Telehealth Payments in the Response to the COVID-19 Pandemic

Overview
Telehealth is a critical tool in the response to the COVID-19 pandemic. This document details steps taken to expand the availability of telehealth services.

Federal Response


**Related Medicare Administrative activity**
On March 17, CMS provided new information regarding the implementation of this new waiver authority, including a [press release](https), [fact sheet](https) and updated [FAQ](https). The key takeaways from the announcement are as follows:

- **Effective for services starting March 6, 2020 and for the duration of the COVID-19 Public Health Emergency, Medicare will make payment for Medicare telehealth services furnished by physicians and other qualified professionals to beneficiaries in all areas of the country in all settings. This includes any healthcare facility and the patient’s home.**

- **These visits are considered the same as in-person visits and are paid at the same rate as regular, in-person visits.**

- **The Medicare coinsurance and deductible would generally apply to these services. However, the HHS Office of Inspector General (OIG) is providing flexibility for healthcare providers to reduce or waive cost-sharing for telehealth visits paid by federal healthcare programs (see additional information below).**

- **To the extent the 1135 waiver requires an established relationship, HHS will not conduct audits to ensure that such a prior relationship existed for claims submitted during this public health emergency.**

CMS further reiterated the telehealth waivers in several updates to a [MLN Matters Special Edition Article](https), which provides additional detail on telehealth waivers.

In materials CMS has issued, including the March 17 fact sheet and the MLN Matters Special Edition Article, CMS also notes the availability of certain communication technology-based services, including virtual check-in and e-visits, which are not the same as telehealth services. To clarify the difference:
• **Medicare telehealth services** must ordinarily be furnished in-person using interactive, real-time telecommunication technology. When furnished under telehealth rules, many of these services are still reported using codes that describe “face-to-face” services but are furnished using audio/video, real-time communication technology. For a list of covered services payable under the Medicare Physician Fee Schedule, visit here.

• **Communication technology-based services**, in contrast, are commonly furnished using telecommunications technology, but that do not usually require the patient to be present in-person with the practitioner when they are furnished. These services include, but are not limited to, remote physician interpretation of diagnostic tests, care management services, and virtual check-ins among many others. They are considered physicians’ services and are covered and paid in the same way as services delivered without the use of telecommunications technology, but are not considered Medicare telehealth services and are not subject to the statutory conditions of payment that govern Medicare telehealth services.¹

On March 23, CMS issued a FAQ regarding provider enrollment, including flexibilities to ease certain enrollment requirements under the national emergency, including waiving Medicare requirements for licensure in a state if a physician/clinician is enrolled in Medicare in another state and meets certain conditions; however, states must also waive or modify licensure requirements for the physician/clinician to practice in such state. As part of that FAQ, CMS also provided information on a toll-free hotline that could be used by physician and non-physician practitioners to initiate temporary Medicare billing privileges. CMS clarified (per question 12) that a provider can practice from home. [Note that this FAQ has been updated to address changes in policy CMS has instituted since March 23.]

On March 26, CMS issued a memorandum and FAQs announcing enforcement discretion for CLIA laboratories to ensure that pathologists may review and report pathology data, results, and slides remotely if certain conditions are met.

CMS also created the following tool kits to provide resources for providers seeking to provide care via telehealth:

- General Practitioners
- End-Stage Renal Disease Providers
- Long-Term Care Nursing Homes Telehealth and Telemedicine Tool Kit

On March 30, 2020, CMS issued another round of sweeping changes to Medicare policies related to the delivery of telehealth services and communication technology-based services through an Interim Final Rule with Comment (IFC) that apply effective March 1, 2020 and through the duration of the COVID-19 public health emergency (PHE). (Note that the effective date of these policies does not align with the March 6 effective date of the original telehealth waivers, which eliminated geographic restrictions on the use of Medicare telehealth services. Absent further guidance from CMS, the geographic restrictions are only waived effective March 6, 2020.) CMS also issued an accompanying press release and fact sheet. Key changes from the IFC include, but are not limited to:

- Adding more than 80 codes to the list of Medicare telehealth services. These include emergency department visits, initial nursing facility and discharge visits, and home visits, which must be provided by a clinician that is allowed to provide telehealth, and more.

¹ These are included at 1834(m).

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• Providing new coverage and payment for telephone-only evaluation or assessment services, including exercising enforcement discretion to allow this service to be furnished to new patients. These are not considered Medicare telehealth services.
• Clarifying that Medicare telehealth services must be furnished via an “interactive telecommunications system”, defined as “multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner,” thereby allowing the use of telephones with audio and video capabilities to furnish telehealth (but not allowing services on the list of Medicare telehealth services to be furnished using audio-only telephone).
• Allowing telehealth to fulfill many face-to-face visit requirements for clinicians to see patients in inpatient rehabilitation facilities, hospice, and home health.
• Allowing home health agencies and hospice providers to provide more services to beneficiaries using telehealth when certain requirements are met.
• Providing clarification on the definition of “homebound” to allow more beneficiaries to qualify for home health services.
• Allowing several communication technology-based services to be provided to both new and established patients (rather than only established patients), including virtual check-ins, remote evaluation of patient-submitted video or images, and online digital E/M services (in some cases by applying enforcement discretion).
• Providing new guidance on selecting office and outpatient E/M levels based on time or MDM and removing requirements regarding documentation of history and/or physical exam for services provided via telehealth only.
• Providing new guidance on billing to enable clinicians to be paid for services as if they were provided in person, by instructing physicians and practitioners who bill for telehealth services to report the POS code that would have been reported had the service been furnished in person, rather than POS 02, and using a CPT modifier, modifier 95, to designate the use of telehealth instead.
• Removing frequency limits on certain codes when provided via telehealth, including critical care consultation codes, subsequent inpatient visits, and subsequent nursing facility visits.
• Allowing “hands-on” visits required for ESRD monthly capitation payments to be conducted via telehealth, and providing enforcement discretion related to face-to-face visits for patients receiving home dialysis.
• Allowing direct supervision to be provided using real-time interactive audio and video technology.
• Modifying requirements for teaching physicians, including but not limited to allowing the “presence requirement” for the teaching physician to be met through direct supervision by interactive telecommunications technology.
• Allowing the therapy and counseling portion of the weekly bundle of services furnished by opioid treatment programs (OTPs), as well as the add-on code for additional counseling or therapy, to be furnished using audio-only telephone calls rather than via two-way interactive audio-video communication technology during the PHE if applicable requirements are met.
• Specifying that face-to-face encounter requirements included in NCDs and LCDs would not apply during the PHE.
• Allowing RHCs and FQHCs to provide and receive payment for online digital evaluation and management services on an interim basis.

