

# Reducing insulin costs for seniors: Thoughts for plan sponsors considering participation in the Medicare Part D Senior Savings Model

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On March 11, 2020, the Centers for Medicare and Medicaid Services (CMS) announced the [Part D Senior Savings Model \(the Model\)](#) to reduce beneficiary cost sharing for insulin products in Medicare Part D.<sup>1</sup> The Model will take effect on January 1, 2021, and is designed to make prescription drugs more affordable for insulin-taking Medicare beneficiaries and restructure how plan sponsors offer supplemental benefits in the coverage gap. Under this voluntary model, plans select a set of insulins to cover from a list of Model-participating manufacturers. Plans cover the selected insulins at a maximum \$35 copay per 30-day supply in the first three phases of the Part D benefit (i.e., deductible, initial coverage phase, and coverage gap), resulting in consistent and predictable out-of-pocket insulin costs for beneficiaries.

CMS also released two Requests for Application (RFAs): one for eligible pharmaceutical manufacturers (with a March 19, 2020, deadline) and one for Part D plan sponsors.<sup>2</sup> Plan sponsors are required to submit a letter of intent by April 10, 2020, and must apply by May 1, 2020. This article intends to provide an overview of the Model and highlights key considerations for plan sponsors.

## What are the guidelines for participating in the Model?

**What types of plans are Model-eligible?** Model participation is available in all states and territories to plan sponsors for enhanced alternative Part D plans. This applies to both standalone prescription drug plans (PDPs) and Medicare Advantage plans with prescription drug coverage (MA-PDs), but not to employer group waiver plans (EGWPs). Chronic and institutional special needs plans (C-SNPs and I-SNPs) are eligible, but dual eligible special needs plans (D-SNPs) are not. Plan sponsors can select which of their plan offerings to include in the Model.

**Which beneficiaries are eligible to enroll?** Non-low income (NLI) beneficiaries who enroll in a Model-participating plan will pay the flat copays for selected insulins.

**Which insulins do plans need to cover?** As a requirement of participation, Part D plans must cover a set of insulin products marketed by pharmaceutical manufacturers participating in the Model. On March 23, 2020 CMS published a list of participating manufacturers and national drug codes (NDCs) on the Model website<sup>3,4</sup>. The Model requires plans cover a set of insulins that includes, at minimum, one vial and pen dosage form of the following four insulin types: rapid-acting, short-acting, intermediate-acting, and long-acting. CMS acknowledges some plan sponsors may cover a product or line of products for a particular type of insulin that exists in only one dosage form (i.e., vial or pen). In these cases, plan sponsors would not need to cover both dosage forms for that type of insulin to meet Model requirements. CMS offers the option, and strongly encourages plan sponsors to also include other insulin formulations, such as mixes and concentrated forms. CMS specifies the list of NDCs may be updated periodically "...based on NDC or drug changes from participating manufacturers"<sup>4</sup>.

**How do participating plans structure the benefit?** Participating Part D plans are required to offer a supplemental benefit with a maximum copay of \$35 per 30-day supply in the deductible, initial coverage, and coverage gap phases of the benefit. Each Model insulin can have its own unique copay. If plans choose to offer a lower copay, it must remain constant throughout the three benefit phases. The copay maximum applies to preferred and non-preferred retail and mail pharmacies. Model insulins not covered on the formulary would not be subject to these maximum copays.

<sup>1</sup> CMS. Part D Senior Savings Model. Retrieved March 20, 2020, from <https://innovation.cms.gov/initiatives/part-d-savings-model>

<sup>2</sup> CMS. Part D Senior Savings Model Request for Application. Retrieved March 20, 2020, from <https://innovation.cms.gov/Files/x/partd-seniorsav-plan-rfa.pdf>

<sup>3</sup> CMS. Pharmaceutical Manufacturer Model Participation and Part D Sponsor Requirements. Retrieved March 25, 2020, from <https://innovation.cms.gov/Files/x/partd-seniordav-mnfr-sponsors.pdf>.

<sup>4</sup> CMS. Model Drug National Drug Code (NDC) List. Retrieved March 25, 2020 from <https://innovation.cms.gov/Files/x/partd-seniordav-ndclist.pdf>.

## How will the Model affect the calculation of coverage gap discount program (CGDP) payments?

For Model applicable drugs, the supplemental benefits would apply after the manufacturer 70% discount in the coverage gap. This differs from the current stakeholder liability calculation in the coverage gap phase. For example, for a \$500 insulin claim for an NLI beneficiary in the coverage gap<sup>2</sup>, consider payments in three scenarios: (1) with defined standard cost sharing, (2) the current Part D program with a \$35 gap copay, and (3) the Part D Senior Savings Model with a \$35 gap copay.

- With defined standard cost sharing, manufacturer CGDP is 70% of the negotiated drug cost, or \$350. The member pays \$125 (25% of the negotiated drug cost), and the plan liability is the remaining \$25.

