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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 400, 405, 409, 410, 412, 414, 415, 417, 418, 421, 422, 423, 425, 440, 482 and 510

[CMS-1744-IFC]

RIN 0938-AU31

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

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period (IFC) gives individuals and entities that provide services to Medicare beneficiaries needed flexibilities to respond effectively to the serious public health threats posed by the spread of the 2019 Novel Coronavirus (COVID-19).

Recognizing the urgency of this situation, and understanding that some pre-existing Medicare payment rules may inhibit innovative uses of technology and capacity that might otherwise be effective in the efforts to mitigate the impact of the pandemic on Medicare beneficiaries and the American public, we are changing Medicare payment rules during the Public Health Emergency (PHE) for the COVID-19 pandemic so that physicians and other practitioners, home health and hospice providers, inpatient rehabilitation facilities, rural health clinics (RHCs), and federally qualified health centers (FQHCs) are allowed broad flexibilities to furnish services using remote

communications technology to avoid exposure risks to health care providers, patients, and the community. We are also altering the applicable payment policies to provide specimen collection fees for independent laboratories collecting specimens from beneficiaries who are homebound or inpatients (not in a hospital) for COVID-19 testing. We are also expanding, on an interim basis, the list of destinations for which Medicare covers ambulance transports under Medicare Part B. In addition, we are making programmatic changes to the Medicare Diabetes Prevention Program (MDPP) and the Comprehensive Care for Joint Replacement (CJR) Model in light of the PHE, and program-specific requirements for the Quality Payment Program to avoid inadvertently creating incentives to place cost considerations above patient safety. This IFC will modify the calculation of the 2021 and 2022 Part C and D Star Ratings to address the expected disruption to data collection and measure scores posed by the COVID-19 pandemic and also to avoid inadvertently creating incentives to place cost considerations above patient safety. This rule also amends the Medicaid home health regulations to allow other licensed practitioners to order home health services, for the period of this PHE for the COVID-19 pandemic in accordance with state scope of practice laws. We are also modifying our 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.

DATES: Effective date: These regulations are effective on [Insert the date of display at the Office of the Federal Register].

Applicability date: These regulations are applicable beginning on March 1, 2020.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [Insert date 60 days after date of display at the Office of the Federal Register.]

ADDRESSES: In commenting, please refer to file code CMS-1744-IFC.

Comments, including mass comment submissions, must be submitted in one of the

following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.
2. By regular mail. You may mail written comments to the following address ONLY:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1744-IFC,
P.O. Box 8016,
Baltimore, MD 21244-8016.
Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1744-IFC,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Jamie Hermansen, (410) 786-2064, for general information, contact one of the following:
HAPG_COVID-19@cms.hhs.gov, for issues related to telehealth services, and
communication technology-based services; frequency limits on subsequent care services in

inpatient and non-facility settings, critical care consultations, required “hands-on” visits for ESRD monthly capitation payments; removal of restrictions on technology, and supervision of interactive telecommunications technology; clinical laboratory fee schedule; services furnished by opioid treatment programs; payment under Medicare Part B for teaching physician services and resident moonlighting; remote physiologic monitoring; physician supervision flexibility for outpatient hospital services; payment for office/outpatient evaluation and management visits; counting of resident time at alternate locations; Ambulance Fee Schedule; rural health clinic services; federally qualified health center services; and inpatient hospital services furnished under arrangements outside of the hospital. (Note this email address has an underscore “_” between “HAPG” and “COVID-19”.)

IRFCoverage@cms.hhs.gov, for issues related to the Medicare inpatient rehabilitation facility benefits.

NCDsPublicHealthEmergency@cms.hhs.gov, for issues related to national coverage determination and local coverage determination requirements.

PartCandDStarRatings@cms.hhs.gov, for issues related to Medicare Parts C and D quality rating system.

MedicaidHomeHealthRule@cms.hhs.gov, for issues related to Medicaid home health provider flexibility.

Hillary Loeffler, (410) 786-0456, HomeHealthPolicy@cms.hhs.gov, or HospicePolicy@cms.hhs.gov, for issues related to the Medicare home health and hospice benefits.

Megan Hyde, (410) 786-3247, and Rebecca Cole, (410) 786-1589, for issues related to Innovation Center Models, and alternative payment model treatment under the Quality Payment Program.

Kim Spalding Bush, (410) 786-3232, and Fiona Larbi, (410) 786-7224, for issues related

to the Medicare Shared Savings Program.

Molly MacHarris, (410) 786-4461, for issues related to the Merit-based Incentive Payment System (MIPS)

Heather Holsey, (410) 786-0028, for Comprehensive Care for Joint Replacement model.

Amanda Rhee, (410) 786-3888, and Elizabeth Matthews, (410) 786-5433, for Medicare Diabetes Prevention Program expanded model.

Brittany LaCouture, (410) 786-0481, for Alternative Payment Model provisions of the Quality Payment Program.

CAPT Scott Cooper, USPHS, (410) 786-9496, for issues related to special requirements for psychiatric hospitals

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <http://regulations.gov>. Follow the search instructions on that website to view public comments.

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Addenda Available Only Through the Internet on the CMS Website

The Addenda along with other supporting documents and tables referenced in this interim final rule with comment period (IFC) are available through the Internet on the CMS website at <https://www.cms.gov/>. For this IFC, refer to item CMS-1744-IFC. Readers who experience any

problems accessing any of the Addenda or other documents referenced in this IFC and posted on the CMS website identified above should contact HAPG_COVID-19@cms.hhs.gov.

CPT (Current Procedural Terminology) Copyright Notice

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I. Background

The United States is responding to an outbreak of respiratory disease caused by a novel (new) coronavirus that was first detected in China and which has now been detected in more than 190 locations internationally, including in all 50 States and the District of Columbia. The virus has been named “SARS-CoV-2” and the disease it causes has been named “coronavirus disease 2019” (abbreviated “COVID-19”).

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak a “Public Health Emergency of international concern” (PHEIC). On January 31, 2020, Health and Human Services Secretary, Alex M. Azar II, declared a PHE for the United States to aid the nation’s healthcare community in responding to COVID-19 (hereafter referred to as the PHE for the COVID-19 pandemic). On March 11, 2020, the WHO publicly characterized COVID-19 as a pandemic. On March 13, 2020 the President of the United States declared the COVID-19 outbreak a national emergency.

Coronaviruses are a large family of viruses that are common in people and many different species of animals, including camels, cattle, cats, and bats. Rarely, animal coronaviruses can infect people and then spread between people such as with MERS-CoV, SARS-CoV, and now with this new virus (COVID-19).

The complete clinical picture with regard to COVID-19 is not fully known. Reported illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, a report out of China suggests serious illness occurs in 16 percent of cases. Older people and people of all ages with severe chronic medical conditions — like heart disease, lung disease and diabetes, for example — seem to be at higher risk of developing serious COVID-19 illness.¹

A pandemic is a global outbreak of disease. Pandemics happen when a new virus emerges to infect people and can spread between people sustainably. Because there is little to no pre-existing immunity against the new virus, it spreads worldwide. The virus that causes COVID-19 is infecting people and spreading easily from person-to-person. This is the first pandemic known to be caused by the emergence of a new coronavirus.²

People in places where ongoing community spread of the virus that causes COVID-19 has been reported are at elevated risk of exposure, with the level of risk dependent on the location. Healthcare workers caring for patients with COVID-19 are at elevated risk of exposure. Close contacts of persons with COVID-19 also are at elevated risk of exposure.

Early information out of China, where COVID-19 first started, shows that some people are at higher risk of getting very sick from this illness. This includes:

- Older adults, with risk increasing by age.
- People who have serious chronic medical conditions like:
 - ++ Heart disease.
 - ++ Diabetes.
 - ++ Lung disease.

¹ <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/summary.html>.

² <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/summary.html>.

The Centers for Disease Control and Prevention (CDC) has developed guidance to help in the risk assessment and management of people with potential exposures to COVID-19, including recommending that health care professionals make every effort to interview a person under investigation for infection by telephone, text monitoring system, or video conference.³

As the healthcare community works to implement and establish recommended infection prevention and control practices, regulatory agencies under appropriate waiver authority granted by the PHE for the COVID-19 pandemic declaration are also working to revise and implement regulations that work in concert with healthcare community infection prevention and treatment practices. Based on the current and projected increase in rate of incidence of the COVID-19 disease in the US population, and observed fatalities in the elderly population, who are particularly vulnerable due to age and co-morbidities, and additionally, impact on health workers that are at increased risk due to treating the population, we believe that certain Medicare and Medicaid regulations that may offer providers flexibilities in furnishing services to combat the COVID-19 pandemic should be reviewed and revised as appropriate. We are addressing some of these regulations in this interim final rule with comment period (IFC) to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the programs under Title XVIII (Medicare) and Title XIX (Medicaid) of the Social Security Act (the Act).

In this extraordinary circumstance, we recognize that public exposure greatly increases the overall risk to public health. We believe that this increased risk produces an immediate change, not only in the circumstances under which services can safely occur, but also results in an immediate change to the business relationships between providers, suppliers, and practitioners. By increasing access to services delivered using telecommunications technology,

³ <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/summary.html>.

increasing access to testing in a patient's home, and improving infection control, this IFC will provide the necessary flexibility for Medicare beneficiaries to be able to receive medically necessary services without jeopardizing their health or the health of those who are providing those services, while minimizing the overall risk to public health.

II. Provisions of the Interim Final Rule

In this IFC, we are defining the term, "Public Health Emergency," in the regulation at 42 CFR 400.200, which contains definitions that apply under the entirety of Chapter 400 of Title 42 of the CFR. The definition identifies the PHE determined to exist nationwide by the Secretary of Health and Human services under section 319 of the Public Health Service Act on January 31, 2020, as a result of confirmed cases of COVID-19, 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 payment amounts and circumstances under which Medicare makes payment for a discrete set of services, all of which must ordinarily be furnished in-person, when they are instead furnished using interactive, real-time telecommunication technology. When furnished under the telehealth rules, many of these specified Medicare telehealth services are still reported using codes that describe "face-to-face" services but are furnished using audio/video, real-time communication technology instead of in-person. The list of these eligible telehealth services is published on the CMS website at <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html>.

In contrast, Medicare pays separately for other professional services that are commonly furnished remotely using telecommunications technology, but that do not usually require the patient to be present in-person with the practitioner when they are furnished. These services, including remote physician interpretation of diagnostic tests, care management services and virtual check-ins among many others, are considered physicians' services in the same way as services that are furnished in-person without the use of telecommunications technology. They are

covered and paid in the same way as services delivered without the use of telecommunications technology, but are not considered Medicare telehealth services and are not subject to the conditions of payment under section 1834(m) of the Act.

On March 17, 2020, we announced the expansion of telehealth services on a temporary and emergency basis pursuant to waiver authority added under section 1135(b)(8) of the Act by the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Pub. L. 116-123, March 6, 2020). Starting on March 6, 2020, Medicare can pay for telehealth services, including office, hospital, and other visits furnished by physicians and other practitioners to patients located anywhere in the country, including in a patient's place of residence. In the context of the PHE for the COVID-19 pandemic, we recognize that physicians and other health care professionals are faced with new challenges regarding potential exposure risks, for people with Medicare, for health care providers, and for members of the community at large. For example, the CDC has urged health care professionals to make every effort to interview persons under investigation for infection by telephone, text messaging system, or video conference instead of in-person. To facilitate the use of telecommunications technology as a safe substitute for in-person services, we are, on an interim basis, adding many services to the list of eligible Medicare telehealth services, eliminating frequency limitations and other requirements associated with particular services furnished via telehealth, and clarifying several payment rules that apply to other services that are furnished using telecommunications technologies that can reduce exposure risks.

As discussed in this IFC and in prior rulemaking, several conditions must be met for Medicare to make payment for telehealth services under the Physician Fee Schedule (PFS). For further details, see the full discussion of the scope of Medicare telehealth services in the "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and

Medicare Diabetes Prevention Program” final rule (82 FR 53006, November 17, 2017) (hereinafter referred to as the CY 2018 PFS final rule) and in our regulations at 42 CFR 410.78 and 414.65.

1. Site of Service Differential for Medicare Telehealth Services

Under the PFS, there are two payment rates for many physicians’ services: the facility rate; and the non-facility, or office, rate. The PFS non-facility rate is the single amount paid to a physician or other practitioner for services furnished in their office. The PFS facility rate is the amount generally paid to a professional when a service is furnished in a setting of care, like a hospital, where Medicare is making a separate payment to an entity in addition to the payment to the billing physician or practitioner. This separate payment, often referred to as a “facility fee” reflects the facility’s costs associated with the service (clinical staff, supplies and equipment) and is paid in addition to what is paid to the professional through the PFS.

We note that, in accordance with section 1834(m)(2)(B) of the Act, a facility fee is, in most cases, paid to the “originating site” where the beneficiary is located at the time a telehealth service is furnished. The payment amount for the telehealth originating site facility fee is a nationally applicable flat fee, paid without geographic or site of service adjustments that generally apply to payments for different kinds of services furnished by Medicare providers and suppliers.

For Medicare telehealth services, we currently make payment to the billing physician or practitioner at the PFS facility rate since the facility costs (clinical staff, supplies, and equipment) associated with furnishing the service would generally be incurred by the originating site, where the patient is located, and not by the practitioner at the distant site; and because the statute requires Medicare to pay an originating site facility fee to the site that hosts the patient.

When a physician or practitioner submits a claim for their services, including claims for telehealth services, they include a place of service (POS) code that is used to determine whether

a service is paid using the facility or non-facility rate. Currently, CMS requires that claims for Medicare telehealth services include the POS code 02, which is specific to telehealth services.

Under the waiver authority exercised by the Secretary in response to the PHE for the COVID-19 pandemic, Medicare telehealth services can be furnished to patients wherever they are located, including in the patient's home. As provided by the amendments to section 1135(b)(8) of the Act, when telehealth services are furnished under the waiver to beneficiaries located in places that are not identified as permissible originating sites in section 1834(m)(4)(C)(ii)(I) through (IX) of the Act, no originating site facility fee is paid. We also recognize that as physician practices suddenly transition a potentially significant portion of their services from in-person to telehealth visits in the context of the PHE for the COVID-19 pandemic, the relative resource costs of furnishing these services via telehealth may not significantly differ from the resource costs involved when these services are furnished in person. For example, we expect that physician offices will continue to employ nursing staff to engage with patients during telehealth visits or to coordinate pre- or post-visit care, regardless of whether or not the visit takes place in person, as it would have outside of the PHE for the COVID-19 pandemic, or through telehealth in the context of the PHE for the COVID-19 pandemic. Consequently, the assumptions that have supported payment of telehealth services at the PFS facility rate would not apply in many circumstances for services furnished during the PHE for the COVID-19 pandemic. Instead, we believe that, as more telehealth services are furnished to patients wherever they are located rather than in statutory originating sites, it would be appropriate to assume that the relative resource costs of services furnished through telehealth should be reflected in the payment to the furnishing physician or practitioner as if they furnished the services in person, and to assign the payment rate that ordinarily would have been paid under the PFS were the services furnished in-person. For example, a physician practicing in an office setting who, under the PHE for the COVID-19 pandemic, sees patients via telehealth instead of

in person would be paid at the non-facility, or office, rate for these services. Similarly, a physician who typically sees patients in an outpatient provider-based clinic of a hospital would be paid the facility rate for services newly furnished via telehealth.

To implement this change on an interim basis, we are instructing physicians and practitioners who bill for Medicare telehealth services to report the POS code that would have been reported had the service been furnished in person. This will allow our systems to make appropriate payment for services furnished via Medicare telehealth which, if not for the PHE for the COVID-19 pandemic, would have been furnished in person, at the same rate they would have been paid if the services were furnished in person. Given the potential importance of using telehealth services as means of minimizing exposure risks for patients, practitioners, and the community at large, we believe this interim change will maintain overall relativity under the PFS for similar services and eliminate potential financial deterrents to the clinically appropriate use of telehealth. Because we currently use the POS code on the claim to identify Medicare telehealth services, we are finalizing on an interim basis the use of the CPT telehealth modifier, modifier 95, which should be applied to claim lines that describe services furnished via telehealth. We note that we are maintaining the facility payment rate for services billed using the general telehealth POS code 02, should practitioners choose, for whatever reason, to maintain their current billing practices for Medicare telehealth during the PHE for the COVID-19 pandemic.

2. Adding Services to the List of Medicare Telehealth Services

In the “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2003 and Inclusion of Registered Nurses in the Personnel Provision of the Critical Access Hospital Emergency Services Requirement for Frontier Areas and Remote Locations” final rule with comment period (67 FR 79988, December 31, 2002) (hereinafter referred to as the CY 2003 PFS final rule with comment period), we established a process for adding services to or deleting services from the list of Medicare telehealth services in accordance

with section 1834(m)(4)(F)(ii) of the Act. This process provides the public with an ongoing opportunity to submit requests for adding services, which we then review. We have also routinely reviewed potential services for addition to the list of telehealth services and sought comment on any such proposed additions. Under this process, we assign any potential addition 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 list of telehealth services. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter, a practitioner who is present with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the service; for example, the use of interactive audio and video equipment.

- Category 2: Services that are not similar to those on the current list of telehealth services. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to furnish the service produces demonstrated clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits.

Some examples of clinical benefit include the following:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.

- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
- Reduced rate of complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment.
- Decreased pain, bleeding, or other quantifiable symptom.
- Reduced recovery time.

The list of telehealth services, including the additions described later in this section, can be located on the CMS website at <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html>.

On an interim basis, we are adding the following services to the Medicare telehealth list on a Category 2 basis for the duration of this PHE for the COVID-19 pandemic, for telehealth services with dates of service beginning March 1, 2020 through the end of the declared PHE including any subsequent renewals. When we previously considered adding these services to the list of telehealth services, either through a public request or through our own internal review, we considered whether or not these services met the category 1 or category 2 criteria. In many cases we reviewed requests to add these services on a category 1 basis but did not receive or identify information that allowed us to review the services on a category 2 basis. While we do not believe the context of this PHE for the COVID-19 pandemic changes the assessment of these services as category 1, we have reassessed all of these services on a category 2 basis in the context of the widespread presence of COVID-19 in the community. Given the exposure risks for beneficiaries, the health care work force, and the community at large, in-person interaction between professionals and patients poses an immediate potential risk that would not have been

present when we previously reviewed these services. This new risk creates a unique circumstance where health care professionals need to weigh the risks associated with disease exposure so they can bill Medicare for the service. For example, certain persons, especially older adults who are particularly vulnerable to this specific virus, those considered at risk because of underlying health conditions, and those known to be recently exposed or diagnosed, and therefore, likely to spread the virus to others, are often being directed by local public health officials to self-isolate as much as possible. At the same time, we note that the risks to medical professionals treating patients is high and we consider it likely that medical professionals will try to treat patients as effectively as possible without exposing themselves or their patients unnecessarily. In some cases, use of telecommunication technology could mitigate the exposure risk, and in such cases, there is a clear clinical benefit of using such technology in furnishing the service. In other words, patients who should not be seen by a professional in-person due to the exposure risk are highly likely to be without access to clinically appropriate treatment or diagnostic options unless they have access to services furnished through interactive communication technology. Therefore, in the context of the PHE for the COVID-19 pandemic, we believe all of the following services meet the category 2 criteria to be added to the list of telehealth services on the basis that there is a patient population that would otherwise not have access to clinically appropriate treatment. We note that, as with other services on the Medicare telehealth list, it may not be clinically appropriate or possible to use telecommunications technology to furnish these particular services to every person or in every circumstance. However, in the context of the PHE for the COVID-19 pandemic with specific regard to the exposure risks noted above, we recognize the clinical benefit of access to medically reasonable and necessary services furnished using telecommunications technology as opposed to the potential lack of access that could occur to mitigate the risk of disease exposure. In light of the PHE for the COVID-19 pandemic, the demand for physicians in areas heavily impacted by

COVID-19 or under served by clinicians may intensify, resulting in a need for critical care services for patients with suspected or diagnosed COVID-19 and those who are in acute care settings due to other conditions. These practitioners may be working with nurses, consulting with other healthcare professionals, writing orders, looking at images, communicating with family members for patients with a number of acute conditions. The CPT codes describing E/M services reflect an assumption that the nature of the work involved in evaluation and management visits varies, in part, based on the setting of care and the patient's status. Consequently, there are separate sets of E/M codes for different settings of care, such as office/outpatient codes, nursing facility codes, or emergency department codes. We expect physicians and other practitioners to use the E/M code that best describes the nature of the care they are providing, regardless of the physical location or status of the patient. Under ordinary circumstances, we would expect the kind of E/M code reported to generally align with the physical location or status of the patient. In the context of the PHE, we recognize that the relationship among the setting of care, patient status, and kind of E/M code reported may depend on the needs of local communities and the capacity of local health care institutions. Consequently, we are reiterating that practitioners should report the E/M code that best describes the nature of the care they are providing.

We are adding the following codes to the existing list of telehealth services on a Category 2 basis for the PHE for the COVID-19 pandemic:

3. Emergency Department Visits: CPT codes

- 99281 (*Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided*)

consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor.)

- 99282 (*Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity.)*)

- 99283 (*Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity.)*)

- 99284 (*Emergency department visit for the evaluation and management of a patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity, and require urgent evaluation by the physician, or other qualified health care professionals but do not pose an immediate significant threat to life or physiologic function.)*)

- 99285 (*Emergency department visit for the evaluation and management of a patient, which requires these 3 key components within the constraints imposed by the urgency of the patient's clinical condition and/or mental status: A comprehensive history; A comprehensive*

examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity and pose an immediate significant threat to life or physiologic function.)

4. Initial and Subsequent Observation, and Observation Discharge Day Management: CPT codes

- 99217 (*Observation care discharge day management (This code is to be utilized to report all services provided to a patient on discharge from outpatient hospital "observation status" if the discharge is on other than the initial date of "observation status." To report services to a patient designated as "observation status" or "inpatient status" and discharged on the same date, use the codes for Observation or Inpatient Care Services [including Admission and Discharge Services, 99234-99236 as appropriate.]*)

- 99218 (*Initial observation care, per day, for the evaluation and management of a patient which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission to outpatient hospital "observation status" are of low severity. Typically, 30 minutes are spent at the bedside and on the patient's hospital floor or unit.)*

- 99219 (*Initial observation care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs.*

Usually, the problem(s) requiring admission to outpatient hospital "observation status" are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit.)

- 99220 *(Initial observation care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission to outpatient hospital "observation status" are of high severity. Typically, 70 minutes are spent at the bedside and on the patient's hospital floor or unit.)*

- 99224 *(Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: Problem focused interval history; Problem focused examination; Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering, or improving. Typically, 15 minutes are spent at the bedside and on the patient's hospital floor or unit.)*

- 99225 *(Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 25 minutes are spent at the bedside and on the patient's hospital floor or unit.)*

- 99226 (*Subsequent observation care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant complication or a significant new problem. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit.*)

- 99234 (*Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually the presenting problem(s) requiring admission are of low severity. Typically, 40 minutes are spent at the bedside and on the patient's hospital floor or unit.*)

- 99235 (*Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually the presenting problem(s) requiring admission are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit.*)

- 99236 (*Observation or inpatient hospital care, for the evaluation and management of a patient including admission and discharge on the same date, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually the presenting problem(s) requiring admission are of high severity. Typically, 55 minutes are spent at the bedside and on the patient's hospital floor or unit.*)

5. Initial hospital care and hospital discharge day management: CPT codes

- 99221 (*Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of low severity. Typically, 30 minutes are spent at the bedside and on the patient's hospital floor or unit.*)

- 99222 (*Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of moderate severity. Typically, 50 minutes are spent at the bedside and on the patient's hospital floor or unit.*)

- 99223 (*Initial hospital care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive*

examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of high severity. Typically, 70 minutes are spent at the bedside and on the patient's hospital floor or unit.)

- 99238 (*Hospital discharge day management; 30 minutes or less*)
- 99239 (*Hospital discharge day management; more than 30 minutes*)

6. Initial nursing facility visits and nursing facility discharge day management: CPT codes

● 99304 (*Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these 3 key components: A detailed or comprehensive history; A detailed or comprehensive examination; and Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of low severity. Typically, 25 minutes are spent at the bedside and on the patient's facility floor or unit.)*

● 99305 (*Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of moderate severity. Typically, 35 minutes are spent at the bedside and on the patient's facility floor or unit.)*

● 99306 (*Initial nursing facility care, per day, for the evaluation and management of a patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination*

of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the problem(s) requiring admission are of high severity. Typically, 45 minutes are spent at the bedside and on the patient's facility floor or unit.)

- 99315 (*Nursing facility discharge day management; 30 minutes or less*)
- 99316 (*Nursing facility discharge day management; more than 30 minutes*)

7. Critical Care Services: CPT codes

- 99291 (*Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes*)
- 99292 (*Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (List separately in addition to code for primary service)*)

8. Domiciliary, Rest Home, or Custodial Care services: CPT codes

- 99327 (*Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity. Typically, 60 minutes are spent with the patient and/or family or caregiver.*)
- 99328 (*Domiciliary or rest home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the*

patient is unstable or has developed a significant new problem requiring immediate physician attention. Typically, 75 minutes are spent with the patient and/or family or caregiver.)

- 99334 (*Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self-limited or minor. Typically, 15 minutes are spent with the patient and/or family or caregiver.)*

- 99335 (*Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 25 minutes are spent with the patient and/or family or caregiver.)*

- 99336 (*Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 40 minutes are spent with the patient and/or family or caregiver.)*

- 99337 (*Domiciliary or rest home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive*

interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent with the patient and/or family or caregiver.)

9. Home Visits: CPT codes

- 99341 (*Home visit for the evaluation and management of a new patient, which requires these 3 key components: A problem focused history; A problem focused examination; and Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low severity. Typically, 20 minutes are spent face-to-face with the patient and/or family.)*

- 99342 (*Home visit for the evaluation and management of a new patient, which requires these 3 key components: An expanded problem focused history; An expanded problem focused examination; and Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate severity. Typically, 30 minutes are spent face-to-face with the patient and/or family.)*

- 99343 (*Home visit for the evaluation and management of a new patient, which requires these 3 key components: A detailed history; A detailed examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other*

physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. Typically, 45 minutes are spent face-to-face with the patient and/or family.)

- *99344 (Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of high severity. Typically, 60 minutes are spent face-to-face with the patient and/or family.)*

- *99345 (Home visit for the evaluation and management of a new patient, which requires these 3 key components: A comprehensive history; A comprehensive examination; and Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant new problem requiring immediate physician attention. Typically, 75 minutes are spent face-to-face with the patient and/or family.)*

- *99347 (Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are self limited or minor. Typically, 15 minutes are spent face-to-face with the patient and/or family.)*

- 99348 (*Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of low to moderate severity. Typically, 25 minutes are spent face-to-face with the patient and/or family.*)

- 99349 (*Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are moderate to high severity. Typically, 40 minutes are spent face-to-face with the patient and/or family.*)

- 99350 (*Home visit for the evaluation and management of an established patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of moderate to high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the presenting problem(s) are of moderate to high severity. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 60 minutes are spent face-to-face with the patient and/or family.*)

- 99468 (*Initial inpatient neonatal critical care, per day, for the evaluation and management of a critically ill neonate, 28 days of age or younger*)
- 99469 (*Subsequent inpatient neonatal critical care, per day, for the evaluation and management of a critically ill neonate, 28 days of age or younger*)
- 99471 (*Initial inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 29 days through 24 months of age*)
- 99472 (*Subsequent inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 29 days through 24 months of age*)
- 99473 (*Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration*)
- 99475 (*Initial inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 2 through 5 years of age*)
- 99476 (*Subsequent inpatient pediatric critical care, per day, for the evaluation and management of a critically ill infant or young child, 2 through 5 years of age*)

11. Initial and Continuing Intensive Care Services: CPT codes

- 99477 (*Initial hospital care, per day, for the evaluation and management of the neonate, 28 days of age or younger, who requires intensive observation, frequent interventions, and other intensive care services*)
- 99478 (*Subsequent intensive care, per day, for the evaluation and management of the recovering very low birth weight infant (present body weight less than 1500 grams)*)
- 99479 (*Subsequent intensive care, per day, for the evaluation and management of the recovering low birth weight infant (present body weight of 1500-2500 grams)*)
- 99480 (*Subsequent intensive care, per day, for the evaluation and management of the recovering infant (present body weight of 2501-5000 grams)*)

12. Care Planning for Patients with Cognitive Impairment: CPT code

- 99483 (*Assessment of and care planning for a patient with cognitive impairment, requiring an independent historian, in the office or other outpatient, home or domiciliary or rest home, with all of the following required elements: Cognition-focused evaluation including a pertinent history and examination; Medical decision making of moderate or high complexity; Functional assessment (eg, basic and instrumental activities of daily living), including decision-making capacity; Use of standardized instruments for staging of dementia (eg, functional assessment staging test [FAST], clinical dementia rating [CDR]); Medication reconciliation and review for high-risk medications; Evaluation for neuropsychiatric and behavioral symptoms, including depression, including use of standardized screening instrument(s); Evaluation of safety (eg, home), including motor vehicle operation; Identification of caregiver(s), caregiver knowledge, caregiver needs, social supports, and the willingness of caregiver to take on caregiving tasks; Development, updating or revision, or review of an Advance Care Plan; Creation of a written care plan, including initial plans to address any neuropsychiatric symptoms, neuro-cognitive symptoms, functional limitations, and referral to community resources as needed (eg, rehabilitation services, adult day programs, support groups) shared with the patient and/or caregiver with initial education and support. Typically, 50 minutes are spent face-to-face with the patient and/or family or caregiver.)*)

13. Group Psychotherapy: CPT code

- 90853 (*Group psychotherapy (other than of a multiple-family group)*)

14. End-Stage Renal Disease (ESRD) Services: CPT Codes

- 90952 (*End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month*)

- 90953 (*End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month*)

- 90959 (*End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month*)

- 90962 (*End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 1 face-to-face visit by a physician or other qualified health care professional per month*)

15. Psychological and Neuropsychological Testing: CPT codes

- 96130 (*Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour*)

- 96131 (*Psychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)*)

- 96132 (*Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and*

interactive feedback to the patient, family member(s) or caregiver(s), when performed; first hour)

- 96133 (*Neuropsychological testing evaluation services by physician or other qualified health care professional, including integration of patient data, interpretation of standardized test results and clinical data, clinical decision making, treatment planning and report, and interactive feedback to the patient, family member(s) or caregiver(s), when performed; each additional hour (List separately in addition to code for primary procedure)*)

- 96136 (*Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; first 30 minutes)*)

- 96137 (*Psychological or neuropsychological test administration and scoring by physician or other qualified health care professional, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)*)

- 96138 (*Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; first 30 minutes)*)

- 96139 (*Psychological or neuropsychological test administration and scoring by technician, two or more tests, any method; each additional 30 minutes (List separately in addition to code for primary procedure)*)

16. Therapy Services

We have received a number of requests, most recently for CY 2018 PFS rulemaking, that we add therapy services to the Medicare telehealth list. In the CY 2018 PFS final rule, we noted that section 1834(m)(4)(E) of the Act specifies the types of practitioners who may furnish and bill for Medicare telehealth services as those practitioners under section 1842(b)(18)(C) of the Act. Physical therapists, occupational therapists and speech-language pathologists are not among the practitioners identified in section 1842(b)(18)(C) of the Act. We stated in the Medicare

Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements” final rule (81 FR 80198, November 15, 2016) (hereinafter referred to as the CY 2017 PFS final rule) that because these services are predominantly furnished by physical therapists, occupational therapists and speech-language pathologists, we did not believe it would be appropriate to add them to the list of telehealth services at this time. In a subsequent request to consider adding these services for 2018, the original requester suggested that we might propose these services to be added to the list so that they can be furnished via telehealth when furnished by eligible distant site practitioners. Since the majority of the codes are furnished over 90 percent of the time by therapy professionals, who are not included on the statutory list of eligible distant site practitioners, we stated that we believed that adding therapy services to the telehealth list could result in confusion about who is authorized to furnish and bill for these services when furnished via telehealth.

In light of the PHE for the COVID-19 pandemic, we believe that the risks associated with confusion are outweighed by the potential benefits for circumstances when these services might be furnished via telehealth by eligible distant site practitioners. We believe this is sufficient clinical evidence to support the addition of therapy services to the Medicare telehealth list on a category 2 basis. However, we note that the statutory definition of distant site practitioners under section 1834(m) of the Act does not include physical therapists, occupational therapists, or speech-language pathologists, meaning that it does not provide for payment for these services as Medicare telehealth services when furnished by physical therapists, occupational therapists, or speech-language pathologists.

CPT codes:

- 97161 (*Physical therapy evaluation: low complexity, requiring these components: A history with no personal factors and/or comorbidities that impact the plan of care; An examination of body system(s) using standardized tests and measures addressing 1-2 elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with stable and/or uncomplicated characteristics; and Clinical decision making of low complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 20 minutes are spent face-to-face with the patient and/or family.*)

- 97162 (*Physical therapy evaluation: moderate complexity, requiring these components: A history of present problem with 1-2 personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures in addressing a total of 3 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; An evolving clinical presentation with changing characteristics; and Clinical decision making of moderate complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 30 minutes are spent face-to-face with the patient and/or family.*)

- 97163 (*Physical therapy evaluation: high complexity, requiring these components: A history of present problem with 3 or more personal factors and/or comorbidities that impact the plan of care; An examination of body systems using standardized tests and measures addressing a total of 4 or more elements from any of the following: body structures and functions, activity limitations, and/or participation restrictions; A clinical presentation with unstable and unpredictable characteristics; and Clinical decision making of high complexity using standardized patient assessment instrument and/or measurable assessment of functional outcome. Typically, 45 minutes are spent face-to-face with the patient and/or family.*)

- 97164 (*Re-evaluation of physical therapy established plan of care, requiring these components: An examination including a review of history and use of standardized tests and measures is required; and Revised plan of care using a standardized patient assessment instrument and/or measurable assessment of functional outcome Typically, 20 minutes are spent face-to-face with the patient and/or family.*)

- 97165 (*Occupational therapy evaluation, low complexity, requiring these components: An occupational profile and medical and therapy history, which includes a brief history including review of medical and/or therapy records relating to the presenting problem; An assessment(s) that identifies 1-3 performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of low complexity, which includes an analysis of the occupational profile, analysis of data from problem-focused assessment(s), and consideration of a limited number of treatment options. Patient presents with no comorbidities that affect occupational performance. Modification of tasks or assistance (eg, physical or verbal) with assessment(s) is not necessary to enable completion of evaluation component. Typically, 30 minutes are spent face-to-face with the patient and/or family.*)

- 97166 (*Occupational therapy evaluation, moderate complexity, requiring these components: An occupational profile and medical and therapy history, which includes an expanded review of medical and/or therapy records and additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 3-5 performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of moderate analytic complexity, which includes an analysis of the occupational profile, analysis of data from detailed assessment(s), and consideration of several treatment options. Patient may present with comorbidities that affect occupational performance. Minimal to moderate*

modification of tasks or assistance (eg, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 45 minutes are spent face-to-face with the patient and/or family.)

