Hospice: 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 blanket 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 blanket 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

CMS will continue to pay approximately $40 per dose for administering COVID-19 vaccines in outpatient settings for Medicare beneficiaries through the end of the calendar year that the PHE ends.

Effective January 1 of the year following the year that the PHE 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.

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

CMS also established an additional payment amount of approximately $35.50 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, and we geographically adjust the additional amount and administration rate based on where the provider or supplier administers the vaccine.

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

We'll continue to pay a total payment of approximately $75 per dose to administer COVID-19 vaccines in the home for certain Medicare patients through the end of the calendar year that the PHE ends.

Note: The Calendar Year 2023 Physician Fee Schedule proposed rule includes proposals that could impact these policies, and we anticipate issuing the final rule later this year.

More information: COVID-19 vaccine toolkits

- Providers
  - Payment
  - Billing
  - Coding
- Health & Drug Plans
- State Medicaid programs

COVID-19 Monoclonal Antibodies

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 COVID-19 public health emergency (PHE), 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.

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 purchased 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 that the PHE ends, CMS will pay for monoclonal antibodies:

- 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.

Note: The Calendar Year 2023 Physician Fee Schedule proposed rule includes proposals that could impact these policies, and we anticipate issuing the final rule later this year.

COVID-19 VEKLURY™ (remdesivir) in the Outpatient Setting

On January 21, 2022, the FDA updated the approval of VEKLURY™ (remdesivir) and authorized its use in the outpatient setting. 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.

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 and Telecommunications Technology

Hospice providers can provide services to a Medicare patient receiving routine home care through telecommunications technology (e.g., remote patient monitoring; telephone calls (audio only and TTY); and two-way audio-video technology), if it is feasible and appropriate to do so. Only in-person visits are to be recorded on the hospice claim. This waiver will expire at the end of the PHE.

- Face-to-face encounters for purposes of patient recertification for the Medicare hospice benefit can now be conducted via telehealth (i.e., two-way audio-video telecommunications technology that allows for real-time interaction between the hospice physician/hospice nurse practitioner and the patient). This waiver will expire the first day after the 151st day following the end of the PHE.

Workforce

- *Training and Assessment of Aides*: CMS has been waiving the requirement at 42 CFR §418.76(h)(2) for Hospice and 42 CFR §484.80(h)(1)(iii) for HHAs, which require a registered nurse, or in the case of an HHA a registered nurse or other appropriate skilled professional (physical therapist/occupational therapist, speech language pathologist) to make an annual onsite supervisory visit (direct observation) for each aide that provides services on behalf of the agency. In accordance with section 1135(b)(5) of the Act, we are postponing completion of these visits. All postponed onsite assessments must be completed by these professionals no later than 60 days after the expiration of the PHE. CMS will end this waiver at the conclusion of the PHE.

- *Annual Training*. CMS is modifying the requirement at 42 CFR §418.100(g)(3), which requires hospices to annually assess the skills and competence of all individuals furnishing care and provide in-service training and education programs where required. Pursuant to section 1135(b)(5) of the Act, we are postponing the deadline for completing this requirement throughout the COVID-19 PHE until the end of the first full quarter after the declaration of the PHE concludes. This does not alter the minimum personnel requirements at 42 CFR §418.114. Selected hospice staff must complete training and have their competency evaluated in accordance with unwaived provisions of 42 CFR Part 418. CMS will end this waiver at the conclusion of the PHE.

- *Quality Assurance and Performance Improvement (QAPI)*: CMS is modifying the requirement at 42 CFR §418.58 for Hospice and §484.65 for HHAs, which requires these providers to develop, implement, evaluate, and maintain an effective, ongoing, hospice/HHA-wide, data-driven QAPI program. Specifically, CMS is modifying the requirements at §418.58(a)–(d) and §484.65(a)–(d) to narrow the scope of the QAPI program to concentrate on infection control issues, while retaining the requirement that remaining activities should continue to focus on adverse events. This modification

decreases burden associated with the development and maintenance of a broad-based QAPI program, allowing the providers to focus efforts on aspects of care delivery most closely associated with COVID-19 and tracking adverse events during the PHE. The requirement that HHAs and hospices maintain an effective, ongoing, agency-wide, data-driven quality assessment and performance improvement program will remain. CMS will end this flexibility at the conclusion of the PHE.

- *Waived requirement for hospices to use volunteers:* CMS has been waiving the requirement at 42 CFR §418.78(e) that hospices are required to use volunteers (including at least 5% of patient care hours). It is anticipated that hospice volunteer availability and use will be reduced related to COVID-19 surge and anticipated quarantine. This waiver will terminate at the end of the COVID-19 PHE.

