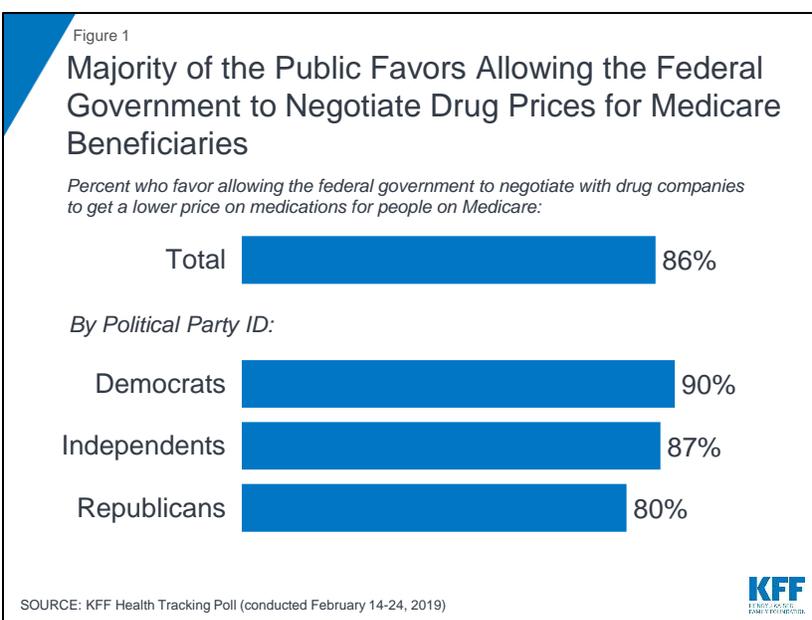


What's the Latest on Medicare Drug Price Negotiations?

Juliette Cubanski, Tricia Neuman, Sarah True, and Meredith Freed

Introduction

Prescription drug costs are a major concern for consumers and a fiscal challenge for public and private payers. In response, lawmakers are considering a broad range of policy options, including allowing the federal government to negotiate the price of prescription drugs on behalf of people enrolled in [Medicare Part D](#) drug plans, which is prohibited under current law. Members of the 116th Congress have introduced bills to change the law and allow government drug price negotiation—a change which is also supported by some 2020 presidential candidates—and House Speaker Nancy Pelosi is [reportedly working on a related proposal](#). Recent public opinion polls show [strong](#) and [bipartisan support](#) for allowing the federal government to negotiate drug prices in Medicare (Figure 1).



This issue brief begins with a brief description of the statutory prohibition on government negotiations and its history and reviews assessments made by the Congressional Budget Office (CBO) on the potential for government negotiations to achieve savings for Medicare and beneficiaries. The brief also describes the various legislative proposals introduced in the current Congressional session that would give the Health and Human Services Secretary authority to negotiate drug prices on behalf of Medicare beneficiaries.

A number of questions arise in evaluating proposals to allow the HHS Secretary to negotiate drug prices, such as: Would the Secretary negotiate prices for all drugs or a subset of drugs? What process would be used in settling on a negotiated price, and what would be the fallback if the negotiation process is unsuccessful? Would the negotiated price apply to Part D only or more broadly to other payers as well? How the various legislative proposals address these and other questions would have a significant effect on how many people could be affected and the magnitude of savings that could be achieved by Medicare drug price negotiation.

A brief history of Medicare drug price negotiation

Even before the Medicare Part D benefit took effect in 2006, some policymakers were proposing a change in law that would allow the Secretary of HHS to negotiate prescription drug prices with drug manufacturers on behalf of Medicare beneficiaries. The Medicare Modernization Act of 2003 (MMA), the law that established the Part D benefit, includes a provision, [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 direct role in negotiating or setting drug prices in Medicare Part D.

