

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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DATE: May 22, 2020 (*rev. from April 21, 2020*)

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

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

On March 10, 2020, the Centers for Medicare & Medicaid Services (CMS) issued guidance notifying Medicare Advantage Organizations (MAOs) and Part D sponsors of a number of flexibilities they may implement during the coronavirus disease 2019 (COVID-19) public health emergency to support efforts that can help curb the spread of the virus and to help ensure MA and Part D enrollees do not experience disruptions in care or disruptions in pharmacy and prescription drug access. Since issuing this guidance, CMS has continued to receive requests for additional guidance regarding CMS's expectations with respect to other CMS and MAO and Part D sponsor policies and requirements during this public health emergency. This memo supersedes and replaces the March 10, 2020 memorandum.

Due to the public health emergency posed by COVID-19 and the urgent need to ensure access to health care items and services covered by MA, Part D and Medicare-Medicaid plans, particularly in light of isolation and social distancing measures that are necessary to contain the spread of COVID-19, CMS is exercising its enforcement discretion to adopt a temporary policy of relaxed enforcement in connection with the policies discussed in this memo under the conditions outlined herein.

We believe that any guidance in this memorandum relating to CMS's enforcement discretion is a statement of agency policy not subject to the notice and comment requirements of the Administrative Procedure Act (APA). 5 U.S.C. § 553(b)(A). CMS additionally finds that, even if this guidance were subject to the public participation provisions of the APA, due to the urgent need to ensure that MA and Part D enrollees do not experience disruptions in care or disruptions in pharmacy and prescription drug access during the public health emergency posed by COVID-19, prior notice and comment for this guidance is impracticable, and there is good cause to issue this guidance without prior public comment and without a delayed effective date. 5 U.S.C. § 553(b)(B) & (d)(3). Similarly, even if this guidance were subject to the public participation provisions of 42 USC § 1395hh(b)(1), CMS finds that these public participation provisions also do not apply to this guidance because, for the reasons explained above, 5 U.S.C. § 553(b) does not apply to this guidance pursuant to 5 U.S.C. § 553(b)(B). 42 USC § 1395hh(b)(2)(C).

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

Coverage of Testing and Testing-Related Services for COVID-19

Under Section 6003 of the Families First Coronavirus Response Act and Section 3713 of the CARES Act, MAOs must not charge cost sharing (including deductibles, copayments, and coinsurance) for:

- clinical laboratory tests for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19 and the administration of such tests;
- specified COVID-19 testing-related services (as described in section 1833(cc)(1)) for which payment would be payable under a specified outpatient payment provision described in section 1833(cc)(2)¹; and
- COVID-19 vaccines and the administration of such vaccines, as described in section 1861(s)(10)(A).

The limit on cost sharing (including deductibles, copayments, and coinsurance) for COVID-19 testing and specified testing-related services applies to services furnished on or after March 18, 2020 and during the emergency period identified in section 1135(g)(1)(B) of the Act (that is, the public health emergency declared by the Secretary pursuant to section 319 of the Public Health Service Act on January 31, 2020, entitled “Determination that a Public Health Emergency Exists Nationwide as the Result of the 2019 Novel Coronavirus,” and any extensions thereof) (“applicable emergency period”). In addition, MAOs may not impose any prior authorization or other utilization management requirements with respect to the coverage of these services when those items or services are furnished on or after March 18, 2020 and during the applicable emergency period.

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 emergency declaration or for 30 days, if no end date is identified in the declaration. To date, declarations have been made in all 50 States, the District of Columbia, and the Territories.²

MAOs must follow the requirements for disasters and emergencies outlined in 42 CFR § 422.100(m). Under 42 CFR § 422.100(m), MAOs must ensure access to benefits in the following manner:

- (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.

¹ CMS has identified the specified services and outpatient payment provisions in section 1833(cc) of the Act in recent guidance: https://www.cms.gov/outreach-and-education/outreachffsprovpartprogprovider-partnership-email-archive/2020-04-07-mlnc-se#_Toc37139913.

² Medicare Advantage Organizations and Part D Sponsors may wish to consult <https://www.nga.org/coronavirus/> for information on COVID-19 declarations by Governors.

(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.)

