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CMS IMPLEMENTS MASSIVE RULE CHANGE TO BOLSTER TELEHEALTH AMID COVID-19

WHAT PROVIDERS NEED TO KNOW TO SERVE THEIR PATIENTS

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CMS IMPLEMENTS MASSIVE RULE CHANGE TO BOLSTER TELEHEALTH AMID COVID-19: WHAT PROVIDERS NEED TO KNOW TO SERVE THEIR PATIENTS

On March 30, 2020, the Centers for Medicare & Medicaid Services released a stunning and far-reaching interim final rule to address the coronavirus (COVID-19) crisis. The rule is a comprehensive set of policy changes designed to—almost overnight—shift the provision of healthcare services to Medicare beneficiaries from face-to-face care to remote care through telehealth. Healthcare providers must quickly understand what the rule entails to ensure that they can continue to treat their needy patient populations while maintaining compliance with Medicare billing and benefit rules.

The Centers for Medicare & Medicaid Service's (CMS) effort on this interim final rule (IFR) is, perhaps, legendary—the display copy is 220 pages long and the team at CMS had just three weeks after the passage of initial legislation Coronavirus Preparedness and Response Supplemental Appropriations Act (the CPRSAA) and just a few days after the passage of the Coronavirus Aid, Relief, and Economic Security (CARES) Act to assess, formulate, and draft a massive policy change. (Note that some provisions of the IFR may not perfectly align with the CARES Act due to timing, but they are generally in synch.) The IFR, above all else, prioritizes distancing patients from their care teams and other patients and, if adopted en masse by healthcare providers, will save lives.

The IFR touches on nearly every aspect of the Medicare program, from home health and hospice to intensive care services, to radiation therapy management and everything in between. The thematic elements of the IFR are simple: Keep patients away from their physicians, care teams, and other patients. Reduce or eliminate any barriers to remote care. And incentivize physicians and health systems alike to adopt remote treatment mechanisms as quickly as possible. The IFR does this by expanding the types of codes Medicare providers and suppliers can bill for telehealth services, permitting greater flexibility in terms of patient consent, telecommunication modalities, and increasing reimbursement for services particularly important to the COVID-19 fight: specimen collection and physician evaluation and management services.

The vast majority of the policy changes in the IFR are applicable only during the declared Public Health Emergency (PHE) and will most likely sunset at the conclusion of this crisis. That said, the American healthcare system is in a state of rapid evolution. When looked at from the broader perspective of the changing expectations of healthcare consumers and the significant transformative steps CMS has taken over the past few years to meet those expectations, it is likely that this is the dress rehearsal for a seismic shift in how patients consume healthcare. Telehealth has been expanding rapidly since the widespread adoption of high-quality, mobile audio/video technology. CMS, for instance, has already worked on side-stepping the statutory restrictions of Social Security Act 1834(m) when implementing virtual check-ins and evisits (asynchronous communications between patient and physician, also known as "store-and-forward") in calendar year (CY) 2019. Now, with the world facing a pandemic that necessitates the use of remote technologies to safely deliver healthcare services while protecting patients and healthcare workers from COVID-19, telehealth may be here to stay.

Below we outline every provision of the IFR, which went into effect on March 1, 2020. Providers should remember that, after reviewing the provisions of the rule, they may need to adjust March claims to comply with CMS's billing instructions. Morgan Lewis stands ready to assist healthcare providers in understanding and implementing the IFR.

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

In light of the COVID-19 pandemic and resulting PHE, as well as the fact that physician practices are "suddenly transition[ing]" a significant portion of services to telehealth, CMS has decided to temporarily place a substantial number of Current Procedural Terminology (CPT) Codes that previously could not be

billed as Medicare telehealth services on the Medicare telehealth code list. As part of this, anticipating that many physicians will be practicing in non-facility settings, it is increasing Medicare payment rates for physician services to the non-facility rate, which is often higher than the facility rate.

Importantly, CMS is instructing physicians billing for this expanded code list during the PHE to "report the POS (place of service) code that would have been reported had the service been furnished in person." CMS asserts that this temporary process should "maintain overall relativity under the [Physician Fee Schedule] for similar services and eliminate potential financial deterrents to the clinically appropriate use of telehealth. CMS further instructs providers to bill with modifiers when they provide seemingly face-to-face services through telehealth **using a new "95" modifier**. This will allow CMS to accurately track these types of services.

Nearly two decades ago, CMS established a process to evaluate the provision of remote services. This process allows the public to submit CPT Codes for potential evaluation as telehealth services, which CMS breaks down into two categories:

- **Category 1**: Services that are similar to professional consultations and office visits that are currently on the list of telehealth services. In reviewing these requests, CMS evaluates similarities between the requested and existing telehealth services for physician-patient interaction and type of telecommunication system used.
- **Category 2**: Services that are not similar to those on the current list of telehealth services. CMS evaluates whether the service can be performed via telehealth and whether the service has demonstrable clinical benefit to the patient when performed remotely.

If a service is ultimately covered by CMS, it does not matter if it is a Category 1 or Category 2 service. However, CMS asserts that for Category 2 services reimbursed during the PHE, "it may not be clinically appropriate or possible to use telecommunications technology to furnish these particular services to every person or in every circumstance."

