March 1, 2024

Submitted via email to PartDRedesignPI@cms.hhs.gov.

Dr. Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator & Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Draft CY 2025 Part D Redesign Program Instructions

Dear Dr. Seshamani:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments on the Centers for Medicare & Medicaid Services' (CMS) CY 2025 Part D Redesign Program Instructions (Guidance) regarding the implementation of section 11201 of the Inflation Reduction Act (IRA) of 2022.[1]

PCMA is the national association representing America's PBMs, which administer prescription drug plans and operate specialty pharmacies for more than 275 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and through the exchanges established by the Affordable Care Act. Our members work closely with plans and issuers to secure lower costs for prescription drugs and achieve better health outcomes.

As a partner in the timely and effective execution of the new Part D benefit for CY 2025, PCMA offers the following feedback to facilitate CMS's implementation of the most significant changes to the Part D program since its inception. We recognize the challenges CMS faces in carrying out the Part D benefit redesign in 2025, but we urge CMS to promptly provide more specific guidance on many facets of its implementation. Part D plans require the certainty of timely, comprehensive guidance that delineates their responsibilities and risks for CY 2025, under a significantly altered Part D benefit, to submit competitive and financially sustainable bids. Our comments can be summarized as follows:

- CMS should exercise its existing waiver authority under section 402 to narrow the Part D risk corridors set forth in section 1860D-15(e)(3)(C) of the Social Security Act to ensure a stable transition towards the new Part D benefit. CMS should also consider other policies that will help stabilize premiums for beneficiaries.

[1] Draft CY 2025 Part D Redesign Program Instructions (January 31, 2024), https://www.cms.gov/inflation-reduction-act-and-medicare/part-d-improvements.

- Consistent with the plain language of the statute, CMS should confine the scope of the term "incurred cost" under section 1860D-2(b)(4)(C)(iii)(II) of the Act to encompassing solely EGWP supplemental coverage, and exclude supplemental coverage provided by Part D enhanced alternative (EA) plans.
- CMS should maintain its current interpretation of "third-party payments" for purposes of the "incurred cost" statutory provision.
- For purposes of calculating true out-of-pocket (TrOOP)-eligible costs, CMS should count only the $35 cost-sharing amounts for insulin toward TrOOP (as opposed to the full cost of the drug).
- CMS should finalize its proposed revisions to the reinsurance methodology.
- CMS should clarify how the revised definition of creditable coverage will affect individuals who were eligible under the previous definition but not under the new one.
- In assessing the value of EA plan designs in CY 2025, CMS should incorporate the value of excluded drugs into the appraisal of EA plans
- Rather than the proposed 15% threshold for prescription drug plan (PDP) meaningful difference, CMS should finalize a 12 percent overall differential between basic and enhanced plans.
- PCMA opposes the elimination of basic alternative (BA) plans at this time because we urge CMS to refrain from treating Part D supplemental benefits as TrOOP-eligible.
- CMS should issue the final M3P guidance as soon as feasible.

I. SECTION 20 – DETAILED DESCRIPTION OF THE REDESIGNED PART D BENEFIT IN 2025

A. To protect beneficiary access to a competitive Part D marketplace, CMS should exercise its statutory authority to mitigate the potential financial instability of the Part D benefit redesign.

Background: The defined standard (DS) Part D drug benefit will undergo substantial alterations and the existing four benefit stages will be condensed to three. These modifications affect all Part D plans, including employer group waiver plans (EGWPs). Plans may continue to offer basic alternative, alternative equivalent, and enhanced alternative benefit designs derived from the defined standard.

Comment: PCMA acknowledges that the changes to the Part D benefit are mandated by statute. The legislative intent behind the Part D benefit redesign was to enhance the affordability of drugs for Part D beneficiaries. However, PCMA respectfully requests that CMS, as the administrator of the Part D program, foresee and explicitly acknowledge that some elements of the IRA, including but not limited to the Part D benefit redesign provisions, risk creating a series of untenable consequences for Part D plans that could jeopardize comprehensive access to

Part D drugs, in the absence of specific relief granted by CMS, either through existing statutory flexibility or its broad waiver authority.

For instance, Part D plans must absorb the losses of enrollees' failure to pay due amounts under the Medicare Prescription Payment Plan (M3P). We remain concerned that instructions issued to date for this program are creating a system through which beneficiaries either through confusion or lack of incentives often will not pay back the owed cost-sharing amounts. As designed so far, the program unreasonably transfers the loss of nonpayment from the pharmacy to the plan.[2] Moreover, additional guidance for implementing M3P is needed before Part D plans prepare bids for CY 2025.

The interaction between the Medicare Negotiation Program and the Part D program imposes additional limitations on Part D plans' ability to offer a competitive benefit package. In the first place, the Maximum Fair Price (MFP) diverts the rebates that Part D plans would have negotiated with manufacturers—rebates which could have been used to lower premiums for enrollees. Moreover, the statutory requirement that Part D plans cover all selected drugs undermines the negotiation leverage that Part D plans have to generate additional rebates that can help offset plan costs and enable lower premiums and more robust drug coverage.[3]

Lastly, the Part D benefit redesign will generally make Part D enrollees less cost-conscious given the cap on their cost-sharing. While this is not a negative outcome per se, it does create incentives that are contrary to Part D plans' objectives of balancing a comprehensive prescription drug benefit with the financial viability of such a benefit. CMS should consider allowing Part D plans to exercise more flexibility in the use of utilization management programs to reduce the risk of excess waste that increases program costs with little additional member value.

