

Medicare Advantage and Part D Plans: 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.

Reducing Administrative Burden

- *Flexibility to Provide Expanded Benefits:* CMS [announced](#) in guidance it is exercising enforcement discretion to allow Medicare Advantage plans to expand telehealth services and other mid-year benefit enhancements beyond those included in their approved 2020, 2021, 2022, and 2023 bids describing covered benefits, when such mid-

year benefit enhancements are provided in connection with the COVID-19 outbreak, are beneficial to enrollees, and are provided uniformly to all similarly situated enrollees.

CMS will continue these flexibilities for the duration of the COVID-19 PHE.

- *Prior Authorization for Part D Drugs:* Part D Sponsors may waive prior authorization requirements at any time that they otherwise would apply it to Part D drugs used to treat or prevent COVID-19 if or when such drugs are identified. Part D Sponsors can also choose to waive or relax PA requirements at any time for other formulary drugs in order to facilitate access with less burden on beneficiaries, plans, and providers. **This flexibility will continue for the duration of the COVID-19 PHE.**
- *Part D “Refill-Too-Soon” Edits and Maximum Day Supply:* Consistent with section 3714 of the CARES Act, during the public health emergency for COVID-19, Part D sponsors must permit enrollees to obtain the total supply prescribed for a covered Part D drug up to a 90-day supply in one fill or refill if requested by the enrollee, prior authorization or step therapy requirements have been satisfied, and no safety edits otherwise limit the quantity or days’ supply. Part D plan sponsors must relax their “refill-too-soon” edits. Part D sponsors continue to have operational discretion as to how these edits are relaxed, as long as access to Part D drugs is provided at the point of sale. For purposes of section 3714 of the CARES Act, relaxed refill-too-soon edits are safety edits, and Part D sponsors must not permit enrollees to obtain a single fill or refill that is inconsistent with a safety edit. **This requirement will end with the COVID-19 PHE.**
- *Home or Mail Delivery of Part D Drugs:* In situations when a disaster or emergency makes it difficult for enrollees to get to a retail pharmacy, or enrollees are actually prohibited from going to a retail pharmacy (e.g., in a quarantine situation), Part D sponsors have been permitted to voluntarily relax any plan-imposed policies that may discourage certain methods of delivery, such as mail or home delivery, for retail pharmacies that choose to offer these delivery services in these instances. **This flexibility will continue for the duration of the COVID-19 PHE.**
- *Audit Reviews:* CMS temporarily reprioritized audit activity in 2020 under our oversight discretion, returned to normal oversight activities in 2021, and continued providing flexibility to audited organizations when needed.

COVID-19 Vaccines

- *CMS reminds MA organizations that they must pay for the COVID-19 vaccine and its administration (including approved booster doses), without cost-sharing in-network, beginning January 1, 2022, for beneficiaries enrolled in their plans.*

COVID-19 Diagnostic Testing

- *Coverage of Testing and Testing-Related Services for COVID-19:* As a result of the Families First Coronavirus Response Act and the CARES Act, Medicare Advantage Organizations are not permitted to charge cost sharing for clinical laboratory tests for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19, the administration of such tests, and specified COVID-19 testing-related services during the period March 18, 2020, through the end of the COVID-19 public health emergency declared by the Secretary under section 319 of the Public Health Service Act. In addition, Medicare Advantage organizations may not impose any prior authorization or other utilization management requirements with respect to the coverage of COVID diagnostic tests, its administration and specified testing-related services furnished on or after March 18, 2020, and during the applicable emergency period.

COVID-19 Oral Antivirals:

- The FDA issued an emergency use authorization (EUA) for oral antivirals for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients. Oral antivirals that are procured by the U.S. government (USG) and provided to pharmacies are provided to patients at no cost. **This process will continue while oral antivirals are being procured by the USG.**
- CMS has permitted Part D sponsors to pay pharmacy claims for dispensing fees USG-procured Emergency Use Authorization (EUA) oral antiviral drugs for treatment of COVID-19 without enrollee cost-sharing, and report prescription drug events (PDEs) for the dispensing fee claims. Additionally, the agency has strongly encouraged Part D sponsors to pay dispensing fees to for these drugs that may be higher than a sponsor's usual negotiated dispensing fees, given the unique circumstances during the COVID-19 PHE. **This flexibility will continue following the end of the COVID-19 PHE while USG-procured product remains available.**

Payment After the End of the PHE

Oral antivirals for COVID-19 that otherwise meet the statutory requirements for Part D coverage at section [1860D-2\(e\)](#) of the Social Security Act and are not procured by the US Government must be covered by Part D plans, as a formulary product or through the formulary exception process. This applies to oral antivirals for COVID-19 with emergency use authorization (EUA) under section 564 of the Federal Food, Drug and Cosmetic Act through December 31, 2024, consistent with Section 4131 of the Consolidated Appropriations Act, 2023 and any such products that receive FDA approval.

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 PHE ends, these flexibilities may only be provided 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> and <https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers>.
- Updated Guidance for Medicare Advantage Organizations can be found at: <https://www.cms.gov/files/document/updated-guidance-ma-and-part-d-plan-sponsors-42120.pdf>.
- COVID-related HPMS memos. MA and Part D plan guidance. [Current emergencies | CMS](#).
- HPMS memos on Part C and Part D programs are on this page under the “downloads” section: <https://www.cms.gov/medicare/health-plans/healthplansgeninfo>.<https://www.cms.gov/medicare/health-plans/healthplansgeninfo>.
- Most recent memo: <https://www.cms.gov/files/document/extendedcovidflexibilitieshpmsmemo1142022.pdf>.