February 10, 2025
Submitted via email to PartDRedesignPI@cms.hhs.gov.

Ms. Stephanie Carlton
Acting Deputy Administrator and 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 2026 Part D Redesign Program Instructions

Dear Acting Administrator Carlton:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments on the Centers for Medicare & Medicaid Services' (CMS) Draft for Calendar Year (CY) 2026 Part D Redesign Program Instructions (Draft Guidance) regarding the implementation of section 11201 of the Inflation Reduction Act (IRA) of 2022.[1]

PCMA is the national association representing America's Pharmacy Benefit Managers (PBM), 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 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.

Our comments can be summarized as follows:

- CMS should permit greater use of utilization management programs, including for selected drugs, to combat incentives created by the new Part D benefit. CMS should also expressly state an objective of mitigating the potential unsustainability of the Part D benefit redesign and continue any demonstration or waiver program necessary to maintain the stability and affordability of the program for seniors.
- PCMA asks that CMS consider phasing in its proposed creditable coverage methodology over three years to allow more employers to adapt their coverage to meet the creditable coverage requirement, while maintaining the quality of the prescription drug benefit.
- CMS should not adopt a specific threshold in evaluating Enhanced Alternative (EA) plan designs and should refrain from prohibiting the option of offering excluded drugs as a means to meet EA benefit design requirements. Instead, CMS should adopt an approach

[1] Draft CY 2026 Part D Redesign Program Instructions (Jan. 10, 2025), https://www.cms.gov/files/document/draft-cy-2026-part-d-redesign-program-instructions.pdf.

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- to measuring EA plan value that adequately takes into account the factors enrollees actually value and that expands plan choices.
- CMS should reduce the meaningful difference threshold from 15% to 12% to provide Part D plan sponsors with more flexibility in designing plan benefit packages, especially considering the significant enhancements to the standard Part D benefit introduced by the IRA.
- CMS should allow Part D sponsors to maintain the flexibility to replace a selected drug from its formulary via immediate substitution, regardless of when the relevant generic or interchangeable biological product came to market in the calendar year. Furthermore, should CMS proceed with its proposal, we urge the agency to preserve formulary flexibility for plan sponsors, including utilization management, placement, tiering, and cost-sharing of selected drugs.

I. Section 20 – Redesigned Part D Benefit in CY 2026

Background: In the Draft Guidance, CMS notes that beginning in CY 2026, with the maximum fair prices (MFPs) negotiated under the Negotiation Program beginning to take effect on January 1, 2026, the IRA makes further changes to payment obligations in Part D related to selected drugs during the price applicability period. As such, there will be specific changes to the Part D defined standard (DS) benefit for CY 2026 beyond those already implemented in CY 2024 and CY 2025. For example, during the initial coverage phase, CMS will pay a 10% subsidy for selected drugs during the price applicability period, until the enrollee has reached the annual Out Of Pocket (OOP) threshold of $2,100 for CY 2026, in lieu of the 10% manufacturer obligation under the Discount Program for non-selected drugs. Moreover, in the catastrophic phase, CMS will provide 40% reinsurance for selected drugs during a price applicability period (for non-selected drugs, the manufacturer obligation under the Discount Program is 20%, while CMS pays a reinsurance equal to 20%). In both the initial coverage and catastrophic phases, however, Part D plans remain subject to a significant increase in liability that results directly from the changes made by the IRA, implemented beginning in CY 2023.