Note that some of these policies supersede information included in previous CMS announcements (e.g. the March 17 fact sheet notes that virtual check-ins and e-visits are limited to established patients, which is no longer the case under the IFC).
Additional guidance documents related to coronavirus waivers and flexibilities are posted on this page, including an April 6 “Dear Clinician” letter summarizing certain flexibilities afforded to clinicians and other provider and supplier types, including but not limited to information on Medicare telehealth visits and other virtual services.

On April 8, CMS hosted a Special Open Door Forum (SODF) focused on telehealth, where CMS answered questions submitted by callers on various aspects of telehealth, including payment for telephone only services; addition of new types of providers who can provide telehealth (e.g. therapists); delivery of services using telecommunication technology when patients and practitioners are at the same location; and more. The recording of this SODF is posted on the CMS Podcasts and Transcripts page. Questions on assorted telehealth issues have also been raised on other CMS calls posted on the same page.

CMS also discussed the use of telehealth for intermediate care facilities for individuals with intellectual disabilities (ICF/IIDs) and psychiatric residential treatment facilities in March 30 guidance on infection control for these facilities.

On April 30, 2020, CMS issued a second Interim Final Rule with comment period addressing COVID-19. This rule is intended to give individuals and entities that provide services to Medicare, Medicaid, Basic Health Program, and Exchange beneficiaries additional flexibilities to respond to the serious public health threats posed by the spread of COVID-19 during the public health emergency (PHE). This rule is effective as of the date of publication in the Federal Register, which is currently scheduled for May 8, 2020. However, policies are applicable beginning March 1, 2020, or January 27, 2020, except as further described in the Applicability Date Table. CMS also implemented policy changes using its broad waiver authority. Information on CMS’ changes is included in the press release and on the CMS Coronavirus Waivers and Flexibilities page. Key changes from the IFC related to telehealth and virtual care include:

- Increasing payment for audio-only telephone E/M services by increasing work RVUs and direct practice expense inputs based on crosswalks to office/outpatient E/M codes (cross-walking 99441-3 to 99212-4, respectively).²
- Specifying that for the flexibility for level selection for office/outpatient E/M visits furnished via telehealth, that for purposes of level selection based on time, the typical times are the times listed in the CPT code descriptor.
- Finalizing that changes to the Medicare Telehealth Services may be made via a subregulatory process during the PHE.
- Specifying that when a registered outpatient is receiving a telehealth service, the hospital may bill the originating site facility fee for telehealth services furnished by a physician or other practitioner who ordinarily practices in that outpatient setting. CMS notes that hospitals should only furnish outpatient services to a patient who is registered as a hospital outpatient after the patient’s home has been made provider-based to the hospital for provision of such services.
- Allowing providers to furnish certain partial hospitalization program (PHP) services remotely in certain circumstances during the PHE.
- Revising requirements for opioid treatment programs to allow periodic assessments to be furnished during the PHE via two-way interactive audio-video communication technology. CMS also noted that the

2 On May 4, CMS released an updated MLN Matters article providing detailed RVU information for the audio-only telephone calls.

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periodic assessments may be furnished using audio-only telephone calls, provide all other applicable requirements are met.

- Specifying that virtual check-ins, remote evaluation e-visits, telephone E/M services, and specified codes when furnished via telehealth will be included in the assignment methodology for the Medicare Shared Savings Program.
- Updating teaching physician requirements by:
  o Adding codes for virtual services (e.g. virtual check-ins, telephone E/M services, e-visits, and more) to the list of codes for the Primary Care Exception that applies related to teaching physician services for lower and mid-level complexity when furnished by a resident without the physical presence of a teaching physician in primary care settings
  o Allowing that teaching physicians may meet the requirement – to review with each resident during or immediately after each visit the patient’s medical history, physical examination, diagnosis, and record of tests and therapies – through virtual means via audio/video real-time communications technology; and
  o Clarifying that CMS’ flexibilities for office/outpatient E/M visit level selection when furnished via telehealth also apply to office/outpatient E/M visits furnished under the Primary Care Exception.

In conjunction with its April 30 IFC, CMS updated the following guidance documents (among others) that may summarize or provide additional detail regarding telehealth provisions included in the IFC, or that discuss additional changes effectuated through additional waivers:

- A summary of COVID-19 emergency declaration waivers & flexibilities for health care providers, addressing certain requirements regarding telemedicine provided by hospitals and CAHs; use of telehealth for visits provided in SNFs and other nursing facilities, as well as by federally qualified health centers and rural health clinics; and use of telehealth related to ESRD care. In this document, CMS also removes its previously established requirement that physicians and practitioners must update their enrollment records with their home addresses to bill for telehealth services furnished from their home. CMS updated this document on April 9 to allow for additional workforce flexibilities, including allowing physicians in remote locations to conduct physician supervision for CAHs using telecommunications technology. Following CMS’ April 30, changes, this document includes the following new provisions related to telehealth:

  o CMS is waiving the requirements that specify the types of practitioners that may bill for services when furnished as Medicare telehealth services from the distant site. Under this waiver, all professionals who are eligible to bill Medicare for their professional services may furnish such services via telehealth, including physical therapists, occupational therapists, speech language pathologists, and others.
  o CMS is waiving the requirements for use of interactive telecommunications systems to furnish telehealth services, to the extent they require the use of video technology, for certain services. That is, the use of audio-only equipment is permitted to furnish designated services, as identified on the Medicare telehealth services list, including behavioral health counseling and educational services and advance care planning services.
  o CMS also updated the Medicare telehealth services list to include new services that would be eligible for payment when furnished via telehealth.
  o CMS is allowing community mental health centers (CMHCs) to provide partial hospitalization services and other CMHC services in individuals’ homes, including through the use of telecommunication technology.
• A separate set of FAQs regarding Medicare fee-for-service, which discusses delivery of services via telehealth and telecommunications technology across a range of settings. These were originally posted on March 23 and last updated on April 9.

