Policy Update

CMS Expands Flexibilities in Response to COVID-19

On March 30, 2020, the Centers for Medicare and Medicaid Services (CMS) released a series of temporary waivers and an Interim Final Rule with Comment in response to the Coronavirus (COVID-19) pandemic. These actions stem from the January 27, 2020, public health emergency (PHE) declaration by Health and Human Services Secretary Alex Azar and a series of three bills passed by Congress and signed into law by the president. The rule and accompanying waivers provide unprecedented relaxation of regulations in a broad range of areas, including capacity expansion for hospitals and the healthcare workforce, reduction of administrative burden and promotion of telehealth services. Comments are due by June 1, 2020.

Key Takeaways

- This rule and accompanying waivers provide increased flexibility to enable hospitals to expand their capacity.
- The agency seeks to increase the healthcare workforce capacity by promoting telehealth and allowing professionals to work at the top of their license.
- CMS adds 80 codes to its telehealth list, increases payment for office-based telehealth visits, and waives licensing requirements for the purposes of reimbursement.
- CMS seeks to reduce burden by easing supervision rules, reducing face-to-face requirements for a range of services, and suspending audits and other administrative requirements.
- CMS establishes separate payment for SARS-CoV-2 specimen collection for homebound patients.
- The agency uses a range of tools to support quality program participants who are adversely affected by the COVID-19 pandemic.

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Medicare's Goals and Objectives

The Interim Final Rule with Comment (Revisions in Response to the COVID-19 Public Health Emergency (1744-IFC)) (IFC) attempts to protect patients and practitioners from direct or potential exposure to COVID-19 while continuing to provide viable mechanisms for patients to seek treatment and care. It clarifies parameters and changes processes related to the diagnosis, treatment and care of COVID-19 patients. The IFC also identifies specific regulatory relief that will allow providers to focus on treating and caring for patients while mitigating the burden of existing quality and other programs affected by the pandemic.

The agency intends for these temporary regulatory flexibilities to have an immediate and significant impact on hospitals, health systems and healthcare professionals across the country, allowing them to respond more nimbly to the current healthcare crisis. Most of these flexibilities are scheduled to run only through the duration of the PHE although there is speculation by stakeholders if any of the broad and encompassing changes will remain once the PHE ends.

Capacity Building

In the IFC, CMS seeks to increase the US healthcare system's capacity to address the current PHE. A significant focus of the IFC is increasing acute care hospital capacity through the Hospitals without Walls initiative, which allows hospitals to provide services in locations outside of existing facilities. Below, we highlight key areas from the IFC that facilitate increased hospital and workforce capacity.

Expanding Hospital Capacity

Unique to Medicare, "under arrangement" rules describe scenarios where one hospital subcontracts to another the technical services provided to its patients. In this scenario, the hospital subcontracting the technical services bills for the services, even though the supplying entity provides the technical care. Current Medicare policy limits the delivery of routine hospital services "under arrangement." In response to the current PHE, the IFC changes this policy to allow hospitals additional flexibility in how inpatient services are delivered. By allowing routine services to be provided under arrangement, CMS removes a potential barrier to expanding locations of care consistent with the Hospitals without Walls strategy.

A related change is the use of an 1135 waiver to relax certain hospital conditions of participation, which also allows currently enrolled ambulatory surgical centers (ASCs) to temporarily enroll as hospitals and provide hospital services. The waiver also notes that freestanding EDs could pursue enrolling as an ASC and the pursue enrolling as a hospital.

Expanding Healthcare Workforce Capacity

During the PHE, CMS has used two strategies for increasing workforce capacity. One strategy is promoting telehealth to facilitate care delivery while prioritizing beneficiary and healthcare

workforce safety and preserving hospital capacity to treat COVID-19 cases. Another strategy is identifying and addressing opportunities to allow the healthcare workforce to practice at the top of their licenses.

In light of the complexity of the virus itself and the unprecedented challenges facing the healthcare system, CMS is continually examining how to give providers the most flexibility. One such challenge relates to situations where a physician is required to be physically present for supervision purposes. In many cases, supervision requirements in physician office settings necessitate the presence of the physician or non-physician practitioner in a specific location, usually the same location as the beneficiary at the time the service is provided. Direct supervision means that the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed. The IFC revises the definition of direct supervision to include supervision provided using real-time interactive audio and video technology, and gives individual practitioners more discretion to make decisions based on their clinical judgment in particular circumstances.

