Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

[CMS-1744-IFC]

SUMMARY

On March 31, 2020, the Centers for Medicare and Medicaid Services (CMS) placed on public display an interim final rule with comment (IFC) to offer flexibilities in providing services during the COVID-19 pandemic and support the health and safety of Medicare beneficiaries, Medicaid recipients, and healthcare workers.

The IFC reflects changes to CMS's emergency waiver authority under section 1135 of the Social Security Act (the Act) included in the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Public Law 116-123) which was enacted on March 6, 2020. CMS was developing this IFC while Congress was making further changes to the law in the Families First Coronavirus Response Act (Public Law 116-127) and the Coronavirus Aid, Relief, and Economic Security Act or "CARES Act" (Public Law 116-136). Even though the IFC was released after these laws were enacted, the IFC may not reflect new or revised policies contained in these more recent laws. For issues addressed in both the IFC and recent legislation, the summary may describe the statutory provision and its relation to the same provision in the IFC. Where provisions of these more recent laws are not reflected in the IFC, CMS will likely follow up with expedited implementation, including more interim final rulemaking, to update its policies accordingly.

CMS believes it would be contrary to public interest to undertake normal notice and comment and waives both the notice and comment rulemaking and the delay in the effective date. **Policies in the IFC are effective as of March 1, 2020** – the date the President declared the beginning of the national emergency for the COVID-19 pandemic. The interim final rule is scheduled to be published in the April 6, 2020 issue of the *Federal Register.* The 60-day comment period for the IFC ends at close of business on June 1, 2020.

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I. BACKGROUND

On January 31, 2020, the Secretary of Health and Human Services (HHS) declared a Public Health Emergency (PHE) for the "coronavirus disease 2019" (known as COVID-19[1]) for the U.S. On March 11, 2020, the World Health Organization (WHO) declared the COVID-19 outbreak as a pandemic. On March 13, 2020, the President declared the COVID-19 outbreak a national emergency.

In this interim final rule with comment period (IFC), CMS addresses certain regulations with a goal to increase access to services delivered using telecommunications technology, increase access to testing in a patient's home, and improve infection control.

II. Provisions of the Interim Final Rule

CMS defines the term "Public Health Emergency" in the regulation at 42 CFR 400.200. This definition identifies the PHE determined to exist nationwide by the Secretary of HHS, on

[1] The virus causing COVID-19 has been named SARS-CoV-2.

January 31, 2020, under section 319 of the Public Health Service (PHS) Act, including any subsequent renewals.

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

Section 1834(m) of the Act specifies the circumstances and payment amounts under which Medicare makes payment for a discrete set of services which must ordinarily be furnished in-person when they are instead furnished using interactive, real-time telecommunication technology.[2] The list of eligible Medicare telehealth services, described as "face-to-face" services furnished using audio/video, real-time communication technology, is published at https://www,cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.

Medicare also pays for other professional services that are furnished using telecommunications technology but do not usually require face-to-face interaction with the provider. These services, including remote physiologic interpretation of diagnostic tests, care management services, and virtual check-ins, are considered physician services and paid in the same way as services delivered without the use of telecommunications technology. These are not considered telehealth services and not subject to the conditions of payment under section 1834(m) of the Act.

1. Site of Service Differential for Medicare Telehealth Services

In accordance with section 1834(m)(2)(B) of the Act, a facility fee is generally paid to the "originating site" where the beneficiary is located at the time a telehealth service is provided. Payment is made to the billing physician or practitioner at the Physician Fee Schedule (PFS) facility rate since the facility costs associated with providing the service are incurred by the originating site. CMS requires that claims for Medicare telehealth services include the place of service (POS) code 02, which is specific to telehealth services.
The waiver authority for the COVID-19 pandemic allows for the provision of Medicare telehealth services furnished to patients wherever they are located, including the patient's home; no originating site facility fee is paid.[3] During this PHE, CMS believes that telehealth services furnished to patients should include the relative resource costs of services paid under the PFS when the services are furnished in-person.

CMS finalizes an interim change to pay physicians and practitioners based on the setting they typically see patients. For example, a physician practicing in an office setting and seeing patients via telehealth would be paid at the non-facility (or office) rate for these services. Similarly, a physician who typically see patients in an outpatient provider-based clinic of a hospital would be paid the facility rate for telehealth services. For claims submission, on an interim basis, CMS finalizes the following:

- CPT modifier 95 (Telehealth service) should be applied to claim lines that describe services furnished by telehealth; and

[2] The full scope of the Medicare telehealth services is discussed in the 2018 Physician Final Rule (82 FR 53006, November 17, 2017) and regulations at 42 CFR 410.78 and 414.65.
[3] As provided in section 1834(m)(4)(C)(ii)(I) through (IX) of the Act.

- POS code 02 (Telehealth) should be used for claims when the practitioner chooses to maintain their current billing practices during the pandemic.

2. Adding Services to the List of Medicare Telehealth Services

In the 2003 PFS final rule (67 FR 79988), CMS established a process for adding or deleting services form the list of Medicare telehealth services. CMS assigns additions to the list of telehealth services to one of the following two categories:

- Category 1: Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the telehealth service list. In reviewing requests to add services to category 1, CMS looks for similarities between existing services and requested services.
- Category 2: Services that are not similar to those on the current list of telehealth services. In reviewing requests to add services to category 2, CMS evaluates whether the service demonstrates clinical benefit to the patient.

On an interim basis, for the duration of this PHE, CMS is adding services to the Medicare telehealth list on a Category 2 basis. This policy covers telehealth services with dates of services beginning March 1, 2020 through the end of the declared PHE, including any subsequent renewals.

CMS notes that in the context of the PHE for the COVID-19 pandemic, it believes all of the added services meet the category 2 criteria because there is a patient population that would otherwise not have access to clinically appropriate treatment. CMS expects providers will use the E/M code that best describes the nature of the care provided, regardless of the physical location or status of the patient.

CMS adds the following codes to the existing list of telehealth services[4] on a category 2 basis for the PHE for the COVID-19 pandemic:

List of Services Added to List of Telehealth Services for the PHE for the COVID-19 Pandemic*	
Service	**CPT Code**
Emergency department visits	99281 - 99285
Initial and subsequent observation care	99217 – 99220, 99224-99226, 99234 - 99236
Observation discharge day management	99234 - 99326
Initial hospital care	99221 - 99223
Hospital discharge day management	99238 - 99239

[4] This expanded list of telehealth services is available on the CMS website at https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.

List of Services Added to List of Telehealth Services for the PHE for the COVID-19 Pandemic*	
Service	**CPT Code**
Initial nursing facility visits	99304 - 99306
Nursing facility discharge day	99315 - 99316
Critical care services	99291 - 99292
Domiciliary, rest home or custodial care	99327 – 99328, 99334 - 99337
Home visits	99341 – 99345, 99347 - 99350
Neonatal and pediatric critical care	99468 – 99469, 99471, 99472, 99475 – 99476
Intensive care services	99477 - 99480
Care planning for patients with cognitive impairment	99483
Group psychotherapy	90853
End-stage renal disease monthly services	90952-90953, 90959, 90962
Psychological and Neuropsychological Testing	96130- 96133, 96136 - 96139
Therapy services	92507, 92521 - 92524, 97110, 97112, 97116, 97161 - 97168, 97535, 97750, 97755, 97760, and 97761
Radiation Treatment Management	77427
* This information is based on the list available at: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.	

Therapy Services. CMS notes that physical therapists, occupational therapists and speech-language pathologists are not among the types of practitioners who may furnish and bill for Medicare telehealth services.[5] Because therapy services are furnished over 90 percent of the time by therapy professionals who are not included on the statutory list of eligible practitioners, CMS believed that adding therapy services to the telehealth list could cause confusion about who is authorized to furnish and bill for these services when furnished by telehealth. In light of the PHE, CMS believes that the risks associated with the confusion are outweighed by the potential benefits when these services might be furnished by eligible practitioners.

Radiation Treatment Management. In addition to reviewing the radiation dose and various treatment paraments, radiation treatment management includes weekly face-to-face visits to assess the patient's response to treatment. CMS added CPT code 77427 (Radiation treatment management) to the telehealth list because it believes this weekly face-to-face visit could be conducted via telehealth when the billing practitioner weighs the exposure risks to COVID-19 against the value of in-person assessment. CMS considers this code to be similar to the inclusion of the transitional care management code on the telehealth list; for both codes the non-face-to-face portion of the services are not considered telehealth services.

[5] Section 1834(m)(4)E) of the Act specifies the types of practitioners who may furnish and bill for telehealth services as those practitioners under section 1842(b)(18)(C) of the Act.

CMS seeks input on whether there are other services where the use of telecommunications technology could mitigate the exposure risk and where there is clinical benefit to using the technology to provide the service.

Regulatory Impact. CMS anticipates that the additions to the list of Medicare telehealth services, the change in the site of service payment amount, and the broader flexibilities in supervision will allow physicians and other practitioners to maintain the needed care for Medicare beneficiaries and protect against COVID-19 exposure risks. To the extent that physicians utilize these new flexibilities for patients that would have been treated in traditional settings, these additional flexibilities would not result in any significant changes to aggregate Medicare payments for physicians' services. It is possible that the flexibilities and changes will increase aggregate Medicare payments but this needs to be balanced against maintaining care and reducing exposure risks.

B. Frequency Limitations on Subsequent Care Services in Inpatient and Nursing Facility Settings, and Critical Care Consultations and Required "Hands-on" Visits for ESRD Monthly Capitation Payments

1. Frequency Limitations

In adding certain services to the Medicare telehealth list, CMS included certain restrictions on how frequently a service can be furnished via Medicare telehealth. Specifically, CMS currently limits the provision of subsequent hospital care services through telehealth to once every 3 days and the provision of subsequent nursing facility care services furnished through telehealth to once every 30 days. CMS also currently limits critical care consultations through telehealth to only once per day, given the patient acuity involved in critical care.

CMS believes that these frequency limitations are no longer appropriate or necessary for the duration of the PHE. CMS was concerned that patients might not receive the necessary in-person services for nursing facility or hospital inpatient services and that the use of telehealth visits would mitigate exposure risk for these patients as well as critical care patients. Thus, on an interim basis, CMS removes the frequency restrictions for subsequent inpatient visits and subsequent nursing facility visits furnished via Medicare telehealth for the duration of the PHE. It also removes the restriction that critical care consultation codes may only be furnished to a Medicare beneficiary once per day. This removal of frequency limitation applies for each of the following codes:

- Subsequent inpatient visits - CPT codes 99231, 99232 and 99233. Codes vary, for example, by level of medical decision making to the typical time spent at the bedside and on the patient's hospital floor or unit (i.e., from 15, 25 and 35 minutes).
- Subsequent nursing facility visits - CPT codes 99307, 99308, 99309 and 99310. Codes vary, for example, by level of medical decision making to the typical time spent at the bedside and on the patient's facility floor or unit (i.e., from 10, 15, 25, and 35 minutes).
- Critical care consultation services - HCPCS codes G0508 and G0509. Physicians typically spend 60 minutes communicating with the patient and provider via telehealth for G0508 and 50 minutes for G0509.

