

June 5, 2023

Submitted via PartDBenefits@cms.hhs.gov

RE: CY 2025 Part D Redesign

The MAPRx Coalition (MAPRx) appreciates the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments regarding the agency's request via an HPMS memo on April 11 for comments related to the meaningful differences policy and tiering models under the new Part D benefit instituted under the Inflation Reduction Act (IRA).

Our group, MAPRx, is a national coalition of beneficiary, caregiver, and healthcare professional organizations committed to improving access to prescription medications and safeguarding the well-being of Medicare beneficiaries with chronic diseases and disabilities. The undersigned members of the MAPRx Coalition are pleased to provide CMS with our official commentary in response to your request for feedback on evolving key plan design features due to the new Part D benefit design starting in 2025.

MAPRx appreciates the opportunity to comment on how CMS should address any possible changes to the meaningful differences policy, non-defined standard cost-sharing thresholds, and formulary models. We support the continued policy around meaningful differences in order to help Part D beneficiaries understand the choices offered by a plan sponsor. As CMS continues to formulate policy related to the broader Part D benefit redesign, MAPRx is pleased to offer our proactive thoughts around other key pieces of the redesign, especially the smoothing mechanism and formulary coverage of drugs negotiated between manufacturers and CMS.

Maintaining Meaningful Differences, Cost-Sharing Thresholds, and Tiering Models under the Part D Benefit Redesign

MAPRx is appreciative for CMS proactively seeking feedback on issues such as the meaningful differences policy, cost-sharing thresholds, differences between basic and enhanced standalone prescription drug plans (PDPs), and tiering models under the new benefit. First, MAPRx supports the continuation of the meaningful differences policy. A key reason for implementing the policy initially was to minimize the confusion among prospective enrollees given the vast, if sometimes overwhelming, number of PDP options in a given region. As this organization highlighted in its initial support of the policy, prospective enrollees would often get confused over the differences (e.g., deductible, drug coverage, tiering) among the various plan options offered by a plan sponsor. According to an Xcenda analysis of the Contract Year (CY) 2023 Part D landscape, PDP enrollees, on average, have 24 PDPs available to them in 2023.¹ While we support beneficiaries having access to a robust number of plans, we believe strongly in maintaining a policy that will prevent the re-saturation of PDPs in the market and therefore, exacerbating confusion among beneficiaries.

¹ Xcenda analysis of the PDP and MA landscape files from 2015 to 2023.

Additionally, another factor for the initial policy was to prevent PDP sponsors from enrolling relatively healthier Part D beneficiaries by having enhanced offerings with lower premiums compared to their basic counterparts. For this reason, MAPRx supports maintaining the meaningful difference specifically between basic and enhanced offerings. We recognize that CMS removed the requirement between two enhanced offerings in CY 2019, but we believe the agency should maintain it between a sponsor's basic and enhanced PDP. Additionally, we know that CMS has removed a specific out-of-pocket cost (OOPC) threshold between basic and enhanced PDPs and now employs an outlier analysis for each sponsor. We urge CMS to continue employing a rigorous analysis to ensure the differences between the basic and enhanced offering are discernible for prospective enrollees.

Second, MAPRx supports maintaining defined cost-sharing thresholds for the possible formulary tiers under the new benefit design. While the new OOP cap and the smoothing mechanism will certainly alleviate much of the financial burden that standard beneficiaries ineligible for the low-income subsidy have faced for expensive therapies, we believe having this protection in place is important. As Part D beneficiaries will have to proactively enroll into the smoothing benefit, there could be a significant proportion of Medicare Part D beneficiaries who do not enroll and therefore face a relatively high OOP cost for an initial fill before hitting the OOP cap. To help minimize this financial burden, we support maintaining set thresholds for each tier. While we do not have specific recommendations for the specific copayments or coinsurance rates per tier, we generally support lowering the thresholds from CY 2023 and 2024 levels to help more evenly distribute OOP costs for beneficiaries who do not enroll into smoothing.

Third, we are happy to provide our guidance related to formulary tiering models, starting in 2025. As mentioned, we recognize the new OOP cap and smoothing mechanism will help minimize the OOP burden for standard beneficiaries; however, we strongly believe in ensuring tiering models that will maintain beneficiary protections. We appreciate the challenging position that Part D plans will face under the redesign, especially for paying a greater share of costs after the OOP \$2,000 cap for high-cost medications. Based on this higher liability, we recognize the importance for plans to have some flexibility to effectively manage the benefit. Therefore, we understand the need for plans to maintain some level of tiering on formularies arrayed by product cost. Knowing that plans may maintain similar structures to the 5-tier formularies on the market today, we respectfully request CMS to in turn maintain the tiering exception process so beneficiaries can appeal for a lower OOP cost. For years, MAPRx has held that Part D beneficiaries taking products covered under specialty tier should be able to request a tiering exception, and we strongly continue to hold this belief moving forward under any allowed formulary structures or designs by CMS.

We also want to use this opportunity to underscore the importance of requiring coverage for Medicare's six protected classes of drugs. Medicines in the six protected classes treat serious health conditions, and many medicines are not interchangeable.

