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SUMMARY OF CMS INTERIM FINAL RULE AND NEW 1135 WAIVERS IN RESPONSE TO COVID-19 CRISIS

Overview

On March 30, 2020, CMS issued a 220-page Interim Final Rule (“IFR”) setting forth policy and regulatory revisions to the Medicare program in response to the Public Health Emergency for the COVID-19 pandemic (“the PHE”). CMS did so “with the goal of offering healthcare professionals flexibilities in furnishing services while combatting the COVID-19 pandemic.” By issuing an IFR, CMS exercised its statutory discretion to waive the usual notice-and-comment rules that require publication of a proposed rule and a 60-day comment period on the ground that adhering to the usual rulemaking procedure would delay implementation of the Rule and, as such, would be contrary to the public interest. Likewise, CMS exercised its statutory discretion to waive the requirement of a 30-day delay before a final rule becomes effective. CMS went a step farther by making the policies and regulatory revisions set forth in the IFR effective retroactive to March 1, 2020—the date the President declared to be the beginning of the national emergency concerning the COVID-19 outbreak.

The document will be divided into two sections, the first being provisions of the IFR and the second being a general overview of expanded waivers.

Interim Final Rule with Comment Period

The provisions of the IFR most applicable to LUGPA members relate to the payment of telehealth services and expanded coverage for services furnished through telecommunications technology. Unless otherwise noted, the policy and rule changes described below are being adopted on an interim basis, retroactive to March 1, 2020, and will be in effect for the duration of the PHE. Key takeaways are as follows:

- CMS did not relax the requirement that telehealth services must include a video component;
- With respect to payment for telehealth services, CMS took the following action:
 - CMS eliminated the site of service differential for Medicare telehealth services. Previously, telehealth services had to be billed with POS code 02, which is specific to telehealth services.
 - In the IFR, CMS stated that “we believe, as more telehealth services are furnished to patients wherever they are located....it would be appropriate to assume that the relative resource costs of services furnished through telehealth should be reflected in the payment to the furnishing physician or practitioner as if they furnished the services in person, and to assign the payment rate that ordinarily would have been paid under the PFS were the service furnished in-person.” Thus, for a physician practicing in the office setting who sees patients via telehealth, instead of in person, the physician will be paid at the office rate for these services.
 - CMS stated that physicians and other practitioners should report the POS code that would have been reported had the service been furnished in person. CMS finalized, on an interim basis for the duration of the PHE, the use of modifier 95 to be applied to claim lines that describe services furnished via telehealth.
 - CMS revised its payment policy to specify that the office E/M level selection for E/M services, when furnished via telehealth, can be based on MDM or time with time defined as all of the time associated with the E/M on the day of the encounter. CMS also removed any requirements regarding documentation of history and/or physical exam in the medical record.
 - CMS added services to the list of eligible Medicare telehealth services and eliminated frequency limitations as well as other requirements associated with particular services furnished via telehealth. One such addition is CPT 77427 (Radiation Tx Management Services). CMS stated that the weekly face-to-face visit component of this service could be conducted via telehealth when the billing practitioner weighs the exposure risks against the value of in-person assessment on a case-by-case basis.
- Although CMS did not expand coverage of telehealth services to include audio-only options, CMS clarified that “phones” with video capability are acceptable. Specifically, CMS stated that “an 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 distance site physician or practitioner.”
- CMS is altering the definition of “direct supervision” to state that “necessary presence of the physician for direct supervision includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider.” CMS expressly stated that it is seeking to provide greater flexibility with respect to the supervision

requirements that are otherwise applicable to the furnishing of physician-administered drugs in the physician office setting.

- While virtual supervision is clearly authorized for instances where there is a face to face service being administered to a patient by an APP in the physician's office or at the patient's home, CMS does not specifically extend this to indirect supervision via telemedicine of a service performed by an APP.
- To clarify, CMS did not specifically authorize an APP performing telemedicine to be considered "incident-to" a physician service if they are supervised virtually by a physician, to do so may be outside CMS's intent.
- CMS finalized a rule to permit payment for services furnished to new and established patients via telecommunications technology that are not deemed telehealth services (e.g., remote patient monitoring services and interpretation of diagnostic tests when furnished remotely). The Physician Fee Schedule Rule for 2019 had only permitted payment for these services in connection with established patients. In the IFR, CMS states that consent to receive these services can be documented by auxiliary staff under general supervision (as well as by the billing practitioner).
- CMS announced a change in its payment policy with respect to telephone E/M services. In light of the PHE, CMS determined that it should not continue to consider these telephonic E/M services to be categorically non-covered services.
 - CMS explained that "[i]n the context of the goal of reducing exposure risks associated with the PHE for the COVID-19 pandemic, especially in the case that two-way, audio and video technology required to furnish a Medicare telehealth service might not be available, we believe there are many circumstances where prolonged, audio only communication between the practitioner and the patient could be clinically appropriate yet not fully replace a face-to-face visit."
 - CMS went on to say that the existing telephone E/M codes, in both description and valuation, are the best way to recognize the relative resource costs of these kind of services. Accordingly, CMS has adopted separate payment for CPT Codes 98966-98968 and CPT codes 99441-99443. Payment for these services are extended to new and established patients.
- CMS announced that to the extent a National Coverage Determination or Local Coverage Determination (including articles) would otherwise require a face-to-face or in-person encounter for evaluations, assessments, certifications or other implied face-to-face services, those requirements will not apply for the duration of the PHE.