Reducing Administrative Burden

- *Comprehensive Assessments*: CMS has been waiving certain requirements for Hospice 42 CFR §418.54 related to update of the comprehensive assessments of patients. This waiver applies the timeframes for updates to the comprehensive assessment (§418.54(d)). Hospices must continue to complete the required assessments and updates, however, the timeframes for updating the assessment may be extended from 15 to 21 days. CMS will end this waiver at the conclusion of the PHE.

- *Waive Non-Core Services*: CMS has been waiving the requirement for hospices to provide certain non-core hospice services during the national emergency, including the requirements at 42 CFR §418.72 for physical therapy, occupational therapy, and speech-language pathology. CMS will end this waiver at the conclusion of 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

- *Specific Life Safety Code (LSC) for Hospice and CAHs:* CMS has been waiving and modifying particular waivers under 42 CFR §418.110(d) for inpatient hospice. Specifically, CMS is modifying these requirements as follows:

  - Alcohol-based Hand-Rub (ABHR) Dispensers: We are waiving the prescriptive requirements for the placement of alcohol-based hand rub (ABHR) dispensers for use by staff and others due to the need for the increased use of ABHR in infection control. However, ABHRs contain ethyl alcohol, which is considered a flammable liquid, and there are restrictions on the storage and location of the containers. This includes restricting access by certain patient/resident population to prevent accidental ingestion. Due to the increased fire risk for bulk containers (over five

gallons) those will still need to be stored in a protected hazardous materials area. **CMS will end this waiver at the conclusion of the PHE.**

- Refer to: 2012 LSC, sections 18/19.3.2.6. In addition, facilities should continue to protect ABHR dispensers against inappropriate use as required by 42 CFR §418.110(d)(4) for inpatient hospice. CMS will end this waiver at the conclusion of the PHE.

    - Fire Drills: Due to the inadvisability of quarterly fire drills that move and mass staff together, we will instead permit a documented orientation training program related to the current fire plan, which considers current facility conditions. The training will instruct employees, including existing, new or temporary employees, on their current duties, life safety procedures and the fire protection devices in their assigned area. Refer to: 2012 LSC, sections 18/19.7.1.6. ***(Terminated waivers for fire drills at §418.110(d) for inpatient hospice; §483.470(j) for ICF/IIDs; and §483.90(a) for SNF/NFs terminated on 6-6-2022 per QSO-22-15-NH & NLTC & LSC).***

    - Temporary Construction: CMS has been waiving requirements that would otherwise not permit temporary walls and barriers between patients. Refer to: 2012 LSC, sections 18/19.3.3.2. ***(Terminated waivers for temporary construction at §418.110(d) for inpatient hospice; §483.470(j) for ICF/IIDs; and §483.90(a) for SNF/NFs on 6-6-2022 per QSO-22-15-NH & NLTC & LSC).***

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 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 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 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 will continue to apply, consistent with existing regulatory authority.**

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 C.F.R. §§ 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 C.F.R. § 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 C.F.R. § 424.514, resumed collecting application fees.)***

- *Revalidation:* CMS postponed all revalidation actions. This did not prevent a provider who wants 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 October 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.**

- *Opt-Out Enrollment:* CMS allowed practitioners to cancel their opt-out status early and enroll in Medicare to provide care to more patients. CMS also allowed MACs to accept opt-out cancellation requests via email, fax, or phone call to the hotline. CMS allowed a provider to submit an application (an 855-I or 855-R for example) to cancel their opt-out. Providers were not required to submit a written notification to cancel their opt-out status. **When the PHE ends, this waiver will terminate and opted-out practitioners will not be able to cancel their opt-out statuses earlier than the applicable regulation at 42 CFR 405.445 allows for.**

- *Reporting Home Address:* During the PHE, CMS allowed practitioners to render telehealth services from their home without reporting their home address on their Medicare enrollment while continuing to bill from their currently enrolled location. **When the PHE ends, practitioners will be required to resume reporting their home address on the Medicare enrollment.**

- *State Licensure:* During the PHE, CMS allowed licensed physicians and other practitioners to bill Medicare for services provided outside of their state of enrollment. **CMS has determined that, when the PHE ends, CMS regulations will continue to allow for a total deferral to state law.** Thus, there is no CMS-based requirement that a provider must be licensed in its state of enrollment.

- *Cost Reporting*. CMS delayed the filing deadline for all provider types impacted during the COVID-19 PHE, including hospitals, SNFs, HHAs, hospices, ESRDs, RHCs, FQHCs, CMHCs, OPOs, histocompatibility labs, and home office cost statements, with a fiscal year ending on or between October 31, 2019 through December 31, 2020. Providers that continue to experience the impacts of the COVID-19 PHE and require additional time to file their cost report ending after December 31, 2020, they 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 COVID-19 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 describe standards of practice for infection control and prevention of COVID-19 in hospices at https://www.cms.gov/files/document/qso-20-16-hospice.pdf

- 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.