CMS seeks information on how these services are furnished via telecommunications technology to ensure that patients are safe and receiving adequate care.

In the CY 2005 PFS final rule, CMS added ESRD related services to the Medicare telehealth list, but required that the clinical examination of the vascular access site must be furnished face-to-face or "hands-on" by the physician, clinical nurse specialist, nurse practitioner (NP), or physician assistant (PA).[6] In light of the PHE for the COVID-19 pandemic and on an interim basis, CMS is permitting the required clinical examination to be furnished as a Medicare telehealth service during the PHE.

2. Required "Hands-on" Visits for ESRD Monthly Capitation Payments

CMS also notes that sections 1881(b)(3) and 1834(m) of the Act allow an individual determined to have ESRD receiving home dialysis to choose to receive certain monthly ESRD-related clinician assessments via telehealth on or after January 1, 2019. The Bipartisan Budget Act of 2018 amended section 1881(b)(3)(B) of the Act to require a certain number of face-to-face visits without telehealth: at least monthly in the case of the initial 3 months of home dialysis and at least once every 3 consecutive months after the initial 3 months.

CMS states that on an interim basis during the PHE it is exercising enforcement discretion to relax enforcement in connection with the statutory requirement that these visits be furnished without the use of telehealth services. Specifically, CMS will not conduct a review to consider whether those visits were conducted face-to-face, without the use of telehealth. The following 19 CPT codes for ESRD monthly capitation payments, when furnished via Medicare telehealth, are impacted by these policies: CPT codes 90951-90970. These CPT codes differ by age, number of visits, home dialysis, and full or less than a full month of service.

C. Telehealth Modalities and Cost-sharing

1. Clarifying Telehealth Technology Requirements

CMS' regulation at §410.78(a)(3) states that telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system for Medicare telehealth services. CMS does not interpret this to apply to mobile computing devices that include audio and video real-time interactive capabilities, even though they are considered phones and can be used for audio-only telecommunications. CMS believes during the PHE it is important to avoid the potential perception that this language might prohibit use of any device that could otherwise meet the interactive requirements for Medicare telehealth.

On an interim basis during the PHE, CMS is revising §410.78(a)(3) to add an exception to this language:

> "*Exception*: For the duration of the public health emergency as defined in §400.200 of this chapter, *Interactive telecommunications system* means multimedia communications

[6] See 69 FR 77278

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."

In addition, during the PHE, the HHS Office for Civil Rights is exercising enforcement discretion and waiving penalties for HIPPA violations against health care providers that service patients in good faith through everyday communications technologies, such as Skype.[7] CMS notes that HHS, OIG, and DOJ will continue to actively monitor for any healthcare fraud and abuse.

2. Beneficiary Cost-sharing

The OIG issued a Policy Statement[8] notifying physicians and other practitioners that they will not be subject to administrative sanctions for reducing or waiving any cost-sharing obligations for Federal health care beneficiaries for a broad category of non-face-to-face services through various modalities including telehealth visits and virtual check-in services. The Policy Statement applies to services provided remotely through information or communication technology or a hospital or other eligible individual or entity billing for these services when the provider has reassigned their right to receive payments to the billing individual or entity.

D. Communications Technology-Based Services (CTBS)

Under current PFS payment rule, Medicare pays for many service that are considered communication-technology-based services (CTBS), but are not considered telehealth services because they are not services ordinarily furnished in person and instead are routinely furnished using a telecommunications system.[9]

HCPCS code G2010 (Remote evaluation of recorded video/image established patient) and G2012 (Virtual check-in provided to established patient). In the 2019 PFS final rule, CMS finalized separate payments for these services for physicians and practitioners who can furnish E/M services. These services are limited to established patients and require documentation of beneficiary consent, obtained annually, in the medical record. The code descriptors include that the services can not originate from a related E/M service provided within the previous 7 days nor lead to an E/M service or procedure within the next 24 hours or soonest available appointment.

On an interim basis during the PHE, CMS finalizes that these services can be furnished to both new and established patients and that consent may be obtained at the same time the service is provided by either auxiliary staff under general supervision or by the billing provider. CMS notes it is retaining the requirement that when the CTBS originates from a related E/M service (including a telehealth service) provided within the previous 7 days by the same physician or

[7] See https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html.
[8] https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/policy-telehealth-2020.pdf.
[9] See 83 FR 59482

other qualified health care professional, the service is considered bundled into the previous E/M service and not separately billed.

CPT codes 99421 and 99422 (Online digital E/M management for established patient) and HCPCS codes G2061, G2062, and G6063 (Qualified nonphysician healthcare professional online assessment and management service for established patient). In the 2020 PFS final rule, CMS finalized separate payment for these services. In response to questions regarding the benefit category of these codes, CMS clarifies that there are several types of practitioners who can bill for these services including, licensed clinical social workers, clinical psychologists, physical therapist, occupational therapist, and speech language pathologists.

On the interim basis during the PHE, CMS is exercising enforcement discretion to allow the provision of these services to both new and established patients and it will not conduct review to consider whether these services were furnished only to established patients.

Expansion of Eligible Types of Billing Practitioners. On an interim basis, during the PHE, CMS is broadening the scope of practitioners who can bill for CTBS:

- HCPCS codes G2010 and G2012 (remote evaluation of patient images/videos and virtual check-in) can be provided by licensed clinical social workers, clinical psychologists, physical therapist, occupational therapist, and speech language pathologists instead of other in-person services. **CMS seeks input on other kinds of practitioners who might be furnishing these kinds of services during the PHE**.
- HCPCS codes G2010, G2012, and G2061–G2063 are designated as CTBS "sometimes therapy" services that a occupational therapist, physical therapist, and speech-language pathologists can provide to a new or established patient that is being treated under a plan of care. The private practice therapist billing these services are required to include the corresponding GO, GP, or GN therapy modifier on claims for these services.

E. Direct Supervision by Interactive Telecommunications Technology

Direct supervision is currently defined in §410.32(b)(3)(ii) to mean that the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed. On an interim basis during the PHE, CMS is altering the definition of direct supervision to indicate that the necessary presence of the physician for direct supervision includes virtual presence through audio/video real-time communications technology when the use of the technology is indicated to reduce exposure risks for the beneficiary or health care provider.

CMS discusses that during the PHE patients routinely receiving medically necessary physician-administered drugs may lose access to the drug because the physician supervising the administration or the patient may be isolated in their homes. CMS believes real-time, audio and video telecommunications allows for a billing practitioner to observe the patient and the in-person clinical staff. CMS also believes the individual practitioner is in the best position to make

decisions on when direct supervision can be provided using real-time interactive audio and video technology.

CMS seeks comments as to whether there should be any guardrails for allowing direct supervision through telecommunications technology and what risk this might introduce for beneficiaries while reducing the risk of COVID-19 spread. CMS notes this does not change the underlying payment or coverage policies related to the scope of Medicare benefits, including Part B drugs. CMS states that to be covered under Part B, drugs furnished "incident to" are typically injectable drugs bought by the physician and billed by the physician to the Medicare Administrative Contractor (MAC).[10] CMS also notes that applicable rules regarding safe transportation and proper waste disposal continue to apply.

During the PHE, direct supervision through virtual presence can include instances where the physician enters into a contractual arrangement for auxiliary personal[11] to provide care that would be provided incident to a physician's service, including services allowed via telehealth. CMS provides examples of contractual arrangements, including contractual arrangements with a home health agency and a qualified infusion therapy supply. In these circumstances, the provider/supplier would seek payment for services from the billing practitioner and not submit claims to Medicare.

For telehealth services that need to be personally provided by a physician, such as an E/M visit, the physician would need to personally perform the E/M visit and report the service as a Medicare telehealth service. CMS notes that other services could be provided incident to a physicians' nurse or other auxiliary personnel, as long as the billing practitioner is providing appropriate supervision through telecommunications technology. CMS does not expect services furnished at a patient's home incident to a physician service would occur during the same period as a home health episode of care and it will monitor claims to ensure that services are not being inappropriately unbundled from the home health PPS payment.

Supervision Changes for Certain Hospital and Critical Access Hospital (CAH) Diagnostic and Therapeutic Services. CMS adopts similar changes in the regulations at §410.28(e)(1) for the supervision requirements of diagnostic services furnished directly or under arrangement in the hospital or in an on-campus or off-campus outpatient department of the hospital. Specifically, during the PHE, the presence of the physician includes virtual presence through audio/video real-time communications technology when the use of the technology is indicated to reduce exposure risks for the beneficiary or health care provider.

For the duration of the PHE, CMS makes similar changes to specify that direct supervision for pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation services includes virtual presence through audio/video real-time communications when it is indicated to reduce exposure risks (§410.227(a)(1)(iv)(D)).

[10] CMS states that "incident to a physician's professional service" requires the item or service to be billed by the physician.
[11] Auxiliary personnel are defined in §410.26(a)(1).

F. Clarification of Homebound Status under the Medicare Home Health Benefit

Sections 1841(a)(2)(C) and 1835(a)(2)(A) of the Act specify the requirements for payment for home health services when a physician certifies that services are and were required because the beneficiary is or was confined to their home. CMS note that the definition of "confined to the home" allows patients to be considered homebound if it is medically contraindicated for the patient to leave the home.

For the PHE for COVID-19, CMS states this would apply to the following patients: (1) a physician determined it is medically contraindicated for the beneficiary to leave the home because they have a confirmed or suspected diagnosis of COVID-19 or (2) a physician determined it is medically contraindicated for a beneficiary to leave the home because the patient has a condition that may make them more susceptible to contracting COVID-19. CMS provides examples of conditions that a physician might determine it is medically contraindicated to leave a home, including a patient with an exacerbation of chronic obstructive pulmonary disease (COPD) or a cancer patient receiving chemotherapy treatment. In cases where it is medically contraindicated for the patient to leave the home, the medical record must document why the condition of the patient requires remaining at home. CMS notes that for a pandemic of any infectious disease, this could include reviewing and applying any guidance on risk assessment and public health management issued by the CDC. A patient who is exercising "self-quarantine" would not be considered homebound unless a physician certifies it is medically contraindicated for the patient to leave the home.

In addition to being homebound, the patient must meet all the other home health eligibility requirements to receive home health services. CMS notes that a home health visit solely to obtain a nasal or throat culture is not considered a skilled service because it can be obtained by an appropriately-trained medical assistant or laboratory technician. (Discussed below in Section M.)