Comment: PCMA acknowledges that the changes to the Part D DS 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, a goal which we support. However, PCMA respectfully requests that CMS, as the administrator of the Part D program, 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, under current guidance, Part D plans must absorb the losses of enrollees' failure to pay due amounts under the Medicare Prescription Payment Plan (M3P) and, as currently

proposed in the CY 2026 Policy & Technical rule, treat such losses as administrative expenses. 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 risk of nonpayment from the pharmacy to the plan.[2]

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 otherwise negotiated with manufacturers that are often used to reduce premiums for enrollees. Moreover, the statutory requirement that Part D plans cover all selected drugs on the formulary undermines Part D plans' negotiation leverage to generate additional rebates that allow plans to offset plan costs and premiums and provide more robust drug coverage.[3]

The Part D benefit redesign will also 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 an affordable benefit for seniors. CMS should explicitly recognize — through guidance or future rulemaking — Part D plans' clear ability to exercise flexibility in the use of utilization management programs for selected drugs, to enable even greater competition and lower prices for these therapies, and to preserve the market-driven power of PBMs to lower costs for CMS and Medicare patients.

Lastly, and as reiterated in previous PCMA comments,[4] CMS's reinterpretation of the definition of "incurred costs" arbitrarily and unjustifiably punishes Part D plans for providing enhanced alternative (EA) coverage with lower enrollee cost-sharing by counting those reductions as True Out-Of-Pocket (TrOOP) -eligible costs that accelerate the enrollee's movement through the benefit, therefore exposing these plans to even greater risk. This also creates 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, in choosing a more expensive drug, would pay less out of pocket and reach his or her TrOOP faster, but at a higher cost to the Part D plan and the Medicare program, which is contrary to CMS's stated goals. We reiterate our position that CMS's reinterpretation of the term "incurred costs" to include supplemental benefits offered by EA Part D plans reads into the relevant statute text that does not exist, and that it is in conflict with the Supreme Court's decision in *Loper Bright Enterprises v. Raimondo*, which requires that an agency's interpretation reflect the single correct reading of the statute.[5] While

[2] Social Security Act § 1860D-2(b)(2)(E)(v)(VI).
[3] Social Security Act § 1860D-4(b)(3)(I).
[4] See https://www.pcmanet.org/wp-content/uploads/2024/11/PCMA-Prerule-Comments-for-CY-2026-Rulemaking-and-Guidance-November-1-2024.pdf.
[5] *Loper Bright Enterprises v. Raimondo,* 144 S.Ct. 2244, 2266 (2024).

the underlying statute may be "ambiguous" on the treatment of EA coverage insofar as it is not expressly referenced, it does not follow that "reimbursed through insurance" must necessarily include EA coverage. CMS itself acknowledges that "one goal of the IRA amendments … was to address the unique situation of *Employer Group Waiver Plan (EGWP) beneficiaries* who faced higher OOP costs due to the treatment of EGWP supplemental coverage."[6] If Congress wanted to specifically include EA coverage as well, it would have explicitly stated so.

PCMA Recommendation: CMS should permit greater use of utilization management programs, including for selected drugs, 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 and continue any demonstration or waiver program necessary to maintain the stability and affordability of the program for seniors.

II. Section 30 – Creditable Coverage

Background: Because of the changes made by the IRA to enhance the DS Part D benefit, CMS states it needs to make changes to its existing methodology for determining whether a group health plan's prescription drug coverage qualifies as "creditable coverage" for purposes of the Part D late-enrollment penalty. CMS states in the Draft Guidance that it will permit non-retiree drug subsidy group health plans to use a new, simplified methodology to determine creditable coverage to reflect the more robust Part D benefit in 2026. Under the revised simplified determination methodology, the coverage will be deemed to provide prescription drug coverage with an actuarial value that equals or exceeds the actuarial value of DS Part D coverage if it is 1) designed to pay on average at least 72% of participants' prescription drug expenses (as opposed to 60% under the existing methodology); 2) provides reasonable coverage for brand-name and generic prescription drugs and biological products; and 3) provides reasonable access to retail pharmacies.

Comment: PCMA is concerned that CMS's proposed methodology is overly stringent. Given the robustness of the DS Part D benefit resulting from changes made by the IRA, under CMS's new methodology, a significant number of individuals will be enrolled in group health plans that do not meet the stringent criteria and will thus be subject to a penalty.

PCMA Recommendation: PCMA asks that CMS consider phasing in this methodology over three years to allow more employers to adapt their coverage to meet the creditable coverage requirement, while maintaining the quality of the prescription drug benefit.

