

ALSTON & BIRD

TO: Health Care Clients

FROM: Alston & Bird LLP

DATE: April 8, 2020

RE: A&B Summary – Policy and Regulatory Provisions in Response to the COVID-19 Public Health Emergency (CMS-1744-IFC)

On March 30, 2020, the Centers for Medicare & Medicaid Services released an interim final rule with comment period (IFC) entitled, *Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency* (the IFC).¹ The IFC is intended to provide flexibilities for individuals and entities that provide health care services to Medicare beneficiaries so that they can respond effectively to the public health threats associated with the 2019 Novel Coronavirus (COVID-19).

In addition to the specific changes described below, CMS is defining the term “public health emergency” at 42 CFR 400.200 to mean the Department of Health and Human Services (HHS) Secretary’s January 31, 2020 determination (under section 319 of the Public Health Service Act) that a nationwide public health emergency (PHE) exists due to COVID-19.

CMS is finalizing regulatory changes impacting:

1. Coverage and payment rules (related to telehealth and technology-based services and National Coverage Determination (NCD) and Local Coverage Determination (LCD) requirements);
2. Hospitals;
3. Physicians;
4. Post-acute care providers;
5. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Part B suppliers;
6. Clinical laboratories;
7. Ambulances;
8. Medicare Advantage and Part D quality star ratings;
9. Medicaid/CHIP; and
10. CMS Innovation Center Models and Demonstrations.

In general, and unless otherwise noted, these changes will apply on a temporary or interim basis (i.e., only during the COVID-19 PHE) and have retroactive applicability to March 1, 2020. **Comments to the IFC are due no later June 1, 2020.**

¹ See, <https://www.govinfo.gov/content/pkg/FR-2020-04-06/pdf/2020-06990.pdf>.

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I. Coverage and Payment Rules

a. Telehealth and Technology-Based Services

i. Payment

1. Background

In general, Medicare pays for a discrete set of services, all of which must ordinarily be furnished in-person, when they are instead provided using interactive, real-time telecommunication technology (as specified under section 1834(m) of the Social Security Act).² Other professional services commonly furnished remotely through telecommunications technology (e.g., remote physician interpretation of diagnostic tests, care management services, virtual check-ins) are considered physicians' services in the same way as they are furnished in-person. These services are covered and paid the same way, but are not considered Medicare telehealth services and therefore are not subject to section 1834(m) of the Social Security Act (SSA).

Under its SSA section 1135 waiver authority,³ CMS temporarily expanded Medicare payment for telehealth services, including adding services to the list of eligible Medicare telehealth services, eliminating frequency limitations and other requirements, and clarifying payment rules for other telecommunication technology services that can reduce COVID-19 exposure risks. This IFC makes additional temporary changes to payment for telehealth services during the COVID-19 PHE.

2. Site of Service Differential for Medicare Telehealth Services

CMS is permitting physicians and practitioners who bill for Medicare telehealth services to report the place of service (POS) code that would have been reported had the service been furnished in person. Normally, the general POS code 02 for Medicare telehealth services results in physicians being paid at the facility, as opposed to non-facility rate. This was established because originating sites were also able to bill the facility fee to cover technical expenses, such as the technology platform and communications infrastructure. Now that telehealth services may be provided to patients in their homes and in other non-eligible originating sites, and the practitioner bears the cost of the technology platform and communications infrastructure, using a non-facility POS code allows the practitioner to receive greater reimbursement than using the POS code 02 that takes some of these costs into account.

CMS states that this will allow its systems to make appropriate payment for services furnished via Medicare telehealth which, if not for the COVID-19 PHE, would have been furnished in person, at the same rate they would have been paid if the services were furnished in person. In addition, CMS is finalizing the temporary use of the CPT telehealth modifier (modifier 95) that should be applied to telehealth service claim lines (instead of the POS code 02). This modifier is being used to reflect that a service is being provided via telehealth and the appropriate facility or non-facility rate will apply based on the POS code reported. The general POS code 02 will be maintained should practitioners choose to maintain the current Medicare telehealth billing practice.

² A list of eligible telehealth services, including the additions described in the IFC, is available here: <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html>.

³ Specifically, section 1135(b)(8) added by the *Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020*. Note that this section was further modified by the *Coronavirus Aid, Relief, and Economic Security (CARES) Act*, but were not captured in this IFC. CMS has indicated that it will assess the new statutory authority provided by the CARES Act and release additional guidance.

3. Adding Services to the List of Medicare Telehealth Services

CMS is adding, for the COVID-19 PHE, the following services to the Medicare telehealth list on a Category 2 basis⁴ for dates of services beginning March 1, 2020:

- Emergency Department visits (CPT codes 99281-99285)
- Initial and Subsequent Observation, and Observation Discharge Day Management (CPT codes 99217-99220, 99224-99226, 99234-99236)
- Inpatient hospital care and hospital discharge day management (CPT codes 99221-99223, 99238-99239)
- Initial nursing facility visits and nursing facility discharge day management (CPT codes 99304-99306, 99315-99316)
- Critical care services (CPT codes 99291-99292)
- Domiciliary, rest home, or custodial care services (CPT codes 99327-99328, 99334-99337)
- Home visits (CPT codes 99341-99345, 99347-99350)
- Inpatient neonatal and pediatric critical care (CPT codes 99468-99469, 99471-99473, 99475-99476)
- Initial and continuing intensive care services (CPT codes 99477-99480)
- Care planning for patients with cognitive impairment (CPT code 99483)
- Group psychotherapy (CPT code 90853)
- ESRD services (CPT codes 90952-90953, 90959, 90962)
- Psychological and Neuropsychological testing (CPT codes 96130-96133, 96136-96139)
- Therapy services⁵ (CPT codes 97161-97168, 97110, 97112, 97116, 97535, 97750, 97755, 97760-97761, 92521-92524, 92507)
- Radiation treatment management services (CPT code 77427)

CMS notes that it previously considered and declined to add many of these services to the Medicare telehealth list due to concerns over patient acuity and the feasibility of fulfilling the required elements of a service via communication technology. However, CMS recognizes the clinical benefit in light of the COVID-19 exposure risks. CMS is interested in learning of any potential negative consequences of temporarily adding these CPT codes to the telehealth services list.

ii. 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

CMS notes when adding services to the Medicare telehealth list, it does so while including certain frequency limitations to ensure the services meet the Category 1 or Category 2 criteria. Specifically, CMS previously stated that due to concerns regarding the potential acuity of hospital inpatients, it would limit the provision of subsequent hospital care services through telehealth to once every three days. Similarly, subsequent

⁴ Category 1 services are those that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services. Category 2 services are services not similar to those on the current list of telehealth services. Normally, CMS reviews requests to include these services as telehealth services based on 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.

⁵ Note, however, that section 1834(m) of the SSA does not include physical therapists, occupational therapists, or speech-language pathologists, meaning there would be no payment for Medicare telehealth services furnished by these providers.

nursing facility visits provided through telehealth would be limited to once every 30 days and critical care consultations were limited to once per day.