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

Permissive Actions

Additional or Expanded Benefit Offerings. In response to the unique circumstances resulting from the outbreak of COVID-19, CMS is exercising its enforcement discretion to adopt a temporary policy of relaxed enforcement in connection with the prohibition on mid-year benefit enhancements (73 Federal Register 43628), such as expanded or additional benefits or more generous cost-sharing under the conditions outlined in this memorandum, 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. MAOs may implement additional or expanded benefits that address issues or medical needs raised by the COVID-19 outbreak, such as covering meal delivery or medical transportation services to accommodate the efforts to promote social distancing during the COVID-19 public health emergency. CMS will exercise its enforcement discretion regarding the administration of MAOs' 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. We expect MAOs to share information regarding these mid-year benefit enhancements with their CMS account managers.

Medicare Advantage Cost-Sharing. We acknowledge the positive impact that waiving or reducing enrollee cost-sharing would have on patient experience and therefore encourage MAOs to 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 treatment, telehealth benefits or other services to address the outbreak provided that MAOs waive or reduce cost-sharing for all similarly situated plan enrollees on a uniform basis. CMS clarifies that this flexibility is limited to when a waiver or reduction in cost-sharing can be tied to the COVID-19 outbreak. 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(l).

Telehealth. 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 a 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(l).

Model of Care Flexibility. CMS also recognizes that in light of the COVID-19 outbreak, an MAO with one or more special needs plans (SNPs) may need to implement strategies that do not fully comply with their approved SNP model of care (MOC) in order to provide care to enrollees while ensuring that enrollees and health care providers are also protected from the spread of COVID-19. CMS will consider the special circumstances presented by the COVID-19 outbreak when conducting MOC monitoring or oversight activities. For example, CMS recognizes that there may be requirements in the MOC that require face-to-face contact with enrollees and would exercise enforcement discretion should a plan choose not to fulfill that MOC requirement in person.

Involuntary Disenrollment - Temporary Absence Flexibilities. Due to the public health emergency posed by COVID-19 and the urgent need to ensure that enrollees have continued coverage and access to sufficient health care items and services to meet their medical needs, CMS is exercising its enforcement discretion to adopt a temporary policy of relaxed enforcement with respect to MA organizations that choose to delay to a later date the involuntary disenrollment of enrollees who are temporarily absent from the service area for greater than 6 months when that absence is due to the COVID-19 national emergency. CMS will not enforce the requirement at § 422.74(d)(4) and will allow MA organizations to extend the period of time members may remain enrolled while temporarily absent from the plan service area through the end of the year, or the end of the public health emergency, whichever is earlier. Individuals who remain absent from the service area will be disenrolled January 1, 2021, if the public health emergency is still in effect at that time, or 6 months after the individual left the service area, whichever is later. CMS reminds MAOs of their requirements under 42 CFR § 422.100(m) to provide coverage for care from non-contracted providers, as outlined above in this memo under “Special Requirements.”

Involuntary Disenrollment – Loss of Special Needs Status. Due to the public health emergency posed by COVID-19, we are aware that plans may experience delays recertifying SNP eligibility because they are reliant on determinations and information from States or providers who, themselves, are experiencing workforce shortages. For example, states have indicated to CMS they are unable to meet federal timeliness standards for renewing Medicaid eligibility due to these workforce shortages and office closures and the added challenge of the increased volume of applications. Because we feel it is important to ensure that enrollees have continued coverage and access to sufficient health care items and services to meet their medical needs, CMS will also exercise enforcement discretion during calendar year 2020 to adopt a temporary policy of relaxed enforcement with respect to MA organizations that choose to delay to a later date the involuntary disenrollment of enrollees who are losing special needs status and cannot recertify SNP eligibility due to the COVID-19 national emergency. Under this policy, CMS will also not take action against MA organizations that have a policy of deemed continued eligibility and choose to delay to a later date the involuntary disenrollment of enrollees who fail to regain special needs status during the period of deemed continued eligibility (see § 422.52(d))³ due to

³ If an SNP determines that the enrollee no longer meets the eligibility criteria, but can reasonably be expected to again meet

the COVID-19 national emergency. CMS will not enforce the requirement for mandatory disenrollment at § 422.74(b)(2)(iv) and will allow MA organizations to extend the period of deemed continued eligibility under § 422.52(d) during 2020. Individuals who do not regain eligibility must be disenrolled the later of January 1, 2021, or upon expiration of the usual period of deemed continued eligibility that begins the first of the month following the month in which information regarding the loss is available to the MA organization and communicated to the enrollee, including cases of retroactive Medicaid terminations.