FIGURE 1: NO GAP SUPPLEMENTAL BENEFITS

Coverage gap payments for each prescription for an applicable drug with a \$500 negotiated price and no supplemental benefits

Manufacturer coverage gap discount applied	70%	×	\$500	=	\$350
Beneficiaries' responsibility applied	25%	×	\$500	=	\$125
Part D sponsor's liability applied	5%	×	\$500	=	\$25

Source: CMS

- Under the current program, if a plan sponsor chooses to lower cost sharing for applicable insulin drugs to a \$35 copay in the gap, the manufacturer CGDP applies only to the beneficiary cost sharing rather than the full negotiated drug cost. The manufacturer CGDP would be 70% of the listed \$35 copay, or \$24.50, and the member would pay the remaining 30% of the copay, or \$10.50. Plan liability increases to \$465, mostly due to the reduced CGDP amount. The increased plan liability in the gap provides a strong disincentive for plans to offer lower gap cost sharing on applicable drugs.

FIGURE 2: GAP SUPPLEMENTAL BENEFITS

If a plan wanted to offer a reduced copay of \$35 in the coverage gap under current law for the same \$500 applicable drug per prescription

First, Part D sponsor's liability assumed	\$500	-	\$35	=	\$465
Second, manufacturer discount applied	70%	×	\$35	=	\$24.50
Remainder is paid by the enrollee	\$500	-	(\$465 + \$24.50)	=	\$10.50

Source: CMS

- The Part D Senior Savings Model aims to remove this disincentive by applying the manufacturer CGDP before the beneficiary copay. Under the Model, manufacturer CGDP would apply first (at \$350), consistent with the defined standard scenario. The member copayment would be \$35, and the plan liability would be the remaining \$115.

FIGURE 3: PART D SENIOR SAVINGS MODEL INSULIN DEMONSTRATION

### Example 3

\$500 Insulin with \$35 Copay in Coverage Gap under Demonstration

First, manufacturer discount is applied	\$500	×	70%	=	\$350
Second, Beneficiary Copay applied					\$35
Remainder is paid by the plan	\$500	-	(\$350 + \$35)	=	\$115

Source: Milliman

## How will participating in the Model affect Part D bids?

Manufacturer CGDP payments will likely increase. With reduced insulin cost-sharing, NLI beneficiaries will accrue to the True-Out-of-Pocket (TrOOP) threshold more slowly and may spend more time in the coverage gap phase.

Impact on plan liability will vary depending on plan design and the other prescription drugs that beneficiaries take in addition to insulins. If current insulin cost sharing is greater than the copays under the Model, plan liability will likely increase in the deductible and initial coverage phases. Few plans currently offer enhanced benefits for applicable drugs in the coverage gap, so plan liability for insulins in the coverage gap would also likely increase compared to the current defined standard benefit. The effect of shifting claims from the catastrophic phase to the coverage gap could be mixed: plan liability on non-insulin applicable drugs may be reduced, while plan liability on generics may increase.

The low income cost-sharing subsidy (LICS) under the Model is calculated using the non-Model tier copay rather than the \$35 (or less) Model copay, so LICS will not be affected by the Model.

## What market dynamics should plan sponsors evaluate prior to participating?

Plan sponsors should compare their expected liabilities under their current cost-sharing structure for insulins to their expected costs under the Model. Plan sponsors should also evaluate how their competitors cover insulins and assess the probability other plans will participate in the Model. CMS intends for the Model to be integrated into the Medicare Plan Finder, so beneficiaries will be able to determine how participating plans could lower their out-of-pocket cost.

If participating would result in more enhanced insulin coverage than what is offered in the market, the plan sponsor needs to consider its ability to manage the cost of insulin-taking members – particularly MA-PD plans at risk for a member's total cost of care including medical benefits. Coverage strategies for these insulin products could also affect total Model-eligible insulin drug costs. If insulin vials and pens are offered at the same copay level, utilization may shift from typically lower cost vials to higher cost pens.

Plan sponsors may also want to consider the amount of non-insulin diabetic users currently enrolled in their plan, and the potential for these beneficiaries to become insulin users. It is also important to assess the rate at which insulin-taking members accelerate through the benefit phases, and other prescription drugs these members use as lower insulin copays may affect adherence for other prescription drugs.

## How will the Model affect MA-PD and PDP plans differently?

Two potential outcomes of making insulins more affordable for beneficiaries through this Model are increased insulin adherence and improved health outcomes. It is common for diabetics to have higher than average medical and pharmacy claims due to typically higher rates of comorbidities (e.g., obesity, heart disease), beyond the costs of insulin alone.