In light of the COVID-19 PHE, CMS does not believe the frequency limitations are appropriate or necessary. Therefore, CMS is temporarily removing the frequency restrictions for each of the following codes for subsequent Medicare telehealth inpatient visits and nursing facility visits.

- Subsequent inpatient visits (CPT codes 99231-99233)
- Subsequent nursing facility visits (CPT codes 99307-99310)
- Critical care consultation services (HCPCS codes G0508-G0509)
- Required “hands-on” visits for ESRD monthly capitation payments⁶ (CPT codes 90951-90955, 90957-90970)

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

iii. Modalities and Cost-Sharing

1. Clarifying Telehealth Technology Requirements

CMS is revising its regulations at 42 CFR 410.78(a)(3) to add a temporary exception during the COVID-19 PHE such that “interactive telecommunications system” means multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between a patient and distant site physician or practitioner. CMS also clarified that, even under the existing regulation that excludes telephones from the definition of interactive telecommunications systems, CMS does not interpret that language apply to “mobile computing devices” that include audio and video real-time interactive capabilities, even though they are referred to colloquially as “phones.” CMS is revising the language to avoid any misperceptions that such devices may be prohibited.

CMS reiterates that the HHS Office of Civil Rights (OCR) is exercising enforcement discretion and waiving penalties for Health Insurance Portability and Accountability Act (HIPAA) violations against providers serving patients in good faith through everyday communications technologies (e.g., FaceTime or Skype) during the COVID-19 PHE. However, CMS also notes that HHS, the Office of Inspector General (OIG), and the Department of Justice (DOJ) continue to monitor for any fraud and abuse, including potential Medicare COVID-19-related scams.

2. Beneficiary Cost-Sharing

CMS referenced the OIG policy statement⁷ that notified physicians and other practitioners that they would not be subject to administrative sanctions for reducing or waiving beneficiary cost-sharing obligations for telehealth services. CMS notes that this policy statement applies to a broad category of non-face-to-face services provided through various modalities, including telehealth visits, virtual check-in services, e-visits, monthly remote care management, and monthly remote patient monitoring. Further, the policy statement applies to a physician or other practitioner billing for services or a hospital or other eligible individual or

⁶ CMS is exercising enforcement discretion on an interim basis to relax enforcement in connection with the requirements of section 1881(b)(3)(B) of the SSA that certain services be furnished *without* the use of telehealth for services provided during the PHE. CMS will not conduct review to consider whether those visits were conducted without the use of telehealth.

⁷ See, <https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/policy-telehealth-2020.pdf>.

entity billing on behalf of the physician or practitioner for such services (when the provider has reassigned rights to such individual or entity).

iv. Communication Technology-Based Services (CTBS)

CMS notes that in the 2019 Physician Fee Schedule (PFS) final rule, it stated that Medicare routinely pays for services furnished via telecommunications technology that are not considered Medicare telehealth services. These CTBS include certain kinds of remote patient monitoring and interpretations of diagnostic tests when furnished remotely. In addition, in the 2019 PFS final rule, CMS finalized separate payment for services provided via telecommunications technology, including HCPCS code G2010 and G2012. CMS notes that these codes were finalized as part of the set of codes only reportable by physicians and practitioners furnishing evaluation and management (E/M) services and that these services are limited to established patients. CMS also finalized in its 2020 PFS final rule a modification to the beneficiary consent, requiring that it be obtained annually. These requirements also apply to monthly care management and remote patient monitoring services.

In light of the COVID-19 PHE, CMS is finalizing that CTBS, 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. CMS also is clarifying that consent to receive services can be documented by auxiliary personnel under general supervision. In addition, while consent must be obtained annually, it may be received at the same time a service is furnished. Finally, CMS is retaining the requirement that when a brief CTBS originates from an E/M service (including one furnished via telehealth) provided within the previous seven days by the same physician or other qualified health care professional, that service would be considered bundled into the previous E/M service and would not be separately billable.

In the 2020 PFS final rule, CMS finalized separate payment for CPT codes 99421-99423 and HCPCS codes G2061-G2063. During the COVID-19 PHE, CMS does not believe limitation of these services to established patients is warranted and therefore is exercising enforcement discretion to temporarily relax enforcement of this aspect of the code descriptors. Specifically, CMS will not conduct reviews to consider whether those services were furnished to established patients.

In addition, in the 2020 PFS final rule, CMS stated that HCPCS codes G2061-G2063 may describe services outside the scope of the current Medicare benefit categories and as such, may not be eligible for Medicare payment. In this IFC, CMS is clarifying that there are several types of practitioners who could bill for these services, including licensed clinical social workers (CSWs), clinical psychologists (CPs), physical therapists (PTs), occupational therapists (OTs), or speech language pathologists (SLPs). These practitioners also can report these online assessment and management services.

CMS also is temporarily broadening the availability of HCPCS codes G2010 and G2012, which describe remote evaluation of patient images/video and virtual check-ins. In addition to CSWs, CPs, PTs, OTs, and SLPs, CMS seeks input on other practitioners who might furnish these kinds of services in the context of the COVID-19 PHE.

Finally, CMS is designating HCPCS codes G2010, G2012, and G2061-G2063 as CTBS “sometimes therapy” services to facilitate billing of these services by therapists. The therapist would have to include the corresponding therapy modifier (GO, GP, or GN) on claims for services. In addition, CTBS therapy services would include those furnished to new or established patients.

v. Direct Supervision by Interactive Telecommunications Technology

CMS recognizes that due to the COVID-19 PHE, physical proximity of the physician or practitioner might present additional exposure risks. In these cases, CMS believes current supervision requirements would limit access to procedures and tests that could be appropriately supervised by an isolated physician. CMS believes 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 (e.g., the 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, eliminating the need for the physician to be physically present in that location).

CMS notes that even during the COVID-19 PHE, in many cases, furnishing services without the physical presence of the physician in the same location would not be appropriate. However, CMS also believes that practitioners are in the best position to make decisions based on their clinical judgment in particular circumstances. Therefore, CMS is temporarily revising the definition of direct supervision (42 CFR 410.32(b)(3)(ii)) to state that the necessary presence of the physician for direct supervision includes virtual presence through real-time audio/video communications technology when the use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider. This change will essentially allow direct supervision to be provided using real-time interactive audio and visual technology. CMS seeks comments on whether there should be guardrails and what kind of risk this might introduce for beneficiaries. Further, CMS notes that this change is limited to the manner in which supervision can be met and does not change underlying payment or coverage policies, including for Part B drugs.

In addition, CMS is adopting similar regulations with respect to the supervision of diagnostic services furnished directly or under arrangement in the hospital or in a hospital on-campus or off-campus outpatient department (42 CFR 410.28(e)(1)). Further, with respect to pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services (42 CFR 410.47 and 410.49), CMS is adopting a similar change to specify that direct supervision for these services includes virtual presence through audio/video real-time communications technology when the use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider (42 CFR 410.27(a)(1)(iv)(D)).

vi. Remote Physiologic Monitoring

CMS believes remote physiologic monitoring (RPM) – CPT codes 99091, 99453-99454, 99457-99458, 99473-99474 – supports the Centers for Disease Control and Prevention (CDC)'s goal of reducing human exposure to COVID-19 while also increasing access to care and improving patient outcomes. Normally, RPM services are considered to be CTBS.