- 97167 (*Occupational therapy evaluation, high complexity, requiring these components: An occupational profile and medical and therapy history, which includes review of medical and/or therapy records and extensive additional review of physical, cognitive, or psychosocial history related to current functional performance; An assessment(s) that identifies 5 or more performance deficits (ie, relating to physical, cognitive, or psychosocial skills) that result in activity limitations and/or participation restrictions; and Clinical decision making of high analytic complexity, which includes an analysis of the patient profile, analysis of data from comprehensive assessment(s), and consideration of multiple treatment options. Patient presents with comorbidities that affect occupational performance. Significant modification of tasks or assistance (eg, physical or verbal) with assessment(s) is necessary to enable patient to complete evaluation component. Typically, 60 minutes are spent face-to-face with the patient and/or family.)*)

- 97168 (*Re-evaluation of occupational therapy established plan of care, requiring these components: An assessment of changes in patient functional or medical status with revised plan of care; An update to the initial occupational profile to reflect changes in condition or environment that affect future interventions and/or goals; and A revised plan of care. A formal reevaluation is performed when there is a documented change in functional status or a significant change to the plan of care is required. Typically, 30 minutes are spent face-to-face with the patient and/or family.)*)

- 97110 (*Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility)*)

- 97112 (*Therapeutic procedure, 1 or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities*)
- 97116 (*Therapeutic procedure, 1 or more areas, each 15 minutes; gait training (includes stair climbing)*)
- 97535 (*Self-care/home management training (eg, activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes*)
- 97750 (*Physical performance test or measurement (eg, musculoskeletal, functional capacity), with written report, each 15 minutes*)
- 97755 (*Assistive technology assessment (e.g., to restore, augment or compensate for existing function, optimize functional tasks and/or maximize environmental accessibility), direct one-on-one contact, with written report, each 15 minutes*)
- 97760 (*Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity(ies), lower extremity(ies) and/or trunk, initial orthotic(s) encounter, each 15 minutes*)
- 97761 (*Prosthetic(s) training, upper and/or lower extremity(ies), initial prosthetic(s) encounter, each 15 minutes*)
- 92521 (*Evaluation of speech fluency (eg, stuttering, cluttering)*)
- 92522 (*Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria)*)
- 92523 (*Evaluation of speech sound production (eg, articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression (eg, receptive and expressive language)*)
- 92524 (*Behavioral and qualitative analysis of voice and resonance*)

- 92507 (*Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual*)

17. Radiation Treatment Management Services

The code used to report radiation treatment management services includes several components, including reviewing the radiation dose and various treatment parameters, as well as weekly face-to-face visits with the patient to assess the patient's response to treatment and manage any symptoms the patient may be experiencing. We believe that in the context of the PHE for the COVID-19 pandemic, the weekly face-to-face visit component of this service could be conducted via telehealth when the billing practitioner weighs the exposure risks against the value of in-person assessment on a case-by-case basis. Therefore, we are adding CPT code 77427 (*Radiation treatment management, 5 treatments*) to the telehealth list so that the required face-to-face visit can be furnished via telehealth.

We believe that allowing the services listed above to be furnished as Medicare telehealth services will significantly increase the ability of Medicare physicians and practitioners to work without increasing exposure risk to themselves, their patients, and the broader community. Given widespread concerns regarding the health and safety of our beneficiaries and health care providers during the PHE for the COVID-19 pandemic, we seek input on whether there are other services where the use of telecommunications technology could mitigate the exposure risk, and where there is clear clinical benefit to using such technology in furnishing the service.

We note that the inclusion of this code on the telehealth list to ensure that the included visits can be furnished via telehealth is similar to the inclusion of the transitional care management codes on the telehealth list. In both of these cases, the non-face-to-face portions of the service are not considered telehealth services that are subject to any of the payment provisions specific to telehealth services under section 1834(m) of the Act.

- CPT code 77427 (*Radiation treatment management, 5 treatments*)

As we noted above, we have previously considered adding many of these services to the Medicare telehealth list in prior rulemaking and declined, in many cases citing concerns over patient acuity and the feasibility of fulfilling all of the required elements of a service via communication technology. However, in the context of the PHE for the COVID-19 pandemic with specific regard to the exposure risks noted above, we recognize the clinical benefit of access to medically reasonable and necessary services furnished using telecommunications technology as opposed to the potential lack of access that could occur to mitigate the risk of disease exposure. We are also interested in learning of any potential negative consequences of adding these CPT codes to the list of telehealth services on an interim basis.

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

In adding some services to the Medicare telehealth list, we have done so while including certain restrictions on how frequently a service may be furnished via Medicare telehealth to ensure that the services met the category 1 or 2 criteria. For example, in the CY 2011 PFS final rule (75 FR 73317 through 73318), we added the subsequent hospital care services to the Medicare telehealth list. We stated that, because of our concerns regarding the potential acuity of hospital inpatients, we would limit the provision of subsequent hospital care services through telehealth to once every 3 days. Similarly, when we added subsequent nursing facility visits to the Medicare telehealth list, we stated our concerns regarding the potential acuity and complexity of nursing facility (NF) patients, we would limit the provision of subsequent nursing facility care services furnished through telehealth to once every 30 days.

Given our assessment that under the PHE for the COVID-19 pandemic, there is a patient population that would otherwise not have access to clinically appropriate in-person treatment, we do not believe these frequency limitations are appropriate or necessary. In our prior analysis, for

example, we were concerned that patients might not receive the necessary in-person services for nursing facility or hospital inpatient services. Since in the context of this PHE, telehealth visits mitigate exposure risk, fewer in-person visits may reflect the most appropriate care, depending on the needs of individual patients. Consequently, on an interim basis, we are removing the frequency restrictions for each of the following listed codes for subsequent inpatient visits and subsequent NF visits furnished via Medicare telehealth for the duration of the PHE for the COVID-19 pandemic. Similarly, we note that we previously limited critical care consultations through telehealth to only once per day, given the patient acuity involved in critical care. However, we also understand that critical care patients have significant exposure risks such that more frequent services furnished via telehealth may reflect the best available care in the context and for the duration of the PHE for the COVID-19 pandemic. For this reason, we are also removing the restriction that critical care consultation codes may only be furnished to a Medicare beneficiary once per day. These restrictions were established through rulemaking and implemented through systems edits.

1. Subsequent Inpatient Visits: CPT codes

- 99231 (*Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Medical decision making that is straightforward or of low complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering or improving. Typically, 15 minutes are spent at the bedside and on the patient's hospital floor or unit.*)

- 99232 (*Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of*

moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 25 minutes are spent at the bedside and on the patient's hospital floor or unit.)

- 99233 (*Subsequent hospital care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is unstable or has developed a significant complication or a significant new problem. Typically, 35 minutes are spent at the bedside and on the patient's hospital floor or unit.)*)

2. Subsequent Nursing Facility Visits: CPT codes

- 99307 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A problem focused interval history; A problem focused examination; Straightforward medical decision making. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is stable, recovering, or improving. Typically, 10 minutes are spent at the bedside and on the patient's facility floor or unit.)*)

- 99308 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: An expanded problem focused interval history; An expanded problem focused examination; Medical decision making of low complexity. Counseling and/or coordination of care with other physicians, other qualified health*

care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient is responding inadequately to therapy or has developed a minor complication. Typically, 15 minutes are spent at the bedside and on the patient's facility floor or unit.)

- 99309 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A detailed interval history; A detailed examination; Medical decision making of moderate complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. Usually, the patient has developed a significant complication or a significant new problem. Typically, 25 minutes are spent at the bedside and on the patient's facility floor or unit.)*

- 99310 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires at least 2 of these 3 key components: A comprehensive interval history; A comprehensive examination; Medical decision making of high complexity. Counseling and/or coordination of care with other physicians, other qualified health care professionals, or agencies are provided consistent with the nature of the problem(s) and the patient's and/or family's needs. The patient may be unstable or may have developed a significant new problem requiring immediate physician attention. Typically, 35 minutes are spent at the bedside and on the patient's facility floor or unit.)*

3. Critical Care Consultation Services: HCPCS codes

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

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

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

4. Required “Hands-on” Visits for ESRD Monthly Capitation Payments

In the “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005” final rule with comment period (69 FR 66236, November 15, 2004) (hereinafter referred to the CY 2005 PFS final rule with comment period), we added ESRD related services to the Medicare telehealth list; however, we specified that the required clinical examination of the vascular access site must be furnished face-to-face “hands on” (without the use of an interactive telecommunications system) by physician, clinical nurse specialist (CNS), nurse practitioner (NP), or physician assistant (PA) (69 FR 66278). On an interim basis in light of the PHE for the COVID-19 pandemic, we are instead permitting the required clinical examination to be furnished as a Medicare telehealth service during the PHE for the COVID-19 pandemic. We note 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 clinical assessments via telehealth on or after January 1, 2019. The Bipartisan Budget Act of 2018 (Pub. L. 115-123, enacted on February 9, 2018) (BBA of 2018) amended section 1881(b)(3)(B) of the Act to require that such an individual must receive a face-to-face visit, without the use of 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. Due to the conditions presented by the PHE, we are also exercising enforcement discretion on an interim basis to relax enforcement in connection with the requirements under section 1881(b)(3)(B) of the Act that certain visits be furnished without the use of telehealth for services furnished during the PHE. Specifically, CMS will not conduct review to consider whether those visits were

conducted face-to-face, without the use of telehealth. The following CPT codes, when furnished via Medicare telehealth, are impacted by these policies:

- 90951 (*End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month*)

- 90952 (*End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month*)

- 90953 (*End-stage renal disease (ESRD) related services monthly, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month*)

- 90954 (*End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month*)

- 90955 (*End-stage renal disease (ESRD) related services monthly, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month*)

- 90957 (*End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and*

development, and counseling of parents; with 4 or more face-to-face visits by a physician or other qualified health care professional per month)

- 90958 (*End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 2-3 face-to-face visits by a physician or other qualified health care professional per month)*)

- 90959 (*End-stage renal disease (ESRD) related services monthly, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents; with 1 face-to-face visit by a physician or other qualified health care professional per month)*)

- 90960 (*End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 4 or more face-to-face visits by a physician or other qualified health care professional per month)*)

- 90961 (*End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 2-3 face-to-face visits by a physician or other qualified health care professional per month)*)

- 90962 (*End-stage renal disease (ESRD) related services monthly, for patients 20 years of age and older; with 1 face-to-face visit by a physician or other qualified health care professional per month)*)

- 90963 (*End-stage renal disease (ESRD) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents)*)

- 90964 (*End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents)*)

- 90965 (*End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents*)
- 90966 (*End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older*)
- 90967 (*End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients younger than 2 years of age*)
- 90968 (*End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 2-11 years of age*)
- 90969 (*End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 12-19 years of age*)
- 90970 (*End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 20 years of age and older*)

C. Telehealth Modalities and Cost-sharing

1. Clarifying Telehealth Technology Requirements

Our regulation at § 410.78(a)(3) states that telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications systems for purposes of Medicare telehealth services. As we interpret it, this regulation does not apply to mobile computing devices that include audio and video real-time interactive capabilities, even though such devices are now referred to colloquially as “phones” since they can also be used for audio-only telecommunications. In light of the PHE for the COVID-19 pandemic, we believe 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, especially given that leveraging use of such readily available technology may be of critical importance.

Therefore, we are revising § 410.78(a)(3) to add an exception to this language on an interim basis for the duration of the PHE for the COVID-19 pandemic. We are adding the following language at § 410.78(a)(3)(i): “*Exception.* For the duration of the public health emergency as defined in § 400.200 of this chapter, *Interactive telecommunications system* means multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.”

In addition, the HHS Office for Civil Rights (OCR) is exercising enforcement discretion and waiving penalties for HIPAA⁴ violations against health care providers that serve patients in good faith through everyday communications technologies, such as FaceTime or Skype, during the PHE for the COVID-19 pandemic. For more information, see <https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/index.html>. While OCR is not imposing penalties for noncompliance with the regulatory requirements under HIPAA against covered providers in connection with the good faith provision of telehealth during the PHE for the COVID-19 pandemic, HHS, OIG, and DOJ continue to actively monitor for any healthcare fraud and abuse, including potential Medicare coronavirus scams.

2. Beneficiary Cost-sharing

In response to the unique circumstances resulting from the outbreak of COVID-19 and the Secretary’s January 31, 2020 determination under section 319 of the Public Health Service Act that a PHE exists and has existed since January 27, 2020 (COVID-19 Declaration), the Office of Inspector General (OIG) issued a Policy Statement⁵ to notify physicians and other practitioners that they will not be subject to administrative sanctions for reducing or waiving any cost-sharing obligations Federal health care program beneficiaries may owe for telehealth

⁴ Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104-191, enacted August 21, 1996).

⁵ <https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/policy-telehealth-2020.pdf>.

services furnished consistent with the then applicable coverage and payment rules. OIG's Policy Statement is not limited to the services governed by § 410.78 but applies to a broad category of non-face-to-face services furnished through various modalities, including telehealth visits, virtual check-in services, e-visits, monthly remote care management, and monthly remote patient monitoring. The Policy Statement applies to a physician or other practitioner billing for services provided remotely through information or communication technology or a hospital or other eligible individual or entity billing on behalf of the physician or practitioner for such services when the physician or other practitioner has reassigned his or her right to receive payments to such individual or entity.

D. Communication Technology-Based Services (CTBS)

In the "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program-Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program-Accountable Care Organizations-Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act" final rule (83 FR 59452 through 60303) (hereinafter referred to as the CY 2019 PFS final rule), we noted that under current PFS payment rules, Medicare routinely pays for many kinds of services that are furnished via telecommunications technology (83 FR 59482), but are not considered Medicare telehealth services. These communication technology-based services (CTBS) include, for example, certain kinds of remote patient monitoring (either as separate services or as parts of bundled services), and interpretations of diagnostic tests when furnished remotely. These services are different than the kinds of services specified in section 1834(m) of the Act, in that they are not the kind of

services that are ordinarily furnished in person but are routinely furnished using a telecommunications system.

In the CY 2019 PFS final rule, we finalized separate payment for a number of services that could be furnished via telecommunications technology, but that are not Medicare telehealth services. Specifically, we finalized Healthcare Common Procedure Coding System (HCPCS) code G2010 (*Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment*), and HCPCS code G2012 (*Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion*). We finalized these codes as part of the set of codes that is only reportable by the physicians and practitioners who can furnish evaluation and management (E/M) services. We stated that we believed this was appropriate since the service describes a check-in directly with the billing practitioner to assess whether an office visit is needed. However, we did note that similar check-ins provided by nurses and other clinical staff can be important aspects of coordinated patient care (83 FR 59486).

We also finalized that these services be limited to established patients, and that beneficiary consent must be documented in the patient's medical record for each service (83 FR 59487). This latter provision was amended in the CY PFS 2020 final rule to allow for a single beneficiary consent to be obtained annually (84 FR 62699). These requirements also apply to monthly care management and remote patient monitoring services.

In the context of the PHE for the COVID-19 pandemic, when brief communications with practitioners and other non-face-to-face services might mitigate the need for an in-person visit that could represent an exposure risk for vulnerable patients, we believe that these services should be available to as large a population of Medicare beneficiaries as possible. In some cases, use of telecommunication technology could mitigate the exposure risk, and in such cases, the clinical benefit of using technology to furnish the service is self-apparent. This would be especially true should a significant increase in the number of people or health care professionals needing treatment or isolation occur in a way that would limit access to brief communications with established providers. Therefore, on an interim basis, during the PHE for the COVID-19 pandemic, we are finalizing that these services, which may only be reported if they do not result in a visit, including a telehealth visit, can be furnished to both new and established patients. We are also making clear that the consent to receive these services can be documented by auxiliary staff under general supervision. While we continue to believe that beneficiary consent is necessary so that the beneficiary is notified of any applicable cost sharing, we do not believe that the timing or manner in which beneficiary consent is acquired should interfere with the provision of one of these services. Therefore, we are finalizing on an interim basis during the PHE for the COVID-19 pandemic that, while consent to receive these services must be obtained annually, it may be obtained at the same time that a service is furnished. We are also re-emphasizing that this consent may be obtained by auxiliary staff under general supervision, as well as by the billing practitioner. We are retaining the requirement that in instances when the brief communication technology-based service originates from a related E/M service (including one furnished as a telehealth service) provided within the previous 7 days by the same physician or other qualified health care professional, that this service would be considered bundled into that previous E/M service and would not be separately billable.

In the “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” (84 FR 62568, November 15, 2019) (hereinafter referred to as the CY 2020 PFS final rule), we finalized separate payment for CPT codes 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*), and 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*). We also finalized separate payment for HCPCS codes G2061 (*Qualified nonphysician healthcare professional online assessment and management, for an established patient, for up to seven days, cumulative time during the 7 days; 5–10 minutes*), G2062 (*Qualified nonphysician healthcare professional online assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 11–20 minutes*), and G2063 (*Qualified nonphysician qualified healthcare professional assessment and management service, for an established patient, for up to seven days, cumulative time during the 7 days; 21 or more minutes*) (84 FR 62796).

In the context of the PHE for the COVID-19 pandemic, where communications with practitioners might mitigate the need for an in-person visit that could represent an exposure risk for vulnerable patients, we do not believe the limitation of these services to established patients is warranted. While some of the code descriptors refer to “established patient,” during the PHE,

we are exercising enforcement discretion on an interim basis to relax enforcement of this aspect of the code descriptors. Specifically, we will not conduct review to consider whether those services were furnished to established patients.

Additionally, in the CY 2020 PFS final rule (84 FR 62796), we stated that HCPCS codes G2061-G2063, specific to practitioners who do not report E/M codes, may describe services outside the scope of current Medicare benefit categories and as such, may not be eligible for Medicare payment. We have received a number of questions regarding which benefit categories HCPCS codes G2061-G2063 fall under. In response to these requests, we are clarifying here that there are several types of practitioners who could bill for these service. For example, the services described by these codes could be furnished as licensed clinical social worker services, clinical psychologist services, physical therapist services, occupational therapist services, or speech language pathologist services, so practitioners that report services in those benefit categories could also report these online assessment and management services.

On an interim basis, during the PHE for the COVID-19 pandemic, we are also broadening the availability of HCPCS codes G2010 and G2012 that describe remote evaluation of patient images/video and virtual check-ins. We recognize that in the context of the PHE for the COVID-19 pandemic, practitioners such as licensed clinical social workers, clinical psychologists, physical therapists, occupational therapists, and speech-language pathologists might also utilize virtual check-ins and remote evaluations instead of other, in-person services within the relevant Medicare benefit to facilitate the best available appropriate care while mitigating exposure risks. We note that this is not an exhaustive list and we are seeking input on other kinds of practitioners who might be furnishing these kinds of services as part of the Medicare services they furnish in the context of the PHE for the COVID-19 pandemic.

Further, to facilitate billing of the CTBS services by therapists for the reasons described above, we are designating HCPCS codes G2010, G2012, G2061, G2062, or G2063 as CTBS

“sometimes therapy” services that would require 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. CTBS therapy services include those furnished to a new or established patients that the occupational therapist, physical therapist, and speech-language pathologist practitioner is currently treating under a plan of care.

E. Direct Supervision by Interactive Telecommunications Technology

Many services paid under the PFS can be paid when provided under a level of physician or nonphysician practitioner (NPP) supervision rather than personal performance. In many cases, the supervision requirements in physician office settings necessitate the presence of the physician or NPP in a particular location, usually in the same location as the beneficiary when the service is provided. For example, as described at § 410.26, services incident to a physicians’ service usually require the direct supervision of a physician. As currently defined in § 410.32(b)(3)(ii), direct supervision means 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.

Given the circumstances of the PHE for the COVID-19 pandemic, we recognize that in some cases, the physical proximity of the physician or practitioner might present additional exposure risks, especially for high risk patients isolated for their own protection or cases where the practitioner has been exposed to the virus but could otherwise safely supervise from another location using telecommunications technology. In these cases, we believe that the current requirement would necessarily limit access to procedures and tests that could be appropriately supervised by a physician isolated for purposes of limiting exposure to COVID-19. For example, we consider the possibility that patients routinely receiving medically necessary physician-administered drugs at the office of a physician may lose access to the provision of that

drug should the physician who regularly supervises the provision of that drug be isolated for purposes of minimizing exposure risks. Likewise, should that same patient need to be isolated for purposes of exposure risk based on presumed or confirmed COVID-19 infection, administering such a drug in the patient's home would require the billing professional to accompany the clinical staff to the patient's home, presumably with the necessary personal protective equipment (PPE) available to both the physician and the clinical staff.

In some cases, depending upon the unique circumstances of individual patients and billing physicians, we believe that telecommunications technology could be used in a manner that would facilitate the physician's immediate availability to furnish assistance and direction without necessarily requiring the physician's physical presence in the location where the service is being furnished, such as the office suite or the patient's home. For example, we believe that use of real-time, audio and video telecommunications technology allows for a billing practitioner to observe the patient interacting with or responding to the in-person clinical staff through virtual means, and thus, their availability to furnish assistance and direction could be met without requiring the physician's physical presence in that location. We note that to be covered under Part B, drugs furnished "incident to" are typically injectable drugs that are bought by the physician, in ordinary circumstances are administered in the physician's office, and then billed by the physician to the Medicare Administrative Contractor (MAC). By definition, "incident to a physician's professional service" requires the item or service to be billed by the physician. We also note that the supervision requirements that apply to both services incident to a physicians' service and diagnostic tests do not necessarily reflect the appropriate level of supervision for particular patients, services, and health care workers. Instead, we view these levels as the minimum possible requirement for provision of the service for purposes of Medicare payment. Likewise, even in the context of the PHE for the COVID-19 pandemic and the inherent exposure risks for Medicare beneficiaries, physicians and other health care providers, we believe that in

many cases furnishing services without the physical presence of the physician in the same location would not be appropriate. However, we recognize that in some cases, technology would allow appropriate supervision without the physical presence of a physician. In the context of the PHE for the COVID-19 pandemic, given the risks of exposure, the immediate potential risk to needed medical care, the increased demand for health care professionals in the context of the PHE for the COVID-19 pandemic, and the widespread use of telecommunications technology, we believe that individual practitioners are in the best position to make decisions based on their clinical judgement in particular circumstances. Consequently, we are revising the definition of direct supervision to allow, for the duration of the PHE for the COVID-19 pandemic, direct supervision to be provided using real-time interactive audio and video technology. We are seeking information from commenters as to whether there should be any guardrails and what kind of risk might this policy introduce for beneficiaries while reducing risk of COVID-19 spread. We note that this change is limited to only the manner in which the supervision requirement can be met, and does not change the underlying payment or coverage policies related to the scope of Medicare benefits, including Part B drugs. We also note that any and all applicable rules regarding safe transportation and proper waste disposal continue to apply.

We note that in specifying that direct supervision includes virtual presence through audio/video real-time communications technology during the PHE for the COVID-19 pandemic, this can include instances where the physician enters into a contractual arrangement for auxiliary personnel as defined in § 410.26(a)(1), to leverage additional staff and technology necessary to provide care that would ordinarily be provided incident to a physicians' service (including services that are allowed to be performed via telehealth). For example, physicians may enter into contractual arrangements with a home health agency (defined under section 1861(o) of the Act), a qualified infusion therapy supplier (defined under section 1861(iii)(3)(D) of the Act), or entities that furnish ambulance services in order to utilize their nurses or other clinical staff as

auxiliary personnel under leased employment (§ 410.26(a)(5)). In such instances, the provider/supplier would seek payment for any services they provided from the billing practitioner and would not submit claims to Medicare for such services. 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 that service as a Medicare telehealth service. However, we acknowledge that there may be instances where the physician may want to use auxiliary personnel to be present in the home with the patient during the telehealth service, though this is not required for telehealth services under section 1834(m) of the Act. Other services, including both face-to-face and non-face-to-face services, could be provided incident to a physician's service by a nurse or other auxiliary personnel, as long as the billing practitioner is providing appropriate supervision through audio/video real-time communications technology (or in person), when needed. We would not expect that services furnished at a patient's home incident to a physician service would usually occur during the same period as a home health episode of care, and we will be monitoring claims to ensure that services are not being inappropriately unbundled from payments under the home health PPS.

For the reasons discussed above, on an interim basis for the duration of the PHE for the COVID-19 pandemic, we are altering the definition of direct supervision at § 410.32(b)(3)(ii), to state that necessary presence of the physician for direct supervision includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider. We are revising § 410.32(b)(3)(ii) to include, during a PHE, as defined in § 400.200 of this chapter, the presence of the physician includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider.

1. Supervision changes for certain Hospital and CAH Diagnostic and Therapeutic Services

For all of the same reasons described above, we are adopting similar changes in the regulations at § 410.28(e)(1) with respect to the supervision of diagnostic services furnished directly or under arrangement in the hospital or in an on-campus or off-campus outpatient department of the hospital, as defined in § 413.65. We note that under current Medicare rules, most therapeutic services in the hospital require only general supervision and the supervision requirements for diagnostic services generally conform to the service-level supervision levels required for payment under the PFS. Because we have every reason to believe that potential exposure risks and limits on the availability of medical professionals could equally apply to hospital services, we are amending the definition of direct supervision for hospital services for the duration of the PHE for the COVID-19 pandemic so it continues to conform with the applicable definitions for services paid under the PFS. As stated above, we believe this change is necessary due to the circumstances of the PHE for the COVID-19 pandemic. Specifically, we recognize that in some cases, the physical proximity of the physician or practitioner might present additional exposure risks, especially for high risk patients isolated for their own protection or cases where the practitioner has been exposed to the virus but could otherwise safely supervise from another location using telecommunications technology. In these cases, we believe that the current definition would necessarily limit access to diagnostic procedures and tests that could be appropriately supervised by a physician, including one who is isolated for purposes of limiting exposure to COVID-19.

In addition, with respect to pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services described in the regulations at §§ 410.47 and 410.49, respectively, we are adopting a similar change under § 410.27(a)(1)(iv)(D), for the duration of the PHE for the COVID-19 pandemic, for all the reasons described above, to specify that direct supervision for these services includes virtual presence through audio/video real-time communications

technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider.

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

Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act state that payment for home health services is made when a physician certifies that such services are or were required because the individual is or was confined to his home and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or, in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy. In addition, the physician must certify that a plan for furnishing such services to such individual has been established and is periodically reviewed by the physician and that such services are or were furnished while the individual was under the care of a physician. Also, in the case of a certification made by a physician after January 1, 2010, prior to making such certification the physician must document that the physician himself or herself, or an NP or clinical nurse specialist (CNS) (as those terms are defined in section 1861(aa)(5) of the Act) who is working in collaboration with the physician in accordance with State law, or a certified nurse-midwife (as defined in section 1861(gg) of the Act) as authorized by State law, or a PA (as defined in section 1861(aa)(5) of the Act) under the supervision of the physician, has had a face-to-face encounter (including through use of telehealth, subject to the requirements in section 1834(m) of the Act, and other than for encounters that are incident to services involved, as described in section II.E. of this IFC) with the individual within a reasonable timeframe as determined by the Secretary.

Most recently, we have been asked by stakeholders to provide more clarity on whether patients who are instructed to remain in their homes or are under “self-quarantine” are considered “confined to the home” or “homebound” for purposes of the Medicare home health

benefit in the context of the PHE for the COVID-19 pandemic. Per sections 1814(a) and 1835(a) of the Act, an individual shall be considered to be “confined to his home” if the individual has a condition, due to an illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered “confined to his home”, the condition of the individual should be such that there exists a normal inability to leave home and, that leaving home requires a considerable and taxing effort by the individual.

The definition of “confined to the home” (that is, “homebound”) allows patients to be considered “homebound” if it is medically contraindicated for the patient to leave the home. As an example for the PHE for COVID-19 pandemic, this 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. A patient who is exercising “self-quarantine” for one’s own safety would not be considered “confined to the home” unless a physician certifies that it is medically contraindicated for the patient to leave the home. For the PHE for the COVID-19 pandemic, the CDC is currently advising that older adults and individuals with serious underlying health conditions stay home (CDC’s guidance is interim and is expected to continue to be updated as warranted).⁶ As such, we expect that many Medicare beneficiaries could be considered “confined to the home”. However, determinations of whether home health services are

⁶ <https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/high-risk-complications.html>.

reasonable and necessary, including whether the patient is homebound and needs skilled services, must be based on an assessment of each beneficiary's individual condition and care needs.

In cases where it is medically contraindicated for the patient to leave the home, the medical record documentation for the patient must include information as to why the individual condition of the patient is such that leaving the home is medically contraindicated. With regards to a pandemic outbreak of an infectious disease, this can include reviewing and applying any guidance on risk assessment and public health management issued by the CDC. For example, the CDC interim guidance "Preventing the Spread of Coronavirus Disease 2019 in Homes and Residential Communities" applies for both confirmed or suspected COVID-19 states that patients who are medically stable enough to receive care in the home must isolate at home during their illness.⁷ Additionally, these guidelines state that patients should restrict activities outside the home, except for getting medical care. These restrictions include that the individual not go to work, school, or public areas, as well as avoiding use of public transportation, ride-sharing, or taxis; making it such that there exists a normal inability for an individual to leave home and leaving home would require a considerable and taxing effort.

In regards to those circumstances in which the patient does not have confirmed or suspected diagnosis of an infectious disease, such as COVID-19, but the patient's physician states that it is medically contraindicated for the patient to leave the home because the patient's condition may make the patient more susceptible to contracting a pandemic disease, the patient would be considered "confined to the home" or "homebound" for purposes of this eligibility requirement. For example, if a patient is having an exacerbation of chronic obstructive pulmonary disease (COPD) and the physician certifies that it is medically contraindicated to

⁷ <https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-prevent-spread.html>.

leave the home because the patient's compromised respiratory system makes him or her more likely to contract an infectious disease, such as COVID-19, the patient would be considered "confined to the home" in alignment with Medicare home health eligibility criteria. Another example of this type of scenario would be a cancer patient receiving chemotherapy treatment and where the physician states that it is medically contraindicated for the patient to leave the home because the patient may be more at risk of contracting an infectious disease because of the patient's immunocompromised state. In both examples, the medical contraindication makes it such that there exists a normal inability for an individual to leave home and leaving home safely would require a considerable and taxing effort.

In addition to being considered "confined to the home" or "homebound", the patient must meet the other Medicare home health eligibility requirements to receive Medicare home health services. That is, the beneficiary must be under the care of a physician; receiving services under a plan of care established and periodically reviewed by a physician; be in need of skilled nursing care on an intermittent basis or physical therapy or speech-language pathology; or have a continuing need for occupational therapy. Even if the patient is confined to the home because of a suspected diagnosis of an infectious disease as part of a pandemic event, a home health visit solely to obtain a nasal or throat culture would not be considered a skilled service because it would not require the skills of a nurse to obtain the culture as the specimen could be obtained by an appropriately-trained medical assistant or laboratory technician. However, a home health nurse, during an otherwise covered skilled visit, could obtain the nasal or throat culture to send to the laboratory for testing. Please see section II.M. of this IFC for further discussion about how a Medicare patient without a skilled need who is under self-quarantine may be tested at home.

We believe this clarification is not limited to the PHE for the COVID-19 pandemic, but would also apply for other outbreaks of an infectious disease and instances where the condition of a patient is such that it is medically contraindicated for the patient to leave his or her home.

We solicit comments on this clarification.

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

Section 1895 of the Act outlines the statutory parameters of the home health prospective payment system (HH PPS) that was implemented on October 1, 2000. The HH PPS provides payment for all services furnished under the Medicare home health benefit as outlined in section 1861(m) of the Act in the form of a “bundled” 30-day unit of payment that is adjusted for case-mix and area wage differences in accordance with section 1895(b) of the Act. Section 1895(e)(1)(A) of the Act states that nothing under section 1895 of the Act prevents a home health agency (HHA) from furnishing services via a telecommunications system, 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 purposes of eligibility or payment. In the CY 2019 HH PPS proposed rule (83 FR 32425), we stated 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. In the CY 2019 HH PPS final rule with comment (83 FR 56527), for purposes of the Medicare home health benefit, we finalized the definition of “remote patient monitoring” in regulation at 42 CFR 409.46(e) as the collection of physiologic data (for example, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the HHA. We also included in regulation at § 409.46(e) that the costs of remote patient monitoring are considered allowable administrative costs (operating expenses) if remote patient monitoring is used by the HHA to augment the care planning process (83 FR 56527).

We received positive feedback from the policy changes finalized in the CY 2019 HH PPS final rule with comment period. Commenters encouraged us to even go further in adopting and promoting technology use in home health. Recently, we have been asked by stakeholders to

provide more clarity on how HHAs can leverage technology to keep home health clinicians and patients safe during outbreaks of an infectious disease, such as the PHE for the COVID-19 pandemic. While we remain statutorily-prohibited from paying for home health services furnished via a telecommunications system if such services substitute for in-person home health services ordered as part of a plan of care and for paying directly for such services under the home health benefit, for the duration of the PHE for the COVID-19 pandemic, we are amending the regulations at § 409.43(a) on an interim basis to provide HHAs with the flexibility, in addition to remote patient monitoring, to use various types of telecommunications systems (that is, technology) in conjunction with the provision of in-person visits. Specifically, we are amending the regulations at § 409.43(a) on an interim basis to state that the use of 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. We are also amending the regulations at § 409.43(a) on an interim basis to state that the use of technology must be included on the home health plan of care along with a description of how the use of such technology will help to achieve the goals outlined on the plan of care without substituting for an in-person visit as ordered on the plan of care. As a reminder, the plan of care must be signed prior to submitting a final claim to Medicare for payment (§ 409.43(c)(2)); therefore, HHAs have flexibility on the timing in which they obtain physician signatures for changes to the plan of care when incorporating the use of technology into the patient's plan of care. In addition, HHAs may also provide services based on verbal orders in accordance with the regulations at §§ 484.60(b) and 409.43(d). Finally, on an interim basis HHAs can report the costs of telecommunications technology as allowable administrative and general (A&G) costs by identifying the costs using a subscript between line 5.01 through line 5.19.

We reiterate that by law the use of technology may not substitute for an in-person home visit ordered as part of the plan of care and services furnished via a telecommunications system

cannot be considered a home health visit for purposes of eligibility or payment. However, we acknowledge that the use of such technology may result in changes to the frequency or types of visits outlined on the plan of care, especially to combat the PHE for the COVID-19 pandemic. For example, a patient recently discharged from the hospital after coronary bypass surgery was receiving home health skilled nursing visits three times a week for medication management, teaching and assessment. The patient developed a fever, cough, sore throat and moderate shortness of breath and now has a confirmed COVID-19 diagnosis, which the doctor has determined can be safely managed at home with home health services. The patient has been prescribed new medications for symptom management and oxygen therapy to support the patient's respiratory status. The patient's home health plan of care was updated to include an in-person skilled nursing visit once a week to assess the patient and to monitor for worsening symptoms. The plan of care was updated also to include 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 relays to the nurse during the consultation.

With regards to payment under the HH PPS, if the primary reason for home health care is to provide care to manage the symptoms resulting from COVID-19, this 30-day period of care would be grouped into the Medication, Management, Teaching and Assessment (MMTA) – Respiratory clinical group, and it would be an early 30-day period of care with an institutional admission source. Assuming a medium functional impairment level with “low” comorbidities, the low-utilization payment adjustment (LUPA) threshold would be 4 visits. Regardless if the patient continued to receive the original 3 in-person skilled nursing visits per week (12 visits total in the 30-day period) rather than the once per-week in-person skilled nursing visits (4 visits total in the 30-day period) the HHA would still receive the full 30-day payment amount (rather than paying per visit if the total number of visits was below the LUPA threshold). In this

example, the use of technology is not a substitute for the provision of in-person visits as ordered on the plan of care, as the plan of care was updated to reflect a change in the frequency of the in-person visits and to include “virtual visits” as part of the management of the home health patient.

