DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, Maryland 21244-1850



DATE: March 10, 2020

TO: All Medicare Advantage Organizations, Part D Sponsors, and Medicare-Medicaid Plans

SUBJECT: Information Related to Coronavirus Disease 2019 - COVID-19

The Centers for Medicare & Medicaid Services (CMS) is issuing this information to Medicare Advantage Organizations and Part D Sponsors to inform them of the obligations and permissible flexibilities related to disasters and emergencies resulting from COVID-19.

Medicare Advantage Organizations

Special Requirements

Special requirements during a disaster or emergency related to Part A/B and supplemental Part C benefit access can be found at 42 CFR 422.100(m). A declaration by the Governor of a State or Protectorate is one of the triggering events for these special requirements. Under the regulation, special requirements are in effect until the end date identified in the State declaration or for 30 days, if no end date is identified in the declaration. To date, declarations have been made in at least 8 States.¹

When these special requirements are in effect, under 42 CFR 422.100(m)(2), the requirements for Medicare Advantage Organizations under 42 CFR 422.100(m)(1) are:

- (i) Cover Medicare Parts A and B services and supplemental Part C plan benefits furnished at non-contracted facilities subject to § 422.204(b)(3), which requires that facilities that furnish covered A/B benefits have participation agreements with Medicare.
- (ii) Waive, in full, requirements for gatekeeper referrals where applicable.
- (iii) Provide the same cost-sharing for the enrollee as if the service or benefit had been furnished at a plan-contracted facility.
- (iv) Make changes that benefit the enrollee effective immediately without the 30-day notification requirement at § 422.111(d)(3). (Such changes could include reductions in cost-sharing and waiving prior authorizations as described below.)

¹ Medicare Advantage Organizations and Part D Sponsors may wish to consult https://www.nga.org/coronavirus/ for information on COVID-19 declarations by Governors.

These changes must be uniformly provided to similarly situated enrollees who are affected by the disaster or emergency.

Permissive Actions

Additionally, in response to the unique circumstances resulting from the outbreak of COVID-19, CMS advises that Medicare Advantage Organizations may waive or reduce enrollee cost-sharing for beneficiaries enrolled in their Medicare Advantage plans impacted by the outbreak. For example, Medicare Advantage Organizations may waive or reduce enrollee cost-sharing for COVID-19 laboratory tests, telehealth benefits or other services to address the outbreak provided that Medicare Advantage Organizations waive or reduce cost-sharing for all similarly situated plan enrollees on a uniform basis. Specifically, CMS will exercise its enforcement discretion regarding the administration of Medicare Advantage Organizations benefit packages as approved by CMS in conjunction with implementing a voluntary waiver or reduction of cost-sharing as described. CMS consulted with the HHS Office of Inspector General (OIG) and HHS OIG advised that should an Medicare Advantage Organization choose to voluntarily waive or reduce enrollee cost-sharing, as approved by CMS herein, such waivers or reductions would satisfy the safe harbor to the Federal anti-kickback statute set forth at 42 CFR 1001.952(1).

Medicare Advantage Organizations may also provide enrollees access to Medicare Part B services via telehealth in any geographic area and from a variety of places, including beneficiaries' homes. In response to the unique circumstances resulting from the outbreak of COVID-19, should an Medicare Advantage Organization wish to expand coverage of telehealth services beyond those approved by CMS in the plan's benefit package for similarly situated enrollees impacted by the outbreak, CMS will exercise its enforcement discretion regarding the administration of Medicare Advantage Organizations' benefit packages as approved by CMS until it is determined that the exercise of this discretion is no longer necessary in conjunction with the COVID-19 outbreak. CMS consulted with the HHS OIG and HHS OIG advised that should a Medicare Advantage Organization choose to expand coverage of telehealth benefits, as approved by CMS herein, such additional coverage would satisfy the safe harbor to the Federal anti-kickback statute set forth at 42 CFR 1001.952(1).

CMS will notify Medicare Advantage Organizations and Part D Sponsors through the Health Plan Management System when CMS is ending the enforcement discretion described herein.

