person with whom the accrediting organization owner(s), surveyors or employees have a lineal or immediate familial or marital relationship, including all of the following:

(i) A husband or wife.

(ii) Birth or adoptive parent, child, or sibling.

(iii) Stepparent, stepchild, stepbrother, or stepsister.

(iv) Father-in-law, mother-in-law, son-in-law, daughter-in-law, brother–in–law, or sister-in-law.

(v) Grandparent or grandchild.

(vi) Spouse of a grandparent or grandchild.

Immediate jeopardy means a situation in which the DMEPOS supplier's non-compliance with one or more DMEPOS quality standards or other applicable CMS requirement has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient or to the health and safety of the general public.

Reasonable assurance means that a DMEPOS accrediting organization has demonstrated to CMS' satisfaction all of the following:

(i) Its DMEPOS accreditation program requirements meet or exceed the Medicare program requirements.

(ii) The DMEPOS suppliers that the DMEPOS accrediting organization accredits meet or exceed Medicare program requirements.

(iii) The DMEPOS accrediting organization is compliant with all provisions of this section.

Unannounced survey means both of the following:

(i) A survey that is conducted without any prior notice of any type (through any means of communication or forum) to the DMEPOS supplier to be surveyed such that the supplier does not expect the survey until the surveyors arrive.

(ii) The DMEPOS accrediting organization schedules its surveys so that DMEPOS suppliers cannot predict when they will be performed.

(c) *Initial application procedures*--(1) *Required information.* An independent DMEPOS accrediting organization applying for initial approval of its DMEPOS accreditation program is required to furnish CMS with all the following information and materials to demonstrate that the DMEPOS accrediting organization provides reasonable assurance (as defined in paragraph (b) of this section) regarding its program.

(i) A list of the types of DMEPOS supplies, products, and services for which the organization is requesting approval.

(ii) A detailed comparison of the organization's accreditation requirements and standards with the applicable DMEPOS quality standards, such as a crosswalk.

(iii) A detailed description of the organization's operational, survey, and other accreditation processes to confirm that the DMEPOS suppliers it accredits meet or exceed the DMEPOS quality standards and Medicare program requirements. This must include all of the following:

(A) Procedures for performing unannounced surveys.

(B) Frequency of the surveys performed.

(C) Copies of the organization's survey forms.

(D) Guidelines and instructions to surveyors.

(E) Quality review processes for deficiencies identified with accreditation requirements.

(F) Dispute resolution processes and policies when there is a negative survey finding or decision.

(G) If the DMEPOS accrediting organization has the discretion to perform a survey in certain instances, how it determines whether to perform one. This must include a suggested methodology for sampling locations for surveys under a single tax identification number or organization.

(iv) Procedures used to notify DMEPOS suppliers of compliance or noncompliance with the accreditation requirements.

(v) Procedures used to monitor the correction of deficiencies found during an accreditation survey.

(vi) Procedures for coordinating surveys with another DMEPOS accrediting organization if the organization does not accredit all supplies, products, and services the DMEPOS supplier provides.

(vii) Detailed professional information about the individuals who perform surveys for the DMEPOS accrediting organization, including the size and composition of accreditation survey teams for each type of DMEPOS supplier accredited, and the education and experience requirements that surveyors must meet. The information must also include the following:

(A) The content and frequency of the continuing education training provided to survey personnel.

(B) The evaluation systems used to monitor the performance of individual surveyors and survey teams.

(C) Policies and procedures for a surveyor or institutional affiliate of the DMEPOS accrediting organization that participates in a survey or accreditation decision regarding a DMEPOS supplier with which that individual or institution is professionally or financially affiliated.

(D) The organization's policies and procedures to avoid conflicts of interest and the appearance thereof involving individuals who conduct surveys or participate in accreditation decisions. This must include the organization’s policies and procedures for all of the following:

(*1*) The separation of its consulting services from its accreditation services.

(*2*) Protecting the integrity of the DMEPOS accrediting organization's accreditation program (including the requirements of paragraphs (m) and (n) of this section).

(*3*) The prevention and handling of potential or actual conflicts of interest that could arise from situations in which a DMEPOS accrediting organization owner, surveyor, or employee has an interest in, or relationship with, a DMEPOS supplier to which the accrediting organization provides accreditation services. Such interests or relationships include, but are not limited to the following:

(*i*) Being employed as a DMEPOS accrediting organization surveyor.

(*ii*) Being employed by a DMEPOS supplier that is accredited by the DMEPOS accrediting organization.

(*iii*) Having an ownership, financial, or investment interest in a DMEPOS supplier that is accredited by the DMEPOS accrediting organization.

(*iv*) Serving as a director of or trustee for a DMEPOS supplier that is accredited by the DMEPOS accrediting organization.

(*v*) Serving on a utilization review committee of a DMEPOS supplier that is accredited by the DMEPOS accrediting organization.

(*vi*) Accepting fees or payments from a DMEPOS supplier or group of DMEPOS suppliers that is/are accredited by the DMEPOS accrediting organization.

(*vii*) Accepting fees for personal services, contract services, referral services, or for furnishing supplies to a DMEPOS supplier that is accredited by the DMEPOS accrediting organization.

(*viii*) Providing consulting services to a DMEPOS supplier that the DMEPOS accrediting organization accredits.

(*ix*) Having any immediate family member (as defined in paragraph (b) of this section) engaged in any of the activities described in paragraphs (c)(1)(vii)(D)(*3*)(*i*) through (*viii*) of this section.

(*x*) Engaging in any activities during the course of the survey of the facility that would be or cause a conflict of interest.

(*4*) For notifying CMS when a conflict of interest is discovered.

(*5*) For the purposes of this section, a conflict of interest exists when a DMEPOS accrediting organization, the DMEPOS accrediting organization's successors, transferees, or assigns, the DMEPOS accrediting organization owner(s), surveyors, or employees, or the immediate family members of the DMEPOS accrediting organization owners(s), surveyors and other employees have an employment, business, financial or other type of interest in or relationship with a DMEPOS supplier that the DMEPOS accrediting organization accredits.

(E) The organization's policies and procedures for ensuring it has an adequate number of surveyors at all times.

(viii) Its processes for identifying and correcting deficiencies within its DMEPOS accreditation program.

(ix) A description of the organization's data management, analysis and reporting system for its surveys and accreditation decisions, including the kinds of reports, tables, and other displays generated by that system. This must also include a detailed description of how the organization uses its data to ensure the compliance of its DMEPOS accreditation program with Medicare program requirements.

(x) Procedures for responding to, investigating, and (as applicable) closing out complaints against accredited facilities, including policies and procedures regarding coordination of these activities with appropriate licensing bodies, ombudsman programs, the applicable National Provider Enrollment contractor, and CMS. This must also include a detailed outline of all of the following:

(A) The steps and research the DMEPOS accrediting organization will undertake in its initial review of the complaint as described in paragraph (e)(3) of this section.

(B) How the DMEPOS accrediting organization determines whether, in accordance with a complaint, non-compliance with a DMEPOS quality standard or other applicable CMS requirement exists, including the information it considers in its review and when and how it would take action against the DMEPOS supplier.

(xi) The organization's policies and procedures for notifying CMS of DMEPOS suppliers that fail to meet the DMEPOS accrediting organization's requirements.

(xii) A description of all types, categories, and durations of accreditations offered by the organization.

(xiii) A list of the following:

(A) All currently accredited DMEPOS suppliers.

(B) The types, categories, and product codes of accreditation currently held by each DMEPOS supplier.

(C) The effective and expiration dates of each DMEPOS supplier's current accreditation.

(D) The upcoming survey cycles for all DMEPOS suppliers' accreditation surveys scheduled to be performed by the organization.

(xiv) A written presentation that demonstrates the organization's ability to furnish CMS with electronic data in ASCII comparable code.

(xv) A resource analysis that demonstrates that the organization's staffing, funding, and other resources are adequate to perform fully the required surveys and related activities.

(xvi) Information that demonstrates the DMEPOS accrediting organization's knowledge, expertise, and experience in DMEPOS.

(xvii) Information about the DMEPOS accrediting organization’s ability to conduct timely reviews of DMEPOS supplier accreditation applications.

(xviii) A description of the organization's accreditation decision-making process. This includes its policies and procedures for approving, denying, or terminating accreditation status for DMEPOS suppliers that fail to meet the DMEPOS accrediting organization's standards or requirements. This must include an explanation of the reasons for which it will deny or terminate a supplier's accreditation.

(xix) Policies and procedures for both of the following:

(A) Determining whether and when a survey is performed (for example, the DMEPOS supplier is providing a new item type). This includes the circumstances under which the DMEPOS accrediting organization will impose a corrective action plan (CAP) in lieu of performing a follow-up survey for an identified DMEPOS supplier deficiency.

