

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

For RHCs and FQHCs, COVID-19 vaccines and their administration are paid the same way as influenza and pneumococcal vaccines and their administration. That is, COVID-19 vaccines and their administration are paid at 100 percent of reasonable cost through the cost report. **CMS will continue to pay this way after the PHE ends.**

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

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

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

*There are currently no COVID-19 monoclonal antibodies approved or authorized for use against the dominant strains of COVID-19 in the United States.*

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 EUA declaration for drugs and biologicals with respect to COVID-19, 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. That is, for RHCs and FQHCs, COVID-19 monoclonal antibody products (when purchased from the manufacturer) and their administration are paid at 100 percent of reasonable cost through the cost report. There is no beneficiary cost sharing and no deductible for COVID-19 monoclonal antibody products when RHCs and FQHCs administer them. In the event these products become approved or authorized for use, they will continue to be covered and paid this way until the end of the calendar year in which the Secretary ends the EUA declaration. **This coverage and payment will continue even if the PHE ends.**

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

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

Effective January 1 of the year following the year in which the Secretary ends the EUA declaration for drugs and biologicals with respect to COVID-19 that the PHE ends, CMS will pay for monoclonal antibodies used for the treatment or for post-exposure prophylaxis of COVID-19:

- 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.

Monoclonal antibodies that are used for pre-exposure prophylaxis prevention of COVID-19 will continue to be paid under the Part B preventive vaccine benefit if they meet applicable coverage requirements.

### ***COVID-19 VEKLURY™ (remdesivir)***

As of April 25, 2022, VEKLURY™ (remdesivir) is approved for the treatment of COVID-19. 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. In most cases, the Medicare patient's yearly Part B deductible and 20% co-insurance apply.

*Medicare 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***

*Payment for Medicare Telehealth Services:* Section 3704 of the CARES Act authorized 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. (Some telehealth services can be furnished using audio-only technology.) RHCs and FQHCs with this capability could provide and be paid for telehealth services furnished to Medicare patients located at any site, including the patient's home, through December 31,

2024. Telehealth services could be furnished by any health care practitioner working for the RHC or the FQHC within their scope of practice. Practitioners could furnish telehealth services from any distant site location, including their home, during the time that they are working for the RHC or FQHC, and could furnish any telehealth service that is included on the list of Medicare telehealth services under the Physician Fee Schedule (PFS), including those that have been added on an interim basis during the PHE. A list of these services, including which could be furnished via audio-only technology, is available at <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes>.

### ***Mental Health Visits Furnished Using Telehealth***

- Beginning on or after January 1, 2022, RHCs and FQHCs can report and receive payment for mental health visits furnished via real-time telecommunication technology in the same way in-person visits are reported and reimbursed, including audio-only visits when the beneficiary is not capable of or does not consent to, the use of video technology. Payment under HCPCS code G2025 will no longer apply to mental health visits furnished via telehealth. This payment policy for mental health visits was made permanent for RHCs and FQHCs in the [CY 2022 PFS final rule](#).

### ***Virtual Communication Services***

- Beginning March 1, 2020, and for the duration of the COVID-19 PHE, virtual communication services have been expanded to include online digital evaluation and management services, which are non-face-to-face, patient-initiated, digital communications using a secure patient portal. The payment rate for the virtual communication services HCPCS code (G0071) reflects the online digital evaluation and management CPT codes (99421, 99422, and 99423) in addition to HCPCS codes for virtual communication services (G2012 and G2010). Therefore, payment for HCPCS code G0071 is set at the average of the national non-facility PFS payment rates for these five codes. All virtual communication services would also be available to new patients that had not been seen in the RHC or FQHC within the previous 12 months. Additionally, in situations where obtaining prior beneficiary consent would interfere with the timely provision of these services, or the timely provision of the monthly care management services, consent could be obtained when the services are furnished instead of prior to the service being furnished, but must be obtained before the services are billed. We also have allowed patient consent to be acquired by staff under the general supervision of the RHC or FQHC practitioner for the virtual communication and monthly care management codes.