MA-PD plans should consider the extent to which both medical and pharmacy costs may be affected by increased insulin adherence among their diabetic members as well as the timing of when those effects would ultimately materialize. With better insulin adherence, complications such as heart attacks, strokes, retinopathy, and amputations may be reduced over time while short-term complications related to poorly controlled blood sugar (episodes of ketoacidosis/hypoglycemia) may be avoided, which can often result in fewer emergency room visits and inpatient admissions. MA-PD plans should consider the potential for such medical cost offsets when considering participation in this Model.

PDPs, on the other hand, will not benefit directly from any medical cost offsets generated by increased insulin adherence and should keep this in mind when determining whether to participate. All plans should still consider whether an overall reduction in prescription drug utilization of diabetics could result from improved health outcomes associated with better insulin adherence.

## What should plan sponsors discuss with their pharmacy benefits manager (PBM)?

Plan sponsors should understand the extent to which formularies and rebates may change under this Model. For example, some insulin products may move on or off the formulary or change preferred formulary status, which could affect terms under existing rebate contracts. Even if there are no changes to the formulary, rebate contracts may still be affected. Changes to the CGDP and potential increases in insulin adherence and utilization could be relevant to discussions between PBMs and manufacturers.

- *Claim adjudication for Model insulins:* Plans will need to maintain two separate benefits for LI and NLI beneficiaries enrolled in participating plans. For NLI beneficiaries, certain claims will be subject to different cost sharing and CGDP payments. Plans and PBMs will need a systematic way to identify these claims to ensure proper administration of benefits and accumulation to the TrOOP threshold.
- *Prescription drug event (PDE) submissions for Model insulins:* CMS provides guidance as to how PDE submissions should be completed for Model insulins inside and outside the coverage gap. This guidance represents a change in how plans and PBMs are currently required to submit PDEs, and the degree of change required to operationalize this guidance likely varies by plan and PBM.

Assuming PBMs can manage the operational complexities of the Model, plan sponsors may still have limited flexibility over some decisions. These include, for example: the list of Model insulins, the cost sharing applied to Model insulins, and the degree to which these items are allowed to vary by plan. PBMs may charge additional fees to customize these options or participate in the Model altogether, given its administrative complexity. Plans that own a PBM (or vice versa) will likely have more autonomy over these decisions, but they would still face similar operational challenges.

## How will the risk corridors protect participating plans?

Beyond the current Part D risk corridor program, CMS is offering plan sponsors the option of additional risk corridor protection for plan years 2021 and 2022 as part of this Model. Plan sponsors must prospectively decide whether to participate in the supplemental risk corridor. If a participating plan enrolls more insulin users than average for similar plan types (e.g., PDP, MA-PD, C-SNP, I-SNP), it is subject to a narrower corridor threshold of +/- 2.5% (rather than the standard +/- 5%). Otherwise it is subject to the standard risk corridor parameters.

When considering both the additional risk corridor protection as well as the larger Model program, plan sponsors should consider their expected insulin users as a proportion of total enrollment. Because the risk corridor program is two-sided, plan sponsors share a portion of losses and gains with CMS. Plan sponsors should consider expected profit margin, with and without the modified risk corridor, when determining whether to participate in the risk corridor.

## What if plan sponsors would like to offer Part D rewards and incentives (RI) under this model?

As part of the Model, plan sponsors may also offer Part D RI programs aimed at improving one or more of the following: beneficiary health outcomes, medication adherence, and efficient use of healthcare resources. RI programs are already available under other models administered by the Center for Medicare and Medicaid Innovation (CMMI), but plans may only offer RI under one model at a time.

In determining whether to offer RI in tandem with participating in this Model, plans should consider:

- Whether RI are already being offered under a separate CMMI model and whether it makes sense to abandon those RI programs in favor of RI under the Part D Senior Savings Model
  - What specific RI to offer and how their value compares to expected costs under the Model
  - For MA-PD plans, how RI offered under this Model may overlap with or complement initiatives already in place for medical benefits, and the extent to which such RI could affect medical costs
- When the value or potential savings of the RI is expected to be realized (i.e., less than one year or more than one year) because the Model is currently only being offered by CMS for five years, 2021 through 2025
  - How any RI could affect the perceived value of the plan to beneficiaries, relative to competing plans in the market, and how this may play into a plan's strategy to attract and retain certain beneficiaries

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

**Letters of intent are due to CMS by 11:59 p.m. EDT on April 10, 2020.** The letter is non-binding and should list the proposed contract(s), plan benefit package(s) (PBPs), and segments plan sponsors intend to include in the Model. The Model website will provide additional details on submitting this letter.

**Model applications are due to CMS by 11:59 p.m. EDT on May 1, 2020.** Plan sponsors should follow instructions on the Model website to submit the following information:

- The proposed contract(s), PBP(s), and segments
- The name, strength, dosage form, and copay for each Model insulin
- For plan sponsors proposing to offer RI, a description of their RI programs
- For plan sponsors interested in participating in the narrower first risk corridor threshold, indicate this in the application

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