Expanded Waiver Authority¹

CMS also instituted a number of changes that were not within the IFR. When the President declares a disaster or emergency under the Stafford Act or National Emergencies Act and the HHS Secretary declares a public health emergency under Section 319 of the Public Health Service Act, the Secretary is authorized to take certain actions. For example, under section 1135 of the Social Security Act, the Secretary may temporarily waive or modify certain Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in Social Security Act programs in the emergency area and time periods and that providers who provide such services in good faith can be reimbursed and exempted from sanctions (absent any determination of fraud or abuse).

In past emergencies, once an 1135 Waiver was authorized, health care providers have submitted requests to operate under that authority to the State Survey Agency or CMS Regional Office. The requests generally have included a justification for the waiver and expected duration of the modification requested. Providers and suppliers have been asked to keep careful records of beneficiaries to whom they provide services, in order to ensure that proper payment may be made. The State Survey Agency and CMS Regional Office reviews the provider's request and make appropriate decisions, usually on a case-by-case basis. CMS has approved specific waivers and modifications only to the extent that the provider in question has been affected by the disaster or emergency. Providers are expected to come into compliance with any waived requirements prior to the end of the emergency period.

General 1135 Waivers Issued by CMS

The majority of waivers issued by CMS are not specifically applicable to LUGPA practices, and cover items such as:

- Increasing hospital capacity by allowing use of outside facilities;
- Allowing hospitals to increase benefits to their medical staffs;
- Increasing flexibility for ambulances to transport to a variety of locations;
- Expansion of the special purpose dialysis facilities;
- Allowing emergency departments to perform other ambulatory or inpatient services; and
- Easing Medicare enrollment requirements

1135 Waivers Applicable to LUGPA Practices

There are a number of waivers that apply to different sectors of the healthcare market with substantially different eligibility requirements. A complete review of these waivers is beyond the scope of this analysis; below is language that has been excerpted or adapted from CMS documents. Unlike the evaluation of the IFR, which constitutes an analysis of the document, the waiver review is presented as a resource for informational purposes only. There are three documents appended to this communication: 1) an excellent

¹ Excerpted from: "1135 Waivers At A Glance." Accessed at: <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Downloads/1135-Waivers-At-A-Glance.pdf>.

summary of waivers available to physicians' offices; 2) an excerpt of the hospital waiver document that pertains to ASCs; and 3) instructions on how to determine if your practice is eligible for local waivers

The summary of the physician waivers appended is an excellent resource and does not need to be replicated here and the reader is referred to the appendix on this. There are two waivers in the hospital document that may be of interest to LUGPA practices, one narrow and the other more broadly applicable:

- The narrower initiative is the ability for physician-owned hospitals to temporarily increase the number of their licensed beds, operating rooms, and procedure rooms, even though such expansion would otherwise be prohibited under the Stark Law. For example, a physician-owned hospital may temporarily convert observation beds to inpatient beds to accommodate patient surge during the COVID-19 pandemic in the United States.
- The broader initiative is CMS is relaxing certain conditions of participation (CoPs) for hospital operations to maximize hospitals' ability to focus on patient care. The same initiative will also allow currently enrolled ambulatory surgical centers (ASCs), to temporarily enroll as hospitals and to provide hospital services to help address the urgent need to increase hospital capacity to take care of patients. Other interested entities, such as freestanding emergency departments, could pursue enrolling as an ASC and then pursue converting their enrollment as a hospital during the PHE. ASCs that wish to enroll to receive temporary billing privileges as a hospital should call the COVID-19 Provider Enrollment Hotline to reach the contractor that serves their jurisdiction, and then will complete and sign an attestation form specific to the COVID-19 PHE. An FAQ for providers released by CMS for those interested in pursuing these waivers is appended to this document for additional information.

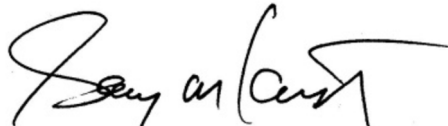
Summary

While the recently released IFR provides additional relief to independent practices, the majority of this relief is not relevant to LUGPA practices as most of the additional CPT codes are not generally performed by LUGPA member practices. That said, there is important enhancement of reimbursement, easing of billing requirements and relaxation of direct supervision for telemedicine visits which are certainly beneficial to independent practices of all specialties. On the waiver side, although the majority of changes are more applicable to institutions than independent practices, there are important enhancements to the capabilities of ambulatory surgical facilities. These will require LUGPA members to engage directly with their local MAC to determine if the waiver is applicable in their state and to assess if they are eligible.

Respectfully submitted



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Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19

The Trump Administration is issuing an unprecedented array of temporary regulatory waivers and new rules to equip the American healthcare system with maximum flexibility to respond to the 2019 Novel Coronavirus (COVID-19) pandemic. Made possible by President Trump's recent emergency declaration and emergency rule making, these temporary changes will apply immediately across the entire U.S. healthcare system for the duration of the emergency declaration. The goals of these actions are to 1) to ensure that local hospitals and health systems have the capacity to handle a potential surge of COVID-19 patients through temporary expansion sites (also known as CMS Hospital Without Walls); 2) remove barriers for physicians, nurses, and other clinicians to be readily hired from the community or from other states so the healthcare system can rapidly expand its workforce; 3) increase access to telehealth in Medicare to ensure patients have access to physicians and other clinicians while keeping patients safe at home; 4) expand in-place testing to allow for more testing at home or in community based settings; and 5) put Patients Over Paperwork to give temporary relief from many paperwork, reporting and audit requirements so providers, health care facilities, Medicare Advantage and Part D plans, and States can focus on providing needed care to Medicare and Medicaid beneficiaries affected by COVID-19.

