

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

*** Indicates items added or revised in the most recent update*

Since the beginning of the COVID-19 Public Health Emergency, the Centers for Medicare & Medicaid Services has issued 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. 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) ensure all Americans have access to a COVID-19 vaccine;
- 2) expand the healthcare system workforce by removing barriers for physicians, nurses, and other clinicians to be readily hired from the community or from other states;
- 3) ensure that local hospitals and health systems have the capacity to handle a potential surge of COVID-19 patients through temporary expansion sites;
- 4) increase access to telehealth in Medicare to ensure patients have access to physicians and other clinicians while keeping patients safe at home;
- 5) expand in-place testing to allow for more testing at home or in community based settings; and
- 6) 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.

Ensuring all Americans Have Access to a COVID-19 Vaccine

On October 28, 2020, CMS released an Interim Final Rule with Comment Period (IFC) that establishes that any vaccine that receives Food and Drug Administration (FDA) authorization, through an Emergency Use Authorization (EUA) or licensed under a Biologics License Application (BLA), will be covered under Medicare as a preventive vaccine at no cost to beneficiaries. The IFC also implements provisions of the CARES Act that ensure swift coverage of a COVID-19 vaccine by most private health insurance plans without cost sharing from both in and out-of-network providers during the course of the public health emergency (PHE).

After the FDA either approves or authorizes a vaccine for COVID-19, CMS will identify the specific vaccine codes, by dose if necessary, and specific vaccine administration codes for each dose for Medicare payment. CMS and the American Medical Association (AMA) are working collaboratively on finalizing a new approach to report use of COVID-19 vaccines.

The Medicare payment rates for COVID-19 vaccine administration will be \$28.39 to administer single-dose vaccines. For a COVID-19 vaccine requiring a series of 2 or more doses, the initial dose(s) administration payment rate will be \$16.94, and \$28.39 for the administration of the final dose in the series. These rates will be geographically adjusted and recognize the costs involved in administering the vaccine, including the additional resources involved with required public health reporting, conducting important outreach and patient education, and spending additional time with patients answering any questions they may have about the

vaccine. Medicare beneficiaries, those in Original Medicare or enrolled in Medicare Advantage, will be able to get the vaccine at no cost.

For calendar years 2020 and 2021, Medicare will pay directly for the COVID-19 vaccine and its administration for beneficiaries enrolled in Medicare Advantage (MA) plans. Providers should submit COVID-19 claims to Original Medicare for all patients enrolled in MA in 2020 and 2021. MA plans will not be responsible for reimbursing providers to administer the vaccine during this time. MA beneficiaries also pay nothing for COVID-19 vaccines and their copayment/coinsurance and deductible are waived.

CMS is working to increase the number of providers that will administer a COVID-19 vaccine to Medicare beneficiaries when it becomes available, to make it as convenient as possible for America's seniors. New providers are now able to enroll as a "Medicare mass immunizers" through an expedited 24-hour process. The ability to easily enroll as a mass immunizer is important for some pharmacies, schools, and other entities that may be non-traditional providers or otherwise not eligible for Medicare enrollment. To further increase the number of providers who can administer the COVID -19 vaccine, CMS will continue to share approved Medicare provider information with states to assist with Medicaid provider enrollment efforts. CMS is also making it easier for newly enrolled Medicare providers also to enroll in state Medicaid programs to support state administration of vaccines for Medicaid recipients.

For more information, view our COVID-19 vaccine toolkits for providers, private health plans and state Medicaid programs at www.cms.gov/covidvax.

*****Coverage for Monoclonal Antibody Therapies***

The Food and Drug Administration has issued emergency use authorizations (EUA) for monoclonal antibody therapies 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. During the COVID-19 public health emergency (PHE), Medicare will cover and pay for these infusions the same way it covers and pays for COVID-19 vaccines (when furnished consistent with the EUA). This will allow a broad range of providers and suppliers, including freestanding and hospital-based infusion centers, home health agencies, nursing homes, and entities with whom nursing homes contract for this, to administer these treatments in accordance with each product's EUA and in accordance with any state scope of practice and licensure requirements. Please refer to Section BB of the [COVID-19 Frequently Asked Questions \(FAQs\) on Medicare Fee-for-Service \(FFS\) Billing](#) document for more information about coverage for COVID-19 Monoclonal Antibody Therapies.