(B) Ensuring that all onsite surveys are unannounced, including procedures that protect against unannounced surveys becoming known to the DMEPOS supplier before the visit.

(xx) Policies and procedures regarding when the DMEPOS accrediting organization will apply a CAP to a DMEPOS supplier. This must include the following:

(A) The specific circumstances under which the DMEPOS accrediting organization will apply a CAP as opposed to, as applicable, denying or terminating accreditation and the rationale for why the accrediting organization believes a CAP in these situations is more appropriate.

(B) How a CAP is developed, implemented, and enforced, including the following:

(*1*) How the DMEPOS accrediting organization determines whether a CAP is acceptable.

(*2*) The requirements of (and the timeframe and deadline for) the DMEPOS supplier's resumption of compliance.

(*3*) How the DMEPOS accrediting organization determines whether the DMEPOS supplier has resumed compliance and maintains compliance.

(*4*) The circumstances under which the DMEPOS accrediting organization will impose a CAP in lieu of performing a follow-up survey for an identified DMEPOS supplier deficiency.

(xxi) An explanation of the following:

(A) What the DMEPOS accrediting organization considers to be a DMEPOS supplier deficiency and how it defines the term deficiency.

(B) Whether the DMEPOS accrediting organization has different levels of DMEPOS supplier deficiencies.

(xxii) In performing the functions described in this section, its processes for both of the following:

(A) Detecting and addressing potential fraud, waste, and abuse by DMEPOS suppliers (including identifying the accrediting organization's definitions of the terms fraud, waste, and abuse).

(B) Reporting this activity to CMS and, as applicable, law enforcement.

(xxiii) A statement on the DMEPOS accrediting organization's letterhead that is signed and dated by the accrediting organization's chief executive officer (or similar official with authority to commit the organization to adhere to Medicare laws and regulations) acknowledging that, as a condition for CMS approval or continued approval of a DMEPOS accrediting organization's accreditation program, the organization agrees to all of the following:

(A) Provide CMS, within 3 business days of CMS's request, both of the following:

(*1*) Any of the information described in paragraph (e)(1)(i) of this section.

(*2*) Any other information CMS deems necessary to facilitate its oversight of the DMEPOS accrediting organization's accreditation program.

(B) Provide CMS written notification when an accreditation survey or complaint investigation identifies an immediate jeopardy situation (as that term is defined in paragraph (b) of this section). Consistent with paragraph (e)(1)(iii) of this section, this notice must be provided within 2 business days of the finding.

(C) Provide written notification to CMS of any proposed changes to the DMEPOS accrediting organization's accreditation program and that it will not implement the proposed

changes without prior written notice of continued program approval from CMS consistent with paragraph (e)(2) of this section.

(D) Notify CMS in writing of any decision to terminate, revoke, withdraw, or amend the accreditation status of a specific DMEPOS supplier within 3 business days of the date the organization took such action.

(E) Notify CMS of any decision to apply a CAP to a specific DMEPOS supplier within 10 calendar days of the decision. This notification must include the following:

(*1*) The reason for the decision.

(*2*) A detailed explanation and justification as to why the DMEPOS accrediting organization applied a CAP instead of, as applicable, denying or terminating the DMEPOS supplier's accreditation.

(*3*) The details of the DMEPOS supplier's CAP.

(F) Submit timely, accurate, and complete data to support CMS's evaluation of the DMEPOS accrediting organization's performance.

(*1*) Data to be submitted includes, but is not limited to, DMEPOS supplier identifying information, survey schedules, survey findings, and notices of accreditation decisions.

(*2*) The organization must submit necessary data according to the instructions and timeframes CMS specifies.

(G) In response to a written notice from CMS to the organization of a change in the CMS quality standards, survey process, or other requirement, provide CMS with proposed corresponding changes in the organization's requirements for its DMEPOS accreditation program to ensure continued comparability with the CMS quality standards, survey process, and requirements. This includes compliance with the following requirements:

(*1*) Submission of the data required in paragraph (e)(7) of this section.

(*2*) The proposed changes must be submitted to CMS within 30 calendar days of the date of the written CMS notice to the organization.

(*3*) The organization must not implement its proposed corresponding changes without prior CMS approval.

(H) Apply and adhere to in its accreditation activities any CMS-established--

(*1*) Definition(s) of deficiency; and

(*2*) Deficiency levels and categories.

(I) The DMEPOS accrediting organization will permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(J) If CMS permits the DMEPOS accrediting organization to perform surveys via a sampling process, the accrediting organization:

(*1*) Will submit to CMS its planned sampling methodology in detail; and

(*2*) Will not undertake sampling until CMS has approved the accrediting organization's submitted methodology.

(K) Will not include the following as patient medical records in its DMEPOS supplier surveys:

(*1*) Mock files.

(*2*) Fictional patient records.

(*3*) Simulated documentation.

(*4*) Templates.

(*5*) Duplicate patient records.

(L) Have a binding written agreement with each DMEPOS supplier the DMEPOS accrediting organization accredits regarding whether the accrediting organization, the supplier in question, or both will assume the costs of a survey that CMS directs the accrediting organization to perform in accordance with paragraph (e)(8)(ii) of this section.

(M) Submit all required information to CMS both before and after approval of its DMEPOS accreditation program in a truthful, accurate, and complete manner.

(N) Adhere to all of the requirements of this section at all times, including the policies, procedures, practices, and agreements it outlined in paragraph (c) of this section as part of its initial or reapproval application and any CMS-approved changes thereto under paragraph (e)(2) or (7) of this section.

(2) *Additional information needed*. If CMS determines that additional information is necessary to make a determination for approval or denial of the organization's initial application, CMS notifies the organization and affords it an opportunity to provide the additional information.

(3) *Withdrawing an application.* A DMEPOS accrediting organization may withdraw its initial application for CMS' approval of its DMEPOS accreditation program at any time before CMS posts the notice described in paragraph (c)(6) of this section.

(4) *Reasons for denial.* CMS may deny a DMEPOS accrediting organization's application for any of the following reasons:

(i) The DMEPOS accrediting organization has failed to comply with all application, data, and agreement submission requirements outlined in this paragraph (c).

(ii) The DMEPOS accrediting organization has failed to provide reasonable assurance (as defined in paragraph (b) of this section).

(iii) The current number of CMS-approved DMEPOS accreditation programs is sufficient to ensure the continued administration of CMS' DMEPOS accreditation program.

(iv) The DMEPOS accrediting organization's DMEPOS accreditation program was previously terminated, suspended, or placed on probation by CMS under, respectively, paragraph (h), (i), or (j) of this section.

(v) The DMEPOS accrediting organization, or any owner (as defined in § 424.502), managing employee (as defined in § 424.502), governing body member, W-2 or contracted surveyor, or W-2 or contracted health care or administrative or management services personnel thereof--

(A) Is excluded by the Office of Inspector General (OIG) from Medicare, Medicaid, and any other Federal health care program;

(B) Is debarred, suspended, or otherwise excluded from participating in any Federal procurement or non-procurement activity in accordance with section 2455 of the Federal Acquisition Streamlining Act (FASA);

(C) Within the preceding 10 years--

(*1*) Was convicted of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries;

(*2*) Has had a Medicare enrollment revoked under § 424.535;

(*3*) Has had a license to provide health care suspended or revoked by any State licensing authority; or

(*4*) Has been suspended or terminated from participating in a Federal or State health care program.

(vi) The DMEPOS accrediting organization has submitted false or misleading information on its application in order to gain CMS approval or reapproval as a DMEPOS accrediting organization.

(vii) The AO is non-compliant with any provision in this section.

(viii) CMS otherwise determines that approval of the applicant as a DMEPOS AO would not be in the best interests of the Medicare program and its beneficiaries.

(5) *Notice of approval or denial of application.* CMS sends to the DMEPOS accrediting organization a notice of its decision to approve or deny the application within 210 calendar days from the date CMS determines the accrediting organization's application is complete. The final notice specifies the following:

(i) The basis for the decision.

(ii) If applicable, the effective date of approval.

(iii) If applicable, the term of the approval (not to exceed 6 years).

(6) *Decision announcement.* CMS announces on its website its decision to approve or deny the DMEPOS accrediting organization's application.

(i) This announcement is posted within 210 calendar days from the date that CMS determines that the DMEPOS accrediting organization's application was complete.

(ii) If the application is approved, the posting states the approval's effective date (no later than the announcement's posting date) and length (6 years or less).

(7) *Term of approval.* CMS may approve a DMEPOS accreditation organization for any period up to a maximum of 6 years.