PCMA recommendation: CMS should permit greater use of utilization management programs to combat perverse incentives created by the new Part D benefit. CMS should expressly state an objective of mitigating the potential unsustainability of the Part D benefit redesign. At a minimum, to preserve the competitiveness of the Part D program, and as discussed more below, CMS should exercise its existing waiver authority under section 402, as originally established by the Social Security Amendments of 1967, to modify the Part D risk corridors set forth in section 1860D-15(e)(3)(C) of the Social Security Act. We also urge CMS to consider options available to reduce up-front premium increases that enrollees may face.

[2] Social Security Act § 1860D-2(b)(2)(E)(v)(VI).
[3] Social Security Act § 1860D-4(b)(3)(I).

II. SECTION 30 - CHANGES IN TRUE OUT-OF-POCKET COSTS (TROOP)

A. The best reading of the amended "incurred cost" definition includes only EGWP supplemental coverage and not the supplemental coverage of EA Part D plans.

Background: CMS interprets the statutory provision at 1860D-2(b)(4)(C)(iii)(II) as modifying the meaning of "incurred costs" to encompass "supplemental coverage provided by enhanced alternative (EA) Part D plans and other health insurance (OHI)", thereby rendering these costs eligible to be counted as incurred costs and factored into the determination of TrOOP. This encompasses supplemental coverage furnished by EGWPs, as well as plan diminutions in cost sharing for enrolled beneficiaries, such as diminutions by Medicare-Medicaid Plans and D-SNPs.

Comment: We respectfully submit that CMS's interpretation of section 1860D-2(b)(4)(C)(iii)(II) of the Act is erroneous and contrary to the plain meaning and purpose of the statutory amendment enacted by the IRA. The statute does not require CMS to include supplemental Part D coverage provided by enhanced alternative (EA) plans and other health insurance (OHI) in the definition of incurred costs for the purpose of calculating TrOOP. Rather, the statute only excludes basic Part D coverage from the definition of incurred costs, leaving ambiguous the status of supplemental Part D coverage. Moreover, the statute's reference to "insurance, a group health plan, or certain other third party payment arrangements" does not clearly encompass Part D coverage, which is distinct from non-Part D commercial insurance and other reimbursement arrangements.

CMS's interpretation also disregards the legislative history and intent of this provision the IRA, which was designed to address the specific and unique situation of EGWP enrollees who faced higher out-of-pocket costs and longer stays in the coverage gap due to their supplemental coverage.[4] The IRA aimed to close the coverage gap and ensure consistent and fair application of the Part D benefit structure to Part D basic enrollees and EGWP enrollees. CMS's interpretation, however, arbitrarily and unjustifiably punishes Part D plans for providing EA plans with lower enrollee cost-sharing by counting those reductions as TrOOP-eligible costs that accelerate the enrollee's movement through the benefit and impose a greater burden on Part D plans. The proposal will also create a perverse incentive for beneficiaries to choose a more expensive drug over a cheaper alternative within the same formulary tier. This is because the beneficiary would pay less out of pocket and reach their TrOOP faster, but at a higher cost to the Part D plan and the Medicare program, which is contrary to CMS's stated goals.

CMS's interpretation will also create confusion for beneficiaries who may not understand how their actual out-of-pocket expenses relate to the $2,000 limit for entering catastrophic coverage. Under this method, CMS would use the DS benefit cost-sharing amounts to track the

[4] *See* "EGWPS are at risk: Help Retirees Keep their Coverage," An Evernorth Policy Perspective (July 2021).

beneficiary's progress toward TrOOP, even if the beneficiary pays less or more than those amounts in their EA plan. For instance, if the beneficiary pays less than the DS cost-sharing in the initial coverage phase, CMS would still count the higher DS amount toward TrOOP. On the other hand, if the beneficiary pays more than the DS cost-sharing in the initial coverage phase, CMS would only count the actual EA amount toward the $2,000 threshold. CMS should count the beneficiary's real out-of-pocket costs from an EA plan toward TrOOP, instead of using the DS benefit as a proxy, to avoid beneficiary confusion. Furthermore, CMS's interpretation would be extremely difficult and burdensome to operationalize, as it would require significant changes to the Part D data systems, reporting mechanisms, and coordination of benefits processes. CMS has not provided any guidance or technical specifications on how Part D plans and OHI would report and track supplemental coverage payments and how CMS would verify and audit such payments. CMS has also not addressed the potential for errors, disputes, and fraud that could arise from the inclusion of supplemental coverage in the definition of incurred costs.