CMS states this clarification is not limited to the PHE for COVID-19 bu would also apply for other outbreaks of an infectious disease and instances where the condition of a patient makes it medically contraindicated for the patient to leave their home. **CMS seeks comments on this clarification.**

G. The Use of Technology Under the Medicare Home Health Benefit During the PHE for the COVID-19 Pandemic

A home health agency (HHA) can furnish services via a telecommunications systems, as long as such services do not: (1) substitute for in-person home health services ordered as part of a plan of care certified by a physician; and (2) are not considered a home health visit for purpose of eligibility or payment. In the 2019 HH PPS final rule (83 FR 56527), CMS finalized that remote patient monitoring is one type of service that can be furnished via a telecommunications system to augment a home health plan of care without substituting for an in-person visit. Remote patient monitoring was defined as the collection of physiologic data digitally stored and/or transmitted

by the patient and/or caregiver to the HHA. The costs of remote patient monitoring are considered allowable administrative costs if the monitoring is used by the HHS to augment the care planning process (83 FR 56527).

On an interim basis for the duration of the PHE, CMS is amending the regulations at §409.43(a) to provide HHAs with the flexibility to use various types of telecommunications systems, in addition to remote patient monitoring, in conjunction with the provision of in-person visits. Specifically:

- The plan of care must include any provision of remote patient monitoring or other services furnished via a telecommunications system, and that these services cannot substitute for a home visit ordered as part of the plan of care and cannot be considered a home visit for the purposes of patient eligibility or payment.
- The plan of care must include a description of how the use of such technology will help to achieve the goals outlined on the plan of care.
- The use of the technology must be related to the skilled services being furnished by the nurse/therapist/therapy assistant to optimize the services furnished during the home visit or when there is a home visit.

In addition, on an interim basis, HHAs can report the costs of telecommunications technology as allowable administrative and general costs by identifying the costs using a subscript between line 5.01 through line 5.19. **CMS seeks comments on these interim changes**.

CMS provides a payment example for a scenario involving a patient recently discharged from the hospital after coronary bypass surgery and receiving home health skilled nursing visits three times a week for medication management, teaching and assessment. The patient develops respiratory symptoms, has a confirmed COVID-19 diagnosis, and the patient's home health plan of care is updated to include an in-person skilled nursing visit once a week to assess the respiratory condition and a video consultation twice a week between the skilled nurse and the patient for medication management, teaching and assessment, as well as to obtain oxygen saturation readings that the patient provides to the nurse.

CMS also provides examples on how technology can be used in providing care in the home setting.

H. Technology Under the Hospice Benefit

In response to requests to provide clarity about the use of technology by hospices, on an interim basis for the duration of the PHE, CMS is amending the regulations at §418.204 to specify that when a patient is receiving home care, hospices may provide services via a telecommunications system if it is feasible and appropriate to ensure the patient continues to receive care without jeopardizing the patient's health or the health of the providers. The use of the technology must be included on the plan of care and must be tied to the patient-specific needs. CMS notes there is no payment beyond the per diem amount for the use of the technology; only in-person visits (with the exception of social work telephone calls) should be reported on the claim. Hospices can report the costs of telecommunications technology as "other patient care services" using

Worksheet A, cost center line 46, or a subscript of line 46 through 46.19 cost center 4600 through 4619, and identify this cost center as "PHE for COVID-19". **CMS seeks comments on these interim changes**.

I. Telehealth and the Medicare Hospice Face-to-Face Encounter Requirement

CMS discusses how the Medicare hospice face-to-face encounter solely for the purpose of recertification for Medicare hospice services is considered an administrative requirement related to certifying the terminal illness.[12] CMS believes the statute is silent as to whether this face-to-face encounter could be conducted via telecommunications by the hospice physician or NP.

On an interim basis for the duration of the PHE, CMS amends the regulations at §418.22(a)(4) to allow the use of telecommunications technology by the hospice physician or NP for the face-to-face visit when the visit is solely for the purpose of recertifying a patient for hospice services. Telecommunications means the use of multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and the hospice physician or NP. These encounters would not be a separately billed service but considered an administrative expense. **CMS seeks comments on these interim changes**.

J. Modification of the Inpatient Rehabilitation Facility (IRF) Face-to-Face Requirement for the PHE During the COVID-19 Pandemic

Under 42 CFR 412.622(a)(3)(iv), CMS requires that for an inpatient rehabilitation facility (IRF) claim to be considered reasonable and necessary, there must be a reasonable expectation at the time of the patient's admission to the IRF that the patient requires physician supervision by a rehabilitation physician. The requirement for medical supervision means that the rehabilitation physician must conduct face-to-face visits with the patient at least 3 days per week throughout the patient's stay in the IRF.

During the PHE for the COVID-19 pandemic, CMS believes that it is essential to temporarily allow the face-to-face visit requirements at §§412.622(a)(3)(iv) and 412.29(e) to be conducted via telehealth to safeguard the health and safety of Medicare beneficiaries and the rehabilitation physicians treating them. This allows rehabilitation physicians to use telehealth services to conduct the required 3 physician visits per week during the COVID-19 pandemic.

CMS finalizes revisions to its regulations at §§412.622(a)(3)(iv) and 412.29(e). In 412.622(a)(3)(iv), CMS revises this paragraph to state that physician supervision by a rehabilitation physician is required, except that during the PHE, as defined in §400.200, such visits may be conducted using telehealth services (as defined in section 1834(m)(4)(F) of the Act). In §412.29(e), CMS revises this paragraph to allows the required 3 physician visits to be conducted using telehealth services during the PHE.

[12] See section 1814(a)(7)(D)(i) of the Act.

K. Removal of the IRF Post-Admission Physician Evaluation Requirement for the PHE for the COVID-19 Pandemic and Clarification Regarding the "3-Hour" Rule

1. Removal of the IRF Post-Admission Physician Evaluation Requirement

Under its regulations, the patient's medical record at the IRF must contain a post-admission physician evaluation that meets all of the following requirements:

- It is completed by the rehabilitation physician within 24 hours of the patient's admission to the IRF.
- It documents the patient's status on admission to the IRF, includes a comparison with the information noted in the preadmission screening documentation, and serves as the basis for the development of the overall individualized plan of care.
- It is retained in the patient's medical record at the IRF.

CMS is removing the post-admission physician evaluation requirement at §412.622(a)(4)(ii) for all IRFs during the PHE for the COVID-19 pandemic. It believes that by doing so it will reduce physician's administrative burden and free up their time to focus instead on caring for patients and helping with the PHE for the COVID-19 pandemic. CMS notes, however, that this does not preclude an IRF patient from being evaluated by a rehabilitation physician within the first 24 hours of admission if the IRF believes that the patient's condition warrants such an evaluation.

2. Clarification Regarding the "3-Hour" Rule

CMS also provides clarity with regard to the intensive rehabilitation therapy requirements for IRF coverage at §412.622(a)(3)(ii), commonly known as the "3-hour" rule, during this PHE for the COVID-19 pandemic. Under current industry standards, this intensive rehabilitation therapy program generally consists of at least 3 hours of therapy (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics therapy) per day at least 5 days per week. In certain well-documented cases, this intensive rehabilitation therapy program might instead consist of at least 15 hours of intensive rehabilitation therapy within a 7-consecutive day period, beginning with the date of admission to the IRF. The required therapy treatments must begin within 36 hours from midnight of the day of admission to the IRF.

CMS states that IRFs may have difficulties in meeting these requirements because normal staffing shifts may be disrupted as staff who would conduct the therapy program may have COVID-19, be self-isolated, or be unavailable for other reasons related to the PHE. As such, CMS clarifies that in cases where an IRF's intensive rehabilitation therapy program is impacted by the PHE for the COVID-19 pandemic (for example, due to staffing disruptions resulting from self-isolation, infection, or other circumstances related to the PHE), the IRF should not feel obligated to meet the industry standards referenced in §412.622(a)(3)(ii), but should instead make a note to this effect in the medical record.

L. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Expansion of Virtual communication Services Furnished by RHCs and FQHCs

Background. CMS reviews the payment systems applicable to RHCs and FQHCs and describes current practice relating to payment for telehealth services provided by RHCs and FQHCs. In general, RHCs are paid an all-inclusive rate (AIR) for medically-necessary, face-to-face visits with an RHC practitioner. The rate is subject to a payment limit, except for those RHCs that have an exception to the payment limit for being "provider-based" (see §413.65). FQHCs are paid the lesser of their actual charges or the FQHC PPS rate for medically-necessary, face-to-face visits with an FQHC practitioner. Only medically-necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner can be RHC or FQHC billable visits.

Services furnished by non-physician providers are considered to be incident to the visit and are included in the per-visit payment. RHCs and FQHCs may also be paid for care management services that are typically non-face-to-face services. In addition, in the CY 2019 PFS final rule[13], payments for Virtual Communication Services (HCPCS code G0071) became effective January 1, 2019.

In the case of an RHC or FQHC that is located in an area in which there is a shortage of Home Health Agencies (HHAs), existing rules permit part-time or intermittent nursing care and related medical supplies (other than drugs and biologicals) to be furnished by a nurse (an RN or LPN) to a homebound individual under a written plan of treatment that is established and periodically reviewed by an RHC or FQHC physician, or established by a NP or PA and periodically reviewed and approved by the RHC or FQHC physician. The nurse providing the services must be employed by, or receive compensation from the RHC or FQHC; the treatment plan must be reviewed at least every 60 days by a supervising physician of the RHC or FQHC (or established by an NP, PA or certified nurse midwife (CNM) and reviewed at least every 60 days by a supervising physician); and it must be signed by the supervising physician, NP, PA or CNM of the RHC or FQHC.

Provisions of the IFR: Virtual Communication Services Provided by RHCs and FQHCs. To facilitate the ability of RHCs and FQHCs to provide care during the public health emergency period, CMS is expanding on an interim basis, the services that can be included in HCPCS code G0071. The following three CPT codes may include:

[13] Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations Final Rule; and Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine Interim Final Rule (84 *Federal Register* 62588)

- 99421 (Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes)
- 99422 (Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes)
- 99423 (Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes)

In addition, the payment rate for HCPCS code G0071 is revised to include the national non-facility payment rate for these codes. Beginning with services furnished on or after March 1, 2020 and extending through the emergency period, the payment rate will be the average of the PFS national non-facility payment rate for HCPCS code G2012 (communication technology-based services), HCPCS code G2010 (remote evaluation services), CPT code 99421, CPT code 99422, and CPT code 99423. Face-to-face requirements will be waived for these services.

In addition, during the emergency period, the requirement that a beneficiary has been seen by an RHC or FQHC practitioner during the previous 12 months is waived; and the requirement for prior consent is modified so that consent can be obtained when the services are furnished (but it must be obtained before the services can be billed). Such consent may be acquired by staff under the supervision of the RHC or FQHC practitioner.

