

Patient-driven Recommendations for the Medicare Drug Price Negotiation Program



I Background

New Authority for Centers for Medicare and Medicaid Services (CMS):

The Inflation Reduction Act (IRA) grants CMS the authority to negotiate drug prices based on multiple factors, including clinical benefit and comparative effectiveness research.

Lack of Formal Patient Engagement Plan:

CMS is interested in considering patient outcomes and experiences but lacks a formal plan for systematic patient engagement beyond listening sessions, which only grant brief public comments by 20 randomly selected individuals representing any member of the public and offer no opportunity for back and forth with CMS.

I Overarching themes

- **Patient engagement should not be a “check-the-box” exercise.** Collect information that is meaningful to patients and explain how patient engagement impacted decisions.
- **Continuous engagement of patients is crucial.** Patients should be included as team members and experts throughout the decision-making process.
- **Proactive and inclusive information collection is necessary.** Use multiple approaches to engage patients and caregivers, recognizing that not everyone can provide input online.
- **Trust is built through transparency.** Patients must be informed of how decisions are made and how their input is used.

I Recommendations

Short Term:

- Develop a comprehensive patient engagement plan in partnership with the patient community.
- Establish touch points at key decision points with the patient community for updates and feedback.
- Provide the patient community with information on analyses considered and decisions made before, during and after listening sessions.
- Create a process to share how stakeholder feedback guides decision-making.
- Use plain language and health literacy principles in public materials to ensure patient understanding and inclusivity.

Medium Term:

- Implement a continuous patient engagement approach throughout the negotiation process.
- Train CMS staff in engagement processes.
- Conduct a third-party evaluation of patient and stakeholder engagement to ensure transparency and accountability.

Long Term:

- Continue third-party evaluation for ongoing transparency and accountability in patient engagement.
- Prioritize evidence development using patient-centric principles, such as the 10-Step Framework and Patient-Centered Outcomes Research Institute (PCORI) rubric.

I Key quotes

I think the value of having patients engaged in every step is that it no longer happens in a back room. But a patient shines a little bit of light.

The analogy I've used in another context is that you turn rocks over, and it's muddy and cruddy underneath. But all that dries up when it's shining the light on it, [the] sunshine on it.

From the formulation of the question down to the dissemination of the results, **the whole continuum, the patient should be involved in all of it.**

There should be an opportunity for public input through the whole process. And the process then evolves based on the receipt of that input.

My concern is [that] only using input electronically leaves out a whole segment of [an] important population. **And they really need to look at a way to reach out to rural communities, to underserved communities, to get input in a very specific, open way** that addresses the whole community.

I agree about being heard. **But being part of the process. But what I worry about is being part of the process, and it's just checking off a box. You gotta be part of the process, and knowing that you're listening to me and [that] I'm being heard, and come back to say, yes, I heard you.** This is what happened, and this is, and we're making it better because of what happened during this process. **But just being heard, and me being part of it is not enough. Gotta be heard and, and knowing what I say has relevance and benefit.**

But what I would like to see is **active engagement of patients through the whole process** in a way that **validates that they are equal participants in the process.**

Probably the thing that I would think would provide value is feedback, so people know what is being decided. **Because once you have to tell what you've done, then you're more mindful of what you're doing.** Hearing instead of going into the void of okay, we'll take your opinion, but didn't matter. But hearing back, having that feedback, [and] engaging afterwards.

Not only should the patients be engaged, but that **engagement should be highlighted in CMS's presentation of itself to the public**, and that would begin to speak to the patient as an equal partner, not a subject.

I think the public needs to be not, I don't know what the word, is canvassed or reached out to, that there **needs to be a more active engagement of the public and an understanding that not everyone can do it in writing.** That is a very elitist approach to me to say that it must be in writing; they really need to reach out and talk with people and transcribe what people say.



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