To the extent that CMS proceeds with its interpretation, we urge CMS to provide PDE reporting instructions with additional examples on how TrOOP accumulators should account for all of these costs in 2025. To allow for adequate implementation by Part D plans, CMS must issue such guidance by April 1st. We also request that CMS make sure that the definitions for EGWP benefits be updated in all pertinent materials to account for the fact that EGWPs were previously specifically excluded from the definition of supplemental coverage. Lastly, CMS must provide additional guidance on how the changed definition of incurred costs impacts various benefit offers, including the VBID model. It will be critical to understand the intersection of this significant change to TrOOP calculation with other plan and benefit designs in order to properly educate beneficiaries.

***PCMA recommendation*: CMS should confine the scope of the term "incurred cost" under section 1860D-2(b)(4)(C)(iii)(II) of the Act to encompassing solely EGWP supplemental coverage, and exclude supplemental coverage provided by Part D EA plans. Regardless, CMS must issue PDE reporting instructions on how to account for incurred costs by April 1, 2024, and ensure consistency in the definition of EGWP benefits going forward.**

B. CMS should not expand the "incurred cost" definition to include third-party payments beyond those third-party payments currently included.

Background: CMS recognizes that, under section 1860D-2(b)(4)(C)(iii)(II), the TrOOP calculation must also account for "certain other third party payment arrangements" besides those expressly listed in the statute. However, CMS retains the authority to determine which other third-party arrangements qualify for TrOOP purposes, as the statute does not define such payments. For 2025, CMS will exclude from incurred costs any third-party payments that were not eligible for TrOOP before 2025. CMS invites comments on what other third-party payments could be considered for TrOOP inclusion.

Comment: PCMA agrees with CMS that the current universe of third-party payments included in the "incurred cost" definition are adequate for the time being. Specifically, the term "third party payment arrangements" is defined by regulation as "any contractual or similar arrangement under which a person has a legal obligation to pay for covered Part D drugs."[5] In light of the agency's current imperative to effectuate the significant Part D benefit redesign for CY 2025, preserving consistency in the agency's construction of "third-party payments" for the purposes of the "incurred cost" definition is a suitable course of action.

***PCMA recommendation*: CMS should maintain its current interpretation of "third-party payments" for purposes of the "incurred cost" statutory provision. A broader interpretation would be inconsistent with the statute and further risk destabilizing the Part D market.**

III. SECTION 40 – POLICY FOR DRUGS NOT SUBJECT TO THE DEFINED STANDARD DEDUCTIBLE

A. CMS should clarify whether only the $35 copays for insulin are treated as TrOOP-eligible costs.

Background: CMS explains that, under the statute, an individual qualifies for manufacturer discounts under the Discount Program when they are an "applicable beneficiary." This means that, on the date a Part D or MA-PD plan dispenses a covered Part D drug to them, they are enrolled in such a plan, they are not covered by a qualified retiree prescription drug plan, and they have exceeded the DS deductible with TrOOP-eligible costs. These costs include those drugs not subject to the DS deductible, such as covered insulin products and certain vaccines. Therefore, if an individual has not met their plan deductible but has surpassed the DS deductible with TrOOP-eligible costs, they are both an "applicable beneficiary" and deemed to have met their plan deductible, and the manufacturer must provide discounts for applicable drugs.

Comment: It is unclear whether only the $35 beneficiary contribution for insulin is treated as TrOOP-eligible costs, or the actual cost of the insulin incurred by the Part D plan. We urge CMS to adopt an interpretation that only the $35 for insulin should count towards an enrollee's TrOOP since it represents the cost actually incurred by the enrollee. Including the full cost of insulin could distort Part D plan costs and serve to further undermine plan solvency. Furthermore, it would create perverse incentives for manufacturers to raise their insulin prices to move individuals through the benefit faster.

[5] 42 C.F.R. § 423.100.

***PCMA recommendation*: CMS should count only the $35 cost-sharing amounts for insulin toward TrOOP.**

IV. SECTION 60 – REINSURANCE METHODOLOGY (§§ 423.308, 423.329)

Background: CMS notes that because of the significant changes to the reinsurance payment for a Part D beneficiary under the Part D benefit redesign (decreasing from 80% to 20%), in addition to the distinction between "applicable drugs" and "non-applicable drugs," the methodology for calculating the reinsurance subsidy and allocating direct and indirect remuneration (DIR) towards reinsurance must be reconsidered. CMS outlines a revised reinsurance subsidy calculation methodology, including the calculation of allowable reinsurance costs and final reinsurance subsidy for applicable versus non-applicable drugs.

Comment: We commend CMS for revising the existing reinsurance formula to conform to the IRA's amendments, particularly the differentiation of "applicable" and "non-applicable drugs", and the substantial decrease in federal reinsurance in the catastrophic phase. We concur with CMS's suggested method of computing the reinsurance payment for applicable versus non-applicable drugs separately based on their respective share of gross drug costs that fall in the catastrophic phase.

***PCMA recommendation*: CMS should finalize its proposed revisions to the reinsurance methodology.**

V. SECTION 80 - RISK CORRIDOR METHODOLOGY (§§423.308, 423.336)

A. CMS can lawfully narrow/reduce the risk corridors to safeguard the solvency of Part D plans in light of the major changes in the Part D benefit design that pose serious risks to their financial stability.

