

# Centers for Medicare and Medicaid Services Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

On March 30, the Centers for Medicare and Medicaid Services (CMS) issued an Interim Final Rule with comment period (IFC) in order to allow 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). The American College of Radiology has prepared a detailed summary of this rule outlining the provisions with a potential impact on radiology practices.

#### **Payment for Medicare Telehealth Services**

On March 17, 2020, CMS announced the expansion of telehealth services on a temporary and emergency basis. Beginning 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. To facilitate the use of telecommunications technology as a safe substitute for in-person services, CMS, on an interim basis, adding many services to the list of eligible Medicare telehealth services. The agency is also 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).

#### Site of Service Differential for Medicare Telehealth Services

CMS is instructing 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. This will allow their systems to make appropriate payment for services furnished via Medicare telehealth which, if not 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. Many of the assumptions that support the PFS facility rate do not apply to many services during the COVID pandemic. CMS is 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.

#### Adding Services to the List of Medicare Telehealth Services

CMS will now pay for more than 80 additional services when furnished via telehealth with dates of service from March 1, 2020 until the end of the public health emergency (PHE). These include emergency department visits, initial nursing facility and discharge visits, and home visits, which

must be provided by a clinician that is allowed to provide telehealth. In the context of the PHE, CMS recognizes 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. CMS is reiterating that practitioners should report the E/M code that best describes the nature of the care they are providing. In the context of the PHE for the COVID-19 pandemic, CMS believes 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. The new CPT codes are:

- Emergency Department Visits: 99281–99285
- Initial and Subsequent Observation, and Observation Discharge Day Management: 99217–99220, 99224–99226, 99234–99236
- Initial hospital care and hospital discharge day management: 99221-99223, 99238-99239
- Initial nursing facility visits and nursing facility discharge day management: 99304–99306, 99315–99316
- Critical Care Services: 99291–99292
- Domiciliary, Rest Home, or Custodial Care services: 99327–99328, 99334–99337
- Home Visits: 99341–99350
- Inpatient Neonatal and Pediatric Critical Care: 99468–99469, 99471-99476
- Initial and Continuing Intensive Care Services: 99477–99480
- Care Planning for Patients with Cognitive Impairment: 99483
- Group Psychotherapy: 90853
- End-Stage Renal Disease (ESRD) Services: 90952–90953, 90959, 90962
- Psychological and Neuropsychological Testing: 96130–96139
- Therapy Services: 97161-97168, 97110–97116, 97535, 97750, 97755, 97760, 97761, 92521–92524, 92507
- Radiation Treatment Management Services: 77427 (*Radiation treatment management, 5 treatments*)

## CMS is seeking comment on any potential negative consequences of adding these CPT codes to the list of telehealth services on an interim basis.

#### Radiation Treatment Management Services

As a result of PHE for the COVID-19 pandemic, CMS has added 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. 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. 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.

#### **Telehealth Modalities and Cost-sharing**

#### Clarifying Telehealth Technology Requirements

For the duration of the PHE, *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". This definition has been revised for the duration of the PHE in order to avoid the perception that the previous language may have prohibited use of some devices, including phones, that could otherwise meet the interactive requirements for Medicare telehealth. In addition, the Department of Health and Human Services (HHS) Office for Civil Rights (OCR) is exercising enforcement discretion and waiving 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 PHE for the COVID-19 pandemic. HHS, Office of Inspector General (OIG), and Department of Justice (DOJ) continue to actively monitor for any healthcare fraud and abuse, including potential Medicare coronavirus scams.

#### Beneficiary Cost Sharing

In response to the Secretary's January 31, 2020 PHE determination, the OIG issued a Policy Statement 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 services furnished consistent with the then applicable coverage and payment rules. The Policy Statement 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. Additionally, 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.

#### **Communication Technology-Based Services (CTBS)**

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 telehealth 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, CMS finalized separate payment for a number of services that could be furnished via telecommunications technology, but that are not Medicare telehealth services. Specifically, the agency 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). These codes were finalized 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. CMS stated that this was appropriate since the service describes a check-in directly with the billing practitioner to assess whether an office visit is needed.