(d) *Reapproval process*--(1) *General requirement*--(i) *Timeline for submission*. Except as stated in paragraph (d)(1)(ii) of this section, an approved DMEPOS accrediting organization that seeks to continue as such must apply for reapproval of accreditation no later than 9 months before the expiration of its current term of approval. If the organization fails to do so, CMS, at its discretion, may provide the organization an additional 30 days to reapply.

(ii) *Discretion to request reapproval applications*. CMS may require DMEPOS accrediting organizations to submit reapproval applications under this paragraph (d) any time after January 1, 2026. An application must be submitted within 60 calendar days of CMS' submission request. Failure to submit the application results in the termination of the DMEPOS accrediting organization's approval.

(2) *Submission of information and statements*. As part of its reapproval application, the DMEPOS accrediting organization must submit all information and statements identified in paragraph (c)(1) of this section. CMS may also request information under paragraph (c)(2) of this section.

(3) *Withdrawing an application.* A DMEPOS accrediting organization may withdraw its reapproval application for CMS' approval of its DMEPOS accreditation program at any time before CMS posts the notice described in paragraph (d)(6) of this section.

(4) *Denial reasons.* CMS may deny a DMEPOS accrediting organization's reapproval application for any of the reasons described in paragraph (c)(4) of this section.

(5) *Notice of approval or denial of application.* CMS sends a notice of its decision to approve or deny the DMEPOS accrediting organization's reapproval application within 210 calendar days from the date CMS determines the accrediting organization's reapproval application is complete. The final notice specifies the following:

(i) The basis for the decision.

(ii) If applicable, the effective date of reapproval.

(iii) If applicable, the term of the reapproval (not to exceed 6 years).

(6) *Decision announcement.* CMS announces on its website its decision to reapprove or deny the DMEPOS accrediting organization's reapproval application.

(i) This announcement is posted within 210 calendar days from the date that CMS determines that the DMEPOS accrediting organization's reapproval application was complete.

(ii) If the reapproval application is approved, the posting states the reapproval's effective date (no later than the announcement's posting date) and length (6 years or less).

(7) *Term of approval.* CMS may reapprove a DMEPOS accreditation organization for any period up to a maximum of 6 years.

(e) *Ongoing responsibilities of a CMS-approved DMEPOS accrediting organization.* A DMEPOS accrediting organization approved by CMS must undertake the following activities on an ongoing basis:

(1) *Submission of information*. (i) On a monthly basis, provide to CMS all the following in written format (either electronic or hard copy):

(A) Copies of all accreditation survey results and reports, together with any survey related information that CMS may require. This includes both of the following:

(*1*) CAPs and summaries of findings with respect to unmet CMS requirements.

(*2*) The instances where the DMEPOS accrediting organization had the discretion to perform a survey (for example, sampling) but decided not to, including the reason(s) for the organization's decision.

(B) Notice of all accreditation decisions.

(C) Notice of all resolved deficiencies.

(D) Information about any supplier of DMEPOS and other items and services against which the CMS-approved DMEPOS accrediting organization has taken remedial or adverse action, including termination of the supplier's accreditation.

(ii) CMS may at any time request the DMEPOS accrediting organization to submit any of the information described in paragraph (e)(1)(i) of this section or any other data CMS deems necessary to facilitate its oversight of the accrediting organization's DMEPOS accreditation program. This information must be furnished to CMS within 3 business days of the request.

(iii) Within 2 business days of identifying an immediate jeopardy deficiency of a DMEPOS supplier, provide CMS with written notice of the deficiency and any adverse action implemented by the DMEPOS accrediting organization.

(2) *Standard or requirement changes.* Provide written notice of any proposed changes to its accreditation standards, requirements, or survey process. This includes the addition, modification, or removal of a new DMEPOS product service category to the list of categories for which the organization accredits DMEPOS suppliers.

(i) The notice must be submitted to CMS no less than 60 calendar days before the proposal's planned effective date. It must include the following:

(A) A detailed description of the changes and the rationale for them.

(B) A detailed crosswalk (in table format) that states the exact language of the organization's revised accreditation requirements and the applicable Medicare requirements for each.

(ii) CMS communicates to the DMEPOS accrediting organization in writing its approval or disapproval of the proposal within 30 calendar days of the proposed change's effective date.

(iii) CMS approval is required before the DMEPOS accrediting organization can implement the change. If the organization implements the changes before or without CMS' approval, CMS may terminate its approval of the accrediting organization.

(3) *Addressing complaints.* (i) Upon receipt of a complaint--

(A) Notify CMS in writing of the complaint no later than 5 calendar days after receipt;

(B) Using the DMEPOS accrediting organization's policies and procedures described in paragraph (c)(1)(x) of this section, perform an initial review of the complaint to determine whether, based on the complaint and any other information, the DMEPOS supplier may be non-compliant with one or more DMEPOS quality standards or other applicable CMS requirement; and

(C) Perform a survey of the DMEPOS supplier if the DMEPOS accrediting organization's initial review concludes that such non-compliance may exist. This survey must be performed no later than 21 calendar days after the accrediting organization received the initial complaint.

(ii) No later than 10 calendar days after completing the action in, as applicable, paragraph (e)(3)(i)(B) or (C) of this section, notify CMS in writing of the result of the initial review or, as applicable, the survey. The notice must include information regarding any action the DMEPOS accrediting organization took or plans to take with respect to the DMEPOS supplier, such as a termination of accreditation or a CAP.

(4) *CAPs.* Notify CMS in writing of any decision to apply a CAP to a specific DMEPOS supplier within 10 calendar days of the decision. This notification must include all of the following:

(i) The reason for the decision.

(ii) A detailed explanation and justification as to why the DMEPOS accrediting organization applied a CAP instead of, as applicable, denying or terminating the DMEPOS supplier's accreditation.

(iii) The details of the DMEPOS supplier's CAP (for example, deadline for compliance, the DMEPOS accrediting organization's plans for enforcement and ensuring compliance).

(5) *Denials and terminations.* (i) Notify CMS in writing of any decision to deny accreditation to (or terminate, revoke, withdraw, or amend the accreditation of) a DMEPOS supplier within 5 calendar days of the decision. This notification must include the reason for the denial or termination.

(ii)(A) Notwithstanding any other provision in this section, the DMEPOS accrediting organization must deny accreditation to (or terminate the accreditation of) a DMEPOS supplier if--

(*1*) The supplier does not meet the licensure requirements in § 424.57(c)(1)(ii);

(*2*) The supplier is not operational (as that term is defined in § 424.502);

(*3*) The supplier's location does not meet the accessibility requirements in § 424.57(c)(7)(i)(B);

(*4*) The supplier's Medicare enrollment is revoked due to non-compliance with one or more DMEPOS quality standards and the reenrollment bar under § 424.535(c) has not expired; or

(*5*) Directed by CMS.

(B) If paragraph (e)(5)(ii)(A)(*5*) of this section applies, the DMEPOS accrediting organization must do the following:

(*1*) Deny or terminate the DMEPOS supplier's accreditation no later than 3 business days after receiving written notice from CMS to do so.

(*2*) Notify CMS in writing that it has taken this action within 5 business days of receiving the written notice from CMS.

(6) *Provide an annual summary of data related to accreditation.* Provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(7) *Notification of change from CMS.* (i) Within 30 calendar days of receipt of a written notice from CMS to the organization of a change in the quality standards, survey process, or other requirement, provide CMS with proposed corresponding changes to the organization's requirements for its CMS-approved DMEPOS accreditation program to ensure continued comparability with the CMS quality standards, survey process, or other requirements. This includes all of the following:

(A) An acknowledgment of CMS's notification of the change.

(B) A revised cross walk reflecting the new requirements.

(C) An explanation of how the DMEPOS accrediting organization plans to alter its standards to conform to CMS's new requirements, within the timeframes specified in the notification it received from CMS.

(ii) The DMEPOS accrediting organization must not implement its proposed corresponding changes without prior CMS approval.

(8) *Performance of surveys.* (i) Except as otherwise directed or permitted in writing by CMS (for example, allowing sampling), the DMEPOS accrediting organization must--

(A) Perform a survey of all DMEPOS supplier locations for which the supplier seeks accreditation or reaccreditation with the DMEPOS accrediting organization. This includes, but is not limited to, accreditations for a new item type the supplier has not previously furnished or as required under § 424.551;

(B) Perform all surveys as unannounced surveys; and

(C) Not accredit the DMEPOS supplier before the survey is performed and the DMEPOS accrediting organization determines that the supplier is compliant with the quality standards.

