EACH PIC COALITION

August 17, 2026

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services

RE: Medicare Drug Price Negotiation Program: Draft Guidance for Initial Price Applicability Year 2029 and Manufacturer Effectuation of the Maximum Fair Price (CMS-4215-P)

Dear Dr. Oz,

On behalf of the patient populations we represent, the undersigned organizations appreciate the opportunity to provide input on the negotiation program and urge CMS to improve patient engagement and transparency into how public input is utilized in the process.

While CMS has made some improvements to the public engagement process in past years, there are still deficiencies that make it difficult for the broader public, but most importantly patients, to meaningfully engage with CMS. Further, there is little if any transparency into how CMS has utilized patient input or if patient input has impacted the decision making of regulators.

Therefore, we respectfully urge CMS to incorporate the enclosed recommendations to ensure that patients are heard by policymakers and that data provided is meaningful to the program.

Continue Refining Patient Roundtables

While we applaud CMS for moving to a roundtable format for patient-focused engagement, there is opportunity to improve the roundtables to better accommodate patients, facilitate better discussion, and gather more relevant data.

We encourage CMS to provide participants with more information prior to the roundtables. Participants in the sessions reported feeling unprepared for specific questions as well as not understanding what data was sought by CMS. We therefore encourage CMS to consider providing selected participants with a plain-language briefing document before each session with sample questions and suggestions on information that participants might want to gather in advance. This would allow participants to prepare thoughtful responses and ensure the limited discussion time is used as effectively as possible.

Additionally, we encourage CMS to allow participants to share information on the value of their medications as well as all the factors that impact their care. CMS appropriately seeks to understand the clinical benefit of selected drugs, but patients often define a medication's value more broadly than clinical outcomes alone. Access to treatment, affordability, continuity of care,

and the ability to remain on a therapy without unnecessary disruptions are integral to patients' experiences and quality of life. Participants frequently felt these topics were outside the intended scope of discussion, despite being inseparable from how patients assess a medication's value. CMS should ensure discussion topics reflect the full real-world experience of living with and managing a chronic condition.

CMS should also ensure reasonable accommodations are consistently available for participants with chronic illnesses and disabilities. Several participants reported that remaining seated for ninety-minute sessions without a break was physically challenging.

Improve Transparency into Public Engagement Events

Because participation in patient roundtables and town halls is limited, CMS plays a significant role in determining which patient, caregiver, provider, and patient organization perspectives become part of the official record. However, little information is provided regarding how participants are selected or the qualifications CMS is seeking. This lack of transparency makes it difficult for applicants to understand whether they are well-suited for a particular engagement opportunity and may discourage participation by individuals who could provide valuable insights.

If participant selection is based on factors such as lived experience, therapeutic history, clinical expertise, or other criteria, CMS should clearly communicate those expectations before applications open. Providing transparent selection criteria would help applicants better assess whether they are appropriate candidates, enable patient organizations to recruit individuals who meet CMS's needs, and ensure the agency receives the most relevant perspectives for each discussion. If the intent is instead to hear from the broadest possible range of experiences, CMS should consider expanding participation opportunities so that fewer qualified applicants are excluded from the process.

Strengthen the Written Comment Process

While CMS has continued to refine opportunities for written public input, the current submission process remains unnecessarily complex and difficult to navigate. CMS should continue evaluating the written submission process with the goal of making it more intuitive, efficient, and easier to navigate for all participants.

Individual patients should not be expected to navigate the same submission process as manufacturers, trade associations, or other stakeholders accustomed to participating in federal rulemakings. If CMS's goal is to hear directly from patients and caregivers, it should establish a separate patient-focused submission pathway designed specifically for those audiences. This process should use plain language, clear instructions, straightforward navigation, and questions tailored to patient experiences, reducing unnecessary barriers and making it as simple as possible for patients to share meaningful input.

The current submission process also fails to recognize the distinct role of patient organizations. Many questions are written from the perspective of an individual patient's personal experience, making them difficult for organizations to answer on behalf of the broader patient communities they represent. CMS should develop a separate submission pathway with questions tailored to patient organizations, allowing them to provide the broader evidence they collect through surveys, advisory boards, research, and ongoing patient engagement.

CMS should also permit patient organizations to submit narrative letters or reports in lieu of standardized online text fields and work with patient organizations and Patient Research Partners to develop future submission forms. Their expertise in patient-centered research and question design can help ensure CMS collects more meaningful, actionable patient-reported evidence while making the submission process clearer and more effective.

We also recommend that CMS adjust the written comment period so that it occurs after the patient roundtables and town halls have concluded. This would allow participants to respond to issues raised during the discussions, clarify testimony where appropriate, and provide additional context that may not have been captured during the limited time available for oral comments. It would also ensure that individuals who applied but were not selected to participate still have a meaningful opportunity to contribute to the record. Establishing the written comment period as the final step in the public engagement process would result in a more complete and informed record for CMS's consideration.

Close the Feedback Loop Between Patient Engagement and Decision-Making

Each year, patients, caregivers, providers, and patient organizations invest significant time preparing written submissions, completing applications, participating in roundtables and town halls, and sharing deeply personal experiences about living with serious and chronic diseases. Yet once these activities conclude, participants receive virtually no information regarding what CMS learned from these discussions or how patient experiences informed the negotiation process. Beyond publication of a redacted transcript, there is no explanation of the themes CMS identified, how patient perspectives influenced negotiations, whether recommendations were incorporated, or why certain recommendations were ultimately not adopted.

This lack of transparency risks undermining confidence in the engagement process itself. Participants should not be expected to repeatedly dedicate substantial time and effort without any indication that their experiences meaningfully contribute to agency decision-making. If CMS cannot demonstrate the value of participation, patients, caregivers, providers, and patient organizations may understandably begin to disengage from the process altogether.

To address this gap, CMS should publish a Patient Engagement Summary following each negotiation cycle that identifies the major themes raised during public engagement, explains how those perspectives informed the agency's deliberations, and describes where patient recommendations influenced the negotiation process. Closing this feedback loop would

demonstrate that participation has meaningful value and strengthen confidence in future engagement opportunities.

Leverage Existing Patient Research

Finally, CMS should recognize that patient organizations have already developed robust methods for collecting meaningful patient-reported evidence related to prescription drug affordability, access, and treatment experiences. Rather than developing engagement tools independently, CMS should collaborate with patient organizations and patient research partners experienced in patient-centered research to improve question design, identify meaningful endpoints, and strengthen the collection and interpretation of patient-reported evidence.

Thank you for the opportunity to provide these comments. We appreciate CMS's continued willingness to engage patients and patient organizations throughout implementation of the Medicare Drug Price Negotiation Program and look forward to working collaboratively to strengthen patient engagement as the program continues to evolve.

Sincerely,
EACH/PIC Coalition
AiArthritis Foundation
Aimed Alliance
American Behcet's Disease Association (ABDA)
Biomarker Collaborative
Chronic Care Policy Alliance
Coalition of Skin Diseases
Crohn's & Colitis Foundation
Exon 20 Group
Global Airways and Allergies Patient Platform
ICAN, International Cancer Advocacy Network
International Association of Hepatitis Task Forces
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
MET Crusaders
National Infusion Center Association
Neuropathy Action Foundation (NAF)
Nevada Chronic Care Collaborative
NRG1 Energizers
Partnership to Improve Patient Care
Patients Rising
PDL1 Amplifieds
Spondylitis Association of America
The AIP BIPOC Network