MILKEN INSTITUTE

April 14, 2023

Dr. Meena Seshamani
Deputy Administrator and Director, Center for Medicare
Centers for Medicare & Medicaid Services
US Department of Health and Human Services
Baltimore, MD 21244

Re: Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments

Dear Dr. Seshamani,

FasterCures thanks the leadership of the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on the initial guidance for the implementation of sections 11001 and 11002 of the Inflation Reduction Act (IRA) (P.L. 117-169) which established the Medicare Drug Price Negotiation Program (Negotiation Program). The Negotiation program represents a landmark opportunity to reduce the financial burden of drug costs on Medicare beneficiaries while also curbing CMS' spending on Part D and Part B drugs. However, the tight timeline specified in the IRA for implementation could pose problems for how well CMS is able to obtain feedback from stakeholders, especially patient communities that will be directly impacted by these changes. We offer some considerations to CMS in this letter to ensure that the perspective of patients is effectively incorporated into the Negotiation Program and to guarantee that the overarching goals of reducing the financial burden and improving access to much-needed medical products for patients are met.

FasterCures, a center of the Milken Institute, is driven by a singular goal: to save lives by speeding scientific advancements to all patients. With an independent voice, FasterCures is working to build a system that is effective, efficient, and driven by a clear vision: collaborating with our partners to build a patient-centric system where science is accelerated, unnecessary barriers are overcome, and lifesaving and life-enhancing treatments get to those who need them as rapidly and as safely as possible.

Patient communities have a critical perspective to consider in the medical product development and coverage process. Decision-makers across the continuum, including regulators, are leading the charge in engaging patients, and we consider the Negotiation Program as an important opportunity for CMS to put in place systems that adequately weigh and incorporate factors that matter to patients as part of its decision-making. The initial guidance released by CMS for the Negotiation Program indicates when CMS will consider patient-reported data and insights. We urge CMS to provide details around its approach for doing so in the ways discussed below.

Ensure sufficient timing and process for patient input. The current timeline for stakeholders to provide input to CMS for the Negotiation Program might be prohibitive for patient organizations, most of whom are already dealing with capacity constraints and are balancing competing demands on their limited time and resources. As such, we are concerned that these organizations may not have sufficient time to gather meaningful data to inform CMS' processes. A key example of one such restrictive timeline is the 30-day comment period that is offered for stakeholders to respond to the list of drugs selected by CMS for negotiations. Recognizing that the initial guidance document applies to drugs selected for the initial year 2026 of the Negotiation Program, we urge CMS to establish an ongoing process for soliciting and receiving patient feedback. We applaud CMS's efforts to diligently solicit input from different stakeholder groups all along the way. CMS can formalize that process specifically for patient groups. Such a process

could provide valuable patient insight that can be used to refine guidance for the subsequent years of the Negotiation Program as well as flagging unintended consequences that could be detrimental to patients and counter to the program's intended goals. The FDA offers a roadmap for how it has instituted systems and programs for ongoing patient input over time. Starting as early as 1998 with the establishment of the Office of AIDS Coordination, through the launch of the Patient Focused Drug Development program in 2012, and continuing to the present day, the FDA has multiple opportunities for patients and patient communities to engage with FDA staff and provide input. We urge CMS to consider a formal system for ongoing input from patient communities as part of the Negotiation Program. This may include dedicated staff and a channel for the patient community to engage with CMS staff.

Provide clarity about use of patient experience data. We are pleased with CMS's incorporation of patient experience data into the Negotiation Program process. Patients offer valuable insights into outcomes that matter to them, tolerability and side effects of products, and their perspective on the risks and benefits associated with medical products. As such, they can inform the identification of therapeutic alternatives for selected products for the Negotiation Program. While Section 50.2 of the guidance calls for broad input of stakeholders, including Medicare beneficiaries in the identification of alternative therapies and Section 60.3.3 mentions that CMS will use patient experience data in considering the clinical benefits of selected drugs and their therapeutic alternatives, the guidance currently lacks important details. Specifically, the guidance does not include details on the kinds of data, e.g., registry, natural history studies, patient preferred outcomes and others, that CMS will find beneficial, and how much patient experience data will weigh into its decision regarding revising its offer price for selected products. This kind of detail will help patient communities streamline their efforts as they gather data to share with CMS. We encourage CMS to provide more details to this effect in the final guidance and to prioritize patient input as a substantial part of its consideration.

The use of patient experience data as part of the Negotiation Program also offers an opportunity for CMS and FDA to be aligned in their evidentiary requirements, especially as it pertains to the collection and use of patient input as part of regulatory and coverage decisions. While this particular point may have longer-term implications, we believe that this kind of alignment could galvanize the move toward more patient-centricity in medical product research, development, and access. In the last few years, product manufacturers have recognized the importance of engaging patients from the onset of the drug research and development process. With FDA encouragement, manufacturers are already actively gathering patient input that they are considering in the application process. Some medical product manufacturers have not accepted patient engagement as a core function of their product development lifecycle and may struggle to capture the value in engaging patients in a way that aligns with their organizational priorities. By providing details on the types of patient input that it will be considering as part of its review in the drug negotiation process, CMS will be helping manufactures preempt, align, and address the needs of the regulatory and drug negotiation process from the onset of drug research and development. This could also result in efficiencies for patient organizations that have to respond to multiple demands from medical product manufacturers, often for the same information.

Thank you for the opportunity to provide comments on this important program. We look forward to the updated guidance with stakeholder feedback and welcome any opportunities to support CMS in your efforts as you implement the Negotiation Program.

Sincerely,

Esther Krofah
Executive Vice President of Health
Executive Director, FasterCures and Center for Public Health
Milken Institute