

# Is it worth revisiting the Medicare Part D Payment Modernization (PDM) Model?

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The PDM Model was introduced in 2020, creating a risk-sharing opportunity for Medicare Part D plans based on federal reinsurance spending. Thus far, participation has been very limited, but with increased formulary flexibility, the possible removal of shared downside risk, and the potential for point-of-sale (POS) rebates in 2023, should plan sponsors take another look?

On January 19, 2021, the Centers for Medicare and Medicaid Services (CMS) released the 2022 plan year request for applications (RFA) and fact sheet for the PDM Model.<sup>1,2</sup> The PDM Model is a five-year, voluntary demonstration program, currently in its second year. Only two plan sponsors participate in the model for 2021.<sup>3</sup> Figure 1 answers common questions about the PDM Model, with additional discussion below.

**FIGURE 1: COMMON PDM MODEL QUESTIONS ANSWERED**

QUESTION	ANSWER
<b>What</b> is the PDM Model?	A voluntary Part D shared savings model based on federal reinsurance spending.
<b>Who</b> can participate?	Both standalone PDPs and MAPD plans, including all SNPs.
<b>When</b> are the key dates?	Notice of Intent (NOI) is due <b>March 1, 2021</b> . Completed application is due <b>April 16, 2021</b> . Effective date is <b>January 1, 2022</b> .
<b>How</b> do plans participate?	Plan sponsors specify regions separately for PDPs and MAPDs, and all PDP and/or MAPD plans in that region must participate.
<b>Why</b> might plans be interested?	Opportunity for shared savings and additional flexibilities not available to non-model participants.

<sup>1</sup> CMS. Part D Payment Modernization Model Calendar Year (CY) 2022 Fact Sheet. Retrieved February 10, 2021, from <https://innovation.cms.gov/media/document/partd-payment-modernization-cy22fs>.

<sup>2</sup> CMS. Part D Payment Modernization Model Request for Applications for CY 2022. Retrieved February 10, 2021, from <https://innovation.cms.gov/media/document/partd-payment-modernization-cy22rfa>.

<sup>3</sup> CMS. Part D Payment Modernization Model. Retrieved February 10, 2021, from <https://innovation.cms.gov/innovation-models/part-d-payment-modernization-model>.

Both standalone prescription drug plan (PDP) and Medicare Advantage prescription drug (MAPD) plan sponsors are eligible to participate in the model. For MAPD plans, this includes both general enrollment and special needs plans (SNPs). Certain plan types, such as private fee for service (PFFS), Medicare Cost plans, and employer/union group waiver plans (EGWPs) are not eligible for the model. Plan sponsors must specify participation on a region-by-region basis, and all plan benefit packages (PBPs) they offer in the specified region within the given product type (PDP and/or MAPD) must participate in the model. Depending on the level of interest from plan sponsors, CMS may limit the geographic scope of the model to only certain PDP regions for the 2022 plan year.

CMS's goal of the PDM Model is to decrease federal reinsurance spending. In the current rebate environment, incentives for plan sponsors may not be aligned to accomplish this goal.<sup>4</sup> For example, plans may favor higher list price and higher rebate drugs over lower list price drugs with no rebate. Higher list prices contribute to higher reinsurance spending, while higher rebates offset plan liability and reduce premiums. These potentially conflicting goals may have led to limited model participation thus far. However, new provisions and flexibilities in 2022 and the potential for POS rebates in 2023 may make the PDM Model appeal to plan sponsors.

Interested plan sponsors must submit a nonbinding NOI to participate by March 1, 2021, with completed applications due to CMS by April 16, 2021. In this article, we provide background and discuss key considerations for model participation.

## How does the PDM Model work?

The PDM Model introduces a risk-sharing arrangement for Medicare Part D federal reinsurance spending. For participating plan sponsors, CMS compares actual federal reinsurance spending to a spending target benchmark, which is calculated retrospectively by CMS following the plan year. CMS performs the comparison using federal reinsurance spending net of rebates, separately for PDP and MAPD. It is unclear how the benchmark will be calculated and adjusted to individual plan sponsor characteristics. Plan sponsors participating for the first time in 2022 may be most concerned with this issue, as current model participants may be more familiar with the benchmark calculation methodology.

After comparing actual reinsurance spending to the benchmark, plan sponsors will receive 30% of savings between 0% and 3%, and 50% of savings above 3%. CMS also added a minimum threshold (MT%), estimated to be 0.5%, to the model for 2022: plan sponsors will receive the full payment amount described above if savings exceed the minimum threshold, and no payment if savings do not meet the minimum threshold. Figure 2 summarizes the risk-sharing levels based on the relationship of actual reinsurance spending to the benchmark.

