Searching for Savings in Medicare Drug Price Negotiations

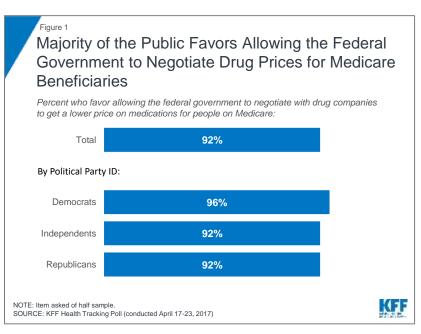
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Introduction

Prescription drug costs continue to raise fiscal concerns for public and private payers and affordability worries for consumers. Nationally, drug spending spiked in 2014, mainly due to new and costly breakthrough treatments for hepatitis C that came to market starting at the end of 2013, along with fewer opportunities to control spending through greater use of generic drugs. For Medicare, which accounted for 29 percent of national retail pharmaceutical spending in 2016¹, average per capita costs in the Part D prescription drug program have been rising, and are projected to grow more rapidly over the next decade. Medicare Part D average per capita costs increased from 2.4 percent between 2007 and 2013 (the year before new hepatitis C treatments became widely available) to 4.4 percent between 2013 and 2016, and are projected to increase annually by 4.7 percent between 2016 and 2026.² This increase will affect both federal spending and beneficiaries' out-of-pocket costs for prescription drugs.

In response to higher drug spending growth and heightened attention to drug prices, some policymakers and experts have proposed allowing Medicare to negotiate the price of prescription drugs. Under current law, the Secretary of the Department of Health and Human Services (HHS) is explicitly prohibited from negotiating directly with drug manufacturers on behalf of Medicare Part D enrollees. Allowing the federal government to negotiate drug prices for Medicare beneficiaries is

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supported by <u>92 percent of the public</u>, including a majority of Democrats (96%), Republicans (92%), and Independents (92%) **(Figure 1)**. This proposal was also endorsed in a <u>recent report</u> from the National Academies of Sciences, Engineering, and Medicine.



President Trump <u>has said</u> he will "bring down drug prices" and has repeatedly criticized the current-law policy that prohibits the government from negotiating with pharmaceutical companies in an effort to lower drug prices in Part D and achieve federal savings.³ He <u>has also said</u> "we don't bid properly and we're going to start bidding." To date, Republican Congressional leaders have not outlined specific proposals to reduce drug costs. Speaker Ryan's <u>A Better Way</u> proposal and <u>recent budget proposals</u> put forward by House Republicans propose changes to Medicare, but do not directly address the issue of Medicare drug spending or prescription drug prices.

Proponents believe that giving the HHS Secretary the authority to negotiate drug prices on behalf of millions of Medicare beneficiaries would provide the leverage needed to lower drug costs, particularly for high-priced drugs for which there is no competition and where private plans may be less able to negotiate lower prices. Opponents believe the Secretary would not be able to get a better deal than private plans already do. They also express concern that price negotiations would limit the ability of pharmaceutical companies to invest in pharmaceutical research and development.

This issue brief provides a short history of the concept of allowing Medicare to negotiate drug prices, describes various approaches, and assessments of their potential savings from the Congressional Budget Office (CBO), and considers the prospects for action in the future.

A brief history of proposals to allow Medicare to negotiate drug prices

The idea of allowing the federal government to negotiate prescription drug prices with drug manufacturers on behalf of Medicare beneficiaries has been raised in Medicare policy discussions for over a decade. In the years leading up to the enactment of the Medicare Part D prescription drug benefit in the Medicare Modernization Act of 2003, lawmakers debated whether the federal government should provide a drug benefit directly, but in the end opted to provide drug coverage through a marketplace of private plans that compete for business based on costs and coverage. Under Part D, private plan sponsors separately negotiate drug prices with pharmaceutical companies, establish formularies, and apply utilization management tools to control costs.

Notably, Congress added language to the MMA, known as the "noninterference" clause, which stipulates that the HHS Secretary "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." In effect, this provision means that the government can have no role in negotiating or setting drug prices in Medicare Part D. This is in stark contrast to how drug prices are determined in some other federal programs; for example, the statutory requirement for mandatory drug price rebates in Medicaid, and a requirement that drug manufacturers charge the Department of Veterans Affairs (VA) no more than the lowest price paid by any private-sector purchaser.

Though the MMA adopted a market-oriented approach to providing the Medicare drug benefit and prohibited any "interference" by the HHS Secretary with respect to drug prices, some lawmakers continued to press for authorizing the Secretary to negotiate drug prices, primarily by striking the

"noninterference" language, a proposal <u>favored by the vast majority of Americans in 2006</u>. Nonetheless, bills proposing this change stalled in Congress in the face of strong opposition from the pharmaceutical industry, and equally strong resistance among Congressional Republicans to any effort to expand the role of government in Medicare's drug benefit.

