



Policy Proposal: Allow Medicare to Negotiate Drug Prices in Part D

What problem is this policy meant to address?

Spending in Medicare Part D reached \$100 billion in 2016, more than double the program's expenditures in 2006.¹ Within five to six years, program costs are expected to reach \$150 billion annually.² Over three-quarters of Part D costs are borne by the federal government, with the remaining portion paid by beneficiaries and state governments.³

Under the Part D program, private prescription drug plans (PDPs) provide drug coverage to Medicare enrollees. PDPs negotiate drug rebates and other discounts with pharmaceutical manufacturers, which reduce program costs and allow plans to compete for beneficiaries based on lowering premiums and patient out-of-pocket costs. However, the federal government is prohibited from negotiating drug prices in the Part D program as part of the Social Security Act's noninterference clause. The clause states that the Department of Health and Human Services "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors, and may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs."⁴ Proponents of government negotiation believe that the HHS could secure lower drug prices than individual PDPs. Ninety-two percent of Americans favor allowing the government to negotiate with drug companies to lower drug prices for people on Medicare.⁵

How could this policy work?

Current law could be updated to permit the HHS to negotiate drug prices on behalf of the approximately 43 million Part D beneficiaries.⁶ The department has significantly larger purchasing power than individual PDPs but would likely need additional authority to achieve discounts beyond those negotiated by PDPs.

In 2007, the Congressional Budget Office (CBO) estimated that allowing the HHS to negotiate Part D drug prices would have a "negligible effect" on spending unless the agency were also given additional authorities, such as the ability to manage a federal formulary.⁷ To date, there is no CBO estimate on the effect that allowing the HHS to negotiate both drug prices and formulary placement could have.

The primary tool that payers use to negotiate discounts, often in the form of rebates, is through preferred formulary status, where plans reduce patient cost-sharing requirements or ease the use of utilization management tools such as prior authorization or step therapy. Preferred formulary status increases the sale of a drug and provides an incentive for manufacturers to offer discounts. This approach is most effective when multiple therapies are available to treat the same condition. In addition to granting the HHS the authority to negotiate drug prices, lawmakers could permit it to establish a formulary for Part D. Alternatively, policymakers could provide the HHS with the ability to set prices administratively if manufacturers do not offer price concessions.

The Improving Access to Affordable Prescription Drugs Act of 2017 would strike the noninterference clause from the law and instead grant the HHS the authority to negotiate Part D drug prices.⁸ The proposal would also give

the HHS the authority to use negotiating techniques involving “formularies, reference pricing, discounts, rebates, other price concessions, and coverage determinations” to lower prices paid to PDPs. The CBO has not released an estimate of the impact such an approach could have on Medicare drug spending.

What should policymakers consider?

In order for negotiations to have an impact on Part D drug prices, the government would need the ability to pressure drug companies to lower their prices through the use of a formulary, utilization management tools, or administrative price setting. Policymakers would also need to consider the potential impact of these policies on patient access to medicines. Opponents argue that allowing the government to negotiate prices would inhibit innovation and limit patient access.

Potential approaches would require policymakers to define the scope of government negotiations, including:⁹

- Which drugs would the HHS have the authority to negotiate?
- Could the HHS negotiate both the price of drugs and formulary design?
- Would the negotiated terms apply to all Part D plans?

A recent proposal would grant the government the ability to negotiate the price on products that face little competition, are subject to the Part D reinsurance benefit,¹⁰ and have a significant impact on Part D spending.¹¹ This proposal would target a significant driver of Part D spending—high-cost medicines.¹²

Under this proposal, the minimum payment amount for a drug could be based on the costs of development. An additional bonus payment based on the value of the product—as measured by quality-adjusted life years¹³—could increase the final price above the minimum payment amount. As leverage, the government could require higher cost sharing for drugs with higher prices or even exclude drugs from coverage. Though the federal government would negotiate the price of these select products for all PDPs, the PDPs themselves would continue to pay claims.

Given the large number of Part D beneficiaries, HHS negotiation has the potential to reduce program costs. However, proposals must be explicit about the scope of the government’s authority and the specific circumstances under which the HHS could negotiate drug prices. Elements to be clarified include what is being negotiated (e.g., prices and/or formulary placement) and what to do if the negotiating parties are unable to reach an agreement.

Endnotes

- 1 Centers for Medicare & Medicaid Services, “2017 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds” (2017), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2017.pdf>.
- 2 Ibid.
- 3 Centers for Medicare & Medicaid Services, “2017 Annual Report,” Table II.B1.
- 4 PDP Regions; Submission of Bids; Plan Approval, 42 U.S.C. § 1395w-111(i)(1) (2009).
- 5 Kaiser Family Foundation, “Kaiser Health Tracking Poll—Late April 2017: The Future of the ACA and Health Care & the Budget” (2017), <https://www.kff.org/report-section/kaiser-health-tracking-poll-late-april-2017-the-future-of-the-aca-and-health-care-the-budget-rx-drugs/>.
- 6 Centers for Medicare & Medicaid Services, “2017 Annual Report,” Table II.B1.
- 7 Congressional Budget Office, “Letter to the Honorable Ron Wyden Regarding the Authority to Negotiate Prices for Single-Source Drugs for Medicare Beneficiaries” (2007), <https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/drugpricenegotiation.pdf>.
- 8 Improving Access to Affordable Prescription Drugs Act, S. 771, 115th Cong. (2017).
- 9 Chuck Shih, Jordan Schwartz, and Allan Coukell, “How Would Government Negotiation of Medicare Part D Drug Prices Work?” *Health Affairs Blog* (2016), <http://healthaffairs.org/blog/2016/02/01/how-would-government-negotiation-of-medicare-part-d-drug-prices-work/>.
- 10 The Medicare reinsurance benefit begins once beneficiaries reach the catastrophic cost coverage threshold, which is \$8,418 in 2018. Above this amount, Medicare pays for 80 percent of drug costs, while PDPs and beneficiaries pay 15 and 5 percent, respectively. Kaiser Family Foundation, “The Medicare Part D Prescription Drug Benefit” (2017), <http://files.kff.org/attachment/Fact-Sheet-The-Medicare-Part-D-Prescription-Drug-Benefit>.
- 11 Richard Frank and Richard Zeckhauser, “A Framework for Negotiation in Part D of Medicare,” Brookings Institution (2017), https://www.brookings.edu/wp-content/uploads/2017/05/wp28_frankzeckhauser_medicarepartd.pdf.
- 12 Office of Inspector General, U.S. Department of Health and Human Services, “High-Price Drugs Are Increasing Federal Payments for Medicare Part D Catastrophic Coverage” (2017), <https://oig.hhs.gov/oei/reports/oei-02-16-00270.asp>.
- 13 The United Kingdom’s National Institute for Health and Care Excellence defines a quality-adjusted life year (QALY) as “a measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year of life in perfect health.” National Institute for Health and Care Excellence, “Glossary,” <https://www.nice.org.uk/glossary?letter=q>.

This fact sheet was updated on Dec. 14, 2017, to reflect additional research related to government negotiation of drug prices.

For further information, please visit:

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Contact: Erin Davis, communications officer

Email: edavis@pewtrusts.org

Project website: pewtrusts.org/en/projects/drug-spending-research-initiative

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