

Amplifying the Patient Voice: Roundtable and Recommendations on CMS Patient Engagement



Setting the Stage

The National Health Council (NHC) held a Roundtable discussion for members of the patient community to chart a course on enhancing opportunities for patient input at the Centers for Medicare and Medicaid Services (CMS). The discussion focused on CMS' 2023 listening sessions during the agency's implementation of the first round of negotiations for the Medicare Drug Price Negotiation Program (MDPNP). The Roundtable identified lessons learned that can be used to inform future listening sessions and CMS' broader patient engagement strategies. The *Inflation Reduction Act of 2022* (IRA) established the MDPNP, whereby manufacturers of CMS-selected drugs negotiate with the government on the price of these drugs in the Medicare Part B and Part D programs.

In October and November 2023, CMS held one listening session for each of the [10 negotiated drugs](#). These sessions, though not required by statute, were the Agency's response to the patient community's request that CMS create a mechanism to hear from people with lived experience with the selected drugs and the conditions they treat. Many of the Roundtable attendees participated in listening sessions or prepared patient advocate speakers. Others did neither but had a strong interest in the sessions and/or are subject matter experts on patient engagement. Many of the participants submitted data through the Agency's Information Collection Request (ICR) either in addition to participating in the listening sessions or in lieu of participating. For a full list of attendees at the Roundtable, see Appendix A.

Experience with the Drug Price Negotiation Program Listening Sessions

All Roundtable participants shared their interest in and engagement with the listening sessions, whether they participated in the 2023 sessions or anticipate engaging in the future. All participants expressed appreciation to CMS for the sessions while recognizing the tight statutory timeline for implementing the first round of negotiations and potential for improvement in future years.

Preparation for the Listening Sessions

The affected patient organizations agreed that once the listening sessions were announced, they began collecting information and recruiting patient advocates, although they had myriad approaches. One advocacy organization hosted a webinar to walk through the format of the sessions and the discussion questions that CMS proposed.¹ Another organization surveyed about 1,000 patients to gather data for use in the sessions. Yet another organization sent a survey of the CMS questions to their highly engaged patient population. Many organizations put together patient testimony based on the advocates' stories and CMS' discussion topics. When asked if anyone knew of patient advocates who participated in the sessions independently, no one did, leading to the conclusion that patient organizations were indeed a critical partner to CMS in identifying participants.

¹ The questions CMS posed can be found on the MDPNP patient-focused listening sessions webpage.

Experience at the Listening Sessions

Roundtable attendees had a similar logistical experience with the listening sessions. The sessions were all virtual, and the organizations and speakers were brought into a waiting room when they signed on. CMS kicked off the session with brief remarks and introduced each speaker, which was the extent of its engagement. No CMS representatives were on camera. Each speaker was called to make a statement, and CMS presented disclosures for each speaker. Speakers had a maximum of three minutes to present, but there was no time-keeping mechanism available on screen. Additionally, the organizations reported that it was unclear how the speaker order was determined, and the speakers indicated that they did not know how CMS selected those to speak and if more speakers registered than the time allowed.² Roundtable attendees also agreed that the schedule allowed for no time flexibility, such as prerecording remarks if a patient was not available at the specific time allotted, even though the sessions were designed with no interaction among participants.

The patient speakers in the sessions all reported differing reactions to the experience. One organization reported a generally positive experience despite a lack of interaction from CMS. Other organizations expressed concern that their patients may have not felt as empowered throughout the process as they could have been, especially due to the experience of speaking about a difficult topic with no one to be seen from CMS as actively “listening” on screen.

In terms of diversity, the organizations agreed that there was some age diversity but no significant racial and ethnic diversity among the speakers. Diversity based on other identities, such as gender, social status, or geographical representation, are unknown. In addition, there was general agreement that there was a lack of accommodation for speakers with a disability, including one with a speech impediment who did not receive any additional time or accommodation. Lastly, while there was live captioning, attendees noted the poor quality.

A final issue Roundtable attendees raised was the apparent lack of acknowledgement by CMS of off-label use. While off-label use and spending were presumably captured in the figures used by CMS during the drug selection process, there is no indication that in their disease designations for drug usage and planning for the listening sessions that CMS captured the off-label use populations. This gap could represent a significant loss in the voice of entire patient populations, with more acute impact in some communities such as rare disease and cancer.