• A fact sheet on new waivers and flexibilities for physicians and other practitioners. This document includes information on a blanket waiver CMS issued related to physician self-referral laws. Under this blanket waiver, CMS loosened some of the restrictions on when a group practice can furnish medically necessary designated health services (DHS) in a patient’s home, and notes that any physician in a group may order medically necessary DHS to be furnished by a technician or nurse in the patient’s home contemporaneously with a physician service that is furnished via telehealth by the physician who ordered the DHS. In addition, this fact sheet identifies certain provisions included in the summary document above, as well as information on changes related to Medicare physician supervision and auxiliary personnel.

• Additional fact sheets that address – among other topics – telehealth flexibilities were also updated on April 30, 2020 for:
  o Home health agencies
  o Hospitals
  o Teaching hospitals, teaching physicians, and medical residents
  o Long-term care facilities
  o Hospices
  o Inpatient rehabilitation facilities
  o Rural health clinics and federally qualified health centers
  o End-stage renal disease facilities
  o Medicare Shared Savings Program

On May 8, CMS also updated a video providing an overview of Medicare coverage and payment of telehealth and other virtual services. A former version of the video is no longer available.

On several Office Hours calls following the release of the April 30 IFC, CMS has clarified that because telephone E/M services have been added to the Medicare telehealth list, they should be reported using the 95 modifier. Call transcripts are expected to be posted to the CMS Podcasts and Transcripts page.

On May 15, CMS announced via an MLN Connects Update that MACs will reprocess claims for telephone E/M visits and additional add on services (CPT codes 90785, 90833, 90836, 90838, 96160, 96161, 99354, 99355, and G0506), consistent with changes included in the March 30 and April 30 IFCs.

**Related other HHS activity**

In conjunction with the March 17 CMS announcement, the Office of Inspector General (OIG) published its opinion that during the emergency period “[a] physician or other practitioner reduces or waives cost-sharing obligations (i.e., coinsurance and deductibles) that a beneficiary may owe for telehealth services furnished consistent with the then-applicable coverage and payment rules.” The opinion further states that this does “not require physicians or other practitioners to reduce or waive any cost-sharing obligations Federal health care program beneficiaries may owe for telehealth services.” For more information, visit the OIG fact sheet [here](https://www.cms.gov/oig). On March 24, OIG issued a FAQ on this topic, including clarifying that this policy would apply to non-face-to-face services furnished through various modalities, including telehealth visits, virtual check-in services, e-visits, monthly remote care management, and monthly remote patient monitoring. On March 30, OIG issued a statement noting its intent to minimize burdens on providers given the COVID-19 pandemic and stating, “Our Office of Audit Services
has extensive experience planning and conducting audits that account for special rules, including rules in effect during emergencies. We use the rules in place from the Department when assessing compliance.”

Previously, on March 13, Secretary Azar waived certain requirements, retroactive nationwide as of March 6, related to HIPAA privacy. Specifically, the announcement states the following:

_Pursuant to Section 1135(b)(7) of the Act, I hereby waive sanctions and penalties arising from noncompliance with the following provisions of the HIPAA privacy regulations: (a) the requirements to obtain a patient’s agreement to speak with family members or friends or to honor a patient’s request to opt out of the facility directory (as set forth in 45 C.F.R. § 164.510); (b) the requirement to distribute a notice of privacy practices (as set forth in 45 C.F.R. § 164.520); and (c) the patient’s right to request privacy restrictions or confidential communications (as set forth in 45 C.F.R. § 164.522); but in each case, only with respect to hospitals in the designated geographic area that have hospital disaster protocols in operation during the time the waiver is in effect._

On March 17, the Office of Civil Rights (OCR) announced enforcement discretion for certain widely used communications. Specifically, the OCR press release states “effective immediately, that it will exercise its enforcement discretion and will waive potential penalties for HIPAA violations against health care providers that serve patients through everyday communications technologies during the COVID-19 nationwide public health emergency. This exercise of discretion applies to widely available communications apps, such as FaceTime or Skype, when used in good faith for any telehealth treatment or diagnostic purpose, regardless of whether the telehealth service is directly related to COVID-19. For more information, see the statement and Bulletin.

On March 20, OCR further announced enforcement discretion regarding HIPAA security, privacy, and breach requirements, while clarifying that this discretion does not apply to the confidentiality of substance use disorder records, given the Substance Abuse and Mental Health Services Administration (SAMHSA) has announced separate enforcement discretion regarding those rules. OCR continues to discourage the use of certain “public facing” platforms such as Facebook Live, Twitch, and TikTok. For additional OCR FAQs, visit here.

HHS also released a Notification of Enforcement Discretion in the Federal Register on April 20, 2020 (for publication on April 21, 2020). In this notification, discussing its enforcement discretion for HIPAA rules in connection with the good faith provision of telehealth using non-public facing communication products during the public health emergency. HHS also listed some vendors who represent that they provide HIPAA-compliant video communication products for covered health care providers that seek additional privacy protections, but notes that the listing does not constitute an endorsement, certification, or recommendation.

On March 24, OCR announced the issuance of guidance on how covered entities may disclose protected health information (PHI) about an individual who has been infected with or exposed to COVID-19 to law enforcement, paramedics, other first responders, and public health authorities in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule.

To summarize its guidance, OCR assembled a bulletin addressing civil rights, HIPAA, and COVID-19. It is important to note, however, that state and/or local requirements regarding privacy and security may still apply.

On April 22, HHS launched telehealth.hhs.gov to serve as a resource for both healthcare providers and patients. It provides information about telemedicine and links to tools and resources for practitioners.
On April 24, the OIG released new FAQs related to COVID-19. Among the FAQs, OIG notes that provision of certain telecommunications technologies (see one question on cell phones, service or data plans, or both; and one question on access to a hospital’s telehealth platform) pose sufficiently low risk of fraud and abuse under the current circumstances, provided certain conditions are met.

**American Medical Association Resources**

In response to the Medicare changes, the American Medical Association (AMA) shared the Quick Guide to Telemedicine in Practice, a new resource to help mobilize remote care with implementation tips, as well as a reference to Current Procedural Terminology (CPT) codes for reporting telemedicine and remote care services. The AMA also offers an education module in the AMA’s STEPS Forward™ that can help physicians use telemedicine in practice, and the Digital Health Implementation Playbook with a 12-steps process for adopting remote monitoring of patients outside the traditional clinical environment. AMA also released special coding advice related to coding of various scenarios related to care for COVID-19 for physicians and other professionals, some of which address telehealth.