2. Home Health Agency Shortage Area Requirements for Visiting Nursing Services

During the PHE period CMS will allow for the provision of visiting nursing services furnished by RHCs and FQHCs in any area typically served by the RHC, and any area that is included in the FQHC's service area plan. Those areas will be considered to have a shortage of HHAs and no request for this determination will be required. CMS notes that RHCs and FQHCs should check the HIPAA Eligibility Transaction System to make sure the patient is not already under a home health plan of care; RHC/FQHC visiting nurse services will not be covered if they overlap with a 30-day period of home health care.

M. Medicare Clinical Laboratory Fee Schedule: Payment for Specimen Collection for Purposes of COVID-19 Testing

CMS will provide for Medicare payment of a nominal specimen collection fee and associated travel allowance to independent laboratories for collection of specimens related to COVID-19 clinical diagnostic laboratory testing for homebound and non-hospital inpatients. With patients confined to their homes for their safety and the safety of others, CMS recognizes that there is an additional need to have patients tested in their homes and minimize exposure to others. This will also provide independent laboratories with additional resources to provide this testing in a manner that prevents exposure for patients and health care workers. CMS notes that its current specimen collection fee on the clinical laboratory fee schedule (CLFS) for homebound and non-

hospital inpatients is $3 and $5, respectively, but that this is not sufficient to address additional resources needed during the PHE for the COVID-19 pandemic.[14]

Under this policy, CMS establishes that the nominal specimen collection fee for COVID-19 testing for homebound and non-hospital inpatients generally will be $23.46 and for individuals in a SNF or individuals whose samples will be collected by laboratory on behalf of an HHA will be $25.46. Medicare-enrolled independent laboratories can bill Medicare for the specimen collection fee using one of two new HCPCS codes for specimen collection for COVID-19 testing and bill for the travel allowance with the current HCPCS codes set forth in section 60.2 of the Medicare Claims Processing Manual (P9603 and P9604).

To identify specimen collection for COVID-19 testing, CMS establishes two new level II HCPCS codes. Independent laboratories must use one of these HCPCS codes when billing Medicare for the nominal specimen collection fee for COVID-19 testing for the duration of the PHE for the COVID-19 pandemic. These new HCPCS codes are:

- G2023, specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source.
- G2024, specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), from an individual in a SNF or by a laboratory on behalf of an HHA, any specimen source.

CMS created the second Level II HCPCS code, G2024, because section 1834A(b)(5) of the Act and its regulations at §414.507(f) require a higher fee for collecting a specimen from an individual in a SNF or by a laboratory on behalf of an HHA.

Specimens for COVID-19 testing using upper respiratory nasopharyngeal swabs, oropharyngeal swabs, or sputum must be collected by trained laboratory personnel, and the specimens are a type that would not require only the services of a messenger or specimen pick-up service. The specimen collection fee would only apply if the specimen collection method must be performed by trained laboratory personnel. COVID-19 tests that allow patients to collect the specimen themselves would not be eligible for the specimen collection fee.

Independent laboratories must use the existing level II HCPCS codes when billing for the travel allowance, that is, the per mile travel allowance as described by HCPCS code P9603 and the flat rate travel allowance as described by HCPCS code P9604.[15] Additionally, CMS clarifies that paper documentation of miles traveled is not required and laboratories can maintain electronic logs with the same information. Laboratories will need to be able to produce these electronic logs

[14] Section 1833(h)(3) of the Act requires the Secretary to provide for and establish a nominal fee for specimen collection for laboratory testing and a fee to cover transportation and personnel expenses for trained personnel to collect specimens from homebound patients and inpatients (not in a hospital).
[15] Per mile travel allowance applies when the round trip to patients' homes is greater than 20 miles and a flat rate allowance applies when travel is less than 20 miles round trip.

in a form and manner that can be shared with MACs. The MACs may provide more information on acceptable formats.

CMS also discusses in some detail the definition of homebound status under the Medicare home health benefit and its applicability in this situation (clarification of homebound is discussed in more detail in section II.F of this summary). CMS states that homebound status would apply for those patients: (1) where a physician has determined that it is medically contraindicated for a beneficiary to leave the home because he or she has a confirmed or suspected diagnosis of COVID-19; or (2) where a physician has determined that it is medically contraindicated for a beneficiary to leave the home because the patient has a condition that may make the patient more susceptible to contracting COVID-19. Given the current CDC guidance advising that older adults and individuals with serious underlying health conditions stay home, CMS expects that many Medicare beneficiaries could be considered "homebound" during the PHE for the COVID-19 pandemic. In light of this clarification regarding the definition of homebound, CMS notes this clarification pertains to the specimen collection fee and travel allowance during the PHE for COVID-19 pandemic testing for homebound patients; that is, a patient is considered homebound for purposes of the fees under sections 1833(h)(3) and 1834A(b)(5) of the Act if it is medically contraindicated for the patient to leave home.

N. Requirements for Opioid Treatment Program (OTP)

In the CY 2020 PFS final rule CMS finalized allowing the use of interactive two-way audio/ video communication technology to furnish the counseling and therapy portions of the weekly bundle of services furnished by OTPs. In this IFR, CMS revises §410.67(b)(3) and (4) to allow the therapy and counseling portions of the weekly bundles, 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 period for beneficiaries who do not have access to two-way audio/video communications technology.

O. Application of Teaching Physician and Moonlighting Regulations During the PHE for the COVID-19 Pandemic

Revisions to Teaching Physician Regulations during a PHE for the COVID-19 Pandemic. CMS believes that the requirement for the physical presence of the teaching physician during the key portion of the service[16] would propose additional exposure risks and limit access to services paid under the PFS.

To increase the capacity of teaching settings to respond to the PHE, on an interim basis for the duration of the PHE, CMS amends the following teaching physician regulations:

- Section 415.172. CMS will allow the teaching physician to provide supervision either with physical presence or to be present through interactive telecommunications technology during the key portion of the service (as described in Section II.E. above).

[16] CMS' regulations regarding PFS payment for teaching physicians services and moonlighting are codified in 42 CFR part 415.

CMS believes the use of real-time audio and video telecommunications technology allows for the teaching physician to interact with the resident through virtual means.

- Section 415.174. CMS will allow all levels of an office/outpatient E/M service[17] provided in a primary care center to be provided under direct supervision of the teaching physician by telecommunications technology. CMS believes the use of real-time audio and video telecommunications technology allows for the teaching physician to interact with the resident through virtual means and meet the requirement for E/M services provided in primary care centers.
- Section 415.80. CMS will allow PFS payment to be made for the interpretation of diagnostic radiology and other diagnostic tests when the interpretation is performed by a resident under direct supervision of the teaching physician by interactive telecommunications technology. CMS notes the teaching physician must still review the resident's interpretation.
- Section 415.184. CMS will allow the requirement for the presence of the teaching physician during the psychiatric service involving a resident may be met by the teaching physician's direct supervision by interactive telecommunications technology.

CMS believes that even in the context of the PHE the requirements for physical presence of the teaching physician for either the entire procedure or key portions of the service for surgical, high-risk or other complex procedures, is still required for patient safety. In addition, the exemptions for teaching physicians during the PHE will also not apply in cases of surgical, high-risk, interventional, or other complex procedures, services performed through an endoscope, and anesthesia services. **CMS seeks comments on whether other procedures should also be exempt from the policy given the complex nature or potential danger to the patient.**

CMS notes the flexibilities described for §§ 415.172, 415.174, 415.180, and 415.184 are intended to ensure there are as many qualified practitioners as possible. Teaching physicians, however, should continue to exercise their clinical judgement to decide whether it is appropriate to utilize these flexibilities in furnishing their services involving residents. **CMS seeks comments on this flexibility for direct supervision by interactive telecommunications and whether any guardrails should be included to both balance the health care risks and patient quality of care.**

Application of the Expansion of Telehealth Services to Teaching Physician Services. On an interim basis for the duration of the PHE, CMS revises its regulations to specify that Medicare may make payments under the PFS for teaching physician services when a resident furnishes telehealth services under direct supervision of the teaching physician when the supervision is provided by interactive telecommunications technology. **CMS seeks comments on this flexibility for direct supervision by interactive telecommunications and whether any guardrails should be included to both balance the health care risks and patient quality of care.**

[17] Under the primary care exception in §415.174, only certain lower and mid-level office/outpatient E/M services in primary care centers are exempt from the physical presence requirement of the teaching physician during the key portion of the service.

Payment under the PFS for Teaching Physician Services when the Resident is Quarantined. CMS acknowledges that because of exposure to COVID-19, residents would be quarantined and although able to work would not be able to provide face-to-face patient care. Because it amended the teaching physician regulations to allow that as a general rule under §415.172, the requirement for the presence of a teaching physician can be met through direct supervision by interactive telecommunications technology, Medicare may also make payments when the resident is furnishing these services while in quarantine. The teaching physician would still be required to provide direct supervision by interactive telecommunications technology.

Revisions to Moonlighting Regulations during a PHE for the COVID-19 Pandemic. A licensed resident physician is considered to be "moonlighting" when they furnish physicians' services to outpatients outside the scope of an approved graduate medical education (GME) program. Current regulations do not consider the services of residents in hospitals in which the residents have their approved GME program as separately billable physicians' services.[18] When a resident furnishes services that are not related to their approved GME programs in an outpatient department or emergency department of the hospital with their training program, these services can be billed separately as physicians' services.[19]

On an interim basis, for the duration of the PHE, CMS is amending its regulations at §415.208 to state that the services of residents that are not related to their approved GME programs and are performed in the inpatient setting of a hospital in which they have their training program are separately billable physicians' services. Payment under the PFS can be made provided that the services are identifiable physician services and meet the conditions of payment for physicians' services to providers in §415.102(a); the resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State in which the services are performed; and the services are not performed as part of the approved GME program.

P. Special Requirements for Psychiatric Hospitals (§482.61)

In performing its most recent review of the hospital CoPs, including the Requirements for Specialty Hospitals at subpart E of 42 CFR part 482, CMS discovered that it inadvertently failed to delete another inappropriate reference to §482.12(c), which is contained in the current provision at §482.61(d) in the Special Medical Record Requirements for Psychiatric Hospitals CoP (pertaining to which hospital personnel may complete progress notes for patients). The provision at §482.12(c) lists the types of physicians that the hospital must ensure that every Medicare patient is under the care of, such as a doctor of medicine or osteopathy. CMS has removed this reference in other provisions, because with a few exceptions, the CoPs apply to all patients, regardless of payment source, and not just Medicare beneficiaries. The current provision at §482.61(d) for Psychiatric Hospitals CoP also contains the term "licensed independent practitioner." Therefore, in the interests of consistency with the other recent

[18] See §§413.75 through 413.83 regarding GME payments.
[19] See 415.208(b)(2) for the criteria when these services can be separately billed and paid under the PFS.

revisions, CMS deletes the reference to §482.12(c) along with the modifier "independent" in this IFC.