SNPs are not required under existing regulations to have a policy of deemed continued eligibility; however, plans must apply the same policy consistently for all enrollees of the applicable SNP. For those SNPs that have elected not to have a policy of deemed continued eligibility, CMS encourages the SNP to consider establishing one.⁴ For those plans that have a policy of deemed continued eligibility for a period of less than 6 months, CMS encourages the SNP to increase this to 6 months. SNPs may make these types of changes mid-year as long as the change is applied to everyone in the plan and the plan notifies its CMS account manager.

Additional Flexibilities. There may be other circumstances where an MAO may need to implement strategies or actions they deem reasonable and necessary, but which do not fully comply with program requirements, in order to furnish or provide coverage of Part A or B benefits to enrollees while ensuring the enrollees are also protected from the spread of COVID-19. CMS will consider the special circumstances presented by the COVID-19 outbreak when conducting monitoring or oversight activities.

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

Prior Authorization. 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 or relax plan prior authorization requirements at any time in order to facilitate access to services with less burden on beneficiaries, plans, and providers. Any such relaxation or waiver must be uniformly provided to similarly situated enrollees who are affected by the disaster or emergency. We encourage plans to consider utilizing this flexibility.

Finally, we remind Medicare Advantage Organizations that the Secretary has issued a waiver under Section 1135(b)(6) of the Social Security Act that permits to CMS 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. CMS has not authorized the MACs to take this action.

that criteria within a 6-month period, the enrollee is deemed to continue to be eligible for the MA plan for a period of not less than 30 days but not to exceed 6 months.

⁴ Guidance on loss of special needs status and deemed continued eligibility can be found in section 50.2.5 of Chapter 2 (Medicare Advantage Enrollment and Disenrollment) of the Medicare Managed Care Manual.

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 sponsors⁵ 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.

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 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. 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. Any such waiver must be uniformly provided to similarly situated enrollees who are affected by the disaster or emergency. We encourage plans to consider utilizing this flexibility.

Drug Shortages

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

Vaccines

Section 3713 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) specifies that a COVID-19 vaccine and its administration will be covered under Medicare Part B, and therefore would be excluded from Part D coverage.

⁵ 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

Additional Flexibilities

Given both the rapidly changing landscape and the need for Part D sponsors to act quickly to ensure enrollee and employee safety during this pandemic, we encourage Part D sponsors to take the actions you deem reasonable and necessary to keep your enrollees and employees safe and curb the spread of this virus, while still ensuring beneficiary access to needed Part D drugs (example actions listed below). CMS fully supports plans taking actions to accommodate the efforts to promote social distancing. We recognize that there may be circumstances where a Part D sponsor may need to implement strategies or actions they deem reasonable and necessary, but which do not fully comply with program requirements, in order to provide qualified prescription drug coverage to enrollees while ensuring their enrollees and employees are also protected from the spread of COVID-19. CMS will consider the special circumstances presented by the COVID-19 outbreak when conducting monitoring or oversight activities.

To that end, due to the public health emergency posed by COVID-19 and the urgent need to ensure enrollee and employee safety during this pandemic, CMS is exercising its enforcement discretion to adopt a temporary policy of relaxed enforcement in connection with, but not limited to, the following:

- Waiving Part D medication delivery documentation and signature log requirements;
- Relaxing to the greatest extent possible prior authorization requirements, where appropriate; and/or
- Suspending plan-coordinated pharmacy audits.

Part D Provisions of the CARES Act

CMS is implementing section 3714 of the CARES Act by this program instruction, as authorized by section 3714(b).

Cost and Utilization Management Requirements

Part D sponsors must suspend all quantity and days' supply limits under 90 days for all covered Part D drugs (as defined in 42 CFR § 423.100) other than such limits resulting from safety edits (discussed below). Part D sponsors may otherwise continue to utilize their formularies, tiered cost-sharing benefit structures, and approved prior authorization (PA) and step therapy (ST) requirements. There are no alterations to mid-year formulary change requirements, and we remind sponsors that new drugs may be added and utilization management requirements removed at any time.

