DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Centers for Medicare & Medicaid Services

DATE: March 16, 2021

TO: All Part D Drug Plan Sponsors

FROM: Laura McWright, Deputy Director
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SUBJECT: Update to Part D Payment Modernization (PDM) Model & Application Process for Calendar Year (CY) 2022

Summary

Today, the Centers for Medicare & Medicaid Services (CMS) announced updates to the Calendar Year (CY) 2022 Request for Applications (RFA) for the Part D Payment Modernization (PDM) Model. Based on stakeholder feedback and other considerations, CMS is not moving forward with two Model design changes discussed in the January 19, 2021 CY 2022 RFA: (1) the Part D Formulary Flexibilities, and (2) removal of downside risk for CY 2022. For CY 2022, the PDM Model will continue to test a modernized Part D payment structure in which participating Part D sponsors take two-sided risk for CMS' federal reinsurance subsidy spending for participating plan benefit packages (PBPs), relative to their Spending Target Benchmark(s). In addition, as discussed in the updated CY 2022 RFA, the Model will also continue to extend the Model participants' the opportunity to adopt the same categories of programmatic flexibilities that were available in CY 2021 (see a full list under the "Part D Payment Modernization (PDM) Model Background Information" section below).

With the release of the updated CY 2022 PDM Model RFA, CMS is announcing the following policies, updates, and clarifications:

- All plan types that were eligible to participate in the Model for CY 2021 are eligible to apply to participate in the Model for CY 2022, regardless of whether the Part D sponsor of such plan submitted a CY 2022 Notice of Intent.
- With respect to the Spending Target Benchmark, CMS will require that a minimum threshold apply for all Performance-Based Gains and Losses. This minimum threshold will be applied separately to Medicare Advantage Prescription Drug Plans (MA-PDs) and Prescription Drug Plans (PDPs). No Performance-Based Payments for Part D sponsors that achieve Performance-Based Gains will be paid unless this minimum threshold for gains is exceeded. Likewise, CMS will not collect any Performance-Based Recoveries from Part D sponsors unless the minimum threshold for Performance-Based Losses is exceeded. CMS has not yet determined the specific minimum threshold percentage for CY 2022; however, this percentage is estimated at 0.5 percent based on historical data. CMS will conduct further analyses on more recent federal reinsurance data to inform the final determination of the CY

2022 minimum threshold amount and will communicate this information in the final CY 2022 contract addendum.

- With respect to Part D Rewards and Incentives (Part D RI) Programs, for CY 2022 multiple Part D RI programs are permitted to be offered in a single PBP under each of the PDM, Part D Senior Savings (PDSS), and Value-Based Insurance Design (VBID) Models. This means that one PBP might include Part D RI Programs offered under up to three different Models. However, an underlying principle for the requirements for how a single PBP may offer RI Programs under more than one Model is avoidance of overlap and duplication for an enrollee. PDPs and MA-PDs participating in the PDSS Model and MA-PDs participating in the VBID Model, and proposing to also offer Part D RI in a PBP that is in this Model, must also comply with the Part D RI requirements of the PDM Model.

Information and Requests for Applications

Part D sponsors may apply to participate in the PDM Model for CY 2022 whether they submitted a Notice of Intent by March 1, 2021. Information on the PDM Model and the Model's Requests for Applications are available here: https://innovation.cms.gov/innovation-models/part-d-payment-modernization-model.

Application Details

In order to facilitate a seamless application process for all interested Part D sponsors, the Model application process consists of two parts.

CMMI Application: First, 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 describes all programmatic flexibilities available under the PDM Model for CY 2022, Part D sponsors may select which programmatic flexibilities they intend to use. CMMI will review all applications to ensure eligibility and alignment with Model requirements.

Bid Submission: Second, 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 a 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 PDM Model application, including changes to participating PBPs.

Part D Payment Modernization (PDM) Model Background Information

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

CY 2022 PDM Model and Overview of Programmatic Flexibilities

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a. **Medication Therapy Management+ (MTM+) Programs:** CMS would like 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). By allowing Part D sponsors to develop MTM+ programs in lieu of the standard Part D MTM program CMS is interested in testing ways MTM programs may be developed and implemented to 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 timeframe 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 improve access to medications, including allowing an enrollee to pay his or her 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 and costs 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 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 their 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 to increase initial determination approvals and decrease re-determinations while allowing enrollees to increase adherence to medications at first fill,

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