In the years leading up to passage of the MMA in 2003, lawmakers debated whether to add a prescription drug benefit directly to Medicare, similar to coverage of hospital and physician services, or whether the drug benefit should be provided through a marketplace of private plans that compete for business based on costs and coverage. The latter approach was adopted in the MMA, whereby Medicare contracts with private plan sponsors to provide a voluntary prescription drug benefit, and gives plans authority to negotiate drug prices with pharmaceutical companies, establish formularies, and apply utilization management tools to control costs. This approach contrasts with how drug prices are determined in some other federal programs, such as mandatory drug price rebates in Medicaid, and the use of [ceiling prices and minimum discounts](#), in conjunction with a national formulary, in the Department of Veterans Affairs (VA).

Since the enactment of the MMA, some lawmakers have continued to press for legislation that would give the Secretary of HHS authority to negotiate drug prices for Medicare beneficiaries. During the first several years of the Part D program, these proposals did not get much attention in Congress, both for philosophical reasons and because Part D benefit spending growth was relatively flat—and [lower than initially projected](#)—with a large number of brand-name drug patent expirations and growing use of generic drugs helping to keep drug spending in check.

In light of recent concerns about the high and rising price of medications, and with government actuaries projecting a more rapid rise in Medicare drug spending in the years to come, there is renewed interest in allowing the federal government to negotiate drug prices for Medicare Part D enrollees. This policy concept has also recently gained more attention in Congress because Democrats, who have historically been its strongest supporters, now hold a majority in the U.S. House of Representatives. Thus far, the Trump Administration has not proposed this change in law nor taken a position on the Congressional proposals to allow the government to negotiate drug prices, although the president did express support for the idea [prior to taking office](#). The Administration has promoted several other policies as part of a broader effort to reduce prescription drug spending.

Proponents of changing this law believe that giving the Secretary of HHS the authority to negotiate drug prices would provide the leverage needed to lower drug costs, particularly for high-priced drugs for which there are no competitors, where private plans may be less able to negotiate lower prices. Opponents counter that the current system of private plan negotiation is working well, and that government

involvement in price negotiations could dampen incentives for pharmaceutical companies to invest in research and development.

What has CBO said about the potential for savings from Medicare drug price negotiation?

In its initial assessments of the Medicare drug price negotiation concept [in 2004](#) and [2007](#), CBO concluded 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.” This conclusion was based on CBO’s 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 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.”

At the same time, CBO suggested that savings could potentially be achieved under a defined set of circumstances. For example, CBO 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. 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.

“Negotiation is likely to be effective only if it is accompanied by some source of pressure on drug manufacturers to secure price concessions. The authority to establish a formulary, set prices administratively, or take other regulatory action against firms failing to offer price reductions could give the Secretary the ability to obtain significant discounts in negotiations with drug companies”. [CBO, April 2007](#).

In addition, [CBO 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. This would include many of today’s high-priced specialty drugs and biologics. At the same time, based on CBO’s assessment of this approach, 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.

In its most recent assessment of the potential for savings from Medicare drug price negotiation in a [May 2019 letter](#) to Senator Chuck Grassley, CBO generally adhered to its previous conclusions: providing the Secretary with broad authority to negotiate without also exerting some form of pressure on drug manufacturers to lower their prices would likely produce negligible savings. According to CBO, “modest” cost savings could be generated by allowing the Secretary to negotiate prices for a targeted set of drugs, such as those with few substitutes and/or high prices. CBO affirmed its previous position that, in order to

achieve significant savings, the Secretary would have to exercise greater leverage over drug companies than now occurs with competing Medicare Part D plans, noting that “in the absence of such pressure, the Secretary’s ability to issue credible threats or take other actions in an effort to obtain significant discounts would be limited.”

To date, CBO has not provided cost estimates of recent legislation (described below) that would grant the Secretary additional authority to secure price concessions from drug manufacturers on behalf of beneficiaries enrolled in Medicare prescription drug plans.

What are the current approaches to allowing Medicare to negotiate drug prices?