**Prescription of Controlled Substances**

On March 20, the Drug Enforcement Agency (DEA) issued a press release noting that DEA-registered practitioners may use telehealth during the public health emergency for the prescription of controlled substances, provided that:

- The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice.
- The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system.
- The practitioner is acting in accordance with applicable Federal and State law.

On March 25, the DEA granted an exception to the requirement that a DEA registrant must be registered in each state in which the practitioner dispenses controlled substances. Under this exception, DEA-registered practitioners are not required to obtain additional registration with the DEA in the additional state(s) where the dispensing (including prescribing and administering) occurs, for the duration of the public health emergency if they are registered in at least one state and have permission under state law to practice using controlled substances in the state where the dispensing occurs, including for the practice of telemedicine. Additional detail is in the linked notice.

On March 27, the DEA announced exceptions to requirements regarding paper delivery of a prescription of an oral emergency prescription, including allowing the prescription to be sent via facsimile, or for the prescription to be photographed, scanned, and sent in place of the paper prescription.

On March 31, 2020, the DEA announced that it is providing flexibility to provide buprenorphine to new and existing patients with opioid use disorder (OUD) for maintenance and detoxification treatment via telephone by otherwise authorized practitioners without requiring such practitioners first conduct an examination of the patient in person or via telemedicine. This policy is effective from March 31, 2020 through the duration of the PHE.

**Application to FQHCs and RHCs.** Section 3704 of CARES allows federally-qualified health centers (FQHCs) and rural health clinics (RHCs) to furnish telehealth services to Medicare beneficiaries and details payment implications.
Additionally, in the March 30 CMS IFC, CMS allows RHCs and FQHCs to provide and receive payment for online digital evaluation and management services on an interim basis. These services will be included in the RHC/FQHC HCPCS code G0071 addressing payment for communication technology-based services. RHCs and FQHCs will be able to use this code with both new and established patients during the PHE.

On April 17, 2020, CMS issued an MLN Matters Special Edition Article addressing information relevant to FQHCs and RHCs under the COVID-19 public health emergency, including related to new payment for telehealth services.

Application to end-stage renal disease (ESRD) care. Section 3705 of CARES allows the Secretary to waive the requirement that a face-to-face clinical assessment is required for each of the first three months and at least once every three consecutive months thereafter for patients receiving home dialysis for the purposes of allowing care to be furnished via telehealth.

Additionally, in the March 30 CMS IFC, CMS expands the list of telehealth services to include additional ESRD services; allows “hands-on” visits required for ESRD monthly capitation payments to be conducted via telehealth; and provides enforcement discretion related to face-to-face visits for patients receiving home dialysis.

Application to hospice care. Section 3706 of CARES directly address a key hospice concern by allowing the requirement under section 1814(a)(7)(D)(i) for a face-to-face encounter for 180-day hospice recertification to be performed via telehealth as part of the pandemic response.

Additionally, in the March 30 CMS IFC, CMS updates hospice regulations to specify that when a patient is receiving routine home care, hospices may provide services via a telecommunications system if it is feasible and appropriate to do so, and other requirements are met. CMS also allows the use of audio and video equipment permitting two-way, real-time interactive communication for completion of the face-to-face recertification visit when the visit is solely for the purpose of recertification during the PHE.

Application to home health. Section 3707 of CARES requires the Secretary to consider ways to encourage the use of telecommunications systems for the purpose of home health services, including for remote patient monitoring.

Additionally, in the March 30 CMS IFC, CMS allows home health agencies to provide more services to beneficiaries using telehealth when certain requirements are met and provides clarification on the definition of “homebound” to allow more beneficiaries to qualify for home health services.

Application to PACE organizations. On April 14, 2020, CMS updated an FAQ document for pace organizations, which includes information on telehealth. CMS also provided guidance regarding telehealth on a document titled “Information for PACE Organizations Regarding Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19).”

Application to Medicare Advantage (MA) and/or Part D Plans. On March 10, CMS issued guidance to MA organizations (MAOs) and Part D sponsors to inform them of the obligations and permitted flexibilities related to disasters and emergencies resulting from COVID-19. This guidance includes allowing MAOs to waive or reduce enrollee cost-sharing affected by the outbreak, including for telehealth benefits. MAOs may also provide Part B services via telehealth in any geographic area and from a variety of locations, including beneficiaries’ homes. CMS also indicated that it would exercise enforcement discretion for MAOs interested in expanding coverage of
telehealth services beyond those included in their plan benefit packages for as long as CMS determines it is necessary in conjunction with the COVID-19 outbreak. On April 10, CMS issued an announcement indicating that MA plans and other organizations that submit data for risk adjustment may submit diagnoses from telehealth visits for the purposes of risk adjustment when the visits meet all criteria for risk adjustment eligibility.

On May 22, 2020, CMS issued the final rule on Policy and Technical Changes to Medicare Advantage and Part D for Contract Year 2021, which included policies that may increase access to telehealth. Specifically, CMS finalized a policy that gives MA plans a 10 percent credit towards network adequacy requirements when a plan contracts with telehealth providers for the following specialties: Dermatology, Psychiatry, Cardiology, Otolaryngology, Neurology, Ophthalmology, Allergy and Immunology, Nephrology, Primary Care, Obstetrics/Gynecology, Endocrinology, and Infectious Diseases. A press release and fact sheet are also available.

Application to EMTALA. CMS updated guidance (updated on March 30, 2020) related to EMTALA requirements, indicating that hospitals may use telehealth equipment to perform medical screening exams by qualified medical personnel, noting that “the use of telehealth to provide evaluation of individuals who have not physically presented to the hospital for treatment does not create an EMTALA liability.”

On April 30, CMS also issued new FAQs related to EMTALA. CMS specified that the use of telehealth to evaluate individuals who have not physically presented to the hospital does not create an EMTALA obligation. CMS also addresses licensing, available codes, and supervision via telehealth in the FAQs.

FDA Guidance
On March 20, the Food and Drug Administration (FDA) issued a final guidance document that allows manufacturers of certain FDA-cleared non-invasive, vital sign-measuring devices to expand their use so that health care providers can use them to monitor patients remotely. The devices include those that measure body temperature, respiratory rate, heart rate and blood pressure.

