Durable Medical Equipment, Prosthetics, Orthotics and Supplies: 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.

- Where Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) are lost, destroyed, irreparably damaged, or otherwise rendered unusable, DME Medicare Administrative Contractors have the flexibility to waive replacement requirements under Medicare, such that the face-to-face requirement, a new physician's order, and

new medical necessity documentation are not required. Suppliers must still include a narrative description on the claim explaining the reason why the equipment must be replaced and are reminded to maintain documentation indicating that the DMEPOS was lost, destroyed, irreparably damaged or otherwise rendered unusable or unavailable as a result of the emergency.

- *Prior Authorization in DMEPOS*: CMS previously paused certain prior authorization requirements for claims for Power Mobility Devices and Pressure Reducing Support Surfaces. CMS additionally delayed the prior authorization requirement for specified Lower Limb Prosthetics. On August 3, 2020, CMS resumed full operations for the prior authorization of Power Mobility Devices and Pressure Reducing Support Surfaces. Additionally, CMS phased in prior authorization requirements for certain Lower Limb Prosthetics in late 2020.

- *DMEPOS Accreditation*: During the initial stage of the PHE, CMS did not require accreditation for newly enrolling DMEPOS suppliers and extended any expiring supplier accreditation for a 90-day time period. Effective July 6, 2020, CMS resumed all accreditation and reaccreditation activities for DMEPOS suppliers, including associated surveys.

- *DMEPOS Supplier Standards:* During the initial stage of the PHE, CMES waived three DMEPOS supplier standards. *See below*. Effective July 6, 2020, CMS resumed enforcement of the three temporarily waived supplier standards.

    - 42 C.F.R. § 424.57(c)(7): Physical access—maintains a physical facility on an appropriate site.
    - 42 C.F.R. § 424.57(c)(9): Business Phone—maintains a primary business telephone that is operating at the appropriate site listed under the name of the business locally or toll-free for beneficiaries.
    - 42 C.F.R. § 424.57(c)(30)(i): Minimum hours of operation—except as specified in 42 C.F.R. § 424.57(c)(30)(ii), is open to the public a minimum of 30 hours per week.

- *DMEPOS Payment Increases:* As required by section 3712(a) of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, CMS will continue to adjust the fee schedule amounts for items and services furnished in rural and non-contiguous, non-competitive bidding areas within the U.S., based on a 50/50 blend of adjusted and unadjusted rates through the remainder of the public health emergency for COVID-19. Through notice-and-comment rulemaking (86 FR 73860, 87 FR 199), CMS has extended the 50/50 blend of adjusted and unadjusted rates in rural and non-contiguous, non-competitive bidding areas after the public health emergency. Also, as required by section 3712(b) of the CARES Act, CMS will continue to adjust the fee schedule amounts for certain DMEPOS

items and services furnished in non-rural, non-competitive bidding areas within the contiguous U.S., based on a 75/25 blend of adjusted and unadjusted rates **through the remainder of the public health emergency for COVID-19**. More information on these changes can be found on the CMS DME Center website: https://www.cms.gov/Center/Provider-Type/Durable-Medical-Equipment-DME-Center.

- *Signature Requirements:* CMS has waived signature and proof of delivery requirements for Part B drugs and Durable Medical Equipment when a signature cannot be obtained because of the inability to collect signatures for the duration of the public health emergency for COVID-19. Suppliers document in the medical record the appropriate date of delivery and that a signature was not able to be obtained because of COVID-19.

- *Signature on Orders:* DMEPOS items, except for Power Mobility Devices (PMDs), can be provided via a verbal order during the public health emergency for COVID-19. A signature is required prior to submitting claims for payment, but the order can be signed electronically. PMDs require a signed, written order prior to delivery.

- *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.

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 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 COVID-19 PHE ends, these flexibilities will continue to apply, consistent with existing regulatory authority.

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.