Background: CMS affirms that it is maintaining the status quo regarding the risk corridors. CMS observes that the statutory provision in section 1860D-15(e)(3)(C) precludes CMS from reducing the risk corridors below the CY 2011 levels and only authorizes their expansion. CMS does not consider expanding the risk corridors to be warranted at this time, but the agency will conduct an annual assessment of risk-sharing payments to ascertain if broader corridors should be implemented for Part D risk sharing.

Comment: CMS's position that it lacks the authority to *narrow or reduce* the risk corridors is untenable and contradicts its own past actions. **We enclose a legal memorandum from Foley Hoag LLP that details CMS's section 402 demonstration authority and how it can be used to achieve the same result as narrowing the risk corridors**. The memo demonstrates that CMS has relied on this authority in the past to modify the risk-sharing parameters for Part D. Thus, CMS clearly has the legal authority to invoke section 402 to narrow the risk corridors, and

CMS's assertion that it cannot narrow the risk corridors is inconsistent with its own past legal interpretation and practice.

Risk corridors protect plans from over- and under-bidding, after the close of the plan year. However, we remain concerned that premiums during the annual enrollment period may shock beneficiaries if CMS doesn't take prospective steps to limit premium increases within the program. While not the subject of the redesign guidance, we are responding to the proposals in the Advance Notice regarding changes to risk adjustment including potentially using separate normalization factors. We respectfully request that CMS provide the interested public with more information about the effect of these proposals on potential plan liability, and consider other approaches such as allowing sponsors to offer a 4th PDP in each region to better segment their risks.

***PCMA recommendation*: CMS should exercise its section 402 demonstration authority, as it has proposed to do in the past, to narrow/reduce the risk corridors to ensure a stable transition towards the new Part D benefit. CMS should also consider other policies that will help stabilize premiums for beneficiaries**.

VI. SECTION 90 – CREDITABLE COVERAGE (§ 423.56)

A. CMS must provide clear guidance on the implications of the revised definition of creditable coverage for individuals who qualified for this status under the former definition but do not meet the new criteria.

Background: CMS proposes the following revised definition for creditable coverage, with the changes in **bold** and *italics*:

> Creditable prescription drug coverage means any of the following types of coverage listed in paragraph (b) of this section only if the actuarial value of the coverage equals or exceeds the actuarial value of defined standard prescription drug coverage under Part D in effect at the start of such plan year, not taking into account the value of any discount ***provided under section 1860D-14C of the Social Security Act***, and demonstrated through the use of generally accepted actuarial principles and in accordance with CMS guidelines.

Comment: PCMA appreciates CMS's conforming amendment to the regulatory definition for creditable coverage that reflects the new manufacturer Discount Program. However, the change to the new Discount Program does raise some questions that CMS should clarify in the final guidance. These include:

- How will CMS treat individuals who had creditable coverage before CY 2025, but whose coverage does not meet the revised definition of creditable coverage? Will these individuals face a penalty if they enroll in Part D for not having creditable coverage? Or will CMS exempt them from the penalty?
- Will CMS issue new guidance to replace the September 18, 2009 "Updated Creditable Coverage Guidance" that the agency acknowledges is no longer a valid method to determine creditable coverage for an entity's prescription drug coverage?

***PCMA recommendation*: CMS should clarify how the revised definition of creditable coverage will affect individuals who were eligible under the previous definition but not under the new one.**

VII. SECTION 120 – DEFINITION OF ENHANCED ALTERNATIVE BENEFIT DESIGN

A. CMS should maintain its approach towards assessing the value of an EA plan until at least CY 2027, and CMS should include the value of including Part D excluded drugs on formulary as a way to further distinguish EA plans.

Background: As the IRA has substantially narrowed the range of supplemental benefits that EA plans can offer, CMS proposes to reconsider the criteria for defining an EA benefit design under the Part D program. CMS acknowledges and rejects some alternatives, such as requiring every EA plan to have a basic benefit component and a separate premium for any additional coverage, or rider/wrap, that enhances the basic benefit. CMS recalls that it proposed this option in a 2014 rulemaking but abandoned it after receiving adverse comments.

CMS suggests that it should instead assess the value of EA plan designs in 2025, using the Part D OOPC model to compare the value of EA plans with the value of the defined standard benefit. Under this method, CMS will estimate the OOPC for each Part D EA plan that reduces the deductible and/or cost-sharing in the initial coverage phase, based on its formulary, and will also estimate the OOPC for the DS benefit, using the same formulary. CMS explains that since this is the first year of applying this method, it will not set any specific value threshold for EA plans, but will only require that the OOPC for an EA plan be lower than the OOPC for the DS benefit, using the same formulary. CMS indicates that it will review these comparisons for CY 2025 and consider imposing a stricter value standard for CY 2026 and beyond.

Comment: We agree with CMS's approach of assessing the EA plan designs in 2025 by comparing the monthly OOPC of the EA plan with the monthly OOPC of the DS, subject to some modifications.

