POLICY BRIEF

Inflation Reduction Act: Medicare Drug Price Negotiation Program

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BACKGROUND

Ensuring affordable, high-value healthcare remains a national priority. Prescription medicines play a critical role in improving health outcomes and quality of life, yet rising costs continue to challenge patients and the sustainability of the healthcare system. U.S. retail prescription drug spending has increased substantially over the past decade, from approximately $322 billion in 2015 to $406 billion in 2022.[1] Spending is projected to continue rising, driven in part by increased utilization and the introduction of new, high-cost therapies.[2]

Policymakers are now exploring new approaches to improve healthcare value by aligning cost, access, and innovation. One such effort is the Inflation Reduction Act (IRA), enacted in August 2022, which authorized the Centers for Medicare & Medicaid Services (CMS) to negotiate prices for a limited number of high-cost drugs under Medicare Parts B and D.

The Medicare Drug Price Negotiation Program (DPNP), established under the IRA, represents a significant shift in federal health policy. The program is intended to improve prescription drug affordability for Medicare beneficiaries while reducing federal spending.[3] Beyond its direct impact on drug prices; however, the program may also influence how value is defined and assessed across the healthcare system, particularly as CMS considers clinical benefit, therapeutic alternatives, unmet medical need, and impacts on specific patient populations as part of the negotiation process.[4]

CMS announced the first 10 drugs selected for negotiation in August 2023, with negotiated prices taking effect in 2026. In January 2025, CMS selected an additional 15 Part D drugs for the second negotiation cycle, with negotiated prices taking effect in 2027. Most recently, in January 2026, CMS selected 15 additional drugs for the third cycle—including, for the first time, drugs covered under Medicare Part B—with negotiated prices scheduled to take effect in 2028.[5]

Taken together, the drugs selected for negotiation represent tens of billions of dollars in annual Medicare spending and treat conditions affecting millions of Medicare beneficiaries, including older adults and people with disabilities.

At the same time, these evolving policy mechanisms raise important questions about how value is defined and assessed—and how resulting decisions may affect patient access, health equity, innovation, and the long-term sustainability of the healthcare system.

IVI emphasizes that efforts to improve affordability, whether through the DPNP or other policy mechanisms, should be grounded in transparency, patient-centered value, and equity. Ensuring that patient perspectives and outcomes are meaningfully considered can help advance affordability while preserving access to high-value care.

WHY IT MATTERS

Prescription medicines are essential to improving health and quality of life, but patients do not always experience their full benefit when affordability and access barriers persist.[5] Policies like the DPNP should aim to strengthen value across the healthcare system, ensuring patients can obtain and adhere to treatments that improve outcomes, not just lowering costs.

A narrow focus on lowering unit prices without considering overall value risks unintended consequences, including reduced investment in therapeutic innovation and inequitable access for certain populations. Since the passage of the Inflation Reduction Act (IRA), early-stage investment in small-molecule therapeutics has declined by 68%, raising concerns about the long-term impact of current pricing policies on the development of new treatments.[6] Value encompasses multiple dimensions, including clinical effectiveness, patient quality of life, caregiver burden, and long-term societal benefits.

CMS considers multiple negotiation factors, including unmet need, therapeutic alternatives, clinical benefit, and evidence of quality, yet the statute provides limited guidance on how these elements should be weighted. This ambiguity creates uncertainty for patients, clinicians, and manufacturers. Growing evidence underscores the need to closely monitor how negotiation policies influence patient choice. A recent review found that therapeutic alternatives to negotiated drugs appeared on only about half of Medicare Part D formularies, while the negotiated products themselves were covered by nearly all plans. This divergence suggests that formulary designs may become more constrained, particularly for patients managing rare or clinically complex conditions.

As CMS implements the DPNP, decisions about pricing should be guided by the broader goal of advancing patient-centered value, ensuring that affordability efforts improve health outcomes, foster innovation, improve access, and strengthen equity across populations.

POLICY RECOMMENDATIONS

1. **Focus on Maximizing Value, Not Simply Minimizing Price.** CMS should anchor the DPNP in a broader definition of value that considers patient outcomes, societal benefits, and system sustainability. Data requirements for price-setting should include patient-level impacts such as out-of-pocket costs, caregiver burden, and personal treatment goals, as well as system-level factors such as innovation incentives and long-term Medicare savings.

2. **Embed Health Equity Across All DPNP Processes.** Equity must be integral to every stage of DPNP implementation. CMS should require formal evaluation of equity impacts when assessing evidence and determining benchmark prices. This includes identifying data gaps for underrepresented populations and incentivizing evidence generation in diverse patient groups. Establishing an enrollee advisory group composed of patients and caregivers from historically marginalized communities would strengthen accountability and ensure that the program aligns with CMS's stated equity goals.