Lawmakers in the 116th Congress have introduced a variety of bills to allow the federal government to negotiate drug prices in Medicare Part D, with the goal of lowering Part D program spending and enrollees’ out-of-pocket costs. Some are stand-alone bills, while others are incorporated in [broader legislation to expand health insurance coverage](#). While these bills seek to achieve the same overall goal of reducing drug prices by allowing the federal government to negotiate prices with drug manufacturers in Medicare, they take different approaches to achieve that end.

Some proposals simply strike the noninterference clause, with no additional legislative language, while others require the Secretary to negotiate drug prices on behalf of Medicare beneficiaries enrolled in Part D plans, but do not specify any further conditions for the negotiations.¹ Some proposals include more specific provisions that aim to achieve scorable savings, based on CBO’s conclusion that the Secretary would need some form of leverage to secure price concessions from drug manufacturers—for example, establishing criteria for which drugs would be subjected to negotiations, such as high-priced drugs for which there are no competitors, drugs that are especially expensive for Medicare beneficiaries, or drugs that have high annual cost increases,² or requiring the Secretary to establish a formulary that would be used in a public Part D plan operating alongside private plans, in a public Part D plan that would replace the current marketplace of private plans, or in all private Part D plans.³

In addition, some proposals include a mechanism to secure lower drug prices in the event that drug companies do not comply with the negotiation process or if the negotiations between the Secretary and drug manufacturers are unsuccessful. These mechanisms are discussed below.

Competitive Licensing

One [congressional proposal](#) would establish the authority of the Secretary to circumvent a manufacturer’s exclusivity rights and issue a competitive license to another manufacturer to produce a generic or biosimilar version of the drug for sale to Part D plans. Any manufacturer producing a drug under this licensing authority would need to provide “reasonable compensation” to the original manufacturer.

The authority to allow the HHS Secretary to issue competitive licenses for prescription drugs rests on existing federal power to exercise compulsory licensing authority encoded in 28 U.S.C. section 1498, a law establishing government immunity from patent claims in cases where infringement serves the public

good, while affirming the right of the patent holder to “reasonable compensation” in exchange.⁴ In the case of pharmaceuticals, if a drug remains under patent protection, the government can authorize production of an equivalent, lower-priced product provided the patent holder receives royalties from its sales.

Section 1498 has not been invoked for pharmaceutical products since the early 1970s. In 2001, former HHS Secretary Tommy Thompson considered invoking section 1498 in order to import generic versions of the antibiotic ciprofloxacin (brand name Cipro), in response to concerns about the potential for an anthrax epidemic at that time. Faced with a potential override of its exclusivity rights by the federal government, Bayer, Cipro’s manufacturer, agreed to offer the drug at a significantly reduced price. *(For additional details, see Appendix: Background on Competitive Licensing)*

Proponents say this approach would give the Secretary the leverage needed to secure price concessions in the negotiation process, because the mere threat of losing exclusivity rights may be sufficient motivation for drug manufacturers to offer reduced prices. Opponents counter that the threat of competitive licensing has the potential to stifle innovation, since drug makers might reduce investment in research and development if there is a chance that their patents might no longer be strictly enforced. The uncertainty of what constitutes “reasonable compensation” for the patent holder may also be a concern for manufacturers, especially since there is no established precedent in the pharmaceutical context.⁵ There may also be implementation challenges, including delays in the availability of competitively licensed products if another company lacks current capacity to manufacture an equivalent generic or biosimilar product.