First, we submit that CMS should continue this approach until at least 2027. Part D plans need stability and predictability as they adjust to the new Part D benefit. By applying this proven

approach for measuring the worth of EA plans, CMS will increase confidence for Part D plans and encourage innovation in the delivery of EA plans under the new benefit framework. Second, we recommend that the agency incorporate the value of excluded drugs into the appraisal of EA plans. Excluded drugs can provide a substantial benefit for enrollees and constitute an "enhancement" to the basic benefit package.

***PCMA recommendation*: CMS should maintain its approach to assessing EA plan designs for at least CY 2025 and 2026 to ensure predictability and improve familiarity with offering EA plans under the new benefit. CMS should also consider including the value of Part D excluded drugs offered under EA plans as a basis for assessing the value of EA plans.**

VIII. SECTION 130 – PDP MEANINGFUL DIFFERENCE

B. CMS should reduce the proposed 15 percent overall differential between PDP basic and EA plans to 12 percent.

Background: To assess whether prescription drug plans (PDPs) offer a meaningful difference to beneficiaries, CMS will adopt a new methodology for contract year CY 2025 that applies an "absolute percent" threshold of 15 percent to the comparison of enhanced alternative (EA) plans and basic plans. This means that CMS will compare the total expected out-of-pocket costs for a representative set of beneficiaries under each plan, and will only consider an EA plan to be meaningfully different from a basic plan if it reduces those costs by at least 15 percent. To assist plan sponsors ahead of the CY 2025 bid deadline, the CY 2025 Bid Review Part D OOPC Model will incorporate the ability for Part D sponsors to run each of their plan's formularies through a DS benefit.

Comment: We commend CMS for its initiative to guarantee that EA plans provide significant improvements to beneficiaries, but we have reservations about the suitability of the proposed 15 percent threshold in the context of the limited options that plans have to augment the value of the basic benefit.

CMS acknowledges in the Guidance that plans attained a 12 percent differential for CY 2024—we suggest that CMS adopt this as the relevant benchmark for CY 2025 in view of the multiple changes that Part D plans will have to incorporate for CY 2025. A 12 percent target appears more aligned with previous experience, and CMS could always modify it later based on acquired knowledge.

***PCMA recommendation*: CMS should finalize a 12 percent overall differential between PDP basic and EA plans.**

IX. SECTION 150 - DIFFERENT TROOP-ELIGIBLE COSTS IN BASIC ALTERNATIVE AND ENHANCED ALTERNATIVE PLANS WITH NON-DEFINED STANDARD DEDUCTIBLE

Background: CMS notes that cost impact of a basic alternative (BA) plan with a reduced deductible is much higher than that of an EA plan, because Part D supplemental benefits are TrOOP-eligible in CY 2025, but basic prescription drug coverage is not. This means that only the amounts paid by enrollees in a BA plan contribute to the DS deductible, while both the amounts paid by enrollees and the Part D supplemental benefits paid by the plan contribute to the DS deductible in an EA plan. Therefore, enrollees in BA plans with lower deductibles will have a longer time before reaching the DS deductible threshold and accessing the Discount Program discounts. This creates a discrepancy between how plan paid amounts for basic prescription drug coverage and Part D supplemental benefits affect the accumulation of TrOOP-eligible costs towards the DS deductible, and a corresponding discrepancy in plan costs. CMS is uncertain whether Part D plans will continue to offer BA plans with lower deductibles under these conditions. If CMS prohibited BA plans from lowering the deductible, BA plans would not be able to offer a different benefit from actuarially equivalent (AE) plans, and there would be no reason for CMS to allow BA plans. CMS requests comments on whether it should continue to permit BA plans with lower deductibles after 2025.

Comment: To the extent CMS proceeds with its flawed interpretation of treating Part D supplemental benefits as TrOOP-eligible, we agree with CMS that the new Part D benefit design may significantly increase the costs for BA plans that have reduced deductibles. However, it is premature to eliminate BA plans until there is actual program experience on whether this plan option continues to be offered and affordable for beneficiaries.

***PCMA recommendation*: CMS should not eliminate BA plans at this time because it should refrain from treating Part D supplemental benefits as TrOOP-eligible.**

X. SECTION 160 – MEDICAL LOSS RATIO (MLR) (§§ 423.2420 AND 423.2460)

Background: CMS explains that the IRA created new types of federal payments for Part D plans, such as Discount Program payment and the Inflation Reduction Act Subsidy Amount (IRASA). CMS instructs Part D plans to exclude these payments and the related costs from the MLR calculation, both from the numerator and the denominator. CMS says this is in line with its previous practice of excluding low-income subsidies (LICS) and CGDP payments from the MLR because they are not plan revenue but pass-through payments from a third party.

CMS also clarifies that any outstanding balances from the Medicare Prescription Payment Plan (M3P) are plan losses, and the Secretary is not responsible for them beyond the estimated losses in plan bids. CMS will provide guidance on how to account for any bad debt from this

program in the MLR calculation in the draft part two guidance for the Medicare Prescription Payment Plan, which CMS expects to publish in early 2024.