(ii) CMS may, at any time, direct the DMEPOS accrediting organization to perform a survey of an accredited DMEPOS supplier or a group thereof. Existence of an actual or suspected supplier deficiency is not a requirement for CMS to direct the performance of a survey of a supplier.

(iii) When performing a survey, the DMEPOS accrediting organization must also confirm that the DMEPOS supplier meets the licensure requirements in § 424.57(c).

(9) *Surveyor witnesses.* Permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(10) *Data entry.* If directed by CMS, enter accreditation, survey, product code, and other data into a CMS-designated system.

(11) *Relationships.* The DMEPOS accrediting organization, or any owner (as defined in § 424.502), managing employee (as defined in § 424.502), governing body member, or any W-2 or contracted surveyor, health care, administrative. or management personnel thereof, must not have any of the following:

(i) A current exclusion by the OIG from Medicare, Medicaid, and any other Federal health care program.

(ii) A current debarment, suspension, or exclusion from participating in any other Federal procurement or non-procurement activity in accordance with section 2455 of the Federal Acquisition Streamlining Act (FASA).

(iii) Within the preceding 10 years--

(A) A conviction of a Federal or State felony offense that CMS determines is detrimental to the best interests of the Medicare program and its beneficiaries;

(B) A Medicare enrollment revocation under § 424.535;

(C) A suspension or revocation of a license to provide health care by any State licensing authority; or

(D) A suspension or termination from participating in a Federal or State health care program.

(f) *Continuing federal oversight of approved DMEPOS accrediting organizations.* CMS evaluates the performance of each CMS-approved DMEPOS accreditation program on an ongoing basis. Means of monitoring include, but are not limited to, the reviews identified in this paragraph (f).

(1) *Equivalency review.* CMS may, at any time, compare the DMEPOS accrediting organization's standards and its application and enforcement of those standards to the comparable CMS requirements and processes.

(2) *Validation survey of DMEPOS supplier*--(i) *Survey scope*. CMS may survey suppliers of DMEPOS and other items and services accredited under this section in order to validate the DMEPOS accrediting organization's survey process. Surveys can be comprehensive or focus on certain standards or requirements.

(ii) *Authorization.* A DMEPOS supplier selected for a validation survey must --

(A) Authorize the validation survey to take place; and

(B) Permit the CMS survey team to monitor the correction of any deficiencies found during the validation survey.

(iii) *Failure to authorize*. If a DMEPOS supplier selected for a validation survey fails to comply with the requirements of paragraph (f)(2)(ii) of this section, it is deemed to no longer meet the DMEPOS supplier quality standards and may have its enrollment revoked.

(iv) *Non-compliance*. If a validation survey results in a finding that the DMEPOS supplier is not in compliance with one or more DMEPOS supplier quality standards, the supplier no longer meets the DMEPOS quality standards and may have its enrollment revoked.

(3) *Deficiencies.* (i) With respect to DMEPOS supplier compliance with the quality standards, CMS has the discretion to do all of the following:

(A) Define the term *deficiency*.

(B) Establish levels and categories of deficiencies.

(C) Revise the quality standards.

(ii) In its DMEPOS accreditation activities, the DMEPOS accrediting organization must apply and adhere to all of the following:

(A) Any CMS-established definition of deficiency.

(B) All CMS-established levels and categories of deficiencies.

(C) All CMS-established quality standards.

(4) *Review of DMEPOS accrediting organization*. (i)(A) CMS may at any time and for any reason conduct a review of the DMEPOS accrediting organization's processes or performance to:

(*1*) Verify the organization's representations to CMS; or

(*2*) Assess the organization's compliance with its own policies and procedures, the provisions of this section, and all other CMS requirements.

(B) The scope, length, and timing of the review are within CMS' discretion. Evidence of the DMEPOS accrediting organization's potential non-compliance with any element addressed in paragraph (f)(4)(i)(A) of this section is not a prerequisite for performing a review.

(ii) Types of CMS reviews include, but are not limited, the following, and may be performed collectively or individually:

(A) Equivalency reviews under paragraph (f)(1) of this section.

(B) Conducting surveys of accredited DMEPOS suppliers under paragraph (f)(2) of this section.

(C) Examining the results of a DMEPOS accrediting organization's surveys of DMEPOS suppliers.

(D) Observing a DMEPOS accrediting organization's onsite surveys and other audits of DMEPOS suppliers.

(E) Conducting onsite inspections of the DMEPOS accrediting organization's operations and offices.

(F) Requesting and reviewing documents.

(G) Interviewing DMEPOS accrediting organization staff.

(H) Observing an accreditation organization’s internal meetings concerning the accreditation process.

(g) *Voluntary termination of CMS-approved DMEPOS accreditation program*--(1) *Timing.* A DMEPOS accrediting organization may voluntarily terminate its CMS-approved accreditation program at any time. In doing so, the accrediting organization must do all of the following:

(i) Notify CMS of its decision to voluntarily terminate its approved DMEPOS accreditation program at least 120 calendar days in advance of the effective date of the termination.

(ii) Provide written notice at least 90 days in advance of the effective date of the termination to each of its accredited DMEPOS suppliers but not before notifying CMS of its decision in accordance with paragraph (g)(1)(i) of this section. The notice to each supplier must do the following:

(A) Describe the provisions in paragraph (g)(2) of this section regarding the expiration dates of the DMEPOS supplier’s accreditation with the terminating DMEPOS accrediting organization.

(B) Inform the DMEPOS supplier that any lapse in its accreditation (including between the date its existing accreditation with the terminating DMEPOS accrediting organization expires and the effective date of its accreditation with a different accrediting organization) may result in the revocation of its enrollment under § 424.535.

(2) *Supplier continuation of accreditation.* Unless the DMEPOS supplier is otherwise determined to be non-compliant with the quality standards or other requirement for accreditation,

the supplier's accreditation with the terminating DMEPOS accrediting organization remains in effect until the earlier of the following:

(i) The expiration of its current term of accreditation with the terminating DMEPOS accrediting organization.

(ii) The effective date of its accreditation with a different CMS-approved DMEPOS accrediting organization.

(h) *Involuntary termination*--(1) *Reasons for termination*. (i) CMS may terminate a DMEPOS accrediting organization's approval for any of the following reasons:

(A) CMS determines that the DMEPOS accrediting organization no longer demonstrates reasonable assurance (as defined in paragraph (b) of this section).

(B) CMS determines that the continued approval of a CMS-approved DMEPOS accreditation program of any DMEPOS accrediting organization poses an immediate jeopardy to the patients of the entities accredited under that program, or the continued approval otherwise constitutes a hazard to the public health.

(C) CMS determines that the DMEPOS accrediting organization is non-compliant with any provision of this section. This includes, but is not limited to, situations where the accrediting organization has failed to do either of the following:

(*1*) Comply with a term or condition of a statement or agreement in paragraph (c)(1)(xxiii) of this section.

(*2*) Adhere to a policy, procedure, or practice it outlined under paragraph (c) of this section as part of its initial application or reapproval application or a CMS-approved change thereto under paragraph (e)(2) or (7) of this section.

(D) There is a pattern or practice of the DMEPOS accrediting organization's accredited DMEPOS suppliers being revoked under § 424.535(a) for failing to comply with the quality standards.

(ii) CMS may terminate the DMEPOS accrediting organization's DMEPOS accreditation program effective the date of the letter described in paragraph (h)(2) of this section or any date thereafter.

(2) *Notification to DMEPOS accrediting organization.* CMS notifies the DMEPOS accrediting organization in writing of its decision to terminate the organization's accreditation approval. The notice must include all of the following:

(i) The reason for the termination.

(ii) The effective date of the termination.

(3) *Announcement*. CMS announces its termination decision (and the effective date thereof) on its website.

(4) *Notification to DMEPOS suppliers.* A DMEPOS accrediting organization whose CMS approval of its DMEPOS accreditation program has been terminated must notify, in writing, each of its accredited DMEPOS suppliers of the termination of CMS approval and its implications no later than 30 calendar days after the CMS website announcement described in paragraph (h)(3) of this section. The notice to each DMEPOS supplier must do all of the following:

(i) Describe the provisions in paragraph (h)(6) of this section regarding the expiration dates of the DMEPOS supplier's accreditation with the terminated DMEPOS accrediting organization.

(ii) Inform the DMEPOS supplier that any lapse in its accreditation (including between the date its existing accreditation with the terminated DMEPOS accrediting organization expires and the effective date of its accreditation with a different DMEPOS accrediting organization) results in the revocation of its enrollment under § 424.535.

(5) *Collaboration.* If CMS terminates a DMEPOS accrediting organization's approved status, the DMEPOS accrediting organization must work collaboratively with CMS to direct its

accredited DMEPOS suppliers to the remaining CMS-approved DMEPOS accrediting organizations within a reasonable period of time.