For the next several years, the push for Congressional action on drug prices waned as Part D benefit spending growth remained relatively flat—and <u>lower than initially projected</u>—with a large number of brand-name drug patent expirations and growing use of generic drugs helping to keep drug spending in check. Interest in this proposal also may have diminished once CBO concluded that proposals to give the Secretary authority to negotiate drug prices would have a "negligible effect" on Medicare drug spending (see below).

What are various approaches to allowing Medicare to negotiate drug prices?

Some proposals to allow Medicare to negotiate drug prices would strike the MMA's non-interference clause and authorize the HHS Secretary to negotiate drug prices on behalf of Medicare beneficiaries enrolled in private Part D plans.⁴ Others would allow the Secretary to negotiate drug prices by establishing a public Part D plan to operate alongside private Part D plans and administered by HHS under the oversight of the Secretary.⁵ Under this approach, the Secretary would establish a formulary for the public Part D plan and negotiate prices for drugs on that formulary. Some recent proposals designed primarily to expand health insurance coverage (including Medicare-for-all and Medicare buy-in proposals) or improve the stability of the Affordable Care Act marketplaces include provisions that would authorize the HHS Secretary to negotiate drug prices.⁶

A middle ground approach, and one that responds specifically to recent concerns over high-priced specialty drugs, would authorize the HHS Secretary to negotiate prices solely for a limited set of relatively expensive drugs, including unique drugs that lack therapeutic alternatives. A recent proposal directs the HHS Secretary to prioritize negotiation on specialty and other high price drugs, but also includes a fallback for achieving savings if the negotiation process fails. The fallback is to essentially use the VA price, which has a narrow formulary and secures much steeper discounts than private payers do. The bill also proposes to give the Secretary authority to establish formularies in Medicare and use other pricing tools he currently lacks. The bill has not been scored by CBO.

What has CBO said about the potential for savings?

<u>CBO has said</u> that giving the Secretary authority to negotiate lower prices for a broad set of drugs on behalf of Medicare beneficiaries would have "a negligible effect on federal spending." It based this assessment on its view that the Secretary would not be able to leverage deeper discounts for drugs than risk-bearing private plans, given the incentives built into the structure of the Part D market, where plan sponsors bid to participate in the program, compete for enrollees based on cost and coverage, and bear some risk for costs that exceed their projections.

CBO has suggested that savings could potentially be achieved under a defined set of circumstances. For example, in addition to simply removing the non-interference clause and allowing the Secretary to negotiate drug prices, CBO has said that in order to obtain price discounts, the Secretary would need authority to establish a formulary that included some drugs and excluded others and imposed other utilization management restrictions, in much the same way that private Part D plans do. And yet, CBO has questioned whether the Secretary would be willing to exclude certain drugs or impose limitations on coverage, as private plans do, "given the potential impact on stakeholders." Savings could also be achieved if the Secretary were authorized to set drug prices administratively or take regulatory action against companies that did not offer discounts of a certain magnitude. CBO has not estimated the potential savings associated with these options.

In addition, <u>CBO has suggested</u> there is some potential for savings if the Secretary had authority to negotiate prices for a select number of drugs or types of drugs, such as unique drugs that lack competitor products or therapeutic alternatives. This would include many of today's high-priced specialty drugs and biologics. But according to <u>CBO's assessment</u> of this approach in 2007, if only a small share of Medicare drug spending was attributable to the selected drugs, overall federal savings from price negotiations would be "modest" and manufacturers could offset potential losses by setting higher launch prices for their drugs. Although this approach was included as a provision of President Obama's proposed budgets for FY2016 and FY2017, neither the Office of Management and Budget (OMB) nor CBO scored any savings associated with this provision.¹⁰

Why has this idea resurfaced and what are its prospects?

With Medicare Part D prescription drug spending growth on the rise, and strong public support for policymakers to take action to ensure the affordability of medications, policy options to lower drug prices, including allowing Medicare to negotiate drug prices, are being mentioned by some policymakers in Congress and by President Trump. Other approaches not addressed here but also proposed as ways to control drug costs include: greater drug price transparency, modifying regulations to speed generic drugs and biosimilars to market, value-based purchasing, reference pricing, reducing drug companies' market exclusivity period, and extending the Medicaid drug price rebate to low-income Medicare Part D enrollees. According to CBO, the rebate proposal would achieve \$145 billion in savings to Medicare over a ten-year period (2017-2026).

