The Complexities of Medicare Directly Negotiating Drug Prices

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KEY POINTS . . .

In response to higher drug spending growth and heightened attention to drug prices, some policymakers have proposed allowing Medicare to negotiate the price of prescription drugs, a proposal supported by a vast majority of the public.

The Congressional Budget Office has said that giving Medicare authority to negotiate lower prices for a broad set of drugs on behalf of Medicare beneficiaries would have "a negligible effect" on federal spending, but savings could be achieved potentially under a defined set of circumstances.

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.

Introduction

After many years of slow growth, prescription drug spending is on the rise, raising fiscal concerns for public and private payers and worries about affordability among consumers. For Medicare, which accounted for 29% of national retail pharmaceutical spending in 2015 [1], higher drug prices are putting increasing pressure on Medicare Part D program spending, along with enrollees' out-of-pocket costs. In response to higher drug spending growth and heightened attention to drug prices, some policymakers 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 prohibited explicitly from negotiating directly with drug manufacturers on behalf of Medicare Part D enrollees.

This article 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, and considers the prospects for action in the future [2].

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 more than a decade. In the years leading up to the enactment of the Medicare Part D prescription drug benefit in the Medicare Modernization Act (MMA) 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 rebates on 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 [3]." This is in stark contrast to how drug prices are determined in some other federal programs; (e.g., 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.)

Although 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 favored by the vast majority of Americans in 2006 [4]. 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, with a large number of brand-name drug patent expirations and growing use of generic drugs helping to keep drug spending in check.

Why the renewed interest in Medicare drug price negotiation?

Although drug-specific rebates are proprietary, data compiled by the Office of the Actuary at the Centers for Medicare & Medicaid Services and released in the annual Medicare Trustees report suggest that Part D plans have been negotiating steadily higher drug price rebates from pharmaceutical manufacturers overall since the program started in 2006, growing from 8.6% that year to an estimated 23.8% in 2017 (Figure 1). These estimates are >

Figure 1: Medicare drug plans have negotiated steadily higher manufacturer rebates since 2006

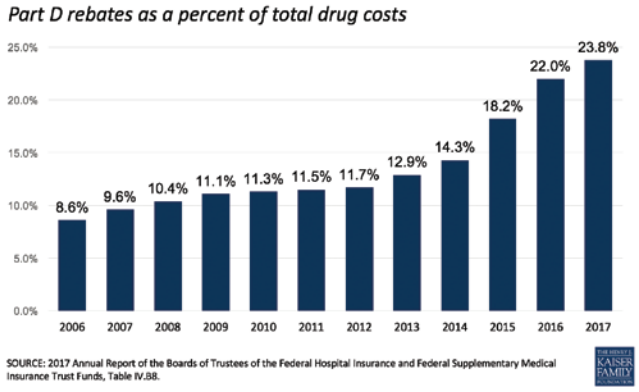
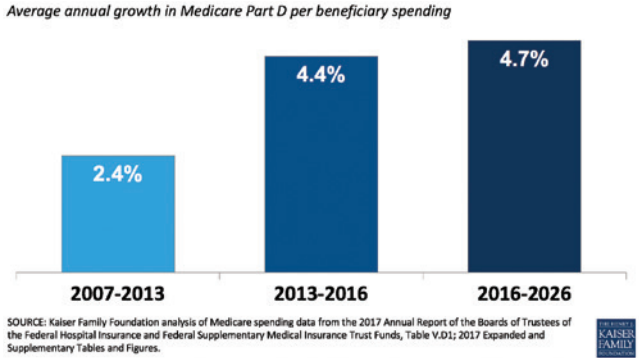


Figure 2: Spending on Medicare Part D prescription drug coverage is projected to grow faster in the coming years than in previous years



rebates as a % of total drug costs and are averaged across both brands and generics. Yet even as plans have negotiated higher average rebates, drug costs are on the rise, relative to historical spending trends. Average per capita costs in Part D are projected to increase annually by 4.7% between 2016 and 2026, faster than the 2.4% average annual rate of growth in per capita costs between 2007 (the program's first full year) and 2013 (the year before new hepatitis C treatments became widely available) [5] (Figure 2).

As further evidence that higher drug prices are putting increasing pressure on Medicare Part D program spending, spending on the reinsurance—or catastrophic—phase of the Part D benefit is the fastest growing segment of Part D spending (outside of beneficiary premiums). This is the benefit phase where, when beneficiaries' total costs exceed approximately $8000 in 2017, Medicare pays 80% of total costs, plans pay 15%, and enrollees pay 5%. Reinsurance spending is expected to grow from $35 billion out of $92 billion in Part D spending in 2016 (38%) to $81 billion out of $193 billion total in 2026 (42%) (Figure 3).