III. Section 40 – Definition of Enhanced Alternative (EA) Benefit Design

[6] Final CY 2025 Part D Benefit Redesign Instructions at 6, https://www.cms.gov/files/document/final-cy-2025-part-d-redesign-program-instructions.pdf (emphasis added).

Background: In the Draft Guidance, CMS proposes several policies with respect to the definition of EA benefit design. For example, CMS states it will consider the waiving of a plan's deductible for a subset of its formulary tiers as an enhancement. CMS also states that EA plans may offer excluded drug coverage as an enhancement, but is not establishing a requirement for the value of such coverage at this time. CMS also questions whether excluded drug offerings demonstrate a significant benefit; notes that it is considering prohibiting the option of *only* offering excluded drugs as a means to meet EA benefit design requirements; and seeks comment on this proposal. For purposes of evaluating EA plan value using the Part D Out-of-Pocket Cost (OOPC)model, CMS is proposing to require that plans meet a specific percentage threshold difference of 15% relative to the DS benefit to offer a plan as an EA plan. Notably, CMS did not require a specific percentage threshold for CY 2025.

Comment: PCMA opposes the proposed 15% threshold, which we believe undermines the ability of Part D plans to offer a range of affordable and competitive plan options to Medicare enrollees and is at odds with the market-driven purposes of the Part D program generally. We are also concerned with CMS's discussion questioning the value and benefit of Part D plans that provide excluded drug offerings. An offering that provides for a more expansive list of covered drugs can provide significant enhanced value to enrollees who would otherwise pay fully out of pocket for such treatments. PCMA believes it is necessary for CMS to review and update the Part D OOPC model, especially considering the changes made by the IRA limiting other options for EA coverage, such as reducing enrollee costs in the catastrophic phase. To preserve a competitive Part D plan landscape full of choices for Medicare enrollees, CMS should at least maintain its approach to assessment of EA plan designs and — to avoid shrinking affordable choices for seniors — it should not move forward with the 15% threshold.

***PCMA Recommendation*: CMS should not adopt a specific threshold in this context and should refrain from prohibiting the option of only offering excluded drugs as a means of meeting EA benefit design requirements. Instead, CMS should adopt an approach to measuring EA plan value that adequately takes into account the factors enrollees actually value and that expands plan choices.**

IV. Section 50 – Meaningful Difference

Background: CMS also includes several policies relating to the agency's approach to assessing meaningful difference between an EA plan and a basic plan for standalone PDPs in CY 2025. CMS states that it will maintain the 15% differential between a PDP organization's basic and EA plans for purposes of meeting the agency's meaningful difference requirements, first established by CMS for CY 2025. Under this policy, for CY 2026, Part D plan sponsors must demonstrate that each EA plan's Part D OOPC value generated from the OOPC model is at least 15% better than the basic plan offered by the same parent organization in the same region. CMS also proposes to require that the share of meaningful difference attributed to

benefit design/tier placement be greater than 50%, and that the share of meaningful difference attributed to formulary robustness be greater than or equal to 0%.

Comment: PCMA opposes CMS's proposal to maintain the 15% differential between PDP basic and EA plans for purposes of measuring meaningful difference in CY 2026. As we have previously communicated to the agency, although we commend CMS for its initiative to guarantee that EA plans provide significant improvements to beneficiaries, we have reservations about the suitability of the 15% threshold. There currently exists significant market instability resulting from the inherent difficulties associated with the implementation of such a monumental reform to the program. At this time, a conservative approach is needed to allow plans time to digest the practical nuances of these program changes and to fully understand what they mean for plan offerings and the Part D program as a whole. For example, in the context of the limited options that plans have to augment the value of the basic benefit under Part D redesign, plans will have to make significant changes to their offerings to meet any meaningful difference requirement. Furthermore, and as discussed above, we also note that there are Part D offerings that can provide great value to enrollees but that are not fully captured by CMS's OOPC model in this context, making it all the more difficult for Plan D plans to meet onerous requirements.