Among the services that CMS is now covering when performed via telehealth are the following:

- Emergency department visit codes (99281-99285)
- Observation codes (initial, subsequent, and discharge) (99217-99236)
- Inpatient hospital codes (99221-99239)
- Nursing facility visit codes (99304-99316)
- Critical care services (99291-99292)
- Rest home/custodial care services (99327-99337)
- Home visits (99341-99350)
- Inpatient neonatal and pediatric critical care (99468-99476)
- Intensive care services (99477-99480)
- Certain care planning services (99483)
- Group psychotherapy (90853)
- End stage renal disease (ESRD) services (90952-90962)
- Psychological and neuropsychological testing (96130-96139)
- Therapy services (97161-97761 and 92507, 92521-92524) *(Note that physical therapists, occupational therapists and speech language pathologists do not constitute eligible distant site practitioners so these services may only be billed by physicians when performed via telehealth.)*
- Radiation treatment management services (face-to-face component of 77427)

Of course, questions remain when considering this code list. For instance, while basic office visit codes are already on the Medicare telehealth code list, should physicians be billing those codes or the "home visit" codes when providing a service to a beneficiary in their home? As noted, CMS has undertaken a Herculean effort to get this rulemaking into place. Nevertheless, it is still looking for immediate feedback and constructive guidance from Medicare providers and suppliers on why to tailor these policies even further to support beneficiary access to care and reduce the spread of COVID-19.

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

As noted above, CMS has long had a process to identify services in Category 1, which reflect professional consultations, office visits, and office psychiatry; and Category 2, which are all other services essentially not in Category 1. Category 2 services generally have frequency limitations. Prior to the COVID-19 PHE, CMS had limited Category 2 telehealth services for subsequent inpatient hospital visits and subsequent nursing facility visits to once every 30 days and critical care consultations to once per day.

The IFR proposes to eliminate these frequency limitations during the COVID-19 PHE, explaining that during the PHE these frequency limitations are not appropriate or necessary. Telehealth visits mitigate exposure risk and fewer in-person clinical visits for now may reflect the most appropriate care. Critical care consultation may need to occur more than once per day due to the acuity and complexity of a patient's condition. The IFR proposes that frequency limitations for inpatient care visits, nursing facility visits, and critical care consultation are not in effect during the PHE. CMS seeks information on how these services may be provided by telecommunications technology to ensure that patients are safe and receiving adequate care.

The CPT Codes impacted include 99231, 99232, and 99233 (Subsequent Hospital Care); 99307, 99308, 99309, and 99310 (Subsequent Nursing Facility Care); and Healthcare Common Procedure Coding System (HCPCS) Codes G0508 and G0509 (Critical Care Consultation Services).

Consistent with the general theme of the IFR, CMS also announced its enforcement discretion with respect to the requirement for face-to-face, "hands on" examination by a physician, clinical nurse specialist, nurse practitioner, or physician assistant of a patient's vascular access site, and permitting the clinical examination to be furnished as a Medicare telehealth service during the PHE. This service was previously excluded from the ESRD-related services added to the Medicare telehealth list, but is temporarily permitted for the duration of the PHE.

In addition, during the PHE, CMS is relaxing its enforcement of the in-person requirements of Section 1881(b)(3) 1834(m) of the Social Security Act, which permitted a beneficiary to receive telehealth ESRD services provided certain in-person visits were conducted on a periodic basis established by the statute (once per month for initial home dialysis patients; once per three months for established home dialysis patients). CMS is not reviewing claims for such services to make a determination as to whether the service was furnished in-person or as part of a telehealth service.

C. Telehealth Modalities and Cost-Sharing

Clarifying Telehealth Technology Requirements

The IFR clarifies what CMS will consider to be interactive telecommunications systems for purposes of Medicare telehealth services during the PHE. 42 CFR § 410.78(a)(3) states that telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system, but CMS notes that it does not interpret the regulation to apply to mobile computing devices that include audio and video real-time interactive capabilities, even though such devices now commonly are referred to as "phones." In order to avoid any confusion about the types of devices that meet the interactive requirements for Medicare telehealth during the COVID-19 pandemic, the IFR creates an exception in a new § 410.78(a)(3)(i) that states that, 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" without the language that telephones, facsimile machines, and electronic mail systems do not qualify. In other words, practitioners may use applications on their cell phones that provide two-way, real-time interactive audio and video capabilities to furnish Medicare telehealth services during the PHE.

The IFR reminds practitioners that the US Department of Health and Human Services (HHS) Office for Civil Rights (OCR) announced that it will exercise enforcement discretion with respect to Health Insurance Portability and Accountability Act (HIPAA) violations resulting from the good faith use of communications technologies to provide telehealth services during the pandemic. But as noted in our March 20, 2020, blog post, HHS to Exercise Enforcement Discretion in Response to CMS Telehealth Waiver, this exercise of discretion applies to nonpublic facing technologies such as FaceTime or Skype, and OCR noted that public-facing video communications technologies such as Facebook Live, Twitch, and TikTok should not be used.

Beneficiary Cost-sharing

The IFR reminds physicians and other practitioners that HHS's Office of Inspector General issued a Policy Statement announcing it will not subject them to administrative sanctions for reducing or waiving any cost-sharing obligations Federal health care program beneficiaries may owe for telehealth services furnished consistent with applicable coverage and payment rules. CMS notes that this policy applies to all services furnished through information or communication technology that are billed by a physician or other practitioner or by a hospital or other eligible individual or entity billing on behalf of the physician or practitioner when the physician or other practitioner has reassigned his or her right to receive payments to such individual or entity.