Under an 1135 waiver, CMS also waives the requirements that a certified registered nurse anesthetist (CRNA) be under the supervision of a physician. CRNA supervision is now at the discretion of the hospital or ASC, and as allowed under state law. CMS also waives 482.12(c)(1-2) and (4), which require that Medicare patients in the hospital be under the care of a physician. This change allows hospitals to expand their use of other practitioners, such as physician assistants and nurse practitioners.

The IFC includes several additional areas where CMS makes changes to allow non-physician practitioners to perform certain services not typically allowed. For example, CMS notes that increased demand for physician direct care services may delay physicians' availability to order home health services. To address this situation, the IFC changes current regulations to allow licensed practitioners, such as nurse practitioners and physician assistants, to order Medicaid home health services during the PHE as long as doing so is consistent with their state's scope of practice laws. CMS also leverages an 1135 waiver to provide the same flexibility under the Medicare Program.

Finally, CMS allows expanded use of home health visiting nursing services in underserved rural and urban communities during the PHE. CMS has previously restricted use of such services to areas where there is a shortage of home health agencies. During the PHE period, however, CMS allows visiting nursing services to be used in any area typically served by a rural health clinic or in any area that is included in a federally qualified health center service area. This change will increase the capacity of underserved rural and urban communities to delivery home nursing care.

Telehealth and Virtual Visits

The administrative and legislative actions mentioned above have triggered a cascade of CMS actions designed to increase access to and use of telehealth services, and to provide flexibilities

for providers to complete certain requirements for a range of healthcare services virtually. These changes aim to minimize patient travel and reduce exposure to COVID-19 for both patients and providers while still allowing the provision of healthcare services. CMS's approach is consistent with other federal guidelines related to reducing the spread of the virus.

Another advantage of telehealth is that it can increase the efficiency and bandwidth of existing providers—a critical factor as health systems brace themselves for patient surges. A potential limitation to this advantage, however, relates to Medicare's requirement that telehealth services use audio/visual technology. During the PHE, this can include use of applications such as Facetime on a smartphone. Some patients do not have access to this type of technology, however, or may not know how to use it. Other patients simply are not comfortable with it and prefer to use an audio-only telephone. As a result, although Medicare has increased flexibility around telehealth services, some providers are still not able to report them.

The IFC significantly expands practitioners' ability to provide telehealth services and includes several regulatory flexibilities that allow virtual visits to replace certain in-person or face-to-face requirements.

Expansion of Telehealth Services

The IFC seeks to expand the use of telehealth services through a few primary mechanisms: adding codes, changing the payment rate for certain telehealth services and waiving specific licensing requirements for the purposes of reimbursement.

Adding New Codes

The IFC adds 80 services to the list of telehealth codes that are eligible for reimbursement. These services can be provided to new or established Medicare beneficiaries, and include items and services related to emergency department visits, hospital discharge, critical care, home visits, inpatient neonatal and pediatric critical care, initial and continuing intensive care, and therapy services.

Site of Service Differential

Telehealth services are paid under the Medicare Physician Fee Schedule. Historically, for telehealth services that have different rates when performed in the office versus the facility, CMS pays the lower facility rate versus the higher non-facility (office) rate, even when an office-based practitioner is providing the telehealth service. The non-facility rate includes the costs of providing the service in the provider's own office (*e.g.*, nurse time, supplies, equipment). Until now, the agency's position has been that when a telehealth service is furnished, these costs are not typically incurred.

CMS loosened the rules around telehealth services on March 6, 2020, such that patients no longer must travel to an originating site but can access the service wherever they are located, even their homes. Because telehealth services can now be furnished wherever the patient is located, CMS believes that the payment to the practitioner should reflect the relative costs of

furnishing the service. The IFC thus provides that for the duration of the PHE, practitioners will be paid at the same rate as if they furnished the service in person. Office-based practitioners will be paid at the non-facility rate, and facility-based practitioners will be paid at the facility rate.