Lingering Questions After the Listening Sessions

The Roundtable participants expressed numerous unknowns after participating in the sessions:

- **Participants felt underprepared.** CMS could have better communicated why it was seeking information from patients and what endpoints it was assessing. Organizations emphasized that the lack of understanding of the intended use of their information made it more difficult for patients to meaningfully participate, particularly in crafting testimony to meet CMS’ needs.

² CMS indicated the selection would be random, though the process remains unclear.

- **It was not clear who could speak at the sessions.** Most organizations did not realize — until talking with others — that they could widely cast their net when choosing speakers (e.g., organization staff members, caregivers, or health care professionals).
- **The disclosure process may negatively impacted participation.** The purpose of disclosing conflicts of interest and the types of conflicts needed to be reported was unclear. There was frustration that stipends from patient organizations were listed in the same vein as funding from pharmaceutical companies, which was perceived by many as perpetuating unfair stereotypes about all patient organizations. While government employees and many professional advocates are accustomed to reporting conflicts, members of the public are likely not. It is possible some participants who declined to report conflicts were not clear on which conflicts should be reported, and the reporting requirements may have dissuaded some from participating. It was also not clear to potential participants whether and how their disclosed conflicts would be communicated during the sessions.

Experience with Submitting the Information Collection Request

In addition to participating in the listening sessions, CMS allowed for a written data submission per an ICR. The patient organizations agreed that the information requested in the ICR could be confusing and onerous, especially for smaller organizations and individuals. Some felt using the term “data” and other technical language made CMS appear disinterested in qualitative information about the patient experience. This was further underscored by the feeling that submissions would not be valued without substantial footnoted resources. Some of the organizations wrote separate letters to CMS to provide their perspective on the negotiated drugs to indicate how the ICR was not user-friendly for the patient community.

CMS Discussion

Kristi Martin (Senior Advisor, Center for Medicare, CMS)

Kristi Martin, Senior Advisor, Center for Medicare, has been heavily involved in the implementation of the MDPNP and the listening sessions. She opened her remarks emphasizing the importance of open dialogue and transparency when implementing complex programs such as the MDPNP. She also stressed that CMS guidance on the listening sessions applied only to the first negotiation cycle, recognizing that CMS is continuing to learn and adjust as the program matures. Martin shared that CMS made an early decision to get patient input on how a drug impacts a patient population, especially after hearing from patient organizations about the need for direct patient engagement. In that light, she encouraged patient organizations to continue the dialogue and invite CMS to participate in patient community events.

Martin recognized that a significant challenge in implementing the listening sessions was CMS’ need to comply with the privacy provisions of the *Health Insurance Portability and Accountability Act* (HIPAA), because they are a payor. This contrasts with the Food and Drug Administration (FDA), which does not have the same requirements. This is why CMS required HIPAA release forms and explains why CMS transcripts of the listening sessions were redacted before release.

During the Q&A session, several questions resulted in valuable clarifications, including:

- CMS cannot legally speak to how specific information from the listening sessions is being incorporated into its decision-making process for the negotiations at this time. More generally, Martin said that CMS views the sessions as an opportunity to share input relevant to how selected drugs affect special populations, address unmet medical needs, and add context to clinical and other data being considered in the negotiation. This information collection falls under Section 1194(e)(2) of the IRA, which mandates CMS consider input on therapeutic alternative(s) to the selected drugs, how the selected drugs address unmet medical need, and the impact of selected drugs on specific populations.
- CMS was broad in its interpretation of who could speak at the listening sessions. Martin stated that they were open to the public, including hearing from current and former users of the drug, caregivers, providers, and disease-specific organizations.
- CMS chose not to actively participate in the listening sessions because the negotiations had already started, limiting its ability to speak on the chosen drugs.

Recommendations for Short- and Long-Term Program Improvements

The Roundtable attendees shared recommendations as CMS develops the next listening sessions for the MDPNP and its patient engagement processes more generally.

