

Ambulances: 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:

- 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

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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 COVID-19 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 COVID-19 PHE ends.

Effective January 1 of the year following the year that the COVID-19 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 COVID-19 PHE ends.

Note: The <u>Calendar Year 2023 Physician Fee Schedule</u> 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
 - o Payment
 - o Billing
 - o Coding
- Health & Drug Plans
- State Medicaid programs

CMS Hospital Without Walls (Temporary Expansion Sites)

 During the Public Health Emergency (PHE) for the COVID-19 pandemic, we have temporarily expanded the list of allowable destinations for ambulance transports.
 During the COVID 19 PHE, ambulance transports may include any destination that is able to provide treatment to the patient in a manner consistent with state and local



Emergency Medical Services (EMS) protocols in use where the services are being furnished. These destinations may include, but are not limited to: any location that is an alternative site determined to be part of a hospital, CAH or SNF, community mental health center, federally qualified health center (FQHC), physician's office, urgent care facility, ambulatory surgery center (ASC), or any other location furnishing dialysis services outside of the ESRD facility, and the beneficiary's home. This topic is included in the CY 2023 Physician Fee Schedule rule, which the agency expects to finalize this fall.

Ambulance Treat in Place

Pursuant to authority granted under section 9832 of the American Rescue Plan Act of 2021, CMS could pay for treatment in place under this waiver, by waiving the requirements under section 1861(s)(7) and section 1834(l) of the Social Security Act, in cases where the individual who would have been transported would have met the Medicare criteria for a medically necessary ground ambulance transport to the nearest appropriate facility that could have treated the patient's condition, but such transport did not occur as a result of community-wide emergency medical service protocols due to the COVID-19 public health emergency. This waiver will end with the end of the PHE.

Reducing Administrative Burden

Repetitive, Scheduled Non-Emergent Ambulance Transport (RSNAT) Prior
 Authorization Model: Effective March 29, 2020, certain claims processing
 requirements for the RSNAT Prior Authorization Model were paused in the model
 states of Delaware, the District of Columbia, Maryland, New Jersey, North Carolina,
 Pennsylvania, South Carolina, Virginia, and West Virginia because of the COVID-19
 pandemic. During the pause, RSNAT claims were not stopped for pre-payment review
 if prior authorization had not been requested by the fourth round trip in a 30-day
 period. CMS (through the MACs) continued to review any prior authorization requests
 that were submitted.

Given the importance of prior authorization activities to CMS' program integrity efforts, CMS discontinued exercising enforcement discretion on August 3, 2020 and resumed full model operations. Following resumption of the model, the MACs conducted postpayment review on RSNAT claims that were paid during the pause without prior authorization. CMS worked with affected providers to develop a schedule for postpayment reviews that did not significantly increase provider burden. Claims that receive a provisional affirmation prior authorization review decision and are submitted with an affirmed Unique Tracking Number (UTN) continue to be excluded from most future medical reviews.



- Medicare Ground Ambulance Data Collection System: Under a section 1135 waiver, CMS modified the data collection period and data reporting period for ground ambulance organizations that were selected by CMS to collect data beginning between January 1, 2020 and December 31, 2020 (year one) and January 1, 2021 and December 31, 2021 (year two) for purposes of complying with the statutory data reporting effort. Under this modification, these ground ambulance organizations selected a new continuous 12-month data collection period that begins between January 1, 2022 and December 31, 2022, to collect data necessary to complete the Medicare Ground Ambulance Data Collection Instrument. CMS modified this data collection and reporting period to increase flexibilities for ground ambulance organizations that would otherwise be required to collect data in 2020-2021 so that they could focus on their operations and patient care.
- Signature Requirements: With respect to ambulance transports where CMS' regulations otherwise require a physician or, in lieu of that, certain non-physician personnel, to sign and certify that the need for the non-emergency ambulance transport is medically necessary, for claims with dates of service during the COVID-19 PHE (January 27, 2020 until expiration), absent indications of potential fraud or abuse, CMS is not reviewing for compliance with such signature requirements. Suppliers and providers document in the medical record that a signature is not able to be obtained because of COVID-19.
- 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 highrisk 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.

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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.