As discussed previously in section II.E “Direct Supervision by Interactive Telecommunications Technology” in this IFC, there may be instances during the PHE for the COVID-19 pandemic where physicians can enter into a contractual arrangement, that meets the definition of auxiliary personnel at § 410.26, with another provider/supplier type. For example, physicians may enter into contractual arrangements with a HHA, a qualified infusion therapy supplier, or other entity to leverage auxiliary personnel under leased employment (§ 410.26(a)(5)), including nurses or other clinical staff, to provide virtual visits for patients in their homes. These virtual visits are considered provided incident to a physician’s service, as long as the billing practitioner is providing appropriate supervision through audio/video real-time communications technology, when needed. Payment for such services would be made to the billing practitioner who would then make the appropriate payment to the contracted entity (for example, the HHA). This payment would be made in accordance with the PFS and would not be considered a home health service under the Medicare home health benefit. This particular flexibility can enable more patients to receive services at home via telehealth for instances in which there are no in-person visits that would trigger payment under the Medicare HH PPS. As such, we would not expect that services furnished at a patient’s home incident to a physician service will usually occur during the same period as a home health episode of care, and we will be monitoring claims that practitioners are billing under arrangement to ensure appropriate services are being billed by the practitioner and not being inappropriately unbundled from payments under the HH PPS.

The remainder of this section includes information on examples of technology that can be leveraged in providing care in the home setting, such as telemedicine, interactive clinician

“consulting” and other patient-facing technologies; and provides a summary of the regulations text we are amending in this IFC.

In general, technology has become an integral part of medicine across the entire spectrum of healthcare. Telemedicine, in particular has the potential to play a large role in enhancing the delivery of healthcare in the home for Medicare beneficiaries, including the provision of information, education, and services provided via telecommunications systems. One of the biggest benefits of telemedicine, separate from its potential to minimize risk to clinicians and patients during an outbreak of an infectious disease, is to increase access to healthcare to geographically disadvantaged and medically underserved populations, providing an improved quality of care.⁸ Telemedicine and remote monitoring can also be used to encourage patient involvement and autonomy, and to increase the tools available for the home health provider.

Recent CMS site visits with HHAs, as well as meetings with industry associations detailed the extent to which HHAs are researching and integrating technology into their care. These organizations provided examples of technology they have tested and/or are currently using, ranging from patient facing apps on cell phones to robotics. Additionally, they provided examples of patients with specific home health needs that they believe would benefit most from leveraging technology in home health care. They indicated a wide variety of uses for technology in home health including medication management and teaching, behavioral/crisis or social work counseling, post-transplant monitoring, dietary counseling, and even functional training through remote occupational or physical therapy. In particular, they highlighted certain diagnoses and conditions for which they are already utilizing telecommunications systems. For diagnoses/conditions such as COPD, congestive heart failure (CHF), sepsis, and wounds,

⁸ Int J Environ Res Public Health. 2013 Dec; 10(12): 6472–6484. Published online 2013 Nov 28. doi: 10.3390/ijerph10126472.

technology can offer an efficient way of monitoring chronic respiratory and cardiovascular diseases that represent an increasingly high burden on healthcare systems.⁹ We referenced some of the benefits of remote patient monitoring of chronic diseases in the CY 2019 HH PPS proposed rule (83 FR 32425), including readmission prevention and improved patient involvement and accountability.

Certain HHAs and industry groups have implemented technology that goes beyond remote patient monitoring for the treatment of chronic diseases. One such HHA utilizes two-way, interactive “consulting” between the nurse furnishing the home visit and a specialty clinician at the agency. The nurse furnishing the home visit can use a tablet to visually connect the patient with the specialty clinician or advanced practice nurse at the agency to assess swelling, breathing, or to review and reconcile medications. These specialty clinicians are also beneficial in treating acute conditions, such as wounds, or monitoring for the prevention of sepsis. Wound, Ostomy, and Continence Nurses (WOCNs) are being utilized for their specialized skills as consultants for the nurse in the home. The nurse furnishing the home visit can use a tablet to connect visually with the WOCN at the agency to consult on the management of the wound. If necessary, the WOCN can contact the physician or surgeon to relay progress or request a change in treatment. Specialized software can even be utilized to assess the wound with precision and accuracy, including measuring surface area and depth, to improve consistency of care.¹⁰ Additionally, incorporating technology into home health may be beneficial in attracting these specialty clinicians, such as cardiac nurses and WOCNs, to homecare, which promotes the provision of a more advanced level of care; a benefit that will become imperative if the home health patient population, as a whole, exhibits more characteristics of an acute care population. Allowing advanced practice clinicians to consult virtually with the RN in the home may

⁹ Breathe (Sheff). 2016 Dec; 12(4): 350–356. doi: 10.1183/20734735.014616.

¹⁰ <https://parablehealth.com/post-acute-inpatient>.

minimize transportation and labor costs and potentially improve patient access to specialty care.

Telecommunications systems are also playing a valuable role in managing patients at risk for sepsis after a hospitalization. Sepsis continues to be a top diagnosis for hospital 30-day readmission rates amongst Medicare patients.¹¹ Utilizing individualized software platforms to monitor appetite, mental changes, biometrics, etc., which alert care providers of any changes that may indicate a problem, can be helpful in treating the patient in the home prior to the patient requiring hospitalization. These patient-facing devices (tablets or apps) can be programmed to require the patient to perform a virtual daily “check-in” to monitor for potential issues. If the “check-in” goes beyond specified individualized parameters, an alert will signal the HHA to follow-up with the critical care team following the patient to accelerate treatment. The software can also be programmed to deliver specific care instructions and reminders regarding hygiene or medications. In addition to disease-specific monitoring, patient-facing technologies can also be integral in promoting patient involvement and compliance. Certain scheduling and communication platforms allow HHAs to interface with patients in more ways than in-person visits or telephone calls. Some devices can “talk” to the patient, even utilizing multiple languages. Others can provide medication reminders, daily health tips, and assist in arranging for community or caregiver support.

Overall, we have seen how technology can expand the reach of healthcare into the home, through consultation with specialized clinicians and critical care teams, as well as through the integration of devices designed to increase patient involvement and compliance. As outlined above, incorporating these various forms of technology, in addition to remote patient monitoring as defined under the home health benefit (§ 409.46(e)), can be appropriate in furnishing home health services when used in conjunction with the provision of in-person visits. In addition,

¹¹ <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb225-Inpatient-US-Stays-Trends.pdf>.

technology can be used to minimize the risk of exposure to clinicians, patients, and the public during an outbreak of an infectious disease, such as the PHE for the COVID-19 pandemic.

Although HHAs have the flexibility, in addition to remote patient monitoring, to use various types of technology, payment for home health services remains contingent on the furnishing of a visit. Therefore, the use of technology must be related to the skilled services being furnished by the nurse or therapist or therapy assistant to optimize the services furnished during the home visit or when there is a home visit. To be eligible for the home health benefit, beneficiaries must need intermittent skilled nursing or therapy services and must be considered homebound. Covered home health services include skilled nursing, home health aide, physical therapy, speech-language pathology, occupational therapy, medical social services, and medical supplies, provided on a visiting basis in a place of residence such as the individual's home (section 1861(m) of the Act). A visit is defined at § 409.48(c) as an episode of personal contact with the beneficiary by staff of the HHA or others under arrangements with the HHA, for the purpose of providing a covered service. Generally, one visit may be covered each time an HHA employee or someone providing home health services under arrangement with the HHA enters the beneficiary's home and provides a covered service to a beneficiary.

To appropriately recognize the role of technology in furnishing services under the Medicare home health benefit, the use of such technology must be included on the plan of care. The inclusion of technology on the plan of care must continue to meet the requirements at § 484.60, and must be tied to the patient-specific needs as identified in the comprehensive assessment and the measurable outcomes that the HHA anticipates will occur as a result of implementing the plan of care. For example, if a physician orders an in-person skilled nursing visit once a week to assess the patient and to monitor for worsening symptoms 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 relays to

the nurse during the consult; the plan of care could specify that the goal of the video consultation is to increase patient adherence with medication regimen and oxygen use with no worsening respiratory symptoms.

In summary, we are amending the plan of care requirements at § 409.43(a) on an interim basis, for the purposes of Medicare payment, to state that 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. We believe that this change will help to increase access to technologies, such as telemedicine and remote patient monitoring, that enable the necessary flexibility for Medicare beneficiaries to be able to receive medically necessary services without jeopardizing their health or the health of those who are providing such services, while minimizing the overall risk to public health during the PHE for the COVID-19 pandemic. As we stated above, HHAs can report the costs of telecommunications technology as allowable A&G costs on an interim basis by identifying the costs using a subscript between line 5.01 through line 5.19. We invite feedback on our interim changes to the plan of care requirements at § 409.43(a).

H. The Use of Telecommunications Technology Under the Medicare Hospice Benefit

As outlined in section II.G. of this IFC, The Use of Technology Under the Medicare Home Health Benefit, technology has become an integral part of medicine across the entire spectrum of healthcare. Telemedicine, in particular has the potential to play a large role in enhancing the delivery of healthcare in the home, including the provision of information, education, and services provided via telecommunications systems. One of the benefits of telemedicine is its potential to minimize risk to clinicians and patients during an outbreak of an infectious disease, such as the PHE for the COVID-19 pandemic. Recently, we have been asked

by stakeholders to provide more clarity on how hospices can leverage technology to keep clinicians and patients safe during the PHE for the COVID-19 pandemic.

For the duration of the PHE for the COVID-19 pandemic, we are amending the hospice regulations at 42 CFR 418.204 on an interim basis to specify that when a patient is receiving routine home care, hospices may provide services via a telecommunications system if it is feasible and appropriate to do so to ensure that Medicare patients can continue receiving services that are reasonable and necessary for the palliation and management of a patients' terminal illness and related conditions without jeopardizing the patients' health or the health of those who are providing such services during the PHE for the COVID-19 pandemic. To appropriately recognize the role of technology in furnishing services under the hospice benefit, the use of such technology must be included on the plan of care. The inclusion of technology on the plan of care must continue to meet the requirements at § 418.56, and must be tied to the patient-specific needs as identified in the comprehensive assessment and the measurable outcomes that the hospice anticipates will occur as a result of implementing the plan of care. The following is an example of where it could be appropriate to furnish hospice services via a telecommunications system during the PHE for the COVID-19 pandemic:

A terminally ill 85-year-old male with heart failure has been receiving hospice services and recently developed a fever, sore throat and cough. The patient has been diagnosed with suspected COVID-19 and his hospice plan of care now includes medications for symptom management. He is mildly short of breath but does not require supportive oxygen therapy. The patient's wife is concerned about potential for worsening cardiac and respiratory symptoms as a result of the patient's risk for increased complications due to COVID-19. The hospice plan of care has been updated to include remote patient monitoring with a telecommunications system to assess the patient's daily weight and oxygen saturation levels. The plan of care identifies the measurable goal that the patient

will maintain an oxygen level above 92 percent and the patient will not gain more than 2 pounds in a 24-hour period. The plan of care identifies interventions if either of these goals are not met. The remote patient monitoring allows for more expedited modifications to the plan of care in response to the patient's changing needs.

We believe that this clarification in the regulations at § 418.204 will help to increase access to technologies, such as telemedicine and remote patient monitoring, that enable the necessary flexibility for patients to be able to receive necessary services without jeopardizing their health or the health of those who are providing those services, while minimizing the overall risk to public health during the PHE for the COVID-19 pandemic. Hospices are paid a per diem payment amount based on the level of care for each day that a patient is under a hospice election (§ 418.302). There is no payment beyond the per diem amount for the use of technology in providing services under the hospice benefit. For the purposes of the hospice claim submission, only in-person visits (with the exception of social work telephone calls) should be reported on the claim. However, hospices can report the costs of telecommunications technology used to furnish services under the routine home care level of care during the PHE for the COVID-19 pandemic as "other patient care services" using Worksheet A, cost center line 46, or a subscript of line 46 through 46.19, cost center code 4600 through 4619, and identifying this cost center as "PHE for COVID-19". We invite feedback on our changes to the special requirements for coverage at § 418.204.

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

To receive hospice services under the Medicare hospice benefit, a beneficiary must be certified as terminally ill with a medical prognosis of a life expectancy of 6 months or less if the illness runs its normal course, in accordance with section 1814(a)(7) of the Act and as codified in § 418.22. A written certification is required at the beginning of the first 90-day period of hospice care, a subsequent 90-day period and each 60-day period thereafter. The hospice must obtain

written certification of terminal illness for each benefit period, even if a single election continues in effect. In accordance with section 1814(a)(7)(D)(i) of the Act, a hospice physician or hospice NP must have a face-to-face encounter with each Medicare hospice patient whose total stay across all hospices is anticipated to reach the 3rd benefit period. The face-to-face encounter must occur prior to, but no more than 30 calendar days prior to, the 3rd benefit period recertification, and every benefit period recertification thereafter, to gather clinical findings to determine continued eligibility for hospice care.

The Medicare hospice face-to-face encounter is an administrative requirement related to certifying the terminal illness as required in section 1814(a)(7)(D)(i) of the Act. By itself, it is not billable, as it is considered administrative (see Pub. 100-04, Medicare Claims Processing Manual, chapter 11, section 40.1.1). However, if a hospice physician, or a hospice NP who is also the patient's designated attending physician, provides reasonable and necessary non-administrative patient care during the face-to-face visit, that portion of the visit would be billable under the Medicare rules. There are additional requirements for billing physician services provided by NPs (see Pub. 100-04, chapter 11, section 40.1.3.2). Therefore, if a hospice physician or the hospice NP acting as the patient's designated attending physician provides direct patient care during the course of the face-to-face encounter, the physician or NP may bill for such direct care services for Medicare beneficiaries under the PFS. As a reminder, the hospice benefit defines an "attending physician" as a doctor of medicine or osteopathy, an NP, or a PA designated by the individual at the time he or she elects to receive hospice care as having the most significant role in the determination and delivery of the individual's medical care (§ 418.3). However, we note that PAs are not authorized to perform the required face-to-face encounter under section 1814(a)(7)(D)(i) of the Act. In the event of a pandemic outbreak of an infectious disease, such as COVID-19, an example of direct patient care during the course of an in-person face-to-face visit for recertification for Medicare beneficiaries could be as follows

An 85-year-old male with a primary diagnosis of end stage heart failure with diabetes, peripheral vascular disease, and hypertension is being seen by the hospice physician for hospice recertification and has developed a fever, cough and mild shortness of breath over the last 24 hours. After discussion with his caregiver, the hospice physician discovers that the patient had a visit from his niece who was found to be COVID-19 positive. The physician washes his hands, puts on gloves and then places a mask on himself, the patient and caregiver. After examining the patient, the physician discusses with the patient and caregiver if he would like to be tested for COVID-19 and if he would like to continue to be treated at home. The patient decides that he would like to be treated at home and that he would like to be tested. The nasopharyngeal and oropharyngeal swabs are performed. The hospice physician discusses with the patient's caregiver infection control techniques, symptomatic treatment, and provides them with gloves and disposable masks. During the course of this recertification visit, the hospice physician provided direct patient care, and therefore, can bill for such services.

While we do not believe that direct patient care for Medicare hospice patients will typically be furnished via telehealth, we note that nothing in statute or regulation precludes a hospice designated attending physician from furnishing services via telehealth in accordance with section 1834(m) of the Act. In response to the PHE for the COVID-19 pandemic, The Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 was signed into law on March 6, 2020. Section 102 of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 gives the Secretary the authority to waive: (1) the telehealth originating site requirements under section 1834(m)(4)(C) of the Act (both geographic and site of service) for telehealth services furnished in an emergency area; and (2) the restriction on use of a telephone for furnishing telehealth services (in § 410.78(a)(3)), but only if the telephone has audio and video capabilities that are used for two-way, real-time interactive

communication. The originating site facility fee would be paid to originating sites on the current list of permissible sites (except for the patient's home) in any geographic location. The provision established a definition of "qualified providers" that specifies the practitioners eligible for furnishing distant site services under the waiver. Specifically, the practitioners currently permitted to furnish distant site telehealth services under section 1834(m) of the Act—physicians (as defined in section 1861(r) of the Act) and NPPs (as defined in section 1842(b)(18)(C) of the Act)—would be eligible to furnish telehealth services under the waiver to patients with an established relationship with the practitioner or a practitioner in the same practice (defined by tax identification number (TIN)). This would be determined based on a patient for whom Medicare payment was made for an item or service furnished by the practitioner (or another practitioner within the same practice) within the previous 3 years.¹² The telehealth waiver is in effect and is limited to the PHE for the COVID-19 pandemic.

The statute is silent as to whether a face-to-face encounter solely for the purpose of Medicare hospice recertification (meaning there is no direct patient care) could be conducted via telecommunications technology by the hospice physician or NP. Given that a face-to-face visit solely for the purpose of recertification for Medicare hospice services is considered an administrative requirement related to certifying the terminal illness as required in section 1814(a)(7)(D)(i) of the Act, we believe that such visit could be performed via telecommunications technology as a result of the PHE for the COVID-19 pandemic. We recognize that public exposure during a pandemic event of an infectious disease greatly increases the overall risk to public health and terminally ill patients are exceptionally vulnerable to complications associated with COVID-19. Therefore, we are amending the regulations at §

¹² We note that HHS will not conduct audits to ensure that such prior relationship existed for claims submitted during this PHE. Also, effective immediately, the HHS Office for Civil Rights (OCR) will exercise enforcement discretion and waive penalties for HIPAA violations against health care providers that serve patients in good faith through everyday communications technologies, such as FaceTime or Skype, during the COVID-19 nationwide PHE.

418.22(a)(4) on an interim basis to allow the use of telecommunications technology by the hospice physician or NP for the face-to-face visit when such visit is solely for the purpose of recertifying a patient for hospice services during the PHE for the COVID-19 pandemic. By telecommunications technology, we mean 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 (from home, or any other site permissible for receiving services under the hospice benefit) and distant site hospice physician or hospice NP.¹³ Such encounters solely for the purpose of recertification would not be a separately billed service, but rather considered an administrative expense. We request feedback on the amendments to the face-to-face visit requirement for hospice recertification during the PHE for the COVID-19 pandemic.

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), for an inpatient rehabilitation facility (IRF) claim to be considered reasonable and necessary under section 1862(a)(1) of the Act, 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, defined as a licensed physician with specialized training and experience in inpatient rehabilitation. 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 to assess the patient both medically and functionally, as well as modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process.

The purpose of the physician supervision requirement is to ensure that the patient's

¹³ Section 410.78(a)(2) defines a "distant site" as the site at which the physician or practitioner delivering the service is located at the time the service is provided via a telecommunications system.

medical and functional statuses are being continuously monitored as the patient's overall plan of care is being carried out.

We continue to believe it is in the patient's best interest to be seen in person by a rehabilitation physician to assess their medical and functional statuses while at the IRF, and we encourage rehabilitation physicians to continue to visit IRF patients in person as long as all necessary precautions, including the use of PPE, are taken to ensure the health and safety of the patient and the physician. However, during the PHE for the COVID-19 pandemic, we believe 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 as defined in section 1834(m)(4)(F) of the Act, to conduct the required 3 physician visits per week during the PHE for the COVID-19 pandemic. By increasing access to telehealth, this IFC will provide the necessary flexibility for Medicare beneficiaries to be able to receive medically necessary services without jeopardizing their health or the health of those who are providing those services, while minimizing the overall risk to public health.

To effectuate these changes, on an interim basis we are finalizing revisions to the regulations at §§ 412.622(a)(3)(iv) and 412.29(e) during the PHE for the COVID-19 pandemic.

In § 412.622(a)(3)(iv), we are revising 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). 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 to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation

process. The post-admission physician evaluation described in paragraph (a)(4)(ii) may count as one of the face-to-face visits.

In § 412.29(e), we are revising this paragraph to state that a procedure must be in effect to ensure that patients receive close medical supervision, as evidenced by at least 3 face-to-face visits per week by a licensed physician with specialized training and experience in inpatient rehabilitation to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process, 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).

We welcome feedback on these revisions to the regulations at §§ 412.622(a)(3)(iv) and 412.29(e) for the duration of the PHE.

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

IRF care is only considered by Medicare to be reasonable and necessary under section 1862(a)(1) of the Act if the patient meets all of the IRF coverage requirements outlined in § 412.622(a)(3), (4), and (5). Failure to meet the IRF coverage criteria in a particular case results in denial of the IRF claim. Under § 412.622(a)(4)(ii), to document that each patient for whom the IRF seeks payment is reasonably expected to meet all of the requirements in § 412.622(a)(3) at the time of admission, 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.

In an effort to provide rehabilitation physicians with as much flexibility as possible, we are removing the post-admission physician evaluation requirement at § 412.622(a)(4)(ii) for all IRFs during the PHE for the COVID-19 pandemic. We believe that removal of this requirement will greatly reduce the amount of time rehabilitation physicians in IRFs spend on completing paperwork requirements when a patient is admitted to the IRF, and will free up their time to focus instead on caring for patients and helping where they may be needed with the PHE for the COVID-19 pandemic. Accordingly, we are amending § 412.622(a)(4)(ii) to note that the post-admission physician evaluation is not required during the PHE for the COVID-19 pandemic. To effectuate this change, on an interim basis, we are revising § 412.622(a)(4)(ii) to specify that the post-admission physician evaluation is not required during the PHE for the COVID-19 pandemic.

We note 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.

We invite feedback on our removal of the post-admission physician evaluation documentation requirement at § 412.622(a)(4)(ii) for all IRFs during the PHE for the COVID-19 pandemic.

In addition, we are providing clarity for all IRFs during the PHE for the COVID-19 pandemic with regard to the intensive rehabilitation therapy requirements for IRF coverage at § 412.622(a)(3)(ii), commonly known as the "3-hour" rule. Section 412.622(a)(3)(ii) generally requires that a beneficiary be reasonably expected to actively participate in, and benefit from, an intensive rehabilitation therapy program on admission to the IRF. 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. Benefit from this intensive rehabilitation therapy program is demonstrated by measurable improvement that will be of practical value to the patient in improving the patient's functional capacity or adaptation to impairments. The required therapy treatments must begin within 36 hours from midnight of the day of admission to the IRF.

We recognize 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, while these requirements remain in place, we are clarifying 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

a. Background

RHC and FQHC visits are face-to-face (in-person) encounters between a patient and an RHC or FQHC practitioner during which time one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, NPs, PAs, certified nurse midwives, clinical psychologists, and clinical social workers, and under certain conditions, a registered nurse (RN) or licensed practical nurse furnishing care to a homebound RHC or FQHC patient. A Transitional Care Management service can also be an RHC or FQHC visit. A Diabetes Self-

Management Training (DSMT) service or a Medical Nutrition Therapy (MNT) service furnished by a certified DSMT or MNT provider may also be an FQHC visit.

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.

The RHC and FQHC payment rates reflect the cost of all services and supplies that an RHC or FQHC furnishes to a patient in a single day, and are not adjusted for the complexity of the patient health care needs, the length of the visit, or the number or type of practitioners involved in the patient’s care. Services furnished by auxiliary personnel (such as nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered to be incident to the visit and are included in the per-visit payment. This may include services furnished prior to or after the billable visit that occur within a medically appropriate time period, which is usually 30 days or less.

RHCs and FQHCs are also paid for care management services, including chronic care management services, general behavioral health integration services, and psychiatric Collaborative Care Model services. These are typically non-face-to-face services that do not require the skill level of an RHC or FQHC practitioner and are not included in the RHC or FQHC payment methodologies.

In the CY 2019 PFS proposed rule (83 FR 35863), we proposed separate payments to RHCs and FQHCs for certain CTBS referred to as “Brief Communication Technology-Based Services” for a “virtual check-in” and separate payment for remote evaluation of recorded video

and/or images. “Virtual check-ins” are brief (5 to 10 minutes), non-face-to-face check ins with a patient via communication technology to assess whether the patient’s condition necessitates an office visit. This service could be billed only in situations where the medical discussion was for a condition not related to an RHC or FQHC visit furnished within the previous 7 days, and does not lead to an RHC or FQHC visit within the next 24 hours or at the soonest available appointment. We also proposed payment for remote evaluation of patient-transmitted information conducted via pre-recorded “store and forward” video or image technology, including interpretation with verbal follow-up with the patient within 24 business hours. We had proposed that payment would be made if the remote evaluation did not originate from a related RHC or FQHC visit furnished within the previous 7 days, or lead to an RHC or FQHC visit within the next 24 hours or soonest available appointment.

In the CY 2019 PFS final rule (83 FR 59683), we finalized requirements and payment for RHCs and FQHCs furnishing Virtual Communication Services. Effective January 1, 2019, RHCs and FQHCs are paid for Virtual Communication Services HCPCS code G0071 *Payment for communication technology-based services for 5 minutes or more of a virtual (non-face-to-face) communication between an RHC or FQHC practitioner and RHC or FQHC patient, or 5 minutes or more of remote evaluation of recorded video and/or images by an RHC or FQHC practitioner, occurring in lieu of an office visit; RHC or FQHC only*). HCPCS code G0071 is on an RHC or FQHC claim, either alone or with other payable services, and at least 5 minutes of communication technology-based or remote evaluation services are furnished by an RHC or FQHC practitioner to a patient who has had an RHC or FQHC billable visit within the previous year, and the medical discussion or remote evaluation is for a condition not related to an RHC or FQHC service provided within the previous 7 days, and does not lead to an RHC or FQHC visit within the next 24 hours or at the soonest available appointment. We added a new paragraph (e) to 42 CFR 405.2464 to reflect this payment.

HCPCS code G0071 is set at the average of the national non-facility PFS payment rates for HCPCS code G2012 (communication technology-based services) and HCPCS code G2010 (remote evaluation services) and is updated annually based on the PFS national non-facility payment rate for these codes. RHC and FQHC face-to-face requirements are waived when these services are furnished to an RHC or FQHC patient. Coinsurance and deductibles apply to RHC claims for HCPCS code G0071 and coinsurance applies to FQHC claims for HCPCS code G0071.

b. Improving Access to Care Management and Virtual Communication Services Furnished by RHCs and FQHCs

RHCs and FQHCs furnish services in rural and urban areas that have been determined to be medically underserved areas or health professional shortage areas. They are an integral component of the Nation's health care safety net, and we want to ensure that Medicare patients who are served by RHCs and FQHCs are able to communicate with their RHC or FQHC practitioner in a manner that enhances access to care, consistent with evolving medical care.

Particularly in rural areas where transportation is limited and distances may be far, we believe the use of CTBS may help some patients to determine if they need to schedule a visit at the RHC or FQHC. If it is determined that a visit is not necessary, the RHC or FQHC practitioner would be available for other patients who need their care.

In the CY 2019 PFS final rule (83 FR 59452), we finalized payment for new online digital assessment services, also referred to as "E-Visits," for practitioners billing under the PFS. These are non-face-to face, patient-initiated communications using online patient portals. An online patient portal is a secure online website that gives patients 24-hour access to personal health information from anywhere with an Internet connection by using a secure username and password. These digital assessment services are for established patients who require a clinical decision that otherwise typically would have been provided in the office. To minimize risks

associated with exposure to COVID-19, and to provide the best care possible during the PHE for the COVID-19 pandemic, we believe that RHCs and FQHC practitioners, like many other health care providers, should explore the use of interactive communications technology in the place of services that would have otherwise been furnished in person and reported and paid under the established methodologies.

To facilitate the ability of RHCs and FQHCs to take such measures when appropriate, on an interim basis, we are expanding the services that can be included in the payment for HCPCS code G0071, and update the payment rate to reflect the addition of these services. Specifically, we are adding the following three CPT codes:

- 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*)

We are revising the payment rate for HCPCS code G0071 to include the national non-facility payment rates for these three new codes. Effective for services furnished on or after March 1, 2020 and throughout the PHE for the COVID pandemic, the payment rate for HCPCS code G0071 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. The RHC and FQHC face-to-face requirements are be waived for these services. Section 405.2464 (e) establishes payment for communication technology-based and remote evaluation services, and no regulatory changes are required.

The services that are payable using HCPCS code G0071 require that the beneficiary has been seen by an RHC or FQHC practitioner during the previous 12 months. Under the current PHE for the COVID-19 pandemic, we believe that it is necessary to make these services available to beneficiaries who would otherwise not have access to clinically appropriate in-person treatment. Therefore, during the PHE for the COVID-19 pandemic, we are finalizing that all virtual communication services that are billable using HCPCS code G0071 will also be available to new patients that have not been seen in the RHC or FQHC within the previous 12 months. Also, in situations where obtaining prior beneficiary consent would interfere with the timely provision of these services, or the timely provision of the monthly care management services, during the PHE for the COVID-19 pandemic consent can be obtained when the services are furnished instead of prior to the service being furnished, but must be obtained before the services are billed. We will also allow patient consent to be acquired by staff under the general supervision of the RHC or FQHC practitioner for the virtual communication and monthly care management codes during the PHE for the COVID-19 pandemic. These changes are consistent with the flexibilities we are establishing for similar services paid under the PFS as described in section II.D. of this IFC.

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

a. Background

Sections 1861(aa)(1)(A) and (B) of the Act describes RHC and FQHC services as services and supplies furnished by a physician, PA, NP, clinical psychologist clinical social worker; and items and services furnished incident to these services, and specifies requirements for these practitioners and services.

In the case of an RHC or FQHC that is located in an area in which there exists a shortage of HHAs, part-time or intermittent nursing care and related medical supplies (other than drugs

and biologicals) are authorized under section 1861(aa)(1)(C) of the Act. These services can be furnished by a registered professional nurse or licensed practical nurse 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.

In § 405.2416, we specify that visiting nurse services are covered if all of the following are met:

- The RHC or FQHC is located in an area in which the Secretary has determined that there is a shortage of HHAs;
- The services are rendered to a homebound individual;
- The services are furnished by a registered professional nurse or licensed practical nurse that is employed by, or receives compensation for the services from the RHC or FQHC;
- The services are furnished under a written plan of treatment that is established and 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. The written plan of treatment must be signed by the supervising physician, NP, PA or CNM of the RHC or FQHC.

Nursing care that is covered by this section includes services that must be performed by a registered professional nurse or licensed practical nurse if the safety of the patient is to be assured and the medically desired results achieved; and personal care services, to the extent covered under Medicare as home health services. These services include helping the patient to bathe, to get in and out of bed, to exercise and to take medications. Household and housekeeping services or other services that would constitute custodial care are not covered.

Section 405.2416 also defines “homebound” as an individual who is permanently or temporarily confined to his or her place of residence because of a medical or health condition, or

if the individual leaves the place of residence infrequently. It does not include a hospital or long term care facility.

In Pub. 100-02, Medicare Benefit Policy Manual, Chapter 13, section 190, we further describe RHC and FQHC visiting nursing services as skilled nursing services that require the skills of a nurse based on the complexity of the service (for example, intravenous and intramuscular injections or insertion of catheters), the condition of the patient (for example, a non-skilled service that, because of the patient's condition, can only be safely and effectively provided by a nurse), and accepted standards of medical and nursing practice. All services must be reasonable and necessary to the diagnosis and treatment of the patient's illness or injury within the context of the patient's unique medical condition, and a service that can be safely and effectively self-administered or performed by a nonmedical person without the direct supervision of a nurse, is not considered a skilled nursing service, even if provided by a nurse. A service which, by its nature, requires the skills of a nurse to be provided safely and effectively continues to be a skilled service even if it is taught to the patient, the patient's family, or other caregivers. If a patient needs skilled nursing care and there is no one trained or able and willing to provide it, the services of a nurse would be reasonable and necessary to the treatment of the illness or injury. We also specify that the determination of whether visiting nurse services are reasonable and necessary is made by the physician based on the condition of the patient when the services were ordered and what is reasonably expected to be appropriate treatment for the illness or injury throughout the certification period.

The requirements for furnishing visiting nursing services include that the patient is considered to be "confined to the home" as defined in section 1835(a) of the Act and that the RHC or FQHC is located in an area that has a shortage of HHAs. The services and supplies must be provided under a written plan of treatment; are furnished on a part-time or intermittent basis only; and drugs and biological products are not provided.

Chapter 13 of the Medicare Benefit Policy Manual, section 190, specifies the requirements for HHA shortage areas for purposes of visiting nursing services furnished by RHCs and FQHCs. The RHC or FQHC must be currently located in a county, parish or similar geographic area in which the Secretary has determined that there is no participating HHA under Medicare; or adequate home health services are not available to RHC or FQHC patients even though a participating HHA is in the area; or, there are patients whose homes are not within the area serviced by a participating HHA; or considering the area's climate and terrain, whose homes are not within a reasonable traveling distance to a participating HHA. RHCs and FQHCs that are located in an area that has not been determined to have a current HHA shortage and are seeking to provide visiting nurse services must make a written request to the appropriate CMS Regional Office along with written justification that the area it serves meets the required conditions.

b. Revision of Home Health Agency Shortage Area Requirements for Furnishing Visiting Nursing Services

To address the PHE for the COVID-19 pandemic and its impact on underserved rural and urban communities, we are implementing, on an interim basis, changes to the requirements for visiting nursing services furnished in the home by RHCs and FQHCs.

Section 405.2416(a)(1) states that visiting nurse services are covered if the RHC or FQHC is located in an area in which the Secretary has determined that there is a shortage of HHAs, and § 405.2417 provides additional requirements for an area to be determined to have a shortage of HHAs. During the PHE for the COVID-19 pandemic, we believe the need for visiting nursing services furnished by RHCs or FQHCs may increase. Therefore, for the duration of the PHE for the COVID-19 pandemic, we are determining that any area typically served by the RHC, and any area that is included in the FQHCs service area plan, is determined to have a shortage of HHAs, and no request for this determination is required.

We believe this flexibility is important for patient access to nursing services in the home

and the potential for HHAs to be overwhelmed during PHE for the COVID-19 pandemic. However, RHCs and FQHCs should check the HIPAA Eligibility Transaction System (HETS) before providing visiting nurse services to ensure that the patient is not already under a home health plan of care. If a patient is under a home health plan of care, the HHA must provide optimal care to achieve the goals and outcomes identified in the patient's plan of care, for each patient's medical, nursing, and rehabilitative needs (§ 484.105). Therefore, RHC/FQHC visiting nurse services would not be covered by Medicare if such services are found to overlap with a 30-day period of home health care. We note that an RHC/FQHC visiting nurse service solely to obtain a nasal or throat culture would not be considered a nursing service because it would not require the skills of a nurse to obtain the culture as the specimen could be obtained by an appropriately-trained medical assistant or laboratory technician. However, during an otherwise covered RHC/FQHC visiting nurse service, the nurse could obtain the nasal or throat culture to send to the laboratory for testing.