Fallback Pricing

Some proposals use a fallback price as the default in the event of unsuccessful negotiations, such as the administered prices paid by other federal programs (the VA, for example), or prices paid for prescription drugs in certain OECD (Organization for Economic Cooperation and Development) countries.⁶

Proponents say that this approach would leverage the lower prices that the federal government is already able to obtain through other programs, or the lower prices that pharmaceutical companies are willing to offer in other countries. The potential reductions in Medicare Part D drug prices to levels in other federal programs or other countries could be large enough to induce drug companies to agree to more moderate price concessions. Opponents say that this approach could result in drug manufacturers setting higher launch prices for their products or changing their pricing strategy in other countries to offset potential price reductions. Moreover, because many drugs are first introduced in the U.S., there may not be an existing reference price from other OECD countries for certain prescription drugs. Other unknowns associated with international reference pricing relate to which countries’ prices would be used in setting the fallback price and whether to consider how prices are set in those countries. For example, drug prices in some other countries may be determined through an evaluation of comparative effectiveness, or value-based assessment—methods which are not currently in widespread use in the U.S.

Binding Arbitration

Another mechanism that could be used in the event of unsuccessful negotiations is to allow an independent arbitrator to set the final price of a drug, based on economic data and other information provided by the drug manufacturer, the Secretary, and independent experts.⁷

Germany's use of binding arbitration has been referenced as an example.⁸ In Germany, manufacturers set an initial price for new drugs entering the market that will apply for 12 months. The therapeutic value of a drug is evaluated within the first six months, and if the drug is found to have added therapeutic benefit, the manufacturer and government negotiate a new price. If the two parties cannot come to an agreement on the new price, they enter binding arbitration, whereby a five-person board votes on a new price which is binding for the following year. If the new drug is not found to have additional benefits compared with similar existing drugs, payment by insurers can be limited to the amount paid for the existing drugs.

Proponents argue that binding arbitration would provide sufficient pressure on drug manufacturers to reach agreement on a negotiated price because the binding arbitration process would give manufacturers less control over the final price of their drug. Opponents have raised concerns about the fairness of the process, as well as the potential for lower revenue to adversely impact investment in research and development. In addition, there are questions related to how the arbitration process would work, such as: what criteria would be used by the Secretary and drug companies to determine prices to put forth during the arbitration process; who would be the arbitrator; how to ensure neutrality in the arbitration process; whether the arbitrator would be required to set a price that is constrained by one of the two prices put forth by the Secretary and the manufacturer; and whether the arbitrator's decision would be subject to appeal.⁹

Financial Penalty

Another mechanism that is [reported to be under discussion](#) is to impose a financial penalty on drug companies that do not comply with the negotiations process or in the event that negotiations fail. This penalty could take the form of a tax on the prior year's sales of a given drug. This type of financial penalty could also be designed to deter drug companies from setting high list prices or taking large annual list price increases.¹⁰

What are the prospects for Medicare drug price negotiation?

With Medicare Part D prescription drug spending on the rise, and [strong public support](#) for policymakers to take action to ensure the affordability of medications, many policy options to lower drug prices are under consideration, including allowing Medicare to negotiate drug prices.¹¹ A number of policy questions arise in evaluating the various legislative proposals to give the HHS Secretary authority to negotiate drug prices in Part D, including:

- What sources of pressure, including financial incentives (or disincentives), would be used to motivate pharmaceutical companies to negotiate with the Secretary?
- Which drugs, and how many, would be subject to negotiation? If all drugs are not subject to price negotiation, what criteria would be used in choosing which drugs would be?
- What process would be used in settling on a negotiated price, and is there a fallback approach in place if the initial negotiation process is unsuccessful?
- Would the negotiated prices apply exclusively to Medicare Part D or more broadly to other payers as well?
- What infrastructure would be established to ensure that the Secretary has sufficient resources to conduct the required drug price negotiations?

To date, CBO has not published estimates of specific proposals introduced in the 116th Congress to allow Medicare drug price negotiation. Based on CBO's assessments, in order to achieve non-negligible savings from drug price negotiation, proposals would need to establish some source of pressure on drug manufacturers to grant steeper price concessions than they currently offer to Part D plans. Exactly how that pressure is applied would likely have significant implications for savings for Medicare and beneficiaries' out-of-pocket drug costs.

