

Insight

The Art of the Drug Deal

TARA O'NEILL HAYES | MAY 21, 2018

Executive Summary

Some contend that the federal government should negotiate drug prices directly to achieve lower prices for consumers, but this proposal has numerous flaws.

- The restriction on government negotiation only applies to Medicare Part D, in which the federal government does not insure anybody directly; rather, the private insurers negotiate on their enrollees' behalf. Allowing the government to negotiate would either lead to the elimination of plan choice in Part D or to no greater savings than already achieved by the private plans.
- Negotiating involves both parties trading one concession for another benefit, and the federal government
 can only obtain lower drug prices by restricting access to drugs made by a manufacturer's competitor.
 This strategy results in a restricted selection of drugs available to patients, and it will not work with
 monopoly manufacturers, who are the most likely to have high prices.
- Private insurers are much better positioned to negotiate for drug prices as well as use other innovative techniques to keep costs down.

The government has one tool that private insurers do not have: the ability to mandate price discounts. In the past, these mandates have created repercussions elsewhere in the market, and insofar as calls for "negotiation" really are calls for more price controls, this strategy will exacerbate existing problems.

Introduction

Calls for allowing the government to negotiate drug prices have become louder and more frequent over the past few years as more expensive drugs come to market and Americans struggle to afford them. Many advocates have focused on the government's inability to negotiate prices directly with drug manufacturers, and to these advocates' consternation, President Trump did not include such negotiations in his recent drug pricing "Blueprint".

Allowing the government to negotiate drug prices is no panacea, however; it has numerous weaknesses. It fails to account for the government's limited leverage, the necessary consequences of such negotiations, the limited effectiveness of such negotiation in certain circumstances, and the advantages that private insurers have.

The Government and Drug Pricing

The federal government and its programs have a complex relationship with drug pricing.

The prohibition on government negotiations only applies to the Medicare Part D program. Furthermore, negotiations with drug manufacturers do occur in Part D: They are conducted by the private insurers offering Part D plans (as detailed below).

In the other federal programs that cover prescription drugs for individuals, the government does not (except in rare circumstances) negotiate prices but rather sets ceiling prices based on specific formulas. In the case of Medicaid, the Veteran's Administration (VA), TRICARE, and other federal purchasers, these formulas are tied to the average price of those drugs in the commercial market. The law requires drug manufacturers to offer the government either the best price they offer to anyone else, or a rebate of up to 23 percent in Medicaid (plus an additional rebate if the price of the drug increases faster than inflation)[1] and at least 24 percent in the other federal programs—whichever provides the lowest price.[2] Drug manufacturers must agree to these terms for each of these programs, or their drugs will not be covered by any of them and they will lose access to approximately 90 million patients.

The government's approach to reimbursement for drugs covered by Medicare Part B—which are primarily physician-administered drugs, as opposed to self-administered drugs picked up at the pharmacy counter—is much different and completely devoid of any incentive or mandate to obtain lower prices.[3] Rather than requiring drug manufacturers to provide a steep discount, the government allows providers to purchase the drugs themselves (using whatever negotiating power they have to get the best price). Medicare then reimburses the provider an amount equal to the average sales price of the drug in the commercial market plus a 6 percent add-on administration fee. The Government Accountability Office, among others, has repeatedly noted the need to revise this Part B reimbursement formula due to the incentive it creates for providers to use more expensive drugs.[4] In fact, the president's Blueprint to reduce drug prices speaks to this exact problem and includes multiple proposals to address it.

To call any of these arrangements a "negotiation" would be incorrect. Negotiating drug prices, as in any negotiation, necessarily requires trade-offs: both parties must relinquish something of value to the other party (otherwise, it is not a negotiation, but rather a commandeering). The government can only effectively negotiate lower drug prices if it is willing to give up something in return. A company dependent on profits for existence will only be willing to trade lower prices (so long as the price stays sufficiently above the cost to produce) for increased quantities sold, in order to maintain its revenue. Thus, the government must be able to guarantee increased sales to the company offering the reduced price, which can only be done by restricting sales to other companies. In other words, the only way for the government to negotiate a lower price for one drug is by restricting access to its competitors.

Trade-offs

The government does occasionally use true negotiation, particularly in the VA. The VA will agree to buy a drug in a particular class exclusively from one manufacturer in exchange for an even greater discount than what is required by law. But as expected, the data demonstrate these negotiations result in significant access restrictions for veterans and the other individuals covered by the VA's formulary, and some beneficiaries may lose access to the only treatment option that works for them as a result.

A 2013 study by The Lewin Group analyzed coverage of the top 300 most commonly used prescription drugs in the United States. The study found that the two Medicare Part D plans with the highest enrollment cover 97 percent and 95 percent, respectively, while the VA covers only 78 percent of the most commonly used drugs.[5] A broader study that assessed VA access to all 4,300 drugs covered by Medicare found that the VA covered less than one-third of those drugs.[6]

Legislation recently introduced by Senators Murphy (D-CT) and Merkley (D-OR) recognizes the necessity of accepting trade-offs in order to negotiate drug prices. The legislation would expand Medicare by creating a public option that would be available for anyone to purchase.[7] Under this plan, the Secretary of Health and

Human Services would be authorized to negotiate prices directly with drug manufacturers. In order to do so, the legislation would also allow the secretary to impose a coverage formulary and drug utilization management tools, both of which would restrict access to certain drugs. In determining which drugs to include on the formulary, the secretary would have to consider the drug's current price, its launch price, the prevalence of disease and usage of the drug, the drug's approved indications, the number of similarly effective alternatives, the budgetary impact of covering the drug, evidence of the drug's safety and effectiveness, and the quality and quantity of the clinical data used in the Food and Drug Administration's approval process for the drug. These same factors would be used in deciding which drugs patients could access without any restrictions and those which patients could only access after exhausting other treatment options or receiving prior authorization, determined on a case-by-case basis.