Section 405.2416(a)(2) states that visiting nursing services are rendered to a homebound individual, and § 405.2416(d) states that homebound means an individual who is permanently or temporarily confined to his or her place of residence because of a medical or health condition, and that the individual may be considered homebound if he or she leaves the place of residence infrequently. We refer the reader to the definition of “homebound” as it pertains the PHE for the COVID-19 pandemic in section II.F. of this IFC, Clarification of Homebound Status under the Medicare Home Health Benefit.

c. Regulatory Changes

To make available additional visiting nursing services during the PHE for the COVID-19 pandemic in areas served by RHCs and FQHCs, we are revising, on an interim basis, § 405.2416 to add paragraph (a)(5), to state that during the PHE for the COVID-19 pandemic, an area typically served by the RHC, and an area that is included in the FQHC's service area plan, is

determined to have a shortage of HHAs, and no request for this determination is required.

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

In response to the PHE for the COVID-19 pandemic and in an effort to be as expansive as possible within the current authorities to have testing available to Medicare beneficiaries who need it, we are changing Medicare payment policies during the PHE for the COVID-19 pandemic to provide payment to independent laboratories for specimen collection for COVID-19 testing under certain circumstances.

In general, 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), in addition to the amounts provided under the Medicare Clinical Laboratory Fee Schedule (CLFS). Section 1833(h)(3)(A) of the Act provides that the Secretary must establish a nominal fee to cover the appropriate costs in collecting the sample on which a clinical diagnostic laboratory test was performed and for which payment is made under Medicare Part B, except that not more than one such fee may be provided with respect to samples collected in the same encounter. The HCPCS codes for the nominal specimen fees currently listed on the CLFS (HCPCS codes 36415, P9612, and P9615) have a payment rate of \$3. Section 216(a) of the Protecting Access to Medicare Act of 2014 (Pub. L. 113-93, enacted April 1, 2014) added section 1834A(b)(5) to the Act which increases by \$2 the nominal fee that would otherwise apply under section 1833(h)(3)(A) of the Act for a sample collected from an individual in a skilled nursing facility (SNF) or by a laboratory on behalf of an HHA. Therefore, effective April 1, 2014, the nominal fee that would otherwise apply for a sample collected from an individual in a SNF or by a laboratory on behalf of a HHA is \$5 (see § 414.507(f)), and the relevant HCPCS code is G0471.

In addition, section 1833(h)(3)(B) of the Act requires the Secretary to provide for and establish a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample, except that such a fee may be provided only with respect to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital). In accordance with this provision, Medicare established a travel allowance for a laboratory technician to draw a specimen from homebound patients and non-hospital inpatients. Under current guidance, the travel allowance is intended to cover the estimated travel costs of collecting a specimen from a Medicare beneficiary and to reflect the technician's salary and travel costs. It is paid only when the nominal specimen collection is also payable and is not available if the technician is merely performing a messenger service to pick a specimen drawn by a physician or nursing home personnel. The methodology for determining the travel allowance varies depending on the round trip mileage to patients' homes. For instance, a per mile travel allowance methodology applies when the round trip to patients' homes is greater than 20 miles and a flat rate travel allowance methodology applies when the round trip to patients' homes is less than 20 miles. Medicare Part B MACs calculate the travel allowance for each claim. We have heard from stakeholders that in some cases the MAC requires them to maintain paper logs of miles traveled to receive the travel allowance.

CMS' current policies for payment of the nominal specimen collection fee and the fee to cover transportation and expenses for trained personnel to collect specimens from homebound patients and non-hospital inpatients are set forth in Pub. 100-04, Medicare Claims Processing Manual, chapter 16, section 60. We also implemented the increased nominal specimen collection fee under section 1834A(b)(5) of the Act in our regulations at § 414.507(f). The manual instructions regarding payment of these fees are available on the CMS website at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c16.pdf>. Neither the annual cash deductible nor the 20 percent coinsurance for Medicare apply to the

specimen collection fees or travel allowance for laboratory tests.

This IFC is establishing the following changes to the specimen collection fee policy for the duration of the PHE for the COVID-19 pandemic. We 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. Stakeholders have informed us that access to COVID-19 testing in facilities especially is limited due to the resource costs associated with acquiring the samples in a manner that prevents exposure for patients and health care workers. With patients confined to their homes for their own safety or the safety of others, there is an additional need to have patients tested in their homes and minimize exposure to others. We believe that providing a specimen collection fee for COVID-19 testing during the PHE will provide independent laboratories with additional resources to provide this testing and at the same time help with efforts to limit patients' exposure to the general population and alleviate patients' unease with leaving the home.

Under this policy, 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). Our policy will also incorporate the clarification in the definition of homebound as discussed in section II.F. of this IFC, relating to the clarification of homebound status under the Medicare home health benefit.

In establishing a nominal fee for COVID-19 specimen collection, we considered the type of trained laboratory personnel required to collect the specimen and the resources this type of

collection could require. As noted previously, the current specimen collection fee HCPCS codes on the CLFS for homebound and non-hospital inpatients are \$3 and \$5, but we recognize that these fees are not intended to address additional resources needed during the PHE for the COVID-19 pandemic. Absent concrete information regarding the costs associated with independent laboratories collecting such specimens for COVID-19 tests in the context of the PHE, we looked to similar services in other settings of care as a potential benchmark. In looking at other Medicare payment systems, we believe the PFS is the best source for a potential payment amount since physicians and other practitioners often bill for services that involve specimen collection by trained, non-institutional staff.

Under the PFS, a Level 1 office visit (CPT code 99211) typically does not require the presence of a physician or other qualified health care professional and the usual presenting problem(s) are minimal. This code is what is typically reported by physician practices when the patient only sees clinical office staff for services like acquiring a routine specimen sample. CPT code 99211, describes an:

Office visit for E/M of an established patient that may be performed by clinical staff under supervision (may not require a physician's presence). Usually the presenting problem(s) are minimal and typically 5 minutes are spent supervising or performing the service.

The CY 2020 national PFS payment amount for Level 1 established patient office visits is \$23.46 on the PFS. We also considered establishing a higher payment amount that considered the Level 1 E/M visit plus the payment amount for CPT code 89220, Sputum obtaining specimen aerosol induced technique, for a specimen collection fee of \$40.06, but we believe there is likely overlapping costs in staff time for these two services and the Level 1 office visit payment rate is adequate.

For initial diagnostic testing for COVID-19, the CDC issued interim guidelines that

recommend collecting and testing for the virus using an upper respiratory nasopharyngeal swab (NP). The CDC guidance also states that collection of oropharyngeal swabs (OP) is a lower priority and if collected should be combined in the same tube as the NP. The CDC guidance advises that collection of sputum should only be done for those patients with productive coughs. See <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>. Similar collection method types, that is, NP or OP swabs are also used in other laboratory developed tests for COVID-19.

Section 1833(h)(3) of the Act does not specifically describe the types of specimen collection methods that are eligible for the nominal fee and transportation and personnel expenses. However, section 1833(h)(3)(B) of the Act does refer to “trained personnel” that would collect the sample from homebound individuals and inpatients in non-hospital inpatient facilities. This suggests that to be medically necessary and for payment to be made for sample collection, the method of sample collection must require some training or skill on the part of the laboratory technician and cannot be conducted by the beneficiary, the beneficiary’s caregiver, or facility staff if the facility does not have a laboratory, and therefore, is using an outside laboratory to perform its testing of patients. The Medicare Claims Processing Manual provides additional guidance on the medical necessity requirements for specimen collection. Specifically, the manual states that “Medicare allows payment for a specimen collection fee when it is medically necessary for a laboratory technician to draw a specimen from either a nursing home patient or homebound patient” and that “the technician must personally draw the specimen.” It also states that “[t]his fee will not be paid to anyone who has not extracted the specimen” and lists “venipuncture or urine sample by catheterization” as examples of a technician personally drawing the specimen. The manual further clarifies what it means for a specimen collection to be medically necessary stating that “...where the specimen is a type that would require only the services of a messenger and would not require the skills of a laboratory technician, for example,

urine or sputum, a specimen pickup service would not be considered medically necessary.”

We note that venipuncture and urine sample by catheterization are currently provided in the Medicare Claims Processing Manual as examples of a technician personally drawing a specimen, however, they are not an exhaustive list of all possible scenarios that require trained personnel to collect a specimen. In the case of collecting a specimen for COVID-19 testing, we believe that in the context of and for the duration of the PHE for the COVID-19 pandemic, collecting specimens using NP or OP swabs or collection of sputum will require a trained laboratory professional, as well as additional precautions that must be taken to minimize exposure risks in handling specimens that are suspected or confirmed for COVID-19. Thus, we believe that collecting a specimen for COVID-19 testing will incur higher costs than similar specimen collection services which require a trained laboratory professional but not additional precautions, to minimize exposure risks. The CDC advises that specimen collection must be performed correctly the first time the specimen is collected. A focus of the response to the PHE for the COVID-19 pandemic is to quickly identify individuals who are infected so that appropriate treatment for the patients being tested is provided in a timely manner. At the same time, another goal is to appropriately isolate those patients and quarantine those exposed to the patients to prevent further spread of the virus. We believe laboratory personnel will need to be trained on how to handle the specimen to maximize accurate test results for COVID-19. Laboratory personnel also will need to be trained on how to minimize risks for spreading the virus to themselves and/or others in the chain of handling the specimen before it arrives at the laboratory for analysis. The CDC guidance states that specimens should be collected as soon as possible once a person under investigation (PUI) is identified, regardless of the time of symptom onset, and that proper infection control must be maintained when collecting specimens. We believe that specimens for COVID-19 testing using NP, OP, 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 manual currently lists collection of sputum as a type that would require only the services of a messenger, and therefore, is not considered medically necessary. However, for the PHE for the COVID-19 pandemic only, we believe a specimen collection fee for sputum collection would be warranted and medically necessary due to the reasons discussed previously. If in the future other types of COVID-19 tests are available, such as serological tests or point of care tests, we note that the specimen collection fee would apply if the specimen collection method must be performed by trained laboratory personnel. However, COVID-19 tests that allow patients to collect the specimen themselves would not be eligible for the specimen collection fee.

To identify specimen collection for COVID-19 testing, we are establishing 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 a HHA, any specimen source.

We created the second Level II HCPCS code, G2024, because section 1834A(b)(5) of the Act and our 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, as described previously in this section of the IFC. We will issue guidance when the PHE for the COVID-19 pandemic is over and when these codes are no longer valid and terminated in the HCPCS file and/or the CLFS as appropriate.

In addition, Medicare payment for transportation and expenses for trained personnel to

collect specimens from homebound patients (as discussed in section II.F. of this IFC, relating to the clarification of homebound status under the Medicare home health benefit) and inpatients (not in a hospital) for purposes of COVID-19 testing will be made in accordance with existing instructions found in the Medicare Claims Processing Manual. 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. Additionally, we are clarifying that paper documentation of miles traveled is not required and laboratories can maintain electronic logs with that information. However, laboratories will need to be able to produce these electronic logs in a form and manner that can be shared with MACs. As stated previously, we have heard from stakeholders that maintaining paper logs of miles is burdensome, especially with the development of GPS systems and various applications for cellular phones in recent years that can track miles traveled. Thus, we are clarifying that there is no requirement that laboratories maintain logs on paper to document travel, and that laboratories may use digital documentation of this information if preferred. The MACs may provide more information on acceptable formats.

In defining an individual who is homebound for purposes of the specimen collection fee and the travel allowance under section 1833(h)(3) of the Act, the manual refers to Chapters 7 and 15 of Pub. 100-02, the Medicare Benefit Policy Manual. The definition of “homebound” in Chapters 7 and 15 of Pub. 100-02 originate from the statutory definition of “confined to the home” (that is, “homebound”) under sections 1814(a) and 1835(a) of the Act. As discussed in section II.F. of this IFC, relating to the clarification of homebound status under the Medicare home health benefit patients are considered “confined to the home” (that is, “homebound”) if it is medically contraindicated for the patient to leave the home. When it is medically contraindicated for a patient to leave the home, there exists a normal inability for an individual to leave home and leaving home safely would require a considerable and taxing effort.

As an example for the PHE for COVID-19 pandemic, this 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. A patient who is exercising “self-quarantine” for his or her own safety, would not be considered “homebound” unless it is also medically contraindicated for the patient to leave the home. Determinations of whether the patient is homebound must be based on an assessment of each beneficiary’s individual condition. For the PHE for the COVID-19 pandemic, the CDC is currently advising that older adults and individuals with serious underlying health conditions stay home (CDC’s guidance is interim and is expected to continue to be updated as warranted).¹⁴ As such, during the PHE for the COVID-19 pandemic, we expect that many Medicare beneficiaries could be considered “homebound”. In light of this clarification regarding the definition of homebound, we are noting this clarification pertains to the specimen collection fee and travel allowance in 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.

In summary, to address the PHE for the COVID-19 pandemic, we are using this IFC as a vehicle to provide additional payment during the PHE in the form of a specimen collection fee of \$23.46 generally, and \$25.46 for an individual in a SNF or by a laboratory on behalf of a HHA, for COVID-19 testing and to provide a travel allowance for a laboratory technician to collect a specimen for COVID-19 testing from a non-hospital inpatients or homebound patients under

¹⁴ <https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/high-risk-complications.html>.

section 1833(h)(3) of the Act.

N. Requirements for Opioid Treatment Programs (OTP)

In the CY 2020 PFS final rule (84 FR 62645 and 62646), we 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 light of the PHE for the COVID-19 pandemic, during which the public has been instructed to practice self-isolation or social distancing, and because interactive audio-video communication technology may not be available to all beneficiaries, we are revising § 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 for the COVID-19 pandemic if beneficiaries do not have access to two-way audio/video communications technology, provided all other applicable requirements are met. We believe this change is necessary to ensure that beneficiaries with opioid use disorders are able to continue to receive these important services during the current PHE.

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

a. Background

In context of the PHE for the COVID-19 pandemic, we have been asked by stakeholders to relax supervision requirements related to the provision of teaching physician services under the PFS. For teaching physicians, section 1842(b) of the Act specifies that in the case of physicians' services furnished to a patient in a hospital with a teaching program, the Secretary shall not provide payment for such services unless the physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which payment is sought. We have also been asked to

allow residents to independently furnish services in their capacity as fully licensed physicians outside of the scope of their approved GME residency in the inpatient setting of the hospital at which they provide services.

b. Revisions to Teaching Physician Regulations during a PHE for the COVID-19 Pandemic

Regulations regarding PFS payment for teaching physician services and moonlighting are codified in 42 CFR part 415. Under § 415.172, if a resident participates in a service furnished in a teaching setting, PFS payment is made only if the teaching physician is present during the key portion of any service or procedure for which payment is sought. The provisions in § 415.174 exempt certain office/outpatient E/M services provided in the outpatient department of a hospital or another ambulatory care entity (that is, primary care centers) from the physical presence requirement for the key portion of the service, pending all provisions of the regulation are met. The regulations in § 415.180 state that for the interpretation of diagnostic radiology and other diagnostic tests, PFS payment is made if the interpretation is performed or reviewed by a physician other than a resident. For § 415.184, the requirement for the presence of the teaching physician during psychiatric services in which a resident is involved may be met by observation of the service by use of a one-way mirror, video equipment, or similar device.

In context of the PHE for the COVID-19 pandemic, teaching hospitals have expressed a need to increase their capacity to respond to the PHE for the COVID-19 pandemic because there has been increased demand for physicians to respond to patient needs. For example, we have been asked by stakeholders to allow Medicare to make payment under the PFS for services billed by teaching physicians when residents have furnished the entirety of a service in the inpatient setting in the area of their approved GME program and have a teaching physician review and sign off on the service, rather than requiring the teaching physician be physically present for the key portion of the service.

Given the circumstances of the PHE for the COVID-19 pandemic, we believe that the requirements for the physical presence of the teaching physician during the key portion of the service would necessarily limit access to services paid under the PFS. We recognize that in some cases, the physical proximity of the physician might present additional exposure risks, especially for high risk patients isolated for their own protection or in cases where the teaching physician and/or the resident has been exposed to the virus and must be under quarantine, or who may be at home caring for family members or providing childcare. If the teaching physician and/or the resident is under quarantine or at home, it could unintentionally limit the number of licensed practitioners available to furnish services to Medicare patients and could have the unintended consequence of limiting access to services paid under the PFS.

To increase the capacity of teaching settings to respond to the PHE for the COVID-19 pandemic as more practitioners are increasingly being asked to assist with the COVID-19 response, on an interim basis, for the duration of the PHE for the COVID-19 pandemic, we are amending 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, at a minimum, through direct supervision by interactive telecommunications technology, as described in section II.E. of this IFC. In other words, the teaching physician must provide supervision either with physical presence or be present through interactive telecommunications technology during the key portion of the service. Specifically, we believe that when use of such real-time, audio and video telecommunications technology allows for the teaching physician to interact with the resident through virtual means, their ability to furnish assistance and direction could be met without requiring the teaching physician's physical presence for the key portion of the service.

Currently, under the primary care exception in § 415.174, certain lower and mid-level office/outpatient E/M services provided in primary care centers are exempt from the physical presence requirement for the key portion of the service. The teaching physician must direct the

care from such proximity as to constitute immediate availability (that is, provide direct supervision). In context of the PHE for the COVID-19 pandemic, the teaching physician may be under quarantine or otherwise at home, or the physical proximity of the teaching physician might present additional exposure risks. Additionally, during the PHE for the COVID-19 pandemic, more patients may present with more complex needs, such as an underlying condition that places them at high risk for COVID-19 and that necessitate a high level office/outpatient E/M service (that is, level 4 or 5 visit). Consequently, on an interim basis, for the duration of the PHE for the COVID-19 pandemic, we are amending § 415.174 to allow that all levels of an office/outpatient E/M service provided in primary care centers may be provided under direct supervision of the teaching physician by interactive telecommunications technology. We believe use of real-time, audio and video telecommunications technology allows for the teaching physician to interact with the resident through virtual means, and thus would meet the requirement for teaching physician presence for office/outpatient E/M services furnished in primary care centers. For § 415.180, for the duration of the PHE for the COVID-19 pandemic, we 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. The teaching physician must still review the resident's interpretation. For § 415.184, for the duration of the PHE for the COVID-19 pandemic, the requirement for the presence of the teaching physician during the psychiatric service in which a resident is involved may be met by the teaching physician's direct supervision by interactive telecommunications technology. For both §§ 415.180 and 415.184, allowing residents to furnish these services under direct supervision of the teaching physician by interactive telecommunications technology would allow for the presence requirement to be met. These diagnostic radiology, diagnostic tests, and psychiatry services could continue to be provided to patients that need them in the event the teaching physician is in quarantine or

otherwise at home, or where the physical proximity of the teaching physician might present additional exposure risk.

The regulations describing PFS payment for teaching physician services do have additional exceptions for specific policies. For example, as described in § 415.172, in the case of surgical, high-risk, or other complex procedures, the teaching physician must be present during all critical portions of the procedure and immediately available to furnish services during the entire service or procedure. In the case of procedures performed through an endoscope, the teaching physician must be present during the entire viewing. As described in § 415.178 for anesthesia services, the teaching anesthesiologist must be present during all critical or key portions of the anesthesia service or procedure involved and the teaching anesthesiologist must be immediately available to furnish anesthesia services during the entire procedure. Given the complex nature of these procedures and the potential danger to the patient, even in the context of the PHE for the COVID-19 pandemic and the inherent exposure risks for patients and physicians, we believe that the requirements for physical presence for either the entire procedure or the key portions of the service, whichever are applicable, are necessary for patient safety. Thus, the PHE for the COVID-19 pandemic exceptions previously described will not apply in the case of surgical, high risk, interventional, or other complex procedures, services performed through an endoscope, and anesthesia services. We seek comment on whether other procedures should also be exempt from this policy given the complex nature or potential danger to the patient.

Collectively, 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. They are also intended to minimize the number of people coming into contact with one another by removing the need for in-person direct supervision. We view direct supervision by interactive telecommunications technology as the minimum requirement for provision of the service for

purposes of Medicare payment. However, teaching physicians may continue to exercise their clinical judgment to decide whether it is appropriate to utilize these flexibilities in furnishing their services involving residents. We also seek comment on our belief that direct supervision by interactive telecommunications technology is appropriate in the context of this PHE, as well as whether any guardrails should be included, and how it balances risks that might be introduced for beneficiaries with reducing exposure risk and the increased spread of the disease, in the context of this PHE.

c. Application of the Expansion of Telehealth Services to Teaching Physician Services

On March 17, 2020, we announced the expansion of telehealth services on a temporary and emergency basis pursuant to waiver authority added under section 1135(b)(8) by the Coronavirus Preparedness and Response Supplemental Appropriations Act¹⁵. Starting on March 1, 2020, Medicare can pay for telehealth services, including office, hospital, and other visits furnished by physicians and other practitioners to patients located anywhere across the country including in a patient's place of residence. We have been asked by stakeholders to clarify whether this expansion applies to teaching physician services, including those furnished under the primary care exception. We believe that allowing Medicare payment for services billed by the teaching physician when the resident is furnishing services, including office/outpatient E/M services provided in primary care centers, via telehealth under direct supervision by interactive telecommunications technology would allow residents to furnish services remotely to patients who may need to be isolated for purposes of exposure risk based on presumed or confirmed COVID-19 infection, and as a result, would increase access to services for patients. To increase the capacity of teaching settings to respond to the PHE for the COVID-19 pandemic as more practitioners are increasingly being asked to assist with the COVID-19 response, we believe that,

¹⁵ <https://www.cms.gov/newsroom/press-releases/president-trump-expands-telehealth-benefits-medicare-beneficiaries-during-covid-19-outbreak>.

for telehealth services involving residents, the requirement that a teaching physician be present for key portions of the service can be met through virtual means. We also believe same is true for telehealth services furnished by the resident in primary care centers. The use of of real-time, audio and video telecommunications technology allows for the teaching physician to interact with the resident through virtual means while the resident is furnishing services via telecommunications technology, and thus, in the circumstances of the PHE, would meet the requirement for teaching physician presence for office/outpatient E/M services furnished in primary care centers. Consequently, on an interim basis for the duration of the PHE for the COVID-19 pandemic, we are revising our regulations to specify that Medicare may make payment under the PFS for teaching physician services when a resident furnishes telehealth services to beneficiaries under direct supervision of the teaching physician which is provided by interactive telecommunications technology. Additionally, on an interim basis, for the duration of the PHE for the COVID-19 pandemic, Medicare may make payment under the PFS for services billed under the primary care exception by the teaching physician when a resident furnishes telehealth services to beneficiaries under the direct supervision of the teaching physician by interactive telecommunications technology. We also seek comment on our belief that direct supervision by interactive telecommunications technology is appropriate in the context of this PHE, as well as whether and how it balances risks that might be introduced for beneficiaries with reducing exposure risk and the increased spread of the disease, in the context of this PHE.

d. Payment under the PFS for Teaching Physician Services when Resident under Quarantine

There also may be circumstances in which the resident may need to furnish services while under quarantine (for example, while at home). We have been asked by stakeholders if residents who have been exposed to COVID-19 and are under quarantine, and otherwise well and able to work, are able to furnish services that do not require face-to-face patient care, such as reading the results of tests and other imaging studies. Because current regulations require the

physical presence of the teaching physician during the key portion of the service, residents would not be able to furnish services from quarantine, which could limit the number of licensed practitioners available to furnish services to Medicare patients and could have the unintended consequence of limiting access to services paid under the PFS. Because we are amending 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, on an interim basis, for the duration of the PHE for the COVID-19 pandemic, Medicare may also make payment under the PFS for teaching physician services when the resident is furnishing these services while in quarantine under direct supervision of the teaching physician by interactive telecommunications technology. We believe this policy will limit exposure to COVID-19 and to allow for the continued access to physicians' services of residents while in quarantine.

e. 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. Under current regulations, the services of residents in hospitals in which the residents have their approved GME program are not considered separately billable as physicians' services and instead are payable under §§ 413.75 through 413.83 regarding direct GME payments, whether or not the services are related to the approved GME training program. When a resident furnishes services that are not related to their approved GME programs in an outpatient department or emergency department of a hospital in which they have their training program, those services can be billed separately as physicians' services and payable under the PFS if they meet the criteria described in our regulation at § 415.208(b)(2).

In light of the PHE for the COVID-19 pandemic, teaching hospitals need to secure as much physician coverage as possible because there has been increased demand for physicians to

respond to patient needs, such as furnishing services to patients in inpatient settings who have either a presumed or confirmed COVID-19 infection. Stakeholders have requested that residents be able to furnish physicians' services to patients in the inpatient setting outside of the scope of their approved GME programs in the hospital where they have their training.

We believe that our regulation at § 415.208(b), which limits the scope of services that can be separately billable by moonlighting residents when furnished outside their approved GME programs to patients in an outpatient department or emergency department of a hospital in which they have their training program, does not adequately meet the needs of teaching hospitals to ensure there are as many qualified practitioners available as possible given the circumstances of the PHE for the COVID-19 pandemic. Under current policy, for example, a resident in a hospital's approved GME program for anesthesia who typically furnishes only anesthesia-related services in an operating room would not be able to provide separately billable physicians' services when treating inpatients in the intensive care unit for COVID-19 infection, even if these services were not part of the resident's approved GME program. As a result, this regulation could unintentionally limit the number of licensed practitioners available to furnish services to Medicare patients and could have the unintended consequence of limiting access to critically needed care. Consequently, on an interim basis, for the duration of the PHE for the COVID-19 pandemic, we are amending our regulation in § 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 for which payment can be made under the PFS provided that the services are identifiable physicians' services and meet the conditions of payment for physicians' services to beneficiaries in 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(d))

In the June 16, 2016 **Federal Register**, we published the “Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care” proposed rule (81 FR 39447), which outlined a number of proposed hospital and CAH Condition of Participation (CoP) requirements, including those focused on infection control, antibiotic use, and scope of practice for NPPs (that is, advanced practice providers (APPs) such as PAs, NPs, psychologists, and CNSs, as well as other qualified, licensed practitioners to whom this revision might also be applicable).

Subsequently, in the September 30, 2019 **Federal Register**, we published the “Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care” final rule (84 FR 51775) that finalized several of these proposed changes to modernize the hospital and CAH requirements, improve quality of care, and support HHS and CMS priorities. In that final rule, we deleted the modifying term “independent” from the Patient’s Rights CoP at 42 CFR 482.13(e)(5) and (e)(8)(ii) regarding which practitioners may order the use of restraints and seclusion. These revisions to the regulatory text were intended to finally make the language of the hospital CoPs consistent with the language of the Children’s Health Act of 2000 (CHA) (Pub. L. 106-310, enacted October 17, 2000) regarding restraint and seclusion orders and licensed practitioners, and upon which the CoP language was originally intended to be based. Additionally, and to remain consistent throughout this CoP, we revised § 482.13(e)(10), (e)(11), (e)(12)(i)(A), (e)(14), and (g)(4)(ii) that contained the term “licensed independent practitioner” by changing the term from “licensed independent practitioner” to simply “licensed practitioner.”

In the final rule, we stated that the revision reflected our goal to have health professionals operate within the scope of practice allowed by state law, and that it also recognized the need to fully utilize the healthcare workforce. We also stated that we believe that this change will reduce

unnecessary burden for hospitals and remove obstacles APPs face when ordering seclusion and restraints. However, we stated that we disagreed with the commenters who stated that the removal of the term “independent” will cause confusion over the applicability of this requirement. Our removal of the term “independent” is consistent with the language used in the CHA, which utilizes the term “other licensed practitioner,” without the independent modifying term. In addition, the order of restraint or seclusion must be ordered by a licensed practitioner who is authorized by hospital policy in accordance with State law to do so.

In the September 30, 2019 final rule, we made additional revisions to address other areas of the hospital CoPs that we viewed as being either conflicting with, or more stringent than, existing state scope-of-practice laws and licensing requirements, and which, if appropriately revised, would give APPs greater flexibility to practice more broadly in the current healthcare system while still being in accordance with respective state scope-of-practice laws.

Therefore, in our review of the Hospital CoPs for the proposed rule, we discovered that there were several provisions that incorrectly reference § 482.12(c)(1), which lists the types of physicians and applies only to patients who are Medicare beneficiaries. Section 482.12(c) states that the governing body of the hospital must ensure that every Medicare patient is under the care of one of the following practitioners:

- A doctor of medicine or osteopathy;
- A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his or her license;
- A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform;
- A doctor of optometry who is legally authorized to practice optometry by the State in which he or she practices;

- A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by X-ray to exist; and
- A clinical psychologist as defined in § 410.71 of this chapter, but only for a clinical psychologist services as defined in § 410.71 of this chapter and only to the extent permitted by State law.

The reference of this “Medicare beneficiary-only” requirement in certain other provisions of the hospital CoPs (which we have listed below) inappropriately links it to *all* patients and not Medicare beneficiaries exclusively. In fact, per section 1861(e)(4) of the Act, every patient with respect to whom payment may be made under this title must be under the care of a physician except that a patient receiving qualified psychologist services (as defined in subsection (ii)) may be under the care of a clinical psychologist with respect to such services to the extent permitted under State law. In accordance with that provision, we have chosen to apply § 482.12(c) to Medicare patients. With the exception of a few provisions in the CoPs such as those directly related to § 482.12(c) described here, the remainder of the CoPs apply to all patients, regardless of payment source, and not just Medicare beneficiaries. For example, the Nursing Services CoP, at § 482.23(c)(1), requires that all drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under § 482.12(c), and accepted standards of practice. Since the CoPs clearly allow hospitals to determine which categories of practitioners would be responsible for the care of other patients, outside the narrow Medicare beneficiary restrictions of § 482.12(c), this reference is inappropriate and unnecessarily restrictive of hospitals and their medical staffs to make these determinations based on State law and practitioner scope of practice.

To clarify that these provisions apply to all patients and not only Medicare beneficiaries, we deleted any inappropriate references to § 482.12(c) in the final rule. Therefore, we deleted references to § 482.12(c) found in the following provisions: § 482.13(e)(5), (e)(8)(ii), (e)(14), and (g)(4)(ii) in the Patients' Rights CoP; and § 482.23(c)(1) and (c)(3) in the Nursing Services CoP. We note here that we did not receive any comments on these changes as they proposed in the June 2016 proposed rule, and therefore, we finalized them without change.

In performing our most recent review of the hospital CoPs, including the Requirements for Specialty Hospitals at subpart E of 42 CFR part 482, we discovered that we inadvertently failed to propose 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 current provision also contains the term "licensed independent practitioner." Therefore, in the interests of consistency with the other recent revisions we have noted here, we are now deleting the reference to § 482.12(c) along with the modifier "independent" in this IFC.

We believe that as currently written and implemented, this requirement requires some clarification for the reasons that we have discussed. As we have already stated and made clear through our recent revisions to the hospital CoPs, we believe that 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.

We believe that NPPs practicing in the psychiatric hospital setting should be able to record progress notes of psychiatric patients for whom they are responsible. Therefore, we 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.

Given the changes made to the requirements under § 482.13 regarding the removal of the word “independent” from the phrase “licensed independent practitioner” when referencing NPPs that we have previously discussed, we are making the same change for this provision. We believe that the regulatory language should be as consistent as possible throughout the hospital CoPs and, in addition, as was the case with the requirement under § 482.13, 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 to the highest levels of their training, education, and experience as allowed by hospital policy in accordance with state law. We believe that this change permits a greater scope of practice for these professionals in the psychiatric hospital context.

Q. Innovation Center Models

1. Medicare Diabetes Prevention Program (MDPP) expanded model Emergency Policy

Through this IFC, we are amending the Medicare Diabetes Prevention Program (MDPP) expanded model to modify certain MDPP policies during the PHE. Specifically, this IFC will permit certain beneficiaries to obtain the set of MDPP services more than once per lifetime, increase the number of virtual make-up sessions, and allow certain MDPP suppliers to deliver virtual MDPP sessions on a temporary basis. These changes are in response to COVID-19, which resulted in an interruption to expanded model services delivered by MDPP suppliers and/or prevented MDPP beneficiaries from attending sessions. Throughout the rulemaking for the MDPP expanded model, we sought to ensure that the MDPP set of services would be delivered in-person, in a classroom based setting, within an established timeline. At the time, the priority

was placed on establishing a structured service that, when delivered within the confines of the rule, would create the least risk of fraud and abuse, increase the likelihood of success, and maintain the integrity of the data collected for evaluation purposes. However, the COVID-19 pandemic has led to suspension of in-person class sessions and guidance from CDC that Medicare-age beneficiaries stay home. In response, we will implement provisions that allow for temporary flexibilities that prioritize availability and continuity of services for MDPP suppliers and MDPP beneficiaries impacted by extreme and uncontrollable circumstances during the COVID-19 PHE. The changes in this IFC are applicable to MDPP suppliers, as defined in § 410.79(b), that are enrolled in MDPP as March 1, 2020, and MDPP beneficiaries as defined in § 410.79(b) who were receiving MDPP set of services as of March 1, 2020. Under these temporary flexibilities, the requirement for in-person attendance at the first core-session will remain in effect. As a result, if beneficiaries are prohibited from attending the first core session in person, suppliers will be unable to start any new cohorts with MDPP beneficiaries. All flexibilities described in this IFC will cease to be available at the conclusion of the PHE. The CDC issued guidance to all National Diabetes Prevention Program suppliers on or about March 12, 2020, providing alternative delivery options during the COVID-19 national emergency, including encouraging organizations to use virtual make-up sessions as necessary, regardless of usual delivery mode; if virtual make-up sessions are not possible, organizations may pause offering classes. When classes resume, the CDC is allowing suppliers to pick up where they left off, or to restart the expanded model program from week one. It is our intent to conform with the CDC guidance where feasible, with the overall intent to minimize disruption of services for MDPP suppliers and MDPP beneficiaries; by allowing MDPP beneficiaries to maintain their eligibility. We are amending the MDPP regulations to provide for certain changes, including allowing MDPP suppliers to either deliver MDPP services virtually or suspend in-person services and resume services at a later date. The limit to the number of virtual make-up sessions is waived for

MDPP suppliers with existing capabilities to provide services virtually, so long as the virtual services are furnished in a manner that is consistent with the CDC Diabetes Prevention Recognition Program (DPRP) standards for virtual sessions, follow the CDC-approved DPP curriculum requirements, and are provided upon the individual MDPP beneficiary's request. In addition, the MDPP supplier may only furnish to the MDPP beneficiary a maximum of one session on the same day as a regularly scheduled session and a maximum of one virtual make-up session per week. Virtual make-up sessions may only be furnished to achieve attendance goals and may not be furnished to achieve weight-loss goals. An MDPP supplier may offer to an MDPP beneficiary no more than: 15 virtual make-up sessions offered weekly during the core session period; 6 virtual make-up sessions offered monthly during the core maintenance session interval periods; and 12 virtual make-up sessions offered monthly during the ongoing maintenance session interval periods.

In addition, these changes permit certain MDPP beneficiaries to obtain the set of MDPP services more than once per lifetime, for the limited purposes of allowing a pause in service and to provide the flexibilities that will allow MDPP beneficiaries to maintain eligibility for MDPP services despite a break in service, attendance, or weight loss achievement.

We are amending our provisions at § 410.79 by adding paragraph (e).