Because allowing Medicare to negotiate drug prices would require a change in the law, bipartisan support would be needed for legislation to move forward in Congress and be signed into law. Congressional Republicans have generally been opposed to allowing the Secretary to negotiate drug prices under Medicare, instead preferring the current market-based approach in Part D, and the pharmaceutical industry continues to express [its resistance](#) to this proposal. Congressional Democrats, who are generally supportive of government negotiations on drug prices, have yet to coalesce around any single legislative proposal. President Trump endorsed the idea prior to taking office, but it was not included in the Administration's [2018 blueprint](#) to lower drug prices nor in its proposed budgets to date, and the Administration has thus far not expressed support for current legislative proposals related to Medicare drug price negotiation.

While the immediate prospects for allowing the federal government to negotiate drug prices in Medicare are unclear, the strength of public support for this idea suggests that it will continue to have traction among policymakers in the near future.

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Appendix: Background on Competitive Licensing

Allowing the HHS Secretary to issue competitive licenses for prescription drugs, as has been [proposed recently](#), rests on existing Federal power to exercise compulsory licensing authority encoded in 28 U.S.C. section 1498, a law establishing government immunity from patent claims in cases where infringement serves the public good, while affirming the right of the patent holder to “reasonable compensation” in exchange.¹² In the case of pharmaceuticals, if a drug remains under patent protection, the government can authorize production of an equivalent, lower-priced product provided the patent holder receives royalties from its sales. Section 1498 has not been invoked for pharmaceutical products since the early 1970s, but has been used in other more recent cases, including one in 2009 when the U.S. Treasury exercised its authority under section 1498 to allow banks to use patented check fraud software, and another in 2014 when the Department of Defense invoked section 1498 to obtain patent-violating lead-free bullets.¹³

Section 1498 originates from a 1910 law waiving total government immunity from liability for patent infringement.¹⁴ Until the law was enacted, private patent holders had no legal recourse for government violation of exclusivity rights, and Congress sought to provide a partial remedy by allowing patent holders to pursue reasonable compensation. In other words, a patent holder cannot stop the government from producing (or authorizing the production of) a patented good, but can seek reasonable royalties when this occurs. The law conveyed the government’s willingness to issue just compensation for the appropriation of patented intellectual property while maintaining its sovereign immunity from liability for the same. A congressional report accompanying the bill clearly stipulated the need to maintain government power to override patent protections when necessary for the public good.

The 1910 law from which section 1498 originated was amended at various points between 1910 and 1942 in order to clarify the immunity of contractors and subcontractors acting on behalf of the government when the latter invokes section 1498 in order to produce a patented good or license its production. In amending the law, Congress also made clear that the government’s power to circumvent patent law could be utilized in cases of excessive pricing, and, in fact, section 1498 was invoked multiple times in the 1950s and 1960s in order to obtain reasonably priced generic drugs. Veterans Affairs and the Department of Defense routinely used section 1498 in the 1960s to obtain generic forms of U.S.-patented medications from overseas. Use of section 1498 for pharmaceuticals trailed off in the 1970s, which some attribute to the rising political influence of the drug industry during that time.¹⁵

In 2001, former HHS Secretary Tommy Thompson considered invoking section 1498 in order to import generic versions of the antibiotic ciprofloxacin, or Cipro, amidst pressure by some members of Congress and consumer advocacy groups due to the threat of an anthrax epidemic at that time. Faced with a potential override of its exclusivity rights by the federal government, Bayer, Cipro’s manufacturer, agreed to offer the drug at a significantly reduced price.¹⁶

Similarly, following the introduction of a group of hepatitis C drugs with high list prices in 2013 and 2014, it was suggested that the federal government should invoke its compulsory licensing power in order to more affordably procure this treatment for a larger number of Medicaid beneficiaries, prisoners, and uninsured individuals with hepatitis C for whom these drugs were unaffordable.¹⁷ In 2017, the Secretary of Health for the state of Louisiana urged the federal government to invoke its sovereign immunity under section 1498 in order to treat underserved populations with Hepatitis C.¹⁸ In order to qualify for hepatitis C treatment with these first-in-class curative drugs, individuals were required to demonstrate severe liver damage bordering on cirrhosis and imminent need for a transplant. The question of federal intervention into this matter has not been addressed by the current Administration.