To remove obstacles to delivering reasonable and necessary care during the COVID-19 PHE, CMS is temporarily finalizing that: (1) RPM services can be furnished to new patients and established patients; (2) consent to receive RPM services only needs to be obtained annually, including at the time services are furnished; and (3) RPM codes can be used for physiologic monitoring of patients with acute and/or chronic conditions (e.g., a patient with an acute respiratory virus to monitor pulse and oxygen saturation levels).

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

In 2008, the CPT Editorial Panel created codes to describe E/M services furnished by a physician or qualified healthcare professional via telephone or online (CPT codes 98966-98968, 99441-99443). At the time, CMS assigned a status indicator of "N" (noncovered) to these services. Although CMS assigned an N status indicator, CMS established the RUC-recommended relative value units (RVUs) for these codes. Normally, CMS believes if a patient's needs are significant enough to require the amount of time and

attention specified in these codes, then either an in-person or telehealth visit would be required. Conversely, if the patient’s needs are less acute and lengthy, a virtual check-in would suffice.

However, due to the COVID-19 PHE, CMS believes 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.” Subsequently, CMS is temporarily finalizing the separate payment for telephone E/M services as follows:

- 98966 – work RVU of 0.25
- 98967 – work RVU of 0.50
- 98968 – work RVU of 0.75
- 99441 – work RVU of 0.25
- 99442 – work RVU of 0.50
- 99443 – work RVU of 0.75

CMS also is finalizing the RUC-recommended direct PE inputs previously finalized, which consist of 3 minutes of post-service RN/LPN/MTA clinical labor time for each code.

CMS also believes that similar to CTBS, these services should be expanded to both new and established patients. As such, CMS will temporarily exercise enforcement discretion to relax enforcement of the “established patient” aspect of the code descriptors and will not review to consider whether the services were furnished to established patients.

In addition, CMS is noting that CPT codes 98966-98968 may be furnished by, among others CSWs, CPs, PTs, OTs, and SLPs when the visit pertains to a service that falls within each practitioner’s benefit category. To facilitate billing, CMS is designating these codes as CTBS “sometimes therapy” (meaning the corresponding modifier must be included on claims for these services, as described above).

viii. E/M Level Selection when Furnished via Telehealth

CMS is temporarily revising its policy to specify that the office/outpatient E/M level selection for these services when furnished via telehealth can be based on medical decision making (MDM) or time, with time defined as all of the time associated with the E/M on the day of the encounter. In addition, CMS is removing any requirements regarding documentation of history and/or physical exam in the medical record. CMS notes that this policy is similar to the policy that will apply to all office/outpatient E/M services beginning in 2021 as finalized in the 2020 PFS final rule. CMS is maintaining the current definition of MDM and finalizing the typical times associated with office/outpatient E/M services for the purposes of level selection.⁸

b. NCD and LCD Requirements

i. Face-to-Face and In-Person Requirements

CMS is temporarily finalizing that 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 COVID-19 PHE. This change does not apply

⁸ See, <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1715-F>.

to the statutory requirements for DMEPOS power mobility devices. In addition, the IFC does not confer changes to the clinical indications of coverage for any NCD or LCD, except as indicated below.

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

CMS is temporarily finalizing that it will not enforce clinical indications for coverage across respiratory, home anticoagulation management and infusion pump NCDs and LCDs (including articles) allowing for maximum flexibility for practitioners during the COVID-19 PHE. 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.

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

To the extent NCDs and LCDs require a specific practitioner type or physician specialty to furnish a service, procedure, or any portion thereof, CMS is temporarily finalizing the chief medical officer (CMO) or equivalent of the facility can authorize another physician specialty or practitioner type to meet those requirements during the COVID-19 PHE. In addition, to the extent NCDs and LCDs require a physician or physician specialty to supervise other practitioners, professionals or qualified personnel, the CMO can authorize that such supervision requirements do not apply during the COVID-19 PHE.

II. Hospitals

a. Inpatient Hospital Services Furnished Under Arrangements Outside of the Hospital

CMS ordinarily prohibits Inpatient Prospective Payment System (IPPS) reimbursement for the following “routine services” if they are furnished by other entities under arrangements outside of the hospital: (1) bed and board; and (2) nursing services and other related services, use of hospital facilities, and medical social services ordinarily furnished by the hospital for the care and treatment of inpatients. There is a limited exception to this prohibition for other diagnostic or therapeutic items or services. CMS is temporarily revising this policy, effective for services provided for discharges for patients admitted to the hospital during the COVID-19 PHE beginning March 1, 2020. During this period, CMS will reimburse routine services provided to hospital inpatients under arrangements outside of the hospital. CMS notes that hospitals must still 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.

b. Physician Supervision Flexibility for Outpatient Hospital Therapeutic Services

CMS is assigning, on an interim basis, all outpatient hospital therapeutic services (falling under 42 CFR 410.27(a)(1)(iv)(E)), a minimum level of general supervision, consistent with the default level of general supervision that applies for most outpatient hospital therapeutic services. Currently, services after the

initiation of non-surgical extended duration therapeutic services (NSEDTS) are subject to general supervision; the initial service is subject to direct supervision. CMS is temporarily changing the minimum level of supervision to general supervision, which will apply to all relevant outpatient hospital therapeutic services, including the initiation of services.

c. Counting Resident Time

In addition to the changes to teaching physician supervision requirements (42 CFR 415.172, 415.174, 415.180, 415.184, described below), CMS is permitting, on an interim basis, 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, to claim that resident for indirect medical education (IME) and direct graduate medical education (DGME) purposes. The resident's services would have to meet the appropriate physician supervision requirements described below.

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

CMS finalized several changes for RHCs and FQHCs related to the use of use of interactive communications technology. The agency also expanded the ability of these providers to provide visiting nurse services.

First, to minimize COVID-19 exposure risk and facilitate the ability of RHCs and FQHCs to 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 established methodologies, CMS is expanding the services that can be included in the payment for HCPCS code G0071 (virtual communications services). As finalized in the 2019 PFS final rule, RHCs and FQHCs are paid for G0071 (either alone or with payable services) for at least five minutes of CTBS or remote evaluation services 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 seven days and does not lead to an RHC or FQHC visit within the next 24 hours or at the soonest available appointment. Specifically, on an interim basis, CMS is adding the following CPT codes: 99421, 99422, and 99423. These codes reflect online digital E/M services for established patients.