Consistent with its recent revisions to the hospital CoPs, CMS believes that advance practice providers (APPs), including PAs, NPs, psychologists, and CNSs (as well as other qualified, licensed practitioners to whom this revision might also be applicable), when acting in accordance with State law, their scope of practice, and hospital policy, should have the authority to practice more broadly and to the highest level of their education, training, and qualifications as allowed under their respective state requirements and laws in this area. Thus, it believes that NPPs practicing in the psychiatric hospital setting should be able to record progress notes of psychiatric patients for whom they are responsible. Therefore, CMS will allow the use of NPPs, or APPs, to document progress notes of patients receiving services in psychiatric hospitals, in addition to MDs/DOs as is currently allowed.

CMS also removes the modifier "independent" in the term "licensed independent practitioner" at §482.61(d) for Psychiatric Hospitals CoP. CMS states that using the term "licensed independent practitioner" may inadvertently exacerbate workforce shortage concerns, might unnecessarily impose regulatory burden on hospitals by restricting a hospital's ability to allow APPs and other NPPs to operate within the scope of practice allowed by state law, and does not recognize the benefits to patient care that might be derived from fully utilizing APPs and their clinical skills. CMS believes that this change permits a greater scope of practice for these professionals in the psychiatric hospital context.

CMS estimates that allowing NPPs or APPs to document progress notes in accordance with State laws and scope-of-practice requirements will result in savings of $153 million as NPPs or APPs will be performing this task one-third of the time instead of physicians/psychiatrists.

Q. Innovation Center Models

1. Medicare Diabetes Prevention Program (MDPP)

The MDPP is designed to emphasize ongoing, in-person participation by beneficiaries in a classroom-based setting. However, to support the activity restrictions imposed by the COVID-19 pandemic, CMS makes multiple changes to increase flexibility for beneficiaries and MDPP suppliers at §410.79(e) as follows:

- In-person attendance is still required for the first core session only, but all other sessions potentially may be delivered virtually, within limits listed below.
    - New cohorts may not include beneficiaries who are unable to satisfy the in-person requirement for the first core service.
- Suppliers may choose either to deliver sessions virtually (after the first core session) or to suspend in-person sessions to be resumed at a future date.
- Limits to the overall number of virtual make-up sessions are waived for suppliers who can provide virtual services, subject to the following restrictions:

- Virtual sessions must address the same topics from the CDC-approved curriculum as the corresponding regular in-person sessions.
- No more than one virtual make-up session may be provided on the same day as a regular session and no more than one may be provided per week.
- Sessions must comply with CDC standards for virtual make-up session delivery.[20]
- Virtual make-up sessions may only be furnished to achieve attendance goals rather than weight-loss goals.
- MDPP suppliers may offer virtual make-up sessions only in response to an individual MDPP beneficiary's request.

Additional restrictions apply to offering virtual make-up sessions as follows: 1) no more than 15 virtual make-up sessions can be offered weekly during the core period (months 1-6); 2) no more than 6 virtual make-up sessions can be offered monthly during core maintenance session interval periods (months 7 through 12); and 3) no more than 12 virtual make-up sessions can be offered monthly during ongoing maintenance session interval periods (months 13-24).

CMS further stipulates that:

- The once per lifetime MDPP requirement is waived, allowing beneficiaries whose sessions were paused or canceled due to the PHE to obtain the set of MDPP services more than once by electing to restart the service set or to resume with the most recent session attended;
- The minimum weight loss requirements applicable during the ongoing maintenance session intervals (months 13-24) are waived; and
- MDPP suppliers may pause or delay the delivery of the service set and subsequently resume services on a delayed schedule as long as the service time periods and intervals specified in existing regulations (at §410.79(c)) are followed.

Finally, the MDPP flexibilities provided in §410.79(e) are available only to organizations enrolled as MDPP suppliers as of March 1, 2020 and to MDPP beneficiaries who are receiving the MDPP set of services as of March 1, 2020.

2. Comprehensive Care for Joint Replacement Model (CJR) Changes

CMS implements two changes to this model to support operational continuity and to adjust potentially unfair financial outcomes related to the COVID-19 PHE.

Performance Year 5 Extension. Performance year 5 (PY5) of the CJR model test period currently is set to end December 31, 2020. CMS has proposed but not yet finalized a 3-year extension of model testing through December 31, 2023 (CMS-5529-P, 84 FR 10516) that would apply to some, but not all, current CJR participant hospitals. To maintain CJR operational continuity for current participants during PY5 who are simultaneously dealing with COVID-19 challenges, CMS is implementing a 3-month extension of PY5, ending on March 31, 2021.

[20] These standards are set through the CDC's Diabetes Prevention Recognition Program.

Extreme and Uncontrollable Circumstances Policy Amendment. The current CJR model's extreme and uncontrollable circumstances policy (at §510.305(k)) applies only to episodes occurring during major disaster declarations that result from natural disasters (e.g., wildfires, hurricanes). That policy, therefore, would not be applicable during the COVID-19 PHE. CMS anticipates that the volume of procedures performed under CJR will decline during the PHE, as elective operations are being limited sharply. However, hip replacement episodes for fracture treatment will continue to be triggered and the model's post-discharge period will overlap with the PHE period for some beneficiaries whose episodes were triggered prior to March 2020. As health care costs increase during the PHE, participant hospitals will be financially disadvantaged by being excluded from the CJR extreme and uncontrollable circumstances policy and thereby responsible during financial reconciliation for their higher-then-normal episode costs that are unrelated to the model test itself.

To extend financial safeguards to CJR participants, CMS expands the applicability of the model's extreme and uncontrollable circumstances policy to all episodes (with or without fracture) that 1) have dates of anchor hospitalization admissions on or within 30 days before the date that the emergency period begins or 2) occur through the termination of the emergency period. Under the revised policy, actual episode payments will be capped at the applicable target price as determined for that episode under §510.300. The revised policy is codified at §510.305 (k)(3) and (4).

3. Alternative Payment Model Treatment under the Quality Payment Program

CMS notes that flexibilities to respond effectively to the COVID-19 PHE may be necessary and appropriate for Alternative Payment Model (APM) entities, participants, and beneficiaries receiving care under the models, including models being tested by the Innovation Center under the authority of section 1115A of the Act. CMS further notes that APMs have distinct designs and policies that might require specific, targeted adjustments to be applied during the PHE to limit burden or other negative consequences for each model. CMS closes by stating that additional rulemaking to amend or suspend APM policies will be considered as circumstances related to COVID-19 warrant.

R. Remote Physiologic Monitoring

CMS finalized payment for seven remote physiologic monitoring (RPM) codes (see table below). RPM are considered CTBS and billable only for established patients. In addition, CMS requires verbal consent from a beneficiary to receive these services and this consent must be documented in the medical record.

Remote Physiologic Monitoring Codes	
CPT Code	**Description**
99091	Collection & interpretation of physiologic data digitally stored and/or transmitted

Remote Physiologic Monitoring Codes	
CPT Code	**Description**
99453	Remote monitoring of physiologic parameter, initial
99454	Remote monitoring of physiologic parameter, each 30 days
99457	Remote physiologic monitoring treatment management services, first 20 minutes
99458	Remote physiologic monitoring treatment management services, additional 20 minutes
99473	Self-measured blood pressure
99474	Separate self-measurements of blood pressure readings

On an interim basis during the PHE, CMS finalizes that RPM services can be furnished to new and established patients. It will also allow consent for RPM services to obtained once annually, including at the time services are furnished. The consent must be documented in the medical record.

S. Telephone Evaluation and Management (E/M) Services

For 2008, the CPT Editorial Panel created CPT codes to describe E/M services furnished by a physician or qualified health care professional via telephone (see table below). CMS assigned a status indicator of "N" (Noncovered) because the services are non-face-to-face and the CPT code descriptors include language that recognizes the provision of services to parties other than the beneficiary for whom Medicare does not provide coverage (e.g. a guardian).

CMS no longer believes it should consider these services to be categorically non-covered. Although they are classified as E/M services, it does not believe these codes describe full E/M services but are analogous to the virtual check-in services. On an interim basis during the PHE, CMS finalizes separate payment for telephone E/M services and finalize work RVUs recommended in 2008 by the AMA Health Care Professionals Advisory Committee (HCPAC) for CPT codes 98966–98968 and the work RVUs recommended in 2008 by the AMA Relative Value Scale Update Committee (RUC) for CPT codes 99441–99443.

Telephone Evaluation and Management (E/M) Services		
CPT Code	**Description**	**Work RVUs***
	Service provided by qualified non-physician health care provider	
98966	Telephone assessment & management, 5-10 minutes	0.25
98967	Telephone assessment & management, 11-20 minutes	0.50
98968	Telephone assessment & management, 21-30 minutes	0.75
	Service provided by physician or provider who may report E/M services	
99441	Telephone E/M service, 5-10 minutes	0.25
99442	Telephone E/M service, 11-20 minutes	0.50
99443	Telephone E/M service, 21-30 minutes	0.75

Telephone Evaluation and Management (E/M) Services		
CPT Code	**Description**	**Work RVUs***
*Direct PE for each code consists of 3 minutes of post-service RN/LPN/MTA clinical labor time		

Similar to the CTBS services, CMS believes it is important to extend these services to both new and established patients. CMS notes that although some of the CPT code descriptors refer to "established patients" during the PHE it is exercising enforcement discretion and will not conduct reviews to consider whether CPT codes 98966-98968 were provided to established patients. CMS also notes that the services provided by a qualified non-physician health care provider includes licensed clinicals social workers. Clinical psychologists, physical therapist, occupational therapists and speech language pathologists when the visit pertains to a service within the benefit category of the practitioner. To facilitate billing of these services by therapists, CMS is designating CPT codes 98966-98968 as CTBS "sometimes therapy services. This requires the private practice occupational therapist, physical therapist, and speech-language pathologist to include the corresponding GO, GP, or GN therapy modifier on claims for these services.

T. Physician Supervision Flexibility for Outpatient Hospitals - Outpatient Hospital Therapeutic Services Assigned to the Non-Surgical Extended Duration Therapeutic Services (NSEDTS) Level of Supervision

Required features of Non-Surgical Extended Duration Therapeutic Services (NSEDTS) are 1) an extended monitoring component; 2) not being surgical; 3) low complication risk once the NSEDTS initial assessment is completed; 4) a requirement for direct supervision during initiation of an NSEDTS; and 5) a requirement for general supervision after initiation of the NSEDTS, determined at the discretion of the billing physician. To preserve beneficiary access to all indicated services during the COVID-19 pandemic, CMS changes the minimum supervision level to general for the entire time during which an NSEDTS is provided (§410.27(a)(1)(iv)(E)). General supervision is met when the service is furnished under the overall direction and control of the billing physician; physician physical presence is not required.

