

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

At the beginning of the COVID-19 Public Health Emergency (PHE), CMS used emergency waiver authorities and various regulatory authorities to enable flexibilities so providers could rapidly respond to people impacted by COVID-19. CMS has developed a cross-cutting initiative to use a comprehensive, streamlined approach to reestablish certain health and safety standards and other financial and program requirements at the eventual end of the COVID-19 public health emergency.

This CMS cross-cutting initiative aims to evaluate CMS-issued PHE blanket waivers and flexibilities to prepare the health care system for operation after the PHE. This review is being done in three concurrent phases:

1. CMS is assessing the need for continuing certain blanket waivers based on the current phase of the PHE. Since the beginning of the PHE, CMS has both added and terminated flexibilities and waivers as needed. In doing so, CMS considered the impacts on communities — including underserved communities — and the potential barriers and opportunities that the flexibilities may address.
2. CMS is assessing which flexibilities would be most useful in a future PHE, such as natural and man-made disasters and other emergencies, to ensure a rapid response to future emergencies, both locally and nationally, or to address the unique needs of communities that may experience barriers to accessing health care.
3. CMS is continuing to collaborate with federal partners and the health care industry to ensure that the health care system is holistically prepared for addressing future emergencies.

As CMS identifies barriers and opportunities for improvement, the needs of each person and community served will be considered and assessed with a health equity lens to ensure our analysis, stakeholder engagement, and policy decisions account for health equity impacts on members of underserved communities and health care professionals disproportionately serving these communities.

### **COVID-19 Vaccines**

On October 28, 2020, CMS released an Interim Final Rule with comment period (IFC) announcing that Medicare Part B would establish coding and payment rates for COVID-19 vaccines and their administration as preventive vaccines, without cost-sharing, as soon as the Food and Drug Administration (FDA) authorized or approved the product through an

Emergency Use Authorization (EUA) or Biologics License Application (BLA). The IFC also implemented provisions of the CARES Act to ensure swift coverage of COVID-19 vaccines by private health insurance plans participating in the Health Insurance Marketplace, without cost sharing, from both in- and out-of-network providers, during the course of the public health emergency (PHE).

### **Payment After the End of the PHE**

CMS will continue to pay approximately \$40 per dose for administering COVID-19 vaccines in outpatient settings for Medicare beneficiaries through the end of the calendar year that the PHE ends.

Effective January 1 of the year following the year that the PHE ends, CMS will set the payment rate for administering COVID-19 vaccines to align with the payment rate for administering other Part B preventive vaccines.

### **Additional Payment for Administering the Vaccine in the Patient's Home**

CMS also established an additional payment amount of approximately \$35.50 per dose to administer COVID-19 vaccines in the home for certain Medicare patients. For vaccines requiring multiple doses, this payment applies for each dose in the series, including any additional or booster doses, and we geographically adjust the additional amount and administration rate based on where the provider or supplier administers the vaccine.

### **Additional Payment for Administering the Vaccine in the Patient's Home After the End of the PHE**

We'll continue to pay a total payment of approximately \$75 per dose to administer COVID-19 vaccines in the home for certain Medicare patients through the end of the calendar year that the PHE ends.

**Note:** The [Calendar Year 2023 Physician Fee Schedule](#) proposed rule includes proposals that could impact these policies, and we anticipate issuing the final rule later this year.

### **More information: COVID-19 vaccine toolkits**

- [Providers](#)
  - [Payment](#)
  - [Billing](#)
  - [Coding](#)
- [Health & Drug Plans](#)
- [State Medicaid programs](#)

### **COVID-19 Monoclonal Antibodies**

The FDA issued emergency use authorizations (EUA) for monoclonal antibody therapies used for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients with positive COVID-19 test results who are at high risk for progressing to severe COVID-19 and/or

hospitalization. The FDA also issued an EUA for a monoclonal antibody product used as a pre-exposure prophylaxis of COVID-19 in adults and pediatric patients with certain conditions.

During the COVID-19 public health emergency (PHE), CMS covers and pays for these infusions or injections the same way it covers and pays for COVID-19 vaccines when furnished consistent with the EUA. There's also no beneficiary cost sharing and no deductible for COVID-19 monoclonal antibody products when providers administer them.

CMS doesn't pay for the COVID-19 monoclonal antibody product when a health care setting has received it for free. If a health care setting purchased the product from the manufacturer, Medicare pays the reasonable cost or 95% of the average wholesale price.

More information: [COVID-19 Monoclonal Antibodies](#)

### **Payment After the End of the PHE**

Effective January 1 of the year following the year that the PHE ends, CMS will pay for monoclonal antibodies:

- As we pay for biological products under [Section 1847A of the Social Security Act](#).
- Through the applicable payment system, using the appropriate coding and payment rates, similar to the way we pay for administering other complex biological products.