The payment rate for G0071 for services furnished on or after March 1, 2020 and throughout the PHE for COVID-19 is revised to reflect the average of HCPCS code G2012 (CTBS), HCPCS code G2010 (remote evaluation services), and the newly added CPT codes (99421-99423). The RHC and FQHC face-to-face requirements are waived for these services. Further, during the COVID-19 PHE, all virtual communication services that are billable using HCPCS code G0071 will be available to new patients who have not been seen in the RHC or FQHC within the previous 12 months, and prior beneficiary consent may be obtained when the services are furnished rather than prior to the service being furnished. Consent must still be obtained prior to services being billed. Patient consent may also be acquired by staff under the general supervision of the RHC or FQHC practitioner.

Second, ordinarily, RHCs and FQHCs may provide visiting nurse services (furnished by a registered professional nurse or licensed practical nurse employed by or compensated by the RHC or FQHC) for homebound individuals in areas in which the Secretary has determined that there is a shortage of home health agencies (HHAs). For the duration of the COVID-19 PHE, CMS will consider any area typically served by an RHC, and any area that is included in an FQHC's service area plan, to have a shortage of HHAs. Visiting nursing services are not covered for patients that are under a home health plan of care, and RHCs and FQHCs should check the HIPAA Eligibility Transaction System (HETS) before providing

visiting nursing services to avoid providing overlapping services. As described in other parts of the IFC, “homebound” includes, during the COVID-19 pandemic, patients whose physician has determined that it is medically contraindicated for the patient to leave the home because of a confirmed or suspected diagnosis of COVID-19 or because of a condition that may make the patient more susceptible to contracting COVID-19. “Homebound” does not include patients who are merely exercising “self-quarantine.” 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 specimen.

e. Psychiatric Hospitals

CMS is implementing a change to the hospital Conditions of Participation (CoPs) for psychiatric hospitals at 42 CFR 482.61(d), which sets forth the standard for progress notes and includes a requirement that progress notes be recorded by physicians, psychologists, or other licensed independent practitioners responsible for the care of the patient. This change consists of removing reference to 42 CFR 482.12(c) and the word “independent” from “licensed independent practitioner.”

First, this change removes the inappropriate reference to 42 CFR 482.12(c), which requires a hospital to ensure that a Medicare beneficiary is under the care of a physician, clarifying that the psychiatric hospital CoPs apply to *all* patients, not only Medicare beneficiaries. Second, this change also permits “licensed practitioners,” such as non-physician practitioners, to record progress notes of psychiatric patients for whom they are responsible and to practice at the highest level of their education, training, and qualifications under state law. This change was made in other parts of the CoPs in September of 2019, and the change in this IFC is made to be consistent with such other changes. Note that this change is not limited to the COVID-19 PHE.

III. Physicians

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

i. MIPS Improvement Activities Inventory Update

CMS is adding a new Improvement Activity for the 2020 Performance Period: “COVID-19 Clinical Trials.” This high-weighted 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. To receive credit, clinicians must report findings through an open source clinical data repository or clinical data registry.

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

CMS is applying the MIPS automatic extreme and uncontrollable circumstances policy (42 CFR 414.1380(c)(2)(i)(A)(8) and (c)(2)(i)(C)(3)) for the 2019 performance period (2021 payment year). In addition, because the automatic policy does not apply to groups or virtual groups, CMS is providing additional relief by extending the deadline for such entities to submit an application for reweighting the Quality, Cost, Improvement Activities, and Promoting Interoperability performance categories based on extreme and uncontrollable circumstances from December 31, 2019 to April 30, 2020 (or a later date that CMS may specify).

CMS also is modifying its existing policy for the 2019 performance period so that if a MIPS eligible clinician, group, or virtual group that submits a reweighting application by the extended deadline, any data

submitted or will be submitted, will not void the reweighting application and the performance categories will be reweighted (subject to CMS' approval of the application).

b. Requirements for Opioid Treatment Programs (OTPs)

In the 2020 PFS final rule, CMS finalized 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 COVID-19 PHE and the fact that some beneficiaries may not have audio/video communication, CMS is revising 42 CFR 410.67(b)(3) and (4) to allow 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 audio-video communications technology if the beneficiary does not have access to two-way audio-video communications, provided all other applicable requirements are met.

c. Teaching Physician Services and Moonlighting Regulations (42 CFR part 415)

i. Revisions to Teaching Physician Regulations (42 CFR 415.172, 415.174, 415.180, 415.184)

CMS notes that teaching hospitals have expressed a need to increase their capacity to respond to the COVID-19 PHE due to an increased demand for physicians to respond to patient needs. CMS is temporarily amending the teaching physician regulations (42 CFR 415.172) such that the requirement for the presence of a teaching physician can be met, at a minimum, through direct supervision by interactive telecommunications technology (described above). Specifically, a teaching physician must provide supervision either with physical presence or be present through interactive telecommunications technology during the key portion of the service. In addition, during the COVID-19 PHE, Medicare may make PFS payments for teaching physician services when the resident is furnishing the services while in quarantine under direct supervision of the teaching physician by interactive telecommunications technology.

CMS also is temporarily amending the primary care exception (42 CFR 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.

In addition, CMS will temporarily allow PFS payment to be made for the interpretation of diagnostic radiology and other diagnostic tests (42 CFR 415.180) 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.

Finally, CMS will temporarily allow the requirement for the presence of a teaching physician during psychiatric services in which a resident is involved (42 CFR 415.184) to be met by the physician's direct supervision by interactive telecommunications technology.

CMS views direct supervision by interactive telecommunications technology as the minimum requirement to provide the service for the purposes of Medicare payment. However, CMS states that teaching physicians may exercise their clinical judgment to decide whether it is appropriate to utilize these flexibilities. CMS seeks comment on whether these flexibilities are appropriate and whether any guardrails should be included.

CMS notes that these flexibilities will **not** apply in the case of surgical, high-risk, interventional, or other complex procedures, services performed through an endoscope, and anesthesia services. CMS seeks comment on whether additional procedures should be exempt from the additional flexibility due to their complex nature or potential danger to the patient.

ii. Revisions to Moonlighting Regulations

CMS is temporarily amending its regulations related to residents furnishing services that are not related to their approved graduate medical education (GME) programs in an outpatient department or emergency department of a hospital in which they have their training program (42 CFR 415.208). Specifically, CMS is amending 42 CFR 415.208 to state that the services of residents not related to their approved GME programs and are performed in the inpatient setting of hospital in which they have their training program, are separately billable physicians' services for which PFS payment can be made. The services must be identifiable physicians' services and meet the conditions of payment for physicians' services to beneficiaries. In addition, the resident must be fully licensed to practice by the State in which the services are performed and the services are not performed as part of the approved GME program.

IV. Post-Acute Care Providers

a. Home Health

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

Beneficiaries must be under a physician plan of care and certified by a physician as homebound in order to receive home health services. CMS indicates that many Medicare beneficiaries could be considered "confined to the home" during the COVID-19 pandemic and therefore eligible for home health care services under a plan of care. During the PHE for COVID-19 pandemic, patients may be considered homebound both: (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.

ii. The Use of Technology Under the Medicare Home Health Benefit

CMS reiterates that home health agencies may furnish services via telecommunications systems, including remote patient monitoring, but specifies that the statute does not allow use of technology to substitute for in-person home health services or to be counted as a home health "visit" for purposes of eligibility or payment. CMS seeks to give HHAs flexibility to use various types of telecommunications systems in conjunction with in-person visits.