2. Changes to the Comprehensive Care for Joint Replacement (CJR) Model to Extend the Length of Performance Year 5 by Three Additional Months and to Change the Extreme and Uncontrollable Circumstances Policy to Account for the COVID-19 Pandemic

Through this IFC, we are implementing two changes to the Comprehensive Care for Joint Replacement (CJR) model to support the continuity of model operations and to ensure that CJR participants do not unfairly suffer financial consequences from the impact of COVID-19 due to their participation in CJR. Specifically, we are implementing a 3-month extension to CJR performance year (PY) 5 such that the model will now end on March 31, 2021, rather than

ending on December 31, 2020. On February 24, 2020, we published a proposed rule titled “Medicare Program: Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing” (85 FR 10516). We wish to ensure continuity of CJR model operations in participant hospitals during this PHE for the COVID-19 pandemic so that we do not create any additional disruptions to the standard care procedures hospitals have in place during this challenging time. Therefore, we are implementing a 3-month extension of CJR PY 5 and amending the provisions at 42 CFR 510.2 and 510.200(a) to reflect that extension.

Further, recognizing that the current CJR model policy for extreme and uncontrollable circumstances policy is not applicable to the PHE for the COVID-19 pandemic, we also are implementing a change to that policy in this IFC such that it will be applicable to episodes impacted by the COVID-19 pandemic. Currently, the CJR extreme and uncontrollable circumstances policy, which is codified at § 510.305(k), applies only during major disaster declarations where a participant hospital and its beneficiaries are affected by natural disasters, such as, hurricanes, earthquakes, wildfires.¹⁶ Although the COVID-19 outbreak in the United States was declared as a national emergency on March 13, 2020,¹⁷ the current CJR extreme and uncontrollable circumstances policy does not apply to this national emergency. Although we do not expect many new CJR episodes to initiate as we have recently issued guidance¹⁸ stressing the need to avoid elective surgeries in light of the COVID-19 virus, we recognize that a number of beneficiaries are in active CJR episodes that initiated prior to March 2020. Further, we acknowledge that CJR hip fracture episodes, which generally result from emergent accidents and are not necessarily avoidable, will continue to occur. Given the challenges to the health care delivery system in responding to COVID-19 cases and the expenses associated with treating this

¹⁶ 82 FR 57066.

¹⁷ See: <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

¹⁸ See: <https://www.cms.gov/files/document/31820-cms-adult-elective-surgery-and-procedures-recommendations.pdf>.

highly contagious virus, we want to avoid inadvertently creating incentives to place cost considerations above patient safety within the CJR model during this COVID-19 pandemic. Therefore, to enable the CJR model to adjust for the effect of COVID-19, we are broadening the extreme and uncontrollable circumstances policy by applying certain financial safeguards to participant hospitals that have a CCN primary address that is located in an emergency area for episodes that overlap with the emergency period, as those terms are defined in section 1135(g) of the Act, for which the Secretary issued a waiver or modification of requirements under section 1135 of the Act on March 13, 2020, which applies nationwide.¹⁹ Accordingly, all participant hospitals are located in the emergency area and qualify for applicable financial safeguards during the emergency period.

Amending the extreme and uncontrollable circumstances policy to account for all participant hospitals affected by the COVID-19 pandemic allows participant hospitals to concentrate on patient care and ensures that participant hospitals are not held financially liable for episode costs that escalate due to effects from the COVID-19 pandemic. While this amendment greatly broadens the extreme and uncontrollable circumstances policy, the significant impact the health care delivery system faces in responding to COVID-19 cases and the expenses associated with treating this highly-contagious virus justifies modifying the extreme and uncontrollable circumstances policy and increasing the financial safeguards. Specifically, we are stating that for a fracture or non-fracture episode with a date of admission to the anchor hospitalization that is on or within 30 days before the date that the emergency period (as defined in section 1135(g) of the Act) begins or that occurs through the termination of the emergency period (as described in section 1135(e) of the Act), actual episode payments are capped at the target price determined for that episode under § 510.300. Though different financial safeguards

¹⁹ See <https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx>.

apply for fracture and non-fracture episodes when a major disaster declaration is declared, we believe applying equal financial safeguards for both episodes during the COVID-19 pandemic is more appropriate due to its nationwide impact on hospitals and post-acute care facilities ability to provide care for beneficiaries during this PHE.

We are codifying these provisions at § 510.305 (k)(3) and (4).

3. Alternative Payment Model treatment under the Quality Payment Program

As has been described previously in this IFC, we are seeking to give entities and individuals that provide services to Medicare beneficiaries needed flexibilities to respond effectively to the serious public health threats posed by the spread of the COVID-19, and to address the needs of health care providers specific to this declared national emergency. We further recognize that flexibilities may be necessary and appropriate in the context of Alternative Payment Models (APMs), including applicable model tests conducted under section 1115A of the Act by the CMS Center for Medicare and Medicaid Innovation (Innovation Center), as well as the Medicare Shared Savings Program. We note that aspects of APM policies under the Quality Payment Program are designed to follow on from the specific designs, policies, and operations of individual APMs. We recognize that our current regulations may be insufficient for purposes of adequately responding to the still-emerging COVID-19 national emergency and that additional action may be necessary and appropriate to prevent APM participants from facing undue burden in or negative consequences through the Quality Payment Program.

We acknowledge that possible changes might be needed to address issues that may arise for APM participants in light of the current emergency. We will consider undertaking additional rulemaking, including possibly another interim final rule, to amend or suspend APM QPP policies as necessary to ensure accurate and appropriate application of Quality Payment Program policies in light of the PHE due to COVID-19.

R. Remote Physiologic Monitoring

In recent years, we have finalized payment for seven CPT codes in the Remote Physiologic Monitoring (RPM) code family. We finalized payment in the CY 2018 PFS final rule for CPT code 99091 (*Collection and interpretation of physiologic data digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation requiring a minimum of 30 minutes of time*). The following year, we finalized payment for CPT codes 99453 (*Remote monitoring of physiologic parameter(s)(e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment*), 99454 (*Remote monitoring of physiologic parameter(s)(e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days*), and 99457 (*Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes*). Most recently, for the CY 2020 PFS final rule (84 FR 62645 and 62646), we finalized a treatment management add-on code (CPT code 99458 *Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes*) and two self-measured blood pressure monitoring codes, CPT code 99473 (*Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration*) and CPT code 99474 (*Separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient*).

We are concerned that under the PHE for the COVID-19 pandemic, physicians and other health care professionals are faced with challenges regarding potential exposure risks for themselves and their patients. In response, the CDC has urged health care professionals to make every effort to interview patients by telephone, text monitoring, or video conferencing instead of in-person. We believe that RPM services support the CDC's goal of reducing human exposure to the novel coronavirus while also increasing access to care and improving patient outcomes.

RPM services are considered to be CTBS and, as such, would be billable only for established patients. Our goal during the PHE for the COVID-19 pandemic is to reduce exposure risks to the novel coronavirus for practitioners and patients and to increase access to services by eliminating as many obstacles as possible to delivering necessary services. Allowing RPM services to be furnished only to established patients could be an obstacle to delivery of reasonable and necessary care particularly during current conditions. Thus, in response to the PHE for the COVID-19 pandemic, we are finalizing on an interim basis, that RPM services can be furnished to new patients, as well as to established patients.

In addition to current policy that there be an established patient-practitioner relationship, we require for CTBS at least verbal consent from a Medicare beneficiary to receive the services. We finalized this requirement to avoid scenarios where beneficiaries are unexpectedly responsible for copays for services that do not involve the typical in-person, face-to-face service that a patient receives during an office visit. We continue to believe that patient consent is important. However, we also believe that acquiring patient consent should not interfere with the provision of RPM services during the PHE for the COVID-19 pandemic. Therefore, we are finalizing on an interim basis that consent to receive RPM services can be obtained once annually, including at the time services are furnished, during the duration of the PHE for the COVID-19 pandemic. However, to enhance beneficiary protection, for both new and established patients, we suggest that the physician or other health care practitioner review

consent information with a beneficiary, obtain the beneficiary's verbal consent, and document in the medical record that consent was obtained.

Finally, we are clarifying that RPM codes can be used for physiologic monitoring of patients with acute and/or chronic conditions. The typical patient needing RPM services may have a chronic condition (for example, high blood pressure, diabetes, COPD). However, RPM can be used for other conditions. For example, RPM services allow a patient with an acute respiratory virus to monitor pulse and oxygen saturation levels using pulse oximetry. Nurses, working with physicians, can check-in with the patient and then using patient data, determine whether home treatment is safe, all the while reducing exposure risk and eliminating potentially unnecessary emergency department and hospital visits.

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

For CY 2008, the CPT Editorial Panel created CPT codes to describe E/M services furnished by a physician or qualified healthcare professional via telephone or online, including CPT codes 98966 (*Telephone assessment and management service provided by a qualified nonphysician health care professional to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion*), 98967 (*Telephone assessment and management service provided by a qualified nonphysician health care professional to an established patient, parent, or guardian not originating from a related assessment and management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion*), 98968 (*Telephone assessment and management service provided by a qualified nonphysician health care professional to an established patient, parent, or guardian not originating from a related assessment and*

management service provided within the previous 7 days nor leading to an assessment and management service or procedure within the next 24 hours or soonest available appointment; 21-30 minutes of medical discussion), 99441 (Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion), 99442 (Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 11-20 minutes of medical discussion), and 99443 (Telephone evaluation and management service by a physician or other qualified health care professional who may report evaluation and management services provided to an established patient, parent, or guardian not originating from a related E/M service provided within the previous 7 days nor leading to an E/M service or procedure within the next 24 hours or soonest available appointment; 21-30 minutes of medical discussion). We assigned a status indicator of “N” (Noncovered) to these services because: (1) These services are non-face-to-face; and (2) the code descriptors include language that recognizes the provision of services to parties other than the beneficiary for whom Medicare does not provide coverage (for example, a guardian).

We do not believe that we should continue to consider these to be categorically non-covered services. In PFS rulemaking subsequent to CY 2008, we established separate payment for numerous non-face-to-face services, including care management services and prolonged non-face-to-face E/M services. We have also noted, for example in CY 2017, that we recognize that in current medical practice, practitioner interaction with caregivers is an integral part of

treatment for some patients. Accordingly, the descriptions for several payable codes under the PFS include direct interactions between practitioners and caregivers (81 FR 80331).

When we established separate payment for services like virtual check-ins and e-visits, we recognized that non-face-to-face services had become an important part of overall physician care of Medicare beneficiaries, especially relative to care for chronic conditions. The current Medicare policy regarding the CPT codes that describe telephone E/M services predated our ongoing recognition of the need to pay separately for these kinds of services. Despite the fact that these are classified as E/M services in the coding, we do not believe that these codes describe full E/M services, but rather are closely analogous to the virtual check-in services. Although we assigned a “Noncovered” status indicator for the telephone E/M codes, we still established the American Medical Association’s RUC-recommended RVUs for them. To establish the payment rate for the virtual check-in service, we used the RUC-recommended valuation for the lowest level telephone E/M code. However, the telephone E/M codes provide additional stratification by time for circumstances when a practitioner spends more than a brief amount of time in direct communication with the patient. We believe that under ordinary circumstances outside of the PHE, if the needs of the patient are significant enough to require the amount of time and attention from the practitioner specified in the codes for higher level telephone evaluations or assessments, either an in-person visit or a telehealth visit would be required. Alternatively, if the needs of the patient are less acute and lengthy, a virtual check-in would suffice. However, in the context of the goal of reducing exposure risks associated with the PHE for the COVID-19 pandemic, especially in the case that two-way, audio and video technology required to furnish a Medicare telehealth service might not be available, we believe there are many circumstances where prolonged, audio-only communication between the practitioner and the patient could be clinically appropriate yet not fully replace a face-to-face visit. We believe that the existing telephone E/M codes, in both description and valuation, are

the best way to recognize the relative resource costs of these kinds of services. Therefore, we are finalizing, on an interim basis for the duration of the PHE for the COVID-19 pandemic, separate payment for CPT codes 98966-98968 and CPT codes 99441-99443. For these codes, we are finalizing on an interim basis for the duration of the PHE for the COVID-19 pandemic, work RVUs as recommended by the AMA Health Care Professionals Advisory Committee (HCPAC) for CY PFS 2008 rulemaking as discussed in the CY 2008 PFS final rule (72 CFR 66371) of 0.25 for CPT code 98966, 0.50 work RVUs for CPT code 98967, and 0.75 for CPT code 98968, and work RVUs as recommended by the AMA Relative Value Scale Update Committee (RUC) of 0.25 for CPT code 99441, 0.50 for CPT code 99442, and 0.75 for CPT code 99443. We are finalizing the HCPAC and RUC-recommended direct PE inputs which consist of 3 minutes of post-service RN/LPN/MTA clinical labor time for each code.

Similar to the CTBS described in section II.D. of this IFC, we believe it is important during the PHE to extend these services to both new and established patients. While some of the code descriptors refer to “established patient,” during the PHE we are exercising enforcement discretion on an interim basis to relax enforcement of this aspect of the code descriptors. Specifically, we will not conduct review to consider whether those services were furnished to established patients. CPT codes 98966-98968 described assessment and management services performed by practitioners who cannot separately bill for E/Ms. We are noting that these services may be furnished by, among others, LCSWs, clinical psychologists, and physical therapists, occupational therapists, and speech language pathologists when the visit pertains to a service that falls within the benefit category of those practitioners.

To facilitate billing of these services by therapists, we are designating CPT codes 98966-98968 as CTBS “sometimes therapy” services that would require 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

Non-surgical extended duration therapeutic services (NSEDTS) describe services that have a significant monitoring component that can extend for a sizable period of time, that are not surgical, and that typically have a low risk of complications after the assessment at the beginning of the service. The minimum default supervision level of NSEDTS was established in the CY 2011 OP/ASC final rule with comment period (75 FR 72003 through 72013) as being direct supervision during the initiation of the service, which may be followed by general supervision at the discretion of the supervising physician or the appropriate NPP (§ 410.27(a)(1)(iv)(E)). In this case, initiation means the beginning portion of the NSEDTS which ends when the patient is stable and the supervising physician or the appropriate NPP determines that the remainder of the service can be delivered safely under general supervision. We established general supervision as the appropriate level of supervision after the initiation of the service because it is challenging for hospitals to ensure direct supervision for services with an extended duration and a significant monitoring component, particularly for CAHs and small rural hospitals.

In the CY 2020 OP/ASC final rule with comment period (84 FR 61359 through 61363), we changed the generally applicable minimum required level of supervision for most hospital outpatient therapeutic services from direct supervision to general supervision for hospitals and CAHs. Given the circumstances of the PHE for the COVID-19 pandemic, we believe it is critical that hospitals have the most flexibility as possible to provide the services Medicare beneficiaries need during this challenging time. Changing the minimum default level of supervision to general supervision for NSEDTS during the initiation of the service will give providers additional flexibility they will need to handle the burdens created by the PHE for the COVID-19 pandemic.

Therefore, we are assigning, on an interim basis, all outpatient hospital therapeutic services that fall under § 410.27(a)(1)(iv)(E), a minimum level of general supervision to be consistent with the minimum default level of general supervision that applies for most outpatient hospital therapeutic services, and we are revising § 410.27(a)(1)(iv)(E) to reflect this change in the minimum level of supervision. General supervision, as defined in our regulation at § 410.32(b)(3)(i) means that the procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure.

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

National Coverage Determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under Title XVIII. Local Coverage Determinations (LCDs) are determinations by a Medicare Administrative Contractor (MAC) with respect to whether or not a particular item or service is covered under section 1862(a)(1)(A) of the Act in the particular MAC's geographical areas. Articles are often published alongside LCDs and contain coding or other guidelines that complement an LCD. NCDs and LCDs contain clinical conditions a patient must meet to qualify for coverage of the item or service. Some NCDs and LCDs may also 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 the item or service. These requirements are more often present in NCDs and LCDs for durable medical equipment than for other items and services.

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

For the duration of this PHE for the COVID-19 pandemic, it is in the best interest of patients, health care professionals and suppliers to limit face-to-face encounters and avoid exposure of vulnerable Medicare beneficiaries to COVID-19. Therefore, on an interim basis, we

are finalizing that to the extent an NCD or LCD (including articles) would otherwise require a face-to-face or in-person encounter for evaluations, assessments, certifications or other implied face-to-face services, those requirements would not apply during the PHE for the COVID-19 pandemic.

We note that some face-to-face encounter requirements for DMEPOS Power Mobility Devices (PMDs) are mandated by statute for program integrity purposes. This IFC does not apply to those statutory requirements. For example, PMD face-to-face encounter requirements are found in section 1834(a)(1)(E)(iv) of the Act, as codified in § 410.38, and our regulation already permits the use of telehealth in accordance with Medicare guidelines. We have extended flexibilities to permit a broader use of telehealth services during the PHE for the COVID-19 pandemic.

It should be noted that this does not confer changes to the clinical indications of coverage for any LCD or NCD unless specifically indicated below.

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

During the PHE for the COVID-19 pandemic, it is possible that patients receiving services for respiratory related indications will be required to receive care in unexpected settings, including the home. This may be necessary as COVID-19 and other patients are shifted across healthcare settings to accommodate an increase in patient volume.

Therefore, we are finalizing on an interim basis that we will not enforce the clinical indications for coverage across respiratory, home anticoagulation management and infusion pump NCDs and LCDs (including articles) allowing for maximum flexibility for practitioners to care for their patients. This enforcement discretion will only apply during the PHE for the COVID-19 pandemic. 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.
- LCD L33794 External Infusion Pumps.

At the conclusion of the PHE for the COVID-19 pandemic, we will return to enforcement of these clinical indications for coverage.

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

Staffing is being adjusted in both facility and non-facility settings to accommodate for the needs of patients during the PHE for the COVID-19 pandemic. These staffing decisions may impact the availability of physicians and physician specialists to furnish evaluations, consultations and procedures or to supervise others. To the extent NCDs and LCDs require a specific practitioner type or physician specialty to furnish a service, procedure or any portion thereof, we are finalizing on an interim basis the chief medical officer or equivalent of the facility can authorize another physician specialty or other practitioner type to meet those requirements during the PHE for the COVID-19 pandemic. Additionally, to the extent NCDs and LCDs require a physician or physician specialty to supervise other practitioners, professionals or qualified personnel, the chief medical officer of the facility can authorize that such supervision requirements do not apply during the PHE for the COVID-19 pandemic.

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

In December 2017, we issued an interim final rule with comment period, titled “Medicare Shared Savings Program: Extreme and Uncontrollable Circumstances Policies for Performance Year 2017” (hereinafter referred to as the “December 2017 interim final rule with comment period”), which appeared in the **Federal Register** on December 26, 2017 (82 FR 60912 through 60919). The December 2017 interim final rule with comment period established a policy for determining quality performance scores for accountable care organizations (ACOs) participating in the Medicare Shared Savings Program (Shared Savings Program), when the ACO, its participating ACO providers and suppliers, and assigned beneficiaries were located in geographic areas that were impacted by extreme and uncontrollable circumstances, such as hurricanes, wildfires, or other triggering events, during performance year (PY) 2017, including the applicable quality data reporting period for the performance year if the quality reporting period was not extended. In the CY 2019 PFS final rule we extended the extreme and uncontrollable circumstances policy finalized for PY 2017 to PY 2018 and subsequent performance years. Under the policy adopted in that final rule, for a given performance year, including the applicable quality data reporting period for the performance year if the quality reporting period is not extended, we will use an alternative approach to calculating the quality score for ACOs affected by extreme and uncontrollable circumstances (42 CFR 425.502(f)).

Under this current policy at § 425.502(f), the Shared Savings Program extreme and uncontrollable circumstances policy does not apply for a performance year if an extreme and uncontrollable circumstance occurs during the quality reporting period for that performance year and the quality reporting period is extended. For all performance years starting in 2019, the original quality reporting period was January 2, 2020, through March 31, 2020. In response to the PHE for the COVID-19 pandemic, we have determined that the 2019 MIPS data submission deadline will be extended by 30 days until April 30, 2020, to give eligible clinicians more time to report quality and other data for purposes of MIPS. This extended timeline also applies to

Shared Savings Program ACOs because they are required to report quality data via the CMS Web Interface and we align the Shared Savings Program data submission timeline with the timeline for MIPS data submission. While the extended timeframe for data submission is intended to give eligible clinicians sufficient time to complete all the elements of MIPS reporting during the PHE for the COVID-19 pandemic, we realize that this extension alone may not be sufficient to ease the burden of reporting given the increased burden of providing care to all patients during this time. For this reason, under the Quality Payment Program, we have determined that the MIPS automatic extreme and uncontrollable circumstances policy will apply to MIPS eligible clinicians, who do not submit their MIPS data by the extended timeline. Under this automatic extreme and uncontrollable circumstances policy, MIPS eligible clinicians, who are not participants in APMs, who do not submit any MIPS data will have all performance categories reweighted to zero percent, resulting in a score equal to the performance threshold, and a neutral MIPS payment adjustment. However, under the policy, if a MIPS eligible clinician submits data on two or more MIPS performance categories, they will be scored and receive a 2021 MIPS payment adjustment based on their final score.

The automatic extreme and uncontrollable circumstances policy described above does not apply to MIPS eligible clinicians who are subject to the APM scoring standard (82 FR 53899), such as MIPS eligible clinicians participating in Shared Savings Program ACOs. Instead, these MIPS eligible clinicians will continue to be scored under the existing APM scoring standard. Generally, if no MIPS eligible clinicians in an APM Entity submit data by the extended deadline for the Quality and Promoting Interoperability performance categories due to extreme and uncontrollable circumstances, the APM scoring standard would apply as follows. The Cost performance category will be weighted at zero percent, as usual. The Improvement Activities performance category will be scored as usual. The Quality performance category will be reweighted to zero percent where the APM has waived quality reporting for purposes of the

APM as in these circumstances CMS determines that there are not sufficient measures or activities applicable and available to MIPS eligible clinicians, consistent with § 414.1370(h). Finally, if all MIPS eligible clinicians in an APM Entity have been excepted from reporting the Promoting Interoperability performance category, then the Promoting Interoperability performance category weight will be reweighted to zero for the APM Entity for that MIPS performance period (§ 414.1370(g)(4)(iii)(A)). As a result, in these circumstances, the Quality, Cost, and Promoting Interoperability categories would all be weighted at zero percent. And as only one performance category will be scored, the Improvement Activities performance category, such MIPS eligible clinicians would receive a neutral MIPS payment adjustment.

For MIPS eligible clinicians participating in Shared Savings Program ACOs that do not report quality and obtain a neutral payment adjustment under MIPS, according to the existing APM scoring standard described above, the Shared Savings Program must determine that the ACOs are impacted by an extreme and uncontrollable circumstance and waive the quality reporting requirement under the Shared Savings Program. As currently written, the Shared Savings Program extreme and uncontrollable circumstances policy does not allow for the determination that an ACO has been impacted by an extreme and uncontrollable circumstance that occurs during the quality reporting period if quality reporting period is extended, as it has been for performance years starting in 2019.

In addition, under the Shared Savings Program, if an ACO fails to report quality data by the submission deadline, the ACO will not have met the quality performance standard and will receive a quality score of zero, unless the extreme and uncontrollable circumstances policy under § 425.502(f) applies. In the event an ACO receives a quality performance score of zero, the ACO would be ineligible to share in savings, if earned and would owe maximum losses if participating under Track 2 or the ENHANCED track. The current Medicare Shared Savings Program extreme and uncontrollable circumstances policy for purposes of determining an ACO's

quality score for use in determining shared savings or losses applies if twenty percent or more of an ACO's assigned beneficiaries or its legal business entity are located in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance for the performance year, including the quality reporting period if the quality reporting period is not extended.

The effect of the MIPS quality reporting period extension is that the current Shared Savings Program extreme and uncontrollable circumstance policy does not apply, because the current extreme and uncontrollable circumstances policy is only available for extreme and uncontrollable circumstances that occur during the quality reporting period, such as the current PHE for the COVID-19 pandemic, if the quality reporting period is not extended. The inability to apply the extreme and uncontrollable circumstances policy to waive the quality reporting requirements under the Shared Savings Program during the PHE may adversely impact ACOs and their participating ACO providers and suppliers, because the extended timeline to submit data alone may not be sufficient to support ACOs and their participating ACO providers and suppliers, who are focused on care delivery during the national emergency.

The intent of the Shared Savings Program extreme and uncontrollable circumstance policy is to mitigate any impact on quality performance and the resultant effect on financial reconciliation due to emergency circumstances outside of the ACO's control. Accordingly, we believe it is necessary to revise the policies governing the availability of the Shared Savings Program extreme and uncontrollable circumstances policies to extend the protection to ACOs that may not be able to completely and accurately report their quality data for 2019, despite the extension of the quality reporting period. To provide relief to all ACOs participating in the Shared Savings Program during 2019, we need to modify the extreme and uncontrollable circumstances policy as it applies to disasters that occur during the reporting period to eliminate the restriction that the extreme and uncontrollable circumstances policy applies only if the

reporting period is not extended.

As explained above, the PHE for the COVID-19 pandemic was declared during the quality reporting period for performance years starting in 2019. The PHE for the COVID-19 pandemic applies to all counties in the United States, and we believe it is appropriate to offer relief under the Shared Savings Program extreme and uncontrollable circumstances policy to all Shared Savings Program ACOs that are unable to completely and accurately report quality for 2019 by the extended deadline due to the PHE for the COVID-19 pandemic. Due to the PHE for the COVID-19 pandemic and our desire to provide relief for Shared Savings ACOs who need to focus resources on patient care at this time, we believe that this policy must be effective starting with the quality reporting period for performance years starting in 2019. Further, as illustrated by the current PHE for the COVID-19 pandemic, there may be unanticipated situations in the future, during which extension of a quality reporting window alone would not provide sufficient relief from reporting burden at a time when ACOs and their ACO providers and suppliers need to focus on patient care. Accordingly, in this IFC, we are revising the regulation at § 425.502(f) to remove the restriction which prevents the application of the Shared Savings Program extreme and uncontrollable circumstances policy for disasters that occur during the quality reporting period if the reporting period is extended, to offer relief under the Shared Savings Program to all ACOs that may be unable to completely and accurately report quality data for 2019 due to the PHE for the COVID-19 pandemic. Specifically, we are amending the regulation at § 425.502(f) to remove the phrase “if the quality reporting period is not extended,” effective with quality reporting for PY 2019.

We are considering whether the current policy, which assigns an ACO the higher of the mean quality score across all ACOs and the ACO’s own quality score, in the event the ACO is determined to be impacted by an extreme and uncontrollable circumstances, will continue to be appropriate for PY 2020 and beyond. Any change to that current policy would be made through

future notice and comment rulemaking.

Regarding Shared Savings Program financial reconciliations for performance years starting in 2019, we note that because the PHE for the COVID-19 pandemic was declared during the reporting period for those performance years, the provisions that allow for an adjustment to the amount of shared losses for ACOs found to be affected by an extreme and uncontrollable circumstance during a performance year would not apply for performance years starting in 2019. However, for PY 2020 financial reconciliation, we will reduce the amount of an ACO's shared losses by an amount determined by multiplying the shared losses by the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance, and the percentage of the ACO's assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance. At this time, the PHE for the COVID-19 pandemic applies to all counties in the country; therefore, 100 percent of assigned beneficiaries for all Shared Savings Program ACOs reside in an affected area and the total months affected by an extreme and uncontrollable circumstance will begin with March and continue through the end of the current PHE, as defined in § 400.200.

Additionally, the Medicare Shared Savings Program financial methodology includes updating each ACO's benchmark at the end of each performance year based on the performance year expenditure trend. The factors used to update ACOs' benchmarks will reflect the national and regional trends related to spending and utilization changes during 2020, including any changes arising from the PHE for the COVID-19 pandemic.

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

In the CY 2020 PFS final rule ((84 FR 62847 and 62848), we finalized a number of changes to the framework of the office/outpatient E/M requirements for CY 2021. Beginning January 1, 2021 for office/ outpatient E/M visits, the code level will be selected based on either the level of MDM or the total time personally spent by the reporting practitioner on the day of

the visit (including face-to-face and non-face-to-face time). We noted that there was broad support for these changes from the AMA and other specialty societies. Currently, telehealth office/outpatient E/Ms can be furnished to beneficiaries in their homes only when they are for individuals with a substance use disorder (SUD) diagnosis for purposes of treatment of such disorder or co-occurring mental health disorder. For these services, the primary factor in selecting the appropriate level of E/M service to bill would be time spent counseling the patient. Under the waiver issued by the Secretary pursuant to section 1135(b)(8) of the Act, telehealth office/outpatient E/Ms can be furnished to any patient in their home regardless of their diagnosis or medical condition. However, the current E/M coding guidelines would preclude the billing practitioner from selecting the office/outpatient E/M code level based on time in circumstances where the practitioner is not engaged in counseling and/or care coordination.

On an interim basis, we are revising our policy to specify that the office/outpatient E/M level selection for these services when furnished via 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; and to remove any requirements regarding documentation of history and/or physical exam in the medical record. This policy is similar to the policy that will apply to all office/outpatient E/Ms beginning in 2021 under policies finalized in the CY 2020 PFS final rule. It remains our expectation that practitioners will document E/M visits as necessary to ensure quality and continuity of care. To reduce the potential for confusion, we are maintaining the current definition of MDM. We note that currently there are typical times associated with the office/outpatient E/Ms, and we are finalizing those times as what should be met for purposes of level selection. The typical times associated with the office/outpatient E/Ms are available as a public use file at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1715-F>. This policy

only applies to office/outpatient visits furnished via Medicare telehealth, and only during the PHE for the COVID-19 pandemic.

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

In section II.O. of this IFC, "Application of the Teaching Physician Regulations During the PHE for the COVID-19 pandemic," we state that the teaching supervision requirement can be met in certain circumstances through direct supervision using interactive telecommunications technology, including when a medical resident is quarantined at home. Regarding claiming of the residents for indirect medical education (IME) and Direct graduate medical education (DGME) purposes, under current regulations, if a resident is training in a hospital, that hospital claims the resident for IME and DGME (per § 413.78(a)), and if a resident is training in a nonprovider site such as a doctor's office or clinic, the hospital or hospitals that pays the resident's salaries and fringe benefits claims the resident for IME and DGME (per § 413.78(g)). Currently, there is no provision in the regulations for a hospital to claim a resident for IME or DGME if the resident is performing patient care activities within the scope of his or her approved program in his or her own home, or in a patient's home. For the duration of this emergency situation, we are permitting the hospital that is paying the resident's salary and fringe benefits for the time that the resident is at home or in the home of a patient that is already a patient of the physician or hospital, but performing patient care duties within the scope of the approved residency program (and meets appropriate physician supervision requirements as stated in section II.O. of this IFC) to claim that resident for IME and DGME purposes.

Y. Addressing the Impact of COVID-19 on Part C and Part D Quality Rating Systems

1. Background

a. Legislative Authority for Star Ratings

Based on its authority to disseminate comparative information, including about quality, to beneficiaries under sections 1851(d) and 1860D-1(c) of the Act and authority to collect various

types of quality data under section 1852(e) of the Act, CMS develops and publicly posts a 5-star ratings system for MA and Part D plans. That system is also the basis for determining quality bonus payment (QBP) status for MA plans under section 1853(o) of the Act. Section 1876 cost plans are also included in the MA and Part D Star Rating system as codified at 42 CFR 417.472(k) and are also required by § 417.472(j) to make CAHPS survey data available to CMS. In a final rule, Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plans, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program, published on April 16, 2018 (83 FR 16519 through 16589), we adopted regulations to govern this quality rating system for cost MA and Part D plans, which are generally rated at the contract level. In a final rule, Medicare and Medicaid Program; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-for-Service, and Medicaid Managed Care Programs for Years 2020 and 2021, published April 16, 2019 (84 FR 15830 and 15831), we amended the regulations governing the quality rating program for MA and Part D plans. Those final rules contain a more detailed discussion of CMS' authority in this area and we encourage readers to refer to those final rules.

In the CY 2020 Final Call Letter and the CY 2020 final rule, published in the **Federal Register** on April 16, 2019 (84 FR 15830 and 15831), we finalized a set of rules for adjusting the calculation of Star Ratings for the cost and Parts C and D organizations that are impacted by extreme and uncontrollable circumstances. We provided in the 2021 Advance Notice that the same policy as used for adjustments to 2020 Star Ratings based on extreme and uncontrollable circumstances would be continued for CY 2021 Star Ratings. We did not envision the unprecedented circumstances surrounding the PHE for the COVID-19 pandemic when we developed the adjustments for extreme and uncontrollable circumstances for the Part C and D

Star Ratings program; as they exist currently, they are not sufficient in the case of the PHE for the COVID-19 pandemic.

b. Overview of Star Ratings

The Star Ratings are generally based on measures of performance during a period that is 2 calendar years before the year for which the Star Ratings are issued; 2021 Star Ratings will generally be based on performance during 2019 and the 2022 Star Ratings will similarly be based on performance in 2020. We use multiple data sources to measure quality and performance of contracts. Various regulations require plans to report on quality improvement and quality assurance and to provide data which we can use to help beneficiaries compare plans (for example, §§ 417.472(j) and (k), 422.152(b), 423.153(c), and 423.156). In addition, we may require plans to report statistics and other information in specific categories (§§ 422.516 and 423.514). Data from these sources and other sources are used to calculate measures of plan sponsor performance each year, as provided in §§ 422.162 and 423.182. The Star Ratings serve an important purpose in providing comparative information to enrollees and are also used to identify whether an MA plan is eligible for a QBP under section 1853(o) of the Act. The Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by the Healthcare and Education Reconciliation Act (Pub. L. 111-152), provides for quality ratings, based on a 5-star rating system and the information collected under section 1852(e) of the Act, to be used in calculating payment to MA organizations beginning in 2012. Specifically, sections 1853(o) and 1854(b)(1)(c) of the Act were added and amended to provide, respectively, for an increase in the benchmark against which MA organizations bid and in the portion of the savings between the bid and the benchmark available to the MA organization to use as a rebate. We assign both low and high performing icons that are displayed on www.Medicare.gov to help Medicare beneficiaries make plan decisions based on either consistently low performance for 3 or more years or receiving 5 stars for the highest rating, respectively. Additionally, plans that demonstrate

exceptional performance due to achieving a 5 Star Rating for their highest rating can market year round and beneficiaries receive a special election period that allows the eligible beneficiary to enroll in a 5-star plan during the contract year. We also have the authority to terminate plans that have below a 3-star rating for 3 or more years. The Star Ratings therefore serve a number of important purposes for cost, MA and Part D plans; we believe that plans engage in behavior during the performance measurement period to improve their Star Ratings and to achieve higher Star Ratings.

Healthcare Effectiveness Data and Information Set (HEDIS) and Consumer Assessment of Healthcare Providers and Systems (CAHPS) data are the basis for the calculation of the majority of measures for both the Part C and Part D Star Ratings. HEDIS measures include clinical measures assessing the effectiveness of care, access/availability measures, and service use measures and are calculated by CMS through a contract with the National Committee for Quality Assurance (NCQA). Many of the HEDIS measures require plans to perform reviews of patients' medical records or to obtain information directly from physician offices, which is a time-intensive activity.

CAHPS refers to a comprehensive family of surveys that ask consumers and patients to evaluate experiences of care. Cost plans, Part C plans, and Part D plans are all required by regulation (§§ 417.472, 422.152, and 423.156, respectively) to contract with approved Medicare CAHPS survey vendors to conduct the Medicare CAHPS satisfaction survey of Medicare plan enrollees in accordance with CMS specifications and submit the survey data to CMS. The Star Ratings system uses measures from HEDIS and CAHPS extensively, and there are negative consequences for a plan's Star Ratings (overall and on specific measures) if the necessary data for the HEDIS and CAHPS measures are not reported or validated. Although the 2021 Star Ratings reflect performance in 2019 for most of the measures, data collection for HEDIS and CAHPS is conducted in the first half of CY 2020 to feed into the 2021 Star Ratings that are

finalized by October 2020. Similarly, the Health Outcomes Survey will occur in 2020 to collect data used for the 2022 Star Ratings and the same concerns about survey activities apply to that survey.