Comment: PCMA acknowledges CMS's efforts to maintain consistency in the treatment of Discount Program payments and IRASA. However, we request CMS to issue final M3P guidance as early as feasible as implementation of this program is proving to be both actuarially and operationally difficult. We have received feedback from our Part D plan partners regarding the uncertainty of adequately accounting for the bad debt associated with the M3P into premium rate-setting. We have also been facing some of the operational issues in implementation. We require final guidance for the M3P guidance as soon as possible

PCMA recommendation: CMS should issue the final M3P Guidance as soon as feasible.

XI. CONCLUSION

We thank CMS for the opportunity to provide comments on the most significant changes related to the Part D program redesign since its inception. PBMs support the Administration's efforts to update the Part D program and increase patient affordability and access to needed medicines. If you need any additional information, please reach out to me at tdube@pcmanet.org.

Sincerely,

Tim Dube

Tim Dube,
Senior Vice President, Policy & Regulatory Insights

Attachment: February 25, 2024, Foley Hoag memo, "Applicability of Section 402 Demonstration Authority to the Part D Risk Corridors"

cc: Debjani Mukherjee, Senior Director, Regulatory Affairs, PCMA

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Confidential: Attorney-Client Privileged

Memo

Date:	February 25, 2024
To:	Tim Dube, Senior Vice President, Policy & Regulatory Insights, PCMA
cc:	Debjani Mukherjee, Senior Director, Regulatory Affairs, PCMA
From:	Ross Margulies, Partner Haider Andazola, Senior Associate
Regarding:	Applicability of Section 402 Demonstration Authority to the Part D Risk Corridors

This memo is intended to support PCMA's Part D redesign comments that the Centers for Medicare & Medicaid Services (CMS) may exercise its section 402 demonstration authority, as originally established by the Social Security Amendments of 1967 (hereinafter "section 402"),[1] to modify the Part D risk corridors set forth in section 1860D-15(e)(3)(C) of the Social Security Act (the Act) to address the potential for unexpected drug expenses under Part D benefit redesign in CY 2025.

We conclude that section 402 grants CMS ample legal authority to amend Title XVIII of the Act, including the risk corridor provisions under section 1860D-15(e)(3)(C) (hereinafter "risk corridor provisions"). CMS can defend its decision to waive the risk corridor provisions as a means of "increasing the efficiency and economy of health services" without "adversely affecting the quality of such services."[2] In particular, narrowing the risk corridors would help Part D plans cope with the major changes in the Part D benefit structure for CY 2025. Specifically, CMS previously proposed a comparable demonstration in 2019 during a similar transition regarding a proposed change to the treatment of manufacturer rebates under the Part D program. The situation that Part D plan sponsors face going into 2025 is of a similar magnitude and scope and warrants a similar approach from CMS. [3]

[1] 42 U.S.C. § 1395b-1.
[2] *Id.* at § 1395b-1(a)(1)(A).
[3] According to CMS's estimates, the OIG rule would have led to premium increases of approximately 25% year over year. While CMS has not estimated the effects of 2025's Part D benefit redesign with any specificity, we understand the effects could be as much as a doubling of total plan liability, which of courses passes through in part to potential enrollees selecting these plans.

We provide additional details below.

I. LEGAL BACKGROUND

A. Part D Risk Corridors

The Part D statute, in addition to providing reinsurance subsidies to Part D plans to account for high-cost enrollees,[4] also provides for "risk corridors" that limit plan exposure for unexpected expenses not already included in the reinsurance subsidy.[5] For purposes here, we will focus only on the "upper limit" risk corridors which are triggered when the plan's costs exceed their expected expenditures. We would note, however, that the two-sided nature of the risk corridors protects CMS in the event that plans *underbid* to capture enrollment.

The Part D statute requires CMS to calculate a "target amount" based the total amount of payments to a Part D plan for the coverage year for all risk-adjusted standardized bid amounts, less administrative expenses.[6] For the portion of plan's eligible risk corridor costs that are between the target amount and the first threshold upper limit, currently 105 percent of the target amount, the Part D plan pays 100 percent and no reinsurance payments are made.[7] For costs between 105 percent and 110 percent of the target, CMS will contribute towards paying 50 percent of the Part D plan's costs.[8] For costs above 110 percent of the target amount, CMS contributes to covering 80% of the Part D plan's costs through additional payments.[9]

Importantly, the statute prohibits the Secretary from lowering/narrowing the 5% or 10% upper threshold limits, although the Secretary retains the discretion to increase/widen these upper threshold limits.[10] For instance, CMS may "increase/widen" the first upper limit threshold from 5% to 7%, thereby requiring the Part D plan to incur a higher proportion of the unexpected Part D costs before CMS begins to share in those costs. By contrast, the statute prohibits CMS from "decreasing/narrowing" the 5% to 3%, which would trigger CMS's obligation to share in the Part D plan's costs sooner.