On an interim basis, CMS is amending regulations (42 CFR 409.43(a)) to specify that 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. Further, 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. CMS describes scenarios where a plan of care might be amended to reduce the number of in-person visits and to include technology services (e.g., video consultations). Low-utilization payment adjustment (LUPA) thresholds will continue to apply.

On an interim basis, CMS will also allow HHAs to report the costs of telecommunications technology as allowable administrative and general cost on cost reports.

b. Hospice

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

CMS is amending hospice regulations (42 CFR 418.204) on an interim basis to specify that 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 care providers. 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 existing requirements 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.

While there is no payment beyond the per diem amount for the use of technology in providing services under the hospice benefit, CMS, on an interim basis, will allow hospices to report the costs of telecommunications technology used to furnish services as "other patient care services" (Worksheet A, cost center line 46, identifying the cost center as "PHE for COVID-19").

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

CMS is amending hospice regulations (42 CFR 418.22(a)(4)) on an interim basis to allow the use of telecommunications technology (meaning two-way, real-time interactive, audio and video) by the hospice physician or nurse practitioner 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.

c. Inpatient Rehabilitation Facilities (IRFs)

i. Modification of the Face-to-Face Requirement

CMS is amending IRF regulations (42 CFR 412.662(a)(3)(iv) and 412.29(e)) during the PHE for the COVID-19 pandemic to allow certain services to be conducted using telehealth services. Specifically, the use of telehealth is temporarily expanded to the following: (1) physician supervision by a rehabilitation physician; and (2) the at least three 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) and to modify the course of treatment to maximize the patient's capacity to benefit. The post-admission physician evaluation (42 CFR 412.622(a)(4)(ii)) may count as one of the face-to-face visits.

ii. Removal of the Post-Admission Physician Evaluation Requirement and Clarification Regarding the "3-Hour" Rule

To document that each patient for whom the IRF seeks payment is reasonably expected to meet all of the requirements (42 CFR 412.622(a)(3)) at the time of admission, the IRF medical record must contain a post-admission physician evaluation that meets certain requirements (completed within 24 hours of admission, documents patient's status on admission, retained in the medical record at the IRF). CMS, on an interim basis, is removing the post-admission physician evaluation requirement (42 CFR 412.622(a)(4)(ii)) for all IRFs to reduce time spent completing paperwork requirements.

In addition, CMS is clarifying for the duration of the COVID-19 PHE that in cases where an IRF's intensive rehabilitation therapy program is impacted (e.g., due to staffing disruptions resulting from self-isolation,

infection, or other circumstances related to the COVID-19 PHE), “the IRF should not feel obligated to meet the” 3-hour rule (42 CFR 412.622(a)(3)(ii)),⁹ and instead make a note to this effect in the medical record.

V. DMEPOS Part B Suppliers

CMS is modifying existing advance payment rules (42 CFR 421.214), which currently limit CMS’ ability to make advance payments in situations where a CMS contractor is unable to process claims within established time limits. Specifically, CMS is revising the definition of advance payment (42 CFR 421.214(b)) to state that the conditional partial payment will be made by the “contractor” (as opposed to the carrier). CMS also is adding language to permit payments in exceptional circumstances as added in new paragraph (j). This new paragraph addresses exceptional circumstances and PHEs, during which CMS will approve advance payments. Under this new paragraph (j), CMS may approve advance payments if: (1) the contractor is unable to process the claim timely (or is at risk of being untimely); or (2) the supplier has experienced a temporary delay in preparing and submitting bills to the contractor beyond its normal billing cycle. CMS also is increasing the limit of the anticipated payment from 80 percent to 100 percent based on the historical assigned claims payment data for claims paid to the supplier if the requirements of paragraph (j) are met. CMS also is adding a criterion that suppliers in bankruptcy would not be eligible to receive advance payments.

VI. Clinical Laboratories

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

a. Background on Home Health Agency (HHA)/Skilled Nursing Facility (SNF) Nominal fees

Under current law, the HHS Secretary must establish and provide a nominal fee for specimen collection for laboratory testing and a fee to cover transportation and expenses for personnel that collect the specimens from homebound patients and inpatients (not in a hospital setting), in addition to the amounts provided under the Medicare Clinical Laboratory Fee Schedule (CLFS). The HHS Secretary must establish a nominal fee to cover the appropriate costs in collecting the sample and 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 nominal specimen fees (36415, P9612, and P9615) have a payment rate of \$3 and the Protecting Access to Medicare Act of 2014 increased these amounts by \$2 for a sample collected from an individual in a SNF or by a laboratory on behalf of an HHA. 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 an HHA is \$5 and the relevant HCPCS code is G0471.

b. Background on Transportation and Personnel Expenses

Current law requires the HHS Secretary to establish a fee to cover the transportation and personnel expenses to travel to the location of an individual to collect the sample, except that such fee may be provided only with respect to an individual who is homebound or an inpatient (not in a hospital setting). Medicare established a travel allowance for a laboratory technician to draw a specimen from homebound patients and

⁹ The 3-hour rule 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. This program generally consists of at least three hours of therapy per day at least five days per week.

non-hospital inpatients. The 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 only paid when the specimen collection is also payable and is not available if the technician is performing a "messenger service" to pick up a specimen drawn by a physician or nursing home personnel. The methodology for the allowance depends on the roundtrip mileage to and from where the patient is located (e.g., a per mile travel allowance applies when the round trip to patients' homes is greater than 20 miles and a flat rate for less than 20 miles).¹⁰

c. Summary of Changes

CMS will provide Medicare payment for a nominal specimen collection fee and associated travel allowance to independent laboratories for collection of specimens related to COVID-19 clinical diagnostic testing for homebound and non-hospital inpatients throughout the COVID-19 PHE. 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 SNF individuals or individuals whose samples will be collected by a 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 COVID-19 testing and bill the travel allowance with the current HCPCS codes in the Medicare Claims Procession Manual (P9603 and P9604).¹¹ The policy will incorporate the IFC's clarification of the definition of homebound for the purposes of the Medicare home health benefit (as discussed above). CMS states these changes are intended to minimize patient exposure to others and improve testing capabilities while providing laboratories with additional resources to provide testing.

In developing the amount, CMS considered the type of trained laboratory personnel required to collect the specimen and the resources this type of collection may require. CMS looked to other similar services in other settings of care as a potential benchmark and decided the PFS was the most practical comparison since physicians and other practitioners often bill for services that involve specimen collection by trained, non-institutional staff under the PFS. CMS used the Level 1 office visit (CPT code 99211) as a base payment since it is used when a physician practice is acquiring a routine specimen sample. CMS considered establishing a higher payment amount that considered the Level 1 visit plus the payment amount for CPT code 89220 (sputum obtaining specimen aerosol induced technique) for a specimen collection fee of \$40.06, but CMS believes there may be overlapping costs in staff time for the two services and elected to move forward with the Level 1 office visit payment rate.

