



ENSURING ACCESS THROUGH COLLABORATIVE HEALTH

July 2, 2024

Meena Seshamani, M.D., Ph.D.
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RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Dear Dr. Seshamani,

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 we were pleased that patient listening sessions were added as a component of the negotiations, there is much room for improvement to ensure that substantive feedback from patients is obtained. We appreciate CMS is willing to listen to our suggestions and make adjustments as the program evolves. Therefore, 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 due to increased utilization management.

Listening Session Feedback

Patients and patient organizations who participated in the listening sessions are appreciative for the opportunity to ensure our voices were counted. However, it is still unclear, even after the fact, what CMS sought to accomplish through the initial round of listening sessions and what, if any, information they gleaned or acted upon from the events.

While we understand CMS did not provide clear instructions or parameters for public comments as a way to encourage broad, unscripted participation, the lack of guidance and clear data points left participants feeling unsure if their testimony was useful for the agency. Further, patients were provided last-minute guidance and rules on their comments during some, but not all, of the pre-session conferences, creating discrepancies across sessions and leading to confusion among participants.

Due to the testimonial format imposed by CMS, many of the patients we represent who participated in the listening sessions were left feeling confused as to whether they were heard, as their comments were not acknowledged by regulators and no feedback was provided. Also, inadequate accommodations were available for speakers who might have health hardships or disabilities. Additionally, the sessions themselves necessitated patients share personal stories and information in a very public and national forum. Sessions were held exclusively online and during traditional business hours, prohibiting anyone without a flexible schedule or work situation from participating.

Furthermore, the process to apply and submit requested forms was complicated. The application itself was quite lengthy and not seemingly tailored to a patient or layman audience.



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For example, one form was sent as a PDF file and another as a Word document. Patients who did not have these applications on their computer relied on patient organization staff or family members to assist them. The Word document had formatting issues, so if the person could not figure out how to add information in a different way, it's possible they did not return it. One patient electronically signed the PDF, but was told she was unable to sign in that manner.

Listening Session Guidance

To address these concerns, we suggest that CMS adopt a roundtable format for future listening sessions. This would encourage more patient participation and enable participants to provide substantive input, rather than short statements. Roundtables could also be organized by stakeholder type, to allow for patients to participate only with other patients, to facilitate sharing and discussion.

Additionally, we encourage CMS to vary the times, locations, and formats for the sessions - including the opportunity to submit pre-recorded, virtual comments. This would allow a broader population of citizens to participate, including those with alternative schedules and those who do not have access or comfort with conference technology. CMS should hold in-person sessions in multiple regions of the country to ensure that all communities can be heard. These smaller and less formal formats will likely also increase patient comfort in sharing the personal health experiences that are so important for CMS to hear.

Further, we recommend that CMS issue clear guidance in advance of the roundtables, including topics for discussion and the information being sought by regulators, so that participants can share relevant and focused information. Additionally, we encourage CMS to simplify the application process and provide multiple options for submission, including online forms, to broaden the opportunity for individuals with less technological expertise. This includes providing the opportunity for applicants to disclose any special needs and request any necessary accommodations in advance.

Implement Patient Protections Against Increased Utilization Management

As noted in the guidance, 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 incorporate this topic into future listening sessions to ensure the issue is being monitored and patients have opportunity to provide direct feedback to regulators.



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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 (EACH) Coalition
Advocates for Compassionate Therapy Now
AiArthritis
Aimed Alliance
Alliance for Aging Research
Alliance for Patient Access
Arthritis Foundation
Autoimmune Association
Biomarker Collaborative
California Hepatitis C Task Force
Caring Ambassadors Program
Chronic Care Policy Alliance
Exon 20 Group
HealthHIV
HIV+Hepatitis Policy Institute
ICAN, International Cancer Advocacy Network
Infusion Access Foundation
International Association of Hepatitis Task Forces
MET Crusaders
Multiple Sclerosis Foundation
National Eczema Association
Neuropathy Action Foundation
Partnership to Improve Patient Care
PD-L1 Amplifieds
Rare Access Action Project
Spondylitis Association of America

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