Safety Edits

Part D sponsors may continue to use, or may immediately implement, point-of-sale safety edits consistent with the requirements of 42 CFR § 423.153(c)(2) and this guidance. CMS generally does not consider safety edits implemented as quality assurance measures under 42 CFR § 423.153(c)(2) to be subject to the CMS formulary review and approval process and does not require notice from plans when new safety edits are implemented. Safety edits include, but are not limited to, the following:

- Quantity Limits (QLs) based on clearly stated maximum dosing limits specified in the FDA-approved label;
- QLs that are intended to prevent clinical abuse/misuse or hoarding by limiting quantities/days supply of specific Part D drugs that the sponsor determines are at risk while continuing to allow for dispensing of sufficient quantities/days supplies to treat medically accepted indications;
- Refill-too-soon edits (discussed further below);

- Point-of-sale claim edits for frequently abused drugs that are specific to an at-risk beneficiary in a drug management program as described in 42 CFR § 423.153(f)(3)(i); and/or
- Opioid safety edits (see below).

Opioid Safety Edits

Part D sponsors are expected to continue to apply existing opioid point-of-sale safety edits during the COVID-19 emergency, including the care coordination edit at 90 morphine milligram equivalents (MME) per day, optional hard edit at 200 MME per day or more, hard edit for seven-day supply limit for initial opioid fills (opioid naïve), soft edit for concurrent opioid and benzodiazepine use, and soft edit for duplicative long-acting (LA) opioid therapy. However, due to the increased burden on the healthcare system as a result of the COVID-19 pandemic, we encourage plans to waive requirements for pharmacist consultation with the prescriber to confirm intent to lessen the administrative burden on prescribers and pharmacists. Additionally, CMS is exercising its enforcement discretion to adopt a temporary policy of relaxed enforcement in connection with any Part D medication delivery documentation and signature log requirements related to these edits during the COVID-19 emergency, as noted above.

“Refill-Too-Soon” Edits

During the public health emergency for COVID-19 described in section 1135(g)(1)(B) of the Social Security Act, pursuant to section 3714 of the CARES Act, Part D sponsors must relax “refill-too-soon” edits. 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.

90-day Supply

Part D sponsors must permit enrollees to obtain the total days supply prescribed for a covered Part D drug (as defined in 42 CFR § 423.100) up to a 90-day supply in one fill (or one refill) if:

- Requested by the enrollee,
- PA or ST requirements have been satisfied; and
- No safety edits otherwise limit the quantity or days supply.

This requirement also applies to transition fills.

Long-term Care Dispensing

CMS intends to exercise enforcement discretion with respect to the requirement at 42 CFR § 423.154(a)(1)(i) that limits dispensing of solid oral doses of brand-name drugs, as defined in §423.4, to enrollees in long-term care (LTC) facilities to no greater than 14-day increments at a time. For enrollees residing in LTC facilities, Part D sponsors may permit pharmacies to expand the use of submission clarification code 21 (LTC dispensing, 14 days or less not applicable) to allow for greater than 14 day supplies for all applicable Part D drugs to provide more flexibility for LTC facilities and pharmacies to coordinate with each other.

Emergency Period

These program instructions apply to fills and refills on or after March 27, 2020, and these requirements

will remain in place for the remainder of the emergency period described in section 1135(g)(1)(B) of the Social Security Act.

Medicare-Medicaid Plans

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

Additionally, we note that MMPs should have received guidance from their contract management teams about the submission and review of materials for enrollees regarding precautions to contain the spread of COVID-19 and information about the public health emergency. MMPs with questions about this guidance should contact their contract management teams.

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 or update their business continuity plans to ensure that any necessary planning for business operations disruption due to a pandemic public health emergency is included.