D. Communication Technology-Based Services

CMS modifies certain billing requirements for Communication Technology-Based Services (CTBS) for several HCPCS Codes and CPT Codes to make CTBS services available to as large a population of Medicare beneficiaries as possible, in order to mitigate risk in light of the COVID-19 PHE.

HCPCS G2010 & HCPCS G2012

HCPCS Codes G2010 (including remote evaluation of recorded video and/or images submitted by an established patient, e.g., store and forward) and G2012 (brief communication technology-based service (e.g., virtual check-in)) were finalized under the CMS CY 2019 Physician Fee Schedule (PFS) final rule as services that could be furnished via telecommunication technology, but that are not Medicare telehealth services. Consent for these services must be obtained annually (84 FR 62699). These codes were finalized as a set of codes that is only reportable by the physicians and practitioners who can furnish evaluation and management (E/M) services. However, CMS noted that similar check-ins provided by nurses and other clinical staff can be important aspects of coordinated patient care.

On an interim basis, CMS modifies these services so they can be furnished to new and established patients. CMS also emphasizes that consent to receive these services can be documented by auxiliary personnel under general supervision. Further, CMS notes that the timing or manner in which beneficiary consent is obtained should not interfere with the provision of services. Consent still must be obtained annually, but that it may be obtained at the same time that a service is furnished. CMS does not modify the billing requirements for bundling E/M services when services are provided within the previous seven days by the same physician or other qualified health professional.

CMS also broadens the availability of these codes to several types of practitioners, such as licensed clinical social workers, clinical psychologist services, physical therapist services, occupational therapist services, or speech language pathologist services. CMS notes that this is not an exhaustive list.

CPT 99421, 99422, 99423 & HCPCS G2061, G2062, G2063

In the CMS CY 2020 PFS final rule, CMS finalized CPT Codes 99421, 99422, and 99423 for various lengths of time for online digital E/M services for established patients and HCPCS Codes G2061, G2062, and G2063 for various lengths of time for qualified non-physician healthcare professional online assessment and management for established patients.

On an interim basis, CMS is exercising enforcement discretion for "established patient" requirements on this code to mitigate the need for in-person visits that could represent exposure risks. CMS will not conduct reviews to determine whether those services were furnished to established patients.

HCPCS G2061-G2063

In the CY 2020 PFS final rule, CMS stated that HCPCS Codes G2061-G2063, which are 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 now clarifies that there are several types of practitioners who can bill for these services, including licensed clinical social workers, clinical psychologist services, physical therapist services, occupational therapist services, and speech language pathologist services, so those practitioners may report online assessment and management services.

HCPCS G2010, G2012, G2061, G2062, G2063

CMS designates HCPCS Codes G2010, G2012, G2061, G2062, G2063 as CTBS "sometimes therapy" services that would require the private practice occupational therapist, physical therapist, and speech-language pathologist to include the corresponding GO, GP, or GN therapy modifier on claims for these services.

E. Direct Supervision by Interactive Telecommunications Technology

The IFR alters the definition of direct supervision to state that the necessary presence for "direct supervision" includes virtual presence through audio/video real-time communications technology when use of such technology may reduce exposure risks for the beneficiary or healthcare provider.
The modified definition for "direct supervision" applies to physicians' services, diagnostic services furnished directly or under arrangement in the hospital or in an on-campus or outpatient department of the hospital, and pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services.

Physicians' Services

For physicians' services, "direct supervision" is currently defined such that a physician must be physically present in the office suite and immediately available to furnish assistance and direction throughout the performance of a procedure. The current rule does not require that the physician be physically present in the room when the procedure is performed.

Under the modified definition of "direct supervision," CMS indicates that furnishing services in the absence of a physician's physical presence may not be appropriate in all circumstances. CMS defers to the professional judgment of physicians to make decisions based on their clinical judgment in particular circumstances.

CMS also addresses the administration of Part B drugs furnished "incident to a physician's professional service," and notes that the current supervision requirements for incident to physicians' services and diagnostic services do not reflect the appropriate level of supervision. CMS views these levels as the minimum possible requirement.

CMS's position does not change the underlying coverage or payment policies related to the scope of Medicare benefits, and it does not alter applicable rules regarding safe transportation and proper waste disposal.

CMS also recognizes that during the PHE, physicians may enter into contractual arrangements with auxiliary personnel to leverage additional staff and technology necessary to provide care that would ordinarily be provided incident to a physician's services. These auxiliary personnel should seek payment directly from the provider.

Hospital Diagnostic Services and Rehabilitation Services

For changes to the definitions of "direct supervision" for hospital diagnostic services, and pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation, CMS refers to its reasoning from its discussion on the definition change for physicians' services.

For changes to the definition of "direct services" for hospital diagnostic services, CMS notes that under current Medicare rules, most therapeutic services in the hospital require only general supervision, and the supervision requirements for diagnostic services generally conform to the service-level supervision levels required for payment under PFS.