U. Application of Certain National Coverage Determination and Local Coverage Determination Requirements During the PHE for the COVID-19 Pandemic

CMS discusses how some National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), including some articles providing coding or other guidelines for a LCD, may contain requirements for face-to-face, timely evaluations or re-evaluations for a patient to initially qualify for coverage or to qualify for continuing coverage of an item or service.

1. Face-to-face and In-person Requirements

For the duration of this PHE, on an interim basis, CMS finalizes that to the extent an NCD or LCD, including an article, requires a face-to-face or an in-person encounter for evaluations, assessments, certifications or other implied face-to-face services, these requirements would not apply. CMS notes that except for the clinical indications discussed below, this does not confer changes to the clinical indications for coverage.

This interim policy change does not apply to face-to face encounters that are statutorily required, such as the face-to-face encounter requirement for Power Mobility Devices. CMS notes that the flexibilities for telehealth services would permit the use of telehealth in accordance with Medicare guidelines.

2. Clinical Indications for Certain Respiratory, Home Anticoagulation Management and Infusion Pump Policies

CMS finalizes, on an interim basis, that it will not enforce the clinical indications for coverage of respiratory, home anticoagulation management and infusion pump NCDs and LCDs, including articles. At the conclusion of the PHE, CMS will return to enforcement of the clinical indications for coverage.

These policies include, but are not limited to:

- NCD 240.2 Home Oxygen;
- NCD 240.4 Continuous Positive Airway Pressure for Obstructive Sleep Apnea;
- LCD L33800 Respiratory Assist Devices (ventilators for home use);
- NCD 240.5 Intrapulmonary Percussive Ventilator;
- LCD L33797 Oxygen and Oxygen Equipment (for home use);
- NCD 190.11 Home Prothrombin Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Management;
- NCD 280.14 Infusion Pumps; and
- LCD L33794 External Infusion Pump.

3. Requirements for Consultations or Services Furnished by or with the Supervision of a Particular Medical Practitioner or Specialist

CMS finalizes, on an interim basis, that if a NCD or LCD requires a specific practitioner type or physician specialty to furnish a service, the chief medical officer or equivalent of the facility can authorize another physician specialty or other practitioner type to meet those requirements. In addition, if the NCD or LCD requires a physician or physician specialty to supervise other practitioners, professionals or qualified personnel, the chief medical officer of the facility can authorize that the supervision requirements do not apply.

V. Changes to the Medicare Shared Savings Program Extreme and Uncontrollable Circumstances Policy

The first extreme and uncontrollable circumstances (EUC) policy applicable to Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs) was established for performance year (PY) 2017 through an interim final rule with comment period (82 FR 60912-60919). The policy provided for alternative quality scoring and mitigation of shared losses to be implemented for ACOs located in areas experiencing EUC trigger events (e.g., hurricanes, wildfires). The CY 2019 PFS final rule extended the PY 2017 EUC policy to PY 2018 and subsequent years. The COVID-19 PHE meets the criteria for triggering the MSSP EUC policy.

1. Alternative Quality Scoring for Extreme and Uncontrollable Circumstances

In accordance with MSSP policy, the PY 2019 quality reporting period originally was set to run from January 2, 2020 through March 31, 2020. The MSSP quality reporting period runs in parallel to the MIPS quality reporting period, so that when CMS extended the MIPS reporting period until April 30, 2020 due to the COVID-19 PHE, the MSSP reporting period was similarly extended. The continued evolution of the COVID-19 pandemic has caused CMS to become concerned that the extended reporting period does not sufficiently reduce reporting burden for clinicians whose expanded patient care demands may preclude timely, accurate quality data submission. Therefore, CMS has determined to automatically apply the quality scoring adjustments of the MIPS EUC policy to all clinicians who are subject to the general MIPS scoring standard.

However, MSSP clinicians, who are subject to the MIPS APM scoring standard and whose quality scoring is done at the group (ACO) level, do not benefit from the MIPS EUC automatic quality scoring adjustments. They are potentially further disadvantaged because the MSSP's EUC policy does not permit alternative quality scoring of ACOs for a performance year if the reporting period for that year has been extended, as has already been done for the PHE for PY 2019. CMS, therefore, has chosen to modify the MSSP's EUC policy by revising §425.502(f) to allow alternative quality scoring of ACOs in any performance year, whether or not the reporting period for that year has been extended. CMS notes that this permanent regulation change will better serve the MSSP during any future unanticipated situations like the COVID-19 pandemic.

ACOs who cannot report their performance year 2019 quality data due to extreme and uncontrollable circumstances instead will receive the mean MSSP ACO quality score and the Quality category score will be reweighted to zero for the affected clinicians. If partial reporting is feasible and yields a quality score that is higher than the mean, the ACO and its clinician group will be awarded the higher score. CMS notes that whether to continue to apply the higher of the mean or the ACO's own score is under consideration but also notes that any change would occur only through notice-and-comment rulemaking.

2. Mitigating Shared Losses During Extreme and Uncontrollable Circumstances

The MSSP's EUC policy provides for mitigation of an ACO's shared losses (reduction in repayment to CMS) at the time of financial reconciliation for a performance year during which extreme and uncontrollable circumstances affected the ACO. Because the COVID-19 PHE was declared in 2020, mitigation of shared losses by ACOs will be available during reconciliation for PY 2020. The reduction in shared losses will be calculated according to the policy's formula.

$$\text{Reduction} = \text{Shared Losses} * \left(\frac{\text{affected months}}{\text{total performance months in performance year}}\right) * \left(\frac{\text{affected assigned ACO beneficiaries}}{\text{total ACO assigned beneficiaries}}\right)$$

CMS states that 100 percent of ACO beneficiaries will be counted as residing in affected areas since the PHE applies to all U.S. counties. The counting of affected months will begin with March 2020 and continue through the end of the COVID-19 PHE. CMS concludes by noting that national and regional trend factors are included in the annual ACO benchmark updating process, and that these factors will reflect any national and regional changes in spending and utilization occurring in 2020, including changes related to the COVID-19 PHE.

W. Level Selection for Office/Outpatient E/M Visits When Furnished Via Medicare Telehealth

In the 2020 PFS final rule, CMS finalized that beginning January 1, 2021 for office/outpatient E/M visits the code level will be selected based on either the level of medical decision making (MDM) or the total time personally spent by the reporting provider on the day of the visit (including face-to-face and non-face-to-face time). Under the waiver issued by the Secretary, telehealth office/outpatient E/M visits can be furnished to any patient in the home, regardless of their diagnosis or medical condition. The current E/M coding guidelines, however, preclude selecting the code level based on time except when the provider is engaged in counseling or care coordination.

During the PHE, on an interim basis, CMS revises this policy to specify that the office/outpatient E/M level selection for services furnished by telehealth can be based on MDM or time, with time defined as all of the time associated with the E/M on the day of the encounter. CMS is also removing any requirements regarding documentation of history and/or physical examination in the medical record, although CMS states it expects that providers will document E/M visits as necessary to ensure quality and continuity of care. CMS notes it finalizes the typical times associated with the CPT office/outpatient E/M codes.[21]

[21] The public use typical E/M code time file is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Regulation-Notices-Items/CMS-1715-F.

X. Counting of Resident Time During the PHE for the COVID-19 Pandemic

Earlier in section II.O, the requirements for direct supervision of residents when providing certain services to Medicare beneficiaries were modified to allow supervision to be provided by teaching physicians through interactive telecommunications technology. The modified definition is applicable for the duration of the COVID-19 PHE and to services provided in many settings.[22] The permitted settings include when the resident is furnishing services in a patient's home and when the resident is under quarantine but otherwise well and able to furnish non-face-to-face patient care services (e.g., image interpretation being performed in the resident's home).

Current regulations do not describe a mechanism for a teaching hospital to claim a resident for IME or DGME purposes when the resident is at home or in the home of a patient who is already under the care of a teaching physician(s) or the teaching hospital. During the COVID-19 PHE, CMS will permit the hospital that is paying a resident's salary and fringe benefits for the time when the resident is working in a patient's home or while in quarantine to claim that resident.

Y. Part C and Part D Quality Rating Systems

Background. CMS describes the background and authority for the existing 5-star rating system for Medicare Advantage (MA) and Prescription Drug (PD) plans including the use of, timing of collection, and reporting of Healthcare Effectiveness Data and Information Set (HEDIS) and Consumer Assessment of Healthcare Providers and Systems (CAHPS) data. Those data are the basis for the calculation of a majority of measures for the Parts C and D Star Ratings.

CMS notes that it made changes in the 2020 Call Letter[23] and 2020 Final Rule[24] for adjusting the calculation of the Star Ratings under Extreme and Uncontrollable Circumstances. In this IFC, CMS makes further adjustments in light of the current public health emergency related to COVID-19, stating that the earlier changes did not anticipate the current circumstances and may not be sufficient for the existing conditions.

Under normal circumstances, if MA and section 1876 plans do not fully complete their HEDIS data collection activities and successfully meet NCQA's HEDIS audit requirements, CMS assigns each of the HEDIS Star Ratings measures 1 star. Similarly, if the CAHPS data cannot be completed and submitted on time by Part C, section 1876 cost, and Part D plans, CMS has historically assigned each of the CAHPS Star Ratings measures 1 star. Unreliable CAHPS measure scores are excluded from the Part C and D Star Ratings calculations.

With respect to both the HEDIS and CAHPS data, CMS is concerned that data collection activities cannot be safely continued in light of CDC recommendations for social distancing, and

[22] Some services and settings continue to require in-person direct supervision, such as major procedures.
[23] 2020 Medicare Advantage and Part D Advance Notice Part II and Draft Call Letter available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.
[24] MAPD final 2020 rule

further that those activities would divert attention of physicians, their staff and the staff of health plans from handling emergencies related to the COVID-19 PHE.

Provisions of the IFC. Under the IFC, CMS (1) Replaces 2021 Star Ratings measures based on HEDIS and CAHPS data collections with earlier values from the 2020 Star Ratings; (2) Establishes an approach for calculating Star Ratings for 2021 in the event that CMS' functions are restricted to only essential Agency functions; (3) Modifies the current rules for the 2021 Star Ratings to replace any measure that has a data quality issue for all plans due to the COVID-19 outbreak with the measure-level Star Ratings and scores from the 2020 Star Ratings; (4) In the event that HOS data collection for 2020 cannot be completed, replaces measures calculated based on Health Outcomes Survey (HOS) data collections with earlier values that are not affected by the public health threats posed by COVID-19 for the 2022 Star Ratings; (5) Removes guardrails for the 2022 Star Ratings; and (6) Expands the existing hold harmless provision for the Part C and D Improvement measures to include all contracts for the 2022 Star Ratings.