**Note:** The [Calendar Year 2023 Physician Fee Schedule](#) proposed rule includes proposals that could impact these policies, and we anticipate issuing the final rule later this year.

### **COVID-19 Oral Antivirals**

The FDA issued an emergency use authorization (EUA) for oral antivirals for the treatment of mild-to-moderate coronavirus disease (COVID-19) in adults and pediatric patients with positive COVID-19 test results and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

During the COVID-19 public health emergency (PHE), oral antivirals are procured by the U.S. government (USG) and provided to pharmacies when furnished consistent with the EUA. There's also no beneficiary cost sharing and no deductible for COVID-19 oral antivirals.

### **Payment After the End of the PHE**

Oral antivirals for COVID-19 that otherwise meet the statutory requirements for Part D coverage at section [1860D-2\(e\)](#) of the Social Security Act must be covered by Part D plans, as a formulary product or through the formulary exception process, immediately upon FDA approval.

### **COVID-19 VEKLURY™ (remdesivir) in the Outpatient Setting**

On [January 21, 2022](#), the FDA updated the approval of VEKLURY™ (remdesivir) and authorized its use in the outpatient setting. The federal government didn't purchase a supply of remdesivir. Medicare Part B provides payment for the drug and its administration under the applicable Medicare Part B payment policy when a facility or practitioner provides it in the outpatient setting, according to the FDA approval and authorization. In most cases, the Medicare patient's yearly Part B deductible and 20% co-insurance apply.

*Coverage for Over-the-Counter COVID-19 Tests.* On April 4, 2022, Medicare implemented a demonstration program to allow people with Medicare to receive up to eight tests per calendar month at no cost. This is the first time that Medicare has covered an over-the-counter, self-administered, test. This new initiative enables people with Medicare Part B, including those enrolled in a Medicare Advantage plan, to receive tests at no cost from providers and suppliers who are eligible to participate. Pharmacies and other health care providers interested in participating in this initiative can get more information here:

<https://www.cms.gov/COVIDOTCtestsProvider>. This program will end at the end of the COVID-19 public health emergency.

### **Medicare Telehealth**

During the PHE, the Secretary has been using the waiver authority under section 1135 of the Act to create flexibilities in the requirements of section 1834(m)(1) of the Act and 42 CFR § 410.78 for use of interactive telecommunications systems to furnish telehealth services. This allowed clinicians to furnish more services to beneficiaries via telehealth so that they can take care of their patients while mitigating the risk of the spread of the virus. During the public health emergency, all beneficiaries across the country have been able to receive Medicare telehealth and other communications technology-based services wherever they are located. Clinicians are able to provide these services to new and established patients. **Additionally, after the PHE ends, the Consolidated Appropriations Act, 2022 provides for a 151-day extension for some of these flexibilities.**

CMS has also been using these section 1135 waivers to create further PHE flexibilities to the requirements of section 1834(m)(1) of the Act and 42 CFR § 410.78(a)(3) for the use of interactive telecommunications systems to furnish telehealth services, to the extent they require use of video technology, for certain services. This waiver allows the use of audio-only equipment to furnish services described by the codes for audio-only telephone evaluation and management services, and behavioral health counseling and educational services. Unless provided otherwise, other services included on the [Medicare Telehealth Services List](#) must be furnished using, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site.

CMS has waived the requirements of section 1834(m)(4)(E) of the Act and 42 CFR § 410.78 (b)(2), which specify the types of practitioners who may bill for their services when furnished as Medicare telehealth services from a distant site. The waiver of these requirements expands the types of health care professionals who can furnish distant site telehealth services to include all those who are eligible to bill Medicare for their professional services. As a result, a broader range of practitioners, such as physical therapists, occupational therapists, and speech language pathologists can use telehealth to provide many Medicare services.

Additionally, we modified the process to add services to the Medicare Telehealth Services List during the PHE, allowing us to consider adding appropriate services on a sub-regulatory basis, as they were requested, as practitioners were actively learning how to use telehealth. A complete list of all Medicare telehealth services can be found here:

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

To reduce exposure risk, during the PHE and for an extended period of time for many services, the following have been added to the Medicare Telehealth Services List:

- 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; CPT code G9685).
- Cardiac Care Services (CPT codes 93797-93798).
- Critical Care Services (CPT codes 99291-99292).
- Domiciliary, Rest Home, or Custodial Care Services, New and Established patients (CPT codes 99324- 99328; CPT codes 99336-99337 — CPT codes 99334 and 99335 were added permanently).
- ESRD Services (CPT code 90953; CPT code 90956; CPT code 90959; CPT code 90962).
- Eye Examinations (CPT code 92002; CPT code 92004; CPT code 92012; CPT code 92014).

