



June 26, 2025

Chris Klomp, MBA
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services

RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair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

Dear Deputy Administrator Klomp,

On behalf of the patient populations we represent, the undersigned organizations applaud CMS for continuing to seek input on how best to engage and protect patients through the negotiation process.

While the EACH/PIC Coalition appreciates efforts by CMS to improve patient engagement in the 2027 negotiation process, we continue to urge ongoing outreach and adjustments to ensure that patients are meaningfully engaged and their feedback is fully considered. We respectfully encourage CMS to incorporate the enclosed recommendations to ensure patients are heard by policymakers, the data collected is meaningful to the process, and access to medications is not compromised.

Better Utilize Patient Input

Patients and patient organizations who participated in the roundtables and town halls are appreciative for the opportunity to ensure our voices were counted. However, as we enter into the third round of negotiations, we continue to be discouraged by the lack of transparency regarding how patient input impacts CMS decision making. It is still completely unclear how or if CMS utilizes information provided by patient voices. Given that patients are the ultimate consumers and their health could be directly impacted, their testimony and input should be utilized as a key factor in how negotiation is implemented.

Further, CMS must heed patient concerns and monitor for adverse impact in the years following negotiation. Outreach to patients so far has only been conducted in advance of negotiation implementation, and CMS has given no indication that it will provide patients any opportunity to report adverse effects or conduct any patient focused outreach sessions after negotiated prices take effect.

Continue to Improve Patient Engagement

We were encouraged this year that CMS adopted a roundtable format for patient engagement. These events provided more opportunity for patient and patient organization participation and enabled participants to provide substantive input, rather than short statements. We also appreciated the decision to hold the roundtable sessions privately, which allowed patients a more comfortable environment for sharing personal stories and disclosing sensitive health information.



While the roundtable format was an improvement, it also had limitations that could be improved upon.

- **The number of patients that could engage was limited.** We encourage CMS to continue improving opportunity by holding multiple roundtables for each selected drug to ensure all patients and patient organizations are provided an opportunity to be heard.
- **Participants should be required to have reasonable knowledge of the drug under review and the diseases treated by it.** While an improvement from last year, some roundtables included participants who had little to no knowledge of the drug or diseases impacted by its use. While their comments were valuable regarding broader processes, it also took away time from patients and organizations who had more to contribute. We encourage CMS to screen for this knowledge in the application process and only select participants who confirm their knowledge of or lived experience with the drug and diseases it treats.
- **Encourage use of the chat feature as a secondary mode of communication.** While we appreciate dedicated 90-minute sessions to communicate with CMS, some participants still felt there was not enough time for everyone to have an opportunity to answer questions. However, some reported the use of the chat to share their perspectives was a good alternative, particularly because there was a chat moderator dedicated to the conversation. We recommend clearly stating at the beginning of the session that the chat could be used to provide additional responses if time did not allow for participation.
- **The times for the sessions should be varied to allow those with less flexible schedules to participate.** We understand these sessions are scheduled during CMS working hours, however, this can be difficult for people who have other daytime responsibilities to commit.

Simplify The Application Process

The process to apply for the sessions was once again complicated and cumbersome. Several participants expressed concern upon reading they were required to disclose their home addresses. First, many questioned, “Is CMS coming to my house?” While we assured them they are not, this likely deterred others from participating. Given this information is not related to the sessions in any way, CMS should revise their standard forms and tailor them to these events and a patient audience.

Implement Patient Protections Against Increased Utilization Management

Many of the changes to Medicare that are currently being implemented, including but not limited to negotiation, could lead to plans to implement more utilization management provisions that could limit patient access to medications. We encourage CMS to proactively implement patient protections against harmful and abusive practices, rather than wait for plans to act against patient interests before stepping in.

In the interest of patients, we also encourage CMS to create a dedicated portal and/or methodology for patients to provide immediate and direct feedback to CMS on any detrimental policies they experience. CMS should publicize the existence and importance of feedback directly to Medicare beneficiaries, as well as senior advocates, including area agencies on aging and other servicers. Finally, we encourage CMS to start holding listening sessions and



roundtables with patients *following* implementation to ensure patients taking the selected drugs have the opportunity to provide direct feedback to regulators on how negotiation has impacted their access, costs, and care.

Ensure Physician Reimbursement Rates Do Not Impede Patient Access

Under IPAY 2028, drugs covered under Part B will be subject to negotiation for the first time, and we encourage CMS to carefully consider how provider reimbursement rates could impact patient access. Physician reimbursement rates are already being squeezed. If these rates are lowered further due to negotiation, opportunities for treatment costs to be recouped by providers will also decrease. As a result, physicians could be forced to adjust treatment recommendations to avoid facing financial deficits, leaving patients with fewer treatment options.

The majority of patients who rely on Part B medications are those with chronic conditions, which are incredibly complex to treat. Each patient faces a unique experience and should be able to work with their doctor to identify the treatment that works best for them.

Substituting or requiring patients to change drugs based on cost considerations instead of medical needs can disrupt the continuity of care and result in complications and higher overall medical costs. Therefore, we encourage CMS to take great care in establishing physician reimbursement rates under the negotiation program to ensure they are made financially whole and patient access is not compromised.

We greatly appreciate efforts by CMS to ensure patients and their advocates are heard and look forward to engaging on these and other issues as the negotiation program progresses. If you have any questions, please reach out to Tiffany Westrich-Robertson at tiffany@aiarthritis.org.

Sincerely,

Ensuring Access through Collaborative Health/Patient Inclusion Council (EACH/PIC Coalition)
Advocates for Compassionate Therapy Now

AiArthritis

Alliance for Patient Access

Autoimmune Association

Biomarker Collaborative

Caring Ambassadors Program

Chronic Care Policy Alliance

Community Liver Alliance

Cystic Fibrosis United

Exon 20 Group

GLOBAL ALLERGY & AIRWAYS PATIENT PLATFORM

ICAN, International Cancer Advocacy Network

Infusion Access Foundation

MET Crusaders

National Infusion Center Association

National Scleroderma Foundation

Nevada Chronic Care Collaborative

Partnership to Improve Patient Care

PDL1 Amplifieds





Spondylitis Association of America
The AIP BIPOC Network

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