1. HEDIS, CAHPS, and HOS Data Collection and Submission for 2021 and 2022 Star Ratings

Guidance issued on September 9, 2019 established the due date for HEDIS data for the 2019 measurement year.[25] Instead, under this IFC, submission of HEDIS data for the 2019 measurement year is eliminated. CMS requests that plans curtail HEDIS data collection work immediately to allow providers to focus on patient care.

CMS also eliminates the requirement for plans to collect and submit CAHPS survey data to CMS in 2020. CMS notes that HEDIS and CAHPS data that have already been collected could be used by plans for their internal quality improvement efforts. CMS also states that the amendments in this IFC do not prohibit plans from continuing such data collection efforts. CMS, however, does not expect plans to do so.

The HOS that NCQA administers in partnership with CMS, which was scheduled to be administered from April through July 2020, will instead be administered in late summer. CMS will provide MA plans more information in the upcoming months and will continue to monitor in case further adjustments may be needed.

To address any potential gaps in HOS data if the data collection for the survey cannot proceed in the summer, CMS will permit the use of Star Ratings and measure scores for the 2021 Star Ratings for any measures that come from the HOS survey. (The measures from the HOS survey include the following: Improving or Maintaining Physical Health; Improving or Maintaining Mental Health; Reducing the Risk of Falling; Improving Bladder Control; and Monitoring Physical Activity.)

[25] Health Plan Management System (HPMS) memo dated September 9, 2019, "Reporting Requirements for 2020 HEDIS®, HOS, and CAHPS® Measures."

2. Adjustments to the 2021 Star Ratings Methodology due to Lack of HEDIS and CAHPS Data

CMS will use the HEDIS measure scores and Star Ratings based on the 2018 measurement year (that is, the data used for the 2020 Star Ratings) for the 2021 Star Ratings. With respect to CAHPS data, CMS will use the CAHPS data submitted to CMS in June 2019 for 2021 Star Ratings. CMS believes this approach will be reliable given that measure scores and stars do not fluctuate significantly year to year. It considered the option of removing CAHPS and HEDIS measures from the 2021 Star Ratings but says it would then not have enough measures to rate plans, and would have a significant impact on payment for MA organizations.

For all other measures, the measurement period will not change from those finalized in the April 2018 final rule, nor are there changes in measure-level cut points for any of the HEDIS and CAHPS measures. Data for the Plan All-Cause Readmissions measure will be posted on the display page for 2021 ratings as previously finalized.

CMS will carry forward the measure-level improvement change score codified at §§422.164(f)(4)(i) and 423.184(f)(4)(i) from the 2020 Star Ratings for all HEDIS or CAHPS measures for the 2021 Star Ratings Part C and D improvement measure calculations. CMS codifies that policy at §§ 422.166(j)(1)(iii) and 423.186(j)(1)(ii).

3. Use of 2020 Star Ratings for 2021 Star Ratings in the Event of Extraordinarily Compromised CMS Capabilities or Systemic Data Issues

In the event that there are unprecedented disruptions in CMS' or contractors' abilities to complete the normal Star Ratings calculations process, CMS is concerned that the normal notice and comment rulemaking process could be too slow and could prevent CMS from taking the necessary actions to address those disruptions. CMS describes the potential implications for plan reimbursement and beneficiaries' plan choices and benefits. To avoid disruptions, CMS establishes rules in this IFC in the event that CMS staff and its contractors are compromised or can only continue essential agency functions.

Under the IFC, CMS codifies that in the event that there are extraordinary circumstances resulting from the COVID-19 pandemic that compromise CMS resources to the extent that it cannot calculate or issue 2021 Star Ratings by October 2020, CMS will adopt the 2020 Star Ratings as the 2021 Star Ratings.

In addition, to address data quality issues for any non-HEDIS or non-CAHPS 2021 Star Ratings measures, CMS adopts a special rule applicable for the PHE period. Under the special rule, CMS has the authority to substitute for all plans the 2020 Star Ratings score and star for a measure used in the calculation of the 2021 Star Ratings when there is a systemic data quality issue for all plans resulting from the COVID-19 pandemic.

CMS explains that the special rule process will enable CMS to meet statutory deadlines for calculating 2022 MA payments and will provide for stability and certainty in the program. It

believes substitution of 2020 scores and stars is a better solution than potentially removing multiple measures from the Star Ratings and the impact this could have on the quality bonus payments.

4. 2022 Star Ratings

CMS states that with respect to 2022 Star Ratings, plans will be expected to submit HEDIS data in June 2021 and to administer the CAHPS survey in 2021 as usual, and it notes that the majority of measures for the 2022 Star Ratings are based on the 2020 measurement year, which is ongoing during the PHE period.

CMS makes several changes to the methodology for the 2022 Star Ratings to address any potential negative incentives that could keep plans and providers from focusing on care and administrative actions needed to address the COVID-19 pandemic. The changes also will provide certainty to plans and providers about how performance changes caused by the COVID-19 pandemic will be addressed in the Star Ratings that use this performance period.

Delay Implementation of Guardrails. CMS delays the implementation of guardrails limiting how much measure cut-points can change from year to year to begin with the 2023 Star Ratings issued in October 2022. Under existing rules, beginning with the 2022 Star Ratings, guardrails were to be implemented for measures that have been in the program for more than 3 years. The guardrails will prevent the measure-threshold-specific cut points for non-CAHPS measures from increasing or decreasing by more than 5 percentage points from one year to the next. The guardrails are intended to increase the predictability of the cut points. However, when performance across the board changes by more than 5 percentage points, the guardrails could prevent the ability of the measures score trends to keep pace with changes in performance across the country. CMS is concerned that the guardrails could prevent cut points for measures from lowering even if the COVID 19 PHE lowers plan performance for some measures across-to-board.

Further, CMS explains that earlier guidance[26] to limit or delay all non-essential planned surgeries and procedures to help limit exposure to and spread of the COVID-19 virus may impact the data collected during the 2020 measurement year. That guidance could have the impact of driving changes in 2020 performance across the board in the measure scores used for the 2022 Star Ratings. CMS is concerned that if the guardrails as currently constructed were implemented, plans will not have incentives to focus on urgent care in this PHE period.

Improvement Measure. As with the guardrails policy, CMS is concerned there may be an overall decline in industry performance related to COVID-19 and that existing improvement measure and methodology policies could provide incentives that discourage plans from taking the necessary steps to address the COVID-19 pandemic.

[26] CMS Adult Elective Surgery and Procedures Recommendations, March 18, 2020, https://www.cms.gov/files/document/31820-cms-adult-elective-surgery-and-procedures-recommendations.pdf

In the IFC, CMS revises the methodology for the Part C and D improvement measure for the 2022 Star Ratings to expand the hold harmless rule to include all contracts at the overall and summary rating levels. Currently, for MA-PD contracts with an overall rating of 4 or more stars, if the inclusion of the improvement measure(s) reduces a contract's overall Star Rating, the Part C and D improvement measures are excluded from the overall Star Ratings calculations for that contract. Similarly, for MA-only contracts with 4 or more stars, if the inclusion of the Part C improvement measure reduces the Part C summary Star Rating, it is excluded from the calculations for that contract. For the 2022 Star Ratings only, CMS expands application of this current hold harmless rule to all contracts regardless of their ratings and also applies it to the Part C and D summary ratings.

Categorical Adjustment Index. CMS provides an explanation of the Categorical Adjustment Index (CAI) to avoid uncertainty for Medicare health and drugs plans; no changes to that process are made in this IFC. CMS explains that the CAI, initially implemented with the 2017 Star Ratings, adjusts for the average within-contract disparity in performance associated with the percentages of enrollees who receive a low-income subsidy and/or are dual eligible and/or have disability status. For the 2022 Star Ratings, the CAI values will be calculated based on the 2021 Star Ratings data, which use the older HEDIS and CAHPS data from the 2020 Star Ratings. For each measure, adjusted measure scores which are used to construct the CAI values will be calculated using the enrollment year associated with the year of data being used for that measure (that is, 2018 enrollment year data for HEDIS and CAHPS measures, 2019 enrollment year data for all other measures).

QBP Calculations for New Contracts. CMS establishes a special rule applicable only to the 2022 QBP ratings that are based on 2021 Star Ratings. Under existing rules, a new MA plan is defined as an MA contract offered by a parent organization that has not had another MA contract in the previous 3 years. For the 2022 QBP ratings, based on 2021 Star Ratings, CMS will treat an MA plan as a new MA plan if it is offered by a parent organization that has not had another MA contract for the previous 4 years.

This change recognizes that new plans that started in 2019 and that would have reported HEDIS and CAHPS data to CMS for the first time in 2020 for the 2021 Star Ratings will not to do so because CMS has eliminated those HEDIS and CAHPS data submissions (see above for a description of that provision.) The new plans will not have enough measures to calculate the 2021 Star Ratings and, consequently, the 2022 QBP rating.

Z. Changes to Expand Workforce for Medicaid Home Health Services (§440.70)

To take into account the increased demand on physicians during the PHE for the COVID-19 pandemic, CMS is amending Medicaid rules to permit licensed practitioners practicing within their scope of practice, including, but not limited to NPs and PAs, to order Medicaid home health services during the existence of the PHE for the COVID-19 pandemic. Under existing rules, an individual's physician must order home health services as part of a written plan of care. This

change is made to address workforce demands during the PHE, to eliminate administrative burden on states and providers and to better align with Medicare policy.

The provision applies to the ordering of Medicaid home health nursing and aide services, medical supplies, equipment, appliances and physical therapy, occupational therapy, speech pathology and audiology services.

AA. Origin and Destination Requirements Under the Ambulance Fee Schedule

Medicare coverage of ambulance services is covered in regulations at §410.40. Under §410.40 (e)(1), nonemergency transportation by ambulance is appropriate if either the beneficiary is bed-confined, and it is documented that the beneficiary's condition is such that other methods of transportation are contraindicated; or, if his or her medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required. The origin and destination requirements for coverage of ambulance services are addressed in its regulations at §410.40(f).

CMS states that while it believes that its current regulatory requirements governing coverage of ambulance services are appropriate under normal circumstances, it recognizes that additional flexibility is needed in the context of the PHE for the COVID-19 pandemic. Therefore, on an interim basis, CMS will expand the list of destinations at §410.40(f) for which Medicare covers ambulance transportation to include all destinations, from any point of origin, that are equipped to treat the condition of the patient consistent with Emergency Medical Services (EMS) protocols established by state and/or local laws where the services will be furnished. Based on these protocols, a patient suspected of having COVID-19 that requires a medically necessary transport may be transported to a testing facility to get tested for COVID-19 instead of a hospital in an effort to prevent possible exposure to other patients and medical staff.

These destinations may include, but are not limited to: any location that is an alternative site determined to be part of a hospital, CAH or SNF, community mental health centers, FQHCs, RHCs, physicians' offices, urgent care facilities, ambulatory surgery centers (ASCs), any location furnishing dialysis services outside of an ESRD facility when an ESRD facility is not available, and the beneficiary's home. This expanded list of destinations will apply to medically necessary emergency and non-emergency ground ambulance transports of beneficiaries during the PHE for the COVID-19 pandemic. Consistent with section 1861(s)(7) of the Act, there must be a medically necessary ground ambulance transport of a patient in order for an ambulance service to be covered.