In order to ensure immediate access during the COVID-19 PHE, there is no beneficiary cost sharing and no deductible for monoclonal antibody COVID-19 products to treat COVID-19 when administration is provided in a Medicare-enrolled care setting (consistent with Section 3713 of the CARES Act).

Coding and Payment: CMS has identified specific billing code(s) for each of the authorized COVID-19 monoclonal antibody products and specific administration code(s) for Medicare payment. When the monoclonal antibody COVID-19 product is given to providers and suppliers

for free, the HCPCS code for the monoclonal antibody product should **not** be included on the claim. Because Medicare will cover and pay for these infusions the same way it covers and pays for COVID-19 vaccines, COVID-19 monoclonal antibody products are not eligible for the New COVID-19 Treatments Add-on Payment (NCTAP) under the Inpatient Prospective Payment System (IPPS). Initially, for the infusions of bamlanivimab or casirivimab and imdevimab (administered together), the Medicare national average payment rate for the administration will be approximately \$310. This payment rate is based on one hour of infusion and post-administration monitoring in the hospital outpatient setting. Should additional products come to market, [get the most up to date list of billing codes, payment allowances and effective dates.](#)

Provider Enrollment: Health care providers administering the COVID-19 monoclonal antibody infusions will follow the same Medicare enrollment process as those administering the COVID-19 vaccines. Review information about [provider enrollment.](#)

Enforcement Discretion: In order to facilitate the **efficient** administration of COVID-19 monoclonal antibody products to SNF residents, CMS will exercise enforcement discretion with respect to certain statutory provisions as well as any associated statutory references and implementing regulations, including as interpreted in pertinent guidance (collectively, “SNF Consolidated Billing Provisions”). Through the exercise of that discretion, CMS will allow Medicare-enrolled immunizers including, but not limited to, pharmacies working with the United States, as well as infusion centers, and home health agencies to bill directly and receive direct reimbursement from the Medicare program for administering this treatment to Medicare SNF residents.

Additional Resources:

For specific instructions on how to bill the Medicare program for monoclonal antibody treatments, please see the [Monoclonal Antibody Program Instruction.](#)

View an infographic on coverage of monoclonal antibody therapies at <https://www.cms.gov/files/document/covid-infographic-coverage-monoclonal-antibody-products-treat-covid-19.pdf>.

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, health care providers can waive Medicare copayments for these telehealth and other non-face-to-face services for beneficiaries in Original Medicare.

Under the CARES Act, CMS is waiving the requirements of section 1834(m)(1) of the ACT and 42 CFR § 410.78(a)(3) for 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 is waiving the requirements of section 1834(m)(4)(E) of the Act and 42 CFR § 410.78 (b) (2) which specify the types of practitioners that may bill for their services when furnished as Medicare telehealth services from the distant site. The waiver of these requirements expands the types of health care professionals that can furnish distant site telehealth services to include all those that 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 are modifying the process to add services to the Medicare telehealth services list and instead, will consider adding appropriate services as they are requested, on a sub-regulatory basis as practitioners are actively learning how to use telehealth as broadly as possible. A complete list of all Medicare telehealth services can be found here: <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes>.

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- 99469; CPT codes 99471-99473; CPT codes 99475- 99476)
- Initial and Continuing Intensive Care Services (CPT code 99477- 994780)
- Care Planning for Patients with Cognitive Impairment (CPT code 99483)
- Group psychotherapy (CPT code 90853)
- 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)

Remote Evaluations, Virtual Check-Ins & E-Visits

- Medicare patients may have a brief communication service with practitioners via a number of communication technology modalities including synchronous discussion over a telephone or exchange of information through video or image. Clinicians can provide remote evaluation of patient video/images and virtual check-in services (HCPCS codes G2010, G2012) to both new and established patients. These 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. E-visits are non-face-to-face communications with their practitioner by using online patient portals. (HCPCS codes G2061-G2063).

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

- A broad range of clinicians, including physicians, can now 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 are furnishing an evaluation and management (E/M) service that would otherwise be reported as an in-person or telehealth visit, using audio-only technology, practitioners may 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 new waiver authority, CMS is also allowing many behavioral health and education services to be furnished via telehealth using audio-only communications. The full list of telehealth services 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

- 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)
- Current CPT coding guidance states that the remote physiologic monitoring service described by CPT code 99454 (device(s) supply with daily recordings or programmed alerts transmission each 30 day(s)), cannot be reported for monitoring of less than 16 days. For purposes of treating suspected COVID-19 infections, Medicare will allow the service to be reported for shorter periods of time than 16 days as long as the other code requirements are met.

