

Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs): 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

- *Payment for Medicare Telehealth Services:* Section 3704 of the CARES Act authorizes RHCs and FQHCs to furnish distant site telehealth services to Medicare beneficiaries during the COVID-19 PHE. Medicare telehealth services generally require an interactive audio and video telecommunications system that permits real-time communication between the practitioner and the patient. (During the PHE, some telehealth services can be furnished using audio-only technology.) RHCs and FQHCs with this capability can provide and be paid for telehealth services furnished to Medicare patients located at any site, including the patient’s home, for the duration of the COVID-19 PHE. Telehealth services can be furnished by any health care practitioner working for the RHC or the FQHC within their scope of practice. Practitioners can furnish telehealth services from any distant site location, including their home, during the time that they are working for the RHC or FQHC, and can furnish any telehealth service that is included on the list of Medicare telehealth services under the Physician Fee Schedule (PFS), including those that are added on an interim basis during the PHE. A list of these

services, including which can be furnished via audio-only technology, is available at <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes>.

Workforce

- *Home Nursing Visits:* RHCs and FQHCs can provide visiting nursing services to a beneficiary's home with fewer requirements, making it easier for beneficiaries to get care from their home.
 - Any area typically served by the RHC, and any area that is included in the FQHC's service area plan, is determined to have a shortage of home health agencies, and no request for this determination is required;
 - Any RHC/FQHC visiting nurse service solely to obtain a nasal or throat culture would not be considered a nursing service because it would not require the skills of a nurse to obtain the culture as the specimen could be obtained by an appropriately-trained medical assistant or laboratory technician; and
 - The revised definition of "homebound" will apply to patients receiving visiting nursing services from RHCs and FQHCs.
- *Certain staffing requirements:* CMS is waiving the requirement in the second sentence of 42 CFR §491.8(a)(6) that a nurse practitioner, physician assistant, or certified nurse-midwife be available to furnish patient care services at least 50 percent of the time the RHC and FQHC operates. CMS is not waiving the first sentence of §491.8(a)(6) that requires a physician, nurse practitioner, physician assistant, certified nurse-midwife, clinical social worker, or clinical psychologist to be available to furnish patient care services at all times the clinic or center operates. This will assist in addressing potential staffing shortages by increasing flexibility regarding staffing mixes during the PHE.
- *Physician supervision of Nurse Practitioners in RHCs and FQHCs:* We are modifying the requirement at 42 C.F.R. 491.8(b)(1) that physicians must provide medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff, only with respect to medical supervision of nurse practitioners, and only to the extent permitted by state law. The physician, either in person or through telehealth and other remote communications, continues to be responsible for providing medical direction for the clinic or center's health care activities and consultation for the health care staff, and medical supervision of the remaining health care staff. This allows RHCs and FQHCs to use nurse practitioners to the fullest extent possible and allows physicians to direct their time to more critical tasks.

CMS Facility without Walls (Temporary Expansion Sites)

- *Temporary Expansion Locations:* CMS is waiving the requirements at 42 CFR §491.5(a)(3) (iii) which require RHCs and FQHCs be independently considered for Medicare approval if services are furnished in more than one permanent location. Due to the current PHE, CMS is temporarily waiving this requirement removing the location restrictions to allow flexibility for existing RHCs/FQHCs to expand services locations to meet the needs of Medicare beneficiaries. This flexibility includes areas which may be outside of the location requirements 42 CFR §491.5(a)(1) and (2) for the duration of the PHE.
- *Bed Count for Provider-Based RHCs and RHC Payment Limit:* RHCs that are provider-based to a hospital with fewer than 50 beds are exempt from the national RHC payment limit. For the duration of the PHE, the number of beds prior to the start of the PHE will be the official

hospital bed count for application of this policy so that hospitals are not discouraged from increasing bed capacity if needed. Allowing for these provider-based RHCs to continue to receive the payment amounts they would otherwise receive in the absence of the PHE will help maintain their ability to provide necessary health care services to underserved communities.

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

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.

Payment

- **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.

Cost Reporting

- CMS is delaying the filing deadline of certain cost report due dates due to the COVID-19 outbreak. We are currently authorizing delay for the following fiscal year end (FYE) dates. CMS will delay the filing deadline of FYE 10/31/2019 cost reports due by March 31, 2020 and FYE 11/30/2019 cost reports due by April 30, 2020. The extended cost report due dates for these October and November FYEs will be June 30, 2020. CMS will also delay the filing deadline of the FYE 12/31/2019 cost reports due by May 31, 2020. The revised extended cost report due date for FYE 12/31/2019 will be August 31, 2020. For the FYE 01/31/2020 cost report, the extended due date is August 31, 2020. For the FYE 02/29/2020 cost report, the extended due date is September 30, 2020.

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>.
- Guidance for Infection Control and Prevention of Coronavirus Disease (COVID-19) in Outpatient Settings: FAQs and Considerations: <https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and-guidance-infection-control-and-prevention-coronavirus-disease-covid-19-outpatient-settings-faqs>.