NATIONAL HEALTH COUNCIL

Amplifying the Patient Voice:

Reflections and Recommendations from the Second Cycle of CMS Patient Engagement

August 2025

Introduction

The National Health Council (NHC) held a roundtable discussion on June 30, 2025, with members of the patient advocacy community to reflect on and enhance opportunities for patient input at the Centers for Medicare and Medicaid Services (CMS). The discussion specifically focused on CMS' patient engagement activities during the second cycle of the Medicare Drug Price Negotiation Program (MDPNP), undertaken in April 2025. Established by the Inflation Reduction Act of 2022 (IRA), MDPNP allows for negotiation between the government and manufacturers on the pricing of CMS-selected drugs for Medicare Part B and D. The number of drugs selected for negotiation increases annually; in this second cycle, 15 drugs were selected, up from 10 in 2024.

As part of this MDPNP cycle, CMS held 15 patient roundtables—one for each selected drug—which were a new format from the previous cycle. CMS also convened a town hall session for clinicians for the first time. In addition, as in previous years, CMS sought public input through an Information Collection Request (ICR). Participants of the NHC roundtable included patient groups who took part in one or more of these activities for this cycle, and some who also provided input in the previous cycle. Those that experienced both cycles reported improvements in ease of participation and interaction with CMS.

Building on insights gathered during a similar NHC roundtable following the first cycle of negotiations and captured in Amplifying the Patient Voice: Roundtable and Recommendations on CMS Patient Engagement, this discussion identified new lessons learned and actionable recommendations to strengthen CMS' future patient engagement strategies. Patient groups continue to be grateful for the opportunity to provide input into the MDPNP, especially as it is not required by law, and look forward to continuing engagement with CMS.

Changes in Process from Cycle 1 to Cycle 2

Session Format

In the first cycle, CMS hosted 10 patient-focused listening sessions for each of the 10 selected drugs selected in that cycle. These virtual sessions included an introduction of the purpose of the meeting from CMS staff, followed by statements from each patient without an interactive component. As the NHC previously reported, participants in these sessions appreciated the opportunity to provide input to CMS, but felt underprepared, unsure of who could speak at the sessions, and confused around the disclosure of conflicts of interest.

In guidance for the second cycle, CMS acknowledged the NHC's report (see pg. 112) and indicated plans to make adjustments to the process in response to the report and the comments made on the draft guidance. These changes included creating discussion-based roundtables instead of listen-only sessions. According to CMS, these patient-focused roundtables were designed for patients, patient advocacy organizations, and caregivers to share input on patients' experiences with the selected drugs, conditions and diseases, and other medications to treat those diseases.

While the first round of listening sessions was live-streamed and open to the public, the roundtables were only open to participants. In both instances, participants appreciated having a virtual option. No attendees said that they would have preferred an in-person meeting. In response to comments on the first cycle, CMS also hired a contractor to facilitate the roundtable discussions and had CMS staff introduce themselves with their titles.

In the second cycle, CMS also added a separate town hall component, designed for clinicians and researchers to share input on clinicians' experience with prescribing and/or managing treatment and the clinician considerations that drive treatment choice between the selected drug and therapeutic alternatives.

Participant Selection

In the first round, CMS randomly selected patients to participate in listening sessions. In the second round, CMS stated it would use an "intentional process" to select speakers in response to comments that called for a more diverse set of patient experiences.

ICR Submission

In both cycles, all members of the public had the opportunity to submit written comments via the Negotiation Data Elements and Drug Price Negotiation ICR. The same ICR is used by manufacturers and patients to provide input on each drug, prompting changes before the second cycle, based on comments that highlighted the difficulty patients had with navigating the form.

Reactions to the Second Cycle

Improvements

Compared to the previous round, groups reported that it was easier for patients to participate. They mentioned that the meetings ran smoother and the roundtable format was less intimidating for the patient participants than last year. They also were pleased to report more interaction and back-and-forth discussion than in the previous cycle, a change CMS indicated in the guidance for this cycle.

Groups appreciated the work that CMS has done to develop meeting formats specific to different types of participants, with roundtables for patients and a town hall for clinicians and researchers. Varied avenues for sharing input and information made it easier for each group to participate.

Lingering Concerns

Despite these improvements, participants continued to report a lack of clarity of the public engagement process, even when information is available from CMS.

