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FasterCures

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Chris Klomp
Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
US Department of Health and Human Services
Baltimore, Maryland 21244

Re: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028

Dear Mr. Klomp,

The FasterCures team at the Milken Institute is honored to provide its expert response to the Request for Comments on the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191–1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028.

As a nonprofit, nonpartisan think tank, the Milken Institute believes in the power of capital markets to address urgent social and economic challenges, thereby improving lives. Its guiding belief is that societies thrive when they cultivate an educated, healthy workforce, foster transparent and efficient capital markets, and sustain effective social institutions.

FasterCures is driven by a singular goal: to save lives by speeding scientific advancements to all patients. For over two decades, it has strengthened patient involvement in biomedical research by uniting diverse stakeholders to identify gaps, develop solutions, and create tools that support evidence-based decisions.[1] FasterCures has also been a steadfast partner in driving the integration of patient perspectives into biomedical research by advocating for legislation, regulatory guidance, and other resources that support patient-focused research. We were also a driver for the development of the Food and Drug Administration's (FDA) Patient-Focused Drug Development (PFDD) program.

Person-centered care—sometimes referred to as patient-centered care—is already a core principle at the Centers for Medicare & Medicaid Services (CMS).[2] CMS recognizes that value-based care succeeds only when it addresses patients' comprehensive, long-term needs and aligns with their preferences and values. CMS's reach extends beyond care delivery and quality; the agency also wields considerable influence over Medicare coverage decisions for medical products, often setting precedents for private insurers. As such, person-centered principles should inform coverage determinations, ensuring that patient preferences are fully reflected in decisions about medical products.

FasterCures views the rollout of the Medicare Drug Price Negotiation Program (MDPNP) as a pivotal moment to broaden CMS's person-centered approach. To that end, we offer several recommendations for embedding patients' experiences and perspectives, fostering a sustainable, scientifically grounded model for patient engagement moving forward.

Summary of Recommendations:

- Adopt transparency in how the information gathered from the patient listening sessions and Information Collection Request (ICR) provided by patients, caregivers, and patient organizations would inform the MDPNP processes and outcomes.
- Adapt best practices tested and developed by the FDA and evolve them together to facilitate effective, meaningful, fit-for-purpose patient engagement to inform CMS's MDPNP.
- Establish a designated structure for patient engagement beyond the scope of the MDPNP that is integrated into coverage decisions for innovative medical products, such as those approved through the accelerated approval pathway.

I. Transparency on How the Data from Patient Listening Sessions Are Impacting CMS Decision-Making

We commend CMS for its continuous commitment to patient-centered engagement throughout the Cycle 2028 negotiation.[3] Robust, well-coordinated listening sessions will enhance understanding of patient preferences, given that patients will experience the direct impact of negotiated prices. We also welcome CMS's pledge to publish redacted transcripts from private patient-focused roundtables and the public town hall meeting. This continuous commitment represents a significant step forward in transparency. In response to CMS's request, we submit recommendations to strengthen the scientific and systematic nature of patient engagement within the MDPNP.

In September 2024, FasterCures launched Vital Voices to equip patient communities to engage more effectively with CMS during access-related decision-making for medical products. Motivated by new legislative avenues for patient input into the MDPNP, we applaud the inaugural Cycle 2026 implementation team for creating pathways that include patients, caregivers, and patient organizations. Each successive negotiation cycle has demonstrated measurable progress in elevating these essential voices.

Our research consistently highlights a single, urgent request: patients, caregivers, and their advocates want to know how their input shapes CMS decisions. Engagement requires significant time, resources, and dedication, particularly for smaller, under-resourced organizations. Accordingly, CMS should articulate how insights from patient-focused events are incorporated into MDPNP deliberations and outcomes.

Transparency breeds trust. CMS already embodies this principle through the Medicare Coverage Database,[4] which publicly documents national and local coverage decisions, as well as through Administrator rulings that clarify complex statutory provisions. We are confident that perspectives from the patient-focused roundtables and the ICR will inform forthcoming negotiations. At a minimum, CMS should notify participating patients and organizations about the methods used to evaluate and apply their contributions during the price-negotiation process.

We recommend that the agency consider increasing transparency in how the information gathered from patient-focused events and the ICR Section I is reflected in drug price negotiation processes.

II. Enhancing Official Collaboration with the FDA for Scientific and Systemic Patient Engagement for Biologics and Complex Small Molecules

Under the Inflation Reduction Act (IRA), comparative effectiveness should be considered in the context of a drug's effect on specific populations, "such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations," learned from patients to whom the negotiation outcomes will impact. Patient engagement is science. The impact of patient engagement on achieving better health outcomes and satisfaction is well understood. Like any scientific research, it requires an understanding of the patient population in a condition and a basic knowledge of current and alternative treatments. Additionally, patient engagement should have a specific focus and clear expected outcomes.