Involuntary Disenrollment - MA and Part D Premium and Grace Period Flexibilities

To ensure that Medicare Advantage and Part D beneficiaries continue to have access to needed care during the COVID-19 national emergency, CMS would like to remind plans of their ability to apply flexible policies to members who are unable to pay plan premiums. Plans are not required under existing regulations to disenroll members due to failure to pay plan premiums; however, plans must apply the same policy consistently for all enrollees of the applicable plan. For those plans that have elected a policy to disenroll for non-payment of premium, we encourage you to consider changing the policy so that the plan would not disenroll members for non-payment of premium. If a plan chooses not to eliminate its disenrollment policy, we encourage the plan to increase the mandatory grace period (at least two months) to a longer period of time. Plans may make these types of changes mid-year as long as the change is applied to everyone in the plan and the plan notifies its CMS account manager. Detailed information regarding disenrollment and non-payment of premiums requirements are at § 422.74(b)(1)(i) and section 50.3.1 of Chapter 2 of the Medicare Managed Care Manual for MA and at § 423.44(b)(1)(i) and section 50.3.1 of Chapter 3 of the Medicare Prescription Drug Benefit Manual for Part D.

Marketing and Communication

CMS wants to ensure that plans are able to quickly distribute information to their enrollees regarding COVID-19 (such as information on precautions and the public health emergency, reminders or announcements about benefits coverage as described in existing guidance, etc.). Plans are reminded that, based on the definitions of "marketing" and "communications" under

MA and Part D regulations in Subpart V of Parts 422 and 423, COVID-19 messages to members of this sort would almost invariably be communications and thus not require HPMS submission and review prior to dissemination.

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.

ADDENDUM

Temporary Permissive Action for Waiver of Part D Cost Sharing Related to COVID-19

Section 1860D-4(b)(1)(C)(iii) of the Social Security Act (hereafter referred to as "the Act") requires that the Secretary's rules on pharmacy network access "include adequate emergency access for enrollees." Using that authority, the Centers for Medicare & Medicaid Services (CMS) is providing information to Part D sponsors⁶ about their ability to implement flexibilities in light of the COVID-19 public health emergency declared by the Secretary of Health and Human Services to help ensure Part D enrollees do not experience disruptions in pharmacy and prescription drug access. We understand that some Part D sponsors are interested in fully or partly waiving Part D cost sharing for any covered Part D drugs that they determine have medically accepted indications⁷ for COVID-19. This flexibility is an example of an action that sponsors may deem reasonable and necessary in order to provide qualified prescription drug coverage during the COVID-19 outbreak. Given the complex nature of the Part D benefit and the need to submit accurate information to CMS in prescription drug event (PDE) data and plan bids, we are providing additional guidance regarding CMS expectations with respect to this approach for both the current contract year (CY) 2020, for which we are exercising enforcement discretion to permit cost-sharing waivers in the middle of the contract year, and for CY 2021 bid submission to permit sponsors to waive cost sharing outside of their benefit for a portion of the benefit year up to the entire benefit year.

Flexibility to Waive Part D Cost sharing for CY 2020

CMS is exercising its enforcement discretion to allow Part D sponsors to fully or partly waive cost sharing for covered Part-D drugs with medically accepted indications for COVID-19, even if this cost-sharing waiver when exercised would be inconsistent with the approved CY 2020 bid and plan benefit package.⁸ CMS will exercise this enforcement discretion to allow plan sponsors to waive cost sharing,

⁶ 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-DrugCoverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf

⁷ Medically accepted indications include both the uses approved by the Food and Drug Administration (FDA) and off-label uses supported by one or more citations included or approved for inclusion in any of three compendia specified in section 1927(g)(I)(B)(i) of the Social Security Act.

⁸ CMS policy does not permit Part D sponsors to make mid-year changes to cost sharing, including directly or indirectly waiving cost sharing (73 FR 43628, 43631 (July 28, 2008)).