HRSA and AHRQ Resources
Section 3212 of the CARES Act reauthorizes HRSA grant programs that promote the use of telehealth technologies for health care delivery, education, and health information services.

On April 22, HHS announced HRSA awards of nearly $165 million to address COVID-19 in rural communities, including more than $11.5 million awarded to 14 HRSA-funded Telehealth Resource Centers.

On April 30, HHS announced HRSA awards of $20 million to increase telehealth access and infrastructure for providers and families to help prevent and respond to COVID-19, including through assisting with cross-state licensure. HRSA’s Maternal and Child Health Bureau awarded $15 million to four recipients, and the Federal Office of Rural Health Policy awarded $5 million to two additional recipients. Additional details are available in the press release.

On May 4, AHRQ announced the availability of easy-to-understand telehealth consent forms and guidance for clinicians on how to obtain informed consent.

On May 13, HRSA awarded $15 million to 159 organizations across five health workforce programs to increase telehealth capabilities: Geriatrics Workforce Enhancement Program; Area Health Education Centers Program; Centers of Excellence Program; Nurse Education, Practice, Quality and Retention – Veteran Nurses in Primary Care

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Training Program; Nurse Education Practice, Quality and Retention – Registered Nurses in Primary Care Training Program. A complete list of award recipients is available here.

On May 14, AHRQ issued a White Paper Commentary on an AHRQ Evidence Report discussing the evidence base for telehealth. Links to previous AHRQ evidence reviews are included.

Additionally, while these programs are not specifically in response to COVID-19, there are funding opportunities that can promote the use of telehealth:

- HRSA Telehealth Network Grant Program (Application dates from 2/1/2020 to 6/15/2020)
- HRSA Rural Telementoring Training Center (Application dates from 4/17/2020 to 6/16/2020)

Indian Health Services
On April 8, the Indian Health Services (IHS) announced expansion of telehealth across IHS federal facilities.

VA and Telehealth
To bypass state licensure, the Veterans Administration (VA) issued a final rule “that ensures that VA health care providers can offer the same level of care to all beneficiaries, irrespective of the State or location in a State of the VA health care provider or the beneficiary” and “achieves important Federal interests by increasing the availability of mental health, specialty, and general clinical care for all beneficiaries.”

The VA also offers VA Video Connect to provide telehealth services.

TRICARE
On May 8, the Department of Defense issued this interim final rule with comment to: provide an exception to the prohibition on telephone, audio-only telehealth services; to authorize reimbursement for interstate or international practice by TRICARE-authorized providers when such authority is consistent with governing state, federal, or host nation licensing requirements; and to eliminate copayments and cost-shares for telehealth services. The changes in this rule will be effective for the period of the coronavirus 2019 (COVID-19) pandemic.

FCC Resources
The Federal Communications Commission (FCC) has developed and approved a $200 million program to fund telehealth services and devices for medical providers using funds from the CARES Act. Hospitals and other health centers will be able to apply for up to $1 million to cover the cost of new devices, services and personnel. The FCC will also move forward with a Connected Care telehealth pilot program for veterans and low-income individuals using existing FCC subsidy mechanisms. The final order is posted in the Federal Register. The application portal for this program opened on April 13, 2020. FCC began approving the first set of applications by April 16, 2020. Information on following approvals is available on the FCC website.

Actions Related to the Private Market
Section 3701 of the CARES Act clarifies that high deductible health plans (HDHPs) could opt to waive deductibles for telehealth services and still be considered a HDHP (i.e., be within a safe harbor).

On March 24, CMS issued FAQs addressing the availability and usage of telehealth services through private health insurance coverage, encouraging issuers to promote the use of telehealth services and encouraging states to support issuers’ efforts. CMS specifically urged states to consider whether state licensing laws could be relaxed.

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CMS also noted its plan to exercise enforcement discretion with respect to changes in plan benefits during the year to provide or expand coverage for telehealth services and encouraged states to take a similar enforcement approach. CMS also noted enforcement discretion to allow catastrophic plans to provide pre-deductible coverage for telehealth services, even if the services are not related to COVID-19 and encouraged states to take a similar approach.

On April 11, the Department of Health and Human Services, the Department of Labor, and the Department of Treasury issued joint FAQs regarding implementation of provisions enacted through COVID-19 legislation. In the FAQs, the Departments strongly encourage all plans and issuers to promote the use of telehealth and other remote care services, and encourage states to support such efforts, noting the flexibilities added in section 3701 of the CARES Act. The FAQs also note that the Departments will apply non-enforcement policies where a plan or issuer adds benefits or reduces or eliminates cost sharing for telehealth and other remote care services. See the FAQs for additional details.

On April 27, CMS issued an FAQ discussing which telehealth services are valid for data submission for the HHS-operated risk adjustment program for issuers.

**Fraud, Waste, and Abuse Considerations**

On April 1, 2020, the HHS OIG issued a report titled, “96 Percent of South Carolina’s Medicaid Fee-for-Service Telemedicine Payments Were Insufficiently Documented or Otherwise Unallowable.” This report highlights documentation challenges that arise with telemedicine that could garner additional information as the use of telehealth spreads.

**Security Considerations**

On April 24, the National Security Agency released guidance on selecting and safely using Collaboration Services for Telework, which includes video platforms that may be used for telehealth.

**State Response**

For a list of current state laws as well as legislation and regulation related to telehealth policies, visit the Center for Connected Health Policy website.

**State Licensing and Interstate “Compacts”**

Many states have taken action to reduce barriers to licensing. The Federation of State Medical Boards (FSMB) has posted a few resources that you can find at the links below:

- A chart identifying states’ policies regarding licensure requirements and renewals in response to COVID-19.
- A chart identifying states waiving in-state licensing requirements for telehealth.
- A chart identifying steps states are taking to expedite licensure for inactive or retired licenses in response to COVID-19.

The National Council of State Boards of Nursing has also prepared a chart on state actions addressing nursing licensure.

Additionally, given challenges with clinicians providing care across state lines, FSMB established the Interstate Medical License Compact Commission (IMLCC). According to IMLCC, “[t]he Interstate Medical Licensure Compact...”