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

CMS clarifies that during the PHE, patients who are instructed to remain in their homes or are under "self-quarantine" may be considered "confined to the home" or "homebound" for purposes of the Medicare home health benefit if a physician determines it is medically contraindicated for the patient to leave the home. For example, a physician may determine 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 condition that may make the patient more susceptible to contracting COVID-19 (e.g., Chronic Obstructive Pulmonary Disease or chemotherapy treatment). The patient's medical record must include information as to why the individual condition of the patient is such that leaving the home is medically contraindicated, which can include application of Centers for Disease Control and Prevention (CDC) guidance. In addition to being considered "confined to the home" or "homebound", the patient must also have a skilled need to receive Medicare home health services.

G. Use of Technology Under the Medicare Home Health Benefit

Recognizing the potential benefit of telemedicine to minimize risk to clinicians and patients during a PHE, CMS is amending the plan of care requirements at 42 CFR 409.43 on an interim basis, to allow home health agencies the flexibility to provide more services to beneficiaries using technology such as telemedicine and remote patient monitoring. The home health agency's use of technology must be (1) related to the skilled services being furnished by the provider to optimize the services furnished during the home visit or when there is a home visit, and (2) 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. On an interim basis, CMS will allow the home health agency to report the costs of telecommunications technology as allowable administrative and general costs when properly identified.

H. Use of Technology Under the Medicare Hospice Benefit

CMS recognizes the use of telehealth services in healthcare delivery, as well as the ability to minimize risk to clinicians and patients during infectious disease outbreaks. For the duration of the PHE for the COVID-19 pandemic, CMS proposes amending 42 CFR 418.204, which previously provided for continuous nursing care to maintain an individual at home, to allow hospices to provide home care services via a telecommunications system if it is feasible and appropriate to do so. The use of technology must be included on the plan of care and continue to meet the requirements at § 418.56. Specifically, the use of

technology must be tied to the patient-specific needs as identified in the comprehensive assessment and the anticipated measurable outcomes.

CMS does not provide additional payment for the use of technology in providing services beyond the per diem amount under the hospice benefit. Additionally, only in-person visits (with the exception of social work telephone calls) should be reported on hospice claims. However, CMS indicates that hospices can report the costs of telecommunications technology used to furnish services under the routine home care level of care during the PHE for the COVID-19 pandemic as "other patient care services."

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

CMS acknowledges that the Medicare statute is silent as to whether telecommunications technology can be used for a face-to-face encounter solely for the purpose of Medicare hospice recertification. CMS provides clarification that the hospice physician or nurse practitioner can use telecommunication technology to perform a face-to-face encounter. Similarly, CMS indicates that while it does not believe that direct patient care will typically be conducted using telecommunication technology, hospice designated attending physicians are not precluded from furnishing services via telehealth.

That said, CMS does specify that the telecommunication technology used for the virtual face-to-face visit be "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient" and the hospice physician or nurse practitioner.

J. Modification of Inpatient Rehabilitation Facility Face-to-Face Requirement

CMS is revising its regulations at §§ 412.622(a)(3)(iv) and 412.29(e), temporarily to relax its requirements for medical supervision in the inpatient rehabilitation facility (IRF) setting. Generally, the regulations require that the rehabilitation physician must conduct face-to-face visits with the patient at least three days per week throughout the patient's stay in the IRF to assess the patient both medically and functionally, as well as modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process. While CMS emphasizes that it continues to believe that in-person visits by rehabilitation physician, with appropriate personal protection equipment, are the best way to assess a patient's function for purposes of rehabilitation care, it is amending its relevant regulations to permit furnishing such services via telehealth services (as defined in § 1834(m)(4)(F) of the of the Social Security Act).

This is designed to allow greater flexibility for IRF patients to receive close physician supervision without exposing the patients or the provider unnecessarily to the risk of infection during the PHE.

K. Removal of IRF Post-Admission Physician Evaluation Requirement and Clarification on 'Three-Hour' Rule

As additional relief for IRFs during the PHE, CMS is temporarily eliminating the comprehensive post-admission physician evaluation requirement for newly admitted patients. Typically, under § 412.622(a)(4)(ii), in order to document that each patient for whom the IRF seeks payment is reasonably expected to meet all of the requirements in § 412.622(a)(3) at the time of admission, the IRF must include in the patient's medical record a post-admission physician evaluation that meets certain detailed regulatory requirements. However, in recognition that IRFs may be faced with staffing issues and stretched resources due to the PHE, CMS is temporarily eliminating the requirement for the initial post-admission physician evaluation. In other words, it will not be counted as a Medicare condition of payment for an IRF during the PHE. CMS emphasizes that IRFs may still conduct such post-admission evaluations as they deem necessary for patient care, but that the temporary elimination of the requirement is designed to free physician staff from the time associated with the preparation of such documentation.

In addition, CMS has also granted flexibility with respect to another IRF condition of payment—the intensive rehabilitation therapy requirements for IRF coverage at § 412.622(a)(3)(ii), commonly known as the "three-hour" rule. Generally, this intensive rehabilitation therapy program generally consists of at least three hours of therapy (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics therapy) per day at least five days per week based on industry standards. While CMS is not waiving or eliminating this requirement, it has offered relief in the form of a clarification that "where an IRF's intensive rehabilitation therapy program is impacted by the PHE for the COVID-19 pandemic (for example, due to staffing disruptions resulting from self-isolation, infection, or other circumstances related to the PHE), the IRF should not feel obligated to meet the industry standards referenced in § 412.622(a)(3)(ii), but should instead make a note to this effect in the medical record." Thus, an IRF that needs to take advantage of this relief due to the PHE should ensure that it has appropriately documented the patient's medical record.