Medicare Telehealth

Clinicians can now provide more services to beneficiaries via telehealth so that clinicians can take care of their patients while mitigating the risk of the spread of the virus. Under the public health emergency, all beneficiaries across the country can receive Medicare telehealth and other communications technology-based services wherever they are located. Clinicians can provide these services to new or established patients. In addition, providers can waive Medicare copayments for these telehealth services for beneficiaries in Original Medicare.

To enable services to continue while lowering exposure risk, clinicians can now provide the following additional services by telehealth:

- Emergency Department Visits, Levels 1-5 (CPT codes 99281-99285)
- Initial and Subsequent Observation and Observation Discharge Day Management (CPT codes 99217- 99220; CPT codes 99224- 99226; CPT codes 99234- 99236)
- Initial hospital care and hospital discharge day management (CPT codes 99221-99223; CPT codes 99238- 99239)
- Initial nursing facility visits, All levels (Low, Moderate, and High Complexity) and nursing facility discharge day management (CPT codes 99304-99306; CPT codes 99315-99316)
- Critical Care Services (CPT codes 99291-99292)
- Domiciliary, Rest Home, or Custodial Care services, New and Established patients (CPT codes 99327- 99328; CPT codes 99334-99337)
- Home Visits, New and Established Patient, All levels (CPT codes 99341- 99345; CPT codes 99347- 99350)
- Inpatient Neonatal and Pediatric Critical Care, Initial and Subsequent (CPT codes 99468- 99473; CPT codes 99475- 99476)

- Initial and Continuing Intensive Care Services (CPT code 99477- 994780)
- Care Planning for Patients with Cognitive Impairment (CPT code 99483)
- Psychological and Neuropsychological Testing (CPT codes 96130- 96133; CPT codes 96136- 96139)
- Therapy Services, Physical and Occupational Therapy, All levels (CPT codes 97161- 97168; CPT codes 97110, 97112, 97116, 97535, 97750, 97755, 97760, 97761, 92521- 92524, 92507)
- Radiation Treatment Management Services (CPT codes 77427)
- Licensed clinical social worker services, clinical psychologist services, physical therapy services, occupational therapist services, and speech language pathology services can be paid for as Medicare telehealth services.

A complete list of all Medicare telehealth services can be found here:

<https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes>

Virtual Check-Ins & E-Visits

- Additionally, clinicians can provide virtual check-in services (HCPCS codes G2010, G2012) to both new and established patients. Virtual check-in services were previously limited to established patients.
- Licensed clinical social workers, clinical psychologists, physical therapists, occupational therapists, and speech language pathologists can provide e-visits. (HCPCS codes G2061-G2063).
- A broad range of clinicians, including physicians, can now provide certain services by telephone to their patients (CPT codes 98966 -98968; 99441-99443)

Remote Patient Monitoring

- Clinicians can provide remote patient monitoring 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. For example, remote patient monitoring can be used to monitor a patient's oxygen saturation levels using pulse oximetry. (CPT codes 99091, 99457-99458, 99473-99474, 99493-99494)

Removal of Frequency Limitations on Medicare Telehealth

To better serve the patient population that would otherwise not have access to clinically appropriate in-person treatment, the following services no longer have limitations on the number of times they can be provided by Medicare telehealth:

- A subsequent inpatient visit can be furnished via Medicare telehealth, without the limitation that the telehealth visit is once every three days (CPT codes 99231-99233);
- A subsequent skilled nursing facility visit can be furnished via Medicare telehealth, without the limitation that the telehealth visit is once every 30 days (CPT codes 99307-99310)
- Critical care consult codes may be furnished to a Medicare beneficiary by telehealth beyond the once per day limitation (CPT codes G0508-G0509).

Other Medicare Telehealth and Remote Patient Care

- For Medicare patients with End Stage Renal Disease (ESRD), clinicians no longer must have one “hands on” visit per month for the current required clinical examination of the vascular access site.
- For Medicare patients with ESRD, we are exercising enforcement discretion on the following requirement so that clinicians can provide this service via telehealth: individuals must receive a face-to-face visit, without the use of telehealth, at least monthly in the case of the initial 3 months of home dialysis and at least once every 3 consecutive months after the initial 3 months.
- 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 would not have to meet those requirements during the public health emergency.
- Beneficiary consent should not interfere with the provision of telehealth services. Annual consent may be obtained at the same time, and not necessarily before, the time that services are furnished.
- Physician visits: CMS is waiving the requirement in 42 CFR 483.30 for physicians and non-physician practitioners to perform in-person visits for nursing home residents and allow visits to be conducted, as appropriate, via telehealth options.