Prior to 2022, the model also included a downside risk component, with plan sponsors required to share 10% of actual reinsurance spending in excess of the benchmark. However, CMS removed this downside risk for the 2022 plan year, with the intention of reintroducing downside risk in future model years. It is important to note CMS states in the PDM Model fact sheet that the temporary removal of shared downside risk is being made "...in light of the changes to the discount safe harbor under the Federal anti-kickback statute (effective January 1, 2022)."<sup>5</sup> Due to the recent delay of the effective date for this rule, from January 1, 2022, to January 1, 2023, CMS could decide to change this provision for 2022.<sup>6</sup> At the time of this article's publication, the temporary removal of shared downside risk remains in effect for 2022.

**FIGURE 2: 2022 PDM MODEL RISK-SHARING LEVELS**

ACTUAL REINSURANCE SPENDING RELATIVE TO BENCHMARK	% SHARED SAVINGS
Any losses	0% (no downside risk)
Savings of 0% to MT%*	0% (minimum threshold)
Savings of MT%* to 3%	30% of all savings, including savings up to the MT%*
Savings greater than 3%	50% of savings in excess of 3.0% + 30% of first 3.0% from above

\* MT%: Minimum Value Threshold; value is unknown but CMS estimates it at 0.5%

The PDM Model also provides additional flexibilities for plan sponsors, including new formulary flexibilities for 2022. We discuss these additional flexibilities below.

<sup>4</sup> MedPAC (June 2020). Report to the Congress: Medicare Payment Policy. Retrieved February 10, 2021, from [http://www.medpac.gov/docs/default-source/reports/jun20\\_reporttocongress\\_sec.pdf?sfvrsn=0](http://www.medpac.gov/docs/default-source/reports/jun20_reporttocongress_sec.pdf?sfvrsn=0).

<sup>5</sup> Part D Payment Modernization Model Calendar Year (CY) 2022 Fact Sheet, op cit.

<sup>6</sup> Pharmaceutical Care Management Association vs. U.S. Department of Health and Human Services, et al. (January 30, 2021). Retrieved February 10, 2021, from: <https://www.pcmnet.org/wp-content/uploads/2021/01/2021-01-30-D.E.-19-Order.pdf>.

## What formulary flexibility is available?

A significant change to the PDM for 2022 is the addition of two new formulary flexibilities:

1. Removal of status from five of the six Medicare Part D “protected” classes (under this flexibility, antiretrovirals would stay protected until the 2023 plan year).
2. Reduction in the requirement of two drugs per class to one drug per class in formulary development.

All other Part D formulary requirements and beneficiary protections will remain, including the coverage determination and appeal process and expedited exception process. Plans implementing the new formulary flexibilities must provide an enhanced transition process, including proactive outreach to affected beneficiaries and an extended transition supply for multiple temporary fills for the first 120 days of enrollment in the plan.

These two new flexibilities provide Part D plans with additional leverage to lower reinsurance spending. They may also afford plans the opportunity to negotiate with manufacturers for potentially larger rebates in return for more exclusive access on the formulary. As well, a tighter formulary may provide plans more flexibility to steer beneficiaries to lower-cost drugs.

While these new flexibilities offer intriguing opportunities, plans will need to consider several potential obstacles for implementation in 2022. First, plans will need their pharmacy benefit managers (PBMs) to be able to generate savings based on these new flexibilities. As most PBMs are already in the negotiation phase of rebate contracts with manufacturers and well into the 2022 formulary development process, PBMs may not have the time or resources to develop a successful formulary with these new flexibilities.

Plans will also need to take into account the impact of multiple transition fills. Some beneficiaries may be able to get up to a four-month supply of a drug that is removed from the formulary. More fills of noncovered drugs can reduce the projected rebate revenue to the plan. Participating plans will need to consider these transition fills in projected Part D rebates for 2022.

In addition, if the PBM is able to develop a new formulary that takes advantage of one or both of the new flexibilities, plans will need to make sure any additional fees charged by the PBM do not outweigh the savings generated. The cost of creating a formulary with these new flexibilities may be high. If the model has limited participation, the extra charges from the PBM to the participating plan could be significant on a per member basis.

Plans choosing to implement one or both of these flexibilities may also need to consider the potential impact of formulary resubmission. Plans are required to submit bid pricing in early June, before CMS completes its standard formulary performance and content review process. If formulary resubmission is required, plan sponsors may not be able to adjust bid pricing to align with the revised formulary. This risk exists every year, but if the model’s flexibilities lead to formulary changes that are more significant than normal, then the formulary resubmission and bid pricing risk may likewise be greater. This could also create complications for PDPs required to pass meaningful difference tests between basic and enhanced plans using CMS’s Out-of-Pocket Cost (OOPC) Model.