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 Telemedicine 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 non-face-to-face 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.
- *Opioid Treatment Programs:* Patient counseling and therapy services can be provided by telephone only in cases where the beneficiary does not have access to two-way interactive audio-video communication technology. Periodic patient assessments can be conducted via two-way interactive audio-video communication technology and may be provided by telephone only in cases where the beneficiary does not have access to two-way interactive audio-video communication technology.

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.
- *Supervision Requirements for Non-Surgical Extended Duration Therapeutic Services:* Direct supervision is not 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 can be provided for the entire duration of these services, so the supervising physician or practitioner is not required to be immediately available.
- *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 Advanced Practice Nonphysician Practitioners:* Nurse practitioner(NPs), clinical nurse specialists (CNSs), certified nurse-midwives (CNMs), and physician assistants (PAs) can supervise diagnostic tests as authorized under state law and licensure. These practitioners will need to continue the required statutory relationships with supervising or collaborating physicians.
- *Physical Therapists and Occupational Therapists:* The treating physical or occupational therapist who developed or is responsible for the maintenance program plan may delegate the performance of maintenance therapy services to a therapy assistant when clinically appropriate. This will free up the therapist to furnish other needed services during the PHE requiring his/her evaluative and assessment skills.
- *Pharmacists:* We are now allowing pharmacists, as well as other auxiliary personnel that are able to order lab tests under state scope of practice and other relevant laws, to order COVID-19 tests for Medicare beneficiaries during the PHE. This does not mean that pharmacists and other auxiliary personnel become Medicare providers; rather, it allows Medicare to pay for tests that they order.
- *Teaching Physicians:* Under the so-called primary care exception at section 415.174, a teaching physician may meet the requirement to review a visit furnished by a resident remotely using audio/video real time communications technology during the PHE. This flexibility 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.
- *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.
- CMS is exercising enforcement discretion and will not enforce 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.
- *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.

- **Modification of 60-day limit for Substitute Billing Arrangements (Locum Tenens):** CMS is modifying 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. Without this flexibility, the regular physician or physical therapist generally could not use a single substitute for a continuous period of longer than 60 days, and would instead be required to secure a series of substitutes to cover sequential 60-day periods. 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 Armed Forces may continue to use the same substitute for an unlimited time even after the emergency ends.

- **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 cancel their opt-out status early and enroll in Medicare to provide care to more patients.
- **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 redocument, information added to the medical record by any member of the health care team. During the public health emergency, this principle applies across the spectrum of all Medicare-covered services, and will also apply 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.

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 will be 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.
- **COVID-19 Diagnostic Testing:** Practitioners can be paid for assessment and specimen collection for COVID-19 testing using the level 1 evaluation and management code CPT code 99211. In light of the public health emergency, Medicare will recognize this code to be billed for all patients, not just established patients. This approach helps physician practices to operate testing sites during the PHE.
- **Physician or Practitioner Order:** In the COVID-19 Public Health Emergency Interim Final Rule #3 (CMS-3401-IFC) we revised a previous policy that covered multiple COVID-19 tests for an individual beneficiary without a physician or other practitioner order. Moving forward, Medicare will cover a beneficiary's first COVID-19 test without an order. Subsequent tests will require a physician's or other practitioner order. This change will ensure that beneficiaries receive appropriate medical attention if they feel they need multiple tests, as well as reduce the risk of fraud. FDA requirements for a prescription and state requirements around ordering diagnostic tests would still apply. CMS has also removed certain documentation and recordkeeping requirements associated with orders for these COVID-19 diagnostic tests and related tests as these requirements would not be relevant in the absence of an order. CMS still expects laboratories to furnish the results of COVID-19 tests to the beneficiary. Consistent and regular reporting of all testing results to local officials is critical to public health management of the pandemic, we would expect any clinician or laboratory receiving results to report those results promptly consistent with state and local public health requirements, typically within 24 hours.