CMS explained that in the context of collecting a specimen for COVID-19 testing, collecting specimens using nasopharyngeal (NP) swabs, oropharyngeal (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 COVID-19. CMS believes that collecting a specimen for COVID-19 testing will incur higher costs than similar specimen collection services that require a trained laboratory professional, but not additional precautions to minimize exposure risks. Further, the COVID-19 OP, NP, and sputum specimens 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. CMS stated that sputum typically only requires the services of a messenger, but during the COVID-19 PHE period, sputum collection must be performed by trained laboratory personnel to be considered "medically necessary" for payment purposes. CMS stated that, if in the future serological or point of care tests are available, the

¹⁰ The manual for payment of these fees is available here: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c16.pdf>

¹¹ See section 60.2 of the Medicare Claims Processing Manual here: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c16.pdf>

specimen collection fee would apply if the specimen collection method is performed by trained laboratory personnel. COVID-19 tests that allow patients to collect the specimen themselves would not be eligible for the specimen collection fee.

CMS is establishing two new level II HCPCS codes to identify specimen collection for COVID-19 testing. Independent laboratories must use one of the codes when billing Medicare for the nominal specimen collection fee for COVID-19 testing for the duration of the COVID-19 PHE. The codes are:

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

CMS established the second code (G2024) because the relevant statute (SSA 1834A(b)(5)) and regulation (42 CFR 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. CMS will issue guidance when the codes are no longer valid.

The travel allowance will be billed according to current instructions, per mile rate for round trips greater than 20 miles and a flat rate for less than 20 miles traveled. CMS clarifies that paper documentation of miles traveled is not required (i.e., these can be maintained in electronic logs), but laboratories must be able to share electronic records with Medicare Administrative Contractors.

In defining a “homebound” individual for purposes of specimen collection and the travel allowance, CMS is building on existing definitions under current law (SSA 1814(a) and 1135(a)) and previously described changes made through this IFC. Specifically, a person is homebound if it is “medically contraindicated for the patient to leave the home.” This exists when it would require a “considerable and taxing” effort for a patient to safely leave home. CMS provides the following examples during the COVID-19 PHE:

- 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
- 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 home. Determining whether a patient is homebound is based on an assessment of each beneficiary’s condition. Given many Medicare beneficiaries will be considered homebound, a patient is considered homebound if it is medically contraindicated for the patient to leave the home.

In summary, this IFC provides additional payment for specimen collection to \$23.46, slightly increased to \$25.46 for an individual in a SNF or by a laboratory on behalf of an HHA. Additionally, this IFC provides a travel allowance for a laboratory technician to collect a specimen for COVID-19 testing from a non-hospital inpatient or homebound patient.

VII. Ambulances – Origin and Destination Requirements Under the Ambulance Fee Schedule

CMS is temporarily expanding the list of destinations (42 CFR 410.40(f)) for which Medicare will cover ambulance transportation. This will include **all** destinations, from any point of origin, 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. CMS notes that a patient suspected of having

COVID-19 who requires medically necessary transport may be transported to a testing facility instead of a hospital to prevent possible exposure to others. In addition, CMS notes that the expanded 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 (CMHCs); 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 will apply to medically necessary emergency and non-emergency ground ambulance transports. In addition, there must be a medically necessary ground ambulance transport in order for an ambulance service to be covered. CMS states that a beneficiary's home may be an appropriate destination for a COVID-19 patient discharged from the hospital to home to be under quarantine.

VIII. Medicare Advantage (MA) and Part D Quality Star Ratings

CMS explained that data used to set the 2021 Star Ratings is based on performance in 2019 and compiled in the first half of 2020. Similarly, Health Outcomes Survey (HOS) data in the Consumer Assessment of Healthcare Providers and Systems (CAHPS) will occur in 2020. This survey data is used to help develop 2022 Star Ratings. Currently, data collection for the Healthcare Effectiveness Data and Information Set (HEDIS) is ongoing. MA contracts are required to submit their HEDIS summary-level data to the National Committee for Quality Assurance (NCQA) by June 15, 2020, as well as to submit their HEDIS patient-level data to CMS the same day. Some of these measures require medical record review or obtaining information directly from physician offices. All MA plans, cost plans, and Part D plan sponsors are required to contract with a CMS-approved CAHPS survey vendor to conduct satisfaction surveys and then submit the captured data. CMS is 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. CMS has similar concerns about the Health Outcomes Survey (HOS) data collection scheduled for later in 2020. CMS notes that it is not possible to conduct HEDIS and CAHPS data collection activities while complying with social distancing recommendations.

This IFC amends the calculations for the 2021 and 2022 Part C and D Star Ratings to address the expected impact of the COVID-19 PHE on data collection and performance. Specifically, this IFC:

1. Replaces the 2021 Star Rating measures calculated based on HEDIS and Medicare CAHPS data collections with earlier values from the 2020 Star Ratings (which were not affected by the public health threats posed by COVID-19);
2. Establishes how CMS 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 CMS is unable to complete HOS data collection in 2020 (for the 2022 Star Ratings), replaces the measures calculated based on HOS data collection 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

CMS is eliminating the HEDIS 2020 submission requirement that covers the 2019 measurement year and requesting that Medicare health plans, including MA and cost plan organizations, curtail HEDIS data collection work immediately. This is intended to allow health plans, providers, and physician offices to focus on caring for Medicare beneficiaries during the COVID-19 emergency period. Medicare health plans can use any HEDIS data that they have collected for internal quality improvements. CMS is also amending the regulations requiring the submission of the CAHPS survey data to CMS for Medicare health and drug plans. CMS is revising the Part C regulation at 42 CFR 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.

CMS is revising the cost plan regulation at 42 CFR 417.472: (1) in paragraph (i), to add a requirement for cost plans to comply with 42 CFR 422.152(b)(6); and (2) in paragraph (j), to make the obligation for cost plans to conduct CAHPS surveys subject to paragraph (i) (as revised).

This IFC also revises 42 CFR 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. CMS is also adding 42 CFR 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.

CMS states that these revisions do not 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. However, CMS does not expect plans to do so.

The HOS survey was scheduled to be administered from April through July 2020, however now the survey will be administered in "late summer" and CMS will provide additional information for MA plans in the coming months. In the event that the pandemic continues beyond this summer and HOS survey data cannot be collected, CMS is amending the regulations for Part C 2022 Star Ratings by adding 42 CFR 422.166(j)(2), which will allow CMS to use the Star Ratings and measure scores for the 2021 Star Ratings for any measures that come from the HOS survey. The measures from the HOS survey include: 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

CMS is making a series of adjustments to the Star Ratings methodology for a variety of reasons that are associated with the disruptions resulting from the COVID-19 pandemic. Specifically, CMS will use the HEDIS measure scores and the Star Ratings based on the 2018 measurement year (i.e., the data used for the 2020 Star Ratings) for the 2021 Star Ratings. For the 2021 Star Ratings, CMS will also use the CAHPS data submitted to CMS in June 2019. To accomplish this, CMS is revising 42 CFR 422.166 and 423.186 to add new regulation language 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.

