



June 26, 2025

Chris Klomp
Deputy Administrator and Director
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1859

Re: Medicare Drug Price Negotiation Program Draft Guidance

Dear Director Klomp:

Aimed Alliance is a non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") draft guidance on the implementation of the Medicare Drug Price Negotiation Program for 2026, 2027, and 2028.

To ensure that the experiences of patients, providers, and caregivers appropriately inform the prescription drug negotiation process, Aimed Alliance urges CMS to:

- (1) Implement a clear and continuous consumer engagement process;**
- (2) Ensure CMS is transparent regarding how it weighs and considers patient input in decision-making; and**
- (3) Track and report on the impact of negotiations on consumer prescription drug costs and access.**

A. Implement a Continuous Consumer Engagement Process

To effectively include the perspectives of patients, providers, and caregivers, public engagement must be a continuous process, not a one-time event. Chronic conditions, complex treatments, and access barriers evolve as individuals age and symptoms progress. To reflect these realities, Aimed Alliance urges CMS to create opportunities for ongoing feedback beyond the single-event roundtables and town halls currently provided.

Moreover, during the upcoming open enrollment period, beneficiaries will see for the first time how IRA negotiations have impacted prescription drug formularies, tiering, and cost-sharing requirements. As such, this is an opportune time to establish clear channels to allow consumers to share their concerns regarding any access and affordability barriers that are unintended consequences of the IRA negotiations.

Such communication pathways for consumers could include written public comment periods following engagement events, recurring listening sessions, targeted outreach to patient communities, and regular briefings with patient, caregiver and advocacy groups. By fostering a culture of transparency and responsiveness, CMS can effectively address emerging challenges following the adoption of negotiated drug prices.

B. Ensure Transparency and Clarify the Role of Patient Input



Transparency requires an open and honest disclosure of how consumer feedback will be valued and weighted in CMS decision-making. Transparency is essential to building trust and ensuring that patient engagement provides meaningful and helpful insights to negotiation decision-makers.

Aimed Alliance appreciates CMS's decision to release a redacted transcript of the roundtable discussions. To further demonstrate that participant feedback is genuinely considered, CMS should publish clear, accessible summaries after each roundtable that highlight the key themes, experiences, and perspectives shared. In addition, CMS should clearly articulate how patient input is integrated into its decision-making process. A clear decision-making framework would strengthen transparency, promote confidence in the negotiation process, and affirm that patient experiences are treated as valuable evidence and indicators in the negotiation process.

C. Track and Report the Impact of Negotiation on Patient Access & Affordability

To fully realize the commitment of the IRA to lower costs for Medicare beneficiaries, CMS must not only consider patient input during negotiations but also monitor the real-world consequences of its pricing decisions. Specifically, Aimed Alliance urges CMS to track and publicly report how negotiated prices impact:

- (1) Patient access to therapies, including whether lower prices lead to changes in formulary placement, prior authorization, step therapy requirements, or other utilization management practices that could create new barriers for patients seeking treatment; and
- (2) Out-of-pocket costs to assess how negotiated prices affect the financial burdens on patients.

A post-negotiation monitoring process would allow CMS to identify any unintended consequences caused by the IRA's negotiations and modify the negotiation process as necessary to ensure that future negotiations do not negatively impact patient well-being, access, or affordability. This oversight will be particularly important with Part B prescription drugs becoming eligible for negotiation, as Part B prescription drugs are not subject to the same cost-sharing caps as Part D medications. Thus, consumers' Part B prescription drug costs may be impacted differently than those Part D drugs that are protected by the \$2,000 out-of-pocket cap and the "smoothing" program.

I. Conclusion

In conclusion, Aimed Alliance urges CMS to implement a continuous consumer engagement process; ensure transparency in decision-making; and report on the impact of negotiations on patient access and affordability. We appreciate the opportunity to comment on this issue and commend CMS for its efforts to incorporate patient perspectives during the drug negotiation process. Please contact us at policy@aimedalliance.org if you have any questions or would like to further discuss our concerns.

Sincerely,

Olivia Backhaus
Staff Attorney