L. Rural Health Clinics and Federally Qualified Health Centers

Recognizing the important safety net aspects of rural health clinics (RHCs) and federally qualified health centers (FQHCs), CMS is enhancing payment rates for certain telehealth services billed through the G0071 code. Specifically, three CPT Codes (99421, 99422, and 99423) are being added to calculate the average payment rate for G0071. These new codes reflect an online digital evaluation and management service for up to seven days, with time over that period determining this specific code (5-10 minutes, 11-20 minutes, or 21 or more minutes). Essentially, this is a store-and-forward platform to avoid requiring patients to come to RHCs or FQHCs for treatment. Like other aspects of the IFR, CMS is also waiving the requirement that these codes only be used for established patients—new Medicare patients may also receive services through these store-and-forward codes.

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

The IFR also modified its rules regarding specimen collection and payment associated with the collection of specimens for COVID-19. The modifications include changes with regard to payment for specimen collection and the recognition of travel costs associated with traveling to obtain the specimen from a homebound patient.

Prior to the IFR, nominal specimen collection fees were paid at an amount of $3. This payment was tied, primarily to three HCPCS Codes: 36415, P9612, and P9615. The IFR advises that the specimen collection fee will be increased for COVID-19 patients to $5 in SNFs or HHAs, and the relevant HCPCS Code is G0471.

The IFR also recognizes the increased need to reimburse for travel costs associated with specimen collection. Travel costs will be reimbursed by Medicare for independent laboratories with respect to collection of specimens for COVID-19 for both homebound and non-hospital patients. For this purpose, the nominal specimen collection fee for homebound and non-hospital patients is $23.46, and $25.46 for SNFs and labs collecting on behalf of an HHA.

Additional training of personnel on specimen collection will also be required and CMS has created two level II HCPCS Codes for use during the PHE: (1) G2023 for any source; and (2) G2024 for a specimen drawn in an SNF or by a laboratory on behalf of an HHA.

The IFR also addresses complaints about the requirement for laboratories to keep paper logs to document travel allowance reimbursement. In response to the complaints, the IFR clarifies that digital documentation by a global positioning system (GPS) will be sufficient at this time.

N. Requirements for Opioid Treatment Programs

Currently, two-way audio/visual conferencing is allowed for purposes of payment of the bundle of services for Opioid Treatment Program (OTP) services. Due to the PHE, CMS recognizes that two-way

audio/visual capabilities may not be present in every counseling and therapy patient encounter. Therefore, the requirements for both audio and visual access is eliminated and audio only access is allowable for purposes of meeting the requirement for the counseling and therapy weekly bundle for OTP services. The change was determined necessary to ensure opioid treatment services go uninterrupted during the pandemic.

O. Application of Teaching Physician and Moonlighting Regulations

For the period of the PHE, teaching physician billing requirements regarding physical presence during the key portions of the service can be met through direct supervision via interactive telecommunications technology. The primary care exception, which allows preceptor physicians in primary care clinics to bill for the services of residents, has also been amended. There as well, CMS is allowing for direct supervision to be met through interactive telecommunications technology. Similarly, residents performing interpretations of diagnostic tests, including radiology, as well as residents performing psychiatric services, can be supervised through interactive telecommunications technology. CMS has declined, however, to extend this policy to surgical, high risk, interventional, endoscopy, anesthesia, and complex procedures.

CMS is also modifying its moonlighting regulations. For the duration of the PHE, residents can have their services billed as physician services even if furnished in the inpatient area of the hospital at which they are training, so long as they are not related to the resident's training program. This could include, for instance, furnishing services to COVID-19 patients where such services are not part of their training.

P. Special Requirements for Psychiatric Hospitals

CMS modifies § 482.61(d) (Special Medical Record Requirements for Psychiatric Hospital Conditions of Participation) to address potential workforce shortage concerns and avoid unnecessarily imposing regulatory burdens on hospitals. CMS deletes an inappropriate reference to § 482.12(c) and removed the term "independent" in the term "licensed independent practitioner" to maintain consistency with the same modification in other sections of the regulation. Prior to this change, the regulation restricted a hospital's ability to allow non-physician practitioners (NPPs)— such as physician assistants (PAs), nurse practitioners, psychologists, and clinical nurse specialists (CNSs)—to operate within the scope of practice allowable under state law when ordering seclusion and restraint.

CMS clarifies that it believes that NPPs (as well as other qualified, licensed practitioners to whom the revision may be applicable)—when acting in accordance with state law, their scope of practice, and hospital policy—should have authority to practice more broadly and to the highest level or their education, training, and qualifications allowable under state requirements.

CMS also notes that it would allow NPPs to document progress notes of patients receiving services in psychiatric hospitals.

Finally, CMS clarified the application of certain conditions of participation to ensure that they apply equally to all patients, not just Medicare patients.

Q. Innovation Center Models

During the PHE, CMS is implementing changes to the current Innovation Center Models for Medicare Diabetes Prevention Program (MDPP), the Comprehensive Care for Joint Replacement Model (CJR), and the Alternative Payment Model provisions for the Quality Payment Program (QPP) to assure continuity of services.

