DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop 00-00-00
Baltimore, Maryland 21244-1850

Centers for Medicare & Medicaid Services

DATE: January 19, 2021

TO: All Prescription Drug Plan Sponsors

FROM: Laura McWright, Deputy Director
Seamless Care Models Group
Center for Medicare and Medicaid Innovation

SUBJECT: Part D Payment Modernization (PDM) Model Application Process for Calendar Year (CY) 2022

Summary

Today, CMS released the Request for Applications (RFA) for the CY 2022 Part D Payment Modernization (PDM) Model. This memo provides additional information and application details for Part D sponsors interested in applying to participate in the PDM Model for 2022. It also includes details on an upcoming webinar. Interested Part D Sponsors must submit a non-binding Notice of Intent (NOI) to apply to join the Model by March 1, 2021. All PDM Model applications will be due on April 16, 2021.

Information and Requests for Applications

Information on the PDM Model and the Model's Requests for Applications is available here: https://innovation.cms.gov/innovation-models/part-d-payment-modernization-model.

Notice of Intent (NOI) & Application Details

To participate in any component of the PDM Model, Part D sponsors must complete both an NOI to apply for the Model and the CMMI application. Sponsors interested in participating must also include the necessary information in their CY 2022 bid submission.

NOI Submission: First, by 11:59 PM PT on March 1, 2021, eligible organizations must submit to CMS, via the following link, or via email to PartDPaymentModel@cms.hhs.gov, a non-binding notice of intent to participate in the PDM Model. The non-binding notice of intent must be submitted by an authorized individual at the organization. While the notice of intent is non-binding, organizations must submit a notice of intent to be eligible to apply for participation in the PDM Model.

In order to provide CMS information important to its operational planning, the NOI should include the following information, even if preliminary:

- Parent Organization as listed in Health Plan Management System (HPMS) Contract(s) (to be included in the spreadsheet)

- Plan Benefit Package(s) (PBPs) (to be included in the spreadsheet)
- Prescription Drug Plan region(s) for each PBP (to be included in the spreadsheet)
- Enrollment for each PBP (to be included in the spreadsheet)
- Contact information, including email address and phone number, for the primary point of contact
- Indication for inclusion of any of the optional programmatic flexibilities available under the PDM Model (to be included in the spreadsheet)

If interest in the Model exceeds a certain amount, CMS will restrict participation to certain PDP regions. **If CMS decides to limit participation to certain PDP regions, CMS will communicate eligible PDP regions to Part D plan sponsors with an explanation of the selection methodology to those who submitted NOIs prior to the application portal go-live date.**

CMMI Application: By 11:59 PM PDT on April 16, 2021, applicants must complete an online application to participate in the PDM Model. The online application and associated application materials will be located on the Model's webpage and accessible here by March 23, 2021. While the application includes all PDM Model Components, Part D sponsors may select which voluntary Model components they wish to include. CMMI will review all applications to ensure eligibility and alignment with Model requirements and will provide plans with provisional approvals.

Bid Submission: The final part of the application process is for provisionally approved Part D sponsors to confirm their participation in the Model by the bid submission date of Monday, June 7, 2021, concurrent with and as part of their plan bid submission. In addition to the bid submission requirements, Part D sponsors that were provisionally approved must notify CMS in writing by June 7, 2021 of any changes from their provisionally approved application, including changes to participating PBPs.

The CY 2022 PDM Model RFA provides all requirements for Model participation.

Part D Payment Modernization (PDM) Model Background Information

All Model information, including the PDM Model RFA, webinar recordings and slides, and other Model information is available here: https://innovation.cms.gov/innovation-models/part-d-payment-modernization-model

CY 2022 Updates to the PDM Model and Overview of Programmatic Flexibilities

For CY 2022, in light of the changes to the discount safe harbor to the Federal anti-kickback statute that removes protection for certain reductions in price in connection with the sale or purchase of prescription pharmaceutical products from pharmaceutical manufacturers to Part D sponsors that will take effect on January 1, 2022, the PDM Model is being updated with the following changes:

1. **Part D Formulary Flexibilities:** CMS will permit Part D sponsors participating in the Model to treat five of the six "protected" classes (anticonvulsants, immunosuppressants, antidepressants, antipsychotics, and antineoplastics) as they

would other Part D drugs, eliminating the antiquated requirement that all drugs in these classes be covered in formularies. In addition, for CY 2022, participating Part D sponsors will be required to include on their formulary at least one drug per class (including the five protected classes), under a waiver of the current requirement of two drugs per class. Participating Part D sponsors must, however, continue to comply with all other Part D formulary requirements. All of the existing, comprehensive Part D formulary checks and enrollee protections other than the protected class requirement and two-drugs per class requirement, including the coverage determination and appeal process and other Part D formulary requirements, will remain in place and provide safeguards to ensure beneficiaries retain access to the Part D prescription drugs they need.