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, CMS believes 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, CMS is 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. CMS is also making clear that the consent to receive these services can be documented by auxiliary staff under general supervision. In addition, CMS is 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. CMS is 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.

Additionally, in the 2020 PFS final rule, CMS 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). CMS 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*). 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, CMS does 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, CMS is exercising enforcement discretion on an interim basis to relax enforcement of this aspect of the code descriptors. Specifically, the agency will not conduct review to consider whether those services were furnished to established patients.

Additionally, in the CY 2020 PFS final rule, CMS 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. CMS has received a number of questions regarding which benefit categories HCPCS codes G2061-G2063 fall under. In response to these requests, CMS is clarifying 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, CMS is also broadening the availability of HCPCS codes G2010 and G2012 that describe remote evaluation of patient images/video and virtual check-ins.

The agency recognizes 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. **CMS notes that this is not an exhaustive list and is 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.** 

#### **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.

Given the circumstances of the COVID-19 pandemic, CMS recognizes that the physical proximity of the physician or practitioner might present additional exposure risks. CMS believes that the current direct supervision requirement would limit access to procedures and tests that could be appropriately supervised by a physician isolated for purposes of limiting exposure to COVID-19. Therefore, CMS is altering 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.

CMS states that telecommunications technology could be used so the physician is immediately available to furnish assistance and direction without necessarily requiring the physician's physical presence in the location where the service is being furnished. CMS believes the use of real-time, audio and video telecommunications technology allows for a billing provider/practitioner to observe the patient interacting with or responding to the in-person clinical staff through virtual means, and their availability to furnish assistance and direction could be met without requiring the physician's physical presence in that location.

CMS also notes 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. CMS views supervision levels as the minimum possible requirement for provision of the service for purposes of Medicare payment.

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, CMS believes that individual practitioners are in the best position to make decisions based on their clinical judgement in particular circumstances. Consequently, CMS is 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. CMS is seeking comments 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.

Supervision changes for certain Hospital and CAH Diagnostic and Therapeutic Services

CMS is adopting the same changes to direct supervision 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.

#### Rural Health Clinics (RHCs) and Federally Qualified Health Centers (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 CMS wants 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.

To minimize risks associated with COVID-19 exposure, CMS is encouraging the exploration of interactive communication technologies in place of in-person visits for RHCs and FQHCs. To facilitate this, CMS is expanding the services that can be billed under 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) and updating the

payment rate to include the national non-facility payment rates. CMS is adding the following CPT codes: 99421-99423 (*Online digital evaluation and management service*). These codes will be effective for services furnished on or after March 1, 2020 and throughout the public health emergency, and RHC and FQHC face-to-face requirements are waived for these services.

Additionally, all virtual communication codes that are billable using HCPCS code G0071 will be available to new patients that have not been seen in the RHC or FQHC within the past 12 months. Furthermore, consent may be obtained at the time of the service rather than prior, but must be obtained before services are billed. Consent may also be obtained through staff under the general supervision of the RHC or FQHC practitioner.

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

In context of the PHE for the COVID-19 pandemic, CMS has 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. CMS has 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.

The provisions in the Act 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 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.

CMS has 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, CMS believes 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. The agency recognizes 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, CMS is amending the teaching physician regulations to allow that as a general rule, the requirement for the presence of a teaching physician can be met, at a minimum, through direct supervision by interactive telecommunications technology. The teaching physician must provide supervision either with physical presence or be present through interactive telecommunications technology during the key portion of the service. CMS believes 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.

For the duration of the PHE for the COVID-19 pandemic, CMS will allow PFS payment to be made for the interpretation of diagnostic radiology and other diagnostic tests when the interpretation is performed by a resident under direct supervision of the teaching physician by interactive telecommunications technology. The teaching physician must still review the resident's interpretation. These diagnostic radiology and diagnostic test 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 physical might present additional exposure risk.