Part D OOP Cap and Smoothing Mechanism

In addition to the requested feedback related to meaningful differences and formulary tiering/cost sharing, we believe it is important for our coalition to share our initial thoughts on some of the key aspects as it relates to the implementation of the IRA. First, we are respectfully offering proactive feedback around the new OOP cap, especially around the smoothing mechanism. We believe ardently that there should be strong beneficiary protections built into smoothing. While the new cap will help alleviate OOP costs, the smoothing mechanism will further help patients manage their costs and build in greater predictability around monthly costs.

As we all know, this dynamic will be incredibly helpful as many Part D beneficiaries taking a high-cost medication blow through all four phases of the current design for an initial fill, placing a considerable OOP burden for this first fill compared to subsequent ones. CMS should ensure that beneficiaries are able to activate the smoothing option at the time they face substantial Part D out-of-pocket costs, and not only during an open enrollment period.

Therefore, we believe the smoothing mechanism will only be as helpful as it can be based on the protections afforded to patients and the education of Part D beneficiaries about this new benefit. Smoothing will be a new benefit and likely difficult to understand as participating beneficiaries will have to not only enroll into the program, but they will also have to pay monthly payments based on the more evenly distributed OOP costs, compared to the varying OOP costs under the current benefit design. MAPRx is concerned about Part D plans removing beneficiaries from smoothing for the rest of the CY or even permanently if beneficiaries miss a monthly payment. Therefore, we believe that beneficiaries participating in smoothing should have a grace period for a late payment. CMS should follow a template similar to the premium grace periods for the health insurance marketplaces. Under this process, enrollees have a 90-day grace period to make a payment before coverage is terminated, provided that the enrollee qualifies for an advanced payment of the premium tax credit and has already made one full-month's payment. Additionally, enrollees terminated from a marketplace plan have the ability to appeal the termination. We believe strongly in maintaining similar protections for participating beneficiaries.

Furthermore, as beneficiaries are not auto-enrolled into smoothing, educating prospective participating beneficiaries will be a critical step for the agency. As this new benefit will be confusing and complex, CMS should develop a multi-phased approach in educating beneficiaries. First, CMS should require that Part D plans provide robust education to prospective enrollees in their CY 2025 marketing materials. Additionally, CMS should ensure its educational materials, like the annual Medicare & You handbook, provide upfront and clear information and guidance on smoothing. And most importantly, as many beneficiaries utilize the Medicare Plan Finder tool for enrollment purposes, we believe that CMS should have a process that is easy for patients to not only enroll into a plan, but to also concurrently enroll into smoothing. Finally, CMS should require PDP/MAPD Real-Time Benefit Tools to illustrate cost-sharing for enrollees under their current election (traditional benefit or smoothing benefit). If a patient is not enrolled in the smoothing benefit, the real-time benefit tool should illustrate the cost-sharing for the enrollee if the patient chose to enroll in smoothing prior to filling the drug being considered.

Part D Plan Coverage of Drugs Negotiated with CMS

Earlier in April, MAPRx provided comments on how Medicare intends to negotiate with pharmaceutical manufacturers for lower prices on selected high-cost drugs. MAPRx recognizes the importance of improving access to innovative therapies but wants to ensure that these efforts do not exacerbate barriers to patient access.

Of specific note, MAPRx emphasizes the need for beneficiary protections and access to care while CMS is undergoing the new drug price negotiation process. We appreciate the Inflation Reduction Act's provision requiring all Part D plans to cover each drug with negotiated manufacturer fair prices (MFPs) for all years for which the price is in effect during the price-applicability period. This provision helps ensure beneficiaries will benefit from the negotiation process and have access to the lowest-price drugs. MAPRx encourages CMS to monitor Part D plans to ensure beneficiaries have access to all negotiated drugs and provide opportunities to

comment on beneficiary protections in the future. In addition, we urge CMS to provide strong monitoring and oversight of beneficiary access to both negotiated and non-negotiated drugs. For example, changes in formularies, tiering and cost sharing can impact a beneficiary's ability to access prescription drugs under Part D.

Specifically, we seek clarification on CMS' interpretation of the requirement that negotiated drugs be covered by plans and if Part D plans will be allowed to apply utilization management (UM) tools or high cost sharing for the negotiated drugs. The initial guidance did not address UM techniques (e.g., step therapy, prior authorization, etc.) or cost-sharing requirements employed by Part D plans with respect to drugs with negotiated MFPs. While the patient community is incredibly supportive of the Part D redesign and out-of-pocket cap, we understand plans will face higher liability moving forward and therefore likely restrict coverage and/or access.² Such UM techniques and cost-sharing requirements can create significant barriers and increase costs for patients by delaying the start or continuation of necessary treatment and negatively affecting patient health outcomes.^{3,4,5} Given this likely plan reaction to the higher liability, it is more important than ever that CMS create guardrails to ensure access to medicines by limiting burdensome barriers such as prior authorization and step therapy. By defining coverage requirements, CMS reduces the risk of plans denying coverage for products vital to a patient's comprehensive care plan. We also believe ensuring open access to negotiated drugs is simply the right thing to do. If a plan is receiving a lower price based on a maximum *fair* price, the benefit should be fully conveyed to beneficiaries through *fair* access. Conversely, it is crucial that CMS does not allow plans to prefer non-negotiated drugs by applying utilization management on negotiated drugs.