Medicare Diabetes Prevention Program Expanded Model Emergency Policy

Prior to the PHE, the MDPP Expanded Model anticipated that structured services would be provided through an in-person classroom setting within defined time frames to reduce the potential for fraud and abuse, increase the likelihood of success, and maintain data integrity for evaluation purposes.

Recognizing the need for temporary flexibility, for beneficiaries enrolled in the program as of March 1, 2020 (but not for beneficiaries not previously participating in MDPP as of that date), CMS will require in-person attendance only at the first core session, but other sessions may be provided through virtual sessions, including make-up sessions. If virtual sessions are not possible, the program may be paused and authorized to resume after the PHE. The limit to virtual make-up sessions is waived so long as they are furnished consistent with the CDC Diabetes Prevention Recognition Program for virtual sessions and curriculum requirements. The MDPP supplier may furnish one session per day and one virtual make-up session per week to achieve attendance goals. The lifetime limit of one set of MDPP services is adjusted for the purpose of allowing a pause in service and to maintain eligibility despite a break in service, attendance, or weight loss achievement.

Comprehensive Care for Joint Replacement Model

CMS proposes to implement a three-month extension of the CJR model to March 31, 2021, to assure continuity of the program for participant hospitals and avoid any disruptions to standard care procedures during the PHE. CMS also expands the scope of the "extreme and uncontrollable circumstances" policy to the PHE, allowing certain financial safeguards for participant hospitals. Extending the policy to those hospital participants affected by the COVID pandemic allows these hospitals to focus on patient care and assures that the hospitals will not be financially liable for episode costs that escalate during the PHE.

Alternative Payment Model Treatment Under Quality Payment Program

CMS recognizes that the current regulatory structure is insufficient for the COVID-19 PHE and will consider changes to the current APM policies as may be necessary to achieve the immediate goals of providing beneficiaries and health care providers needed flexibilities, including potential accommodations to the Medicare Shared Savings Program. CMS wants to avoid APM participants from facing undue burden or negative consequences through the QPP. It will consider another interim final rule to amend or suspend the APM QPP as necessary. Stakeholders participating or supporting these model programs should provide comment to CMS.

R. Remote Physiologic Monitoring

CMS notes that it has in recent years extended payment to seven Remote Physiologic Monitoring (RPM) codes, including:

99091 – Collection and interpretation of physiologic data digitally stored (30 minutes minimum)
99453 – Remote monitoring of physiologic parameter(s), including setup and patient education
99454 – Remote monitoring of physiologic parameter(s), per 30 days
99457 – Remote physiologic monitoring treatment management services (20 minutes per month)
99458 – Remote physiologic monitoring treatment management services (additional 20 minutes)
99473 – Self-measured blood pressure—patient education and device calibration
99474 – Blood pressure measurement, twice daily per 30 days, with treatment plan communication

The IFR will remove existing barriers that permit RPM to be furnished only to established patients. In addition, patient consent only needs to be obtained once annually. Finally, CMS encourages suppliers to use RPM not only with patients suffering from traditional chronic conditions, but also for those patients suffering from acute symptoms, such as respiratory illness.

S. Telephone Evaluation and Management Services

Traditionally, CMS has not paid for telephone-only visits. The dam started to crack in 2018 when CMS announced a policy to begin allowing "virtual check-ins", which could be done over the phone. However, longer, higher acuity care rendered over the phone could not be reimbursed.

The IFR announces that, for the duration of the PHE, physicians and NPPs may perform and receive Medicare payment for conducting telephonic visits with their patients. While the related CPT Codes are

historically reserved for only established patients, CMS also announced a policy of enforcement discretion if these codes are used for new patients as well. This means that a physician can, via the phone, diagnose and treat Medicare beneficiaries and receive payment for those services. A word of caution though: Many states do not permit "audio-only" encounters to be used as a means to establish a physician-patient relationship or to make an appropriate prescription decision. While some states have eased this requirement during the COVID-19 crisis, the instances of malpractice related to audio-only encounters remains high, so healthcare professionals should understand the limitations of this technology and advise a patient of getting a telehealth (audio/video) or in-person visit if the circumstances so warrant.

In addition, the valuation of these codes is less than traditional in-person or telehealth E/M services. Below is a table of the relevant codes:

CPT Code	Descriptor	RVU
98966	NPP telephone assessment – 5-10 minutes	.25
98967	NPP telephone assessment – 11-20 minutes	.5
98968	NPP telephone assessment – 21-30 minutes	.75
99441	Physician telephone assessment – 5-10 minutes	.25
99442	Physician telephone assessment – 11-20 minutes	.5
99443	Physician telephone assessment – 21-30 minutes	.75

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

At present, the minimum level of supervision required for the initiation of Non-Surgical Extended Duration Therapeutic Services (NSEDTS), which are services that are not surgical and have a significant monitoring component that can extend over a period of time, is direct supervision. The initiation period may be followed by a period of general supervision at the discretion of the physician or NPP once the patient is stable. General supervision means that the procedure is furnished under the physician's overall direction and control, but that the physician's presence is not required during the performance of the procedure.

CMS notes that it established general supervision as appropriate after the initiation of the service because it is challenging for hospitals to ensure direct supervision for services with an extended duration and a significant monitoring component in normal times. In order to give hospitals as much flexibility as possible to furnish services to Medicare beneficiaries under even more challenging conditions during the COVID-19 PHE, the IFR changes the minimum level of supervision for all outpatient hospital therapeutic services that fall under 42 CFR § 410.27(a)(1)(iv)(E) to general supervision.