- Home Visits, New and Established Patient, All levels (CPT codes 99341- 99345; CPT codes 99349; CPT code 99350 — CPT codes 99347 and 99348 were added permanently).
- Inpatient Neonatal and Pediatric Critical Care, Initial and Subsequent (CPT codes 99468-99469; CPT codes 99471-99473; CPT codes 99475- 99476; CPT codes 99479-99480).
- Initial and Continuing Intensive Care Services (CPT code 99477-99478).
- Care Planning for Patients with Cognitive Impairment (CPT code 99483 was added permanently).
- Group and Individual Psychotherapy (CPT code 90875; CPT code 90901; CPT code 96125; CPT code 96127; CPT codes 96170-96171; CPT codes 97129-97130; CPT codes 97150-97158; CPT code 0362T; CPT code 0373T; G0410; CPT codes G0422-G0423 — CPT code 90853 was added permanently).
- Psychological and Neuropsychological Testing (CPT codes 96130-96133; CPT codes 96136-96139).
- Neurostimulator Services (CPT codes 95970-95972; CPT codes 95983-95984).
- Rehabilitation — Pulmonary and Cardiac (CPT codes 94625-94626; CPT code 94664).
- Speech and Hearing Services (CPT code 92526; CPT code 92550; CPT code 92552; CPT code 92553; CPT codes 92555-92557; CPT code 92563; CPT code 92565; CPT code 92567; CPT code 92568; CPT codes 92601-92604; CPT codes 92607-92610; CPT codes 92625-92627; CPT code 96105; CPT code 96110; CPT codes 96112-96113; CPT code S9152).
- Therapy Services, Physical and Occupational Therapy, All levels (CPT codes 97161-97168; CPT codes 97110, 97112, 97116, 97530, 97535, 97537, 97542, 97763, 97750, 97755, 97760, 97761, 98960-98962, 92521-92524, 92507).
- Radiation Treatment Management Services (CPT code 77427).
- Ventilation Services (CPT codes 94002-94005).
- Telephone E/M (CPT codes 99441-99443).

#### **Remote Evaluations, Virtual Check-Ins & E-Visits**

- Medicare pays for e-visits, which are brief communication service with practitioners, professionals, clinicians, and providers via a number of communication technology modalities, including synchronous discussion over a telephone or exchange of

information through video or image. During the PHE, clinicians can provide remote evaluation of patient video/images and virtual check-in services (HCPCS codes G2010, G2012) to both new and established patients.

- In addition to physicians and other non-physician practitioners, during the PHE, licensed clinical social workers, clinical psychologists, physical therapists, occupational therapists, and speech language pathologists can provide e-visits. E-visits are non-face-to-face communications with the practitioner using online patient portals. (HCPCS codes G2250-G2251).

### **Telephone Evaluation, Management/Assessment and Management Services, and Behavioral Health and Education Services**

- During the PHE, a broad range of clinicians, including physicians, have been able to provide certain services by telephone to their patients.
- Medicare payment for the telephone evaluation and management visits (CPT codes 99441-99443) is equivalent to the Medicare payment for office/outpatient visits with established patients effective March 1, 2020.
- When clinicians have furnished an evaluation and management (E/M) service that otherwise would have been reported as an in-person or telehealth visit, using audio-only technology, practitioners have been able to bill using these telephone E/M codes provided that it is appropriate to furnish the service using audio-only technology and all of the required elements in the applicable telephone E/M code (99441-99443) description are met.
- Using section 1135 waiver authority, CMS has been allowing many behavioral health and education services to be furnished via telehealth using audio-only communications. The full Medicare Telehealth Services List notes which services are eligible to be furnished via audio-only technology, including the telephone evaluation and management visits: <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes>.

### **Remote Patient Monitoring**

- Using the waiver authority under section 1135 of the Act during the PHE, we have permitted clinicians to bill for remote patient monitoring (RPM) services furnished to both new and established patients, and to patients with both acute and chronic conditions. **When the PHE ends, clinicians must once again have an established relationship with the patient prior to providing RPM services.** However, we will continue to allow RPM services to be furnished to patients with both acute and chronic conditions (pre-PHE, an initiating visit was required before RPM services could be billed).