Allowing Medicare to negotiate drug prices would require a change in the law, which means that bipartisan support would be needed for legislation to move forward in Congress. Although the President has endorsed the idea, Republican policymakers in Congress have historically been opposed to it. And there has been, and is still, strong resistance to this idea from the pharmaceutical industry. While the immediate prospects for this proposal and other prescription drug savings proposals are unclear, the issue of drug price affordability is likely to continue to weigh on the minds of consumers at the pharmacy counter.

Endnotes

¹ Kaiser Family Foundation analysis of National Health Expenditure Account data from the Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group, "Table 16, Retail Prescription Drugs Expenditures; Levels, Percent Change, and Percent Distribution, by Source of Funds: Selected Calendar Years 1970-2016."

- ³ Glenn Kessler, "Trump's truly absurd claim he would save \$300 billion a year on prescription drugs," *The Washington Post*, February 18, 2016, available at <a href="https://www.washingtonpost.com/news/fact-checker/wp/2016/02/18/trumps-truly-absurd-claim-he-would-save-300-billion-a-year-on-prescription-drugs/?utm_term=.349568ac59df; Robert Costa and Amy Goldstein, "Trump vows insurance for everybody in Obamacare replacement plan," *The Washington Post*, January 15, 2017, available at <a href="https://www.washingtonpost.com/politics/trump-vows-insurance-for-everybody-in-obamacare-replacement-plan/2017/01/15/5f2b1e18-db5d-11e6-ad42-f3375f271c9c_story.html?utm_term=.b50512b48739.
- ⁴ An example of this approach introduced in the 115th Congress is S.41/H.R.242, "Medicare Prescription Drug Price Negotiation Act of 2017," available at https://www.congress.gov/115/bills/hr242/BILLS-115hr242ih.pdf. https://www.congress.gov/115/bills/hr242/BILLS-115hr242ih.pdf.
- ⁵ An example of this approach introduced in the 114th Congress is S.1884/H.R.3261, "Medicare Prescription Drug Savings and Choice Act of 2013," available at https://www.congress.gov/114/bills/s1884/BILLS-114s1884is.pdf and https://www.congress.gov/114/bills/hr3261/BILLS-114hr3261ih.pdf.
- ⁶ For example, see the "Choose Medicare Act" introduced by Sen. Jeff Merkley (D-OR) and Sen. Chris Murphy (D-CT), available at https://www.murphy.senate.gov/download/medicare-bill.
- ⁷ A variation of this approach as proposed by Richard Frank and Joseph Newhouse would establish a system of binding arbitration between the federal government and pharmaceutical companies to determine a set of temporary administered prices for unique drugs, until such time when competitor products became available; see Richard Frank and Joe Newhouse, "Should Drug Prices Be Negotiated Under Part D of Medicare?" *Health Affairs* 2008; Richard Frank, "Prescription Drug Procurement and the Federal Budget," Kaiser Family Foundation, May 2012, available at http://kff.org/health-costs/issue-brief/prescription-drug-procurement-and-the-federal-budget/.
- ⁸ Congressional Budget Office, Letter to the Honorable William H. Frist, M.D., January 23, 2004, available at https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/fristletter.pdf. See also Congressional Budget Office, Letter to the Honorable Ron Wyden, April 10, 2007, available at https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/drugpricenegotiation.pdf.
- ⁹ The Center for Economic Policy Research produced an estimate of federal savings ranging from \$230 billion to \$541 billion over 10 years if Medicare paid the same prices as in selected other countries where prices are set administratively; drug prices in Canada and Denmark were used as benchmarks; see "Reducing Waste with an Efficient Medicare Prescription Drug Benefit," January 2013. A more recent paper estimated annual savings of around \$15 billion per year if Medicare paid the same prices as in Medicaid and the VA; see Carleton University/Public Citizen, "Mirror, Mirror on the Wall," July 2015.
- Office of Management and Budget, Budget of the United States Government, Fiscal Year 2017, Summary Tables, available at https://www.whitehouse.gov/sites/default/files/omb/budget/fy2017/assets/tables.pdf; and Fiscal Year 2016, Summary Tables, available at: https://www.gpo.gov/fdsys/pkg/BUDGET-2016-BUD/pdf/BUDGET-2016-BUD/edf/Budget. Congressional Budget Office, Proposals for Health Care Programs—CBO's Estimate of the President's Fiscal Year 2016 Budget, available at https://www.cbo.gov/publication/50013. The Congressional Budget Office has not yet released estimates for the President's Fiscal Year 2017 budget.

² 2017 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, June 2016, Table V.D1, available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2017.pdf.