(6) *Continued accreditation.* (i) Unless the DMEPOS supplier is otherwise determined to be non-compliant with the quality standards or other requirement for accreditation, the supplier's accreditation with the terminated DMEPOS accrediting organization remains in effect until the earliest of one of the following:

(A) The expiration of its current term of accreditation with the terminated DMEPOS accrediting organization.

(B) The effective date of its accreditation with a different CMS-approved DMEPOS accrediting organization.

(C) A date specified by CMS based on the circumstances of the termination of the DMEPOS accrediting organization's approval.

(ii) In the event paragraph (h)(6)(i)(C) of this section is applicable, CMS notifies the affected DMEPOS supplier in writing of the deadline by which the supplier must be reaccredited.

(7) *Refunds.* If CMS terminates a DMEPOS accrediting organization's approved status, the terminated organization must refund to a DMEPOS supplier all payments the supplier made to the organization--

(i) As part of the DMEPOS supplier's request for accreditation or reaccreditation; and

(ii) Prior to the organization's notification to the DMEPOS supplier of its final decision regarding the supplier's request.

(i) *Suspension*--(1) *Reasons for suspension*. CMS may suspend a DMEPOS accrediting organization's approval for any of the following reasons:

(i) CMS determines that the DMEPOS accrediting organization no longer demonstrates reasonable assurance (as defined in paragraph (b) of this section).

(ii) CMS determines that the DMEPOS accrediting organization is non-compliant with any provision of this section. This can include, but is not limited to, situations where the DMEPOS accrediting organization has failed to do either of the following:

(A) Comply with a term or condition of a statement or agreement in paragraph (c)(1)(xxiii) of this section.

(B) Adhere to a policy, procedure, or practice it outlined under paragraph (c) of this section as part of its initial application or reapproval application or a CMS-approved change thereto under paragraph (e)(2) or (7) of this section.

(iii) There is a pattern or practice of the DMEPOS accrediting organization's accredited DMEPOS suppliers being revoked under § 424.535 for failing to comply with the DMEPOS quality standards.

(2) *Components of a suspension.* (i) Except as otherwise specified or permitted by CMS, a DMEPOS accrediting organization may not perform any Medicare DMEPOS accreditation activities while suspended.

(ii) CMS determines the length of the suspension, which lasts no longer than 1 year. Upon the expiration of the suspension period, CMS either lifts the suspension or terminates the organization's approval in accordance with paragraph (h) of this section.

(iii) CMS may suspend the DMEPOS accrediting organization's DMEPOS accreditation program effective the date of the letter described in paragraph (i)(3) of this section or any date thereafter.

(3) *Notification to DMEPOS accrediting organization.* (i) CMS notifies the DMEPOS accrediting organization in writing of its decision to suspend the organization's accreditation approval. The notice must include the following:

(A) The reason(s) for the suspension.

(B) The effective date and length of the suspension.

(C) The terms of the suspension.

(D) The steps the DMEPOS accrediting organization must take to have the suspension lifted.

(ii) No later than 3 calendar days after the date it receives the notice of suspension, the DMEPOS accrediting organization must notify CMS in writing its acknowledgment of receipt of such notice.

(iii) No later than 3 calendar days after receipt of such acknowledgment, CMS publishes on its website a notice of its decision to suspend its approval of the organization's DMEPOS accreditation program.

(4) *Status of DMEPOS suppliers*. (i) The accreditation status of DMEPOS suppliers currently accredited by the suspended DMEPOS accrediting organization remains in effect through the length of the suspension unless--

(A) The DMEPOS supplier's current term of accreditation with the suspended DMEPOS accrediting organization expires during the suspension;

(B) The DMEPOS supplier is otherwise determined to be non-compliant with the quality standards or other requirement for accreditation; or

(C) CMS specifies a different accreditation termination date based on the circumstances of the suspension of the DMEPOS accrediting organization's DMEPOS accreditation program.

(ii)(A) If paragraph (i)(4)(i)(A) of this section applies, the DMEPOS supplier must be reaccredited by--

(*1*) Its current DMEPOS accrediting organization if the suspension has been lifted; or

(*2*) A different CMS-approved DMEPOS accrediting organization.

(B) If paragraph (i)(4)(i)(C) of this section applies, CMS notifies the affected DMEPOS supplier in writing of the deadline by which the supplier must be reaccredited.

(iii) Any lapse in the DMEPOS supplier's accreditation (including between the date its existing accreditation with the suspended DMEPOS accrediting organization expires and the

effective date of its accreditation with a different accrediting organization) may result in the revocation of its enrollment under § 424.535(a).

(5) *Lifting of suspension*. (i) CMS lifts a DMEPOS accrediting organization's suspension if it determines all of the following:

(A) The reasons for the suspension no longer exist.

(B) The DMEPOS accrediting organization demonstrates reasonable assurance (as defined in paragraph (b) of this section).

(C) The DMEPOS accrediting organization is in compliance with all provisions of this section.

(ii) If the suspension is lifted:

(A) CMS notifies the DMEPOS accrediting organization thereof in writing.

(B) No later than 3 calendar days after the date it receives the notice described in paragraph (i)(5)(i)(A) of this section, the DMEPOS accrediting organization must notify CMS in writing its acknowledgment of receipt of such notice.

(C) No later than 3 calendar days after receipt of such acknowledgment, CMS publishes on its website a notice of the lifting of the suspension.

(6) *Refunds*. If CMS suspends a DMEPOS accrediting organization's DMEPOS accreditation program, the accrediting organization must refund to a DMEPOS supplier all payments the supplier made to the organization--

(i) As part of the DMEPOS supplier's request for accreditation or reaccreditation; and

(ii) Prior to the organization's notification to the DMEPOS supplier of its final decision regarding the supplier's request.

(7) *Multiple suspensions*. Nothing in this paragraph (i) prohibits CMS from suspending the organization's DMEPOS accreditation program more than once.

(j) *Probation*--(1) *Placement on probation*. CMS may place a DMEPOS accrediting organization's DMEPOS accreditation program on probation and require the organization's successful completion of a corrective action plan (CAP) if CMS determines any of the following:

(i) The DMEPOS accrediting organization no longer demonstrates reasonable assurance (as defined in paragraph (b) of this section).

(ii) The DMEPOS accrediting organization is non-compliant with any provision of this section. This can include, but is not limited to, situations where the accrediting organization has failed to--

(A) Comply with a term or condition of a statement or agreement in paragraph (c)(1)(xxiii) of this section; or

(B) Adhere to a policy, procedure, or practice it outlined under paragraph (c) of this section as part of its—

(*1*) Initial or reapproval application; or

(*2*) A CMS-approved change thereto under paragraph (e)(2) or (7) of this section.

(iii) There is a pattern or practice of the DMEPOS accrediting organization's accredited DMEPOS suppliers being revoked under § 424.535(a) for failing to comply with the quality standards.

(iv) The DMEPOS organization's period of suspension under paragraph (i) of this section has expired and CMS determines that a subsequent probationary period and CAP are warranted.

(2) *Notification to accrediting organization*. (i) CMS notifies the DMEPOS accrediting organization in writing of the probation. The notice must include the following:

(A) The reason(s) for CMS' decision.

(B) The length of the probationary period, which must not exceed 1 year.

(C) The terms of the CAP.

(D) The requirements and deadline for achieving compliance.

(E) A description of how CMS will monitor the DMEPOS accrediting organization's efforts to resume compliance (for example, requests for information, surveys).

(ii) Except as otherwise prescribed in the CAP, the DMEPOS accrediting organization may continue its accreditation activities as normal.

(3) *Conclusion of period*. (i) At the conclusion of the probationary period, CMS notifies the DMEPOS accrediting organization in writing of the following:

(A) Whether the DMEPOS accrediting organization is compliant with all requirements of this section.

(B) The reason for the determination in paragraph (j)(3)(i)(A) of this section.

(C) The consequences of the determination (for example, termination or suspension of accreditation, successful completion of and cessation of the probationary period and CAP).

(ii) If CMS determines that the DMEPOS accrediting organization has resumed compliance with all requirements of this section, CMS may do all of the following:

(A) Send the notice described in paragraph (j)(3)(i) of this section.

(B) Terminate the probationary period.

(C) End the CAP before the conclusion of the assigned probationary period.

(k) *Noncompliance actions.* (1) CMS may impose a certain action in paragraph (h), (i), or (j) of this section in lieu of another such action specified in paragraph (h), (i), or (j) of this section if the same ground(s) for the action exists.