- Current CPT coding guidance states that the RPM services described by CPT codes 99453 and 99454 cannot be reported when fewer than 16 days of data are collected. During the PHE, we used section 1135 waiver authority to allow clinicians to bill CPT codes 99453 and 99454 when as few as two days of data were collected if the patient was diagnosed with, or was suspected of having, COVID-19 and as long as all other billing requirements of the codes were met. **When the PHE ends, clinicians must only bill for these services when at least 16 days of data have been collected.**

### **Removal of Frequency Limitations on Certain Medicare Telehealth Services**

Using section 1135 waiver authority, on an interim basis during the PHE, we removed the frequency restrictions for the following listed codes furnished via Medicare telehealth. These restrictions were established through rulemaking and implemented through systems edits.

**After the PHE, all applicable rules for furnishing these services, unless otherwise specified, will once again take effect:**

- A subsequent inpatient visit could 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 could be furnished via Medicare telehealth, without the limitation that the telehealth visit is once every 14 days (CPT codes 99307-99310).
- Critical care consult codes could be furnished to a Medicare beneficiary by telehealth beyond the once per day limitation (CPT codes G0508-G0509).

### **Other Medicare Telemedicine and Remote Patient Care**

- Medicare patients with end-stage renal disease (ESRD) who are on home dialysis must receive a face-to-face visit, without the use of telehealth, at least monthly in the case of the initial three months of home dialysis and at least once every three consecutive months after the initial three months. We used section 1135 waiver authority during the PHE to allow these visits to be furnished as telehealth services.
- To the extent that a National Coverage Determination (NCD) or Local Coverage Determination (LCD) would otherwise require an in-person, face-to-face visit for evaluations and assessments, we used section 1135 waiver authority to remove those requirements so that these services can be furnished via telehealth during the public health emergency.
- As a flexibility for the COVID-19 PHE, annual beneficiary consent for virtual check-ins may be obtained at the same time as the services are furnished for both new and established patients.



- *Physician visits*: Using the waiver authority under section 1135 of the Act during the PHE, CMS created flexibilities allowing physicians and non-physician practitioners during the PHE to perform in-person visits for nursing home residents and allow visits to be conducted, as appropriate, via telehealth options.
- *Opioid Treatment Programs (OTPs)*: During the PHE, patient counseling and therapy services have been provided by telephone in cases where two-way interactive audio-video communication technology is not available to the beneficiary, and all other applicable requirements are met. This flexibility has been made permanent for OTPs in the [CY 2022 PFS final rule](#). During the PHE, periodic assessments have been conducted via two-way interactive audio-video communication technology and may have been provided by telephone, only in cases where the beneficiary has not had access to two-way interactive audio-video communication technology and all other applicable requirements have been met. **When the PHE ends, OTPs will be required to furnish periodic assessments in person or via two-way interactive audio-video communication technology.**

### **Workforce**

- *Medicare Physician Supervision Requirements*: CMS has temporarily modified the regulatory definition of direct supervision, which requires the supervising physician or practitioner to be “immediately available” to furnish assistance and direction during the service, to include “virtual presence” of the supervising clinician through the use of real-time audio and video technology. This flexibility is currently set to return to pre-PHE rules at the end of the calendar year that the PHE ends.
- *Supervision Requirements for Non-Surgical Extended Duration Therapeutic Services*: During the PHE, direct supervision has not been required at the initiation of non-surgical extended duration therapeutic services provided in hospital outpatient departments and critical access hospitals. Instead, a general level of supervision could be provided for the entire duration of these services, so the supervising physician or practitioner has not been required to be immediately available. **In the [CY 2021 OPPTS/ASC final rule](#), CMS made this provision permanent, so after the PHE ends, this policy will stay in effect (85 FR 85866).**
- *Medicare Physician Supervision and Auxiliary Personnel*: The physician could have entered into a contractual arrangement that meets the definition of auxiliary personnel at 42 CFR 410.26, including with staff of another provider/supplier types, 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, which can provide the staff and technology necessary to provide care that, ordinarily, would have been provided incident to a physician’s service (including services that are allowed to be performed via telehealth). In such instances, the

provider/supplier would have sought payment for any services provided by auxiliary personnel from the billing practitioner and would not have submitted claims to Medicare for such services.

During the PHE, informed consent to receive services furnished by auxiliary personnel, including for example CCM services, must have been obtained prior to the start of the service. Consent has not had to be obtained at the required initiating visit for CCM that must be performed by the billing practitioner, but it could have been obtained at that time. Since the billing practitioner discusses CCM with the beneficiary during the initiating visit, if consent has been separately obtained, it may have been obtained under general supervision and could have been verbal if it was documented in the medical record and included notification of the required information. Further, there need not be an employment relationship between the person obtaining the consent and the billing practitioner. This flexibility is currently set to return to pre-PHE rules at the end of the calendar year that the PHE ends.