The measurement period for all other measures will not change from what has already been finalized in 2018 final rule. For both HEDIS and CAHPS measures, CMS will use 2020 measure-level Star Ratings (and associated measure-level scores) in all the Star Rating calculations for the 2021 Star Ratings (codified at 42 CFR 422.160, 422.162, 422.162, 422.166, 423.180, 423.182, 423.184, and 423.186). 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. CMS will also continue to exclude the Plan All-Cause Readmissions measure for the 2021 Star Ratings, but data associated with the measure will be posted on display for the 2021 ratings.

Since CMS is using the 2020 Star Ratings data for the HEDIS and CAHPS measures, CMS will carry forward measure-level improvement changes from the 2020 Star Ratings for all HEDIS or CAHPS measures for the 2021 Star Ratings Part C and D improvement measure calculations. CMS is codifying this at 42 CFR 422.166(j)(1)(iii) and 423.186(j)(1)(ii).

For the 2021 Star Ratings, CMS will not reduce the HEDIS and CAHPS measures to 1 star for failure to report the 2020 HEDIS or CAHPS data. CMS is codifying this at 42 CFR 422.166(j)(1)(iv) and 423.186(j)(1)(iii).

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

CMS has 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 Quality Bonus Program (QBP) in the event that CMS' functions to calculate the 2021 Star Ratings are impacted. If the COVID-19 pandemic continues to impact CMS and other stakeholders, CMS believes it would be impracticable to begin rulemaking in August. Further, Star Ratings are used to identify which MA plans are eligible for the QBP. Given the QBP goes toward additional benefits or reductions in premiums, CMS believes it is critical that MA organizations understand how ratings would be calculated if the pandemic extends for the next eight to nine months. If CMS' resources become extraordinarily compromised, CMS will use the 2020 Star Ratings as the 2021 Star Ratings. This is codified at 42 CFR 422.166(j)(1)(v) and 423.186(j)(1)(iv), and limited specifically to the COVID-19 PHE.

CMS is also concerned that plans will have difficulty in ensuring non-CAHPS and non-HEDIS measures are fully developed and validated. As an example, plan sponsors report Special Needs Plan (SNP) Care Management and Medication Therapy Management (MTM) data to CMS in March 2020, and these data points are validated by independent entities in April. CMS believes there may be difficulties in completing this work on time. Under normal circumstances, CMS reviews quality data before making a final determination about the inclusion of measures in each year's Star Rating. However, given the potential for data quality issues across plans, CMS is 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 Rating calculations. CMS is adopting authority to substitute the score and star for the measure used in the 2020 Star Ratings when there is a systemic data quality issue for all plans as a result of the COVID-19 pandemic (42 CFR 422.164(i) and 423.184(i)).

CMS notes that they are making these changes to help provide as much certainty for plans and beneficiaries as possible. CMS explains that calculating MA payments are dependent on Star Ratings and many deadlines in the program are statutory and inflexible (e.g., the bid deadline, annual election period, and the start of a new benefit year). CMS believes that taking this approach will allow CMS and MA organizations to move to a new basis for calculating QBPs in the event that the original one (i.e., using data about 2019 performance) is unavailable. CMS also believes this will 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. CMS is codifying these provisions at 42 CFR 422.164, 422.166, 423.184, and 423.186.

d. 2022 Star Ratings

CMS expects plans to submit HEDIS data in June 2021 and to administer CAHPS surveys 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 COVID-19 pandemic. This IFC is making immediate changes to the methodology for the 2022 Star Ratings so plans and healthcare providers are not incentivized to act inappropriately. Except as addressed in this IFC, CMS anticipates the 2022 Star Ratings will be implemented as codified at 42 CFR 422.160, 422.162, 422.164, 422.166, 423.180, 423.182, 423.184, and 423.186.

Changes implemented by plans and providers to care for the elderly and most vulnerable patients during the pandemic will impact performance for the 2020 measurement period, which impacts the 2022 Star Ratings. However, CMS recognizes that plans and providers are focusing their efforts on providing urgent care rather than non-essential procedures and beneficiaries are being asked to remain home. Therefore, CMS is making adjustments to account for the potential decreases in measure-level scores so health plans can have a degree of certainty for upcoming Star Ratings.

To increase the predictability of the cut points used for measure-level ratings, CMS previously finalized “guardrails” for measures that have been in the program for more than three years (starting with the 2022 Star Ratings). The guardrails ensure that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than five percent annually. Although this provides for consistency in cut point variation, it does not account for changes in overall performance across the industry. Further, in the context of the COVID-19 pandemic, CMS believes that these guardrails as currently constructed may result in unintended incentives (e.g., focusing on non-urgent care or administrative efforts) even if those issues are tied to existing Star Ratings measures, instead of focusing attention on urgent care issues. Therefore, CMS is delaying the implementation of the guardrails so that cut points can change by more than 5 percent if national performance declines as a result of the COVID-19 PHE. To implement this, CMS is modifying 42 CFR 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.

CMS anticipates that performance during the 2020 measurement period will decline and believes it is appropriate to adopt a provision to minimize the negative effects of the improvement measure and improvement scores. CMS is 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 COVID-19 PHE may result in a decline in industry performance. Currently, for MA prescription drug plan contracts with an overall rating of 4 or more stars, the Part C and Part D improvement measure(s) are excluded if including the measure would reduce the plan’s overall Star Rating. Similarly, for MA-only contracts with 4 or more stars, the Part C improvement measure is excluded from calculations for that contract if its inclusion reduces the Part C summary Star Rating. CMS is expanding this hold harmless rule 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. CMS is codifying this change at 42 CFR 422.166 and 423.186.

Beginning with the 2017 Star Ratings, CMS implemented the Categorical Adjustment Index (CAI) that adjusts for the average within-contract disparity in performance associated with the percentages of enrollees who received a low-income subsidy and/or are dual eligible and/or have disability status. For the 2022 Star Ratings, CMS will calculate the CAI as codified (42 CFR 422.166(f)(2) and 423.186(f)(2)). The CAI will be calculated using the HEDIS and CAHPS data from the 2020 Star Ratings. Further, adjusted measure scores will be calculated using the enrollment year associated with the year of data being used for that measure (i.e., 2018 enrollment year data for HEDIS and CAHPS measures, 2019 enrollment year data for

all other measures). Given CMS will follow the existing codified rules, there are no regulatory changes in text. Rather, CMS is simply providing an explanation to avoid uncertainty.