Workforce

- *Medicare Physician Supervision requirements:* For services requiring direct supervision by the physician or other practitioner, that physician supervision can be provided virtually using real-time audio/video technology.
- *Medicare Physician Supervision and Auxiliary Personnel:* The physician can enter into a contractual arrangement that meets the definition of auxiliary personnel at 42 CFR 410.26, including with staff of another provider/supplier type, such as a home health agency (defined under § 1861(o) of the Act) or a qualified home infusion therapy supplier (defined under § 1861(iii)(3)(D)), or entities that furnish ambulance services, that can provide the staff and technology necessary to provide care that would ordinarily be provided incident to a physicians’ service (including services that are allowed to be performed via telehealth). In such instances, the provider/supplier would seek payment for any services provided by auxiliary personnel from the billing practitioner and would not submit claims to Medicare for such services.
- *Medicare Physician Supervision requirements:* Direct physician supervision is no longer required for non-surgical extended duration therapeutic services provided in hospital outpatient departments and critical access hospitals. Instead, a physician can provide a general level of supervision for these services so that a physician is no longer required to be immediately available in the office suite.
- *Physician Services:* CMS is waiving 482.12(c)(1-2) and (4), which requires that Medicare patients in the hospital be under the care of a physician. This allows hospitals to use other practitioners, such as physician’s assistant and nurse practitioners, to the fullest extent possible. This waiver should be implemented in accordance with a state’s emergency preparedness or pandemic plan.
- *National coverage determinations (NCDs) and Local Coverage Determinations (LCDs):* To the extent NCDs and LCDs require a specific practitioner type or physician specialty to furnish or supervise a service, during this public health emergency, the Chief Medical Officer or equivalent of a hospital or facility will have the authority to make those staffing decisions.

- **Practitioner Locations:** Temporarily waive Medicare and Medicaid’s requirements that physicians and non-physician practitioners be licensed in the state where they are providing services. State requirements will still apply. CMS waives the Medicare requirement that a physician or non-physician practitioner must be licensed in the State in which s/he is practicing for individuals for whom the following four conditions are met: 1) must be enrolled as such in the Medicare program, 2) must possess a valid license to practice in the State which relates to his or her Medicare enrollment, 3) is 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 or her professional capacity, and 4) is not affirmatively excluded from practice in the State or any other State that is part of the 1135 emergency area. A physician or non-physician practitioner may seek an 1135-based licensure waiver from CMS by contacting the provider enrollment hotline for the Medicare Administrative Contractor that services their geographic area. This waiver does not have the effect of waiving State or local licensure requirements or any requirement specified by the State or a local government as a condition for waiving its licensure requirements
- **Provider Enrollment:** CMS has established toll-free hotlines for physicians, non-physician practitioners and Part A certified providers and suppliers establishing isolation facilities to enroll and receive temporary Medicare billing privileges. CMS is providing the following flexibilities for provider enrollment:
 - Waive certain screening requirements.
 - Postpone all revalidation actions.
 - Allow licensed physicians and other practitioners to bill Medicare for services provided outside of their state of enrollment.
 - Expedite any pending or new applications from providers.
 - Allow practitioners to render telehealth services from their home without reporting their home address on their Medicare enrollment while continuing to bill from your currently enrolled location.
 - Allow opted-out practitioners to terminate their opt-out status early and enroll in Medicare to provide care to more patients.

Patients Over Paperwork

- **“Stark Law” Waivers:** The physician self-referral law (also known as the “Stark Law”) prohibits a physician from making referrals for certain healthcare services payable by Medicare if the physician (or an immediate family member) has a financial relationship with the entity performing the service. There are statutory and regulatory exceptions, but in short, a physician cannot refer a patient to any entity with which he or she has a financial relationship. CMS will permit certain referrals and the submission of related claims that would otherwise violate the Stark Law. They include:
 - Hospitals and other health care providers can pay above or below fair market value to rent equipment or receive services from physicians (or vice versa). For example, a physician practice may be willing to rent or sell needed equipment to a hospital at a price that is below what the practice could charge another party. Or, a hospital may provide space on hospital grounds at no charge to a physician who is willing to treat patients who seek care at the hospital but are not appropriate for emergency department or inpatient care.
 - Health care providers can support each other financially to ensure continuity of health care operations. For example, a physician owner of a hospital may make a personal loan to the hospital without charging interest at a fair market rate so that the hospital can make payroll or pay its vendors.