Short-Term Improvements: The Next Round of Listening Sessions

Clarity and Communication about Intent of Sessions

- **CMS should clarify what information it seeks from the speakers.** Patient organizations request structured guidance about what qualitative and quantitative information CMS needs to aid its price negotiation decisions and how such information will be used in determining their initial offer and/or the final maximum fair price (MFP). Knowing what decisions such questions will drive is important for qualitative research legitimacy and for respecting the patient population as they share their vulnerable stories. Additionally, transparent information about the type of information CMS wants will help patients prepare their testimony.
- **Report on how the patient engagement information and qualitative data was incorporated into negotiations.** At the end of a negotiation cycle, CMS should report, in the aggregate, on how the information gathered specifically from the listening sessions and the qualitative data it received was used to determine the MFP.
- **Host an educational webinar in advance of the listening sessions.** CMS should educate patient groups, patients, and other relevant stakeholders on how the session will be structured and what the agency is looking for in the sessions. Patient organizations need clarity from CMS in advance.

- **Market as stakeholder listening sessions.** CMS should clarify that its outreach includes all members of a disease community, including patients who are currently or were formerly on the medication, caregivers, and practitioners.

Structure of the Sessions

- **Enhance dialogue-based engagement.** CMS should hold listening sessions with smaller groups of patients, with opportunities for dialogue. There is a need for greater collaboration between patients and CMS, but CMS should also properly prepare advocacy groups and patients for what will be asked of them during such a session. CMS could consider having patient organizations and patient speakers work together to tell their testimony through an interview-style format.
- **Clarify the required disclosures.** Currently, the CMS introduction stated whether the speaker disclosed a conflict, they “refuse to disclose” or “have no conflicts.” And for those who did disclose conflicts, there was no description of the nature of such conflict. The disclosure piece should be presented in a less direct manner, and CMS should include how such a disclosure or nondisclosure affects (or does not affect) the patient testimony and why the disclosure is needed. Additionally, greater guidance on what constitutes a true conflict that should be reported during registration.
- **Give patients/speakers the ability to waive HIPAA requirements,** if legally permissible.
- **Clarify how CMS will select speakers.** CMS should be transparent about its strategy in selecting speakers if more than 20 people sign up. Additionally, CMS should streamline internal processes to ensure that speaker slots are not all full before the registration deadline. We also urge CMS to prioritize diversity in their selection process (see below for more on enhancing diversity).
- **Allow for data submissions after the listening sessions.** For this round of the MDPNP, ICR submissions were due before the listening sessions began. CMS should allow for limited written supplements to speakers’ remarks, through the ICR, for a short period after the sessions. Additionally, the perspective shared by participants of the listening sessions may spur additional thoughts from individuals or organizations for their data submission.

Increasing Engagement

- **Increase ways for patients and other relevant stakeholders to engage.** Some patients lack confidence or ability to speak clearly in a public setting or to a government entity, and others fear publicly speaking about their condition for concern about discrimination by employers or others. Many people lack stable and affordable broadband internet. Others may have work or personal responsibilities that do not allow them to participate at a predetermined time. Because of these factors, there should be additional mechanisms for speakers to submit their testimonies, such as written statements or recordings. CMS should also provide more advance notice of listening sessions. Four weeks of notice was too short — and required significant resources — for some patient organizations to identify relevant patients and/or conduct surveys to bring quantitative data to CMS.

- **Enhance efforts to engage speakers from diverse backgrounds.** Recommendations included working with the Office of Minority Health or other offices that specialize in reaching communities of color and other marginalized communities, as well as reaching out to minority-led patient advocacy groups. It was suggested that opportunities for non-English speakers should exist. It was also suggested that CMS increase outreach to better target the disease populations with drugs selected for negotiation. These efforts should engage disease states that use relevant drugs off-label. Additionally, call-in or other options that do not require broadband may help increase diversity.
- **Partner with patient organizations to monitor program impact, especially on access to treatments.** CMS must ensure throughout the implementation of the IRA that patients' access to drugs is not impeded. It is likely changes to the Medicare benefit in the IRA will lead to new incentives that can potentially present challenges to patients. CMS should present data to patient organizations on trends it is observing regarding the impact of the MDPNP, and the redesign of the Part D benefit, on the health care system. Patient advocacy groups can then use this data to educate patients and better prepare them to speak on issues like the program's impact on out-of-pocket costs, access to care, and increased use of utilization management by insurers. CMS should also create a process for patients and patient organizations to submit data or even flag individual instances where new access challenges occur.
- **Record the listening sessions.** This would allow stakeholders that would like to hear the testimony in full to do so even if they are not able to get out of other responsibilities during the daytime. However, we do note this will require approval from presenters.