Importantly, the government's compulsory licensing power under section 1498 differs from other patent "march-in rights" outlined in the Bayh-Dole Act of 1980. The latter applies to products invented with federal government support, allowing their patents to be held by private sector contractors in order to incentivize the use of federal research funds for private sector development.¹⁹ Under Bayh-Dole, the federal government may invoke "march-in rights" to authorize outside production of a patented good developed with federal funding in certain limited circumstances, including to address public health or safety concerns.

By contrast, section 1498 applies to all patented inventions, regardless of whether or not they were produced with federal funding. Further, march-in rights under Bayh-Dole can be requested by a private enterprise, whereas under section 1498, the federal government must initiate compulsory licensing by producing a product itself or requesting a contractor to do so. Lastly, when march-in rights are bestowed, the recipient must comply with established "reasonable terms" which may include royalties paid to the patent holder. Under section 1498, the patent holder obtains compensation from the licensee by initiating court proceedings.

Endnotes

¹ Some examples of this approach introduced in the 116th Congress are H.R.275, "Medicare Prescription Drug Price Negotiation Act of 2019," available at <https://www.congress.gov/116/bills/hr275/BILLS-116hr275ih.pdf>; S.62 "Empowering Medicare Seniors to Negotiate Drug Prices Act of 2019," available at <https://www.congress.gov/116/bills/s62/BILLS-116s62is.pdf>; S.470, "Medicare at 50 Act," available at <https://www.congress.gov/116/bills/s470/BILLS-116s470is.pdf>; and H.R. 1346, "Medicare Buy-In and Health Care Stabilization Act of 2019," available at <https://www.congress.gov/116/bills/hr1346/BILLS-116hr1346ih.pdf>

² An example of this approach introduced in the 116th Congress is S.99/H.R.448, "Medicare Drug Price Negotiation Act," available at <https://www.congress.gov/116/bills/s99/BILLS-116s99is.pdf> and <https://www.congress.gov/116/bills/hr448/BILLS-116hr448ih.pdf>

³ Some examples of these approaches introduced in the 116th Congress are S.3, "Keeping Health Insurance Affordable Act of 2019," available at <https://www.congress.gov/116/bills/s3/BILLS-116s3is.pdf>; S.99/H.R.448, "Medicare Drug Price Negotiation Act," available at <https://www.congress.gov/116/bills/s99/BILLS-116s99is.pdf> and <https://www.congress.gov/116/bills/hr448/BILLS-116hr448ih.pdf>; S.1129, "Medicare for All Act of 2019," available at: <https://www.congress.gov/116/bills/s1129/BILLS-116s1129is.pdf>

⁴ Kapczynski, A., and Kesselheim, A.S. 'Government patent use': A legal approach to reducing drug spending. *Health Affairs*, 35(5), 2016; Rizvi, Z., Kapczynski, A., and Kesselheim, A.S. "A simple way for the government to curb inflated drug prices." *The Washington Post*, May 12, 2016; Zaitchik, A. "How the government can bring down drug prices," *American Prospect*, June 29, 2017; Lee, J. "Can an obscure, 100-year-old patent law take on big pharma?" *Bloomberg*, May 21, 2018; "How the government can lower drug prices [Editorial]" *The New York Times*, June 20, 2018.

⁵ When the government authorizes compulsory licensing in other, non-pharmaceutical contexts, compensation to the patent holder is typically set at around 10 percent, however the uniqueness of the pharmaceutical market may challenge the adaptability of royalties applicable to other areas. See Kapczynski and Kesselheim, 2016.