- *Medicare Nonphysician Practitioners:* We created the flexibility at 42 CFR § 410.32(b), on an interim basis during the PHE, to allow nurse practitioners (NPs), clinical nurse specialists (CNSs), certified nurse-midwives (CNMs), and physician assistants (PAs) to supervise diagnostic tests as authorized under state law and licensure. These practitioners continue the required statutory relationships with supervising or collaborating physicians.
- *Physical Therapists and Occupational Therapists:* The treating physical or occupational therapist who develops, or is responsible for, the maintenance program or plan has been able to delegate the performance of the related maintenance therapy services to a therapy assistant when clinically appropriate. This has freed up the therapist to furnish other needed services during the PHE requiring his/her evaluative and assessment skills. This flexibility has been made permanent via CY 2021 rulemaking, allowing physical and occupational therapists to delegate maintenance therapy services to their therapy assistants as clinically appropriate in the same manner that rehabilitation services are delegated.
- *Pharmacists:* We have been allowing pharmacists, as well as other health care professionals who are authorized to order lab tests under the state scope of practice and other relevant laws, to order COVID-19 tests for Medicare beneficiaries during the PHE. This does not mean that these pharmacists and other health care professionals have been able to enroll in the Medicare program to furnish and bill for services they furnish to beneficiaries; rather, it has allowed Medicare to pay for tests that they order. **This flexibility is currently set to return to pre-PHE rules when the PHE ends.**
- *Teaching Physicians:* During the PHE, services furnished by a resident in a teaching setting could be billed by a teaching physician who is present during the key portion of

the service. If the training setting is located outside of a metropolitan statistical area (MSA), the teaching physician could have a virtual presence through audio/video real-time technology. During the PHE, this virtual presence of the teaching physician is allowed for all teaching settings. Under the so-called primary care exception at section 415.174, a teaching physician may bill for certain services when they direct and review the care furnished by up to four residents at a time. For teaching settings outside of an MSA, the teaching physician may have a virtual presence when directing and reviewing services each resident provides during or at once after each visit. For all teaching settings during the PHE, teaching physicians may direct care and review services each resident provides during or at once after each visit virtually. These flexibilities can be helpful in the event that the teaching physician is not available to be present with the resident due to quarantine or social distancing.

- *Hospital Services:* CMS has waived requirements at § 482.12(c)(1)-(2) and (4) that Medicare patients in the hospital must be under the care of a physician. This has allowed hospitals to use other practitioners, such as physician assistants and nurse practitioners, to the fullest extent possible. This waiver is required to be implemented in accordance with a state's emergency preparedness or pandemic plan and ends upon the conclusion of the PHE.
- *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 the PHE, the Chief Medical Officer or equivalent of a hospital or facility has had the authority to make those staffing decisions. This waiver ends upon the conclusion of the PHE.
- CMS has exercised enforcement discretion and has not enforced the current clinical indications in LCDs for therapeutic continuous glucose monitors during this public health emergency. This change is intended to permit more COVID-19 patients with diabetes to better monitor their glucose and adjust insulin doses from home. This waiver ends upon the conclusion of the PHE.
- *Practitioner Locations:* During the PHE, CMS has waived the Medicare requirement that a physician or non-physician practitioner must be licensed in the state in which they are practicing if the physician or practitioner 1) is enrolled as such in the Medicare program, 2) has a valid license to practice in the state reflected in their 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 section 1135 emergency area. A physician or non-physician practitioner could seek an 1135-based licensure waiver from CMS by contacting the provider enrollment hotline for the Medicare Administrative Contractor that serviced their geographic area. This waiver did 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. **When the PHE ends, current regulations will continue to allow for a deferral to state law.** We originally implemented the waiver out of an abundance of caution; however, it turned out that regulations that existed before the PHE allowed for a deferral to state law.

- *Modification of 60-day limit for Substitute Billing Arrangements (Locum Tenens):* CMS has modified the 60-day limit in section 1842(b)(6)(D)(iii) of the Social Security Act to allow a physician or physical therapist to use the same substitute for the entire time he or she is unavailable to provide services during the COVID-19 emergency, plus an additional period of no more than 60 continuous days after the public health emergency expires. On the 61st day after the public health emergency ends (or earlier if desired), the regular physician or physical therapist must use a different substitute or return to work in his or her practice for at least one day in order to reset the 60-day clock. The modified timetable applies to both types of substitute billing arrangements under Medicare fee-for-service (i.e., reciprocal billing arrangements and fee-for-time compensation arrangements, formerly known as locum tenens).