As for new MA contracts in the 2022 QBP, CMS is modifying the definition (42 CFR 422.252) 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 four years (increased from three years). CMS believes 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 CMS eliminated HEDIS and CAHPS data submissions, these new plans will not have enough measures to calculate the 2021 Star Ratings, which impact the 2022 QBP rating. A new contract as of January 1, 2019 would normally be treated as new for purposes of QBP 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.

IX. Medicaid/CHIP: Expanding Workforce Capacity

In recognition of the demand for more services in home health settings due to COVID-19, CMS is amending 42 CFR 440.70 to allow for nurse practitioners and physician assistants, among other licensed practitioners, to order Medicaid home health services during the COVID-19 PHE. These practitioners must be practicing within the scope of their license. Currently, an individual's physician is required to order home health services as part of a care plan and review the care plan every 60 days while also reviewing medical supplies, equipment, and appliances within the care plan annually.

This change will expand the workforce and is a continuation of the agency's efforts to align with Medicare in terms of who can order services for Medicaid beneficiaries, including those who are dually eligible. CMS stated that the change will eliminate administrative burden to states and providers dealing with inconsistencies between Medicare and Medicaid. This change does not expand the benefit categories where these items can be covered. The IFC clarifies that States must continue to cover and claim under the home health benefit (unless otherwise allowed by federal regulations) home health nursing and aide services, medical supplies, equipment and appliances, and PT, OT, SLP, and audiology services.

X. CMS Innovation Center Models and Demonstrations

a. Changes to Innovation Center Models

i. Medicare Diabetes Prevention Program (MDPP)

CMS is temporarily modifying certain MDPP policies during the COVID-19 PHE to: (1) permit certain beneficiaries to obtain the set of MDPP services more than once per lifetime; (2) increase the number of virtual make-up sessions; and (3) allow certain MDPP suppliers to temporarily deliver virtual MDPP sessions. The changes will apply to MDPP suppliers enrolled and beneficiaries receiving MDPP services as of March 1, 2020.

Under the temporary flexibilities, the requirement for an in-person attendance at the first core-session will remain in effect (i.e., if a beneficiary is prohibited from attending the first core-session in person, suppliers will be unable to start any new cohorts with MDPP beneficiaries). When classes resume, CDC will allow suppliers to resume from when the classes were paused or restart the expanded model program from week one. Further, MDPP suppliers can deliver services virtually or suspend in-person services and resume them at a later date.

The limit to the number of virtual make-up sessions is waived so long as the virtual services are provided in a manner consistent with the CDC Diabetes Prevention Recognition Program standards for virtual sessions, follow the CDC-approved curriculum requirements, and provided upon the MDPP beneficiary's request. In addition, a maximum of one virtual session is permitted on the same day as a regularly scheduled session and a maximum of one virtual make-up session is permitted per week. These make-up sessions may only be provided to achieve attendance goals, not to achieve weight-loss goals. While the limit is waived, CMS is implementing the following caps: 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.

Finally, 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 while maintaining eligibility despite a break in service, attendance, or weight-loss achievement.

ii. Changes to the Comprehensive Care for Joint Replacement (CJR) Model

CMS is implementing two changes to the CJR model to support continuity and prevent unfair financial consequences due to COVID-19: (1) a three-month extension to performance year 5 such that the model will end on March 31, 2021 (instead of December 31, 2020); and (2) broadening the CJR extreme and uncontrollable circumstances policy by applying certain financial safeguards to participant hospitals located in the emergency area (nationwide) such that they qualify for applicable financial safeguards during the emergency period.

iii. Alternative Payment Model (APM) Treatment under the Quality Payment Program (QPP)

CMS acknowledges that changes might be needed to address issues arising for APM participants in light of the COVID-19 PHE. CMS will consider additional rulemaking, including another interim final rule, to amend or suspend APM QPP policies as necessary.

b. Change to Medicare Shared Savings Program (MSSP) Extreme and Uncontrollable Circumstances Policy

1. Background

Under current policy (42 CFR 425.502(f)), the MSSP 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 2019 performance years, the quality reporting period was January 2, 2020 through March 31, 2020. Due to the COVID-19 PHE, CMS extended the Merit-based Incentive Payment System (MIPS) data submission deadline by 30 days (to April 30, 2020). This extension also applies to MSSP Accountable Care Organizations (ACOs) because the MSSP data submission timeline is aligned with that of MIPS data submission. CMS realized that the extended timeframe alone may not be sufficient and therefore determined that the MIPS automatic extreme and uncontrollable circumstances will apply to MIPS eligible clinicians who do not submit their MIPS data by the extended timeline. Under this policy, MIPS eligible clinicians not participating in APMs who do not submit any MIPS data will have all performance categories reweighted to zero percent, resulting in a neutral MIPS payment adjustment. However, if a MIPS eligible clinician submits data on two or more MIPS performance categories, they will be scored and receive a 2021 payment adjustment based on the final score.

This reweighting does not apply to MIPS eligible clinicians subject to the APM scoring standard, including MIPS eligible clinicians participating in an MSSP ACO. In general, 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 the extreme and uncontrollable circumstances, the APM scoring standard would apply as follows:

- Cost – reweighted to zero percent
- Improvement Activities – scored as usual
- Quality – reweighted to zero percent (where the APM has waived quality reporting for purposes of the APM)
- Promoting Interoperability – reweighted to zero percent (if all MIPS eligible clinicians in an APM Entity have been excepted from reporting this performance category)

Because only one performance category will be scored, these MIPS eligible clinicians would receive a neutral payment adjustment. In such circumstances, the MSSP must determine that the ACOs are impacted by an extreme and uncontrollable circumstance and waive the quality reporting requirement. In addition, if an ACO fails to report quality data by the submission deadline, the ACO will receive a quality score of zero and would be ineligible to share in savings (if earned) and would owe maximum losses under Track 2 or the ENHANCED track.

2. Summary of Changes

Because the current MSSP extreme and uncontrollable circumstances policy does not allow for a determination that an ACO has been impacted if a quality reporting period is extended, CMS believes it is necessary to revise the policies regarding extreme and uncontrollable circumstances policies to extend the protection to ACOs. Accordingly, CMS is revising 42 CFR 425.502(f) to remove the restriction that prevents the application of the MSSP extreme and uncontrollable circumstances policy for disasters occurring during the quality reporting period if the reporting period is extended.

CMS also is considering whether the current policy that assigns an ACO to the higher of the mean quality score across all ACOs and the ACO's own quality score in the event the ACO is impacted by an extreme and uncontrollable circumstance, will continue to be appropriate for performance year 2020 and later. Any change would be made through future notice and comment rulemaking.

CMS will reduce the amount of an ACO's shared losses for the performance year 2020 financial reconciliation by an amount determined by multiplying shared losses by the percentage of the total months (March 2020 through the end of the COVID-19 PHE) in the performance year affected by an extreme and uncontrollable circumstance, and the percentage of the ACO's assigned beneficiaries residing in an affected area (100 percent of assigned beneficiaries). In addition, the factors used to update ACOs' benchmarks will reflect the national and regional trends related to spending and utilization changes during 2020, including changes due to the COVID-19 PHE.

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