## What other flexibilities exist?

In addition to the new formulary flexibilities for 2022, the PDM Model continues to offer several other flexibilities to participating plans. Similar to the formulary flexibilities discussed above, plans must indicate which flexibilities they will select as part of the PDM Model application. These additional flexibilities include:

- **Medication Therapy Management+ (MTM+) programs.** MTM+ programs offer participating plans additional flexibilities in targeting populations to manage. This includes the ability to target beneficiaries using advanced characteristics (e.g., medication adherence, socioeconomic characteristics, etc.). These programs could be similar to the separate Enhanced MTM (eMTM) Model available to standalone PDPs; however, unlike the eMTM Model, plans with MTM+ programs would not receive additional payments from CMS.
- **Limited initial days’ supply.** Participating plans can choose to provide patients new to a particular therapy (i.e., “treatment-naïve”) a trial fill with less than a 30-day supply. Plans would need to specify in the application the drugs they will include under this flexibility, along with clinical support for making the selected drugs eligible for this flexibility.
- **Smoothing of beneficiary cost sharing.** Participating plans can choose to “smooth” beneficiary cost sharing throughout the plan year with a monthly payment plan. Such a program would not alter the benefit design itself, only the timing and amount of cost-sharing payments as beneficiaries progress through the benefit. Beneficiaries would need to opt into the payment plan and pharmacies would need to be held harmless, meaning the total payment to the pharmacy at the time of dispensing would not change. The plan sponsor would be responsible for collecting monthly payments from beneficiaries, without assessing interest or other charges.

- **Reduced cost sharing on generics and biosimilars for LIS beneficiaries.** Participating plans may reduce or eliminate cost sharing for low-income subsidy (LIS) beneficiaries for specified generic and biosimilar drugs. If selected, the plan would still receive the full low-income cost-sharing (LICS) subsidy payment from CMS. As part of the application, plans would need to specify which drugs would be subject to reduced or zero-dollar cost sharing for their LIS beneficiaries.
- **Higher *de minimis* threshold.** CMS may increase the *de minimis* threshold for participating plans targeting the low-income benchmark (LIB). If CMS chooses to do this, it would apply to all participating plans targeting the LIB, regardless of which optional flexibilities are chosen. A higher *de minimis* threshold would allow a greater margin of error in premium setting for plans targeting LIS beneficiary enrollment. This provision could allow basic PDPs to keep auto-assigned beneficiaries, even if their premiums exceed the LIB by more than the current *de minimis* threshold of \$2. Plans should remember that any waived *de minimis* amount is not collected for the LIS beneficiaries, which means plans would receive lower revenue than bid, equal to the amount of waived premium.

## What barriers exist to decrease federal reinsurance spending?

The goal of the PDM Model—to decrease federal reinsurance spending—could potentially conflict with the goal of plan sponsors to offer competitive premiums.

In the current rebate environment, net plan sponsor costs may be lower for higher list price and higher rebate drugs than lower list price alternatives. As a result, plans may favor higher list price drugs on their formularies, increasing overall and federal reinsurance spending as well as rebates. Increased rebates allow plans to offer lower premiums, as rebates directly reduce net plan sponsor costs. If reduced reinsurance spending comes at the expense of reduced manufacturer rebates, then net plan sponsor costs and premiums may increase. These potentially conflicting priorities may have contributed to limited model participation.

Plan sponsors may also find it difficult to manage federal reinsurance spending in the current environment. In particular, managing utilization for members reaching the catastrophic phase may prove difficult if those members are taking expensive brand or specialty drugs. Provider prescribing patterns, appeals and exceptions, and polypharmacy may present challenges outside of plan sponsors' direct control. These existing dynamics, even with enhanced flexibilities, might make the PDM Model a challenging proposition for plan sponsors in the current rebate environment.