These tools are precisely those already used by the many private insurers who offer Part D plans and commercial drug coverage in order to negotiate prices. The government would have no greater negotiating power than that of the insurers. In fact, the insurers are better suited to handle these negotiations on behalf of their patients, because insurers have both experience negotiating reimbursement rates as well as have actual patients enrolled in their plans. Those who believe the government would have greater negotiating abilities because they would be negotiating on behalf of *all* beneficiaries rather than a fraction of them, as the insurers are, forget that the government does not actually insure a single patient in Part D and thus has no real market access to bring to the negotiating table. As AAF highlighted in 2014, Part D's prices turned out to be lower than the price caps that were proposed as an amendment to the bill that started the program back in 2003.

The negotiating tactics used by private insurers highlight a central point in the problems with government negotiations: Negotiations work best in a market system when competition is present. Negotiating steeper discounts in exchange for exclusive coverage only works when a drug manufacturer faces competition, yet when manufacturers face competition, they already have incentives to reduce their price so as not to lose customers—making the negotiations themselves far less effective. When a manufacturer has no competition (and thus faces no real market pressure to lower the price), the government's only leverage is to deny the manufacturer any sales in that market. Of course, this is equally a threat to patients, as beneficiaries will lose access to the only treatment option that exists if an agreement is not reached; for many, this will be unacceptable. Therefore, the most effective tool for negotiating lower drug prices may be largely ineffective for the drugs that patients most need the price negotiated.

How the Government Could Negotiate Prices in Part D

There are essentially only two circumstances in which the government would have any leverage to negotiate prices effectively on behalf of Medicare beneficiaries, and they both require a radical change to the current Part D structure.

In the first circumstance, the government could negotiate on behalf of all beneficiaries, while still allowing them to enroll with private insurers. As a result of these negotiations, the drug prices would necessarily be equal for all beneficiaries, and the government would have to impose a national formulary with uniform rules and coverage restrictions.

This structure and the resulting restrictions would have a couple of negative consequences for individuals and the system as a whole. First, these restrictions would have negative consequences for all beneficiaries, but they would certainly hurt some more than others. As discussed, the VA uses this kind of negotiation, with sharp restrictions on which drugs beneficiaries can access. Further, current practices allow certain insurers to negotiate lower prices for certain drugs than other insurers. If the government killed all price variation by negotiating

directly, the only way for drug manufacturers to maintain current revenues (assuming no change in the quantity of drugs sold) would be to set a price somewhere between the current lowest and highest prices. Thus, beneficiaries currently enrolled in the plans that have negotiated the lowest prices would see price increases. Individuals with other forms of insurance would likely face price increases as well, as drug manufacturers would compensate for reduced prices in Medicare with higher prices elsewhere.

The federal government has tried imposing lower prices in Medicaid through the "best price" program and the 340B program, yet manufacturers simply recouped their money by raising prices elsewhere. After the "best price" program began, prices still rose—and rose most sharply for those drugs that Medicaid beneficiaries used the most.[8] The expansion of the 340B program, another program that mandates drug manufacturers provide steep discounts, is also correlated with increasing drug prices.[9] Mandating steeper discounts in Medicare would have a similar effect.

The second impact of government negotiation in this scenario is that there would be very little left for a private insurer to offer, and thus very few factors upon which insurers could compete against each other. Given that competition among insurers is the foundation of the Part D program's success, taking away such tools would completely undermine the program, and most if not all private insurers would leave. Today, seniors have 23 different plan options from which to choose, on average.[10] This provides enrollees the ability to find a plan well-suited to meet their specific needs, which is a primary reason the Part D program has long enjoyed a satisfaction rate of nearly 90 percent.[11] If seniors suddenly had only one option—the government-imposed plan—all the benefits of having so many choices would be eliminated.

In the second circumstance, the government would enroll patients directly in a public option available alongside other Part D plans. Yet, the government would still have no more leverage to negotiate prices than a private insurer who has enrolled just as many patients, as the Congressional Budget Office has noted on several occasions—unless, of course, it imposed the same requirement as that in the other government programs and threatened the loss of access to nearly half the nation's population. (Again, let's not confuse government coercion with negotiation.) Furthermore, private insurers, because of their financial risk, have much greater incentives than the government to utilize other tools that help improve patient health and indirectly lead to additional savings. The government does not have the same profit motive as private insurers, and that motive drives insurers to innovate more and negotiate well. A public option likely would not provide the same quality as private insurance plans over the long term.

Conclusion

In various federal programs, the government primarily obtains lower prices for prescription drugs than the commercial market by mandating them and threatening the loss of 90 million potential customers. These mandated discounts have resulted in increased prices paid by the rest of the health care market. When the government does truly negotiate with drug manufacturers for lower prices, it trades discounts for significantly fewer choices for patients.

- [1] https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html
- [2] http://research.policyarchive.org/3071.pdf
- [3] https://www.medicare.gov/coverage/prescription-drugs-outpatient.html

[4] https://www.gao.gov/products/GAO-15-442
[5] http://www.lewin.com/content/dam/Lewin/Resources/Site_Sections/Publications/PhRMAVAFormulary2013.pdf
[6] http://www.ncpathinktank.org/pub/ba575
[7] https://www.murphy.senate.gov/download/medicare-bill
[8] http://www.ncpathinktank.org/pub/ba575
[9] https://www.americanactionforum.org/research/340bmarketdistortions/
[10] https://www.kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-prescription-drug-plans-in-2018/
[11] https://www.hlc.org/news/new-national-survey-nearly-9-in-10-seniors-satisfied-with-medicare-part-d/