To further expand access, CMS also lifts existing limits on the frequency of certain telehealth services. There has been a limit of once every three days for subsequent inpatient visits furnished via Medicare telehealth. Under the IFC, a subsequent inpatient visit furnished via telehealth can occur without that timing limitation. Similarly, there was a limit once every 30 days for subsequent skilled nursing facility visits furnished via telehealth. The IFC lifted this limit as well. The critical care consult codes may be furnished to a Medicare beneficiary by telehealth beyond the once per day limitation.

As defined in statute, Medicare telehealth services must be provided through the use of audio/visual technology. While stakeholders have pressed CMS to allow the use of audio-only technology for telehealth services, CMS declined to do so in this IFC.

The IFC allows separate payment for telephone evaluation codes (98966-98963 and 99441-99443). These are not considered telehealth services and were previously non-covered services under the Physician Fee Schedule.

Waiving Licensing Requirements

Telehealth may enable providers to treat patients anywhere in the country, but licensing requirements can limit that flexibility. Provider licensure requirements are generally set at the state level, and as a result, a patchwork of different laws is in place. States are adjusting these requirements through state-level emergency declarations. Through the IFC, CMS temporarily waives Medicare and Medicaid's requirements that physicians and non-physician practitioners be licensed in the state where they are providing services for the purposes of reimbursement when the following four conditions are met.

The provider:

1) Must be enrolled as a provider in the Medicare program

2) Must possess a valid license to practice in the state which relates to her Medicare enrollment

3) Must be furnishing services—whether in person or via telehealth—in a state in which the emergency is occurring, in order to contribute to relief efforts in his professional capacity

4) Must not be affirmatively excluded from practice in the state or any other state that is part of the 1135 emergency area.

CMS has not waived or modified state licensing, prescribing and other practice requirements. As states experience the strain of COVID-19 on their health systems, governors, health departments and professional boards have started to ease state licensure and other

requirements through state-level actions, such as declarations of emergency. Secretary Azar applauded these actions in a letter to the governors, but he also called on them to do more. Without an enforceable national policy, however, even the most liberalizing state policy changes will perpetuate the existing dynamic of widely varying state-specific laws, regulations and requirements. Accordingly, providers should continue to monitor and comply with relevant state laws, regulations and orders—even as they change on an almost daily basis. Stakeholders also have an opportunity to communicate with CMS regarding the complications and barriers that state-based regulation presents for national policy, as demonstrated by the current pandemic.

Regulatory Relief for In-Person or Face-to-Face Requirements

Current policy requires various items and services, including certain administrative services, to be completed in-person or face-to-face. These include, for example, certain home health visits, or a physician or specialist's review of patient imaging. In an attempt to stretch limited provider resources, keep patients at home and prevent unnecessary provider exposure to COVID-19, CMS makes several regulatory changes around the availability of remote patient monitoring (RPM) and required face-to-face visits. CMS also eases regulatory burden in other ways, including suspending audits and delaying cost reporting filing deadlines.

Remote Patient Monitoring: Clinicians can now provide RPM services to both new and established patients. These services can be provided for both acute and chronic conditions, and can now be provided for patients with only one disease. The IFC also encourages the use of RPM for certain home health and hospice services.

Lifting Face-to-Face Requirements: There are several Medicare requirements for face-to-face visits and consultations. To the extent CMS believes shifting these to a virtual visit via telecommunications or a telehealth service would not interfere in patient treatment, the IFC encourages providers to do so. These relaxations include:

- For Medicare patients with end stage renal disease, CMS exercises enforcement discretion on the required monthly face-to-face visit so that clinicians can provide this service via telehealth.

- CMS waives the requirement for physicians and non-physician practitioners to perform in-person visits for nursing home residents and allows visits to be conducted, as appropriate, via telehealth options.

- CMS recognizes that practitioners such as licensed clinical social workers, clinical psychologists, physical therapists, occupational therapists and speech-language pathologists might also use virtual check-ins and remote evaluations instead of other in-person services. The IFC therefore broadens the use of relevant remote evaluation codes.

- Medicare generally requires a face-to-face visit for the purposes of hospice recertification. The IFC allows this requirement to be met through a virtual visit.

- Patients being cared for in inpatient rehabilitation facilities must be seen by a rehabilitation physician three times per week in face-to-face encounters. During the PHE, CMS allows these face-to-face encounters to be conducted via telehealth services to protect both patients and clinicians from disease transmission.