⁶ An example of this approach introduced in the 116th Congress is S.99/H.R.448, "Medicare Drug Price Negotiation Act," available at <https://www.congress.gov/116/bills/s99/BILLS-116s99is.pdf> and <https://www.congress.gov/116/bills/hr448/BILLS-116hr448ih.pdf>

⁷ Binding arbitration is not included in any of the current Congressional proposals. 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/>. The Medicare Payment Advisory Commission (MedPAC) has also [suggested the use of binding arbitration](#) but their recommendations specifically relate to negotiation for Part B drugs, not Part D.

⁸ Martin Wenzl and Valérie Paris, "Pharmaceutical Reimbursement and Pricing in Germany," *OECD*, June 2018, available at <http://www.oecd.org/els/health-systems/Pharmaceutical-Reimbursement-and-Pricing-in-Germany.pdf>; See also James C. Robinson, Patricia Ex, and Dimitra Panteli, "Single-Payer Drug Pricing In A Multipayer Health System: Does Germany Offer A Model For The US?" *Health Affairs* blog, March 2019, available at <https://www.healthaffairs.org/doi/10.1377/hblog20190318.475434/full/>.

⁹ MedPAC outlines some considerations for structuring an arbitration process; see http://medpac.gov/docs/default-source/reports/jun17_ch2.pdf, page 61.

¹⁰ Another tax-related proposal that is not directly connected to Medicare drug price negotiation would be to impose a windfall profits tax on drug companies that charge list prices higher than an assessed price based on value; see Topher Spiro, "The Simple Solution to Lower Drug Prices for All Americans," Center for American Progress, June 2019, available at <https://www.americanprogress.org/issues/healthcare/news/2019/06/21/471344/simple-solution-lower-drug-prices-americans/>.

¹¹ [Other approaches](#) not addressed here but also proposed as ways to control drug costs include: greater drug price transparency, getting more generic drugs and biosimilars to market, reference pricing for Part B drugs, reducing drug

companies' market exclusivity period, establishing a new rebate under Part D when drug prices increase faster than inflation, and extending the Medicaid drug price rebate to low-income Part D enrollees.

¹² Kapczynski and Kesselheim, 2016; Rizvi, Kapczynski, and Kesselheim, 2016; Zaitchik, 2017; Lee, 2018; How the government can lower drug prices [Editorial]. *The New York Times*, June 20, 2018.

¹³ Kapczynski and Kesselheim, 2016; Zaitchik, 2017.

¹⁴ Brennan, H., Kapczynski, A., and Monahan, C.H. "A prescription for excessive drug pricing: Leveraging government patent use for health." *Yale Journal of Law and Technology*, 18(1), 275-354, 2017; Bruns, B.S. The Pharmaceutical Access Act: An administrative eminent domain solution to high drug prices. *California Law Review*, 106(6), 2023-2066, 2018; KEIWashDC. (2017, April 19). *Feb. 24, 2017 compulsory licensing workshop - panel discussion*, 28 U.S.C. 1498 [Video file], available at <http://www.youtube.com/watch?v=Za9RbL0jtds>.

¹⁵ How the government can lower drug prices [Editorial]. *The New York Times*, June 20, 2018.

¹⁶ Lee, 2018; How the government can lower drug prices [Editorial]. *The New York Times*, June 20, 2018.

¹⁷ Kapczynski and Kesselheim, 2016; Rizvi, Kapczynski, and Kesselheim, 2016; Zaitchik, 2017; Hepatitis C: Louisiana's plan to increase access to treatment [Amicus]. *Harvard Civil Rights-Liberties Law Review*, 2017.

¹⁸ Hepatitis C: Louisiana's plan to increase access to treatment [Amicus], 2017; Johnson, C.Y. "Louisiana considers radical step to counter high drug prices: Federal intervention." *The Washington Post*, July 3, 2017.

¹⁹ Thomas, J.R. *March-in rights under the Bayh-Dole Act*, CRS Report No. R44597, Congressional Research Service, 2016.