consistent with this guidance, for any remaining portion of the 2020 plan year, up to the rest of the plan year, so long as the public health emergency for COVID-19 declared by the Secretary of Health and Human Services (HHS) is in effect as of the date that the plan sponsor begins the cost-sharing waivers. Part D sponsors may fully or partly waive enrollee copays, deductibles, and coinsurance for covered Part D drugs that are determined to have a medically accepted indication for COVID-19, as defined above, and may choose to waive cost sharing only for those beneficiaries taking such a covered Part D drug for the COVID-19 indication⁹. Although Part D sponsors are not required to waive cost sharing uniformly for all covered Part D drugs that are medically-indicated for COVID-19, sponsors that choose to implement this flexibility must waive cost sharing for all similarly situated plan enrollees uniformly, consistent with the uniformity requirements for qualified prescription drug coverage set forth in § 423.104(b). Part D sponsors may waive the otherwise applicable Part D cost sharing in these instances for any portion of a contract year, up to the end of the plan year, and we encourage Part D sponsors to notify enrollees at such time that they cease such waiver of Part D cost sharing. A Part D sponsor's voluntary waiver of cost sharing can, but need not, include a waiver of additional charges that exceed the plan allowance in instances where the Part D sponsor is reimbursing an enrollee for prescriptions obtained from out-of-network pharmacies to ensure access during a state of emergency, as required in § 423.124(a) of the Part D regulations. We also note that MA plans must comply with 42 CFR Part 423 in furnishing the Part D prescription drug benefit under 42 CFR § 422.500; Part C supplemental benefits do not include payment of Part D cost sharing. An MA-PD plan may offer Part D supplemental benefits under § 423.104(f)(1)(ii) and use the Part C beneficiary rebate to pay the premium for Part D supplemental drug coverage for all enrollees in the Part C plan.

For purposes of PDE reporting, Part D sponsors that opt to waive cost sharing in response to this temporary permissive action should report the waived cost-sharing amount in the "patient liability reduced by other" (PLRO) field and effectively treat the waiver of cost sharing under the plan as an "other health insurance" (OHI) benefit. As such, this waiver of cost sharing would not be included in the calculation of a plan's risk corridors amount. For purposes of reinsurance reconciliation, 80% of the gross covered prescription drug costs above the catastrophic threshold will be included in the calculation, including cost-sharing amounts designated as OHI. As with any payment by the Part D plan to cover beneficiary liability, the waived cost-sharing amount could not be considered an "incurred cost," as defined in section 1860D-2(b)(4)(C) of the Act, and, thus, could not count towards the true out-of-pocket cost (TrOOP) threshold. Also as with any payment by the Part D plan to cover beneficiary liability, such as any supplemental coverage provided under the plan, consistent with the requirements set forth in § 423.329(d) of the Part D regulations and section 1860D-14 of the Act, the waiver of cost sharing must be applied before the low-income cost-sharing subsidy (LICS) is calculated, and if the cost sharing under the plan for a beneficiary not eligible for the low-income subsidy (LIS) after application of the cost-sharing waiver is less than the maximum low-income cost sharing established by statute, the low income beneficiary must be charged only the lesser amount. In other words, Part D sponsors would absorb the entire cost of the cost-sharing amount waived in response to this temporary permissive action for both LIS and non-LIS eligible beneficiaries. If a Part D sponsor elects to waive cost sharing retroactively for members that have already paid cost sharing, the sponsor should revise and resubmit PDEs accordingly to reflect the waiver of cost sharing for the beneficiary. Unless otherwise noted above, Part D sponsors should continue to follow all current PDE reporting instructions, found on the Health Plan Management System (HPMS) and the

⁹ For the purposes of determining whether an enrollee has the COVID-19 indication, plan sponsors must consider all approved COVID-19 tests and qualified physician diagnoses as indicators of COVID-19.

following website: <https://www.csscooperations.com>.

Guidelines for Part D Sponsors Reducing, Eliminating, or Waiving Cost Sharing for CY 2021