Broader Concerns around Patient Access as a Result of the Medicare Drug Negotiation Program

In addition to the concerns over utilization management for covered negotiated drugs, we also provided broader concerns and feedback in our April comment letter. First, we think it is important to highlight our focus areas. Overall as a coalition, we are focused on ensuring the following:

- Patient organizations have ample opportunity and ability to provide feedback on the negotiation process;
- CMS is transparent into how the agency factors external data into its final decisions (including the methodology deployed by the agency);
- The agency maintains access to a wide range of drugs within Part D and looks to minimize affordability challenges; and
- The agency establishes appropriate guardrails and ongoing oversight processes to continually evaluate the program for the purposes of refining when needed.

² Xcenda Managed Care Network Survey of Part D payer contacts. March 2023.

³ American Medical Association. Prior Authorization and Utilization Management Reform Principles. Accessed April 4, 2023. <https://www.ama-assn.org/system/files/principles-with-signatory-page-for-slsc.pdf>

⁴ O'Neil A, Calderbank S, Brown J, et al. Quantification of Utilization Management Barriers for Patients Initiating Therapy to Lower Lipid Levels. *JAMA Netw Open*. 2022;5(11):e2240513. Accessed April 4, 2023. doi:10.1001/jamanetworkopen.2022.40513

⁵ US Congress. House of Representatives. Utilization Management: Barriers to Care and Burdens on Small Medical Practices. 116th Cong, 1st sess. September 11, 2019. Accessed April 4, 2023. <https://www.govinfo.gov/app/details/CHRG-116hhrg37560/CHRG-116hhrg37560>

To that end, MAPRx supports the following points as it relates to the initial guidance:

- Highlighting the need for patient input to effectively maintain oversight and explore necessary program changes in order to ensure the program has the intended effect of increasing access and affordability for patients
- Exploring the removal of the exclusion of orphan drugs from qualifying single-source drugs as this could adversely affect investments in rare disease, especially since patients will suffer the most from such decisions
- Establishing a meaningful feedback process for 1) patients and other stakeholders to provide consistent feedback on the experience of IPAY 2026, and 2) CMS to evaluate policy decisions made for the initial year of negotiation and incorporate necessary changes quickly for future years
- Investigating the unintended consequence of reviewing evidence about therapeutic alternatives for a selected drug may have on future access, especially as manufacturers may opt against focusing on innovations for certain population groups or exploring additional indications to determine if their products have further benefits
- Ensuring clear, accessible, and transparent communication regarding the explanation for the MFP, especially including critical information about what data was used to develop the MFP and how it was specifically used
- Exploring the future operation of the MDPNP by specifically respectfully requesting further information on how the 2026 negotiation process will inform Part B negotiations in future years
- Reconsidering Section 30 of the guidance as we are concerned about the effects that the aggregation of drugs with the same active moiety or active ingredient in the selection process could have on subsequent research, specifically that the aggregation could disincentivize research into additional indications or potential reformulations that improve patient adherence and/or outcomes

Conclusion

We appreciate the opportunity to provide our perspective as a coalition of patient-focused organizations on key features, such as the meaningful differences policy, of the impending Part D benefit redesign. We strongly support building beneficiary protections into the smoothing benefit and that utilization management of covered negotiated drugs does not adversely deter patient access to critical therapies. Additionally, regarding the negotiation program, we strongly uphold that decisions on value are best taken when patient organizations can engage in the process and when patients are not limited by coverage policies that restrict access to products that best meet their individual needs. Thus, we urge CMS to facilitate patient voices being heard and emphasized throughout the negotiation process.

Thank you for your consideration of comments on the meaningful differences policy, defined cost-sharing thresholds, tiering models, and broader Part D benefit concerns. The undersigned members of MAPRx appreciate your leadership to improve beneficiaries' access to products in Medicare Part D. For questions related to MAPRx or the above comments, please contact Bonnie Hogue Duffy, Convener, MAPRx Coalition, at (202) 540-1070 or bduffy@nvgllc.com.

Allergy & Asthma Network
Alliance for Aging Research

Alliance for Patient Access
ALS Association
American Kidney Fund
American Society of Consultant Pharmacists (ASCP)
Arthritis Foundation
Autoimmune Association
Color of Crohn's and Chronic Illness
Derma Care Access Network
Epilepsy Foundation
GO2 for Lung Cancer
HealthyWomen
HIV+Hepatitis Policy Institute
International Foundation for Autoimmune & Autoinflammatory Arthritis
LUNGevery Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Muscular Dystrophy Association
National Health Council
National Kidney Foundation
Partnership to Advance Cardiovascular Health
The AIDS Institute
The Headache and Migraine Policy Forum
The Leukemia & Lymphoma Society
Triage Cancer