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. **CMS seeks comment on whether other procedures should also be exempt from this policy given the complex nature or potential danger to the patient.** 

Application of the Expansion of Telehealth Services to Teaching Physician Services

On March 17, 2020, CMS announced the expansion of telehealth services on a temporary and emergency basis pursuant to waiver authority added by the Coronavirus Preparedness and Response Supplemental Appropriations Act. 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. CMS has been asked by stakeholders to clarify whether this expansion applies to teaching physician services, including those furnished under the primary care exception. CMS believes 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, CMS believes that, 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. CMS also believes the 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, CMS is revising its 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.

CMS seeks comment on its 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.

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). CMS has 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 CMS is amending the teaching physician regulations to allow that as a general rule, 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 COVID19 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. CMS believes this policy will limit exposure to COVID-19 and to allow for the continued access to physicians' services of residents while in quarantine.

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 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 CMS regulations. 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. CMS believes that regulations which limit 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, do 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. On an interim basis, for the duration of the PHE for the COVID-19 pandemic, CMS is amending regulations 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, 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.

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

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.

#### **Innovation Center Models**

Alternative Payment Model (APM) Treatment Under the Quality Payment Program

CMS recognizes the flexibilities that may be appropriate in regards to APMs, including applicable test models under section 1115A of the Social Security Act (this includes the Radiation Oncology Model), as well as the Medicare Shared Savings Program. CMS recognizes that current regulations may be insufficient in responding to the COVID-19 pandemic, and that additional action may be necessary to prevent APM participants from facing burden or negative consequences through the Quality Payment Program.

CMS will consider additional rulemaking, including possibly another interim final rule, to amend or suspend APM QPP policies as necessary to ensure accurate and appropriate application of the QPP in light of COVID-19.

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

CMS defines non-surgical extended duration therapeutic services (NSEDTS) as 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. CMS defined the minimum default supervision level of NSEDTS 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.

In the CY 2020 Hospital Outpatient Prospective Payment System (HOPPS) final rule, CMS 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. On an interim basis, CMS will change the minimum applicable level of supervision to all outpatient hospital therapeutic services to general supervision, in accordance to the change in the CY 2020 HOPPS final rule.

# Application of Certain National Coverage Determination (NCD) and Local Coverage Determination (LCD) Requirements During the PHE for the COVID-19 Pandemic

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.

#### *Face-to-face and In-person Requirements*

During the PHE for the COVID-19 pandemic CMS is finalizing that to the extent an NCD or LCD (including billing and coding articles) would otherwise require a face-to-face or in-person

encounter for evaluations, assessments, certifications or other implied face-to-face services, these requirements will not apply. CMS has 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.

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

CMS is finalizing on an interim basis that they 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. At the conclusion of the PHE for the COVID-19 pandemic, CMS will return to enforcement of these clinical indications for coverage on these policies.

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 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.

# **Change to Medicare Shared Savings Program Extreme and Uncontrollable Circumstances Policy**

In order to give eligible clinicians more time to report, 2019 Merit Based Incentive Payment System (MIPS) submission data has been extended by 30 days until April 30, 2020. Additionally, under the automatic extreme and uncontrollable circumstances policy, MIPS eligible clinicians that do not participate in an APM, who do not submit any MIPS data, will have all performance categories reweighted to zero percent and a neutral payment adjustment. If a MIPS eligible clinician submits data on two or more of the performance categories, they will be scored and receive a payment adjustment.

MIPS eligible clinicians who are subject to the APM scoring standard will continue to be scored under the existing APM scoring standard. If no MIPS-eligible clinician in an APM entity submitted data by the extended deadline for Quality and Promoting interoperability: cost weighted at zero (as usual), improvement activities would be scored as usual, quality reweighted to zero percent, and promoting interoperability reweighted to zero percent, therefore such clinicians would receive a neutral payment adjustment.

CMS is offering relief through the extreme and uncontrollable circumstances policy for Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs) that are unable to report quality measures by the extended deadline. The restriction which would require quality reporting if the reporting period was extended, has been removed, as the current extension may not allow adequate amount of time for MSSP participants to report for PY2019 due to COVID-19. Furthermore, for PY2020, CMS will reduce the amount of a Shared Savings Program ACO's losses 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 an ACO's beneficiaries that reside in an affected area. Currently, this applies to every county in the country and therefore all beneficiaries are affected by extreme and uncontrollable circumstances, and will remain affected counties until the end of the Public Health Emergency. Lastly, the MSSP benchmarks will be calculated to reflect national and regional trends throughout the year.

