

September 12, 2023

Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Drug Negotiation Program, Recommendations for Patient Listening Sessions

Dear Administrator Brooks-LaSure:

As organizations representing patients and people with disabilities, we are writing with regard to the June 30, 2023 guidance from the Centers for Medicare and Medicaid Services (CMS) stating that CMS will be holding “patient-focused listening sessions in Fall 2023 after the October 2, 2023 deadline for patients and other interested parties to share patient-focused input on therapeutic alternatives and other section 1194(e)(2) data regarding selected drugs.” In its guidance, CMS referenced these listening sessions as a resource for understanding unmet medical need, acquiring new information from patients, identifying relevant outcomes from patients and caregivers and related to therapeutic alternatives. We appreciate recent information provided by CMS regarding the patient-focused listening sessions for the selected drug list.

Our recommendations are intended to help CMS ensure that the listening sessions provide meaningful engagement opportunities for patients and people with disabilities. We urge CMS use the listening sessions as an opportunity to get beyond “token” engagement, meaningfully incorporate patient and disability perspectives and achieve both high-level input as well as tailor listening sessions specifically for impacted populations to provide input. Below are a few consensus recommendations from the patient and disability communities:

- We appreciate that CMS is hosting at least one listening session per drug or disease area.
 - We urge CMS to be mindful of allowing time for all interested stakeholders who want to participate;
 - Providers should be included as an engaged stakeholder audience in these discussions;
 - Opportunities should be provided for verbal and written comments;
 - If the meeting is to be held in person, we urge a virtual option.
- CMS should facilitate a two-way dialogue.
 - Offer a concrete list of areas on which CMS is seeking feedback ahead of the listening session – including disease or drug specific questions – to facilitate a two-way dialogue. For example, share potential therapeutic alternatives and ask for feedback on them, to ensure patient groups can optimize their feedback.

- Ensure staff included in meetings are decision-makers within the agency and in a position to engage in conversations with the patient participants that translate into considerations of a drug's therapeutic benefit and unmet need. The dialogue will be more meaningful with the right people involved.
 - For example, we urge including the agency representatives that will determine what evidence is suitable for use in the negotiation process. The goal is to ensure feedback from engaged patients and people with disabilities is reflected in the agency's determinations of what evidence is high-quality and centered on patients and people with disabilities.
- Allow written comments from those unable to attend in person, thereby also providing other patient and disability representatives with opportunities to share their perspectives about the topics discussed and to provide relevant data from their registries or other sources that may be responsive to topics discussed at the listening session.
- To the extent feasible, CMS should share data sources under consideration prior to the listening session so patients are able to provide feedback on the patient-centricity and relevance of the source.
- CMS should publish transcripts of the listening session to the public after the listening session to increase transparency and ensure those who did not join are aware of the topics discussed and therefore are able to provide written responses as appropriate.
- CMS should repeat the listening sessions later in the negotiation process, perhaps after a counteroffer has been made, giving patients an opportunity to react to and provide input on the process (assuming the manufacturer decides to make that information public).
- Following the first year of the negotiated price being enacted, CMS should hold an additional patient/provider listening session to learn about its impact on affordability, access and availability of treatments.

We would like to request a call with the CMS team implementing the listening sessions to discuss the agency's plans and provide feedback as needed. We hope these recommendations are useful as CMS makes plans for the listening sessions. Please reach out to Sara van Geertruyden (sara@pipcpatients.org) to schedule a time.

Sincerely,

ALS Association
American Association of People with Disabilities
Cancer Support Community
Cystic Fibrosis Research Foundation
Partnership to Advance Cardiovascular Health
Partnership to Improve Patient Care