(2) CMS may terminate--

(i) A probation period (either before or in accordance with the probationary period's original expiration date) and impose a suspension or termination if grounds for either action exist.

(ii) A suspension (either before or in accordance with the suspension's original expiration date) and impose a termination if a basis for doing so exists.

(l) *Reconsiderations and rebuttals*--(1) *Reconsiderations.* (i) A DMEPOS accrediting organization may request a reconsideration under part 498 of the following CMS initial determinations identified in § 498.3(b)(21) and (22):

(A) Denial of the DMEPOS accrediting organization's application for initial approval of its DMEPOS accreditation program under paragraph (c)(4) of this section.

(B) Denial of the DMEPOS accrediting organization's application for reapproval of its DMEPOS accreditation program under paragraph (d)(4) of this section.

(C) Termination of the DMEPOS accrediting organization's approval of its DMEPOS accreditation program under paragraph (h)(1) of this section.

(2) *Rebuttals.* (i)(A) If a DMEPOS accrediting organization receives notice from CMS that its DMEPOS accreditation program has been suspended or placed on probation in accordance with paragraph (i) or (j) of this section, the DMEPOS accrediting organization has 15 calendar days from the date of the written notice of the suspension or probation to submit a rebuttal to CMS.

(B) CMS may, at its discretion, extend the 15-day time-period referenced in paragraph (l)(2)(i)(A) of this section.

(ii) A rebuttal submitted under this section must--

(A) Be in writing;

(B) Specify the facts or issues about which the DMEPOS accrediting organization disagrees with CMS' determination, as well as the reasons for disagreement;

(C) Submit all documentation the DMEPOS accrediting organization wants CMS to consider in its review of its determination; and

(D) Be submitted in the form of a letter that is signed and dated by the DMEPOS accrediting organization's CEO (or similar official with authority to commit the organization to adhere to Medicare laws and regulations) or a legal representative (as defined in § 498.10 of this chapter).

(*1*) If the legal representative is an attorney, the attorney must include a statement that he or she has the authority to represent the accrediting organization; this statement would be sufficient to constitute notice of such authority.

(*2*) If the legal representative is not an attorney, the accrediting organization must file with CMS written notice of the appointment of a representative; this notice of appointment must be signed and dated by, as applicable, the accrediting organization's CEO (or similar official with authority to commit the organization to adhere to Medicare laws and regulations) or a legal representative.

(iii) The DMEPOS accrediting organization's failure to submit a rebuttal that is both timely under paragraph (l)(2)(i) of this section and fully compliant with all of the requirements of paragraph (l)(2)(ii) of this section constitutes a waiver of all rebuttal rights under this section.

(iv) Upon receipt of a timely and compliant rebuttal, CMS reviews the rebuttal to determine whether the imposition of the suspension or probation is correct.

(v) CMS is not required to delay the imposition of the suspension or probation pending the completion of the CMS review described in paragraph (l)(2)(iv) of this section.

(vi) A determination made under paragraph (i) or (j) of this section is not an initial determination under § 498.3(b) of this chapter and therefore not appealable.

(m) *Restrictions on consulting*--(1) *Definition.* For purposes of this paragraph (m) only, the terms *consulting* and *consulting services* mean those services provided by a DMEPOS accrediting organization (or its consulting division or separate business entity (such as a company or corporation) that provides such services) for the review of a DMEPOS supplier's standards, processes, policies, and functions for compliance with the accrediting organization's standards, the DMEPOS quality standards, or other Medicare requirements through simulation of a real survey, such as a mock survey, with comprehensive written reports of findings and early intervention and action to correct deficiencies prior to an actual accreditation survey.

(2) *Prohibitions*. Except as provided in paragraph (m)(3) of this section, an accrediting organization or its consulting division or separate business entity (such as a company or corporation that provides consulting) may not provide consulting services in the following instances:

(i) To any new DMEPOS supplier before the initial accreditation survey has been completed.

(A) For purposes of this paragraph (m)(2)(i), the term *initial survey* means the first accreditation survey performed of a supplier by a DMEPOS accrediting organization that has not previously received accreditation services from that accrediting organization.

(B) If a supplier is voluntarily or involuntarily terminated from the services of a DMEPOS accrediting organization and later retains the services of the same or a new DMEPOS accrediting organization, the first accreditation survey performed by the same or new DMEPOS accrediting organization of that supplier would be considered an initial accreditation survey.

(ii) To a DMEPOS supplier that the DMEPOS accrediting organization accredits within 6 months prior to the next scheduled re-accreditation survey of that supplier. For purposes of this paragraph (m)(2)(ii), the term *re-accreditation survey* means any subsequent accreditation survey performed by the accrediting organization following the initial survey.

(iii) To a DMEPOS supplier to which the DMEPOS accrediting organization provides accreditation services, in response to a complaint received by the accrediting organization regarding that supplier.

(3) *Circumstances permitting consulting*. A DMEPOS accrediting organization, its consulting division, or separate business entity, such as a company or corporation that provides consulting, may provide consulting to the DMEPOS suppliers it accredits only under the following circumstances:

(i) During the 6-month period after an initial or re-accreditation survey is performed.

(ii) To address complaints received and investigated by CMS or its contractor regarding a DMEPOS accrediting organization's accredited DMEPOS supplier in which one or more immediate jeopardy deficiencies or grounds for revocation of enrollment under § 424.535 are identified. Such consulting by an accrediting organization may occur only after CMS or the CMS contractor investigation is completed and must only address those issues identified in the investigation.

(iii) Consulting services provided to DMEPOS suppliers that the DMEPOS accrediting organization does not accredit at the time the consulting services are furnished.

(iv) General education provided by the DMEPOS accrediting organization about its DMEPOS accreditation program.

(4) *Submission of report*. The DMEPOS accrediting organization must provide to CMS upon CMS' request and with each initial and reapproval application under paragraphs (c) and (d) of this section a report containing the following information:

(i) Whether the DMEPOS accrediting organization or an associated consulting division or company established by the accrediting organization provides consulting services.

(ii) The names, National Provider Identifiers, and addresses of all DMEPOS suppliers to which the DMEPOS accrediting organization or its associated consulting division or company has provided consulting services during the previous 6-month period.

(iii) The dates the consulting services were provided to each DMEPOS supplier.

(iv) Whether the DMEPOS accrediting organization has ever provided, or is currently providing, accreditation services to any DMEPOS supplier listed in this report.

(v) For each DMEPOS supplier listed in this report, the date--

(A) Of the most recent accreditation survey performed; and

(B) That the next re-accreditation survey is due to be performed.

(vi) A description of the consulting services provided to each DMEPOS supplier listed in this report.

(5) *Consulting firewall policies and procedures*. (i) A DMEPOS accrediting organization, its consulting division, or separate business entity (such as a company or corporation that provides consulting services to the DMEPOS suppliers the accrediting organization accredits) must have and adhere to written consulting policies and procedures, which, at a minimum, must include the following:

(A) The DMEPOS accrediting organization's consulting services must be provided by a separate division of the accrediting organization or separate business entity, such as a company or corporation, that is separate from the accrediting organization's accreditation division.

(B) A DMEPOS accrediting organization's consulting division or separate business entity must maintain separate staff from that of the accrediting organization's accreditation divisions to ensure that the consulting division staff do not perform the accrediting organization's accreditation division functions and that the accrediting organization's accreditation division staff do not perform consulting division functions.

(C) A DMEPOS accrediting organization's accreditation staff and surveyors are prohibited from marketing the accrediting organization's consulting services to the accrediting organization’s accreditation clients.

(ii) A DMEPOS accrediting organization that provides consulting services must submit its written consulting firewall policies and procedures to CMS by a date specified by CMS and with each application submitted seeking initial CMS approval or reapproval of their DMEPOS accreditation programs.

(n) *Conflicts of interest*--(1) *General prohibition regarding relationships*. (i) If a DMEPOS accrediting organization owner, surveyor, or employee (currently or within the previous 2 years) has or had an interest in or relationship (as described in paragraph (c)(1)(vii)(D) of this section) with a DMEPOS supplier that is accredited by the DMEPOS accrediting organization, the accrediting organization owner, surveyor, or employee is not permitted to do any of the following:

(A) Participate in the survey of that DMEPOS supplier.

(B) Have input into the results of the survey and accreditation for that DMEPOS supplier.

(C) Have involvement with the pre-or post-survey activities for that DMEPOS supplier.

(D) Have contact with or access to the records for the survey and accreditation of that DMEPOS supplier.

(ii) For purposes of this paragraph (n)(1), the term *immediate family member* has the same meaning as that term is defined in paragraph (b) of this section.