- Hospitals can provide benefits to their medical staffs, such as multiple daily meals, laundry service to launder soiled personal clothing, or child care services while the physicians are at the hospital and engaging in activities that benefit the hospital and its patients.
- Allowing the provision of certain items and services that are solely related to COVID-19 Purposes (as defined in the waivers), even when the provision of the items or services would exceed the annual non-monetary compensation cap. For example, a home health agency may provide continuing medical education to physicians in the community on the latest care protocols for homebound patients with COVID-19, or a hospital may provide isolation shelter or meals to the family of a physician who was exposed to the novel coronavirus while working in the hospital's emergency department.
- Physician-owned hospitals can temporarily increase the number of their licensed beds, operating rooms, and procedure rooms, even though such expansion would otherwise be prohibited under the Stark Law. For example, a physician-owned hospital may temporarily convert observation beds to inpatient beds to accommodate patient surge during the COVID-19 pandemic in the United States.
- Loosen some of the restrictions when a group practice can furnish medically necessary designated health services (DHS) in a patient's home. For example, any physician in the group may order medically necessary DHS that is furnished to a patient by a technician or nurse in the patient's home contemporaneously with a physician service that is furnished via telehealth by the physician who ordered the DHS.
- Group practices can furnish medically necessary MRIs, CT scans or clinical laboratory services from locations like mobile vans in parking lots that the group practice rents on a part-time basis.
- *National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) on Respiratory Related Devices, Oxygen and Oxygen Equipment, Home Infusion Pumps and Home Anticoagulation Therapy:* Clinicians now have maximum flexibility in determining patient needs for respiratory related devices and equipment and the flexibility for more patients to manage their treatments at the home. The current NCDs and LCDs that restrict coverage of these devices and services to patients with certain clinical characteristics do not apply during the public health emergency. For example, Medicare will cover non-invasive ventilators, respiratory assist devices and continuous positive airway pressure devices based on the clinician's assessment of the patient.
- *Signature Requirements:* CMS is waiving signature and proof of delivery requirements for Part B drugs and Durable Medical Equipment when a signature cannot be obtained because of the inability to collect signatures. Suppliers should document in the medical record the appropriate date of delivery and that a signature was not able to be obtained because of COVID-19.
- *Changes to MIPS:* We are making two updates to the Merit-based Incentive Payment System (MIPS) in the Quality Payment Program. We are modifying the MIPS Extreme and Uncontrollable Circumstances policy to allow clinicians who have been adversely affected by the COVID-19 public health emergency to submit an application and request reweighting of the MIPS performance categories for the 2019 performance year. This is an important change that allows clinicians who have been impacted by the COVID-19 outbreak and may be unable to submit their MIPS data during the current submission period, to request reweighting and potentially receive a neutral MIPS payment adjustment for the 2021 payment year. Additionally, we are adding one new Improvement Activity for the CY 2020 performance year that, if selected, would provide high-weighted credit for clinicians within the MIPS Improvement Activities performance category. Clinicians will receive credit for this Improvement Activity by participating in a clinical trial utilizing a drug or biological product to treat a patient with COVID-19 and then reporting their findings to a clinical data repository or clinical data registry. This would help contribute to a clinician's overall MIPS final score, while providing important data to help treat patients and address the current COVID-19 pandemic.

- **Accelerated/Advance Payments:** In order to increase cash flow to providers impacted by COVID-19, CMS has expanded our current Accelerated and Advance Payment Program. An accelerated/advance payment is a payment intended to provide necessary funds when there is a disruption in claims submission and/or claims processing. CMS is authorized to provide accelerated or advance payments during the period of the public health emergency to any Medicare provider/supplier who submits a request to the appropriate Medicare Administrative Contractor (MAC) and meets the required qualifications. Each MAC will work to review requests and issue payments within seven calendar days of receiving the request. Traditionally repayment of these advance/accelerated payments begins at 90 days, however for the purposes of the COVID-19 pandemic, CMS has extended the repayment of these accelerated/advance payments to begin 120 days after the date of issuance of the payment. Providers can get more information on this process here: www.cms.gov/files/document/Accelerated-and-Advanced-Payments-Fact-Sheet.pdf.

Medicare appeals in Fee for Service, Medicare Advantage (MA) and Part D

- CMS is allowing Medicare Administrative Contractors (MACs) and Qualified Independent Contractor (QICs) in the FFS program 42 CFR 405.942 and 42 CFR 405.962 and MA and Part D plans, as well as the Part C and Part D Independent Review Entity (IREs), 42 CFR 562, 42 CFR 423.562, 42 CFR 422.582 and 42 CFR 423.582 to allow extensions to file an appeal;
- CMS is allowing MACs and QICs in the FFS program 42 CFR 405.950 and 42 CFR 405.966 and the Part C and Part D IREs to waive requirements for timeliness for requests for additional information to adjudicate appeals; MA plans may extend the timeframe to adjudicate organization determinations and reconsiderations for medical items and services (but not Part B drugs) by up to 14 calendar days if: the enrollee requests the extension; the extension is justified and in the enrollee's interest due to the need for additional medical evidence from a noncontract provider that may change an MA organization's decision to deny an item or service; or, the extension is justified due to extraordinary, exigent, or other non-routine circumstances and is in the enrollee's interest 42 CFR § 422.568(b)(1)(i), § 422.572(b)(1) and § 422.590(f)(1);
- CMS is allowing MACs and QICs in the FFS program 42 C.F.R 405.910 and MA and Part D plans, as well as the Part C and Part D IREs to process an appeal even with incomplete Appointment of Representation forms 42 CFR § 422.561, 42 CFR § 423.560. However, any communications will only be sent to the beneficiary;
- CMS is allowing MACs and QICs in the FFS program 42 CFR 405.950 and 42 CFR 405.966 and MA and Part D plans, as well as the Part C and Part D IREs to process requests for appeal that don't meet the required elements using information that is available 42 CFR § 422.562, 42 CFR § 423.562.
- CMS is allowing MACs and QICs in the FFS program 42 CFR 405.950 and 42 CFR 405.966 and MA and Part D plans, as well as the Part C and Part D IREs, 42 CFR 422.562, 42 CFR 423.562 to utilize all flexibilities available in the appeal process as if good cause requirements are satisfied.

Additional Guidance

- The Interim Final Rule and waivers can be found at: <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>.
- CMS has released guidance to providers related to relaxed reporting requirements for quality reporting programs at <https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting>.