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offers a new, voluntary expedited pathway to licensure for qualified physicians who wish to practice in multiple states.” At this time, 29 states, the District of Columbia and the Territory of Guam, have agreed to the compact. Additional information about FSMB and telemedicine policy is available here.

According to the Center for Connected Health Policy of the National Telehealth Policy Resource Center report, State Telehealth Laws & Reimbursement Policies, issued in late 2019, “In line state medical (or osteopathic) boards issue special licenses or certificates related to telehealth. The licenses could allow an out-of-state provider to render services via telemedicine in a state where they are not located, or allow a clinician to provide services via telehealth in a state if certain conditions are met (such as agreeing that they will not open an office in that state).”

In addition to the IMLC, there are additional compacts for nurses, physical therapists and psychologists.

- The Nurses Licensure Compact
- The Physical Therapy Compact
- The Psychology Interjurisdictional Compact
- Audiology and Speech-Language Pathology Compact

On May 5, 2020, CMS issued an MLN Matters Article that clarified that CMS has determined that interstate license compacts for Physician, Physical Therapy, Occupational Therapy, Speech Language Therapy, Nurse Practitioner, and Psychology provider types will be treated as valid, full licenses for the purposes of meeting federal license requirements.

Emergency Management Assistance Compact. Some have suggested that the use of the Emergency Management Assistance Compact, an agreement among the states and U.S. territories allowing sharing of resources during emergencies, would be a good tool to eliminate telehealth licensure barriers. The EMAC includes a provision for someone licensed in one state to be licensed in another facing an emergency when the compact is invoked. According to Bloomberg, Trina Sheets, executive director of the National Emergency Management Association, which administers the compact, said the compact has not been used in the past to provide telehealth services but would make a good vehicle for that purpose.

State Flexibility. The President declared an emergency under the Stafford Act on March 13. As a result of that declaration and the prior public health emergency declaration, CMS has additional waiver authority under section 1812(f) and section 1135. States can gain new authority to use their Medicaid programs to respond to the coronavirus pandemic under the national emergency. For instance, States may be able to expand the use of telehealth services in their Medicaid programs to combat the coronavirus outbreak.

On March 17, CMS issued additional Medicaid telehealth guidance and while also highlighting their main website for telehealth in Medicaid. Per the FAQs, “[n]o federal approval is needed for state Medicaid programs to reimburse providers for telehealth services in the same manner or at the same rate that states pay for face-to-face services.”

On April 2, CMS issued an Informational Bulletin to states that explains how states can use telehealth delivery methods to expand access to Medicaid services, including for substance use disorder (SUD). The guidance outlines how telehealth may be used to service rural communities, high-risk individuals, school-based health centers and SUD programs.
On April 23, CMS issued a Telehealth Toolkit to Accelerate State Use of Telehealth in Medicaid and CHIP. The toolkit includes policy considerations, state checklists, frequently asked questions, and more. CMS also issued an accompanying press release.

State Activity. The list of CMS-approved section 1135 waivers is available here. This list does not necessarily include all telehealth waivers, as noted below.

The Kaiser Family Foundation has developed this state Medicaid tracker to identify the types of approved emergency authorities that have been granted under 1135 waivers and 1915(c) Waiver Appendix K, including waivers related to screening requirements, out-of-state licensing requirements, virtual evaluations, and more.

The Center for Connected Health Policy has also been tracking actions at the state level.

Key Limitations & Additional Considerations

Key Limitations. Despite these recent activities, key gaps remain.

Medicaid. As noted above, CMS has provided flexibility for automatic approval for certain State telehealth waivers. For a list of approved waivers, which do not necessarily include all of the telehealth waivers, visit here.

Private payers (especially ERISA covered plans). While CMS Administrator Seema Verma has made it clear that the Administration is urging private payers to make similar modifications, so far, there has not been a broad announcement to that effect. While some states are moving forward to address the topic at the state level, state activities cannot address ERISA-covered plans.

Coding concerns. Given that this is the first time in which widespread telehealth services would be available, there have been some concerns that the current telehealth codes (for both Medicare and other payers) are not quite comprehensive enough to address all of the needed situations.

Telephone only. Several of the current Medicare codes require audio and visual capabilities. Given that many elderly individuals may not have access to such resources, providers are requesting the ability to perform certain tasks via telephone only. The CARES Act allows for waiver of all telehealth provisions under section 1834(m) of the Social Security Act, offering the Secretary the authority to permit use of telephone only when furnishing telehealth services. In the March 30 CMS IFC, CMS updated regulations to allow the use of telephone-only evaluation/assessment codes, but declined to expand use of audio-only telephone for services on the Medicare list of telehealth services.

Additional Considerations. As providers take steps to implement new telehealth provisions, legal experts suggest that providers should take into account key issues with respect to security (including specific platforms), medical credentials, and recording of those visits. Changes in health care as the coronavirus pandemic progresses may force regulators to adjust barriers around telehealth.

Medical licensing, credentials, and out of network issues. While Secretary Azar was able to waive certain licensure requirements to allow for Medicare and Medicaid payments to providers who do not have a license...
Adequate notes. To ensure proper compliance in the event of an audit, clinicians should ensure that provider notes are adequate and consider the use of audiovisual recording to provide the necessary data to support coding and billing.

Legislative Text. As described above, the text of Public Law No: 116-123, showing changes made by sec. 6010 of the Family First Coronavirus First Response Act and section 3703 of the CARES Act, follows:

SEC. 101. SHORT TITLE.
This division may be cited as the "Telehealth Services During Certain Emergency Periods Act of 2020".