(iii) CMS may request at any time outside of the initial approval and reapproval processes that the DMEPOS accrediting organization furnish any and all information required under paragraph (c)(1)(vii)(D) of this section.

(2) *CMS Contractor*. An entity may not serve as a CMS-approved DMEPOS accrediting organization if it is currently a CMS contractor (or an owner or subsidiary thereof (regardless of the ownership percentage involved)) with any oversight responsibility of DMEPOS suppliers.

(o) *Change of ownership.* A DMEPOS accrediting organization that wishes to undergo a change of ownership is subject to the requirements of § 488.5(f).

§ 424.205 [Amended]

15. Section 424.205 is amended by—

a. In paragraph (a), in the definition of "Coach eligibility end date", removing the phrase "paragraph (d)(5)" and adding in its place the phrase "paragraph (c)(5)".

b. In paragraph (b)(4), removing the phrase "paragraph (d)(5)" and adding in its place the phrase "paragraph (c)(5)".

c. In paragraph (b)(6), removing the phrase "paragraph (d)" and adding in its place the phrase "paragraph (c)";

d. In paragraph (c)(3):

i. Removing the phrase "paragraph (d)(5)" and adding in its place the phrase "paragraph (c)(5)"; and

ii. Removing the phrase “paragraph (e)(1)” and adding in its place the phrase “paragraph (d)(1)”;

e. In paragraph (c)(6), removing the phrase “paragraph (d)(4)” and adding in its place the phrase “paragraph (c)(4)”;

f. In paragraph (c)(8), removing the phrase “paragraph (d)(8)(i)” and adding in its place the phrase “paragraph (c)(8)(i)”;

g. In paragraph (c)(8)(ii):

i. Removing the phrase “paragraphs (d)(8)(i)(B)” and adding in its place the phrase “paragraphs (c)(8)(i)(B)”; and

ii. Removing the phrase “paragraph (d)(8)(i)(C)” and adding in its place the phrase “paragraph (c)(8)(i)(C)”;

h. In paragraph (c)(10), removing the phrase “paragraph (d)(8)” and adding in its place the phrase “paragraph (c)(8)”;

i. In paragraph (c)(11)(iii), removing the phrase “paragraph (d)” and adding in its place the phrase “paragraph (c)”;

j. In paragraph (c)(12), removing the phrase “paragraph (g)” and adding in its place the phrase “paragraph (f)”;

k. In paragraph (c)(15), removing the phrase “paragraph (g)” and adding in its place the phrase “paragraph (f)”;

l. In paragraph (d)(2):

i. Removing the phrase “paragraph (d)(5)” and adding in its place the phrase “paragraph (c)(5)”; and

ii. Removing the phrase “paragraph (e)(1)” and adding in its place the phrase “paragraph (d)(1)”;

m. In paragraph (g)(1):

i. Removing the phrase "§ 424.530(a)(1)" and adding in its place adding "§ 424.530(a)(1) or (18)" each time it appears; and

ii. Removing the phrase "§ 424.535(a)(1)" and adding in its place adding "§ 424.535(a)(1) or (23)" each time it appears;

n. In paragraph (g)(1)(i), removing the phrase "paragraph (h)(1)(i)" and adding in its place the phrase "paragraph (g)(1)(i)" each time it appears;

o. In paragraph (g)(1)(ii):

i. Removing the phrase "paragraph (d)" and adding in its place the phrase "paragraph (c)"; and

ii. Removing the phrase "paragraph (h)(1)(ii)" and adding in its place the phrase "paragraph (g)(1)(ii)" each time it appears;

p. In paragraph (g)(1)(v)(A), removing the reference "§ 424.205(d)(3)" and adding in its place the reference "§ 424.205(c)(3)"; and

q. In paragraph (g)(1)(v)(B), removing the phrase "paragraph (h)(1)(v)" and adding in its place the phrase "paragraph (g)(1)(v)" each time it appears.

16. Section 424.502 is amended by revising the definition of "Deactivate" to read as follows:

§ 424.502 Definitions.

* * * * *

Deactivate means, except in the situations described in § 424.547, that the provider or supplier's billing privileges were stopped, but can be restored upon the submission of updated information.

* * * * *

17. Section 424.510 is amended by—

a. In paragraph (d)(2)(iii) introductory text, removing the phrase "including—" and adding in its place the phrase "including the following:";

b. In paragraph (d)(2)(iii)(A), removing the phrase "; and" and adding a period in its place; and

c. Adding paragraphs (d)(2)(iii)(C) and (d)(10).

The additions read as follows:

§ 424.510 Requirements for enrolling in the Medicare program.

* * * * *

(d) * * *

(2) * * *

(iii) * * *

(C) Any other documentation needed to verify and confirm the information furnished on the enrollment application. This includes, but is not limited to, documentation regarding the provider's or supplier's ownership or management.

* * * * *

(10) *Legal responsibility*. All providers and suppliers are legally responsible for the accuracy, completeness, and truthfulness of all information they provide on or with their applications, regardless of whether another party completed the application.

* * * * *

18. Section 424.516 is amended by revising paragraph (e)(1) to read as follows:

§ 424.516 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

* * * * *

(e) * * *

(1) Within 30 days for a change of ownership or control (including changes in authorized official(s) or delegated official(s)), an adverse legal action, or a change, addition, or deletion of a practice location.

* * * * *

19. Section 424.522 is amended by revising paragraph (a) to read as follows:

§ 424.522 Additional effective dates.

(a) *Reassignments*. (1) The effective date of a reassignment of benefits under § 424.80 is the later of the dates identified in § 424.520(d)(1)(i) and (ii).

(2) Retrospective billing in accordance with a reassignment of benefits and as described in § 424.521(a)(1) is permissible if the circumstances in § 424.521(a)(1) are applicable.

* * * * *

§ 424.530 [Amended]

20. Section 424.530 is amended by–

a. In paragraph (a)(11)(ii), removing the word "drugs" and adding in its place the phrase "one or more drugs"; and

b. In paragraph (a)(18)(v), removing the phrase "or (d)" and adding in its place the phrase "or (c)".

21. Section 424.535 is amended by--

a. Adding paragraphs (a)(8)(i)(D) and (a)(8)(iii);

b. In paragraph (a)(13)(ii), removing the word "drugs" and adding in its place the phrase "one or more drugs";

c. In paragraph (a)(14) introductory text, removing the phrase "Part B or D drugs" and adding in its place the phrase "Medicare-covered drugs";

d. In paragraph (a)(23)(v), removing the phrase "or (d)" and adding in its place the phrase "or (c)";

e. Revising paragraph (g)(1);

f. Redesignating paragraph (g)(2)(viii) as paragraph (g)(2)(xv);

g. Adding a new paragraph (g)(2)(viii) and paragraphs (g)(2)(ix) through (xiv); and

h. Revising newly redesignated paragraph (g)(2)(xv)(D).

The revisions and additions read as follows:

§ 424.535 Revocation of enrollment in the Medicare program.

(a) * * *

(8) * * *

(i) * * *

(D) The beneficiary attests that the item(s) or service(s) identified on the provider's or supplier's claim or claims was not or were not rendered or furnished.

* * * * *

(iii) The effective date of a revocation under this paragraph (a)(8) is—

(A) For revocations under paragraph (a)(8)(i) of this section, the earliest date of service on the claim or claims that is or are triggering the revocation; and

(B) For revocations under paragraph (a)(8)(ii), the last date of service on the claims in question.

* * * * *

(g) * * *

(1) Except as described in paragraphs (a)(8)(iii) and (g)(2) and (3) of this section, a revocation becomes effective 30 days after CMS or the CMS contractor mails notice of its determination to the provider or supplier.

(2) * * *

(viii) For revocations based on a lapse in the IDTF's comprehensive liability insurance under § 410.33(g)(6) of this chapter, the date the insurance lapsed.

(ix) For revocations based on the provider's or supplier's submission of false or misleading information on the enrollment application, the date the application's certification statement was signed.

(x) For revocations based on the provider's or supplier's failure to timely report a change of ownership or adverse legal action, or a change, addition, or deletion of a practice location, the

day after the date by which the provider or supplier was required to report the change, addition, or deletion.

(xi) For revocations based on the surrender of the provider's or supplier's provider's Drug Enforcement Administration certificate of registration in response to a show cause order, the date the certificate was surrendered.

(xii) For revocations based on a State's suspension or revocation of the physician's or practitioner's ability to prescribe one or more drugs, the date of the suspension or revocation.

(xiii) For revocations of any of the provider's or supplier's other enrollments under paragraph (i) of this section, the effective date of the revocation that triggered the revocation(s) of the other enrollment(s).

