

## Laboratories: 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 Trump Administration 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) 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; 2) ensure that local hospitals and health systems have the capacity to handle a potential surge of COVID-19 patients through temporary expansion sites (also known as CMS Hospital Without Walls); 3) increase access to telehealth in Medicare to ensure patients have access to physicians and other clinicians while keeping patients safe at home; 4) expand in-place testing to allow for more testing at home or in community based settings; and 5) put Patients Over Paperwork to give temporary relief from many paperwork, reporting and audit requirements so providers, health care facilities, Medicare Advantage and Part D plans, and States can focus on providing needed care to Medicare and Medicaid beneficiaries affected by COVID-19.

### **\*\* Ensuring all Americans Have Access to a COVID-19 Vaccine When One Becomes Available**

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](http://www.cms.gov/covidvax).

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

- **\*\*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.
- **Laboratory Specimen Collection from Patient's Home:** Medicare will pay when laboratories send trained technicians to collect a sample from a homebound beneficiary or a non-hospital inpatient for COVID-19 diagnostic testing. Medicare will pay a specimen collection fee and for the travel. The nominal specimen collection fee for COVID-19 testing for homebound and non-hospital inpatients generally is \$23.46 and for individuals in a non-covered stay in a SNF or whose samples are collected by a laboratory on behalf of an HHA is \$25.46.
- **Practitioner Payment for Specimen Collection:** 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 may help physician practices to operate testing sites during the PHE.
- **Hospital Payment for Specimen Collection:** Hospital outpatient departments can be paid for symptom assessment and specimen collection for COVID-19 using a new HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19])), any specimen source retroactive to March 1, 2020. The service would be paid as conditionally packaged when furnished with another payable service under the OPPTS. This approach helps hospitals to operate testing sites during the PHE. Medicare will pay a national rate of roughly \$23 for C9803 when it is not billed with a separately payable hospital outpatient service.
- **Home Health Specimen Lab Collection:** If a patient is already receiving Medicare home health services, the home health nurse, during an otherwise covered visit, could obtain the sample to send to the laboratory for COVID-19 diagnostic testing.
- **RHC/FQHC Visiting Nurse Lab Specimen Collection:** If a visiting nurse has an otherwise covered RHC

or FQHC visit, they can obtain a sample to send to the laboratory for COVID-19 diagnostic testing.

- **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 for COVID-19 tests:** 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 an order and state requirements around ordering diagnostic tests would still apply. CMS has also removed certain documentation and recordkeeping requirements associated with orders for COVID-19 diagnostic tests as these requirements would not be relevant in the absence of an order. CMS still requires 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.
- **Pharmacists:** Medicare will pay for COVID-19 tests performed by pharmacists as part of a laboratory enrolled in Medicare. A pharmacy that acquires a CLIA certificate can enroll with Medicare as a clinical diagnostic laboratory to conduct and bill for clinical diagnostic laboratory tests it is authorized to perform under its CLIA certificate. In addition, to help ensure that beneficiaries can get the tests they need, CMS is also continuing to cover tests when ordered by a pharmacist or other healthcare professional permitted by their state to order diagnostic laboratory tests. To be paid by Medicare, laboratory tests are ordinarily, outside the PHE, required to be ordered by a physician or non-physician practitioner. This interim final rule, in revising previous policy for the PHE, continues to allow laboratories to be paid when pharmacists order these tests.
- **Antibody (serology) tests:** FDA-authorized COVID-19 serology testing is a Medicare covered diagnostic test for patients that may have known current or known prior COVID-19 infection or suspected current or suspected past COVID-19 infection. The outcome of the serology test may change the health care decisions made by a patient and their practitioner.

#### **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:

- o 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.
- o 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.
- o 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.
- o 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.
- o 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.
- o 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.
- o 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.
- **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).

- **Provider Enrollment:** CMS has established toll-free hotlines for all providers as well as the following flexibilities for provider enrollment:
  - o Waive certain screening requirements.
  - o Postpone all revalidation actions.
  - o Expedite any pending or new applications from providers.

#### **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.

#### **Clinical Laboratory Improvement Act (CLIA) Guidance**

- CMS will exercise enforcement discretion to facilitate pathologists' ability to review pathology slides remotely without the need for a separate CLIA certificate for the remote location
- CMS will expedite CLIA certificate application review and processing to ensure that laboratories located in the United States wishing to perform COVID-19 testing are able to begin testing as quickly as possible during the public health emergency.

- CMS is allowing laboratories within a hospital/University Hospital Campus to hold a single certificate for the laboratory sites within the same physical location or street address.
- CMS has clarified that alternate specimen collection devices and media may be used to collect and transport COVID-19 samples. CLIA regulations are not prescriptive about the type of transport device, for example, specimen collection swabs and viral transport media, that laboratories use to collect the specimens needed to perform a test. CLIA only requires that the laboratory follow manufacturer's instructions. If a laboratory modifies the manufacturer's instructions, the laboratory must establish performance specifications and validate the assay prior to performing patient testing. CLIA is not prescriptive as to how the study is performed; the Laboratory Director is responsible for defining the validation parameters.

#### **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>.
- Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency can be found at: <https://www.cms.gov/files/document/qso-20-21-clia.pdf-0>.