**When the COVID-19 PHE ends, the payment for virtual communication services (G0071) will no longer include online digital evaluation and management services and these services may only be provided to established patients. Additionally, consent for services will require direct supervision.**

## Workforce

- *Home Nursing Visits:* RHCs and FQHCs have been able to 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 included in the FQHC's service area plan has been determined to have a shortage of home health agencies, and a request for this determination has not been required;
  - Any RHC/FQHC visiting nurse service solely to obtain a nasal or throat culture has not been considered a nursing service because it does not require the skills of a nurse to obtain the culture, as the specimen could have been obtained by an appropriately-trained medical assistant or laboratory technician; and
  - The revised definition of "homebound" would have applied to patients receiving visiting nursing services from RHCs and FQHCs.

**Once the COVID-19 PHE ends, RHCs and FQHCs, located in an area that has not been determined to have a current HHA shortage and seeking to provide visiting nurse services will have to make a written request along with written justification that the area it serves meets the required conditions and that the definition of "homebound" will not apply to patients receiving visiting nursing services from RHCs and FQHCs.**

- *Certain staffing requirements:* CMS has been 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% of the time the RHC and FQHC operates. CMS is not waiving the first sentence of §491.8(a)(6), which 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. **This waiver will terminate at the end of the COVID-19 PHE.**
- *Physician supervision of Nurse Practitioners in RHCs and FQHCs:* We are modifying the requirement at 42 CFR 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. **This flexibility is currently set to return to pre-PHE requirements at the end of the calendar year that the PHE ends.**

### **Temporary Expansion Sites**

- **Temporary Expansion Locations:** CMS has been waiving the requirements at 42 CFR §491.5(a)(3)(iii), which require RHCs and FQHCs to be independently considered for Medicare approval if services are furnished in more than one permanent location. Due to the current PHE, CMS has temporarily waived this requirement, removing the location restrictions to allow flexibility for existing RHCs/FQHCs to expand service locations to meet the needs of Medicare beneficiaries. This flexibility includes areas that may be outside of the location requirements, at 42 CFR § 491.5(a)(1) and (2), for the duration of the PHE. **CMS will end this waiver at the conclusion of the PHE.**
- **Bed Count for Provider-Based RHCs and RHC Payment Limit:** Prior to April 1, 2021, RHCs that are provider-based to a hospital with fewer than 50 beds were exempt from the national RHC payment limit. In an Interim Final Rule with Comment Period (IFC) issued May 8, 2020, CMS allows these provider-based RHCs to continue to receive the payment amounts they would have otherwise received in the absence of the PHE. To do so, CMS has allowed, during the PHE, that the number of beds prior to the start of the PHE would be the official hospital bed count for application of the exemption policy so that hospitals were not discouraged from increasing bed capacity if needed. On December 27, 2020, section 130 of the Consolidated Appropriations Act of 2021 (CAA, 2021) provided special payment rules for certain provider-based RHCs with fewer than 50 beds). In accordance with the CAA, 2021, CMS has continued to allow for increased hospital bed counts, as described in the May 8, 2020, IFC. **The bed count flexibility will terminate when the COVID-19 PHE ends. As such, when Medicare Administrative Contractors (MACs) apply the rate-setting process, they will no longer use the number of beds from the cost reporting period to the start of the PHE as the official hospital bed count when determining if an RHC retains its specified provider-based RHC status.**

### **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 COVID-19 PHE ends, the waivers will terminate and physicians and entities must immediately comply with all**

## provisions of the Stark Law.

### Flexibilities under the “Stark Law” waivers have included:

- o 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.
- o 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.
- o Hospitals could provide benefits to their medical staff, 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.
- o 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.
- o 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.
- o 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.
- o 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.

- **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 CFR §§ 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 CFR § 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 CFR § 424.514, resumed collecting application fees.)*
  - **Revalidation:** CMS postponed all revalidation actions. This did not prevent a provider who wanted 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 November 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.**

### 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 are 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.**

### **Payment**

*COVID-19 Accelerated and Advance Payments (CAAP)*: For the most up to date 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 the late filing of a request for reconsideration. When the COVID-19 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 COVID-19 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 COVID-19 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 COVID-19 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 may only be provided consistent with existing regulatory authority.**
- *Cost Reporting.* Providers that continue to experience the impacts of the PHE and require additional time to file their cost report may submit a request to their MAC in accordance with our regulation at 42 CFR 413.24 (f)(2)(ii). The MAC has the authority to grant up to a 60-day extension of the due date for filing a cost report if the provider's operations are significantly adversely affected due to extraordinary circumstances over which the provider has no control, such as the PHE.

### ***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>.