SEC. 102. SECRETARIAL AUTHORITY TO TEMPORARILY WAIVE OR MODIFY APPLICATION OF CERTAIN MEDICARE REQUIREMENTS WITH RESPECT TO TELEHEALTH SERVICES FURNISHED DURING CERTAIN EMERGENCY PERIODS.
(a) In General.--
(1) Waiver authority.--The first sentence of section 1135(b) of the Social Security Act (42 U.S.C. 1320b-5(b)) is amended--
(A) in paragraph (6), by striking "and" at the end;
(B) in paragraph (7), by striking the period at the end and inserting "; and";
(C) by inserting after paragraph (7) the following new paragraph:
"(8) in the case of a telehealth service (as defined in paragraph (4)(F) of section 1834(m)) furnished in any emergency area (or portion of such an area) during any portion of any emergency period, the requirements of section 1834(m), to an individual by a qualified provider (as defined in subsection (g)(2))--
"(A) the requirements of paragraph (4)(C) of such section, except that a facility fee under paragraph (2)(B)(i) of such section may only be paid to an originating site that is a site described in any of subclauses (I) through (IX) of paragraph (4)(C)(ii) of such section; and
"(B) the restriction on use of a telephone described in the second sentence of section 410.78(a)(3) of title 42, Code of Federal Regulations (or a successor regulation), but only if such telephone has audio and video capabilities that are used for two-way, real-time interactive communication."; and

3 Recent CMS FAQs state the following: Can Medicare fee-for-service rules regarding physician State licensure be waived in an emergency? The HHS Secretary has authorized 1135 waivers that allow CMS to waive, on an individual basis, the Medicare requirement that a physician or non-physician practitioner must be licensed in the State in which s/he is practicing. However, the 1135 waiver is not available unless all of the following four conditions are met: 1) the physician or non-physician practitioner must be enrolled as such in the Medicare program, 2) the physician or non-physician practitioner must possess a valid license to practice in the State which relates to his or her Medicare enrollment, 3) the physician or non-physician practitioner is furnishing services — whether in person or via telehealth — in a State in which the emergency is occurring in order to contribute to relief efforts in his or her professional capacity, and 4) the physician or non-physician practitioner is not affirmatively excluded from practice in the State or any other State that is part of the 1135 emergency area. In addition to the statutory limitations that apply to 1135-based licensure waivers, an 1135 waiver, when granted by CMS, does not have the effect of waiving State or local licensure requirements or any requirement specified by the State or a local government as a condition for waiving its licensure requirements. Those requirements would continue to apply unless waived by the State. Therefore, in order for the physician or non-physician practitioner to avail him- or herself of the 1135 waiver under the conditions described above, the State also would have to waive its licensure requirements, either individually or categorically, for the type of practice for which the physician or non-physician practitioner is licensed in his or her home State. (emphasis added)
(2) Definition of qualified provider.—Section 1135(g) of the Social Security Act (42 U.S.C. 1320b-5(g)) is amended by adding at the end the following new paragraph:

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(a) In general.—Subject to subparagraph (B), an `emergency area' is a geographical area in which, and an `emergency period' is the period during which, there exists—

(i) an emergency or disaster declared by the President pursuant to the National Emergencies Act or the Robert T. Stafford Disaster Relief and Emergency Assistance Act; and

(ii) a public health emergency declared by the Secretary pursuant to section 319 of the Public Health Service Act.

(b) Exception.—For purposes of subsection (b)(8), an `emergency area' is a geographical area in which, and an `emergency period' is the period during which, there exists—

(i) the public health emergency declared by the Secretary pursuant to section 319 of the Public Health Service Act on January 31, 2020, entitled `Determination that a Public Health Emergency Exists Nationwide as the Result of the 2019 Novel Coronavirus'; and

(ii) any renewal of such declaration pursuant to such section 319.
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1834(m) reads as follows:

(m) PAYMENT FOR TELEHEALTH SERVICES.—

(1) IN GENERAL.—The Secretary shall pay for telehealth services that are furnished via a telecommunications system by a physician (as defined in section 1861(r)) or a practitioner (described in section 1842(b)(18)(C)) to an eligible telehealth individual enrolled under this part notwithstanding that the individual physician or practitioner providing the telehealth service is not at the same location as the beneficiary. For purposes of the preceding sentence, in the case of any Federal telemedicine demonstration program conducted in Alaska or Hawaii, the term “telecommunications system” includes store-and-forward technologies that provide for the asynchronous transmission of health care information in single or multimedia formats.

(2) PAYMENT AMOUNT.—

(A) DISTANT SITE.—The Secretary shall pay to a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth individual an amount equal to the amount that such physician or practitioner would have been paid under this title had such service been furnished without the use of a telecommunications system.

(B) FACILITY FEE FOR ORIGINATING SITE.—

(i) IN GENERAL.—Subject to clause (ii) and paragraph (6)(C), with respect to a telehealth service, subject to section 1833(a)(1)(U), there shall be paid to the originating site a facility fee equal to—

(I) for the period beginning on October 1, 2001, and ending on December 31, 2001, and for 2002, $20; and

(II) for a subsequent year, the facility fee specified in clause (I) or this clause for the preceding year increased by the percentage increase in the MEI (as defined in section 1842(i)(3)) for such subsequent year.

(ii) NO FACILITY FEE IF ORIGINATING SITE IS THE HOME.—No facility fee shall be paid under this subparagraph to an originating site described in paragraph (4)(C)(ii)(X).

(C) TELEPRESENTER NOT REQUIRED.—Nothing in this subsection shall be construed as requiring an eligible telehealth individual to be presented by a physician or practitioner at the originating site for the furnishing of a service via a telecommunications system, unless it is medically necessary (as determined by the physician or practitioner at the distant site).

(3) LIMITATION ON BENEFICIARY CHARGES.—

(A) PHYSICIAN AND PRACTITIONER.—The provisions of section 1848(g) and subparagraphs (A) and (B) of section 1842(b)(18) shall apply to...
a physician or practitioner receiving payment under this subsection in the same manner as they apply to physicians or practitioners under such sections.

(B) ORIGINATING SITE.—The provisions of section 1842(b)(18) shall apply to originating sites receiving a facility fee in the same manner as they apply to practitioners under such section.

(4) DEFINITIONS.—For purposes of this subsection:

(A) DISTANT SITE.—The term "distant site" means the site at which the physician or practitioner is located at the time the service is provided via a telecommunications system.

(B) ELIGIBLE TELEHEALTH INDIVIDUAL.—The term "eligible telehealth individual" means an individual enrolled under this part who receives a telehealth service furnished at an originating site.

(C) ORIGINATING SITE.—

(i) IN GENERAL.—Except as provided in paragraphs (5), (6), and (7), the term "originating site" means only those sites described in clause (ii) at which the eligible telehealth individual is located at the time the service is furnished via a telecommunications system and only if such site is located—

(I) in an area that is designated as a rural health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A));

(II) in a county that is not included in a Metropolitan Statistical Area; or

(III) from an entity that participates in a Federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary of Health and Human Services as of December 31, 2000.