3. **Institutionalize Meaningful Patient Engagement.** Patients and their representatives must have a defined role in DPNP decision-making. CMS should establish treatment-specific advisory panels to inform each negotiation, ensuring that patient experiences, preferences, and unmet needs are meaningfully incorporated. Guidance should specify how qualitative patient evidence is weighted alongside clinical and economic data and define mechanisms for shared decision authority.

4. **Ensure Transparency and Rigor in Methods.** CMS's current "qualitative approach" to evidence assessment should be grounded in a clear methodological framework that defines key terms such as "unmet need" and "therapeutic advance" and outlines how evidence is collected, evaluated, and prioritized. Transparent standards for weighing evidence, including patient-reported outcomes and social value, would strengthen trust and consistency. CMS should also invest in research to develop alternatives to traditional measures such as the quality-adjusted life year (QALY) to better capture lived experience and reduce bias.

5. **Evaluate the Real-World Impact of the DPNP.** CMS should evaluate the Drug Price Negotiation Program not only for its fiscal impact but also for its effects on patient out-of-pocket costs, access, and real-world value. Embedding real-world evidence (RWE) generation into implementation would ensure that negotiated prices reflect both affordability and improved health outcomes.

6. **Position the DPNP as a Catalyst for Innovation and Learning.** CMS should use the DPNP as a foundation for advancing methods that encourage innovation, evidence generation, and learning. This includes supporting mixed-method approaches that integrate clinical, economic, and experiential data; developing value metrics that reflect patient diversity; and fostering collaboration with private payers and researchers to align public and private-sector value frameworks.

CONCLUSION

The Inflation Reduction Act's Medicare Drug Price Negotiation Program represents a significant development in the ongoing effort to improve healthcare affordability. Its implementation will influence how value, equity, and innovation are considered in healthcare decision-making for years to come.

IVI emphasizes that as CMS and other stakeholders operationalize this and similar initiatives, they must ensure that affordability measures are aligned with patient-centered value, methodological transparency, and equity, principles that support access to high-value care and continued innovation.

Federal policymakers are implementing new tools to manage rising drug costs, with the Medicare Drug Price Negotiation Program representing one of the most significant shifts in recent years. As program details evolve, it is critical that pricing reforms strengthen, not weaken, patient access, equity, and the evidence base used to guide high-stakes decisions across the healthcare system.

REFERENCES

1 Centers for Medicare & Medicaid Services (CMS), Office of the Actuary. *National Health Expenditure Accounts.* Retail prescription drug spending was approximately $321.9 billion in 2015 and $405.9 billion in 2022.

2 Centers for Medicare & Medicaid Services (CMS), Office of the Actuary. *National Health Expenditure Projections.* CMS projects retail prescription drug spending to be among the fastest-growing major health spending categories, averaging 5.7% annual growth from 2025–2034.

3 Centers for Medicare & Medicaid Services (CMS). *Medicare Drug Price Negotiation Program*. CMS describes the program as allowing Medicare to negotiate prices for certain high-expenditure, single-source drugs, with the goals of improving affordability and strengthening the sustainability of Medicare.

4 Centers for Medicare & Medicaid Services (CMS). Medicare Drug Price Negotiation Program, Final Guidance for Initial Price Applicability Year 2028. CMS considers clinical benefit, therapeutic alternatives, unmet medical needs, effects on specific populations, and manufacturer-specific factors in developing negotiated prices

5 Centers for Medicare & Medicaid Services (CMS). Selected Drugs and Negotiated Prices; *CMS Announces Selection of Drugs for Third Cycle of Medicare Drug Price Negotiation Program*, Jan. 27, 2026. The first 10 drugs were selected in August 2023; 15 additional Part D drugs were selected in January 2025; and 15 Part B and/or Part D drugs were selected in January 2026 for the third cycle.

6 Schulthess, D.G., O'Loughlin, G., Askeland, M., Gassull, D., & Bowen, H.P. "The Inflation Reduction Act's Impact Upon Early-Stage Venture Capital Investments." *Therapeutic Innovation & Regulatory Science,* 59 (2025): 769–780. The study found a 68% decline in aggregate early-stage small-molecule investment following introduction of the IRA.

ABOUT IVI

IVI is an independent nonprofit driving the transformation of a U.S. healthcare toward a system that defines and rewards value through a patient- and family-centered lens.

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