Long-Term Care Hospitals & Extended Neoplastic Disease Care Hospitals: 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 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 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 and authorization. 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.**

Site Neutral Payment Rate Provisions

- *Site Neutral Payment Rate Provisions*: As required by section 3711(b) of the CARES Act, during the Public Health Emergency (PHE) due to COVID-19, certain provisions of section 1886(m)(6) of the Social Security Act were waived relating to certain site neutral payment rate provisions for long-term care hospitals (LTCHs).

    - Section 3711(b)(1) of the CARES Act waived the payment adjustment under section 1886(m)(6)(C)(ii) of the Act for LTCHs that do not have a discharge payment percentage (DPP) for the period that is at least 50% during the COVID-19 PHE period. For the purposes of calculating an LTCH's DPP, all admissions during the COVID-19 PHE period were counted in the numerator of the calculation. In other words, LTCH cases that were admitted during the COVID-19 PHE period were counted as discharges paid the LTCH PPS standard Federal payment rate. At the end of the COVID-19 PHE, the payment adjustment under section 1886(m)(6)(C)(ii) of the Act is applied for LTCHs that do not have a DPP for the period that is at least 50%.

      Section 3711(b)(2) of the CARES Act provides a waiver of the application of the site-neutral payment rate under section 1886(m)(6)(A)(i) of the Act for those LTCH admissions that are in response to the public health emergency and occur during the COVID-19 public health emergency (PHE) period. Under this provision, all LTCH cases admitted during the COVID-19 public health emergency period (that is, admissions occurring on or after January 27, 2020 through the duration of the COVID-19 PHE) were paid the relatively higher LTCH PPS standard Federal rate. When the COVID-19

PHE ends, all LTCH admissions, except those that meet the requirements for exclusion from the site-neutral rate, are subject to the site-neutral payment rate under section 1886(m)(6)(A)(i) of the Act.

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:
  - 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.
  - 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.
  - 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.
  - 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.

- 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.
- 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.
- 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.

- *Care for Patients in Extended Neoplastic Disease Care Hospitals*: For the duration of the public health emergency, CMS issued a program participation requirement waiver to extended neoplastic disease care hospitals to exclude inpatient stays where the hospital admits or discharges patients in order to meet the demands of the emergency from the greater than 20-day average length of stay requirement, which allows these facilities to be excluded from the hospital inpatient prospective payment system and paid an adjusted payment for Medicare inpatient operating and capital-related costs under the reasonable cost-based reimbursement rules. At the end of the COVID-19 PHE, Extended Neoplastic Disease Care Hospitals must comply with the 20-day average length of stay requirement at § 412.23(i)(1).

- *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

- *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 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 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 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

- 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.