Moreover, consistent with flexibilities available to Medicare Advantage Organizations absent a disaster, declaration of a state of emergency, or public health emergency, Medicare Advantage Organizations may choose to waive plan prior authorization requirements that otherwise would apply to tests or services related to COVID-19 at any time.

Finally, we remind Medicare Advantage Organizations that in the event that the Secretary issues a waiver under Section 1135 of the Social Security Act, CMS may authorize Medicare Administrative Contractors MACs to pay for Part C-covered services furnished to beneficiaries enrolled in Medicare Advantage plans and subsequently seek reimbursement from Medicare Advantage Organizations for those health care services retrospectively.

Part D Sponsors

Section 1860D-4(b)(1)(C)(iii) of the Social Security Act requires that the Secretary's rules on pharmacy network access "include adequate emergency access for enrollees." Using that authority, CMS has previously provided information to Part D sponsors² about their ability to take certain actions in response to disasters or emergencies that are reasonably expected to result in disruption in access to covered Part D drugs, which potentially could now include COVID-19. Part D sponsors may also take the following actions to ensure pharmacy access during a disaster or state of emergency resulting from COVID-19.

Relax "Refill-Too-Soon" Edits and Provide Maximum Extended Day Supply

Part D sponsors may relax their "refill-too-soon" edits if circumstances are reasonably expected to result in a disruption in access to drugs. Sponsors 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. Part D sponsors may also allow an affected enrollee to obtain the maximum extended day supply available under their plan, if requested and available.

Part D sponsors may relax edits in the absence of declarations if they determine it is appropriate to ensure pharmacy access, for instance, in advance of an impending disaster, and may consider continuing to relax their "refill-too-soon" edits past the expiration of the declaration. Whenever sponsors make the decision to turn edits back on, they should work closely with all enrollees, particularly those who indicate that they are still displaced or otherwise impacted by the disaster or emergency.

Reimburse Enrollees for Prescriptions Obtained from Out-of-Network Pharmacies

Consistent with §423.124(a) of the Part D regulations, Part D sponsors must ensure enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when those enrollees cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy. Enrollees remain responsible for any cost sharing under their plan and additional charges (i.e., the out-of-network pharmacy's usual and customary charge), if any, that exceed the plan allowance.

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 are 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.

Prior Authorization for Part D Drugs

As is the case for Medicare Advantage Organizations, consistent with flexibilities available to Part D Sponsors absent a disaster or emergency, Part D Sponsors may choose to waive prior authorization requirements at any time that they otherwise would apply to Part D drugs used to treat or prevent COVID-19, if or when such drugs are identified. Any such waiver must be uniformly provided to similarly situated enrollees who are affected by the disaster or emergency.

² Prescription Drug Benefit Manual. Chapter 5, Section 50.12. Pharmacy Access During a Federal Disaster or Other Public Health Emergency Declaration. https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5 093011.pdf

Drug Shortages

Part D plan sponsors should follow the existing drug shortage guidance in Section 50.13 of Chapter 5 of the Part D manual in response to any shortages that result from this emergency.

Vaccines

Under current law, if a vaccine becomes available for COVID-19, Medicare will cover the vaccine. All Part D plans will be required to cover the vaccine if it is a Part D drug.

Medicare-Medicaid Plans

The guidance articulated in this memorandum for Medicare Advantage Organizations and Part D sponsors also applies for Medicare Parts A, B, and D benefits covered by Medicare-Medicaid Plans operating under three-way contracts as part of the Financial Alignment Initiative's capitated model demonstrations.

Medicare Advantage Organizations and Part D Sponsors

Business Continuity Plans

As required under 42 CFR 422.504 (o) and 423.505(p), Medicare Advantage Organizations and Part D sponsors must have business continuity plans to ensure restoration of business operations following disruptions, including emergencies. Medicare Advantage Organizations and Part D sponsors should review their business continuity plans to ensure that any necessary planning for business operations disruption due to a disaster or emergency is included.

Payment

The rules governing CMS's payments to Medicare Advantage Organizations and Part D Sponsors remain unchanged, and are not affected by this memorandum.

Please note that nothing in this memorandum speaks to the arrangements between Medicare Advantage Organizations or Part D Sponsors and their contracted providers or facilities.