2. Impact of COVID-19 on Star Ratings Data Collection

The World Health Organization (WHO) has characterized COVID-19 as a pandemic, and there are alarming levels of spread and severity of COVID-19 across the United States. The CDC and medical professionals recommend that the best way to prevent the spread of the virus is to avoid contact with infected individuals. Social distancing is a method that public health officials use to curb the transmission and spread of infectious illnesses like COVID-19. Prior research has shown that these measures help mitigate the spread of contagious viruses in the absence of vaccines (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3372334/>), as is the case with COVID-19.

To help curb the spread of COVID-19, governors around the country are putting in place actions to protect public health and safety and help mitigate the spread of the virus, including school closures, limiting the size of gatherings and events, and restaurant closures. Employers are moving to mandatory telework when feasible. The intent of these actions is to save lives, keep people safe, and slow the rate of infection. As of March 28, 2020, all 50 states were under a State of Emergency. Additionally, areas of the country are being put under shelter-in-place orders to further curtail the spread of the virus. CDC has provided guidance to health care facilities (for example, <https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/guidance-hcf.html>) that range from rescheduling non-urgent outpatient visits and elective surgeries, promoting telehealth visits, and managing mildly ill COVID-19 patients at home. Also, on March 16, 2020, CDC issued interim guidance (<https://www.cdc.gov/coronavirus/2019-ncov/community/large-events/index.html>) advising the public against holding gatherings of more than 10 individuals. On March 18, 2020, we released

recommendations related to delaying adult elective surgeries, non-essential medical, surgical, and dental procedures during the COVID-19 outbreak to be able to focus health care professionals on those most in need of healthcare (<https://www.cms.gov/newsroom/press-releases/cms-releases-recommendations-adult-elective-surgeries-non-essential-medical-surgical-and-dental>).

On March 13, 2020, President Trump declared a national emergency as a result of the COVID-19 pandemic. The declaration of the PHE for the COVID-19 pandemic allows certain Medicare requirements and conditions of participation to be waived under section 1135 of the Act providing more flexibility to providers in furnishing medically necessary health care to beneficiaries.

Currently, data collection for HEDIS measures is ongoing for services and performance during the 2019 measurement period. MA contracts are required to submit their HEDIS summary-level data to the NCQA by June 15, 2020, as well as to submit their HEDIS patient-level data to CMS the same day. Currently, data collection activities are underway to meet the June deadlines. Some of the HEDIS measures require medical record review or obtaining information directly from physician offices. We recognize that obtaining medical records from physician offices and the necessary documentation from physician offices needed for the plan to meet HEDIS requirements, and requiring plans to participate in HEDIS audits will put a strain on the limited resources available to these health care providers. Some of these activities are generally done in person so compliance with social distancing efforts, travel bans and quarantines raise additional challenges, as well as risks to staff. CMS' top priority is to ensure public health and safety, including that of beneficiaries, health and drug plan staff, and providers, and to allow health and drug plans, providers, and physician offices to focus on what is most important at this time: the provision of care.

Under §§ 417.472(i) and (j), 422.152(b)(5), and 423.156, all coordinated care MA plans,

section 1876 contracts, and Part D sponsors, respectively, are required to contract with a CMS-approved CAHPS survey vendor to conduct the Medicare CAHPS satisfaction survey in accordance CMS specifications and to submit the data to CMS. The administration of the surveys and data collection are currently ongoing until the end of May 2020 for the CAHPS survey data that would be used for the 2021 Star Ratings. We are concerned that the COVID-19 pandemic will pose significant challenges and safety concerns in successfully completing the current CAHPS data collection. Most of the survey administration protocols cannot be completed remotely, requiring staff to work in mail facilities and call centers where telephone interviewers assemble in close quarters to perform the telephone administration of the survey. We are concerned that cost plans, MA organizations, and Part D plan sponsors will not be able to complete this year's data collection without jeopardizing the health and safety of survey vendor staff. We have similar concerns about the Health Outcomes Survey (HOS) data collection scheduled for later in 2020.

This IFC amends, as necessary, the calculations for the 2021 and 2022 Part C and D Star Ratings to incorporate changes to address the expected impact of the PHE for the COVID-19 pandemic on data collection and performance. Plans urgently need to know these changes so as not to further exacerbate the PHE for the COVID-19 pandemic by continuing efforts to complete the HEDIS and CAHPS data collection activities. The HEDIS data collection diverts physicians' offices and health plans from handling the day-to-day emergencies as a result of the PHE for the COVID-19 pandemic. Additionally, we are concerned it is not possible to safely continue the HEDIS and CAHPS data collection activities while complying with the CDC recommendation for social distancing.

Under normal circumstances, if Part C and section 1876 plans do not fully complete their HEDIS data collection activities and successfully meet NCQA's HEDIS audit requirements, we assign 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, we historically have assigned each of the CAHPS Star Ratings measures 1 star. Furthermore, unreliable CAHPS measure scores are excluded from the Part C and D Star Ratings calculations. Without knowing the changes made by this IFC to the methodology for calculating the 2021 and 2022 Star Rating, plans could have conflicting incentives, needing physician offices and plan staff to focus on caring for those impacted by COVID-19 and keeping Medicare beneficiaries and those involved in data collection activities safe, while at the same time wanting to ensure that future Star Ratings and QBP ratings are not impacted by the PHE for the COVID-19 pandemic which could negatively impact future benefits offered by MA organizations. The changes to the calculations for 2021 and 2022 Star Ratings are designed to avoid inadvertently creating incentives for plans to place cost and Star Rating considerations above efforts to address the COVID-19 pandemic.

3. Provisions of IFC

This IFC is modifying the calculation of the 2021 and 2022 Part C and D Star Ratings to address the expected disruption to data collection posed by the PHE for the COVID-19 pandemic. Specifically, this IFC: (1) replaces the 2021 Star Ratings measures calculated based on HEDIS and Medicare CAHPS data collections with earlier values from the 2020 Star Ratings (which are not affected by the public health threats posed by COVID-19); (2) establishes how we will calculate or assign Star Ratings for 2021 in the event that CMS' functions become focused on only continued performance of essential Agency functions and the Agency and/or its contractors do not have the ability to calculate the 2021 Star Ratings; (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 we are unable to complete HOS data collection in 2020 (for the 2022 Star Ratings), replaces the measures calculated based on 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.

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

We issued a Health Plan Management System (HPMS) memo, entitled “Reporting Requirements for 2020 HEDIS®, HOS, and CAHPS® Measures,” on September 9, 2019 to establish the due date for the 2019 measurement year for HEDIS. In light of the public safety issues in continuing to require the submission of HEDIS data for the 2019 measurement year, we are eliminating the HEDIS 2020 submission requirement that covers the 2019 measurement year and we are requesting that Medicare health plans, including MA and section 1876 organizations, curtail HEDIS data collection work immediately. This will allow health plans, providers, and physician offices to focus on caring for Medicare beneficiaries during this PHE for the COVID-19 pandemic and will minimize risk of the spread of infection by eliminating travel and in-person work for the collection of HEDIS data. Our goal is to ensure that offices of health care providers remain focused on patients needing care. Medicare health plans can use any HEDIS data that they have collected for their internal quality improvement efforts.

We are also amending the regulations requiring the submission of the CAHPS survey data to CMS for Medicare health and drug plans to relieve them of the requirement as it applies to the 2020 survey data collection to ensure the safety of survey vendor staff and align with the CDC’s social distancing guidance. Both Part C and D plans can use any CAHPS survey data already collected for their internal quality improvement efforts. Accordingly, we are modifying regulations in parts 417, 422, and 423 to eliminate requirements for the collection of HEDIS and CAHPS data that would otherwise occur in 2020. Specifically, we are revising the Part C regulation at § 422.152 by adding a new paragraph (b)(6), which provides that MA organizations

are not required to submit HEDIS and CAHPS data that would otherwise be required for the calculation of the 2021 Star Ratings. In addition, we are revising the cost plan regulation at § 417.472(i) and (j) in two ways: in paragraph (i), to add a requirement for cost plans to comply with § 422.152(b)(6) and in paragraph (j), to make the obligation for cost plans to conduct CAHPS surveys subject to paragraph (i). Finally, we are revising the Part D regulations at §§ 423.156 and 423.182. We are revising § 423.156 to not require Part D sponsors to submit CAHPS data that would otherwise be required for the calculation of the 2021 Star Ratings. We are also adding § 423.182(c)(3) so that for 2021 Star Ratings only, Part D sponsors are not required to submit CAHPS data that would otherwise be required for the calculation of the 2021 Star Ratings. While our revisions do not outright prohibit cost plans, MA plans, and Part D plans from continuing efforts to collect HEDIS data or conduct CAHPS surveys during 2020, such as to use that data about plan performance in 2019 for the plan's own internal quality initiatives, we do not expect plans to do so. An additional component of the HEDIS data collection is the HOS that NCQA administers in partnership with CMS. This year's HOS survey administration was scheduled to be from April through July 2020. Given the significant safety concerns, similar to the ones related to the administration of the CAHPS survey, we are moving the HOS survey administration to late summer and will provide MA plans more information in the upcoming months. We will continue to monitor the situation to see if any further adjustments are needed. To prepare for the possibility that the PHE for the COVID-19 pandemic continues and the HOS survey data cannot be collected starting in late summer for the 2022 Star Ratings, we are amending the regulations for the Part C 2022 Star Ratings (by adding new § 422.166(j)(2)) to allow us to use the Star Ratings and measure scores for the 2021 Star Ratings for any measures that come from the HOS survey; this will address any gaps in the necessary HOS data if the HOS survey cannot be administered in 2020. 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.

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

In response to the PHE for the COVID-19 pandemic and its impact on health care delivery and data collection, we are making a series of adjustments to the Star Ratings methodology to protect the health and safety of individuals who would collect the HEDIS and CAHPS data; to allow health and drug plans and their providers to focus on caring for Medicare beneficiaries during the PHE for the COVID-19 pandemic; and to address the unusual, unexpected, and uncontrollable changes that this pandemic is likely to have on the Part C and D Star Ratings. Because of the short time frame during which information is collected, analyzed, and used in the calculation of the Star Ratings published in October each year, immediate action is necessary to amend the methodology as a result of the extraordinary circumstances created by the PHE for the COVID-19 pandemic. Data collection is currently underway for both the HEDIS and CAHPS data, and the data are due to CMS in June 2020. A series of adjustments to the 2021 Star Ratings are being made to account for eliminating the need to collect and submit HEDIS and CAHPS data for the 2021 Star Ratings.

The April 2018 final rule (83 FR 16538 through 16546) included the measures finalized for the 2021 Star Ratings. Included in those measures are many that use HEDIS or CAHPS as the data source. In the 2020 Star Ratings, 14 measures had HEDIS as their data source, and nine measures had CAHPS as their data source. The measurement period for most of the Star Ratings measures is 2019; for many of those measures, we (or the plans) already have the data necessary to calculate a measure score and assign a 2021 measure-level rating but validation and analysis of those data remain to be done. For the HEDIS data source, the measurement period finalized in the April 2018 final rule is the calendar year 2 years prior to the Star Ratings year so for the 2021 Star Ratings, the HEDIS measurement period is the 2019 measurement year. However, those data are collected in 2020.

Similarly, for the CAHPS data source, the measurement period finalized for the 2021 Star Ratings is the most recent data submitted for the survey of enrollees. In general, the most recent data would be the survey conducted from March through the end of May each year, which for the 2021 Star Ratings would have corresponded to March through May 2020 data collection. However, these data will not be available for HEDIS and CAHPS measures. CMS considered if we could remove all of the HEDIS and CAHPS measures from the 2021 Star Ratings. If we removed these measures from the Star Ratings, we would not have enough measures to rate plans and to have a complete picture of performance given approximately half of the Star Ratings measures come from HEDIS and CAHPS. Removing all of these measures would severely compromise the integrity of the Part C and D Star Ratings and would have significant impact on payment for MA organizations. Given measure scores and stars do not fluctuate significantly year to year, we believe using the 2020 measure-level stars and scores for the missing HEDIS and CAHPS data provides the best approximation of performance in 2019. This substitution addresses the lack of HEDIS and CAHPS data that would otherwise be used for 2021 Star Ratings while permitting us to calculate and use reliable Star Ratings for 2021 enrollment and 2022 QBP status determinations. Given the issues related to PHE for the COVID-19 pandemic associated with completing the HEDIS data collection for the 2019 measurement year, we 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. For the 2021 Star Ratings, given the safety concerns related to completing the CAHPS surveys and data collection and the inability of survey vendors to fully complete data collection for 2020, we will use the CAHPS data submitted to CMS in June 2019. To accomplish this, we are revising §§ 422.166 and 423.186 to add new regulation text that the measures calculated based on HEDIS data are calculated based on data for the 2018 performance period and the measures calculated based on CAHPS data are calculated based on survey data collected from March through May 2019.

Specifically, we are adding a new paragraph (j) to each of these regulations and are codifying these specific rules about HEDIS and CAHPS data at §§ 422.166(j)(1)(i) and (ii) and 423.186(j)(1)(i).

The measurement period for all other measures will not change from what was finalized in the April 2018 final rule. For both HEDIS and CAHPS measures, we will use 2020 measure-level Star Ratings (and associated measure-level scores) in all the Star Ratings calculations codified at §§ 422.160, 422.162, 422.164, 422.166, 423.180, 423.182, 423.184, and 423.186 in calculating the 2021 Star Ratings. For the 2021 Star Ratings, there will be no changes from the prior year in the measure-level cut points for any of the HEDIS and CAHPS measures. We had previously announced in the April 2019 final rule that the Plan All-Cause Readmissions measure would be moved to display for the 2021 Star Ratings due to the substantive specification change. We will continue to exclude this measure for the 2021 Star Ratings as provided in that final rule, so the data associated with it for the 2018 performance period (collected in spring 2019) will be posted on the display page for 2021 ratings.

Since we will be using the 2020 Star Ratings data for the HEDIS and CAHPS measures, we will carry forward the measure-level improvement change score as described 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. We are codifying this at §§ 422.166(j)(1)(iii) and 423.186(j)(1)(ii).

Under §§ 422.164(g)(1), 422.164(g)(2), and 423.184(g)(2), we reduce HEDIS and CAHPS measures to 1 star when either HEDIS measures used to populate the Star Ratings are not reported or for failure to adhere to CAHPS reporting requirements. For the 2021 Star Ratings, we will not reduce these measures to 1 star for failure to report the 2020 HEDIS or CAHPS data and is codifying that approach at §§ 422.166(j)(1)(iv) and 423.186(j)(1)(iii). We are amending §§ 422.166 and 423.186 by adding paragraph (j) to codify these various special rules

for the 2021 Star Ratings.

c. Use of 2020 Star Ratings to substitute for 2021 Star Ratings in the event of extraordinarily compromised CMS capabilities or systemic data issues

There is great uncertainty about how the COVID-19 pandemic will evolve over the next 6 to 9 months, and the impact on the American population and institutions resulting from the pandemic. We have considered the normal activities required to prepare, calculate, and publish the Star Ratings, as well as finalize the ratings to be used as the basis for MA QBPs in the event that CMS' functions to calculate the 2021 Star Ratings are significantly impacted. The operational timelines for calculating the Star Ratings each year are extremely tight. For example, when we receive all of the measure-level data in early August, we have approximately 1 month to: review the Star Ratings measure data for accuracy; prepare data and supportive material to provide plans with a preview period so they can review their numeric measure scores and raise issues to CMS; work with contractors to calculate the Star Ratings; prepare for a second preview period for plans to see their preliminary measure level and overall star ratings. This work must be completed in the months of August and September so that the Star Ratings are ready for public display on Medicare Plan Finder in early October for the Annual Enrollment Period. If the COVID-19 pandemic or actions necessary in connection with the PHE impact the ability of CMS and its contractors to complete these steps to calculate the 2021 Star Ratings, it would be impracticable and contrary to the public interest to begin rulemaking in August to adopt a policy for how to address such an unprecedented situation. The normal notice and comment rulemaking process would also prevent CMS from providing quality ratings to Medicare beneficiaries choosing a 2021 plan during the Annual Enrollment Period beginning in October and conflict with CMS providing MA organizations the opportunity to appeal their QBP ratings for 2022 payment in time for 2022 bid submissions. There would be insufficient time to engage in notice and comment rulemaking to make changes to the 2021 Star Ratings methodology in

time to issue the Star Ratings on Medicare Plan Finder.

Star Ratings are used to identify which MA plans are eligible for a QBP and for a greater percentage of the amount by which the benchmark for the plan's service area exceeds the plan's bid for covering Part A and Part B benefits; the quality bonus results in an increase to the benchmark for an MA plan's service area and the percentage that determines the amount of the beneficiary rebate. See §§ 422.258(d)(7) and 422.260. Together, these financial consequences for a high Star Rating, can result in higher beneficiary rebates, which are used to pay for supplemental benefits and reductions in the Part B or Part D premium for enrollees in the plan. Given the impact the Star Ratings have on payment and the benefits offered to Medicare beneficiaries, it is critical that MA organizations have certainty in terms of how the ratings would be calculated if this situation should occur.

Adopting a provision to address such extraordinary circumstances before they come to pass in connection with the COVID-19 pandemic will ensure that Medicare health and drug plans and Medicare beneficiaries are aware of the steps CMS will take before those actions become necessary. This advance notice will alleviate uncertainty and provide stability for cost plans, MA organizations, and Part D sponsors so they can focus on continuing to ensure Medicare beneficiaries have access to needed medical care. In case the PHE for the COVID-19 pandemic gets to a point that CMS' functions become focused on only continued performance of essential agency functions or the agency and its contractors do not have the ability to calculate the 2021 Star Ratings, as part of this IFC, we are establishing rules for this circumstance. These rules would only be implemented for the 2021 Star Ratings if the impact of the PHE for the COVID-19 pandemic reaches a point where CMS and its contractors are compromised to the point the 2021 Star Ratings cannot be calculated using the methodology set forth in the April 2018 final rule and this IFC. Calculating the Star Ratings requires a full team of staff and contractors with specialized skill sets. If the PHE for the COVID-19 pandemic escalates, we will

need to devote more resources to activities to address essential Agency functions so that adding staff or resources to calculate the Star Ratings would not be appropriate.

If CMS' resources become extraordinarily compromised, we will use the 2020 Star Ratings as the 2021 Star Ratings. This authority is codified at §§ 422.166(j)(1)(v) and 423.186(j)(1)(iv) and limited specifically to the COVID-19 pandemic.

We are also concerned, given the uncertainties ahead, whether CMS and plans will be able to safeguard against data quality issues for non-CAHPS and non-HEDIS measures for which CMS does not already have data for the 2021 Star Ratings. As an example, sponsors report Special Needs Plan (SNP) Care Management and Medication Therapy Management (MTM) data to CMS by March 2020, and these data undergo independent data validation beginning in April. While validation activities can be conducted remotely between the plans' staff and data validation reviewers, there may be other difficulties in completing the work this year on time and consistent with CMS requirements due to the significant impact of the PHE for the COVID-19 pandemic. Normally, as codified at §§ 422.164(b) and 423.184(b), we review the quality of the data before making a final determination about inclusion of the measures in each year's Star Ratings. Given the potential for multiple measures to have data quality issues across many plans as a result of COVID-19, we are addressing this possibility by adopting a rule to permit replacing the 2021 Star Ratings measure scores and stars with the 2020 Star Ratings measures scores and stars for the impacted measures for all plans rather than excluding multiple measures from the 2021 Star Ratings calculations. Removing multiple measures from the Star Ratings can cause unanticipated changes in the ratings which would create more instability for Medicare health and drug plan sponsors and could have significant impacts on MA QBP's at a time where MA organizations need stability in the ratings when they need to focus on caring for those impacted by COVID-19.

To be prepared if we have data quality issues for any non-HEDIS or non-CAHPS 2021

Star Ratings measures, we are adopting a specific rule limited to the PHE for the COVID-19 pandemic. At §§ 422.164(i) and 423.184(i), we are adopting authority for CMS to substitute the score and star for the measure used in the 2020 Star Ratings in the calculation of the 2021 Star Ratings when there is a systemic data quality issue for all plans as a result of the PHE for the COVID-19 pandemic. Therefore, in the above example, we would use sponsors' SNP Care Management and MTM Program Completion Rate for Comprehensive Medication Review measures' scores and stars from the 2020 Star Ratings as the sponsors' 2021 Star Ratings on those measures.

We are making these adjustments to the Star Ratings methodology since our inability to make calculations at a late stage in the annual Star Ratings publication process would severely jeopardize our ability to calculate 2022 MA payments accurately and consistent with the statutory QBP provision particularly since our ability to change other deadlines based on availability of the Star Ratings (for example, the bid deadline, Annual Election Period, and the start of the new plan benefit year) is limited but the Star Ratings are an integral part of those other activities. In extreme situations like the ones described above, the solicitation and consideration of public comments to establish how CMS should proceed would be impracticable since the process could not be completed in time to issue new Star Ratings that could be used to inform beneficiary choice during the Annual Election Period. The MA statute, at section 1851(d) of the Act, requires that information about plan quality and performance indicators be provided to Medicare beneficiaries to help them make informed plan choices. In addition, MA plans need to know their eligibility for QBPs in advance of the bid deadline to develop their bids; the bid deadline is also set by the statute, as the first Monday in the June prior to the coverage year. The 2021 Star Ratings will be the basis for 2022 QBPs so definitive Star Ratings need to be available to plans in advance of June 2021, to accommodate bid planning and to ensure that plans have the ability to appeal their QBP status if necessary. We understand that MA organizations begin

developing and pricing their plan benefit packages well before the June bid deadline and depend on the release of Star Ratings in the preceding October as a critical milestone in their planning for an upcoming plan year. Adopting the new rule at §§ 422.164(i) and 423.184(i) to address measure-level substitutions of 2020 scores for data quality issues that impact the availability, accuracy, reliability and validity of the measure-level data that would otherwise be used for 2021 ratings will provide stability and certainty for the program. This approach will allow CMS and MA organizations to move seamlessly to a new basis for calculating QBPs in the event that the original one (that is, using the data about 2019 performance) is unavailable. It will also allow MA organizations to incorporate into their planning the possibility that they will be required to use the 2020 Star Ratings for some or all measures in developing their 2022 bids.

To codify these provisions, we are amending §§ 422.164 and 423.184 by adding a new paragraph (i) to each section, as well as by amending § 422.166 by adding a new paragraph (j)(1)(v) and amending § 423.186 by adding a new paragraph (j)(1)(iv).

d. 2022 Star Ratings

For the 2022 Star Ratings, we expect plans to submit HEDIS data in June 2021 and to administer the CAHPS survey in 2021 as usual. The majority of measures for the 2022 Star Ratings are based on the 2020 measurement year, which is ongoing during the PHE for the COVID-19 pandemic. We are using the IFC to make immediate changes to the methodology for the 2022 Star Ratings so as not to inappropriately incentivize actions by plans and healthcare providers that are not directly related to the PHE for the COVID-19 pandemic. By adopting these changes immediately, Medicare health and drug plans will be assured as quickly as possible about how performance changes driven or caused by the COVID-19 pandemic will be addressed in the Star Ratings that use this performance period. Except as addressed in this IFC, we anticipate that the 2022 Star Ratings will be implemented as codified at §§ 422.160, 422.162, 422.164, 422.166, 423.180, 423.182, 423.184, and 423.186.

i. Guardrails

We recognize that health and drug plans and their providers are needing to adapt their current care practices in light of the PHE for the COVID-19 pandemic and the need to care for the most vulnerable patients, such as the elderly and those with chronic health conditions; these changes in how plans and providers care for Medicare beneficiaries as a result of COVID-19 will impact performance for the 2020 measurement period which feeds into the 2022 Star Ratings. On March 18, 2020, we issued guidance (available on the CMS website at <https://www.cms.gov/files/document/31820-cms-adult-elective-surgery-and-procedures-recommendations.pdf>) to delay all non-essential planned surgeries and procedures, including dental, until further notice. Healthcare providers are being asked to encourage patients to remain at home, except for emergencies, to help curb the spread of COVID-19 and to help limit the exposure to the virus. Plans and their providers are focused primarily on providing urgent care to Medicare beneficiaries who may be infected by COVID-19. We realize that this will impact the data collected during the 2020 measurement year which will impact the 2022 Part C and D Star Ratings. Thus, as part of this IFC, we are making some adjustments to account for the potential decreases in measure-level scores so health plans can have some degree of certainty knowing that the Star Ratings will be adjusted and can focus right now on patients who are most in need.

To increase the predictability of the cut points used for measure-level ratings, we previously finalized that, starting with the 2022 Star Ratings, guardrails would be implemented for measures that have been in the program for more than 3 years. As specified at §§ 422.166(a)(2)(i) and 423.186(a)(2)(i), the guardrails ensure that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than 5 percentage points from one year to the next. As noted in the April 2019 final rule, the trade-off for the predictability provided by the bi-directional cap is the inability to fully keep pace with changes in performance across the industry. While cut points that change less than the cap would be

unbiased and keep pace with changes in the measure score trends, changes in the overall performance that are greater than the cap would not be reflected in the new cut points. The performance that will be used for the 2022 Star Ratings is performance in 2020, that is, during the PHE for the COVID-19 pandemic. We anticipate that most, if not all, plans could have performance changes on certain measures as they deal with the demands the PHE for the COVID-19 pandemic will place on the health care system in the United States. Guardrails that prevent the cut points for measures from lowering, even when performance scores are lower across the board, will result in plans having similar low measure-level ratings even if their performance is relatively distinguishable.

Since the Star Ratings are used to calculate the payment to MA organizations by providing an increase in the benchmark against which MA organizations bid and in the portion of the savings between the bid and benchmark available to MA organizations to use as rebates, unanticipated significant declines in the Star Ratings would create significant uncertainty in the program and potential beneficiary access issues if ratings significantly decline across the cost plan, MA and Part D programs. Given the enormity of this situation we believe it is important for plans to be able to focus on patients that are in the most need during the outbreak, and our guardrails, as currently constructed, could have unintended incentives to the contrary. In addition, adopting this policy as soon as possible will minimize incentives for plans and providers to focus on non-urgent care or administrative efforts, even if those issues are tied to existing Star Ratings measures, and focus their attention on urgent care issues. As such, in response to the PHE for the COVID-19 pandemic, we are delaying implementation of the guardrails so that cut points can change by more than 5 percentage points if national performance declines as a result of the PHE for the COVID-19 pandemic. We are modifying §§ 422.166(a)(2)(i) and 423.186(a)(2)(i) to delay the application of the guardrails beginning with the 2023 Star Ratings produced in October 2022. No other aspect of the guardrails policies

finalized in the April 2019 final rule is changing with this modification.

ii. Improvement measure

The existing Star Ratings system and regulations include a well-developed improvement measure and methodology for calculating and using it. However, because we anticipate that performance during the 2020 measurement period may decline for plans across the nation, we believe that it is appropriate to adopt a provision to minimize the negative effect of the improvement measure and improvement scores. As with the guardrails policy, this amendment to the existing regulations is designed to minimize or eliminate incentives in the Star Ratings that might be inconsistent with the steps necessary to address the COVID-19 pandemic. We are revising 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 recognizing that the PHE for the COVID-19 pandemic may result in a decline in industry performance. 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. Our revision will expand the current hold harmless rule and how it works to all contracts regardless of their ratings and also apply it to the Part C and D summary ratings for the 2022 Star Ratings only.

We are codifying a new paragraph (g)(3) at §§ 422.166 and 423.186 and adding text at the end of the existing text in §§ 422.166(f)(1)(i) and 423.186(f)(1)(i) to implement this new hold harmless provision for the 2022 Star Ratings only.

iii. Categorical Adjustment Index

Beginning with the 2017 Star Ratings, we implemented the Categorical Adjustment Index

(CAI) that 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 (LIS/DE) and/or have disability status. For the 2022 Star Ratings, we will calculate the CAI as codified at §§ 422.166(f)(2) and 423.186(f)(2). The CAI values will be calculated based on the 2021 Star Ratings data which will 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). Given we are following the rules codified in regulation, there are no changes to the regulatory text. We are providing this explanation to avoid uncertainty on this point for Medicare health and drugs plans.

iv. QBP Calculations for New Contracts

Under § 422.252, a new MA plan means an MA contract offered by a parent organization that has not had another MA contract in the previous 3 years. For just the 2022 QBP ratings that are based on 2021 Star Ratings, we are modifying this definition to 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 would account for how new plans that started in 2019 would have reported HEDIS and CAHPS data to CMS for the first time in 2020 for the 2021 Star Ratings; because of our elimination of the HEDIS and CAHPS data submissions to CMS, these plans will not have enough measures to calculate the 2021 Star Ratings and, consequently, the 2022 QBP rating. A new contract with an effective date of January 1, 2019 would normally be treated as new for purposes of QBPs for 2019, 2020, and 2021. The 2022 QBP rating would be based on the 2021 Star Ratings which these contracts will not have due to the elimination of HEDIS and CAHPS data.

Z. Changes to Expand Workforce Capacity for Ordering Medicaid Home Health Nursing and

Aide Services, Medical Equipment, Supplies and Appliances and Physical Therapy,
Occupational Therapy or Speech Pathology and Audiology Services

Title XIX of the Act requires that, to receive Federal Medicaid matching funds, a State must offer certain basic services to the categorically needy populations specified in the Act. Home health services for Medicaid-eligible individuals who are entitled to nursing facility services is one of these mandatory services. Individuals “entitled to” nursing facility services include the basic categorically needy populations that receive the standard Medicaid benefit package, and can include medically needy populations if nursing facility services are offered to the medically needy within a State. Home health services include part-time or intermittent nursing, home health aide services, medical supplies, equipment, and appliances, and may include therapeutic services. Current Medicaid regulations require an individual’s physician to order home health services as part of a written plan of care. The plan of care must be reviewed every 60 days, except for medical supplies, equipment and appliances which must be reviewed by a physician annually.

We recognize that increased demand on the direct care services provided by physicians during the PHE for the COVID-19 pandemic could cause a delay in the availability of physicians to order home health services in the normal timeframe. In recognition of the critical need to expand workforce capacity, we are amending 42 CFR 440.70 to allow licensed practitioners practicing within their scope of practice, such as, but not limited to, NPs and PAs, to order Medicaid home health services during the existence of the PHE for the COVID-19 pandemic.

This change to § 440.70 will expand the workforce and is also a continuation of CMS’ efforts to align with Medicare on who can order medical supplies, equipment, and appliances, and allowing smoother access to services for Medicaid beneficiaries, including those who are dually eligible. This alignment will also eliminate administrative burden to states and providers

when dealing with inconsistencies in the practitioners who may order these items between the Medicare and Medicaid programs.

This change applies to who can order Medicaid home health nursing and aide services, medical supplies, equipment and appliances and physical therapy, occupational therapy or speech pathology and audiology services covered under § 440.70(b)(1), (2), (3), and (4).

This change does not expand the benefit categories where these items can be covered. States must continue to cover and claim home health nursing and aide services, medical supplies, equipment and appliances, and physical therapy, occupational therapy or speech pathology and audiology services (that are covered under the home health benefit) under the home health benefit, unless otherwise allowed by federal regulations.

AA. Origin and Destination Requirements Under the Ambulance Fee Schedule

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. We have established regulations at § 410.40 that govern Medicare coverage of ambulance services. Under § 410.40(e)(1), Medicare Part B covers ground (land and water) and air ambulance transport services only if they are furnished to a Medicare beneficiary whose medical condition is such that other means of transportation are contraindicated. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided for the billed services to be considered medically necessary.

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. That section further provides that bed confinement is not the sole criterion in determining the medical

necessity of ambulance transportation but is one factor that is considered in medical necessity determinations. For a beneficiary to be considered bed-confined, § 410.40 (e)(1) states that all of the following criteria must be met: (1) the beneficiary is unable to get up from bed without assistance, (2) the beneficiary is unable to ambulate, and (3) the beneficiary is unable to sit in a chair or wheelchair.

The origin and destination requirements for coverage of ambulance services are addressed in our regulations at § 410.40(f). As provided in that section, Medicare covers the following ambulance transportation:

- From any point of origin to the nearest hospital, critical access hospital (CAH), or skilled nursing facility (SNF) that is capable of furnishing the required level and type of care for the beneficiary's illness or injury. The hospital or CAH must have available the type of physician or physician specialist needed to treat the beneficiary's condition;
- From a hospital, CAH, or SNF to the beneficiary's home;
- From a SNF to the nearest supplier of medically necessary services not available at the SNF where the beneficiary is a resident, including the return trip; and
- For a beneficiary who is receiving renal dialysis for treatment of ESRD, from the beneficiary's home to the nearest facility that furnishes renal dialysis, including the return trip.

We continue to believe that our current regulatory requirements governing coverage of ambulance services are appropriate under normal circumstances. However, in the context of the PHE for the COVID-19 pandemic, we recognize that providers and suppliers furnishing ground ambulance services and other health care professionals are faced with new challenges regarding potential exposure risks, for Medicare beneficiaries and for members of the community at large.

Therefore, on an interim basis, we 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. The EMS protocols are recognized operating procedures that all emergency service professionals such as emergency medical technicians (EMTs) and paramedics must follow for patient assessment, treatment, transportation and delivery to definitive care. These protocols are designed by national, state and/or local medical authorities and institutions. 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.

We are 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. These destinations 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, physician offices, urgent care facilities, ASCs, any location furnishing dialysis services outside of an ESRD facility when an ESRD facility is not available, and the beneficiary's home.

Home may be an appropriate destination for a COVID-19 patient who is discharged from the hospital to home to be under quarantine (as noted above, there must be a medically necessary ground ambulance transport of a patient in order for an ambulance service to be covered).

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

1. MIPS Improvement Activities Inventory Update

The CY 2018 Quality Payment Program final rule (82 FR 53660) finalized that we would add new improvement activities or make modifications to existing improvement activities in the Improvement Activities Inventory through notice-and-comment rulemaking. An improvement activity means an activity that relevant MIPS eligible clinician, organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes. We refer readers to Table H in the Appendix of the CY 2017 Quality Payment Program final rule (81 FR 77177 through 77199), Tables F and G in the Appendix of the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229), Tables A and B in the Appendix 2 of the CY 2019 PFS final rule (83 FR 60286 through 60303), and Tables A, B, and C in the Appendix 2 of the CY 2020 PFS final rule (84 FR 63514 through 63538) for our previously finalized Improvement Activities Inventory. We also refer readers to the Quality Payment Program website at <https://qpp.cms.gov/> for a complete list of the most current list of improvement activities.