(ii) SITES DESCRIBED.—The sites referred to in clause (i) are the following sites:

(I) The office of a physician or practitioner. (II) A critical access hospital (as defined in section 1861(mm)(1)).

(III) A rural health clinic (as defined in section 1861(aa)(2)).

(IV) A Federally qualified health center (as defined in section 1861(aa)(4)).

(V) A hospital (as defined in section 1861(e)). (VI) A hospital-based or critical access hospital-based renal dialysis center (including satellites). (VII) A skilled nursing facility (as defined in section 1819(a)).

(VIII) A community mental health center (as defined in section 1861(ff)(3)(B)). (IX) A renal dialysis facility, but only for purposes of section 1881(b)(3)(B).

(X) The home of an individual, but only for purposes of section 1881(b)(3)(B) or telehealth services described in paragraph (7).

(D) PHYSICIAN.—The term "physician" has the meaning given that term in section 1861(r).

(E) PRACTITIONER.—The term "practitioner" has the meaning given that term in section 1842(b)(18)(C).

(F) TELEHEALTH SERVICE.—

(i) IN GENERAL.—The term "telehealth service" means professional consultations, office visits, and office psychiatry services (identified as of July 1, 2000, by HCPCS codes 99241–99275, 99201–99215, 90804–90809, and 90862 (and as subsequently modified by the Secretary)), and any additional service specified by the Secretary.

(ii) YEARLY UPDATE.—The Secretary shall establish a process that provides, on an annual basis, for the addition or deletion of services (and HCPCS codes, as appropriate, to those specified in clause (i) for authorized payment under paragraph (1).

(5) TREATMENT OF HOME DIALYSIS MONTHLY ESRD-RELATED VISIT.—The geographic requirements described in paragraph (4)(C)(i) shall not apply with respect to telehealth services furnished on or after January 1, 2019, for purposes of section 1881(b)(3)(B), at an originating site described in subclause (VI), (IX), or (X) of paragraph (4)(C)(ii).

(b) TREATMENT OF STROKE TELEHEALTH SERVICES.—

(A) NON-APPLICATION OF ORIGINATING SITE REQUIREMENTS.—The requirements described in paragraph (4)(C) shall not apply with respect to telehealth services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke, as determined by the Secretary.

(B) INCLUSION OF CERTAIN SITES.—With respect to telehealth services described in subparagraph (A), the term "originating site" shall include any hospital (as defined in section 1861(e)) or critical access hospital (as defined in section 1861(mm)(1)), any mobile stroke unit (as defined by the Secretary), or any other site determined appropriate by the Secretary, at which the eligible telehealth individual is located at the time the service is furnished via a telecommunications system.

(C) NO ORIGINATING SITE FACILITY FEE FOR NEW SITES.—No facility fee shall be paid under paragraph (2)(B) to an originating site with respect to a telehealth service described in subparagraph (A) if the originating site does not otherwise meet the requirements for an originating site under paragraph (4)(C).

(7) TREATMENT OF SUBSTANCE USE DISORDER SERVICES FURNISHED THROUGH TELEHEALTH.—The geographic requirements described in paragraph (4)(C)(i) shall not apply with respect to telehealth services furnished on or after July 1, 2019, to an eligible telehealth individual

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with a substance use disorder diagnosis for purposes of treatment of such disorder or co-occurring mental health disorder, as determined by the Secretary, at an originating site described in paragraph (4)(C)(ii) (other than an originating site described in subclause (IX) of such paragraph).

Section 3706 of the CARES Act follows.

SEC. 3706. USE OF TELEHEALTH TO CONDUCT FACE-TO-FACE ENCOUNTER PRIOR TO RECERTIFICATION OF ELIGIBILITY FOR HOSPICE CARE DURING EMERGENCY PERIOD.

Section 1814(a)(7)(D)(i) of the Social Security Act (42 U.S.C. 1395f(a)(7)(D)(i)) is amended—
(1) by striking "a hospice" and inserting "(I) subject to subclause (II), a hospice"; and
(2) by inserting after subclause (I), as added by paragraph (1), the following new subclause:
"(II) during the emergency period described in section 1135(g)(1)(B), a hospice physician or nurse practitioner may conduct a face-to-face encounter required under this clause via telehealth, as determined appropriate by the Secretary; and".

The amendment made the following changes to prior law as shown below (proposed new text added in red):

(7) in the case of hospice care provided an individual—
(A)(i) in the first 90-day period—
(I) the individual’s attending physician (as defined in section 1395x(dd)(3)(B) of this title) (which for purposes of this subparagraph does not include a nurse practitioner), and
(II) the medical director (or physician member of the interdisciplinary group described in section 1395x(dd)(2)(B) of this title) of the hospice program providing (or arranging for) the care, each certify in writing at the beginning of the period, that the individual is terminally ill (as defined in section 1395x(dd)(3)(A) of this title) based on the physician’s or medical director’s clinical judgment regarding the normal course of the individual’s illness, and
(ii) in a subsequent 90- or 60-day period, the medical director or physician described in clause (i)(II) recertifies at the beginning of the period that the individual is terminally ill based on such clinical judgment;

(B) a written plan for providing hospice care with respect to such individual has been established (before such care is provided by, or under arrangements made by, that hospice program) and is periodically reviewed by the individual’s attending physician and by the medical director (and the interdisciplinary group described in section 1395x(dd)(2)(B) of this title) of the hospice program;

(C) such care is being or was provided pursuant to such plan of care; and

(D) on and after January 1, 2011—
(i)(I) subject to subclause (II), a hospice physician or nurse practitioner has a face-to-face encounter with the individual to determine continued eligibility of the individual for hospice care prior to the 180th-day recertification and each subsequent recertification under subparagraph (A)(ii) and attests that such visit took place (in accordance with procedures established by the Secretary);
(II) during the emergency period described in section 1135(g)(1)(B), a hospice physician or nurse practitioner may conduct a face-to-face encounter required under this clause via telehealth, as determined appropriate by the Secretary; and
(ii) in the case of hospice care provided an individual for more than 180 days by a hospice program for which the number of such cases for such program comprises more than a percent (specified by the Secretary) of the total number of such cases for all programs under this subchapter, the hospice care provided to such individual is medically reviewed (in accordance with procedures established by the Secretary);