Improving the Speaker Experience

- **Provide accommodations.** Accommodations are needed for patients with disabilities (e.g., speakers that are blind, hard of hearing, have communication disabilities, or have significant fatigue) and for non-native English speakers.
- **Allow speakers more time and include a timer.** At least five minutes would allow for more thorough testimonies. Also, a timer should be added to the Zoom screen to allow speakers to manage the pacing of their comments.
- **Show CMS representatives on the Zoom screen.** Even if CMS staff cannot converse during the sessions, having their cameras on may help make speakers feel more comfortable and add to the sense that they are engaging with other humans. Speakers need an audience of some sort when commenting.

Long-Term Improvements: The Vision in Five Years

- **Establish a research methodology for patient engagement.** CMS must develop a methodology for incorporating qualitative patient experience data into its program implementation, including, but not limited to, establishing the MFP in the MDPNP. The methodology should be designed with feedback from the patient community.

- **Include the patient perspective at every step of decision-making processes, including negotiations.** When implementing new and existing policies, CMS should establish multiple touchpoints with patient advocacy groups throughout the year. For the MDPNP, CMS should engage patients beyond the first initial offer and should incorporate the patient experience at some level in the negotiations with manufacturers. This can be done through transitioning listening sessions from a one-per-drug model to multiple convenings of one disease area.
- **Increase accessibility to CMS for patients.** It is often difficult to communicate with executive branch agencies given their bureaucracy and the institutional knowledge needed to communicate in an impactful manner. While established patient organizations have contacts at CMS and appreciate their willingness to discuss important topics, the process for initiating a dialogue on all issues of importance to patients should be streamlined, including creating an ombudsman or a clearly identified point of contact.

Other Suggestions

- **Partner with the patient community.** CMS should work with patient advocacy groups and stakeholders through a formalized process to help shape patient engagement, including questions asked of patients, in what format, and how to ensure diversity and representativeness of patients. Format, topics, and representativeness may be different for different disease areas, so CMS should partner with disease-specific organizations to shape input requests. In turn, CMS can communicate what information it seeks, and patient organizations can help CMS get answers.
- **Support and oversight from Congress.** Congress should provide support, funding, and oversight to CMS to carry out their engagement activities. Ideally, they should codify processes to incorporate the patient voice in the MDPNP and other CMS activities.
- **Part B incorporation into the MDPNP.** Part B drugs will be selected for inclusion in the MDPNP in 2026 (with MFPs going into effect in 2028), which will implicate additional stakeholders and insert new layers of complexity in the negotiation process. Because of this, it is critical that CMS begin engaging with patient communities, clinicians, hospitals, and other relevant stakeholders.

Conclusion

The NHC's Roundtable on CMS patient engagement and the MDPNP listening sessions produced actionable recommendations for CMS as it continues to refine its patient engagement strategy. The recommendations focus on the importance of transparency, open communication, and accessibility in patient engagement efforts, while ensuring patient diversity and representativeness. Despite the recognized need for improvement, all Roundtable attendees acknowledged and appreciated CMS' inclusion of the patient voice in the MDPNP and look forward to increased collaboration in the coming months and years.

Appendix A

The organizations that participated in the Roundtable were:

- Alliance for Aging Research
- American Cancer Society - Cancer Action Network
- Arthritis Foundation
- Asthma and Allergy Foundation of America
- AstraZeneca
- Centers for Medicare and Medicaid Services (CMS)
- CLL Society
- Epilepsy Foundation
- EveryLife Foundation for Rare Diseases
- Gilead Sciences
- GO2 for Lung Cancer/GO2 Foundation for Lung Cancer
- International Foundation for Autoimmune & Autoinflammatory Arthritis
- Lupus Foundation of America
- National Multiple Sclerosis Society
- National Organization for Rare Disorders
- National Psoriasis Foundation
- Neurocrine Biosciences
- Novo Nordisk
- Pfizer
- PhRMA
- Prevent Blindness
- StopAfib.org
- Susan G. Komen