The COVID-19 pandemic has been deemed a PHE by the Secretary of the Department of Health and Human Services. Information regarding the PHE for the COVID-19 pandemic may be found at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>. In this IFC, we are adding one new improvement activity to the Improvement Activities Inventory for the CY 2020 performance period in response to this PHE. We refer readers to Table 1 for a full description which includes the type of action that would qualify for this improvement activity. This improvement activity promotes clinician participation in a COVID-19 clinical trial utilizing

a drug or biological product to treat a patient with a COVID-19 infection.²⁰ To receive credit for this clinical improvement, clinicians must report their findings through an open source clinical data repository or clinical data registry. When utilizing the term “open source” we mean making available to the public the results of research, including publications and scientific data, which enables reuse, increases transparency, and facilitates reproducibility of research results.²¹

We believe that participation in this activity is likely to result in improved outcomes by improving the collection of data clinicians use for the care of their patients as they monitor and manage COVID-19 and drive care improvements. We believe that encouraging clinicians to utilize an open source clinical data repository or clinical data registry for data reporting will bring the results of their research to the forefront of healthcare far quicker than if it goes through the cycle of peer review and publishing. In addition, we believe that this could improve clinical practice and care delivery, a relevant stakeholder donated a database for the pandemic so that health officials/clinicians/the public could track patients and drugs that work to better improve outcomes of COVID-19 patients.

In the CY 2019 PFS (83 FR 59778 through 59782), we provided details regarding the Annual Call for Activities and how stakeholders submit potential improvement activities. In general, to nominate a new activity or request a modification to an existing improvement activity, a stakeholder must submit a nomination form available at www.qpp.cms.gov during the Annual Call for Activities. For this new improvement activity, we are making a one-time exception from our established Annual Call for Activities timeframe and processes due to this PHE.

²⁰ For more information on the COVID-19 clinical trials we refer readers to the U.S. National Library of Medicine website at <https://clinicaltrials.gov/ct2/results?cond=COVID-19>.

²¹ More information on open source is available at https://www.nlm.nih.gov/NIHbmic/nih_data_sharing_repositories.htmlhttps://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.

New improvement activities should meet one or more criteria to be included in the Improvement Activities Inventory (82 FR 53660). We believe that this activity meets the improvement activities submission criteria of a “public health emergency as determined by the Secretary,” which was finalized in the 2019 PFS final rule (83 FR 59779). As noted in the CY 2017 Quality Payment Program final rule, we use the criteria for nominating new improvement activities in selecting improvement activities for inclusion in the program (82 FR 53659). We also clarified that those criteria are but one factor in determining which improvement activities we ultimately proposed (83 FR 59780). For MIPS eligible clinicians who wish to submit this new improvement activity, we refer readers to the CY 2019 PFS final rule (83 FR 59778 through 59782) for our previously finalized improvement activities submission requirements. Table 1 displays the new improvement activity.

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. For more information on the COVID-19 clinical trials we refer readers to the U.S. National Library of Medicine website at https://clinicaltrials.gov/ct2/results?cond=COVID-19 .
Weighting:	High

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

As a result of the PHE for the COVID-19 pandemic, we are applying the MIPS automatic extreme and uncontrollable circumstances policy at § 414.1380(c)(2)(i)(A)(8) and (c)(2)(i)(C)(3) to MIPS eligible clinicians for the 2019 MIPS performance period/2021 MIPS payment year. We believe that this application of the policy is appropriate given the impact COVID-19 will likely have on the ability of many MIPS eligible clinicians to complete data submission for the MIPS program for the 2019 MIPS performance period because most of those submissions will occur during CY 2020.

Due to the timing of the PHE, we realize that there may be scenarios where MIPS-eligible clinicians are not covered by the automatic extreme and uncontrollable circumstances policy. For example, as we stated in the CY 2019 PFS final rule, the automatic extreme and uncontrollable circumstances policy does not apply to groups or virtual groups (83 FR 59874 and 59875); however, under § 414.1380(c)(2)(i), individual clinicians, groups and virtual groups could submit an application for reweighting the performance categories based on extreme and uncontrollable circumstances. To provide additional relief to individual clinicians, groups, and virtual groups for whom sufficient MIPS measures and activities may not be available for the 2019 MIPS performance period due to the PHE for the COVID-19 pandemic, we are extending the deadline to submit an application for reweighting the quality, cost, and improvement activities performance categories based on extreme and uncontrollable circumstances (§ 414.1380(c)(2)(i)(A)(6)) and the Promoting Interoperability performance category based on extreme and uncontrollable circumstances (§ 414.1380(c)(2)(i)(C)(2)) from December 31, 2019 to April 30, 2020, or a later date that we may specify. This extended deadline of April 30, 2020 mirrors the MIPS data submission deadline extension. The extended deadline is available only for applications that demonstrate the clinician has been adversely affected by the PHE for the COVID-19 pandemic.

We are also modifying our existing policy for the 2019 performance period/2021 MIPS payment year so that if a MIPS eligible clinician, group, or virtual group submits an application for reweighting based on the PHE for the COVID-19 pandemic by the extended deadline, any MIPS data they have submitted or will submit would not effectively void their application. Under § 414.1380(c)(2)(i)(A)(6) and (c)(2)(i)(C), if an application for reweighting the performance categories based on extreme and uncontrollable circumstances is submitted, but data on measures or activities for a performance category are also submitted, a MIPS eligible clinician will be scored on the submitted data, and the performance categories for which data are

submitted will not be reweighted. However, for the 2019 performance period we believe it is appropriate to modify this policy, because we believe it is possible that a MIPS eligible clinician, group, or virtual group could have submitted some MIPS data prior to the PHE for the COVID-19 pandemic, but due to circumstances related to the PHE for the COVID-19 pandemic, are not able to complete their submission such that the data they submitted may not reflect their actual performance on the measures and activities. As a result, we are modifying the policy at § 414.1380(c)(2)(i)(A)(6) to create an exception for the 2019 performance period/2021 MIPS payment year only, such that if a MIPS eligible clinician demonstrates through an application submitted to CMS that they have been adversely affected by the PHE for the COVID-19 pandemic, but also submits data for the quality, cost, or improvement activities performance categories, the performance categories for which data are submitted would still be reweighted (subject to CMS' approval of the application), and the data submission would not effectively void the application for reweighting. We are also modifying the policy at § 414.1380(c)(2)(i)(C) to create a similar exception for the Promoting Interoperability performance category for the 2019 performance period/2021 MIPS payment year only.

CC. Inpatient Hospital Services Furnished Under Arrangements Outside the Hospital During the Public Health Emergency (PHE) for the COVID-19 Pandemic

1. Overview for Inpatient Hospital Services

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

either by such hospital or by others under such arrangements.

Routine services in the hospital setting are those described in sections 1861(b)(1) and (b)(2) of the Act. Under our current policy for hospital services furnished under arrangements that we adopted in the FY 2012 IPPS/LTCH PPS rulemaking (76 FR 51714), routine services cannot be provided under arrangement outside the hospital. Only the therapeutic and diagnostic services described in section 1886(b)(3) of the Act can be provided under arrangement outside the hospital.

We continue to believe that our current policy prohibiting routine services from being provided under arrangement outside the hospital is consistent with the statute and appropriate for the reasons discussed in the FY 2012 IPPS/LTCH PPS rulemaking. However, we wish to give hospitals that provide services to Medicare beneficiaries flexibility to respond effectively to the serious public health threats posed by COVID-19. Recognizing the urgency of this situation, and understanding that our current policy may inhibit use of capacity in settings that might otherwise be effective in the efforts to mitigate the impact of the pandemic on Medicare beneficiaries and the American public, we are changing our 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.

2. Prior Rulemaking

In the FY 2012 IPPS/LTCH PPS rulemaking (76 FR 51711), we noted that the statute specifies that “routine services,” for example, bed, board, nursing and other related services, except those specified at paragraph (3) of section 1861(b) of the Act are to be provided by “the hospital,” and not just “a hospital.” Similarly, we noted that our implementing regulations at § 409.12 indicate that Medicare pays for nursing and related services, use of hospital facilities, and medical social services as inpatient hospital services or inpatient CAH services only if those services are ordinarily furnished by the hospital or CAH. We pointed out that, consistent with

section 1861(b)(3) of the Act, only with regard to other diagnostic or therapeutic services do the regulations at § 409.16 state that Medicare will also pay for these services if furnished “by others under arrangements made by the hospital or CAH.”.

Under our current policy adopted in the FY 2012 IPPS/LTCH PPS rulemaking, if routine services, that is, services described in sections 1861(b)(1) and (b)(2) of the Act, are provided in the hospital, they are considered as being provided “by the hospital.” We stated that we believe this policy is consistent with the statute because the statutory language specifying that the routine services described in sections 1861(b)(1) and (b)(2) of the Act be provided “by the hospital” suggests that the hospital is required to exercise professional responsibility over the services, including quality controls. In situations in which certain routine services are provided through arrangement “in the hospital,” for example, contracted nursing services, we stated that we believe the arrangement generally results in the hospital exercising the same level of control over those services as the hospital does in situations in which the services are provided by the hospital's salaried employees.

Therefore, if routine services are provided in the hospital to its inpatients, we consider the service as being provided by the hospital. However, if these services are provided to its patients outside the hospital, the services are considered as being provided under arrangement, and not by the hospital. Therefore, consistent with the statute, we stated that only therapeutic and diagnostic services can be provided under arrangement outside the hospital.

Some commenters during the FY 2012 IPPS/LTCH PPS rulemaking stated that our policy to limit the services a hospital may provide under arrangements is not required by the statute or regulations. Some commenters also believed that CMS' proposed reading of the statutory definition of inpatient hospital services is only one possible interpretation of the statute.

In our response to these comments, we noted that we focused on section 1861(b) of the Act because it provides the statutory basis for our policy to limit the services that may be

furnished under arrangement. As we noted in that rulemaking, the reference to diagnostic or therapeutic items or services in section 1861(b)(3) of the Act is to services furnished by the hospital or by others under arrangements. Therefore, we stated that we believe it is consistent with the statutory language to limit the services that may be furnished outside of a hospital under arrangement to only diagnostic and therapeutic services.

We noted that our policy does not alter the definition of inpatient hospital services, but instead limits the services a hospital may provide under arrangements outside the hospital. If a patient of Hospital A is in Hospital B receiving routine services, the patient will still be an “inpatient,” but the services will not be considered “inpatient hospital services” furnished by the hospital for purposes of payment for services defined under section 1861(b) of the Act. If the patient is admitted to Hospital B, then the patient would be an “inpatient” of Hospital B and the routine services furnished to that individual would meet the definition of “inpatient routine services” under section 1861(b) of the Act.

We also discussed in the FY 2012 IPPS/LTCH PPS rulemaking the policy considerations supporting this change. We stated that we became aware that some hospitals were furnishing certain routine services, including ICU services, under arrangement. For example, under certain arrangements, if an inpatient of an IPPS-excluded hospital (“hospital A”) required ICU services, and the IPPS-excluded hospital could not provide these services, the patient was moved to an IPPS hospital (“hospital B”) that could furnish the ICU services. In these situations, the patient was not transferred to hospital B but was moved from an inpatient bed of hospital A to an inpatient bed of hospital B. However, the IPPS-excluded hospital treated these services as being provided under arrangement and included the cost of those services on its cost report. We found it problematic that the patient was, at all times, considered an inpatient of hospital A even though the patient occupied an inpatient bed at hospital B.

Because the two hospitals in the example above are under two different payment systems,

we stated that we believe this arrangement can result in inappropriate and potentially excessive Medicare payments. The IPPS-excluded hospital, hospital A, is paid on a reasonable cost basis, subject to a ceiling. In most cases, this payment is greater than if the hospital were paid under the IPPS for the same patient. Furthermore, although there is a ceiling on the amount of Medicare payment for hospital A, there are also provisions that allow hospital A to receive adjustments to its ceiling in certain circumstances, which in the absence of our policy could allow payment to hospital A above those allowed by its ceiling. Therefore, in the absence of our policy these arrangements could allow hospital A to request an adjustment to its ceiling because its ICU costs had increased beyond what is allowed. In that case, hospital A would receive additional payments beyond its ceiling. We stated that we believe that by limiting the furnishing of routine services under arrangements to situations in which the services are furnished in hospital A, we reduce the opportunity for gaming. In these more limited situations, hospital A exercises sufficient control over the use of hospital resources when furnishing these services such that the services are appropriately included in hospital A's cost report.

Under our current policy adopted in that rulemaking, if hospital A did not have the resources to treat a patient, it would transfer the patient to hospital B for ICU services, and hospital B would bill Medicare consistent with the IPPS provisions. Hospital A would be paid for an inpatient discharge.

3. Inpatient Hospital Services Furnished Under Arrangements outside the Hospital during the PHE for the COVID-19 pandemic

As noted earlier in this section, we continue to believe that our current policy is consistent with the statute and appropriate for the reasons discussed in the FY 2012 IPPS/LTCH PPS rulemaking. However, we wish to give hospitals that provide services to Medicare beneficiaries additional flexibilities to respond effectively to the serious public health threats posed by the spread of COVID-19. Recognizing the urgency of this situation, and understanding

that some pre-existing Medicare payment rules may inhibit use of capacity that might otherwise be effective in the efforts to mitigate the impact of the pandemic on Medicare beneficiaries and the American public, we are changing our under arrangements policy during the PHE for the COVID-19 pandemic beginning March 1, 2020, so that hospitals are allowed broader flexibilities to furnish inpatient services, including routine services outside the hospital.

We believe that our concerns articulated in the FY 2012 rulemaking regarding gaming of routine services provided outside the hospital for payment reasons are significantly mitigated by the existence of the PHE. Hospitals would be treating patients in locations outside the hospital for a variety of reasons, including limited beds and/or limited specialized equipment such as ventilators, and for a limited time period. We do not expect that during the PHE for the COVID-19 pandemic hospitals would be treating patients outside the hospital for gaming reasons.

As noted, we continue to believe that our current policy of limiting the services that may be provided under arrangements outside of the hospital to therapeutic and diagnostic items and services is consistent with the statute and supported by the policy considerations discussed in the FY 2012 IPPS/LTCH PPS final rule. However, we do not believe that the statute would preclude this change in policy to allow routine services to also be provided under arrangements outside the hospital, in light of the compelling circumstances and the need for additional, short-term flexibility during the current PHE for the COVID-19 pandemic. Consistent with this, and as previously summarized in section II.BB.2 of this IFC, we note that we received comments during the FY 2012 rulemaking that our policy to limit the services a hospital may provide under arrangements is not required by the statute and that CMS' reading of the statutory definition of inpatient hospital services is only one possible interpretation of the statute.

While we are changing our under arrangements policy during the PHE for the COVID-19 pandemic to allow hospitals broader flexibilities in furnishing inpatient services, we emphasize that we are not changing our policy that a hospital needs to exercise sufficient control and

responsibility over the use of hospital resources in treating patients, as discussed in the FY 2012 IPPS/LTCH PPS final rule and Section 10.3 of Chapter 5 of the Medicare General Information, Eligibility, and Entitlement Manual (Pub. 100-01). Nothing in the current PHE for the COVID-19 pandemic has changed our policy or thinking with respect to this issue and we are making no modifications to this aspect of the policy. Hospitals need to continue to exercise sufficient control and responsibility over the use of hospital resources in treating patients regardless of whether that treatment occurs in the hospital or outside the hospital under arrangements. 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.

For the reasons set forth above, 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 the hospital.

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

In an effort to be able to be more responsive to situations in which Part B suppliers could request advance payments from CMS, we are making modifications to existing advance payments rules found in 42 CFR 421.214. Currently, § 421.214 limits CMS' ability to make advance payments in situations where a CMS contractor is unable to process claims within established time limits. In light of the PHE Declaration related to COVID-19 and the inability to project the impact it may have in the future on CMS' abilities to ensure timely payment and the potential challenges for suppliers to prepare and submit claims to CMS contractors, we are revising the definition of advance payment in § 421.214(b). Currently, paragraph (b) defines advance payment as a conditional partial payment made by the *carrier* in response to a claim that it is unable to process within established time limits. We are revising this definition to state that

the conditional partial payment will be made by the “contractor” (not the carrier) except as provided in paragraph (j) of this section. We are also adding language to permit payments under an exception at § 421.214(c). In addition, we are also adding paragraph (j) to specifically address emergency situations in which it will be able to make advance payments. Additionally, existing rules limit CMS to no more than 80 percent of the anticipated payment for that claim based upon the historical assigned claims payment data for claims paid to the supplier. Under exceptional circumstances as outlined in paragraph (j) of this section, we are increasing this limit to 100 percent of the anticipated payment for that claim based upon the historical assigned claims payment data for claims paid to the supplier in paragraph (f)(1)(i). We are also adding a criterion to § 421.214 that suppliers in bankruptcy would not be eligible to receive advance payments to ensure that, with such expanded authority, CMS is able to appropriately pay and recover advance payments made to Part B suppliers.

III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule before the provisions of the rule take effect, in accordance with 5 U.S.C. 553(b) of the Administrative Procedure Act (APA) and section 1871 of the Act. Specifically, section 553(b) of the APA requires the agency to publish a notice of the proposed rule in the **Federal Register** that includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. Section 553(c) of the APA further requires the agency to give interested parties the opportunity to participate in the rulemaking through public comment before the provisions of the rule take effect. Similarly, section 1871(b)(1) of the Act requires the Secretary to provide for notice of the proposed rule in the **Federal Register** and a period of not less than 60 days for public comment. 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 procedures are impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the 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 an agency finds good cause to support an earlier effective date. Section 1871(e)(1)(B)(i) of the Act also prohibits a substantive rule from taking effect before the end of the 30-day period beginning on the date the rule is issued or published. Section 1871(e)(1)(B)(ii) of the Act permits a substantive rule to take effect before 30 days if the Secretary finds that a waiver of the 30-day period is necessary to comply with statutory requirements or that the 30-day delay would be contrary to the public interest. Furthermore, section 1871(e)(1)(A)(ii) of the Act permits a substantive change in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability under Title XVIII of the Act to be applied retroactively to items and services furnished before the effective date of the change if the failure to apply the change retroactively would be contrary to the public interest.

The nation is experiencing an emergency of unprecedented magnitude. Ensuring the health and safety of Medicare beneficiaries, Medicaid recipients, and healthcare workers is of primary importance. As this IFC directly supports that goal by offering healthcare professionals 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 is critically important that we implement this IFC as quickly as possible. As we are in the midst of a PHE, we find good cause to waive notice and comment rulemaking as we believe it would be contrary to the public interest for us to undertake normal notice and comment rulemaking procedures. For the same reasons, because we cannot afford any delay in effectuating this IFC, we find good cause to waive the 30-day delay in the

effective date and, moreover, to 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.

On January 30, 2020, the International Health Regulations Emergency Committee of the World Health Organization (WHO) declared the outbreak of the 2019 Novel Coronavirus (COVID-19) to be a Public Health Emergency of International Concern.²² On January 31, 2020, Health and Human Services Secretary Alex M. Azar II declared a Public Health Emergency (PHE)²³ under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to COVID-19. On March 11, 2020, the WHO publicly declared COVID-19 to be a pandemic.²⁴ On March 13, 2020, the President declared that the COVID-19 outbreak in the United States constitutes a national emergency,²⁵ beginning March 1, 2020. This declaration, along with the Secretary's January 30, 2020 declaration of a PHE, conferred on the Secretary certain waiver authorities under section 1135 of the Act. On March 13, 2020, the Secretary authorized waivers under section 1135 of the Act, effective March 1, 2020.²⁶

In support of the imperative to contain and combat the virus in the United States, this IFC will give health care workers and hospitals additional flexibility to respond to the virus and continue caring for patients while minimizing exposure. CDC guidelines are clear that public exposure greatly increases the overall risk to public health and they stress the importance of containment and mitigation strategies to minimize public exposure and the spread of COVID-19. As of March 29th, the CDC reports 122,653 cases of COVID-19 in the United States and 2,112

²² [https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-\(2019-ncov\)](https://www.who.int/news-room/detail/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)).

²³ <https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>.

²⁴ <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>.

²⁵ <https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

²⁶ <https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx>.

deaths.²⁷ Individuals such as healthcare workers who come in close contact with those infected with COVID-19 are at an elevated risk of contracting the disease. To minimize these risks, the CDC has urged healthcare professionals to make every effort to distance themselves from those who are potentially sick with COVID-19 by using modalities such as telephonic interviews, text monitoring systems, or video conference.²⁸ As the healthcare community works to establish and implement infection prevention and control practices, CMS is also working to revise and implement regulations that function in concert with those healthcare community infection prevention and treatment practices.

This IFC offers flexibilities in certain Medicare and Medicaid regulations that support measures to combat the COVID-19 pandemic and safeguard all interests by protecting healthcare providers and vulnerable beneficiaries. The provisions of this IFC better enable and facilitate physicians and other clinicians, to focus on caring for these beneficiaries during this PHE for the COVID-19 pandemic and minimize their own risks to COVID-19 exposure. For example, by increasing access to telehealth and testing in a patient's home, and improving infection control, this IFC will provide flexibilities for Medicare beneficiaries to be able to receive medically necessary services without jeopardizing their health or the health of those who are providing those services, in turn minimizing public exposure and the overall risk to public health. Moreover, changes to Medicare payment rules will confer on practitioners and other healthcare providers the broadest flexibility to use remote communications technology to avoid exposure risks to themselves, their patients, and communities. These changes include greater flexibilities to use communications technology to interact with patients directly and to supervise care directly provided by other clinicians. This IFC alters the applicable payment rules to provide specimen collection fees for independent laboratories collecting specimens from beneficiaries who are

²⁷ <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html>.

²⁸ <https://www.cdc.gov/coronavirus/2019-ncov/php/guidance-evaluating-pui.html>.

homebound or inpatients (not in a hospital) for COVID-19 testing. Additionally, certain new model-specific requirements for Innovation Center Models and program-specific requirements for the Quality Payment Program will reduce or prevent practices that might inappropriately incentivize cost considerations over patient safety. Changes to the calculation of the 2021 and 2022 Part C and D Star Ratings will address the expected disruption to data collection and measure scores posed by the COVID-19 pandemic, and amendments to the Medicaid home health regulations will enable other licensed practitioners to order services, equipment, and therapy they otherwise could not.

We believe it would be contrary to the public interest for us to undertake normal notice and comment procedures and to delay the effective date of this IFC. We find good cause to waive notice of proposed rulemaking under section 553(b)(3)(B) of the APA and section 1871(b)(2)(C) of the Act, and, for the reasons stated, we find that it would be contrary to the public interest to delay the effective date of this IFC, under section 553(d) of the APA and section 1871(e)(1)(B)(i) of the Act.

Furthermore, the President declared that the COVID-19 outbreak in the United States constituted a national emergency beginning March 1, 2020. To ensure the consistent availability throughout the national emergency period of measures we are taking to address the COVID-19 pandemic, we believe it is vital that the effective date of this IFC align with the first day of the national emergency. It is also important to ensure the health care providers that acted expeditiously to implement appropriate physical and operational changes to their practices to adapt to emergency conditions, even in the absence of changes in our policies to address them, are not disadvantaged relative to other health care providers, and will not be discouraged from taking similar appropriate actions in the future. March 1, 2020 precedes the date of publication of this IFC in the **Federal Register**, which means this rule has a retroactive effect. However, section 1872(e)(1)(A)(ii) of the Act permits the Secretary to issue a rule with retroactive effect if

the failure to do so would be contrary to the public interest. As we have explained above, we believe it would be contrary to the public interest not to implement this IFC as soon as we are authorized to do so under the authority of section 1871(e)(1)(A)(ii) of the Act, that is, retroactively to March 1, 2020. We are providing a 60-day public comment period for this IFC as specified in the DATES section of this document.

IV. Collection of Information Requirements

For IFC changes to the MA and Part D Star Ratings program, the elimination of the requirement to collect and submit data for OMB control numbers 0938-1028 (HEDIS) and 0938-0732 (CAHPS) will reduce some burden. Those collections are approved for 164,200 hours and 123,375 hours annually, respectively. Due to the ongoing nature of these information collections, it is difficult to determine the extent of the burden. However, the burden estimates for the HEDIS and CAHPS information collection requests are approved through November 30, 2020 and April 30, 2021, respectively. Upon resubmission for OMB approval, we will revise both information collections to more accurately account for the burden decreases.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

Executive Order 12866 and other laws and Executive Orders require economic analysis

of the effects of proposed and final (including interim final) rules.²⁹ The Office of Management and Budget has designated this rulemaking as “economically significant” under E.O. 12866 and also major under the Congressional Review Act. This IFC’s designation under Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs (82 FR 9339), which was issued on January 30, 2017, will be informed by public comments received.

A. Statement of Need

Throughout this IFC, we discuss several changes to payment and coverage policies intended to allow health care providers maximum flexibility to minimize the spread of COVID-19 among Medicare and Medicaid beneficiaries, health care personnel, and the community at large and increase capacity to address the needs of their patients. The flexibilities and changes contained within this IFC are responsive to this developing pandemic emergency. 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.

We believe that the needs of Medicare patients will likely test the capacity of the health care system over the coming months. Our policies during the PHE for the COVID-19 Pandemic will allow home health agencies and hospices more flexibility to furnish services via telecommunications technologies to minimize exposure risks to patients, clinicians and the general public; and there would be no change in Medicare payment rates or change in the types of patients treated under these policies compared to the absence of these policy changes.

Our additions to the list of Medicare telehealth services will allow more physicians’ services to be furnished in a manner that reduces the exposure risk to patients and physicians. To the extent that physicians utilize these new flexibilities for patients that would have been treated

²⁹ Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104-04, enacted on March 22, 1995) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2020, that amount is approximately \$156 million. This IFC does not mandate, on an unfunded basis, any requirements for State, local, or tribal governments, or for the private sector.

in more traditional offices or hospital settings without this policy change, given the competing demand for physicians' services during the pandemic this additional flexibility would not result in any significant change in aggregate Medicare payments for physicians' services.

Still, it is possible that the flexibilities and changes contained within this IFC would increase aggregate Medicare payments. For example, if its protections against exposure risk are effective, providers may maintain their own health and thus be available to provide more medical treatment overall. Improvements in both provider and/or patient health are intended benefits of this IFC.

We anticipate that the change in the site of service payment amount for telehealth services under the PHE along with the changes that allow for broader flexibilities in supervision will allow physicians and other practitioners to better maintain overall level of needed care to Medicare beneficiaries in the face of exposure risks and competing demands for health care providers.

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

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. Consequently, there should be negligible impacts on payments for MA organizations from these modifications.

B. Special Requirements for Psychiatric Hospitals

In section II.P. of this final rule, we note that existing requirements for psychiatric hospitals specify that progress notes must be recorded by the physicians(s), psychologists, or other licensed independent practitioner(s) responsible for the care of the patient. We believe that this provision requires clarification and revision since the regulatory language is inconsistent

with other recent changes finalized throughout the hospital CoPs as this provision applies to APPs, including PAs, NPs, psychologists, and CNSs.

Continued use of this outdated term may inadvertently exacerbate workforce shortage concerns, might unnecessarily impose regulatory burden on hospitals, especially psychiatric hospitals, by restricting a hospital's ability to allow APPs to operate within the scope of practice allowed by state law. We believe that the existing regulation fails to recognize the benefits to patient care that might be derived from fully utilizing APPs and their clinical skills to the highest levels of their training, education, and experience as allowed by hospital policy in accordance with state law.

Therefore, we are removing the term "licensed independent practitioner(s)" from the regulations. We believe that this revision is non-controversial, and that the public interest will be served by permitting a greater scope of practice for professionals in the psychiatric hospital context and further believe that these trained and qualified practitioners, when acting in accordance with State law, their scope of practice, and hospital policy, should have the authority to record progress notes of psychiatric patients for whose care they are responsible.

At § 482.61(d), we are allowing NPPs, or APPs, to document progress notes in accordance with State laws and scope-of-practice requirements. We believe that clarification of the intent of the regulation is necessary and will result in NPPs (specifically PAs, NPs, and CNSs) documenting in the progress notes for patients receiving services in psychiatric hospitals.

We estimate that MDs/DOs currently spend approximately 30 minutes documenting progress notes in psychiatric hospitals, and that 33 percent of this time would be covered by NPPs. Of the 4,823 Medicare participating hospitals, approximately 620 (or 13 percent) are psychiatric hospitals. According to AHA, there were 36,510,207 inpatient hospital stays in 2017, and therefore, an estimated 13 percent of these stays were at psychiatric hospitals. The change

will result in a savings of \$153.5 million (4,746,327 psychiatric hospital stays x 2 progress notes per stay × 0.5 hours of physician/psychiatrist time × \$98 per hourly wage difference between physicians/psychiatrists (\$198) and NPPs (\$100, the average wage between NPs and PAs) × 33 percent of physician time spent writing progress notes covered by NPPs, or APPs).

C. Anticipated Effects of changes to the MDPP expanded model

1. Effects on Beneficiaries

In section II.Q. of this IFC, we are amending the MDPP expanded model to modify certain requirements of the model in an emergency area during an emergency period, as those terms are defined in section 1135 (g) of the Act, for which the Secretary has issued a waiver under section 1135 of the Act. Specifically, as the Secretary has issued a waiver under section 1135 of the Act, certain MDPP beneficiaries will be permitted to obtain the set of MDPP services more than once per lifetime, the number of virtual make-up sessions is increased, and certain MDPP suppliers will be permitted to deliver time limited virtual MDPP sessions. These changes apply only to MDPP beneficiaries (as defined in § 410.79(b)) who were receiving the MDPP set of services during the emergency period, as defined under section 1135(g) of the Act.

We believe that during this COVID-19 pandemic, Medicare beneficiaries will not be able to attend in-person classes. Because we do not want to disrupt their progress and we want to promote both MDPP beneficiary and MDPP supplier retention, we have modified how the set of services can be delivered to make the program accessible to currently enrolled MDPP beneficiaries during this national emergency. Our policies during the PHE for the COVID-19 Pandemic will allow enrolled MDPP suppliers with active MDPP cohorts more flexibility to furnish virtual sessions, as described by the CDC's DPRP Standards.

With the exception of the requirement for in-person attendance and the in-person body weight measurement at the first core-session, the in-person attendance requirements are waived. MDPP suppliers shall not start any new cohorts with MDPP beneficiaries throughout the

COVID-19 PHE period in the geographic area, as defined under section 1135(g) of the Act, given that most beneficiaries cannot receive in-person services right now.

During the emergency period, the number of virtual make-up sessions is waived for MDPP suppliers, with an MDPP supplier offering MDPP beneficiaries no more than 15 weekly virtual make-up sessions during the core session period, no more than 6 monthly virtual make-up sessions during the core maintenance session interval period, no more than 12 monthly virtual make-up sessions during the ongoing maintenance session interval periods. All flexibilities described in this IFC will cease to be available as of the effective end date of the PHE. When in-person classes resume, the CDC is allowing suppliers to pick up where they left off, or to restart the program from week one. It is our intent to conform with the CDC guidance where feasible, with the overall intent to minimize disruption of services for MDPP suppliers and MDPP beneficiaries; by allowing MDPP beneficiaries to maintain their eligibility. In this IFC, we are amending the MDPP regulations to provide for changes as described in section II.Q.1 of this IFC, including allowing MDPP suppliers to either deliver MDPP services virtually or suspend delivery and resume services at a later date, in an emergency area and during this COVID-19 PHE period, as those terms are defined in section 1135(g) of the Act, for which the Secretary has authorized a waiver under section 1135 of the Act and the Secretary has declared a PHE. In addition, these changes permit certain MDPP beneficiaries to obtain the set of MDPP services more than once per lifetime, for the limited purposes of allowing a pause in service and allow MDPP beneficiaries to maintain eligibility for MDPP services despite a break in service, attendance, or weight loss achievement. These changes will have a positive impact on affected MDPP beneficiaries, as it will allow them to maintain eligibility for the expanded model, and request virtual make-up sessions if needed for successful completion of attendance and weight loss milestones.

2. Effects on the Market

Currently, more than 196 organizations nationally are enrolled as MDPP suppliers. There are approximately 798 locations. We anticipate that of the 1,818 beneficiaries identified through our monitoring data and the CDC’s Diabetes Prevention Recognition Program (DPRP) data, 1,358 beneficiaries may be impacted by allowing both the once-per-lifetime benefit and the minimum weight loss requirement to be waived for those beneficiaries in the first 12 months of MDPP.

TABLE 2:

Recommended Waivers	Cost impact
Adjust the limit to the # Virtual Make-up sessions	\$ -
Waive the once per lifetime requirement	\$ 279,748.00
Waive the minimum weight loss requirement for OM	\$ 53,301.50
Waive the MDPP services time periods and intervals	\$ -
Average Y1 MDPP Payments (Y1) with no COVID action	\$ 177,898.00
Total cost of COVID-19 response	\$ 333,049.50

Assumptions:

--Average MDPP payments in Year 1: \$412, assuming that beneficiaries attended 9 sessions, and reached the 5 percent weight loss during interval 1 of the core maintenance session

--Average MDPP payments in Year 1 with no COVID-19 action: \$131, assuming beneficiaries attended 2 ongoing maintenance sessions

D. Modification to the Extreme and Uncontrollable Circumstances Policy under the Shared Savings Program

In section II.V. of this IFC, we discuss a modification to the extreme and uncontrollable circumstances policy under the Shared Savings Program. The current Medicare Shared Savings Program extreme and uncontrollable circumstances policy for purposes of determining an ACO’s quality score for use in determining shared savings or shared losses applies if twenty percent or more of an ACO’s assigned beneficiaries or its legal business entity are located in an area identified under the Quality Payment Program as being affected by an extreme and uncontrollable circumstance, during the performance year, including the applicable quality data reporting period for the performance year if, the quality reporting period is not extended. In response to the National Emergency for the COVID-19 pandemic declared on March 13, 2020, we have determined that the 2019 MIPS data submission deadline will be extended by 30 days

until April 30, 2020, to give eligible clinicians more time to report quality and other data for purposes of MIPS. This extended timeline also applies to Shared Savings Program ACOs because they are required to report quality data via the CMS Web Interface and we align the Shared Savings Program data submission timeline with the timeline for MIPS data submission. As currently written, our extreme and uncontrollable circumstances policy cannot be applied to waive the quality reporting requirements under the Shared Savings Program because the quality data submission period has been extended.

The PHE for the COVID-19 pandemic applies to all counties in the United States, and we think it is appropriate to offer relief under the Shared Savings Program extreme and uncontrollable circumstances policy to all Shared Savings Program ACOs that are unable to completely and accurately report quality for 2019 by the extended deadline. Accordingly, in this IFC, we are revising the regulation at § 425.502(f) to remove the restriction which prevents the application of the Shared Savings Program extreme and uncontrollable circumstances policy for disasters that occur during the quality period if the reporting period is extended, to offer relief under the Shared Savings Program to all ACOs that may be unable to completely and accurately report quality for 2019 due to the PHE for the COVID-19. As currently written, our extreme and uncontrollable circumstances policy cannot be applied to waive the quality reporting requirements under the Shared Savings Program because the quality data submission period has been extended.

The PHE for the COVID-19 pandemic applies to all counties in the United States, and we think it is appropriate to offer relief under the Shared Savings Program extreme and uncontrollable circumstances policy to all Shared Savings Program ACOs that are unable to completely and accurately report quality for 2019 by the extended deadline. Accordingly, in this interim final rule, we are revising the regulation at § 425.502(f) to remove the restriction which prevents the application of the Shared Savings Program extreme and uncontrollable

circumstances policy for disasters that occur during the quality period if the reporting period is extended, in order to offer relief under the Shared Savings Program to all ACOs that may be unable to completely and accurately report quality for 2019 due to the PHE for the COVID-19 pandemic.