**Note:** Under the Medicare statute, only 1) physicians and 2) physical therapists who furnish outpatient physical therapy services in a health professional shortage area (HPSA), a medically underserved area (MUA), or a rural area can receive Medicare fee-for-service payment for services furnished by a substitute under a substitute billing arrangement. In addition, Medicare can pay for services under a substitute billing arrangement only when the regular physician or physical therapist is unavailable to provide the services. Finally, as provided by law, a regular physician or physical therapist who has been called or ordered to active duty as a member of a reserve component of the U.S. armed forces may continue to use the same substitute for an unlimited time even after the emergency ends.

- *Provider Enrollment:* During the PHE, CMS has established toll-free hotlines for physicians, non-physician practitioners, and Part A certified providers and suppliers who have established isolation facilities to enroll and receive temporary Medicare billing privileges. **When the PHE ends, the hotlines will be shut down.** Additionally, CMS has provided the following flexibilities for provider enrollment:
  - *Screening requirements:*
    - Site Visits: CMS waived provider enrollment site visits for moderate and high-risk providers/suppliers. ***(This waiver terminated on 07-06-2020 and CMS, in accordance with 42 C.F.R. §§ 424.517 and 424.518, resumed all provider enrollment site visits.)***
    - *Fingerprint-based criminal background checks:* CMS waived the requirement for fingerprint-based criminal background checks for 5% or greater owners of

newly enrolling high risk categories of providers and suppliers (e.g., newly-enrolling Home Health Agencies, DMEPOS suppliers, Medicare Diabetes Prevention Programs, Opioid Treatment Programs). ***(This waiver terminated on 10/31/2021 and CMS, in accordance with 42 C.F.R. § 424.518, resumed requesting fingerprints for all newly enrolling high risk providers and suppliers.)***

- ***Application Fees:*** CMS waived the collection of application fees for institutional providers who are initially enrolling, revalidating, or adding a new practice location. ***(This waiver terminated on 10/31/2021 and CMS, in accordance with 42 C.F.R. § 424.514, resumed collecting application fees.)***
- ***Revalidation:*** CMS postponed all revalidation actions. This did not prevent a provider who wants to submit a revalidation application from doing so; MACs processed revalidation applications. ***(This waiver terminated on 10/31/2021 and CMS resumed a phased-in approach to revalidation activities; revalidation letters began being mailed again in October 2021 with due dates in early 2022.)***
- ***Expedited Enrollment:*** CMS expedited any pending or new applications from providers and suppliers, including physicians and non-physician practitioners received on or after March 1, 2020. **When the PHE ends, CMS will resume normal application processing times.**
- ***Opt-Out Enrollment:*** CMS allowed practitioners to cancel their opt-out status early and enroll in Medicare to provide care to more patients. CMS also allowed MACs to accept opt-out cancellation requests via email, fax, or phone call to the hotline. CMS allowed a provider to submit an application (an 855-I or 855-R for example) to cancel their opt-out. Providers were not required to submit a written notification to cancel their opt-out status. **When the PHE ends, this waiver will terminate and opted-out practitioners will not be able to cancel their opt-out statuses earlier than the applicable regulation at 42 CFR 405.445 allows for.**
- ***Reporting Home Address:*** During the PHE, CMS allowed practitioners to render telehealth services from their home without reporting their home address on their Medicare enrollment while continuing to bill from their currently enrolled location. **When the PHE ends, practitioners will be required to resume reporting their home address on the Medicare enrollment.**
- ***State Licensure:*** During the PHE, CMS allowed licensed physicians and other practitioners to bill Medicare for services provided outside of their state of enrollment. **CMS has determined that, when the PHE ends, CMS regulations will continue to allow for a total deferral to state law.** Thus, there is no CMS-based requirement that a provider must be licensed in its state of enrollment.

- *Student Documentation:* In the [CY 2020 Physician Fee Schedule \(PFS\) final rule](#), we adopted simplified medical record documentation requirements for physicians and certain nonphysician practitioners to allow the billing clinician to review and verify, rather than re-document, information added to the medical record by any member of the health care team. During the public health emergency, this principle has applied across the spectrum of all Medicare-covered services, and has also applied to therapists so that they may review and verify, rather than redocument, notes added to the medical record by any other member of the health care team, including therapy or other students. **These simplified medical record documentation requirement policies were finalized and will continue to be in effect after the PHE ends.**

