



Empowering Patient Perspective.

PRINCIPLES FOR CMS ON HARNESSING THE POWER OF PATIENT INVOLVEMENT WHEN IMPLEMENTING THE INFLATION REDUCTION ACT

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OVERVIEW

The [Inflation Reduction Act of 2022 \(IRA\)](#) gives the Centers for Medicare & Medicaid Services (CMS) [sweeping authority](#) to set prices for certain medications under the Medicare Drug Price Negotiation Program. While Congress set a basic framework and timeline for the program, the law does not set any specific guidelines, methodologies or processes for CMS to follow as it moves forward with price negotiations.

While CMS did [issue guidance on March 15, 2023](#) to implement the Drug Pricing Negotiation Program for 2026, it did so without soliciting comments for certain key aspects of the program. The agency claims to have authority to [bypass the notice and public comment rules](#) that are typically required for federal agencies under the law.

Both the Administrative Procedure Act (APA) and the Medicare statute require notice-and-comment periods when agencies issue substantive rules. Congress can allow exemptions, but [courts have interpreted congressional exemptions very narrowly](#). Even though the Negotiation Program is arguably the most consequential measure in the IRA, leaders at CMS say the public regulatory procedures are “impractical, unnecessary, and counter to the public interest,” citing deadlines and “complexity.”

Put simply, CMS's broad exemption claims should concern patients hoping to have a voice in how this law will be implemented. Legality aside, ***CMS has failed to establish transparency and trust*** with communities of patients and caregivers across the United States. Patients in other countries have watched as various Health Technology Assessment bodies have [minimally involved patients](#) and rarely considered their views when making value and coverage decisions. CMS must avoid making those same mistakes with its new negotiation authority. Speed of implementation is ultimately of little value if it [cuts patients out of the process](#).

AIM

Patients are the most reliable authority on value for any healthcare decision. They have the best perspective of their illnesses and the impact a treatment can have on their quality of life. Therefore, it is imperative that CMS work to incorporate the views of patients and caregivers in every aspect

of its Medicare Part D negotiations and prioritize their input over that of academics and health economists while also operating in a lawful, open, and transparent manner.

The Patient Access and Accountability Project proposes the following *patient-centric principles to guide CMS* in their decision making:

CMS must adopt a patients-first approach.

- Make patient health and wellbeing the primary focus of all policy decisions.
- Prioritize patient affordability and access to the highest quality of care.
- Develop a clear and transparent process that incorporates scientific principles, methodologies, and evidence to support patient-centered policies.
- Promote collaboration and encourage patient engagement in all phases of the regulatory process.

CMS must make patients the primary source for determining a medication's value.

- Grant the patient and their caregivers a real voice when assessing therapy's value.
- Consider both clinical and non-clinical benefits and impacts of a medication based on insights from patients, caregivers, and society.
- Incorporate varying needs and contextual factors of individual patients and subgroups, particularly for rare diseases with small patient populations.
- Include clinical trial data, along with safety, long-term health outcomes, patient experience, population health equity, health system resource use, and societal impacts in all valuations.
- Issue coverage recommendations based on the clinical value of treatments, patient input, and real-world evidence.
- Prohibit the use of flawed and discriminatory value measures, like the quality adjusted life year (QALY), and cost models when assessing and pricing drugs for Medicare patients.
- Adopt and encourage the development of patient-centric value measures to guide drug pricing decisions.
- Gather insight from disease-specific specialists who understand how a therapy can impact patients and what factors constitute value from their perspective.
- Establish a clear, transparent methodology for gathering and applying data to quantify patient experience when assessing a drug's value and setting prices.

CMS must increase transparency and remove access barriers.

- Publicize any scientific principles, methodologies, and evidence used to make value and pricing decisions.

- Require all patient out-of-pocket costs for prescriptions to be based on the net price negotiated by the insurer-owned Pharmacy Benefit Manager.
- Conduct a forward-looking audit of the IRA to identify future patient access risks, including increases in utilization management practices by insurance companies.
- Develop risk mitigation strategies to address any future risk to patient access or rationing of care.
- Conduct a wide-ranging audit of the U.S. health system to better understand the actual drivers of healthcare inflation.
- Encourage innovative financial support models to allow patients, not insurance companies, to benefit from any cost savings.

The Patient Access and Affordability Project is a signature program of Patients Rising and aspires to be the leading source for patient-inspired health policy. This program conducts research and analysis, develops policy solutions, and provides commentary and many pressing issues impacting patients. They are a leading source on improving health technology assessment to be humane, ethical, and reflective of what patients value. Their work seeks to tackle the underlying factors driving up the cost of care, such as opaque and perverse financial incentives, inadequate insurance coverage, and rationing access to specialty care. Visit AccessAndAffordability.org.