U. Application of Certain National Coverage Determination and Local Coverage Determination Requirements

In a major concession to the impacts on staffing and the overwhelming patient load being experienced in both facility and non-facility settings, the IFR lifts certain typical requirements in National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) in order to protect healthcare providers and provide the maximum flexibility in furnishing care to Medicare beneficiaries during the COVID-19 PHE.

Face-to-Face and In-Person Requirements

Because some NCDs and LCDs contain requirements for face-to-face, timely evaluations or re-evaluations for a patient to qualify initially for coverage or to qualify for continuing coverage of a particular item or service, and because CMS sensibly wants to limit face-to-face encounters during the PHE to protect not only vulnerable Medicare beneficiaries, but also healthcare professionals, the IFR eliminates on an interim

basis any NCD or LCD requirement for a face-to-face or in-person encounter for evaluations, assessments, certifications or other implied face-to-face services.

The IFR does not apply, however, to face-to-face encounter requirements that are mandated by statute, such as for Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Power Mobility Devices or hospice and home health services.

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

Because CMS recognizes that patients being furnished services for respiratory-related indications likely will be required to receive care in unexpected healthcare settings, including the home, due to being moved across settings to accommodate an increase in patient volume, it will not enforce clinical indications for coverage contained in NCDs and LCDs related to respiratory, home anticoagulation management, and infusion pump services during the PHE in order to give practitioners the greatest flexibility possible in caring for their patients.

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

To the extent that NCDs or LCDs require a specific practitioner type or physician specialty to furnish a service, procedure or any portion thereof, the IFR permits the chief medical officer or equivalent of a facility to authorize another physician specialty or practitioner type to meet those requirements. Similarly, to the extent NCDs or LCDs require a physician or physician specialty to supervise other practitioners, professionals or qualified personnel, the IFR authorizes the chief medical officer of a facility to remove those requirements.

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

CMS is extending the 2019 Merit-based Incentive Payment System (MIPS) data submission deadline will be extended by 30 days until April 30, 2020, to give eligible clinicians more time to report quality and other data for purposes of MIPS. MIPS-eligible physicians and other clinicians who do not submit data by the extended deadline will qualify for the "automatic extreme and uncontrollable circumstances" policy and will automatically avoid a MIPS-related penalty and, instead, receive a neutral payment adjustment for the 2021 MIPS payment year.

CMS also recognizes that Shared Savings Accountable Care Organizations (ACOs) will need to focus resources on patient care during the PHE and has revised § 425.502(f) to remove the restriction preventing ACOs from utilizing the Shared Savings Program extreme and uncontrollable circumstances policy for disasters that occur during the quality reporting period. This change will provide relief under the Shared Savings Program to all ACOs that may be unable to completely and accurately report quality data for 2019 due to the PHE. CMS realizes that we are in an unprecedented period and will further evaluate the financial methodology and related benchmarks through future notice-and-comment rule at the end of each performance year based on the performance.

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

In order to address the PHE, CMS is rushing some of its future policy plans, including changes to evaluation and management coding practices. Although originally scheduled to begin in 2021, CMS is now instructing that all office/outpatient E/M services, when performed via telehealth (99201-99215), should be coded based on either the level of medical decision-making or time (which includes all of the time associated with the service on the day the service is provided). While providers still need to maintain adequate documentation to demonstrate the appropriateness of the service and maintain continuity of care, E/M services will not be coded based on history or physical exam components.

X. Counting of Resident Time

Currently residents can only be included in the full-time equivalent (FTE) resident count for purposes of graduate medical education if the resident is onsite at the hospital or at a specified non-hospital site location. Pursuant to the modification to the regulation, during the public health emergency, residents can be included in the FTE count, even if they are furnishing services from home or from the patient's home, so long as the hospital is paying the resident's salary and fringe benefits.

Y. Addressing PHE Impact on Part C and Part D Quality Rating Systems

CMS makes a number of proposals for the 5-Star Ratings systems for Medicare Part C and D plans, including the MA quality bonus payment (QBP) status. Applying the extreme and uncontrollable circumstances policy standard, CMS recognizes that the prior methodology assumptions are not sufficient for the PHE. The agency also recognizes that normal data collection activities under Healthcare Effectiveness Data and Information Set (HEDIS) and Consumer Assessment of Healthcare Providers and Systems (CAHPS) is not feasible. It intends to amend the Stars Rating methodology to take into account the impact of the PHE.

CMS intends to replace the 2021 Star Rating measures with earlier years' Star Ratings unaffected by the PHE and make corresponding changes for data calculations for 2021 and 2022 Part C and D Star Ratings that will account for the pandemic.

Citing public health and safety dangers inherent in data collection, CMS asks that all HEDIS 2020 data collection work cease immediately to allow health plans, provides, and physician offices to focus on taking care of patients. The National Committee for Quality Assurance (NCQA) survey process is also rescheduled for late summer or possibly later, with details to follow from CMS.

Similarly, the CAHPS 2020 survey data collection efforts should cease to allow for vendor safety and compliance with social distancing guidance. CMS is not prohibiting collection for internal quality measures. For the 2022 Star Ratings, plans will submit HEDIS data in June 2021 and administer CAHPS surveys in 2021 as usual.