## What else should plans consider?

Even though achieving reinsurance savings may be a challenge, the provisions and optional flexibilities offered by the PDM Model may present a unique opportunity for Part D plans. The potential elimination of downside risk for plans with catastrophic spending above their benchmarks in 2022 may also be an attractive feature; however, plans should think carefully about the potential challenges the PDM Model poses, including:

- **Operational complexity.** In addition to the PDM Model, plans and PBMs are already addressing the ongoing COVID-19 pandemic. Resources devoted to this and other efforts may make participation in the PDM Model prohibitively difficult for some plans. Several flexibilities also require changes to how prescription drug event (PDE) submissions are completed by the PBM, and additional guidance from CMS is still required to implement many of those changes.
- **Selection of model flexibilities.** All flexibilities offered by the model are optional. An important part of the decision process for interested plan sponsors will be the selection of the model flexibilities they will offer. This decision will be plan-specific, as enrolled populations, benefit designs, risk appetite, and overall strategies vary widely by organization. For example, the reduced LIS cost-sharing flexibility may not be seen as an effective cost management tool by plans that enroll a low percentage of LIS beneficiaries. Additionally, plans with strategies centered around enhanced benefit designs and comprehensive formulary coverage may not be interested in the new formulary flexibilities.
- **Timing.** At the time of this article's publication, plans have less than one month to consider participating in the PDM Model and submit their NOIs. With CMS's provisional approval of formal applications currently planned for mid-May and Part D bid submissions due June 7, 2021, plans will have a very limited window to accommodate necessary adjustments to participating plan bids.
- **Regional participation.** Participation in the PDM Model is "all or nothing" for each region and product type (i.e., PDP or MAPD). That is, if a plan sponsor wishes to participate, it must do so with all PDPs or MAPDs offered in a PDP region. Further, the service area of many MAPD plans is smaller (e.g., county-level) than the broad PDP regions used to assess participation in this model. This means a plan sponsor's decision to participate in MAPD may require participation on a large number of plans. Interested plan sponsors will want to consider whether to pursue broad or targeted regional participation. Broad participation may minimize the operational complexities of administering certain flexibilities (e.g., formulary), while more targeted approaches may allow plans to uniquely focus on particular competitive environments or geographic markets.

- **Impact on medical costs.** The flexibilities offered by the PDM Model are specific to Part D but could affect beneficiary medical costs, as well. For example, a monthly payment plan may allow beneficiaries the financial flexibility to pursue necessary medical services they may otherwise defer for affordability reasons. Also, to the extent flexibilities improve medication adherence, medical services and costs could decrease, though those savings may take time to materialize.
- **Costs of participation.** Participating plans may incur additional costs or fees from their PBMs in order to implement and administer the model's flexibilities. They should also expect to incur costs related to the application process and ongoing compliance. Plan sponsors must reapply each year, but viewing the decision through a multiyear lens may be important for weighing participation costs with potential benefits. For example, it may not make financial sense for plan sponsors to participate only in 2022 for the potential one-year elimination of downside risk.
- **POS rebates.** On November 20, 2020, the U.S. Department of Health and Human Services (HHS) announced a final rule removing safe harbor protection for manufacturer rebates under the federal anti-kickback statute.<sup>7</sup> The effective date for all items in this rule, previously set to January 1, 2022, was recently delayed to January 1, 2023, and the rule could potentially be dismissed based on challenges from industry stakeholders.<sup>8</sup> If implemented, POS rebates could better align incentives to reduce both federal reinsurance spending and premiums, potentially making the PDM Model more attractive to plan sponsors. With POS rebates still currently on the horizon, albeit after 2022, it is again important for plan sponsors to think beyond 2022 when considering whether or not to participate, because there may be an advantage to learning about benchmark calculation methodology and other model specifics in 2022.

## What are the next steps for interested plan sponsors?

Plan sponsors interested in participating should immediately contact their PBMs to assess whether the available flexibilities are operationally feasible in advance of the bid deadline. In addition, plan sponsors should be aware of the following dates:

- **The Notice of Intent (NOI) is due to CMS by 11:59 p.m. PT on March 1, 2021.** As with other models administered by the Center for Medicare and Medicaid Innovation (CMMI), the NOI is nonbinding. It must include an Excel spreadsheet (available for download on the model's website) and indicate the anticipated contracts, plan benefit packages (PBPs), regions, enrollment, and model flexibility(ies).
- **Model applications are due to CMS by 11:59 p.m. PT on April 16, 2021.** The model application will be accessible on the model's website, beginning March 23, 2021. Upon review, CMS will provide provisional approval to plans in May 2021, with plans confirming their participation as part of their Part D bid submissions by 11:59 p.m. PT on June 7, 2021.

If you are interested in learning more about the program, consider contacting the authors of this article or your local Milliman consultant.

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<sup>7</sup> HHS (November 30, 2020). Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees Final Rule. Federal Register. Retrieved February 10, 2021, from <https://www.govinfo.gov/content/pkg/FR-2020-11-30/pdf/2020-25841.pdf>.

<sup>8</sup> Pharmaceutical Care Management Association vs. U.S. Department of Health and Human Services, et al., op cit.