We estimate based on patterns evident in the financial reconciliation for performance year 2018 that this change would allow roughly 100 ACOs that achieve savings either to qualify to receive shared savings or to receive a higher effective sharing rate. We estimate the average resulting benefit to such ACOs ranging from \$150,000 to \$200,000 per ACO. The total impact of extending the extreme and uncontrollable circumstances policy despite the extension of the quality reporting period for 2019 is therefore estimated to be \$20 million, with a range of uncertainty in such estimate spanning \$15 million to \$25 million.

E. Anticipated effects of changes to the Quality Payment Program

Since it is not possible to comprehensively predict the impact of the evolving PHE for the COVID-19 pandemic at this time, the Office of the Actuary was unable to calculate a discrete impact estimate for the effect of extending CJR PY 5 an additional 3 months. However, given the previous estimate for PY 5 in the Comprehensive Care for Joint Replacement Model Three-Year Extension and Changes to Episode Definition and Pricing proposed rule (CMS-5529-P), we anticipate the impact of the additional 3 months could range between \$0 and \$1.2 million. We will continue to refine this analysis and will provide a more detailed estimate in the final rule if available. Table 3 summarizes the financial impact of extending PY 5 an additional 3 months. Table 3 includes the full amount of FFS episode payments and also includes any reconciliation payments related to the model. Table 3 also shows costs/savings (costs are represented as positive amounts and savings as negative amounts) imposed on non-federal entities (that is, participating medical facilities), as well as net transfers of federal funds (that is, increases in Medicare program expenditures are indicated as positive amounts and decreases in Medicare

program expenditures are indicated as negative amounts).

TABLE 3: Financial Impact of Extending PY 5 an Additional 3 Months

Scenario	Costs/Benefits	Transfers (millions)
Net financial impact of extending CJR model PY 5 by 3 additional months		1.2

F. Overall Impact

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than \$8.0 million to \$41.5 million in any one year). Individuals and states are not included in the definition of a small entity. As its measure of significant economic impact on a substantial number of small entities, HHS uses an adverse change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the provisions in this IFC.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This IFC will not have a significant impact on the operations of a substantial number of small rural hospitals.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This IFC does not have a substantial direct cost impact on state or local governments, preempt state law, or otherwise have federalism implications.

Under the Congressional Review Act (5 U.S.C. 801 et seq.), the Office of Information and Regulatory Affairs designated this rule as a major rule, as defined by 5 U.S.C. 804(2). As such, this rule has been transmitted to the Congress and the Comptroller General for review.

List of Subjects42 CFR Part 400

Grant programs-health, Health facilities, Health maintenance organizations (HMO), Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health insurance, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 421

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 440

Grant programs-health, Medicaid.

42 CFR Part 482

Grant programs-health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 510

Administrative practice and procedure, Health facilities.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 400—INTRODUCTION; DEFINITIONS

1. The authority citation part 400 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh, and 44 U.S.C. Chapter 35.

2. Section 400.200 is amended by adding the definition of “Public Health Emergency” in alphabetical order to read as follows:

§ 400.200 General definitions.

* * * * *

Public Health Emergency (PHE) means the Public Health Emergency determined to exist nationwide as of January 27, 2020, by the Secretary pursuant to section 319 of the Public Health Security Act on January 31, 2020, as a result of confirmed cases of COVID-19, including any subsequent renewals.

* * * * *

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

3. The authority citation part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b-12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

4. Section 405.2416 is amended by adding paragraph (a)(5) to read as follows:

§ 405.2416 Visiting nurse services.

(a) * * *

(5) During a PHE, as defined in § 400.200 of this chapter, an area typically served by the RHC, and an area that is included in the FQHC’s service area plan, is determined to have a shortage of home health agencies, and no request for this determination is required.

* * * * *

PART 409—HOSPITAL INSURANCE BENEFITS

5. The authority citation for part 409 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

6. Section 409.43 is amended by revising paragraph (a)(3) to read as follows:

§ 409.43 Plan of care requirements.

(a) * * *

(3) The plan of care must include the identification of the responsible discipline(s) and the frequency and duration of all visits, as well as those items listed in § 484.60(a) of this chapter that establish the need for such services. All care provided must be in accordance with the plan of care. During a PHE, as defined in §400.200 of this chapter, the plan of care must include any provision of remote patient monitoring or other services furnished via a telecommunications system and such services must be tied to the patient-specific needs as identified in the comprehensive assessment, 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.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

7. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

8. Section 410.27 is amended by revising paragraphs (a)(1)(iv)(D) and (E) to read as follows:

§ 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.

(a) * * *

(1) * * *

(iv) * * *

(D) For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or a doctor of osteopathy, as specified in §§ 410.47 and 410.49, respectively. For purposes of this section, direct supervision means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. During a Public Health Emergency, as defined in § 400.200 of this chapter, the presence of the physician includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider; and

(E) For nonsurgical extended duration therapeutic services (extended duration services), which are hospital or CAH outpatient therapeutic services that can last a significant period of time, have a substantial monitoring component that is typically performed by auxiliary personnel, have a low risk of requiring the physician's or appropriate nonphysician practitioner's immediate availability after the initiation of the service, and are not primarily surgical in nature, Medicare requires a minimum of direct supervision during the initiation of the service which may be followed by general supervision at the discretion of the supervising physician or the appropriate nonphysician practitioner. Initiation means the beginning portion of the nonsurgical extended duration therapeutic service which ends when the patient is stable and the supervising physician or the appropriate nonphysician practitioner determines that the remainder of the service can be delivered safely under general supervision. During a Public Health Emergency, as defined in § 400.200 of this chapter, Medicare requires a minimum level of general supervision for the entire service; and

* * * * *

9. Section 410.28 is amended by revising paragraph (e)(1) to read as follows:

§ 410.28 Hospital or CAH diagnostic services furnished to outpatients: Conditions.

* * * * *

(e) * * *

(1) For services furnished directly or under arrangement in the hospital or in an on-campus or off-campus outpatient department of the hospital, as defined in § 413.65 of this chapter, “direct supervision” means that the physician must be 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 where the procedure is performed. During a Public Health Emergency, as defined in § 400.200 of this chapter, the presence of the physician includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider.

* * * * *

10. Section 410.32 is amended by revising paragraph (b)(3)(ii) to read as follows:

§ 410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

* * * * *

(b) * * *

(3) * * *

(ii) *Direct supervision* in the office setting means 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. During a PHE, as defined in § 400.200 of this chapter, the presence of the physician includes virtual presence through audio/video real-time

communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider.

* * * * *

11. Section 410.40 is amended by adding paragraph (f)(5) to read as follows:

§ 410.40 Coverage of ambulance services.

* * * * *

(f) * * *

(5) During a Public Health Emergency, as defined in § 400.200 of this chapter, a ground ambulance transport from any point of origin to a destination that is equipped to treat the condition of the patient consistent with any applicable state or local Emergency Medical Services protocol that governs the destination location. Such destinations include, but are not limited to, alternative sites determined to be part of a hospital, critical access hospital or skilled nursing facility, community mental health centers, federally qualified health centers, rural health clinics, physician offices, urgent care facilities, ambulatory surgical centers, any location furnishing dialysis services outside of an ESRD facility when an ESRD facility is not available, and the beneficiary’s home.

* * * * *

12. Section 410.67 is amended in paragraph (b), in paragraphs (3) and (4) of the definition of “Opioid use disorder treatment service” by adding a sentence at the end of each paragraph to read as follows:

§ 410.67 Medicare coverage and payment of Opioid use disorder treatment services furnished by Opioid treatment programs.

* * * * *

(b) * * *

(3) * * * During a Public Health Emergency, as defined in § 400.200 of this chapter, where audio/video communication technology is not available to the beneficiary, the counseling services may be furnished using audio-only telephone calls if all other applicable requirements are met.

(4) * * * During a Public Health Emergency, as defined in § 400.200 of this chapter, where audio/video communication technology is not available to the beneficiary, the therapy services may be furnished using audio-only telephone calls if all other applicable requirements are met.

* * * * *

13. Section 410.78 is amended by—

- a. Adding paragraph (a)(3)(i);
- b. Adding and reserving paragraph (a)(3)(ii); and
- c. Revising paragraph (b) introductory text.

The revision reads as follows:

§ 410.78 Telehealth services.

(a) * * *

(3) * * *

(i) *Exception.* For the duration of the public health emergency as defined in § 400.200 of this chapter, *Interactive telecommunications system* means multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

(ii) [Reserved]

* * * * *

(b) *General rule.* Medicare Part B pays for covered telehealth services included on the telehealth list when furnished by an interactive telecommunications system if the following

conditions are met, except that for the duration of the public health emergency as defined in § 400.200 of this chapter, Medicare Part B pays for office and other outpatient visits, professional consultation, psychiatric diagnostic interview examination, individual psychotherapy, pharmacologic management and end stage renal disease related services included in the monthly capitation payment furnished by an interactive telecommunications system if the following conditions are met:

* * * * *

14. Section 410.79 is amended by adding paragraph (e) to read as follows:

§ 410.79 Medicare Diabetes Prevention Program expanded model: Conditions of coverage.

* * * * *

(e) *MDPP expanded model Emergency Policy.* (1) Notwithstanding paragraphs (a) through (d) of this section, the policies described in this paragraph apply during the Public Health Emergency (PHE), as defined in §400.200 of this chapter.

(2) MDPP requirement changes described in paragraph (e)(1) of this section are applicable to:

(i) Organizations that are enrolled as an MDPP supplier as defined in paragraph (b) of this section, as of March 1, 2020; and

(ii) MDPP beneficiaries as defined in paragraph (b) of this section, who are receiving the MDPP set of services as of March 1, 2020.

(3) The following changes apply under this paragraph:

(i) The in-person attendance requirements of paragraphs (c)(1)(ii)(A), (c)(1)(iii)(A), and (c)(3)(ii) of this section are waived. MDPP suppliers shall not start new cohorts with MDPP beneficiaries who are unable to attend the first core session in-person;

(ii) The limit described in paragraphs (d)(2), (d)(3)(i), and (d)(3)(ii) of this section to the number of virtual make-up sessions is waived for MDPP suppliers with capabilities to provide services virtually so long as the provision of virtual services complies with the following:

(A) The curriculum furnished during the virtual make-up session must address the same CDC-approved DPP curriculum topic as the regularly scheduled session;

(B) The MDPP supplier furnishes to the MDPP beneficiary a maximum of one session on the same day as a regularly scheduled session;

(C) The MDPP supplier furnishes to the MDPP beneficiary a maximum of one virtual make-up session per week;

(D) Virtual make-up sessions must be furnished in a manner consistent with the DPRP standards for virtual sessions;

(E) Virtual make-up sessions can only be furnished to achieve attendance goals and cannot be furnished to achieve weight-loss goals;

(F) An MDPP supplier can only offer virtual make-up sessions upon an individual MDPP beneficiary's request;

(G) An MDPP supplier can offer to an MDPP beneficiary:

(1) No more than 15 virtual make-up sessions offered weekly during the core session period, months 1 through 6 of the MDPP services period;

(2) No more than 6 virtual make-up sessions offered monthly during the core maintenance session interval periods, months 7 through 12 of the MDPP services period; and

(3) No more than 12 virtual make-up sessions offered monthly during the ongoing maintenance session interval periods, months 13 through 24.

(iii) The once per lifetime requirement as described in paragraph (c)(1)(i)(B) of this section is waived to permit MDPP beneficiaries whose sessions were paused or cancelled due to

the PHE to obtain the set of MDPP services more than once per lifetime by electing to restart the MDPP set of services or resume with the most recent attendance session of record.

(iv) The minimum weight loss requirements for beneficiary eligibility in the ongoing maintenance session intervals described in paragraphs (c)(1)(ii)(B) and (c)(1)(iii)(B) of this section are waived;

(v) MDPP suppliers may pause or delay the delivery of the MDPP set of services and subsequently resume services on a delayed schedule. The time periods and intervals must be consistent with the MDPP requirements as described in paragraphs (c)(1)(i)(B), (c)(1)(ii)(A), (c)(1)(iii)(A), (c)(2)(i)(A), (c)(2)(i)(B), (c)(2)(i)(A), (c)(3)(i), and (c)(3)(ii) of this section.

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

15. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

16. Section 412.29 is amended by revising paragraph (e) to read as follows:

§ 412.29 Classification criteria for payment under the inpatient rehabilitation facility prospective payment system.

* * * * *

(e) Have in effect a procedure to ensure that patients receive close medical supervision, as evidenced by at least 3 face-to-face visits per week by a licensed physician with specialized training and experience in inpatient rehabilitation to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process, except that during a Public Health Emergency, as defined in § 400.200 of this chapter, such visits may be conducted using telehealth services (as defined in section 1834(m)(4)(F) of the Act).

* * * * *

17. Section 412.622 is amended by revising paragraphs (a)(3)(iv) and paragraph (a)(4)(ii) introductory text to read as follows;

§ 412.622 Basis of payment.

(a) * * *

(3) * * *

(iv) 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 to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process, except that during a Public Health Emergency, as defined in § 400.200 of this chapter, such visits may be conducted using telehealth services (as defined in section 1834(m)(4)(F) of the Act). The post-admission physician evaluation described in paragraph (a)(4)(ii) of this section may count as one of the face-to-face visits.

(4) * * *

(ii) A post-admission physician evaluation that meets all of the following requirements, except for the duration of the Public Health Emergency, as defined in § 400.200 of this chapter --

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

18. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(1).

19. Section 414.1380 is amended by—

- a. Revising paragraphs (c)(2)(i)(A)(6) and (c)(2)(i)(C) introductory text; and
- b. Adding paragraph (c)(2)(i)(C)(11).

The revisions and addition read as follows:

§ 414.1380 Scoring.

* * * * *

(c) * * *

(2) * * *

(i) * * *

(A) * * *

(6) Beginning with the 2020 MIPS payment year, for the quality, cost, and improvement activities performance categories, the MIPS eligible clinician demonstrates through an application submitted to CMS that they were subject to extreme and uncontrollable circumstances that prevented the clinician from collecting information that the clinician would submit for a performance category or submitting information that would be used to score a performance category for an extended period of time. Beginning with the 2021 MIPS payment year, in the event that a MIPS eligible clinician submits data for the quality, cost, or improvement activities performance categories, the scoring weight specified in paragraph (c)(1) of this section will be applied and its weight will not be redistributed, unless an exception applies. Exception: for the 2021 MIPS payment year only, if a MIPS eligible clinician demonstrates through an application submitted to CMS that they have been adversely affected by the public health emergency for the COVID-19 pandemic and also submits data for the quality, cost, or improvement activities performance categories, the preceding sentence will not apply.

* * * * *

(C) Under section 1848(o)(2)(D) of the Act, a significant hardship exception or other type of exception is granted to a MIPS eligible clinician based on the following circumstances for the Promoting Interoperability performance category. Except as provided in paragraphs (c)(2)(i)(C)(10) and (11) of this section, in the event that a MIPS eligible clinician submits data for the Promoting Interoperability performance category, the scoring weight specified in

paragraph (c)(1) of this section will be applied and its weight will not be redistributed.

* * * * *

(11) For the 2021 MIPS payment year only, the MIPS eligible clinician demonstrates through an application submitted to CMS that they have been adversely affected by the public health emergency for the COVID-19 pandemic.

* * * * *

**PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS,
SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN
CERTAIN SETTINGS**

20. The authority citation for part 415 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

21. Section 415.172 is amended by revising paragraphs (a) introductory text, (a)(2) and (b) to read as follows:

§ 415.172 Physician fee schedule payment for services of teaching physicians.

(a) *General rule.* If a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made only if a teaching physician is present during the key portion of any service or procedure for which payment is sought. During the Public Health Emergency, as defined in § 400.200 of this chapter, if a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made if a teaching physician is present during the key portion of the service using interactive telecommunications technology for any service or procedure for which payment is sought.

* * * * *

(2) In the case of evaluation and management services, the teaching physician must be present during the portion of the service that determines the level of service billed. (However, in the case of evaluation and management services furnished in hospital outpatient departments and

certain other ambulatory settings, the requirements of § 415.174 apply.) During a Public Health Emergency, as defined in § 400.200 of this chapter, the teaching physician may be present during the portion of the service that determines the level of service billed using interactive telecommunications technology. (However, in the case of evaluation and management services furnished in hospital outpatient departments and certain other ambulatory settings, the requirements of § 415.174 apply.)

(b) *Documentation.* Except for services furnished as set forth in §§415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document the teaching physician was present at the time the service is furnished. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by the physician or as provided in §410.20(e) of this chapter. During a Public Health Emergency, as defined in § 400.200 of this chapter, except for services furnished as set forth in §§ 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document if the teaching physician was physically present or if the teaching physician was present through interactive telecommunications technology at the time the service is furnished. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by the physician or as provided in §410.20(e) of this chapter.

* * * * *

22. Section 415.174 is amended by adding paragraph (b) to read as follows:

§ 415.174 Exception: Evaluation and management services furnished in certain centers.

* * * * *

(b) During a Public Health Emergency, as defined in § 400.200 of this chapter, carriers may make physician fee schedule payment for a service furnished by a resident if the teaching physician is present through interactive telecommunications technology.

23. Section 415.180 is revised to read as follows:

§ 415.180 Teaching setting requirements for the interpretation of diagnostic radiology and other diagnostic tests.

(a) *General rule.* Physician fee schedule payment is made for the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed or reviewed by a physician other than a resident. During a Public Health Emergency, as defined in § 400.200 of this chapter, physician fee schedule payment may also be made for the interpretation of diagnostic radiology and other diagnostic tests if the interpretation is performed by a resident when the teaching physician is present through interactive telecommunications technology.

(b) [Reserved]

24. Section 415.184 is revised to read as follows:

§ 415.184 Psychiatric services.

To qualify for physician fee schedule payment for psychiatric services furnished under an approved GME program, the physician must meet the requirements of §§ 415.170 and 415.172, including documentation, except that the requirement for the presence of the teaching physician during the service in which a resident is involved may be met by observation of the service by use of a one-way mirror, video equipment, or similar device. During a Public Health Emergency, as defined in § 400.200 of this chapter, the requirement for the presence of the teaching physician during the service in which a resident is involved may be met by direct supervision by interactive telecommunications technology.

25. Section 415.208 is amended by revising paragraph (b)(2) introductory text to read as

follows:

§ 415.208 Services of moonlighting residents.

* * * * *

(b) * * *

(2) Services of residents that are not related to their approved GME programs and are performed in an outpatient department or emergency department of a hospital in which they have their training program are covered as physician services and payable under the physician fee schedule if criteria in paragraphs (b)(2)(i), (ii), and (iii) of this section are met. During a Public Health Emergency, as defined in § 400.200 of this chapter, the services of residents that are not related to their approved GME programs and are furnished to inpatients of a hospital in which they have their training program are covered as physician services and payable under the physician fee schedule if criteria in paragraphs (b)(2)(i), (ii), and (iii) of this section are met.

* * * * *

PART 417—HEALTH MAINTENANCE ORGANIZATIONS COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

26. The authority citation for part 417 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh, and 300e, 300e-5, and 300e-9, and 31 U.S.C.

9701

27. Section 417.472 is amended by revising paragraphs (i) and (j) to read as follows:

§ 417.472 Basic contract requirements.

* * * * *

(i) *HMOs and CMPs.* The HMO or CMP must comply with the requirements at § 422.152(b)(5) and (b)(6) of this chapter.

(j) *Coordinated care and cost contracts.* Subject to paragraph (i) of this section, all coordinated care contracts (including local and regional PPOs, contracts with exclusively SNP

benefit packages, private fee-for-service contracts, and MSA contracts), and all cost contracts under section 1876 of the Act, with 600 or more enrollees in July of the prior year, must contract with approved Medicare Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey vendors to conduct the Medicare CAHPS satisfaction survey of Medicare plan enrollees in accordance with CMS specifications and submit the survey data to CMS.

* * * * *

PART 418—HOSPICE CARE

28. The authority citation for part 418 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh

29. Section 418.22 is amended by--

- a. Redesignating the text of paragraph (a)(4) as paragraph (a)(4)(i); and
- b. Adding paragraph (a)(4)(ii).

The addition reads as follows:

§ 418.22 Certification of terminal illness.

(a) * * *

(4) * * *

(ii) During a Public Health Emergency, as defined in § 400.200 of this chapter, if the face-to-face encounter conducted by a hospice physician or hospice nurse practitioner is for the sole purpose of hospice recertification, such encounter may occur via a telecommunications technology and is considered an administrative expense. Telecommunications technology means the use of interactive multimedia communications equipment that includes, at a minimum, the use of audio and video equipment permitting two-way, real-time interactive communication between the patient and the distant site hospice physician or hospice nurse practitioner.

* * * * *

30. Section 418.204 is amended by adding paragraph (d) to read as follows:

§ 418.204 Special coverage requirements.

* * * * *

(d) *Use of technology in furnishing services during a Public Health Emergency.* When a patient is receiving routine home care, during a Public Health Emergency as defined in § 400.200 of this chapter, hospices may provide services via a telecommunications system if it is feasible and appropriate to do so to ensure that Medicare patients can continue receiving services that are reasonable and necessary for the palliation and management of a patients' terminal illness and related conditions. The use of such technology in furnishing services must be included on the plan of care, meet the requirements at § 418.56, and must be tied to the patient-specific needs as identified in the comprehensive assessment and 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.

PART 421—MEDICARE CONTRACTING

31. The authority citation for part 421 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

32. Section 421.214 is amended by—

- a. Revising paragraphs (b) and (c) introductory text;
- b. Adding paragraph (d)(5);
- c. Revising paragraph (f)(1)(i); and
- d. Adding paragraph (j).

The revisions and additions read as follows:

§ 421.214 Advance payments to suppliers furnishing items and services under Part B.

* * * * *

(b) *Definition.* As used in this section, *advance payment* means a conditional partial payment made by the contractor in response to a claim that it is unable to process within established time limits except as provided in paragraph (j) of this section.

(c) *When advance payments may be made.* Unless otherwise qualified under paragraph (j) of this section, an advance payment may be made if all of the following conditions are met:

* * * * *

(d) * * *

(5) Is in bankruptcy.

* * * * *

(f) * * *

(1) * * *

(i) Unless otherwise qualified under paragraph (j) of this section, a contractor must calculate an advance payment for a particular claim at no more than 80 percent of the anticipated payment for that claim based upon the historical assigned claims payment data as defined in paragraph (f)(1)(ii) of this section for claims paid to the supplier. For suppliers qualifying and approved for advance payments under paragraph (j) of this section, a contractor may calculate an advance payment for a particular claim at up to 100 percent of the anticipated payment for that claim based upon the historical assigned claims payment data as defined in paragraph (f)(1)(ii) of this section for claims paid to the supplier.

* * * * *

(j) *Advanced payments in exceptional circumstances.* CMS may approve, in writing to the contractor, the making of advance payments during the period of a Public Health Emergency, as defined in § 400.200 of this chapter, or during the period under a Presidential Disaster Declaration, under the following exceptional conditions:

(1) The contractor is unable to process the claim timely, or is at risk of being untimely in processing the claim; or

(2) When the supplier has experienced a temporary delay in preparing and submitting bills to the contractor beyond its normal billing cycle.

PART 422—MEDICARE ADVANTAGE PROGRAM

33. The authority citation for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

34. Section 422.152 is amended by adding paragraph (b)(6) to read as follows:

§ 422.152 Quality improvement program.

* * * * *

(b) * * *

(6) Special rule for 2021 Star Ratings only. MA organizations are not required to submit HEDIS and CAHPS data that would otherwise be required for the calculation of the 2021 Star Ratings.

* * * * *

35. Section 422.164 is amended by adding paragraph (i) to read as follows:

§ 422.164 Adding, updating, and removing measures.

* * * * *

(i) *Special rule for 2021 Star Ratings only.* In the event that the threat to health and safety posed by the COVID-19 pandemic compromises the quality of the data, or ability to validate such data for all plans used to calculate a particular measure, CMS will substitute and use the 2021 Star Ratings measure score and Star Rating with the 2020 Star Ratings measure score and Star Rating.

36. Section 422.166 is amended--

a. By revising paragraph (a)(2)(i);

- b. In paragraph (f)(1)(i), by adding a sentence to the end of the paragraph; and
- c. By adding paragraphs (g)(3) and (j).

The revisions and additions read as follows:

§ 422.166 Calculation of Star Ratings.

- (a) * * *
- (2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data. Effective for the Star Ratings issued in October 2022 and subsequent years, CMS will add a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from one year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and Part D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years in the program.

- * * * * *
- (f) * * *
- (1) * * *
- (i) * * *

For the 2022 Star Ratings only, since all contracts may have the improvement measure(s) excluded in the determination of their highest rating and summary rating(s), each contract's weighted variance and weighted mean are calculated both with and without the improvement measures.

- * * * * *
- (g) * * *

(3) For 2022 Star Ratings only, CMS runs the calculations twice for the highest rating for each contract-type (overall rating for MA-PD contracts and Part C summary rating for MA-only contracts) and Part C summary rating for MA-PDs with all applicable adjustments (CAI and the reward factor), once including the improvement measure(s) and once without including the improvement measure(s). In deciding whether to include the improvement measures in a contract's highest and summary rating(s), CMS applies the following rules:

(i) For MA- PDs and MA-only contracts, a comparison of the highest rating with and without the improvement measure is done. The higher rating is used for the highest rating.

(ii) For MA-PDs, a comparison of the Part C summary rating with and without the improvement measure is done. The higher rating is used for the summary rating.

* * * * *

(j) *Special rules for 2021 and 2022 Star Ratings only.* (1) For the 2021 Star Ratings:

(i) The measures calculated based on HEDIS data are calculated based on data from the 2018 performance period.

(ii) The measures calculated based on CAHPS data are calculated based on survey data collected from March through May 2019.

(iii) The measure-level change score calculation described at § 422.164(f)(4)(i) is not applied for HEDIS and CAHPS measures and the measure-level change score used for the 2020 Star Ratings is applied in its place for all HEDIS and CAHPS-based measures.

(iv) The provisions of § 422.164(g)(1) and (2) are not applied for the failure to submit HEDIS and CAHPS-based measures.

(v) In the event that there are extraordinary circumstances resulting from the COVID-19 pandemic that compromise CMS resources to the extent that CMS cannot calculate or issue 2021 Star Ratings by October 2020, CMS will adopt the 2020 Star Ratings as the 2021 Star Ratings.

(2) For the 2022 Star Ratings:

(i) In the event that the threat to health and safety posed by the COVID-19 pandemic compromises the ability to collect the Health Outcomes Survey in 2020, CMS will adopt the 2021 Star Ratings and measure scores for the measures that come from the Health Outcomes Survey as the 2022 Star Ratings and measures scores for the measures that come from the Health Outcomes Survey.

37. Section 422.252 is amended by revising the definition of “New MA plan” to read as follows:

§ 422.252 Terminology.

* * * * *

New MA plan means a MA contract offered by a parent organization that has not had another MA contract in the previous 3 years. For purposes of 2022 quality bonus payments based on 2021 Star Ratings only, new MA plan means an MA contract offered by a parent organization that has not had another MA contract in the previous 4 years.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

38. The authority for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w-101 through 1395w-152, and 1395hh.

39. Section 423.156 is amended by adding a sentence at the end of the paragraph to read as follows:

§ 423.156 Consumer satisfaction surveys.

* * * Part D sponsors are not required to submit CAHPS data that would

otherwise be required for the calculation of the 2021 Star Ratings.

40. Section 423.182 is amended by adding paragraph (c)(3) to read as follows:

§ 423.182 Part D Prescription Drug Plan Quality Rating System.

* * * * *

(c) * * *

(3) For 2021 Star Ratings only, Part D sponsors are not required to submit CAHPS data that would otherwise be required for the calculation of the 2021 Star Ratings.

41. Section 423.184 is amended by adding paragraph (i) to read as follows:

§ 423.184 Adding, updating, and removing measures.

* * * * *

(i) *Special rule for 2021 Star Ratings only.* In the event that the threat to health and safety posed by the COVID-19 pandemic compromises the quality of the data, or ability to validate such data, for all plans, used to calculate a particular measure, CMS will substitute and use the 2021 Star Ratings measure score and Star Ratings with the 2020 Star Ratings measure score and Star Rating.

42. Section 423.186 is amended—

- a. By revising paragraph (a)(2)(i);
- b. In paragraph (f)(1)(i), by adding a sentence to the end of the paragraph; and
- c. By adding paragraphs (g)(3) and (j).

The revisions and additions read as follows:

§ 423.186 Calculation of Star Ratings.

(a) * * *

(2) * * *

(i) The method maximizes differences across the star categories and minimizes the differences within star categories using mean resampling with the hierarchal clustering of the current year's data. Effective for the Star Ratings issued in October 2022 and subsequent years, CMS will add a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from one year to the next. The cap is equal to 5 percentage points for measures having a 0 to 100 scale (absolute percentage

cap) or 5 percent of the restricted range for measures not having a 0 to 100 scale (restricted range cap). New measures that have been in the Part C and D Star Rating program for 3 years or less use the hierarchal clustering methodology with mean resampling with no guardrail for the first 3 years of the program.

* * * * *

(f) * * *

(1) * * *

(i) * * * For the 2022 Star Ratings only, since all contracts may have the improvement measure(s) excluded in the determination of their highest rating and summary rating(s), each contract's weighted variance and weighted mean are calculated both with and without the improvement measures.

* * * * *

(g) * * *

(3) *Special rule for 2022 Star Ratings only.* CMS runs the calculations twice for the highest rating for each contract-type (overall rating for MA-PD contracts and Part D summary rating for PDPs) and Part D summary rating for MA-PDs with all applicable adjustments (CAI and the reward factor), once including the improvement measure(s) and once without including the improvement measure(s). In deciding whether to include the improvement measures in a contract's highest and summary rating(s), CMS applies the following rules:

(i) For MA-PDs and PDPs, a comparison of the highest rating with and without the improvement measure is done. The higher rating is used for the highest rating.

(ii) For MA-PDs, a comparison of the Part D summary rating with and without the improvement measure is done. The higher rating is used for the summary rating.

* * * * *

(j) *Special rules for 2021 Star Ratings only.* (1) For the 2021 Star Ratings:

(i) The measures calculated based on CAHPS data are calculated based on survey data collected from March through May 2019.

(ii) The measure-level change score calculation described at § 423.184(f)(4)(i) is not applied for CAHPS measures and the measure-level change score used for the 2020 Star Ratings is applied in its place for all CAHPS-based measures.

(iii) The provisions of § 423.184(g)(2) are not applied for failure to submit CAHPS-based measures.

(iv) In the event that there are extraordinary circumstances resulting from the COVID-19 pandemic that compromise CMS resources to the extent that CMS cannot calculate or issue 2021 Star Ratings by October 2020, CMS will adopt the 2020 Star Ratings as the 2021 Star Ratings.

(2) [Reserved]

PART 425—MEDICARE SHARED SAVINGS PROGRAM

43. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

§ 425.502 [Amended]

44. Section 425.502 is amended in paragraph (f) introductory text by removing the phrase “if the quality reporting period is not extended”.

PART 440—SERVICES: GENERAL PROVISIONS

45. The authority citation for part 440 is revised to read as follows:

Authority: 42 U.S.C. 1302.

46. Section 440.70 is amended by revising paragraphs (a)(2), (b)(1)(ii), and (b)(3)(iii) and (iv) to read as follows:

§ 440.70 Home health services.

(a) * * *

(2) On his or her physician’s orders as part of a written plan of care that the physician

reviews every 60 days for services described in (b)(1), (2), and (4) of this section, or, for the period of the Public Health Emergency, as defined in § 400.200 of this chapter, orders written by an other licensed practitioner of the healing arts acting within the scope of practice authorized under State law, as part of a written plan of care that the ordering practitioner reviews every 60 days for services described in (b)(1), (2) and (4) of this section.

(b) * * *

(1) * * *

(ii) Receives written orders from the patient’s physician or, for the period of the Public Health Emergency, as defined in § 400.200 of this chapter, other licensed practitioner of the healing arts acting within the scope of practice authorized under State law;

* * * * *

(3) * * *

(iii) A beneficiary’s need for medical supplies, equipment, and appliances must be reviewed by a physician or, for the period of the Public Health Emergency, as defined in § 400.200 of this chapter, an other licensed practitioner of the healing arts acting within the scope of practice authorized under State law, annually.

(iv) Frequency of further physician or, for the period of the Public Health Emergency, as defined in § 400.200 of this chapter, an other licensed practitioner review of a beneficiary’s continuing need for the items is determined on a case-by-case basis based on the nature of the item prescribed;

* * * * *

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

47. The authority citation for part 482 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, 1395rr, and 1395lll unless otherwise noted.

48. Section 482.61 is amended by revising paragraph (d) to read as follows:

§ 482.61 Condition of participation: Special medical record requirements for psychiatric hospitals.

* * * * *

(d) *Standard: Recording progress.* Progress notes for the patient must be documented, in accordance with applicable State scope-of-practice laws and hospital policies, by the following qualified practitioners: doctor(s) of medicine or osteopathy, or other licensed practitioner(s), who is responsible for the care of the patient; nurse(s) and social worker(s) (or social service staff) involved in the care of the patient; and, when appropriate, others significantly involved in the patient’s active treatment modalities. The frequency of progress notes is determined by the condition of the patient but must be recorded at least weekly for the first 2 months and at least once a month thereafter and must contain recommendations for revisions in the treatment plan as indicated, as well as precise assessment of the patient’s progress in accordance with the original or revised treatment plan.

* * * * *

PART 510—COMPREHENSIVE CARE FOR JOINT REPLACEMENT MODEL

49. The authority citation of part 510 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

50. Section 510.2 is amended by revising the definition of “Performance year” to read as follows:

§ 510.2 Definitions.

* * * * *

Performance year means one of the years in which the CJR model is being tested.

Performance years for the model correlate to calendar years with the exceptions of performance year 1, which is April 1, 2016 through December 31, 2016 and performance year 5, which is January 1, 2020 through March 31, 2021.

* * * * *

§ 510.200 [Amended]

51. Section 510.200 is amended in paragraph (a), by removing the phrase that reads “before December 31, 2020” and adding in its place the phrase “before March 31, 2021”.

52. Section 510.305 is amended by adding paragraphs (k)(3) and (4) to read as follows:

§ 510.305 Determination of the NPRA and reconciliation process.

* * * * *

(k) * * *

(3) Extreme and uncontrollable circumstances adjustment for 2019 Novel Coronavirus (previously referred to as 2019-nCoV, now as COVID-19).

(i) The episode spending adjustments specified in paragraph (k)(4) of this section apply for a participant hospital that has a CCN primary address that is located in an emergency area during an emergency period, as those terms are defined in section 1135(g) of the Act, for which the Secretary issued a waiver or modification of requirements under section 1135 of the Act on March 13, 2020.

(ii) [Reserved]

(4) For a fracture or non-fracture episode with a date of admission to the anchor hospitalization that is on or within 30 days before the date that the emergency period (as defined in section 1135(g) of the Act) begins or that occurs through the termination of the emergency period (as described in section 1135(e) of the Act), actual episode payments are capped at the target price determined for that episode under § 510.300.

CMS-1744-IFC

Dated: March 24, 2020.

Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: March 26, 2020.

Alex M. Azar II,

Secretary,

Department of Health and Human Services.