B. Section 402 Demonstration Authority

Section 402 provides the Secretary of the Department of Health and Human Services (HHS) with limited authority to waive compliance with certain requirements of the Medicare program in order to develop and engage in demonstration models for one of eleven delineated purposes. These purposes range from the more general (whether "changes in methods of payment and reimbursement" for healthcare services "would have the effect of increasing the efficiency and

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[4] *Id*. at § 1860D-15(b).
[5] *Id.* at § 1860D-15(e).
[6] *Id.* at § 1860D-15(e)(3)(B).
[7] *Id.* at §§ 1860D-15(e)(2)(A) (specifying no risk corridor payment), 1860D-15(e)(3)(A)(iii) (specifying first threshold upper limit), 1860D-15(e)(3)(C)(i)(III) (specifying 5%).
[8] *Id.* at §§ 1860D-15(e)(2)(B)(i) (specifying 50% risk corridor payments), 1860D-15(e)(3)(A)(iv) (specifying second threshold upper limit), 1860D-15(e)(3)(C)(ii)(III) (specifying 10%).
[9] Id. at §§ 1860D-15(e)(2)(B)(ii)(II) (specifying 80% risk corridor payments), 1860D-15(e)(3)(A)(iv) (specifying second threshold upper limit), 1860D-15(e)(3)(C)(ii)(III) (specifying 10%).
[10] *Id.* at §§ 1860D-15(e)(3)(C)(i)(III) and (C)(ii)(III) (stating that the percentages must be "no less than 5" percent for the first threshold, and "no less than 10 percent" for the second threshold).

economy of health service…")[11] to the very specific ("to determine whether the services of clinical psychologists may be made more generally available…").[12] Section 402 permits the Secretary to use funds from the Hospital Insurance and Supplementary Medical Insurance Trust Funds (together, the Medicare Trust Funds) to fund demonstrations, and imposes no cost neutrality requirements on demonstrations.[13]

Section 402 also permits the Secretary to waive "compliance with the requirements of [Medicare] and [Medicaid]" for purposes of implementing a qualifying demonstration.[14] However, the requirements that may be waived pursuant to this authority must "relate to reimbursement or payment on the basis of reasonable cost, [] or on the basis of reasonable charge, or to reimbursement or payment only for such services or items as may be specified in the experiment…."[15]

II. LEGAL ANALYSIS

A. Waiving the upper-limit risk corridors requirements is consistent with the purpose of a section 402 demonstration.

CMS can exercise its section 402 demonstration authority to waive the risk corridor provisions, namely the limitation on reducing/narrowing the upper limit risk corridors from 5% and/or 10%, because doing so would "increase[] the efficiency and economy of health services under [Part D] through the creation of additional incentives to these ends without adversely affecting the quality of services."[16]

As a result of changes made by the Inflation Reduction Act of 2022, beginning January 1, 2024, the Medicare Part D prescription drug benefit is undergoing a seismic shift of unprecedented scope, marking a watershed moment since the program's inception in 2006. This transformation is characterized by a fundamental restructuring of the program's benefit design, impacting various stakeholders, including beneficiaries, the Federal government, plans, and manufacturers. First, beginning January 1, 2024, Medicare beneficiaries will no longer face 5% coinsurance in the catastrophic phase of benefit design, reducing incentives for beneficiaries to select lower-cost therapeutic. In 2025, Part D plans will face a significant increase in financial liability, with their share of costs in the catastrophic phase of the benefit design skyrocketing from 20% in 2024 to a staggering 60% in 2025, and the beneficiary out-of-pocket maximum shrinking to $2,000 annually.[17] As a result of both changes, the increased plan liability will be seen earlier in the plan benefit with about $4,000-$5,000 less in total drug costs. This nearly 300% increase in financial liability, beginning sooner in the plan year, and imposed within a single year, gives little time to calibrate their bids from their 2024 experience, and thereby increases the likelihood that a Part D plan will encounter higher-than-expected costs. Indeed, in 2024 alone, the average enrollment-weighted monthly premium for Medicare

[11] 42 U.S.C. § 1395b-1(a)(1)(A).
[12] *Id.* at § 1395b-1(a)(1)(I).
[13] *Id*. at § 1395b-1(a)(2).
[14] *Id.* at 1395b-1(b).
[15] *Id.*
[16] *Id.* at § 1395b-1(a)(1)(a).
[17] Social Security Act § 1860D-15(b)(1)(B).

Part D standalone prescription drug plans increased by more than 20%.[18] Plans and CMS will not know whether these increases were sufficient to cover plan liability until early 2025.

These exceptional circumstances present a persuasive opportunity under a section 402 demonstration to "increase[] the efficiency and economy of health services" under Part D by lowering/narrowing the upper-limit risk corridors and hastening the point at which CMS begins to share in Part D plans' unexpected costs. While Part D premiums in both Medicare Advantage and standalone Part D plans are expected to continue a rapid rise in 2025, uncertainty in the bids may lead to plan sponsor decisions on whether to offer plans, risking beneficiary access to affordable care. A more "efficient" and "economical" approach to executing the 2025 Part D benefit redesign would be to effectively institute a transition period, through the lowering/narrowing of the upper-limit risk corridors, under which Part D plans would have at least several years to acclimate to the substantial changes to their financial exposure, thereby allowing plans to weather enrollment shifts created by premium increases.[19]

Moreover, such a demonstration would not "adversely affect the quality of such services" as required by section 402. To the contrary, improving Part D plans' ability to adapt to seismic changes to their financial exposure under the Part D benefit improves their ability to provide comprehensive, affordable, and competitive formularies that *improve* the quality of drug coverage received by Part D enrollees.