CMS is revising, on an interim basis, §410.40 to add a new paragraph (f)(5), to state that during the PHE for the COVID-19 pandemic only, a covered destination includes a ground ambulance transport from any point of origin to a destination that is equipped to treat the condition of the patient consistent with state and local EMS protocols where the services will be furnished.

BB. Merit-based Incentive Payment System (MIPS) Updates

1. MIPS Improvement Activities Inventory Update

Quality Payment Program (QPP) policy for the Improvement Activities (IA) performance category provides for additions and modifications to be made through an Annual Call for Activities followed by notice-and-comment rulemaking.[27] Submission of a new or modified IA through the Annual Call normally requires completion of a nomination form, available at www.qpp.cms.gov. CMS makes a one-time exception through this IFC to the IA call process and timelines in order to add a new IA for QPP performance year 2020 (payment year 2022) to promote participation in COVID-19 clinical trials. The IA is described in Table 1 of the rule (reproduced below with minor modifications). CMS states that participation in this AI is likely to improve outcomes and bring research results forward rapidly.[28]

Table 1: New Improvement Activity for the MIPS CY 2020 Performance Period	
Activity ID:	**IA_ERP_XX**
Subcategory	Emergency Response and Preparedness
Activity Title	COVID-19 Clinical Trials*
Activity Description	To receive credit for this activity, a MIPS-eligible clinician must participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study.**
Weighting	High

*More information on COVID-19 clinical trials is available from the U.S. National Library of Medicine website https://clinicaltrials.gov/ct2/results?cond=COVID-19.
**Clinicians' findings must be reported through an open source repository or registry, meaning that the research results are made available to the public.

2. MIPS Applications for Reweighting Based on Extreme and Uncontrollable Circumstances

CMS is applying the MIPS automatic extreme and uncontrollable circumstances policy to MIPS eligible clinicians for the 2019 QPP performance period (2021 payment year) (see §414.1380(c)(2)(i)(A)(8) and (c)(2)(i)(C)(3)). However, as noted by CMS, clinicians reporting in groups or virtual groups are not covered by the automatic application of this policy. They may instead submit an application for reweighting the MIPS performance categories for that year if their performance in a category(ies) will be negatively affected by extreme and uncontrollable circumstances. Additionally, the deadline for requesting reweighting is being extended from December 31, 2019 to April 30, 2020 (or a later date should CMS so specify). A request for reweighting also may be submitted for the 2019 QPP performance year by individual clinicians, groups, or virtual groups should the MIPS measures and IAs available to them for reporting

[27] IAs finalized for the 2020 performance year were provided in the CY 2020 PFS final rule (84 FR 63514-63538). The most current complete list is maintained at https://qpp.cms.gov/.
[28] Details of the requirements for submission of this IA by clinicians can be found at 83 FR 59778-59782.

prove to be insufficient due to the COVID-19 PHE. Further, the deadline for requesting reweighting of the MIPS Promoting Interoperability performance category is likewise extended. The extended deadline will apply only to applications that demonstrate to CMS that the COVID-19 PHE has adversely affected the requesting clinician(s).

Relatedly, current policy provides that when both a request for reweighting due to extreme and uncontrollable circumstances and performance data for one or more categories are submitted, the data will be scored and the relevant performance categories will not be reweighted. CMS modifies the foregoing policy for the 2019 QPP performance period only: when a MIPS eligible clinician submits both a request and performance data and the request demonstrates adverse effects of the COVID-19 PHE, the performance categories for which data are submitted will be reweighted rather than scored. This exception applies to all four MIPS performance categories (Quality, Cost, IA, and Promoting Interoperability).

CC. Inpatient Hospital Services Furnished Under Arrangements Outside the Hospital

As background, for purposes of Medicare payment, section 1861(b) of the Act defines inpatient hospital services in part as the following items and services furnished to an inpatient of a hospital and (except as provided in paragraph (3)) by the hospital: (1) bed and board; (2) such nursing services and other related services, such use of hospital facilities, and such medical social services as are ordinarily furnished by the hospital for the care and treatment of inpatients, and (3) such other diagnostic or therapeutic items or services, furnished by the hospital or by others under arrangements with them made by the hospital, as are ordinarily furnished to inpatients. Routine services in the hospital setting are those described in sections 1861(b)(1) and (b)(2) of the Act. Only the therapeutic and diagnostic services described in section 1861(b)(3) of the Act can be provided under arrangements outside the hospital.

Recognizing the serious public health threats posed by COVID-19, CMS is changing its under arrangements policy during the PHE for the COVID-19 pandemic so that hospitals are allowed broader flexibilities to furnish inpatient services, including routine services outside the hospital. CMS also emphasizes that its current policy of limiting the services that may be provided under arrangements outside of the hospital to therapeutic and diagnostic items is consistent with statute and supported by its policy considerations discussed in the FY 2012 IPPS/LTCH PPS final rule. It does not believe, however, that the statute would preclude this change in policy to allow routine services to be provided under arrangements outside the hospital, in light of the compelling circumstances and the need for additional short-term flexibility during the PHE for the COVID-19 pandemic.

CMS also emphasizes that is it not changing its policy that a hospital needs to exercise sufficient control and responsibility over the use of hospital resources in treating patients. It stresses that if a hospital cannot exercise sufficient control and responsibility over the use of hospital resources in treating patients outside the hospital under arrangements, the hospital should not provide those services outside the hospital under arrangements.

Thus, CMS states that effective for services provided for discharges for patients admitted to the hospital during the PHE for COVID-19 beginning March 1, 2020, if routine services are provided under arrangements outside the hospital to its inpatients, these services are considered as being provided by a hospital.

DD. Advance Payments to Suppliers Furnishing Items and Services under Part B

Under current regulations, (§ 421.214), CMS may advance payment to Part B suppliers only when a CMS contractor is unable to process claims within established time limits. CMS is revising this provision to permit advance payment during a PHE when a supplier has experienced a temporary delay in preparing and submitting bills to the contractor beyond its normal billing cycle.

Existing rules limit CMS to advancing no more than 80 percent of the anticipated payments based upon the historical claims. In a PHE, the revised regulation would allow the limit to be 100 percent of the anticipated payments. Suppliers in bankruptcy would not be eligible to receive advance payments.

On March 28, 2020, CMS released guidance consistent with this regulatory change.[29] For suppliers, advanced payment is available for 3 months of services. Repayment is due within 210 days of payments being advanced. Medicare will begin offsetting 100 percent of the supplier's Medicare payment 120 days after advancing payment if repayment has not occurred in that timeframe.

To qualify for advance/accelerated payments, the supplier must:

1. Have billed Medicare for claims within 180 days immediately prior to the date of signature on the provider's/supplier's request form,
2. Not be in bankruptcy,
3. Not be under active medical review or program integrity investigation, and
4. Not have any outstanding delinquent Medicare overpayments.

Accelerated/Advanced Payment Request forms vary by contractor and can be found on each individual MAC's website. CMS' guidance also lists information for each MAC as well as the instructions for information to include in an accelerated payment request. MACs are to act on these requests within 7 calendar days of the request.

CMS' guidance does not address interest payments. However, CMS held a nationwide call on April 2, 2020 where the agency indicated that interest payments would not accrue for 210 days after payment is advanced. On the 210th day, the Medicare contractor would issue a demand letter requesting full repayment within 30 days. Interest will be charged at the end of that 30 days if the supplier has not repaid the advance in full. Further guidance from CMS is pending.

[29] https://www.cms.gov/files/document/Accelerated-and-Advanced-Payments-Fact-Sheet.pdf

III. Waiver of Proposed Rulemaking

In accordance with 5 U.S.C. 553(b) of the Administrative Procedure Act (APA) and section 1871 of the Act, CMS ordinarily publishes a notice of proposed rulemaking in the Federal Register and invites public comment on the proposed rule before the provisions of the rule take effect. Section 553(b)(3)(B) of the APA and section 1871(b)(2)(C) of the Act authorize the agency to waive these procedures, however, if the agency finds good cause that notice and comment rulemaking procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of finding and its reasons in the rule issued. Section 553(d) of the APA ordinarily requires a 30-day delay in the effective date of a final rule from the date of its publication in the Federal Register. This 30-day delay in effective date can be waived, however, if the agency finds good cause to support an earlier effective date, and such changes could be applied retroactively to items and services furnished before the effective date of the change if the failure to apply the changes retroactively would be contrary to the public interest.

In light of the COVID-19 pandemic, CMS finds good cause to waive notice and comment rulemaking as it believes it would be contrary to the public interest for it to undertake normal notice and comment rulemaking procedures. CMS states that this IFC offers healthcare professional flexibilities in furnishing services while combatting the COVID-19 pandemic and ensuring that sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare and Medicaid programs. It also waives the 30-day delay in the effective date, and, moreover, make this IFC effective as of March 1, 2020—the date the President of the United States declared to be the beginning of the national emergency concerning the COVID-19 outbreak. CMS is providing a 60-day comment period for this IFC.

IV. Regulatory Impact Analysis

OMB has determined that this interim final rule with comment period is "economically significant" within the meaning of Executive Order 12866. CMS states that given the potentially catastrophic impact to public health, it is difficult to estimate the economic impact of the spread of COVID-19 under current payment rules compared to the rules issued in this IFC. It discusses some of the potential benefits of this rule, but states in totality it does not expect significant differences in aggregate Medicare payment. It highlights the following changes:

- Allows home health agencies and hospices more flexibility to furnish services via telecommunications technologies to minimize exposure risks to patients, clinicians, and the general public.
- Additions to the list of Medicare telehealth services will allow more physician's services to be furnished in a manner that will reduce exposure risk to patients and physicians.
- Changes in the site of service payment amount for telehealth services under the PHE along with the changes that allow for broader flexibilities in supervision are expected to allow physicians and other practitioners to better maintain overall level of needed care to Medicare beneficiaries.

- Changes to Medicaid's regulations to expand the scope of certain providers are anticipated to eliminate some burdens on providers and beneficiaries.

CMS also discusses the impact of certain provisions of the IFC in this section, which are summarized in each of the sections of this summary, respectively.

CMS also believes that the modifications to the calculations for the 2021 and 2022 Part C and D Star Ratings to address the expected disruption to data collection and measure scores posed by the PHE for the COVID-19 pandemic should not have a significant impact on the distribution of ratings across Part C and D sponsors.

Overall, CMS does not believe that this rule will have a significant impact on a substantial number of small entities, small rural hospitals, or a direct cost impact on state or local governments, preempt state law, or otherwise have federalism implications.