Z. Changes to Expand Workforce Capacity for Ordering Medicaid Home Health Nursing and Aide Services, Medical Equipment, Supplies and Appliances, and Physical Therapy, Occupational Therapy, or Speech Pathology and Audiology Services

Medicaid home health regulations now allow that during the existence of the PHE non-physician practitioners, such as, but not limited to, NPs and PAs, may order medical equipment, supplies and appliances, home health nursing and aide services, and physical therapy, occupational therapy, or speech pathology and audiology services, in accordance with state scope of practice laws. CMS advises the change aligns the Medicare and Medicaid programs in terms of the practitioners who may order these items.

AA. Origin and Destination Requirements Under Ambulance Fee Schedule

CMS has expanded the list of destinations for which Medicare covers ambulance transportation to include all destinations, from any point of origin, that are equipped to treat the condition of the patient consistent with by state and/or local Emergency Medical Services (EMS) protocols during the PHE. CMS acknowledges that in these circumstances, based on local protocols, a patient suspected of having COVID-19 that requires a medically necessary transport may be transported to a testing facility to get tested instead of a hospital in an effort to prevent possible exposure to other patients and medical staff. These destinations may include, but are not limited to: any location that is an alternative site determined to be part of a hospital, critical access hospital, or SNF, community mental health centers, FQHCs, RHCs, physicians' offices, urgent care facilities, ambulatory surgery centers (ASCs), any location furnishing dialysis services outside of an ESRD facility when an ESRD facility is not available, and the beneficiary's

home. Further, during the PHE for the COVID-19 pandemic only, a covered destination under § 410.40 includes a ground ambulance transport from any point of origin to a destination that is equipped to treat the condition of the patient consistent with state and local EMS protocols where the services will be furnished.

BB. Merit-Based Incentive Payment System Updates

CMS announced two important changes in the Merit-Based Incentive Payment System as part of its PHE rule modifications. Specifically, CMS added one new improvement activity to the Improvement Activities Inventory for the CY 2020 performance period. This improvement activity promotes clinician participation in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection. To receive credit for this clinical improvement, clinicians must report their findings through an open source clinical data repository or clinical data registry. When utilizing the term "open source" CMS expects the clinician to make available to the public the results of research, including publications and scientific data, which would enable reuse, increase transparency, and facilitate reproducibility of research results. CMS furnished the following table for inclusion in the MIPS CY2020 performance period:

TABLE 1: New Improvement Activity for MIPS CY 2020 Performance Period

Activity ID:	**IA_ERP_XX**
Subcategory:	Emergency Response and Preparedness
Activity Title:	COVID-19 Clinical Trials
Activity Description:	To receive credit for this activity, a MIPS-eligible clinician must participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study. For more information on the COVID-19 clinical trials, visit the US National Library of Medicine website.
Weighting:	High

Next, to provide additional relief to individual clinicians, groups, and virtual groups for whom sufficient MIPS measures and activities may not be available for the 2019 MIPS performance period due to the PHE, CMS is extending the deadline to submit an application for reweighting the quality, cost, and improvement activities performance categories based on extreme and uncontrollable circumstances and the Promoting Interoperability performance category based on extreme and uncontrollable circumstances from December 31, 2019, to April 30, 2020, or a later date that CMS may specify. The extended deadline is available only for applications that demonstrate the clinician has been adversely affected by the PHE.

As a companion to this relief, CMS is modifying its policy to create an exception for the 2019 performance period/2021 MIPS payment year only, such that if a MIPS eligible clinician demonstrates through an application submitted to CMS that they have been adversely affected by the PHE, but also submits data for the quality, cost, or improvement activities performance categories, the performance categories for which data are submitted would still be reweighted (subject to CMS' approval of the application), and the data submission would not effectively void the application for reweighting. A similar exception for the Promoting Interoperability performance category is also being adopted for the 2019 performance period/2021 MIPS payment year only.

CC. Inpatient Hospital Services Furnished Under Arrangements Outside a Hospital

CMS has historically stated that routine services, such as furnishing beds and nursing services, could not be contracted out to another hospital. In other words, the hospital beds must be within the four walls of the hospital itself. However, during the PHE, CMS is allowing hospitals to furnish services to inpatients outside the hospital, so long as the hospital maintains control and responsibility over the use of hospital resources used in treating these patients.

DD. Advance Payments to Suppliers of Items and Services Under Part B

While there is already a provision for advance payment to Medicare suppliers, the process has not been updated for some time and is rarely invoked (the regulation, heretofore, still referenced Medicare carriers instead of contractors). CMS, anticipating certain breakdowns in either suppliers' billing processes or Medicare Administrative Contractor (MAC) adjudication processes, has established an additional emergency exception that will permit 100% of payment if either:

1. The contractor is unable to process the claim timely, or is at risk of being untimely in processing the claim; or
2. When the supplier has experienced a temporary delay in preparing and submitting bills to the contractor beyond its normal billing cycle.

Note that suppliers must nevertheless request advance payments from their MACs. This is not an automatic process.

Coronavirus COVID-19 Task Force

For our clients, we have formed a multidisciplinary **Coronavirus COVID-19 Task Force** to help guide you through the broad scope of legal issues brought on by this public health challenge. We also have launched a resource page to help keep you on top of developments as they unfold. If you would like to receive a daily digest of all new updates to the page, please subscribe now to receive our COVID-19 alerts.

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