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

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), CMS 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. CMS 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. CMS did not envision the unprecedented circumstances surrounding the PHE for the COVID-19 pandemic when they 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. There is concern it is not possible to safely continue the Healthcare Effectiveness and Data Information Set (HEDIS) and Consumer Assessment of Healthcare Providers and Systems (CAHPS) data collection activities while complying with the Centers for Disease Control and Prevention (CDC) recommendation for social distancing. Therefore, CMS is eliminating the HEDIS 2020 submission requirement that covers the 2019 measurement year and is requesting that Medicare health plans, including Medicare Advantage (MA) and section 1876 organizations, curtail HEDIS data collection work immediately.

CMS is modifying regulations for Part C and Part D programs that would eliminate requirements for the collection and submission of HEDIS and CAHPS data that would otherwise be required for the calculation of the 2021 Star Ratings. An additional component of the HEDIS data collection is the Health Outcomes Survey (HOS) that National Committee for Quality Assurance (NCQA) administers in partnership with CMS; the HOS survey administration will move to late summer and MA plans will be provided more information in the upcoming months. Many of the regulatory 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, but they are not expected too. 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, regulations for the Part C 2022 Star Ratings will be amended to allow for previous use of data and measures.

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, CMS will use the CAHPS data submitted to CMS in June 2019. 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. For both HEDIS and CAHPS measures, CMS will use 2020 measure-level Star Ratings (and associated measure-level scores) in all the Star Ratings calculations codified in calculating the 2021 Star Ratings.

## Changes to Expand Workforce Capacity for Ordering Medicaid Home Health Services, Medical Equipment, Supplies and Appliances and Physical Therapy, Occupational Therapy or Speech Pathology and Audiology 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. In order to prevent delay, CMS is temporarily allowing, during existence of the PHE for the COVID-19 pandemic, licensed practitioners practicing within their scope of practice, such as NPs and PAs, to order Medicaid home health services. 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.

## Merit-Based Incentive Payment System (MIPS) Updates

As a result of COVID-19 and the PHE, CMS is applying the MIPS automatic extreme and uncontrollable circumstances policy to MIPS eligible clinicians for the 2019 MIPS performance period/2021 MIPS payment year. CMS finds this appropriate given that MIPS eligible clinicians would most likely complete data submission during CY2020.

Additionally, CMS is extending the deadline to submit an application for reweighting the quality, cost, and improvement activities categories based on extreme and uncontrollable circumstances and the promoting interoperability performance category based on extreme and uncontrollable circumstances to April 30, 2020 (or a later date that may be specified).

CMS is modifying its policy to create an exception such that if a MIPS eligible clinician demonstrated through an application submitted to CMS that they have been adversely affected by the PHE for COVID-19, but also submits data for quality, cost, or improvement activities, the data submission would not void the application for reweighting.

# **Inpatient Hospital Services Furnished Under Arrangements Outside the Hospital During the PHE for the COVID-19 Pandemic**

CMS finds that current policy prohibiting routine services from being provided under arrangement outside the hospital is consistent with the statute and appropriate. During the PHE for the COVID-19 pandemic, CMS will change the under arrangements policy so that hospitals are allowed broader flexibilities to furnish inpatient services, including routine services outside

the hospital. Hospitals will 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.

#### Advance Payments to Suppliers Furnishing Items and Services Under Part B

In response to the PHE for COVID-19, CMS is making modifications to existing advance payments rules for situations in which Part B suppliers could request advance payments from CMS. Currently, CMS 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. CMS is updating this definition to state that the conditional partial payment will be made by the "contractor" and not the carrier, as previously stated. Additionally, to address emergency situations in which it will be able to make advance payments at 100 percent of the anticipated payment for that claim based upon the historical assigned claims payment data, instead of the previous 80 percent.

For questions related to this Interim Final Rule, please e-mail <a href="COVID19@acr.org">COVID19@acr.org</a>.