CMS also includes an exception to requirements under national and local coverage determinations. The IFC clarifies that, to the extent that a National Coverage Determination (NCD) or Local Coverage Determination (LCD) would otherwise require a face-to-face visit for evaluations and assessments, clinicians do not have to meet those requirements during the PHE.

Testing and Treating COVID-19 Patients

The IFC modifies or clarifies prior regulations to accommodate hazards specifically related to transmission of SARS-CoV-2.

Specimen Collection for SARS-CoV-2

In recent weeks, new tests have emerged under the FDA's Emergency Use Authorization program. However, testing capacity is still limited, and many currently available tests require high-complexity methodology that not all laboratories are capable of performing. Additionally, current recommended specimen types include nasopharyngeal swabs and oropharyngeal swabs. Collecting specimens from such sources requires special precautions to minimize the risk that the individual collecting the specimen is exposed to SARS-CoV-2. To accommodate these challenges, CMS creates special specimen collection codes to describe the collection of specimens for diagnostic testing of SARS-CoV-2.

Medicare has traditionally covered and reimbursed a nominal fee for specimen collection, but the IFC creates specific codes with higher levels of payment for collection of specimens for SARS-CoV-2 testing. This is intended to facilitate testing of quarantined patients and promote access to SARS-CoV-2 diagnostic testing offered by independent laboratories. There are two separate codes: G2023 describes specimen collection for SARS-CoV-2 testing in home-bound and non-hospital inpatients, and G2024 describes specimen collection for SARS-CoV-2 testing performed on patients within a skilled nursing facility or on behalf of a home health agency. These codes pay $23.46 and $25.46 respectively. Mileage for specimen transport is paid as usual.

Clarification on Homebound Status and COVID-19

The Medicare Home Health Benefit requires that beneficiaries be confined to the home to be eligible. Home confinement may be due to an inability to leave the home without assistance or to a medical contraindication to leave the home. The IFC does not change this requirement, but

it clarifies that an individual whom a physician has advised to remain at home due to COVID-19 is considered confined to the home. This may include patients who have been advised to remain at home because they have confirmed or suspected COVID-19, or patients who have been advised of a medical contraindication to leaving the home because they are more susceptible to COVID-19. Physician certification that a patient is home confined is still required, so a beneficiary's decision to self-quarantine does not make the beneficiary eligible.

The requirement that a beneficiary must also have a skilled need to qualify for home health services remains unchanged.

Enforcement Discretion of Certain Local and National Coverage Determinations

COVID-19 is a predominantly respiratory illness. CMS anticipates that the pandemic will result in patients with respiratory conditions needing to receive care in unexpected settings, including the home. Therefore, during the PHE, CMS will not enforce clinical indications for certain local and national coverage policies concerning respiratory interventions, home anticoagulation monitoring and infusion pumps.

The specific policies are as follows:

- NCD 240.2 Home Oxygen
- CMS-1744-IFC 129
- 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.

It is unclear whether instructions have been conveyed to Medicare contractors responsible for program integrity regarding the waiver of enforcement. A lack of communication may slow down the implementation of this policy and cause confusion during claims processing.

Modifications to Medicare Quality Programs

The COVID-19 pandemic has disrupted many aspects of the health system, including participation in Medicare quality programs. Providers and plans participating in Medicare quality programs and payment models are evaluated on a range of metrics related to quality performance and resource use. Participation may require the submission of quality and cost data as well as other participation obligations. As a result of the disruptions caused by the current healthcare crisis, participants may not be able to submit their data in timely manner; utilization rates may be skewed due to elective surgeries not being performed (or other factors) and that social distancing is limiting the public's use of routine medical care; and costs may be distorted by the diversion of resources to address COVID-19.

The IFC implements several policies to allow providers to focus on the current crisis without being financially or otherwise penalized for COVID-19's impact on their participation in quality programs. Specifically CMS addresses:

- The Merit-Based Incentive Payment System (MIPS), a Medicare physician quality reporting program
- The Medicare Shared Savings Program (MSSP), a Medicare accountable care organization (ACO) that is qualified as an Advanced Payment Model (APM) under the Quality Payment Program
- The Medicare Diabetes Prevention Program (MDPP), a payment model that is a structured intervention with the goal of preventing type 2 diabetes in individuals with an indication of prediabetes
- The Comprehensive Care for Joint Replacement (CJR) model, a mandatory inpatient episode-based payment model focused on hip and knee joint replacements
- Medicare Advantage.