### **Medicare COVID-19 Diagnostic Testing and Reporting**

- *Price Transparency for COVID-19 Testing:* In an Interim Final Rule with Comment Period (IFC) issued October, 28, 2020, CMS implemented the CARES Act requirement that providers of a diagnostic test for COVID-19 to make public the cash price for such tests on their websites. Providers without websites have been required to provide price information in writing within two business days upon request and on a sign posted prominently at the location where the provider performs the COVID-19 diagnostic test, if such location is accessible to the public. Noncompliance may result in civil monetary penalties up to \$300 per day. **After the PHE, in accordance with the CARES Act, this special price transparency requirement will terminate. Price transparency requirements under other laws and regulations will continue to apply.**
- *COVID-19 Diagnostic Testing:* During the PHE, CMS specified that the level one E/M visit (CPT code 99211), which can ordinarily be billed only when clinical staff perform services incident to the services of the billing physician or practitioner for an established patient, can be billed when clinical staff assess a patient and collect a specimen for a COVID-19 diagnostic test for both new and established patients. **After the PHE, the usual requirements for billing the level 1 E/M visit (CPT code 99211) apply.**
- *Physician or Practitioner Order:* In the September 2, 2020 Interim Final Rule with Comment (85 FR 54837-54840), we revised a previous policy that covered multiple COVID-19 diagnostic laboratory tests for an individual beneficiary without the order of a treating physician or other practitioner. Under this revised policy, each beneficiary may receive Medicare coverage for one COVID-19 test, and certain related tests as described in the May 8, 2020, Interim Final Rule with Comment (85 FR 27550-27629), without the order of a physician or other health practitioner, but Medicare will require such an order to cover further COVID-19 and related tests. CMS believes that broad COVID-19 testing without the order of any healthcare professional —including testing for the related conditions identified in the May 8, 2020, COVID-19 IFC — may result in a beneficiary not receiving the medical attention and oversight required to ensure that diagnosis and treatment is applied consistent with CDC guidelines and other medical standards. Therefore, this policy change helps ensure that beneficiaries receive appropriate

medical attention, especially if they need multiple tests. It is also designed to stop fraudsters from performing or billing for unnecessary tests. In addition, to help ensure that beneficiaries have broad access to testing, CMS will also pay for tests when ordered by a pharmacist or other healthcare professional authorized under applicable state law to order diagnostic laboratory tests. Medicare makes payment for services of pharmacists and certain other healthcare professionals only when they have an arrangement with a physician or other billing practitioner. These changes allow Medicare to continue to pay for these tests during the PHE when they are ordered by pharmacists and other healthcare professionals without such an arrangement. The list of codes for which these ordering requirements apply can be found at <https://www.cms.gov/files/document/covid-ifc-2-flu-rsv-codes.pdf>. This list does not indicate coverage. Practitioners and laboratories should check with their local Medicare Administrative Contractor (MAC) regarding specific questions of coverage.

### **Reducing Administrative Burden**

*“Stark Law” Waivers:* The physician self-referral law (also known as the “Stark Law”) 1) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless the requirements of an applicable exception are satisfied; and 2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for any improperly referred designated health services. On March 30, 2020, CMS issued [blanket waivers of certain provisions of the Stark Law](#). These blanket waivers applied to financial relationships and referrals that are related to the COVID-19 emergency. The remuneration and referrals described in the blanket waivers must be solely related to COVID-19 purposes, as defined in the blanket waiver document. During the PHE, CMS permitted certain referrals and the submission of related claims that would otherwise violate the Stark Law, if all requirements of the waivers were met. **When the PHE ends, the waivers will terminate and physicians and entities must immediately comply with all provisions of the Stark Law.**

Flexibilities under the waivers have included:

- Hospitals and other health care providers could pay above or below fair market value for the personal services of a physician (or an immediate family member of a physician), and parties could pay below fair market value to rent equipment or purchase items or services. For example, a physician practice could rent or sell needed equipment to a hospital at a price below what the practice could charge another party. Or, a hospital could provide space on hospital grounds at no charge to a physician who is willing to treat patients who sought care at the hospital but were not appropriate for emergency department or inpatient care.

- Health care providers could support each other financially to ensure continuity of health care operations. For example, a physician owner of a hospital could make a personal loan to the hospital without charging interest at a fair market rate so that the hospital could make payroll or pay its vendors.
- Hospitals could 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 were at the hospital and engaging in activities that benefited the hospital and its patients.
- Health care providers could offer certain items and services that were 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 could provide continuing medical education to physicians in the community on the latest care protocols for homebound patients with COVID-19, or a hospital could 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 could 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 could temporarily convert observation beds to inpatient beds to accommodate patient surge during the COVID-19 pandemic in the United States.
- Some of the restrictions regarding when a group practice could furnish medically necessary designated health services (DHS) in a patient's home were loosened. For example, any physician in the group could order medically necessary DHS that were furnished to a patient by one of the group's technicians or nurses in the patient's home contemporaneously with a physician service that was furnished via telehealth by the physician who ordered the DHS.
- Group practices could furnish medically necessary MRIs, CT scans or clinical laboratory services from locations like mobile vans in parking lots that the group practice rented 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:* CMS has not enforced clinical restrictions in certain NCDs and LCDs that otherwise would have restricted coverage of these devices and services for COVID-19 patients during the public health emergency. Clinicians have had more flexibility in determining patient needs for respiratory related devices and



equipment and the flexibility for more patients to manage their treatments at home, but need to continue to document those decisions in the medical record. This waiver will end at the end of the PHE.