Hospitals: CMS Flexibilities to Fight COVID-19

The Trump Administration is issuing an unprecedented array of temporary regulatory waivers and new rules to equip the American healthcare system with maximum flexibility to respond to the 2019 Novel Coronavirus (COVID-19) pandemic. Made possible by President Trump's recent emergency declaration and emergency rule making, these temporary changes will apply immediately across the entire U.S. healthcare system for the duration of the emergency declaration. The goals of these actions are to 1) to ensure that local hospitals and health systems have the capacity to handle a potential surge of COVID-19 patients through temporary expansion sites (also known as CMS Hospital Without Walls); 2) remove barriers for physicians, nurses, and other clinicians to be readily hired from the community or from other states so the healthcare system can rapidly expand its workforce; 3) increase access to telehealth in Medicare to ensure patients have access to physicians and other clinicians while keeping patients safe at home; 4) expand in-place testing to allow for more testing at home or in community based settings; and 5) put Patients Over Paperwork to give temporary relief from many paperwork, reporting and audit requirements so providers, health care facilities, Medicare Advantage and Part D plans, and States can focus on providing needed care to Medicare and Medicaid beneficiaries affected by COVID-19.

CMS Hospital without Walls (Temporary Expansion Sites)

- **Hospitals Able to Provide Inpatient Care in Temporary Expansion Sites:** As part of the CMS Hospital Without Walls initiative, hospitals can provide hospital services in other healthcare facilities and sites not currently considered to be part of a healthcare facility or set up temporary expansion sites to help address the urgent need to increase capacity to care for patients. Previously, hospitals were required to provide services to patients within their hospital departments, and have shared concerns about capacity for treating patients during the COVID-19 Public Health Emergency, especially those requiring ventilator and intensive care services. CMS is providing additional flexibilities for hospitals to create surge capacity by allowing them to provide room and board, nursing, and other hospital services at remote locations or sites not considered part of a healthcare facility such as hotels or community facilities. This flexibility will allow hospitals to separate COVID-19 positive patients from other non-COVID-19 patients to help efforts around infection control and preservation of personal protective equipment (PPE). For example, for the duration of the Public Health Emergency, CMS is allowing hospitals to screen patients at offsite locations, furnish inpatient and outpatient services at temporary expansion sites. Hospitals would still be expected to control and oversee the services provided at an alternative location.

- Under an additional initiative, CMS is relaxing certain conditions of participation (CoPs) for hospital operations to maximize hospitals ability to focus on patient care. The same initiative will also allow currently enrolled ambulatory surgical centers (ASCs), to temporarily enroll as hospitals and to provide hospital services to help address the urgent need to increase hospital capacity to take care of patients. Other interested entities, such as freestanding emergency departments, could pursue enrolling as an ASC and then pursue converting their enrollment to hospital during the PHE. ASCs that wish to enroll to receive temporary billing privileges as a hospital should call the COVID-19 Provider Enrollment Hotline to reach the contractor that serves their jurisdiction, and then will complete and sign an attestation form specific to the COVID-19 PHE. See <https://www.cms.gov/files/document/provider-enrollment-relief-faqs-covid-19.pdf> for additional information.
- **Off Site Patient Screening:** CMS is waiving the enforcement of section 1867(a) of the Social Security Act (the Emergency Medical Treatment and Active Labor Act, or EMTALA). This will allow hospitals, psychiatric hospitals, and critical access hospitals (CAHs) to screen patients at a location offsite from the hospital's campus to prevent the spread of COVID-19, so long as it is not inconsistent with the state emergency preparedness or pandemic plan.
- **Paperwork Requirements:** CMS is waiving certain specific paperwork requirements under this section only for hospitals which are considered to be impacted by a widespread outbreak of COVID-19. This allows hospitals to establish COVID-10 specific areas. Hospitals that are located in a state that has widespread confirmed cases would not be required to meet the following requirements:
 - 42 CFR §482.13(d)(2) with respect to timeframes in providing a copy of a medical record.
 - 42 CFR §482.13(h) related to patient visitation, including the requirement to have written policies and procedures on visitation of patients who are in COVID-19 isolation and quarantine processes.
 - 42 CFR §482.13(e)(1)(ii) regarding seclusion.
- **Physical Environment:** CMS is waiving certain requirements under the conditions at 42 CFR §482.41 and §485.623 to allow for flexibilities during hospital, psychiatric hospital, and CAH surges. CMS will permit non-hospital buildings/space to be used for patient care and quarantine sites, provided that the location is approved by the State (ensuring safety and comfort for patients and staff are sufficiently addressed). This allows for increased capacity and promotes appropriate cohorting of COVID-19 patients.
- **Temporary Expansion Sites:** For the duration of the PHE related to COVID-19, CMS is waiving certain requirements under the Medicare conditions of participation at 42 CFR §482.41 and §485.623 (as noted above) and the provider-based department requirements at 42 CFR §413.65 to allow hospitals to establish and operate as part of the hospital any location meeting the conditions of participation for hospitals in operation during the PHE. This waiver also allows hospitals to change the status of their current provider-based department locations to the extent necessary to address the needs of hospital patients as part of the State or local pandemic plan. This waiver will enable hospitals to meet the needs of Medicare beneficiaries. CMS also is offering some additional flexibilities to furnish inpatient services under arrangements.

APPENDIX III

2019-Novel Coronavirus (COVID-19) Medicare Provider Enrollment Relief Frequently Asked Questions (FAQs)

1. How is CMS using its authority under Section 1135 of the Social Security Act to offer flexibilities with Medicare provider enrollment to support the 2019-Novel Coronavirus (COVID-19) national emergency?

