



Mehmet Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 212441

June 26, 2025

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028

Submitted via IRAREbateandNegotiation@cms.hhs.gov Medicare Drug Price Negotiation Program Draft Guidance

Dear Dr. Oz,

The MAPRx Coalition (MAPRx) appreciates the opportunity to provide the Centers for Medicare & Medicaid Services (CMS) with comments regarding the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028.

MAPRx is a national coalition of more than 60 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 coalition has championed policies in Part D that improve the affordability of medications and beneficiary access to those medications, including provisions of the Inflation Reduction Act (IRA) that establish an out-of-pocket cap in Part D and the Medicare Prescription Payment Plan. We are committed to ensuring that the implementation of these and other elements of the IRA, such as the Medicare Drug Price Negotiation Program (MDPNP) is informed by the experiences and needs of beneficiaries living with chronic diseases and conditions.

MAPRx appreciates the opportunity to provide feedback on the Medicare Drug Price Negotiation Program (MDPNP). As detailed in our specific comments below, we advocate for CMS to implement robust, patient-centric processes that:

1. **Inform Negotiation and Value:** Ensure patient perspectives directly inform Medicare negotiation and the understanding of medication value.
2. **Ensure Access and Oversight:** Conduct rigorous oversight to prevent disruptions and guarantee appropriate patient access to necessary medications.
3. **Monitor Program Impact:** Actively monitor and publicly report changes and trends in Part D to allow CMS and all stakeholders to assess the MDPNP's true impact.

Throughout the MDPNP's implementation process, MAPRx has consistently pressed CMS to collect more comprehensive information and data from beneficiaries, caregivers and other stakeholders, including insights into the patient experience of living with conditions treated by CMS' selected drugs or their therapeutic alternatives.

Specific Comments

Part D Formulary Inclusion of Selected Drugs (Sec. 110)

CMS needs to **take transparent steps** to safeguard beneficiary access to essential medicines. This includes both drugs selected for price setting and other drugs within the same therapeutic classes. While the draft guidance reaffirms CMS's intent to monitor plan compliance with formulary requirements, monitoring is not adequate to ensure that there is not a disruption or barrier to accessing critical medications.

Since our 2023 comments on the MDPNP and subsequent feedback on IRA implementation, MAPRx has consistently underscored the urgent need for **beneficiary protections**. These protections are vital to ensure patients maintain access to their prescribed medications, whether they are negotiated or non-negotiated drugs.

We are gravely concerned that the MDPNP, alongside other changes introduced by the IRA, could exacerbate utilization management practices—such as prior authorization and step therapy—and lead to detrimental changes in formularies, tiering, and cost-sharing, ultimately creating insurmountable barriers to care that harms patient outcomes.

While we are pleased that CMS acknowledges these concerns and plans to conduct formulary reviews and monitor Part D plans, the potential for Part D plans to restrict access to medications makes CMS's role in protecting beneficiaries more critical than ever. Therefore, we urge CMS to **establish robust transparent safeguards and conduct continuous, proactive oversight**. This is essential to prevent the negotiation process from yielding unintended consequences that prioritize cost savings over patient care, potentially disadvantaging specific drugs, or entire classes. There is a widespread expectation that Part D plans will increase prior authorization and step therapy, or introduce new access barriers, which can lead to worsened health outcomes, decreased quality of life, and increased overall healthcare costs. A recent report¹ by the USC Schaeffer Center for Health Policy & Economics provides an analysis of increased beneficiary exposure to cost-sharing in 2025.

To genuinely protect beneficiaries, CMS must:

- **Establish and enforce clear guidelines** that limit the excessive and inappropriate use of utilization management practices.
- **Create a continuous monitoring system** that tracks not only changes in policy application but also their measurable impacts on beneficiaries, including cost-sharing, adherence and access.

¹ Trish, Erin, PhD and Blaylock, Barbara, PhD. (2025). Shifting Cost-Sharing Burden to Beneficiaries in Medicare Part D. USC Schaeffer, June. <https://schaeffer.usc.edu/wp-content/uploads/2025/06/2025-06-Cost-Sharing-Burden-Medicare-Part-D.pdf>

- **Develop a structured process** to facilitate meaningful input from beneficiaries and patient organizations on Part D formulary design, cost-sharing, and utilization management.

Patient Engagement in Negotiation Process (Sec. 60.4)

In this draft guidance CMS has unfortunately declined to propose any significant improvements to better incorporate the opinions and lived experiences of key stakeholders. CMS's current attempts to engage patients and providers remain short of meaningful patient engagement standards and fail to provide any transparency into how the collected data is utilized.

We strongly encourage CMS to actively explore and implement diverse methods for obtaining beneficiary input. This should include:

- **Smaller group sessions, roundtable discussions, and focus groups:** These formats enable bidirectional conversations between CMS and participants, enhancing the depth and specificity of collected information relevant to the negotiation process.
- **Post-session information submission:** Allowing participants to submit information after engagement sessions can provide flexibility and accommodate varied preferences.

These varied approaches can also enable CMS to engage more targeted audiences, thereby capturing the heterogeneity of disease populations and the diverse experiences, needs, and preferences of beneficiaries and their caregivers. Crucially, CMS must explore methods to accommodate individuals who face barriers to participating in live sessions, such as employment, school, childcare, privacy concerns, disability, health status, language barriers, or lack of technology access. Options like written or recorded statements, translation services, or other accommodations are vital to ensure truly representative input.

Participants and Selection of Participants: CMS must clearly communicate its process for selecting participants and allow patient organizations and other stakeholders the opportunity to provide input on this selection process. This collaborative approach is vital to ensure participant diversity and genuine representation.

Explanation for the Maximum Fair Price (MFP) (Sec. 60.6.1)

Transparency is critically lacking. The draft guidance reaffirms that CMS will not disclose information on how medicine prices are set until months after they finalize these decisions. Furthermore, CMS has declined to offer any meaningful updates to the MFP explanations, which – if they follow what we saw with the 2026 explanations – do not provide genuine insight into CMS's methodology. MAPRx recommends CMS clearly articulate how it has incorporated and weighed patient and caregiver feedback in the published MFP price explanations.

As noted in our comments on Section 60.4, MAPRx believes it is paramount that CMS communicates how and to what extent information shared by beneficiaries is utilized throughout the negotiation process. This transparency is most crucial when CMS publishes explanations for the MFP. Such disclosure would assure beneficiaries that their input is genuinely meaningful, build trust, and incentivize greater, more diverse, and more representative participation in the program.

Conclusion

MAPRx strongly encourages CMS to forge a robust partnership with patient advocacy organizations to strengthen patient engagement throughout the negotiation process. Patient organizations are uniquely positioned to articulate beneficiary needs, experiences, and preferences, identify

appropriate individuals for patient engagement opportunities, and collect and submit patient-centric data that is not only relevant to a selected drug or therapeutic alternative but also truly representative of a disease population. We commend CMS for its stated willingness to improve how the beneficiary perspective can inform the MDPNP, and we urge concrete action to realize this commitment.

Thank you for your consideration of our comments on draft guidance for the MDPNP for IPAY 2027. MAPRx welcomes opportunities to continue to work with CMS to ensure Medicare beneficiaries have access to quality and affordable care in Part D. For questions related to MAPRx or our comments, please contact Bonnie Hogue Duffy, Convener, MAPRx Coalition, at (202) 540-1070 or bduffy@nvgllc.com.

Sincerely,
The MAPRx Coalition