- *National Coverage Determinations (NCDs) for Percutaneous Left Atrial Appendage Closure, Transcatheter Aortic Valve Replacement, Transcatheter Mitral Valve Replacement and Ventricular Assist Devices:* CMS has not enforced the procedural volume requirements contained in these four NCDs for facilities and providers that, prior to the public health emergency for COVID-19, met the volume requirements. This enforcement discretion ensures that beneficiaries continue to have access to the services that are covered under these NCDs and will end at the end of the PHE.
- *Signature Requirements:* CMS has been waiving signature and proof of delivery requirements for Part B drugs and Durable Medical Equipment (DME) 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. **After the PHE, signature and proof of delivery requirements will be reinstated.**
- *Quality Payment Program (QPP) Merit-based Incentive Payment System (MIPS):* MIPS Automatic Extreme and Uncontrollable Circumstances' (EUC) policy applied for performance year 2021 — individual MIPS eligible clinicians who did not submit any MIPS data by the deadline of March 31, 2022 will automatically have all four MIPS performance categories reweighted to 0% and receive a neutral payment adjustment in the 2023 payment year (this automatic policy does not apply to groups, virtual groups, or Advanced Payment Model Entities). Groups and virtual groups had the option to submit a MIPS EUC application requesting reweighting of one or more performance categories due to the impact of the COVID-19 PHE, while APM entities had the option to request reweighting for all performance categories.

At this time, the MIPS Automatic EUC policy is not being applied to all individual MIPS eligible clinicians for the 2022 performance year. However, individual clinicians, groups, virtual groups, and APM entities have the option to submit a MIPS EUC application and request reweighting. For more information related to the MIPS EUC application visit: <https://qpp.cms.gov/mips/exception-applications>. CMS is continuing to assess the implications of the pandemic to MIPS, and clinicians are encouraged to check QPP.CMS.gov for updates.

- *COVID-19 Accelerated and Advance Payments (CAAP):* For more information related to the CAAP Program please visit <https://www.cms.gov/medicare/covid-19-accelerated-and-advance-payments>.

### **Medicare appeals in Traditional Medicare, Medicare Advantage (MA) and Part D**

- During the PHE, CMS has been allowing Medicare Administrative Contractors (MACs) and Qualified Independent Contractors (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 422.582 and 42 CFR 423.582) to allow extensions to file an appeal. Specifically, 42 CFR 422.582(c) and 42 CFR 423.582(c) allow a Part C or Part D plan to extend the timeframe for filing a request if there is good cause for the late filing. In addition, the Part D IRE may find good cause for late filing of a request for reconsideration. **When the PHE ends, these flexibilities will continue to apply consistent with existing authority and requests for appeals must meet the existing regulatory requirements.**
- During the PHE, CMS has been 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. In addition, under applicable regulations, 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), 42 CFR 422.572(b)(1) and 42 CFR 422.590(f)(1)). **When the PHE ends, these flexibilities will continue to apply consistent with existing authority, and requests for appeals must meet the existing regulatory requirements.**
- During the PHE, CMS has been allowing MACs and QICs in the FFS program (42 CFR 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 (see 42 CFR 422.561 and 42 CFR 423.560 for definitions of “representative”). However, any communication was sent only to the beneficiary. **When the PHE ends, this flexibility will continue to apply, consistent with existing guidance for the MACs and QIC in the FFS program.** For MA and Part D plans, as well as the Part C and Part D IREs, this flexibility will no longer apply. The MA and Part D plans, as well as the Part C and D IREs, must process the appeals based on regulatory requirements (42 CFR 422.582(f)-(g), 42 CFR 423.582(e)-(f), 42 CFR 422.592(d)-(e), and 42 CFR 423.600(g)-(h)).

- During the PHE, CMS has been 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, but instead use information that is available (42 CFR 422.562 and 42 CFR 423.562). **When the PHE ends, requests for appeals must meet the existing regulatory requirements.**
- During the PHE, CMS has been 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 utilize all flexibilities available in the appeal process as if good cause requirements are satisfied. **When the PHE ends, these flexibilities will continue to apply, consistent with existing regulatory authority.**

#### **Additional Guidance**

- The Interim Final Rules 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/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf>.