CMS is exercising its 1135 waiver authority in the following ways:

Physicians and Non-Physician Practitioners Eligible to Enroll in Medicare

- Establish toll-free hotlines to enroll and receive temporary Medicare billing privileges
- Waive the following screening requirements:
 - Criminal background checks associated with fingerprint-based criminal background checks (FCBC) - 42 C.F.R 424.518 (to the extent applicable)
 - Site visits - 42 C.F.R 424.517
- Postpone all revalidation actions

All Other Providers and Suppliers (including DMEPOS) Eligible to Enroll in Medicare

- Expedite any pending or new applications
 - All clean web applications will be processed within 7 business days and all clean paper applications in 14 business days
- Waive the following screening requirements for all enrollment applications received on or after March 1, 2020:
 - Application Fee – 42 C.F.R. 424.514
 - Criminal background checks associated with fingerprint-based criminal background checks (FCBC) – 42 C.F.R. 424.518 (to the extent applicable)
 - Site-visits – 42 C.F.R. 424.517
- Postpone all revalidation actions

2. What are the COVID-19 Medicare Provider Enrollment Hotlines?

CMS has established toll-free hotlines at each of the Medicare Administrative Contractors (MACs) to allow physicians, non-physician practitioners and Part A certified providers and suppliers establishing isolation facilities to initiate temporary Medicare billing privileges. Physicians and non-physician practitioners may also contact the hotline to report a change in practice location.

The hotlines should also be used if providers/suppliers have questions regarding the other provider enrollment flexibilities afforded by the 1135 waiver.

3. What are the Medicare Provider Enrollment Hotline numbers and hours of operation?

2019-Novel Coronavirus (COVID-19) Medicare Provider Enrollment Relief Frequently Asked Questions (FAQs)

Providers and suppliers should only contact the hotline for the MAC that services their geographic area. To locate your designated MAC refer to <https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/MACs-by-State-June-2019.pdf>.

The hotlines are operational Monday – Friday and at the specified times below.

CGS Administrators, LLC (CGS)

The toll-free Hotline Telephone Number: 1-855-769-9920

Hours of Operation: 7:00 am – 4:00 pm CT

First Coast Service Options Inc. (FCSO)

The toll-free Hotline Telephone Number: 1-855-247-8428

Hours of Operation: 8:30 AM – 4:00 PM EST

National Government Services (NGS)

The toll-free Hotline Telephone Number: 1-888-802-3898

Hours of Operation: 8:00 am – 4:00 pm CT

National Supplier Clearinghouse (NSC)

The toll-free Hotline Telephone Number: 1-866-238-9652

Hours of Operation: 9:00 AM – 5:00 PM ET

Novitas Solutions, Inc.

The toll-free Hotline Telephone Number: 1-855-247-8428

Hours of Operation: 8:30 AM – 4:00 PM EST

Noridian Healthcare Solutions

The toll-free Hotline Telephone Number: 1-866-575-4067

Hours of Operation: 8:00 am – 6:00 pm CT

Palmetto GBA

The toll-free Hotline Telephone Number: 1-833-820-6138

Hours of Operation: 8:30 am – 5:00 pm ET

Wisconsin Physician Services (WPS)

The toll-free Hotline Telephone Number: 1-844-209-2567

Hours of Operation: 7:00 am – 4:00 pm CT

- 4. Can Part A certified providers and suppliers establishing isolation facilities utilize the provider enrollment hotline?**

2019-Novel Coronavirus (COVID-19) Medicare Provider Enrollment Relief Frequently Asked Questions (FAQs)

Part A certified providers and suppliers, who are establishing new isolation facilities which will operate during the public health emergency in order to furnish care to patients with COVID-19, can initiate temporary Medicare billing privileges via the hotline. Part A certified providers and suppliers will be asked to provide limited information, including, but not limited to, Legal Business Name, National Provider Identifier (NPI), Tax Identification Number (TIN), state license, address information and contact information (telephone number).

CMS is waiving the following screening requirements:

- Application Fee – 42 C.F.R. 424.514
- Criminal background checks associated with the fingerprint-based criminal background checks (FCBC) – 42 C.F.R. 424.518 (to the extent applicable)
- Site-visits – 42 C.F.R. 424.517

The MAC will attempt to screen the certified provider or supplier over the phone regarding the establishment of an isolation facility, however, temporary Medicare billing privileges will not be established during the phone conversation and may take up to 2 business days since additional certification actions are required to be completed that involve the CMS Location Offices. Once final approval is received from the CMS Location Office, the MAC will notify the certified provider or supplier of their temporary Medicare billing privileges and effective date via email. Note: Certified providers and suppliers who do not pass the screening requirements will not be granted temporary Medicare billing privileges and cannot be paid for services furnished to Medicare beneficiaries.

5. How long will the provider enrollment hotline be operational?

The hotline will be providing Medicare temporary billing privileges and addressing questions regarding the other provider enrollment flexibilities afforded by the 1135 waiver until the public health emergency declaration is lifted.

6. What information should I have available to enroll as a physician or non-physician practitioner when I call the provider enrollment hotline?

To initiate temporary billing privileges, you will be asked to provide limited information, including, but not limited to, Legal Name, National Provider Identifier (NPI), Social Security Number, a valid in-state or out-of-state license, address information and contact information (telephone number).

7. How long will it take the MAC to approve a physician or non-physician practitioner's temporary Medicare billing privileges?

2019-Novel Coronavirus (COVID-19) Medicare Provider Enrollment Relief Frequently Asked Questions (FAQs)

The MAC will attempt to screen and enroll the physician or non-physician practitioner over the phone and will notify the physician or non-physician practitioner of their approval or rejection of temporary Medicare billing privileges during the phone conversation.