(xiv) For revocations based on a DMEPOS supplier's non-compliance with a condition or standard in § 424.57(b) or (c), respectively, the date on which the non-compliance began.

(xv) * * *

(D) For all standard violations not addressed in this paragraph (g)(2), the effective date in paragraph (g)(1) of this section applies if the effective date in paragraph (g)(3) of this section does not.

* * * * *

§ 424.540 [Amended]

22. Section 424.540 is amended in paragraph (a)(8) by removing the phrase "HHA change" and adding in its place the phrase "HHA, hospice, or DMEPOS supplier change".

23. Section 424.541 is amended by--

a. Revising paragraphs (a)(1)(i), (a)(2)(ii)(B)(*2*), and (a)(3); and

b. In paragraph (a)(5), removing the phrases "Title 42" and "60-day stay period" and adding in their places the phrases "this title" and "CMS-assigned stay period", respectively.

The revisions read as follows:

§ 424.541 Stay of enrollment.

(a) * * *

(1) * * *

(i) Is non-compliant with at least one enrollment requirement in this title. (This includes situations where its change of information or revalidation application was rejected under § 424.525(a)(1) or (2).)

* * * * *

(2) * * *

(ii) * * *

(B) * * *

(*2*) The stay ends (as described in paragraph (a)(5) of this section) on or before the expiration of the originally designated stay period.

(3)(i) The effective date of a stay of enrollment is, as applicable--

(A) The date on which the provider's or supplier's non-compliance began; or

(B) The date on which the provider's or supplier's change of information or revalidation application was rejected under § 424.525.

(ii) CMS may establish a stay of enrollment for any period up to a maximum of 60 days.

* * * * *

24. Adding § 424.547 to read as follows:

§ 424.547 Deactivation based on ordering, certifying, or referring services and items.

(a)(1) CMS may deactivate a physician's or practitioner's ability to order, certify, or refer the Medicare services and items identified in § 424.507(a) and (b) if the individual:

(i) Is enrolled via the Form CMS-855O application solely to order, certify, or refer Medicare services or items; and

(ii) Has not been listed as the ordering, certifying, or referring individual on a Medicare Part A or B claim received in the previous 12 consecutive months.

(2) For purposes of this section only, the term *deactivate* means that the physician's or practitioner's ability to order, certify, or refer Medicare services or items has been stopped but can be restored upon the submission of updated information.

(b)(1) For a deactivated physician or practitioner to reactivate an ability to order, certify, or refer Medicare services and items, the individual must recertify that the enrollment information currently on file with Medicare is correct, furnish any missing information as appropriate, and be in compliance with all applicable enrollment requirements in this title.

(2) Notwithstanding paragraph (b)(1) of this section, CMS may, for any reason, require a deactivated physician or practitioner to, as a prerequisite for reactivating the ability to order, certify, or refer, submit a complete Form CMS-855O application.

(c) The effective date of a reactivation of an ability to order, certify, or refer Medicare services and items under this section is the date on which the Medicare contractor received the individual's reactivation submission that was processed to approval.

(d) A physician or practitioner may not order, certify, or refer the Medicare services or items described in § 424.507(a) and (b) while deactivated under this section.

25. Adding § 424.551 to read as follows:

§ 424.551 DMEPOS supplier changes in majority ownership.

(a) *Definition*. For purposes of this section only, a *change in majority ownership* occurs when an individual or organization acquires more than a 50 percent direct ownership interest in a DMEPOS supplier during the 36 months following the DMEPOS supplier's initial enrollment into the Medicare program or the 36 months following the DMEPOS supplier's most recent change in majority ownership (including asset sale, stock transfer, merger, and consolidation). This includes an individual or organization that acquires majority ownership in a DMEPOS supplier through the cumulative effect of asset sales, stock transfers, consolidations, or mergers during the 36-month period after Medicare billing privileges are conveyed or the 36-month period following the DMEPOS supplier's most recent change in majority ownership.

(b) *General principle*. Unless an exception in paragraph (c) of this section applies, if there is a change in majority ownership of a DMEPOS supplier by sale (including asset sales, stock transfers, mergers, and consolidations) within 36 months after the effective date of the DMEPOS supplier's initial enrollment in Medicare or within 36 months after the DMEPOS supplier's most recent change in majority ownership, the Medicare billing privileges do not convey to the new owner. The prospective owner of the DMEPOS supplier must instead do both of the following:

(1) Enroll in the Medicare program as a new DMEPOS supplier under the provisions of § 424.510.

(2) Undergo a survey by, and obtain a new accreditation from, a CMS-approved DMEPOS accrediting organization in accordance with §§ 424.57 and 424.58.

(c) *Exceptions*. The following situations are exceptions to the requirements of paragraph (b) of this section:

(1) A DMEPOS supplier's parent company is undergoing an internal corporate restructuring, such as a merger or consolidation.

(2) The owners of the existing DMEPOS supplier are changing the DMEPOS supplier's current business structure (for example, from a corporation to a partnership (general or limited); from a limited liability company (LLC) to a corporation; or from a general or limited to an LLC) and the owners remain the same.

(3) An individual owner of the DMEPOS supplier dies.

PART 455---PROGRAM INTEGRITY: MEDICAID

26. The authority citation for part 455 continues to read as follows:

Authority: 42 U.S.C. 1302.

§ 455.416 [Amended]

27. Section 455.416 is amended in paragraph (c) by removing the phrase "of the Act and under the" and adding in its place the phrase "of the Act or under the".

PART 484 – HOME HEALTH SERVICES

28. The authority citation for part 484 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 484.45 [Amended]

29. Section 484.45 is amended in paragraph (a) by removing the word "beneficiary" and adding in its place the word "patient" each time it appears.

30. Section 484.55 is amended by revising paragraph (d)(1)(i) to read as follows:

§ 484.55 Condition of participation: Comprehensive assessment of patients.

* * * * *

(d) * * *

(1) * * *

(i) Elected transfer;

* * * * *

31. Section 484.245 is amended by revising paragraph (d)(4) and adding paragraphs (d)(5) and (6) to read as follows:

§ 484.245 Requirements under the Home Health Quality Reporting Program (HH QRP).

* * * * *

(d) * * * *

(4)(i) CMS notifies the HHA, in writing, of its final decision regarding any reconsideration request through at least one of the following methods:

(A) CMS designated data submission system.

(B) The United States Postal Service.

(C) Email from the CMS Medicare Administrative Contractor (MAC).

(ii) CMS grants a timely request for reconsideration, and reverses an initial finding of non-compliance, only if CMS determines that the HHA was in full compliance with the HH QRP requirements for the applicable program year.

(5)(i) An HHA may request, and CMS may grant, an extension to file a reconsideration request if, during the period to request a reconsideration as set forth in paragraph (d)(2) of this section, the HHA was affected by an extraordinary circumstance beyond the control of the HHA (for example, a natural or man-made disaster).

(ii) HHAs must submit the reconsideration extension request no later than 30 calendar days from the date of the written notification of noncompliance.

(iii) The reconsideration extension request must—

(A) Be submitted to CMS via email to CMS HHAPU reconsiderations at HHAPUReconsiderations@cms.hhs.gov; and

(B) Contain all the following information:

(*1*) The CCN for the HHA.

(*2*) The business name of the HHA.

(*3*) The business address of the HHA.

(*4*) Contact information for the HHA's chief executive officer or designated personnel, including the name, telephone number, title, email address, and physical mailing address, which may not be a post office box.

(*5*) A statement of the reason for the request for the extension.

(*6*) Evidence of the impact of extraordinary circumstances, including, for example, photographs, newspaper articles, and other media.

(6) CMS notifies the HHA in writing of its final decision regarding the HHA's request for an extension to file a reconsideration of noncompliance request via an email from CMS.

* * * * *

32. Section 484.358 is amended by adding paragraph (i) to read as follows:

§ 484.358 HHVBP Measure removal factors.

* * * * *

(i) It is not feasible to implement the measure specifications.

PART 498 - APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/IID AND CERTAIN NFs IN THE MEDICAID PROGRAM

33. The authority for part 498 continues to read as follows:

Authority: 42 U.S.C. 1302, 1320a-7j, and 1395hh.

34. Section 498.3 is amended by adding paragraphs (b)(21) and (22) to read as follows:

§ 498.3 Scope and applicability.

* * * * *

(b) * * * *

(21) A denial of a DMEPOS accrediting organization's approval or re-approval under § 424.58(c)(4) or (d)(4) of this chapter, respectively.

(22) An involuntary termination of a DMEPOS accrediting organization's approved DMEPOS accreditation program under § 424.58(h)(1) of this chapter.

* * * * *

Robert F. Kennedy, Jr.,

Secretary,

Department of Health and Human Services

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