Participants still wanted a clearer understanding of who they were speaking to and what their role was in CMS when interacting with CMS representatives during the sessions. One group stated that it felt like "speaking into the void" when CMS staff were off camera.

While CMS stated in its guidance that it would use an "intentional" process to try to include a wider cross section of patients in each discussion, a goal supported by NHC roundtable attendees, participants felt the criteria used in the process was unclear. Some reported that the application process was straightforward, but others said it was difficult to navigate. While participants did not report problems with accessibility, they also could not recall being asked if they needed any accommodation.

On the written ICR, some reported that it was easier to tell which portions applied to patients rather than manufacturers, but others said that the form was still "cumbersome" to navigate. Potential respondents were required to submit an email address to see the questions and determine if they

wanted to respond, making this process different from other ICRs or requests for information (RFIs) that patient advocacy groups frequently interact with. Finally, participants noted that the ICR only provided two weeks for responses, which was too short for many groups who work to connect patients to these input opportunities.

New Issues

Most participants appreciated the differentiation of patient roundtables and the town hall. However, some reported that they were confused by the new meeting names and were unsure which sessions they were allowed to attend.

While the CMS website lays out what information it is seeking in each type of input, participants continue to report that they are not sure how information will be used. Patient participants also felt that they were not qualified to compare therapeutic alternatives, one of the elements that CMS asked for. Some participants also asked that CMS allow patients who are experiencing indirect access issues, like utilization of management changes, to express those barriers, even if they are outside the official meeting parameters.

As the number of drugs being negotiated has increased, participants reported that grouping roundtables by drug may no longer be the most efficient. In this round, CMS held one patient-focused roundtable for each drug, with one exception for Ozempic, Rybelsus, and Wegovy, which were covered in one roundtable. However, attendees felt this grouped together patients with very different conditions despite being on the same drug who felt like certain questions didn't apply to them, or that their condition wasn't given full attention.

Finally, some participants were unsure if they were able to use the roundtables to comment on other existing policy proposals being considered by Congress or the White House.

Questions of Impact

Participants discussed that they would like more information on the impact of the sessions. They would like to know how their information was used and wanted more feedback from CMS on how patient stories are used in negotiation, even if in high level or summary form. Participants would also like more specific guidance on what information CMS is seeking. Providing specific questions to patients in advance and feedback on how information was used in the larger negotiation process would both help people provide CMS with relevant information and feel confident in the usefulness of their participation.

Participants also remain curious about the impact of the MDPNP itself. The IRA requires that drugs that have gone through negotiation be on the formulary for all plans and that savings be passed on to beneficiaries. However, some groups are concerned about negative changes in formulary tier placement or increasing utilization management if, as a result of the lower price, pharmacy benefit managers push patients to other, higher priced drugs.

Recommendations

To assist CMS in addressing these concerns for a smoother, more impactful patient engagement process, roundtable participants provided recommendations:

Participation in the Sessions

Clarity on CMS staff participating. CMS staff participating in the call should explain their roles beyond listing their titles and be on camera if possible. Understanding who they are speaking to will help participants feel more comfortable and appreciate that they are being heard.

Flexibility in session times. CMS should allow for flexibility in scheduling sessions that accounts for sickness, personal responsibilities, and work that may prevent participation. Sessions should be available outside of business hours and accommodate people who live outside of the Eastern time zone. Such flexibility will promote attendance from a wider pool of participants offering different perspectives. This is particularly an issue for the clinician town hall, which only had one session, making it difficult for participants who may be attending to patient needs during that time.

Clearly communicate format and expectations in advance. CMS should inform participants ahead of time that the engagement sessions will follow a question-and-answer format and provide the specific questions in advance. Some participants came prepared with written statements and were caught off guard by the interactive format. Additionally, even with guidance available on the CMS website, many patients remained unsure about what type of input CMS was seeking. To support meaningful participation, CMS should clearly and directly communicate the information it is seeking after participants are registered and with enough time for them to prepare.

Clarity on policies and programs being discussed. CMS should make it clear to participants that this is an opportunity for input into the MDPNP, not input on any other policy or proposal.

Separate information collection requests from respondents. If possible, CMS should develop separate ICRs aimed at different audiences. CMS should also provide a list of all the questions without requiring logging into the system, so individuals can decide first if they want to participate.

Continue to work with the FDA. CMS noted in its guidance that it worked with the FDA to learn and build from the Patient-Focused Drug Development process. CMS should continue that collaboration to learn how the FDA has improved its processes.