The 2028 cycle negotiations are particularly significant because CMS will, for the first time, include Part B drugs among the candidates. Hospital- or clinic-administered biologics generate especially nuanced and robust patient-experience data. Owing to their biological complexity, individual responses—and patients' perceptions of benefit—vary widely. This inherent heterogeneity affects both when patients choose to switch to alternative therapies and when they are required to switch due to changes in their insurer's formulary. Accordingly, preserving an appropriate degree of therapeutic choice is essential to ensure that patients achieve the best possible health outcomes.

We want to highlight that the opportunities to gain better insights into the best practices in patient engagement are close to CMS. Its sister agency, the FDA, has worked on patient engagement in drug development for over four decades. The history of the FDA's efforts since the late 1980s can provide insight into the evolution of the science of patient engagement initiated by HIV/AIDS activists. It was first mandated by the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 and later supported by the 21st Century Cures Act and subsequent reauthorizations of the Medical Device User Fee Amendments (MDUFA) and the Prescription Drug User Fee Act (PDUFA).

Under this program, dedicated staff proactively identify best practices, refining rigorous data sources and collection methods and broadening their understanding of patient experience and preference data in partnership with diverse stakeholders. Critically, the FDA's Clinical Outcome Assessment framework captures far more than quality-of-life measures; it incorporates patients' experiences, perspectives, needs, and priorities regarding medical products—information highly relevant to CMS. FasterCures believes CMS should leverage the MDPNP as a springboard to build on the FDA's progress, accelerating the adoption of a systematic, science-based approach to patient engagement.

We recommend that CMS consider redesigning its fundamental approach to acquiring and integrating patient input, as well as the patient-focused listening sessions. This would require closely coordinating with its sister agency, the FDA, and using its best practices tested in the past decade.

III. Advancing Patient Engagement Beyond the Medicare Drug Price Negotiation Program

Nonmedical switching occurs when a patient's medication is changed for reasons unrelated to efficacy, safety, or adherence, typically because of formulary updates or insurer coverage decisions. These switches can undermine health outcomes, stall progress, and disrupt daily life.[5] The real-life impacts of the MDPNP's ultimate effect on formularies are still to come, but patients, caregivers, and advocacy groups have already voiced tangible concerns.

As of April 2024, CMS makes medical product coverage decisions and reimburses for care for 68.5 million enrollees.[6] CMS has significantly improved and is committed to patient engagement regarding health-care quality and delivery. In its strategy, the agency emphasized that understanding how patients determine their preferences and values is closely tied to successful long-term health management.[7]

Under the Medicare Hospital Quality Initiative, CMS also established the Person and Family Engagement (PFE) Strategy to provide specific, actionable goals and objectives that ensure the public's involvement.[8] The agency has a Consumer Engagement program with resources and tools to encourage nursing home residents, families, and advocates to take an active role in quality care.[9] However, on the coverage determination side, patient engagement by CMS is muted.

Through the IRA, CMS is bestowed unprecedented opportunities to engage patients meaningfully in its coverage decisions of drugs and biologics. The agency must develop and sustain its patient engagement practice and strategies beyond MDPNP through these opportunities. To achieve this, FasterCures believes that CMS must establish a structure, such as an Office of Patient Engagement, to directly engage patients in meaningful, fit-for-purpose, and informative ways. This structure must include a dedicated and trained team of staff who can coordinate with experts and patients to implement such engagement. Patients and patient organizations must also be trained to effectively engage with CMS and other payers, providing valuable insights. FasterCures will be happy to be CMS's resource to help the agency design such an office.

We recommend that CMS engage patients for its coverage decisions beyond MDPNP and build a structure, system, and staff capacity for consistent patient engagement.

FasterCures shares this commitment to building the capacity of patients and patient organizations to help them understand the unique US payer environment that impacts their health. As an example of commitment, we want to introduce an affinity network established for over 15 years by FasterCures. The Research Acceleration and Innovation Network (TRAIN) is a network of nearly 200 patient organizations interested in taking a more strategic and entrepreneurial approach to their role as funders of medical research and brokers of patient participation.[10] Since TRAIN was established, FasterCures has developed numerous resources, tools, and initiatives to help patient organizations enhance their capacity to advance community research efforts.

Each year, FasterCures carves out a set of activities as part of TRAIN to support patient organization research capacity-building, including webinars, workshops, peer sharing sessions, networking opportunities, and resource/toolkit development[11] to target areas of patient organization priority and need as well as to provide thought leadership opportunities for TRAIN leaders to discuss emerging issues, policies, and innovations that present both new challenges and opportunities for the biomedical R&D ecosystem.

FasterCures has a long-standing commitment to a functioning and sustainable health-care ecosystem from bench to bedside, with patients at the center.[12] The future that FasterCures envisions aligns with CMS's commitment to patient-centered health care through transparent communication and quality care insights derived from health-care data. Our recommendations serve an instrumental purpose in advancing patient-centricity that is adequately represented in all aspects of the health-care ecosystem. FasterCures is committed to being a thought partner in CMS's journey toward scientific and systemic patient engagement for MDPNP and beyond.

Sincerely,

Esther Krofah
Executive Vice President, Health
Milken Institute

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[7] Ibid.

[8] "Person and Family Engagement," Centers for Medicare and Medicaid Services, accessed June 3, 2025, https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/person-family-engagement.

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