In summary, the reduction/narrowing of the upper-limit risk-corridors conform to the specific objectives of a section 402 demonstration because it would "increase[] the efficiency and economy of health services under [Part D] through the creation of additional incentives to these ends without adversely affecting the quality of services."[20]

B. <u>Waiving the upper-limit risk corridors complies with the waiver requirements of section 402 because the risk corridors directly relate to the risk-sharing payments that would be authorized under the demonstration.</u>

The Secretary has the authority to waive the statutory cap on the upward risk corridors, as they are a component of the "payment [] for such services or items [under] the experiment…." That the Secretary seeks to conduct.[21] The purpose of the experiment is to evaluate the impact of enhanced risk corridor payments on the cost-effectiveness of the Part D benefit in 2025, and the upward risk corridor limits are an essential prerequisite for the Secretary to provide such payments to Part D plans.

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[18] *See* Kaiser Family Foundation, "Medicare Part D in 2024: A First Look at Prescription Drug Plan Availability, Premiums, and Cost Sharing," November 8, 2023. *See also* Avalere, "Part D Premiums Increasing Despite Stabilization Program," October 17, 2023.

[19] While the Inflation Reduction Act of 2022 included a premium stabilization program, the program's 6% limit is applied to the Part D base beneficiary premium, not each individual's plan premiums. While this program will mitigate premium growth, the 6% subsidy will not entirely offset premium growth for plans with large premium increases.

[20] 42 U.S.C. § 1395b-1(a)(1)(a).

[21] 42 U.S.C. § 1395b-1(b).

C. CMS has previously advanced an interpretation of section 402 demonstration authority that would enable it to waive the Part D risk corridor provisions.

The agency's own stance on the relevance of section 402 demonstration authority to the risk corridor features of the Part D program corroborates that CMS regards such features as falling within the scope of section 402.

HHS issued a proposed rule in 2019 that would have eliminated the protection of the Anti-Kickback Statute's safe harbor for rebates paid by drug manufacturers to sponsors of Part D plans (Proposed Rule).[22] This change was anticipated to contribute to a significant increase to Part D plan costs, in excess of the bids they had already submitted under current law and regulation.[23] Shortly thereafter, CMS issued a memo to Part D plans announcing that if the Proposed Rule is finalized, CMS would conduct a voluntary two-year demonstration that would "test an efficient transition for beneficiaries and plans to such a change in the Part D program."[24] This would be achieved through a waiver of the risk corridor provisions section 1860D-15(e)(3)(B) of the Act under the demonstration authority of section 402.[25] CMS specifically guaranteed that the government would bear or retain 95% of the deviation between the target amount and the actual incurred costs beyond the first 0.5%.[26] That is, CMS waived both the (1) risk corridor thresholds at which CMS would start to share in the Part D plans' expenses, and (2) the amount that the government would agree to pay.

The proposed use of section 402 demonstration authority by CMS to transition Part D plans to a post-rebate environment by waiving Part D risk corridors has direct relevance for the analogous situation of using that authority to assist Part D plans in transitioning to a Part D benefit design that subjects plans to much greater financial exposure. In both cases, CMS is addressing the financial impact on plans of altering legal obligations. Moreover, in both cases, CMS is relying on the risk corridor provisions as the specific tool to mitigate the potential instability that these financial impacts could cause for the provision of comprehensive and competitive Part D prescription drug benefits to Part D enrollees.

In short, there is direct evidence that CMS recognizes the applicability of section 402 demonstration authority to the Part D risk corridors. Furthermore, CMS has previously contemplated using section 402 demonstration authority to address the financial instability that may result from changing the legal obligations of plans, a circumstance that is also present here with the redesigned Part D benefit.

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[22] 84 Fed. Reg. 2340 (Feb. 6, 2019).
[23] Centers for Medicare & Medicaid Services, Office of the Actuary, memorandum regarding proposed safe-harbor regulation (August 28, 2018), www.regulations.gov/document?D=HHSIG-2019-0001-0004.
[24] "Additional Guidance Regarding Part D Bids," CMS (May 20, 2019), Additional Guidance Regarding Part D Bids (cms.gov). *See also* "Guidance Regarding Part D Bids," CMS (April 5, 2019), Guidance Regarding Part D Bids.
[25] *Id.* at 1.
[26] *Id.*

III. CONCLUSION

Under its section 402 demonstration authority, CMS possesses clear legal authority to waive the statutory restriction on modifying the Part D risk corridors as part of a demonstration project, and this use of the agency's section 402 demonstration power aligns with the agency's longstanding view of the scope of this power in relation to the Part D risk corridors.