Consistent with our previous recommendations, we suggest that CMS adopt a 12% differential for CY 2026, consistent with the average differential obtained by plans in CY 2024.

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

V. Section 90 – Successor Regulation Exception to the Formulary Inclusion Requirement for Selected Drugs

Background: In addition to continuing to permit the removal of a selected drug that is a brand-name drug and replacement of it with a generic drug as an immediate substitution, in CY 2026, CMS also will permit Part D plan sponsors to remove a selected drug that is a reference product and replace it with an interchangeable biological product as an immediate substitution. CMS notes, however, that pursuant to the IRA, a Part D plan sponsor is *not* permitted to remove a selected drug that is a brand-name drug or brand name biological product on the basis of adding an *authorized* generic of the brand-name drug or an unbranded biological product marketed *under the same BLA* as the brand-name biological product.

CMS also proposes to clarify issues relating to the timing for such substitutions for CY 2026. Notably, CMS states that if there is a generic drug or interchangeable biological product for a selected drug with an initial price applicability year of 2026 and such generic drug or interchangeable biological product is available on the market *before a Part D plan sponsor's 2026 initial formulary submission*, such Part D plan sponsor would still need to include the selected drug on its 2026 formulary submission, regardless of whether the Part D plan sponsor

had removed the selected drug from its 2025 formulary via an immediate substitution in 2025, to comply with the formulary inclusion requirement in section 1860D-4(b)(3)(I)(i) of the Act. Furthermore, CMS also proposes to prohibit Part D plan sponsors from removing the selected drug from the formulary for 2026 as an immediate substitution and replace it with the generic drug or interchangeable biological product that became available on the market prior to the initial formulary submission for 2026.

Comment: PCMA is concerned that CMS's proposed approach is likely to limit generic and biosimilar uptake, as well as raise barriers to access to lower-cost drug options, and could lead to misalignment between formulary coverage in multiple plan years in cases where new generics or biosimilars come to market later in the calendar year. CMS seems to be taking an overly narrow interpretation of the underlying statute and regulations. This read restricts Part D plans from managing their formularies by covering less expensive, therapeutically equivalent medications and unnecessarily places even greater pressure on Part D plans that are already in a financially difficult situation due to the IRA's changes. CMS's proposal will ultimately restrict access to lower-cost drugs and is in conflict with the agency's overarching goals of promoting access to and uptake of lower-cost generic and biosimilar options and of lowering costs in the Part D program.

We also note that in some instances, the timing factors related to Part D formulary substitutions policies in the recently finalized CY2025 MA & Part D final rule limit their application. The specific time periods finalized do not provide sufficient time for full evaluation and completion of activities prior to making and implementing decisions regarding the current formulary product, including activities such as evaluation of the new product's attributes (e.g., formulation, interchangeability, pricing), confirmation of sufficient availability in the marketplace, communication of changes, and updating of systems. Because of these proposed changes, we urge CMS to uphold current IRA guidance allowing formulary flexibilities related to tiering and UM strategies for selected drugs, preserving the ability of plan sponsors to adopt tiering and UM strategies that allow driving towards the lowest net-cost product.

***PCMA Recommendation*: CMS should allow Part D sponsors to maintain the flexibility to replace a selected drug from its formulary via immediate substitution, regardless of when the relevant generic or interchangeable biological product came to market in the calendar year. Furthermore, should CMS proceed with its proposal, we urge the agency to preserve formulary flexibility for plan sponsors, including utilization management, placement, tiering, and cost-sharing of selected drugs.**

VI. Conclusion

We appreciate the opportunity to provide comments to CMS as it continues to implement the most significant changes to the Part D program since its inception. PBMs support efforts to

update the Part D program and increase patient affordability and access to needed medicines. If you need any additional information, please out to me at tdube@pcmanet.org.

Sincerely,

Tim Dube

Tim Dube, SVP Policy & Regulatory Insights

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