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26 Oct 2023 | **News**

As Medicare Drug Negotiation Patient Sessions Kick Off, Advocates Already Eyeing Improvements

by Sarah Karlin-Smith

Patient advocates see IRA patient listening sessions as an opening to push CMS to have more conversations on access issues in general, but first they want to work on improving the current process.

Patient advocacy groups are excited for Medicare's upcoming listening sessions that will offer patients a chance to provide the Center for Medicare and Medicaid Services insight into the first slate of drugs subject to US government price negotiations while acknowledging that this initial foray into patient engagement with CMS is not ideal and that they are looking for ways to improve the process in the future.

Medicare will kick off 10 days of listening sessions on 30 October. Each 90-minute session will afford 20 speakers three minutes to provide insight on their day-to-day experience with conditions that are treated by the drugs on the negotiation list, along with the drug's impact on them and their experience on access, adherence and affordability compared to alternative treatments. (Also see "*CMS Seeking Patient Comments On Negotiated Drugs Similar To US FDA's PFDD Program*" - Pink Sheet, 29 Aug, 2023.)

Ease Barriers To Participation

One major concern of patient advocates is the amount of time allotted.

Michael Ward, the Alliance for Aging Research's VP of public policy and government relations, said it is difficult to provide meaningful comments in three minutes.

Ward, speaking on 23 October at the BIO Patient & Health Advocacy Summit, also raised concerns about the "barriers to entry" such as people needing to type in an email address before

they could even see what the questions were for the listening sessions.

He also raised concerns about reports that caregivers need a power of attorney designation to share a loved one's story due to privacy concerns. Medicare did not respond by press time to the *Pink Sheet*'s request for more information on this matter.

Ward wants to make sure that CMS realizes that they may need to make improvements to the program so "patients see themselves in the process" and engage more.

CMS extended the amount of time for people to register for the sessions, and Ward knows of organizations that have gotten multiple speaking slots in the randomly assigned process – signs he takes of limited interest in the opportunities.

He doesn't want Medicare's takeaway to be "we had limited interested so we don't need to do this moving forward."

Ward also thought CMS might want to consider whether organizing the sessions around each drug selected for negotiation was ideal or whether doing it by therapeutic area might make more sense next time.

Further he was critical of a written comment opportunity that was due on 2 October related to therapeutic alternatives for the selected negotiated drugs.

The form "felt very complicated, especially if you're looking for input directly from patients," he said with some of the sections calling for technical information and data most patients would not possess. Only after getting through those more technical questions would someone come to the questions more appropriate for patients. He believes this formatting may have deterred patients from commenting.

"It wasn't clear to them that they didn't have to answer every question. It wasn't clear that if they didn't have data on these specific things that CMS is asking about in terms of quantitative data that that their comment was still meaningful, and would have value to the agency," Ward said.

'Be There In Good Faith'

Advocates noted that CMS has been open to hearing from patients in other ways if they didn't get selected for the listening sessions or if they missed the deadline for this form, including setting up direct meetings, said Eric Gascho, VP of policy and government affairs at the National Health Council.

When patients do get their chance to testify, the advocates encouraged them to make the most of

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their minutes by "staying on message" and engaging constructively despite any frustrations with the current process.

"Keep to the point in terms of what these meetings are intended to be, which is to really hear the perspective of folks living with the condition or taking the medicine, not to make it about the constitutionality of the IRA," Gascho said. Nor should, "on the other side, some groups ... say drug companies are evil and all drugs should be free."

"This really needs to be something that they see as a valuable use of their time, not just for negotiation, but I think broadly for the work that they do, and that's going to depend on how folks who interact with them approach it," Gascho said.

"Be there in good faith but figure out how to improve the process in future," Ward said.

Pushing CMS to FDA, NIH Levels of Engagement

Historically CMS has offered fewer opportunities and has less statutory mandates for patient engagement than other federal health agencies like the Food and Drug Administration and the National Institutes of Health, and patient advocates see the IRA sessions as crack in the door that will let them push for further interactions.

"There's a lot more that we can do as a patient community to advocate to CMS to encourage them, how we can do this differently, how can we provide our perspectives to inform not only negotiation, but how we can inform the broader work that CMS is doing ... just as a lot of us are doing on the drug development side, we need to do the same thing when it comes to access," said Patrick Wildman, senior VP of advocacy & government relations for the Lupus foundation of America who also manages the MAPRx Coalition, a group of more than 60 national patient organizations focused on Medicare Part D.

One aspect of the IRA that the advocates feel need more patient attention relates to the Medicare Part D redesign, particularly the implementation of the law's "smoothing" of patient's out-of-pocket costs, which allows people to spread out high copays throughout the course of the year. (Also see "*Medicare Copay 'Smoothing' Plan Shows Nothing Is Simple In Part D*" - Pink Sheet, 10 Sep, 2023.)

"This has turned out to be one of the most complex aspects of the IRA for them to think through and implement," said Ward. Advocates are focusing on pushing for a point-of-sale enrollment into the program at the pharmacy counter, since they fear patients may not otherwise realize they have this option.