In addition, each Part D sponsor that applies to implement the formulary flexibilities will be required to provide an enhanced transition process for enrollees affected by proposed formulary changes for drugs in the protected classes. This transition process must include both proactive outreach to current enrollees and an extended transition supply that provides for multiple temporary fills for new enrollees and current enrollees who have not been able to switch to a formulary medication or complete the coverage determination process.

2. **Removal of downside Model risk for CY 2022:** CMS will not apply the current 10 percent downside Model risk for Part D sponsors participating in the Model in CY2022. CMS intends to apply 10 percent downside Model risk in CY2023 and for the duration of the model thereafter.

In addition to the CY2022 updates, the PDM Model will continue to test a number of complementary programmatic flexibilities and design elements for Part D enrollees for the 2022 plan year, including:

a. **Medication Therapy Management+ (MTM+) Programs:** CMS would like to continue to test Part D sponsors' development of robust, targeted, and effective MTM programs through the PDM Model. To do so, CMS will waive MTM requirements for targeting, interventions, and engagement, as well as uniformity and accessibility of benefits requirements, for participating Part D sponsors that develop innovative MTM programs (termed MTM+ programs in this RFA). By allowing Part D sponsors to develop MTM+ programs in lieu of the standard Part D MTM program CMS is testing ways MTM programs may be developed and implemented that improve beneficiary targeting and engagement, with the aim of improving adherence, coordination of care, and understanding of a beneficiary's medication regimens.

b. Flexibilities to Lower Costs for Beneficiaries:

- **Limited initial days' supply**: Part D sponsors may propose to limit the first fill of a new medication to a clinically and operationally feasible time frame of less than a 30-days' equivalent supply for covered Part D drugs where there is a clinical and drug utilization review rationale to do so.
- **Cost-Sharing Smoothing;** Part D sponsors may propose to CMS innovative approaches to improving access to medications, including allowing an enrollee to pay their prescription cost-sharing over time within the course of the Plan Year (e.g., installment

payments).

c. **Part D Rewards and Incentives Programs:** CMS is testing the impact of allowing Model participants to propose Part D RI programs that, in connection with medication use, focus on promoting improved health, medication adherence and the efficient use of health care resources. Specifically, CMS is interested in testing how Model participants will leverage rewards and incentives to better manage the provision of the Part D benefit.

d. **Reduction or Elimination of Cost-Sharing on Generic Drugs and Biosimilars for Low-Income Subsidy (LIS) Beneficiaries (allowed for basic and enhanced alternative plan types):** CMS will permit Model participants to reduce cost-sharing for generic and biosimilar drugs for LIS beneficiaries to an amount below the statutory maximum copayment and still receive low-income cost-sharing subsidy (LICS) payments that reflect the difference between the plan's cost-sharing amount and the LIS statutory maximum copayment amount.

e. **Additional Flexibility under the De Minimis Policy:** Part D plan sponsors may voluntarily waive the portion of their monthly adjusted basic beneficiary premium that is a *de minimis* amount above the LIS benchmark for eligible individuals, and CMS will not reassign enrollees away from these Part D sponsor plans. To decrease any movement of LIS beneficiaries for Model participants, CMS may allow Model participants to waive a greater *de minimis* amount than non-model participants.

f. **Plan Timeliness for Standard Initial Coverage Determinations:** Regulations at Subpart M of 42 C.F.R. Part 423 require that for standard requests for drug coverage, Part D plan sponsors must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request. Sponsors have stated that these timeframes can prove challenging when additional information is needed from the prescriber to determine whether coverage criteria are met, leading to unnecessary denials and delays in beneficiary access to needed medications. The PDM Model will permit Part D sponsors to increase the standard coverage determination timeframe to 96 hours for requests for drug coverage to allow Model participants, prescribers, and enrollees to increase adherence to medications at first fill, increase initial determination approvals, and decrease re-determinations.

Upcoming Webinar

The CY 2022 PDM Model Overview & Application Webinar will be held on **February 3, 2021**, from 4-5 PM EST. Please register for this webinar at the following link.

For additional information, visit the PDM Overview webpage or contact PartDPaymentModel@cms.hhs.gov