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. On March 30, 2020, CMS issued blanket waivers of certain provisions of the Stark Law regulations. These blanket waivers apply 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. Under the waivers, CMS will permit certain referrals and the submission of related claims that would otherwise violate the Stark Law. These flexibilities include:

- Hospitals and other health care providers can pay above or below fair market value for the personal services of a physician (or an immediate family member of a physician), and parties may pay below fair market value to rent equipment or purchase items or services. 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.
- Health care providers may offer 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.
- Some of the restrictions regarding when a group practice can furnish medically necessary designated health services (DHS) in a patient's home are loosened. For example, any physician in the group may order medically necessary DHS that is furnished to a patient by one of the group's technicians or nurses 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:* CMS will not enforce clinical restrictions in certain NCDs and LCDs that would otherwise restrict coverage of these devices and services for COVID-19 patients during the public health emergency. Clinicians will have more flexibility in determining patient needs for respiratory related devices and equipment and the flexibility for more patients to manage their treatments at the home but will need to continue to document those decisions in the medical record.
- *National Coverage Determinations (NCDs) for Percutaneous Left Atrial Appendage Closure, Transcatheter Aortic Valve Replacement, Transcatheter Mitral Valve Replacement and Ventricular Assist Devices:* CMS will not enforce 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 will continue to have access to the services that are covered under these NCDs and applies only during the period of the public health emergency for COVID-19.
- *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 have made three updates to the Merit-based Incentive Payment System (MIPS) in the Quality Payment Program. Specifically, we are:
 - Modifying the MIPS Extreme and Uncontrollable Circumstances policy – Individual MIPS eligible clinicians who have not submitted any MIPS data by the extended deadline of April 30, 2020 will automatically receive a neutral payment adjustment in 2021 (this automatic policy does not apply to groups or virtual groups). Alternatively, if a MIPS eligible clinician, group, or virtual group has submitted some MIPS data but is unable to complete their 2019 MIPS data submission because they have been adversely affected by the COVID-19 public health emergency, they can submit an application based on extreme and uncontrollable circumstances by April 30, 2020 at 8 p.m. ET to request reweighting of their MIPS performance categories for the 2019 performance year. These are important changes for clinicians who have been impacted by the COVID-19 outbreak and may be unable to submit their MIPS data during the current submission period;
 - For the improvement activity IA_ERP_3 titled “COVID Clinical Trials” we are: 1) expanding the improvement activity to also allow credit for clinicians who participate in the care of patients diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research; 2) updating the title to “COVID-19 Clinical Data Reporting with or without Clinical Trial;” and 3) extending the activity for the CY 2020 and CY 2021 performance periods. In order to receive credit for this improvement activity, a MIPS eligible clinician or group must: 1) participate in a COVID-19 clinical trial utilizing a drug or biological product to treat a patient with a COVID-19 infection and report their findings through a clinical data repository or clinical data registry for the duration of their study; or 2) participate in the care of patients

diagnosed with COVID-19 and simultaneously submit relevant clinical data to a clinical data registry for ongoing or future COVID-19 research.

We are expanding telehealth services to include CPT and HCPCS codes for communications technology-based services (CTBS) and the telephone evaluation and management (E/M) services to the definition of primary care services that is used for purposes of the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS survey in order to ensure these services are included in determining where beneficiaries receive the plurality of their primary care.

- CPT codes: 99421, 99422, and 99423 (codes for online digital E/M service (e-visit)), and 99441, 99442, and 99443 (codes for telephone E/M services); and
- HCPCS codes: G2010 (code for remote evaluation of patient video/images) and G2012 (code for virtual check-in).
- Delaying the implementation of the Qualified Clinical Data Registry (QCDR) measure testing and data collection policies by 1 year. Both QCDR measure approval criteria necessitate that QCDRs collect data from clinicians in order to assess the measure, and we anticipate that QCDRs may be unable to collect, and clinicians unable to submit, data on QCDR measures due to prioritizing the care of COVID-19 patients.
- *Accelerated/Advance Payments:* In order to provide additional cash flow to healthcare providers and suppliers impacted by COVID-19, CMS expanded and streamlined the Accelerated and Advance Payments Program, which provided conditional partial payments to providers and suppliers to address disruptions in claims submission and/or claims processing subject to applicable safeguards for fraud, waste and abuse. Under this program, CMS made successful payment of over \$100 billion to healthcare providers and suppliers. As of April 26, 2020, CMS is reevaluating all pending and new applications for the Accelerated Payment Program and has suspended the Advance Payment Program, in light of direct payments made available through the Department of Health & Human Services' (HHS) Provider Relief Fund. Distributions made through the Provider Relief Fund do not need to be repaid. For providers and suppliers who have received accelerated or advance payments related to the COVID-19 Public Health Emergency, CMS will not pursue recovery of these payments until 120 days after the date of payment issuance. Providers and suppliers with questions regarding the repayment of their accelerated or advance payment(s) should contact their appropriate Medicare Administrative Contractor (MAC).

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 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>.