The recent increase in drug spending growth is in part due to spending on new specialty drugs, including breakthrough treatments for hepatitis C that came to market starting at the end of 2013 [6], along with fewer opportunities to control spending through greater use of generic drugs. Future drug spending projections are also linked to the greater availability of high-cost specialty drugs. These are often unique drugs lacking competitor products, so typically there is little room for private plans to negotiate rebates from pharmaceutical manufacturers.

Taking steps to reduce high drug prices has become a popular talking point among policymakers and resonates strongly with the public as a key pocketbook issue. The public is supportive of several ideas that would or could lower drug costs (Figure 4). Medicare drug price negotiation is at the top of the list, supported by a vast majority of Democrats (96%), Republicans (92%), and Independents (92%). President Trump has said he will "bring down drug prices" [7] and has repeatedly criticized the current law that prohibits the government from negotiating with pharmaceutical companies in an effort to lower drug prices in Part D and achieve federal savings [8]. He has also said, "We don't bid properly and we're going to start bidding [9]." In contrast, Republican Congressional leaders have not outlined specific proposals to reduce drug costs.

Figure 3: Spending on the "reinsurance" (catastrophic) phase of the Medicare Part D benefit is growing fastest

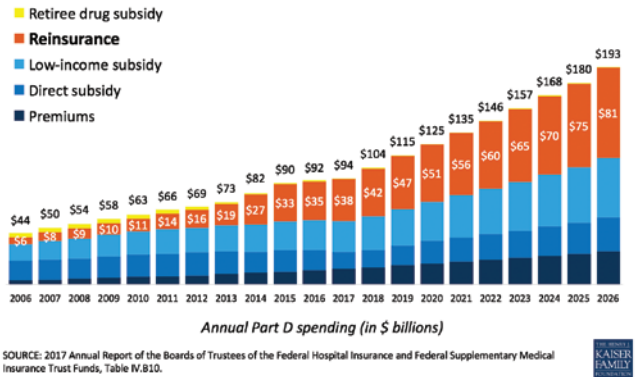
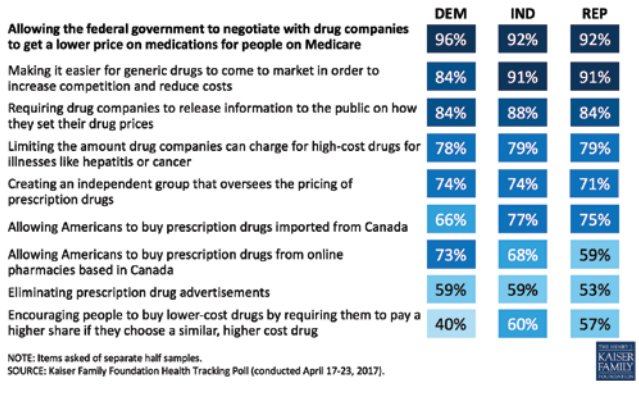


Figure 4: Most of the public favors actions to keep drug costs down; the vast majority support Medicare drug price negotiation



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. Proposals at the other end of the regulatory spectrum would establish a public Part D plan to operate alongside private Part D plans, administered by HHS under the oversight of the Secretary. Under this approach, the Secretary would establish a formulary for the public Part D plan and negotiate prices for drugs on that formulary.

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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 [10] 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. Essentially, the fallback is to 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 the Congressional Budget Office (CBO).

What has the CBO said about the potential for savings?

The CBO has said 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. [11]" This assessment is based 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.

The CBO has suggested that savings potentially could be achieved under a defined set of circumstances. For example, the Secretary would need authority to establish a formulary that included some drugs, excluded others, and imposed other utilization management restrictions, in much the same way that private Part D plans do. And yet, the 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." [12]

In addition, the CBO has suggested 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 [13]. However, according to the CBO's assessment 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.

What are the prospects for Medicare drug price negotiation?

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. Historically, Medicare drug price negotiation has been supported by Democrats and opposed by Republicans. Although President Trump has frequently stated his support for taking some type of action to lower drug prices, the Administration's proposed fiscal year 2018 budget includes no related proposals [14], and no other Republican has gone on record in support of this approach to lowering drug prices. In addition, there has been and is still strong resistance to this idea from the pharmaceutical industry. Yet while the immediate prospects for allowing Medicare to directly negotiate drug prices are unclear, the issue of drug price affordability is likely to continue to weigh on the minds of consumers at the pharmacy counter.

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Additional information:
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