The MAC will follow up with a letter via email to communicate the approval or rejection of the physician or non-physician practitioner's temporary Medicare billing privileges. Note: Physicians and non-physician practitioners who do not pass the screening requirements will not be granted temporary Medicare billing privileges and cannot be paid for services furnished to Medicare beneficiaries.

8. What will be the effective date of my temporary Medicare billing privileges?

Physicians and non-physician practitioners will be assigned an effective date as early as March 1, 2020. They may bill for services furnished on or after the effective date and until the public health emergency is lifted.

9. I am not a physician or non-physician practitioner. Can I use the enrollment hotline to submit my initial enrollment or change of information?

All other providers and suppliers, including DMEPOS suppliers, but excluding Part A certified providers and suppliers establishing isolation facilities, are required to submit initial enrollments and changes of information via the appropriate CMS-855 application. Your MAC will expedite their processing of these applications if received on or after March 1, 2020. Specifically, all clean web applications received on or after March 18, 2020, will be processed within 7 business days, and all clean paper applications received on or after March 18, 2020, will be processed in 14 business days. CMS encourages providers to submit their applications via Internet-Based PECOS (<https://pecos.cms.hhs.gov/pecos/login.do>).

CMS is waiving the following screening requirements for all enrollment applications received on or after March 1, 2020:

- Application Fee – 42 C.F.R. 424.514
- Criminal background checks associated with the FCBC – 42 C.F.R. 424.518 (to the extent applicable)
- Site-visits – 42 C.F.R. 424.517

CMS is also postponing all revalidation actions.

10. Will my temporary Medicare billing privileges as a physician or non-physician practitioner be deactivated once the national emergency is lifted?

2019-Novel Coronavirus (COVID-19) Medicare Provider Enrollment Relief Frequently Asked Questions (FAQs)

Your Medicare billing privileges are being granted on a provisional basis as a result of the public health emergency declaration and are temporary. Upon the lifting of the public health emergency declaration, you will be asked to submit a complete CMS-855 enrollment application in order to establish full Medicare billing privileges, following the MAC's review of your application. Failure to respond to the MAC's request within 30 days of the notification, will result in the deactivation of your temporary billing privileges. No payments can be received for services provided after the deactivation of your temporary billing privileges.

11. Can Medicare fee-for-service rules regarding physician State licensure be waived in an emergency?

The HHS Secretary has authorized 1135 waivers that allow CMS to waive the Medicare requirement that a physician or non-physician practitioner must be licensed in the State in which s/he is practicing for individuals for whom the following four conditions are met: 1) the physician or non-physician practitioner must be enrolled as such in the Medicare program, 2) the physician or non-physician practitioner must possess a valid license to practice in the State which relates to his or her Medicare enrollment, 3) the physician or non-physician practitioner is 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 or her professional capacity, and 4) the physician or non-physician practitioner is not affirmatively excluded from practice in the State or any other State that is part of the 1135 emergency area.

In addition to the statutory limitations that apply to 1135-based licensure waivers, an 1135 waiver, when granted by CMS, does not have the effect of waiving State or local licensure requirements or any requirement specified by the State or a local government as a condition for waiving its licensure requirements. Those requirements would continue to apply unless waived by the State. Therefore, in order for the physician or non-physician practitioner to avail him- or herself of the 1135 waiver under the conditions described above, the State also would have to waive its licensure requirements, either individually or categorically, for the type of practice for which the physician or non-physician practitioner is licensed in his or her home State.

A physician or non-physician practitioner may seek an 1135-based licensure waiver from CMS by contacting the Medicare Provider Enrollment Hotline for the MAC that services their geographic area.

12. Can the distant site practitioner furnish Medicare telehealth services from their home? Or do they have to be in a medical facility?

2019-Novel Coronavirus (COVID-19) Medicare Provider Enrollment Relief Frequently Asked Questions (FAQs)

There are no payment restrictions on distant site practitioners furnishing Medicare telehealth services from their homes. The practitioner is not required to update their Medicare enrollment with the home location. The practitioner should list the home address on the claim to identify where the services were rendered. The discrepancy between the practice location in the Medicare enrollment (clinic/group practice) and the practice location identified on the claim (provider's home location) will not be an issue for claims payment.

13. I am due to revalidate. Will my due date be extended?

CMS is temporarily ceasing revalidation efforts for all Medicare providers or suppliers. Upon the lifting of the public health emergency, CMS will resume revalidation activities.

14. Will the Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS) accreditation and reaccreditation requirements be waived?

CMS is not requiring accreditation for newly enrolling DMEPOS suppliers and extending any expiring supplier accreditation for a 90-day time period. CMS will monitor all billing activity during the emergency and continue to reassess this requirement. Aberrant billing practices may be subject to further action.

15. I have an application pending with the MAC that was submitted prior to March 1, 2020. When will it be approved?

Pending applications for all providers and suppliers received prior to March 1, 2020 are being processed in accordance with existing processing timeframes. Generally, web applications are processed within 45 days and paper applications within 60 days.

16. I am currently opted-out. Can I terminate my opt-out status early and enroll in Medicare?

Under the 1135 waiver authority, the opt-out requirements can be waived to allow practitioners to terminate their opt-out early and enroll. Opted-out physicians and practitioners can contact their MAC through the provider enrollment hotline to terminate their opt-out and establish Medicare temporary billing privileges. Your Medicare billing privileges are being granted on a provisional basis as a result of the public health emergency declaration and are temporary.