

## **Inpatient Rehabilitation Facilities: 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 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 focused on evaluating CMS-issued PHE waivers and flexibilities to prepare the health care system for operation after the PHE. This review happened in three concurrent phases:

1. CMS assessed 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 assessed 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 identified barriers and opportunities for improvement, the needs of each person and community served were 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.

Please note: This fact sheet focuses on Medicare and Medicaid flexibilities only.

### ***COVID-19 Vaccines***

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

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

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

CMS will continue to pay approximately \$40 per dose for administering COVID-19 vaccines in most outpatient settings for Medicare beneficiaries through the end of the calendar year in which the Secretary ends the EUA declaration for drugs and biologicals with respect to COVID-19. The EUA declaration is distinct from, and not dependent on, the PHE for COVID-19.

Effective January 1 of the year following the year that the PHE in which the EUA declaration ends, CMS will set the payment rate for administering COVID-19 vaccines to align with the payment rate for administering other Part B preventive vaccines, that is, approximately \$30 per dose.

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

In calendar year 2023, CMS will pay approximately \$36 in addition to the standard administration amount (approximately \$40) per dose to administer COVID-19 vaccines in the home for certain Medicare patients. For vaccines requiring multiple doses, this payment applies for each dose in the series, including any additional or booster doses. We also geographically adjust the additional amount and administration rate based on where you administer the vaccine. Starting January 1, 2023, we'll also annually update the additional in-home payment rate for administering the COVID-19 vaccine to reflect changes in costs related to administering preventive vaccines.

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

We'll continue to pay a total payment of approximately \$76 per dose to administer COVID-19 vaccines in the home for certain Medicare patients through calendar year 2023. The additional payment is not affected by the end of the PHE.

### ***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. There's also no beneficiary cost sharing and no deductible for COVID-19 monoclonal antibody products when providers administer them. In the event these products become approved or authorized for use, they will continue to be covered and paid under the Medicare Part B preventive vaccine benefit 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.

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

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

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

Effective January 1 of the year in which the Secretary ends the EUA declaration for drugs and biologicals with respect to COVID-19, 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.

### **Medicare Telehealth**

- During the PHE, telehealth may be used to fulfill the requirement for physicians to conduct the required face-to-face visits at least three days a week for the duration of a Medicare Part A fee-for-service patient's stay in an inpatient rehabilitation facility. When the COVID-19 PHE ends, rehabilitation physicians (or, in accordance with the revised regulations, nonphysician practitioners) will be required to visit IRF patients face-to-face at least 3 times per week.

### **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.
- *Intensity of Therapy Requirement ("three-Hour Rule")*: The Coronavirus Aid, Relief, and Economic Security (CARES) Act requires the Secretary to waive § 412.622(a)(3)(ii) (commonly referred to as the "three-hour rule"), the criterion that patients treated in inpatient rehabilitation facilities generally receive at least 15 hours of therapy per week. The waiver of this requirement for all beneficiaries treated in a hospital-based or freestanding IRF provides flexibility for IRFs to provide care for patients during the PHE for the COVID-19 pandemic. IRFs should strive to provide typical IRF levels of care (i.e., inpatient rehabilitation versus acute care hospital care) for beneficiaries admitted during the COVID-19 PHE who require and can benefit from IRF levels of care. **This waiver will expire at the end of the COVID-19 PHE.**
  - *Standards to Rehabilitate Patients*: Medicare payment regulations require IRFs to meet certain standards to rehabilitate patients, including providing interdisciplinary care, ensuring that admitted patients are stable enough for rehabilitation therapy and need at least two types of therapy, and providing close medical supervision by a rehabilitation physician. During the PHE, these standards do not have to apply to patients who are

admitted to freestanding IRFs solely for surge capacity reasons in a state (or region, as applicable) that currently satisfies all of the following, as determined by applicable [state](#) and local officials:

- (i) All vulnerable individuals continue to shelter in place.
- (ii) Individuals continue social distancing.
- (iii) Individuals avoid socializing in groups of more than 10.
- (iv) Non-essential travel is minimized.
- (v) Visits to senior living facilities and [hospitals](#) are prohibited.
- (vi) [Schools](#) and organized youth activities remain closed.

The standard IRF requirements would continue to apply to patients admitted for the IRFs' standard rehabilitative services. During the PHE, freestanding IRFs have taken advantage of these flexibilities for some of their beneficiaries (those who are surge patients from inpatient hospitals) while continuing to provide standard IRF-level care for those beneficiaries who would benefit from IRF-level care and would otherwise receive such care in the absence of the PHE. **This waiver will expire at the end of the COVID-19 PHE.**

- *IRF Teaching Status Adjustment Payments:* To ensure that teaching IRFs can alleviate bed capacity issues by taking patients from inpatient acute care hospitals without being penalized by lower teaching status adjustments, we have frozen the IRFs' teaching status adjustment payments at their values prior to the PHE. For the duration of the COVID-19 PHE, an IRF's teaching status adjustment payments will be the same as they were on the day before the COVID-19 PHE was declared. **CMS will terminate this policy at the end of the COVID-19 PHE.**
- *IRF Quality Reporting Program:* In May 2020, to provide maximum flexibility for IRF providers to respond to the public health threats posed by the COVID-19 PHE and to reduce associated administrative burden, we delayed the compliance dates for collecting and reporting of the Transfer of Health Information quality measures and certain standardized patient assessment data elements (SPADEs) adopted for the IRF. Quality Reporting Program IRFs will be required to begin collecting the Transfer of Health Information quality measures and certain SPADEs on October 1, 2022.
- *Post-Admission Evaluations:* Physicians are no longer required to conduct and document post-admission evaluations for Medicare patients. The post-admission evaluation covers much of the same information as continues to be included in the pre-admission screening of the patient and the patient's plan of care. This reduction in burden gives more time for physicians to take care of patients. **Removal of this requirement is permanent as of October 1, 2020.**

- *Flexibility for Inpatient Rehabilitation Facilities Regarding the 60% Rule:* During the PHE, CMS has been allowing IRFs to exclude patients from the IRF freestanding hospitals or excluded distinct part unit's inpatient population for purposes of calculating the applicable thresholds associated with the requirements to receive payment as an IRF (commonly referred to as the "60% rule") if an IRF admits a patient solely to respond to the emergency and the patient's medical record properly identifies the patient as such. In addition, during the applicable waiver time period, this exception also applied to facilities not yet classified as IRFs, but that were attempting to obtain classification as an IRF. When the COVID-19 PHE ends, all inpatients will again be included in the IRF freestanding hospital's or excluded distinct part unit's inpatient population for purposes of calculating the applicable thresholds associated with the requirements to receive payment as an IRF (commonly referred to as the "60% rule").
- *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.**

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

- During the PHE, CMS has been allowing Medicare Administrative Contractors (MACs) and Qualified Independent Contractors (QICs) in the FFS program (42 CFR 405.942 and 42 CFR 405.962) and MA and Part D plans, as well as the Part C and Part D Independent Review Entity (IREs) (42 CFR 422.582 and 42 CFR 423.582), to allow extensions to file an appeal. Specifically, 42 CFR 422.582(c) and 42 CFR 423.582(c) allow a Part C or Part D plan to extend the timeframe for filing a request if there is good cause for the late filing. In addition, the Part D IRE may find good cause for late filing of a request for reconsideration. **When the 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.
- *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>

#### ***Additional Information***

- The Interim Final Rules 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>.