Impact of the Sessions

Show impact of the input. CMS should, to the extent allowed by law, summarize the information gained in the roundtables and how it impacted the negotiation process.

Use information to prioritize outcomes that meet patient needs. CMS should use information gathered in the roundtables, town hall, and ICR to determine what outcomes matter most to patients, and reward drug companies in the negotiation process that best achieve those outcomes. In the long term, such a policy will push manufacturers to improve their responsiveness to patient preferences.

Share information on price justifications. Participants would benefit from the inclusion of information about how the patient input was incorporated into the outcome of the negotiation for each drug as part of the justifications released at the end of the negotiation. This will encourage continued involvement in future cycles.

Future of the MDPNP

Track long-term outcomes. Participants were eager to know the outcomes of the MDPNP on affordability and access, including price, formulary placement, and utilization management. Congress should call on the Government Accountability Office (GAO) to report on changes in both affordability and access to drugs before and after MDPNP.

Consider changing distribution of sessions. As the number of drugs increases, and more drugs are selected that treat the same conditions, it may make sense for the sessions to be condition-specific instead of drug-specific. This would help CMS focus the sessions on the outcomes that matter most to patients. It would also help avoid sessions about the same drug that include patients experiencing very different conditions with very different answers to questions.

Conclusion

The second cycle of the MDPNP showed meaningful progress in how CMS incorporates patient perspectives. CMS took important steps to make the engagement process more interactive and accessible, and roundtable attendees genuinely appreciated the opportunity to participate, especially since this type of engagement is not required by law.

That said, there is still room to improve. Participants highlighted areas where greater clarity, consistency, and responsiveness would make a real difference, including simplifying ICR submissions and setting clear expectations for patient roundtables to help participants understand how their input influences final decisions.

As CMS looks ahead to future negotiation cycles, continued collaboration with the patient advocacy community will be essential. The feedback and recommendations gathered through the NHC roundtable and included in this report are intended to help strengthen a process that reflects the differences among the Medicare population and centers the outcomes that matter most to patients. The NHC remains committed to supporting CMS in building a more meaningful and effective public engagement process moving forward.

Appendix A

The organizations that participated in the NHC Roundtable and provided input were:

- Alliance for Aging Research
- American College of Rheumatology
- American Diabetes Association
- American Lung Association
- Asthma and Allergy Foundation of America
- Bristol Myers Squibb*
- Chron's and Colitis Foundation
- CLL Society
- Haystack Project
- Huntington's Disease Society of America
- Lupus Foundation of America
- National Psoriasis Foundation
- Neurocrine Biosciences*
- Obesity Action Coalition
- Otsuka*
- Pfizer*
- Susan G. Komen

*Manufacturers were in listen-only mode during the roundtables

Appendix B

Drugs included in the Second Cycle of Negotiations

Drug name	Commonly Treated Conditions	Manufacturer
Austedo®, Austedo XR®	Chorea in Huntington's disease, Tardive dyskinesia	Teva
Breo Ellipta®	Asthma, Chronic obstructive pulmonary disease	GlaxoSmithKline
Calquence®	Chronic lymphocytic leukemia/ small lymphocytic lymphoma, Mantle cell lymphoma	AstraZeneca
Ibrance®	Breast cancer	Pfizer
Janumet®, Janumet XR®	Type 2 diabetes	Merck
Linzess®	Chronic idiopathic constipation, irritable bowel syndrome with constipation	AbbVie
Ofev®	Idiopathic pulmonary fibrosis	Boehringer Ingelheim
Otezla®	Oral ulcers in Behçet's Disease, Plaque psoriasis, Psoriatic arthritis	Amgen
Ozempic®, Rybelsus®, Wegovy®	Type 2 diabetes, Type 2 diabetes and cardiovascular disease, Obesity/overweight and cardiovascular disease	Novo Nordisk
Pomalyst®	Kaposi sarcoma, Multiple myeloma	Bristol Myers Squibb
Tradjenta®	Type 2 diabetes	Boehringer Ingelheim
Trelegy Ellipta®	Asthma, Chronic obstructive pulmonary disease	GlaxoSmithKline
Vraylar®	Bipolar I disorder, Major depressive disorder, Schizophrenia	AbbVie
Xifaxan®	Hepatic encephalopathy, irritable bowel syndrome with diarrhea	Salix Pharmaceuticals
Xtandi®	Prostate cancer	Astellas Pharma