CMS uses a range of tools to support quality program participants who are adversely affected by the COVID-19 pandemic. These actions include extension of deadlines, modifications to the extreme and uncontrollable circumstances policy (which provides relief from program penalties for participants who are located in areas that CMS deems affected by an extreme and uncontrollable circumstance), creation of a COVID-19-related measure, and expanded flexibility in program participation.

Policy Changes for Medicare Quality Programs

MIPS	**Applies to 2019 Performance Year/2020 Payment Year** • The data submission deadline is extended to April 30, 2020.* • CMS modifies the MIPS extreme and uncontrollable circumstances policy such that if a practitioner does not submit any data by the April 30 deadline, the practitioner will be automatically identified and will receive a neutral payment adjustment for the 2021 MIPS payment year (no action is necessary).** • CMS reopens the MIPS extreme and uncontrollable circumstances

	application for individuals, groups and virtual groups that started but are unable to complete their data submission (and for virtual groups that are unable to start).** • An application submitted between April 3 and April 20, 2020, citing COVID-19, will override any previous data submission.** • The MIPS extreme and uncontrollable circumstances policy does not apply to MIPS-eligible clinicians who are subject to the APM scoring standard. • CMS adds a new Improvement Category measure that promotes clinician participation in a COVID-19 clinical trial using a drug or biological product to treat a patient with a COVID-19 infection.
MSSP	**Applies to 2019 Performance Year/2020 Payment Year** • The data submission deadline is extended to April 30, 2020.* • The MSSP extreme and uncontrollable circumstances policy is modified to allow CMS to offer relief to all MSSP ACOs that may be unable to completely and accurately report quality data for 2019. • CMS modifies the performance year 2020 financial reconciliation. CMS will reduce the amount of an ACO's shared losses by an amount determined by multiplying the shared losses by the percentage of the total months in the performance year affected by an extreme and uncontrollable circumstance, and the percentage of the ACO's assigned beneficiaries who reside in an area affected by an extreme and uncontrollable circumstance. CMS indicated that it may revisit this issue.
CJR	**Applies to 2020 Performance Year/Model Year 5** • CJR performance year 5 is extended by three months. The model will now end on March 31, 2021, rather than December 31, 2020. • The extreme and uncontrollable circumstances policy is modified so that episodes during the emergency period so that actual episode payments are capped at the target price determined for that episode.
MDDP	• The once-per-lifetime limit is waived. For the limited purposes of allowing a pause in service, CMS will allow MDPP beneficiaries to maintain eligibility for MDPP services despite a break in service, attendance or weight loss achievement. • The limit on the number of virtual make-up sessions is waived. • MDPP suppliers may deliver all MDPP sessions virtually during the PHE.
MA (Parts C and D) Quality Measures	• Plans are requested to curtail HEDIS data collection work immediately. • The 2021 Star Ratings measures calculated based on HEDIS and Medicare CAHPS data collections (which are submitted in 2020) will be replaced with earlier values from the 2020 Star Ratings (which are based on data submitted in 2019). • Any measure reported in 2021 that has a data quality issue due to the COVID-19 outbreak will be replaced with the scores from the 2020 ratings rather than being given one star.

* Originally announced on March 22, 2020.
** Policy clarified in April 3, 2020, email from CMS.

CMS acknowledges that the IFC may be insufficient to overcome the challenges APM participants face during this evolving PHE. CMS has indicated that it will consider additional rulemaking to amend or suspend APM Quality Payment Program policies.

On March 30, 2020, CMS also issued, via its 1135 waiver authority, other waivers that affect providers. Of note, CMS issued a waiver specifying 18 exceptions to the physician self-referral law (Stark Law) for the duration of the COVID-19 PHE. The exceptions focus on increasing capacity and providing flexibilities related to care provided in alternative settings. CMS also allows flexibility for the Medicare appeals process. Changes include extensions for appeals and responses to requests for additional information. CMS also broadly allows Medicare Administrative Contractors and Qualified Independent Contractors to use all existing flexibilities provided in the appeals process. For more information on the policies implemented through the waivers, click here.

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