CMS is also exercising its enforcement discretion to permit Part D sponsors to waive cost sharing for covered Part D drugs that they determine are medically-indicated for COVID-19 when submitting their CY 2021 bids, if the public health emergency is still in place at the time of CY 2021 bid submission. Given the uncertainty surrounding the duration of the public health emergency, CMS is exercising enforcement discretion to permit sponsors to submit CY 2021 bids and PBPs that reflect cost-sharing waivers for covered Part D drugs they determine have medically accepted indications for COVID-19 for any portion of CY 2021. Sponsors that opt for the flexibility to waive cost sharing in CY 2021 for covered Part D drugs for which there is a medically accepted indication for COVID-19, in lieu of designing a benefit and formulary that would result in full or reduced cost sharing for such drugs, must still reflect the expected costs in the bid pricing tool (BPT) and include support for these projected costs in their supporting documentation. Part D sponsors should provide details pertaining to the duration of the cost-sharing waiver (i.e. for a portion of the contract year versus the full contract year) and describe the enrollee population that is eligible for the cost-sharing waiver (e.g., beneficiaries with the COVID-19 indication) in the MRx Notes section of their plan benefit package (PBP). Given the difficulty anticipating all potential Part D drugs that could have a medically-accepted indications for COVID-19, plan sponsors will not be required to indicate each specific drug for which they intend to waive cost sharing, but should provide as much detail as possible in the MRx Notes field of the PBP. Sponsors taking advantage of this permissive action to waive cost sharing for the entirety of CY 2021 or any portion of CY 2021 should follow the PDE reporting requirements outlined above.

We note that this permissive action to provide flexibility for plan sponsors to waive cost sharing outside of their CY 2021 benefit does not preclude plan sponsors from instead opting to include any or all of these drugs in their benefit or formulary structure for the duration of the contract year (for example, placing a Part D drug for which there is a medically accepted indication for COVID-19 on a \$0 formulary tier), should they choose. Sponsors that include any of these drugs in their benefit and formulary structure for the duration of CY 2021 or for any future contract years following the end of the public health emergency should complete the PBP MRx screens and follow all current Part D PDE reporting instructions as they normally would.

Guidance for Medicare-Medicaid Plans

The guidance articulated in this addendum for Part D sponsors also generally applies to Medicare-Medicaid Plans (MMPs) operating under three-way contracts as part of the Financial Alignment Initiative's capitated model demonstrations. These contracts between CMS, the state, and participating health plans, enable states to test models to integrate primary, acute, behavioral health, and long-term services and supports for their dually eligible beneficiaries. MMPs already have flexibility to waive Part D LIS cost-sharing amounts as detailed in our September 20, 2012, HPMS memorandum posted at https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/Downloads/Part_D_Cost_Sharing_Guidance.pdf. MMPs that have not already eliminated CY 2020 Part D cost sharing may fully or partly waive cost sharing for covered

Part D drugs that have a medically accepted indication for COVID-19. However, MMPs choosing to take advantage of the flexibility to waive cost sharing for covered Part D drugs with a medically accepted indication for COVID-19 must report their PDEs consistent with the guidance in our September 20, 2012, Health Plan Management System (HPMS) memorandum, rather than the guidance applicable to all other Part D sponsors in this addendum. This will ensure that MMPs do not forgo the LICS that reimburses plans for the difference between the defined standard benefits cost-sharing amount and the LIS statutory copayment amounts, as provided in the MMP-specific waiver.

Additionally, MMPs that choose this flexibility for CY 2021 outside their PBP and formulary offering must record the extent of the cost-sharing waiver in the MRx Notes section of their CY 2021 PBPs. Because MMPs do not submit a BPT, the guidance in this addendum about BPT documentation does not apply to MMPs.

MMPs should direct any questions about this guidance to the Medicare-Medicaid Coordination Office at MMCOCapsModel@cms.hhs.gov.

Exemption from Administrative Procedure Act (APA) Requirements

We believe that any guidance in this memorandum relating to CMS's enforcement discretion is a statement of agency policy not subject to the notice and comment requirements of the Administrative Procedure Act (APA). 5 U.S.C. § 553(b)(A). CMS additionally finds that, even if this guidance were subject to the public participation provisions of the APA, due to the urgent need to ensure that MA and Part D enrollees do not experience disruptions in care or disruptions in pharmacy and prescription drug access during the public health emergency posed by COVID-19, prior notice and comment for this guidance is impracticable, and there is good cause to issue this guidance without prior public comment and without a delayed effective date. 5 U.S.C. § 553(b)(B) & (d)(3). Similarly, even if this guidance were subject to the public participation provisions of 42 USC § 1395hh(b)(1), CMS finds that these public participation provisions also do not apply to this guidance because, for the reasons explained above, 5 U.S.C. § 553(b) does not apply to this guidance pursuant to 5 U.S.C. § 553(b)(B). 42 USC § 1395hh(b)(2)(C).