



Insight

Baseball, Arbitration, and Drug Prices

CHRISTOPHER HOLT | JUNE 27, 2019

EXECUTIVE SUMMARY

- Policymakers are considering arbitration as a potential solution to the challenge of high drug prices, although details remain ambiguous.
- Arbitration would represent a stark departure from the federal government's traditional posture toward pricing and markets, and it could stifle drug innovation and impede access to treatment.
- The potential application of arbitration to drug pricing raises a host of questions about how such a program would be implemented; for example, who would select the arbitrator, and what standards would govern the assessment of a reasonable price?

INTRODUCTION

In recent months, members of Congress and other policymakers have proposed arbitration as a solution to multiple policy challenges—including surprise out-of-network hospital charges. The area where arbitration could potentially have the largest impact, however, is drug prices. Proponents of applying arbitration to this area often pair it with changes to the Medicare statute that would allow the Secretary of Health and Human Services (HHS) to negotiate directly with drug companies over how much Medicare pays for pharmaceuticals. Arbitration would be a way of settling these negotiations if they end in a stalemate.

While the idea of some neutral party swooping in and settling issues of “out of control” drug spending might be appealing, such an approach would fundamentally reshape the federal government's relationship to the market. Depending on how arbitration is structured, it would either skirt or completely obliterate the idea that the federal government should not dictate prices for private sector goods because of either popular opinion or federal budget constraints. As a result, arbitration would be a significant departure from the federal government's approach to date. Indeed, at a very basic level, the government would determine the terms of any negotiation or arbitration process by virtue of setting the parameters of the policy and the standards to be used.

It is also important to recognize that such a shift would involve tradeoffs. Other countries that employ such approaches do not have timely access to the breadth of pharmacological breakthroughs that U.S. patients enjoy. [1] If the federal government were to take a more directed approach to managing drug spend, it would almost certainly lead to two types of access issues. The first is simply a question of whether manufacturers would continue to produce and sell targeted products at the government-established price. In other countries that dictate prices, manufacturers have answered this question negatively, leading to reduced access to treatments when compared with the United States. Second, policies aimed specifically at drugs with particularly high prices, or at restricting initial list prices, threaten to upend incentives for the most innovative new medical treatments, which often by their very nature are more expensive to develop and produce, and increasingly serve

small patient populations. Federal policymakers have historically been reticent actively to limit public program beneficiaries' access to the medications they and their doctors determine to be best.

In addition to these fundamental issues, there are myriad questions to be answered about how such a process would work.

BASIC STRUCTURAL QUESTIONS

The American Bar Association (ABA) defines arbitration as “a private process where disputing parties agree that one or several individuals can make a decision about the dispute after receiving evidence and hearing arguments.”^[2] In many ways, arbitration functions similarly to a civil trial. One key difference, however, is that arbitration can be either binding or non-binding depending on the parties' agreement. In binding arbitration, the parties are compelled to accept the decision of the arbitrator, whereas in non-binding arbitration neither party is mandated to agree to the resolution. Though state laws can vary, an arbitrator is typically chosen mutually by both parties to the conflict, often from a list provided by the state government, the ABA, or another similar entity.

While the idea of using arbitration to bring down federal drug spending is gaining attention, there is a dearth of fully developed policy proposals to evaluate. Several questions that emerge initially regard the basic structure and application of arbitration.

What Kind of Arbitration Would Be Used?

There are two distinct types of arbitration. Under conventional arbitration, the arbitrator has discretion in determining the settlement and will typically settle somewhere between the two competing proposals. It is generally accepted that this type of resolution incentivizes extreme positions from the parties. Arguably an arbitrator will need greater information or expertise in the field within which the dispute is occurring as they have greater discretion in determining the resolution.

In the context of drug pricing, advocates for an arbitration-based approach to determining prices have focused on final-offer arbitration—also known as “baseball” arbitration. In Major League Baseball, players that meet certain criteria are eligible for salary arbitration if they and their current team cannot agree on a new contract and they are not under contract for the upcoming season. If both parties are unable to come to terms by mid-January, each party puts forward what it believes to be a reasonable final offer, and an arbitration hearing is scheduled for a date in February. What is distinct about “baseball” or final-offer arbitration is that the arbitrator is limited to only the two proposals offered. The arbitrator is not free to determine what they deem an appropriate level of compensation; rather, they must choose which of the two offers is more appropriate.^[3] It is argued that this method of arbitration both incentivizes the two sides to reach an agreement prior to the arbitration date and to put forward more reasonable final offers so as to make their offer more appealing to the arbitrator. It is this kind of arbitration that would most likely be used, but the decision here would impact the character of negotiations over drug prices.

Would Arbitration Be Used for Medicare Part B Drugs?

While most prescription drugs are covered through the Medicare Part D program, drugs that are administered directly by a physician in an outpatient setting are covered by Medicare Part B. Under Part B, providers

purchase drugs directly from the manufacturer, and—with a few exceptions—Medicare reimburses them for the drugs they administer to beneficiaries at the average sale price of the drug plus a 6 percent add-on payment (ASP+6) intended to cover the provider’s services and any overhead.^[4]

The Medicare Payment Advisory Commission (MedPAC) has considered the idea of arbitration for high-cost Medicare Part B drugs, most recently in their June 2019 report to Congress.^[5] MedPAC also discussed arbitration previously as a part of their 2017 recommendation to establish a “Drug Value Program” (DVP) as an alternative to ASP+6.^[6] In both 2017 and 2019, MedPAC discussed arbitration as a way of addressing increasingly high launch prices. Specifically, MedPAC considered targeting a final-offer style mandatory arbitration arrangement for products with limited competition that launch at a price exceeding some (as-yet undetermined) threshold.

MedPAC did not, in either report, define “limited competition,” nor make specific recommendations for where the price threshold should be set. MedPAC did, however, comment on criteria that an arbitrator would use in choosing between the manufacturer- and government-recommended prices, suggesting comparative clinical effectiveness, prices of existing treatments, the prevalence of the condition being treated, production costs, and affordability.

Would Arbitration Be Used for Medicare Part D?

While many of the high-cost treatments currently roiling the health policy debate are covered by the Part B program, arbitration also comes up in the context of government price negotiation within the Part D program.

Medicare Part D was established as part of the Medicare Modernization Act of 2003 and extended Medicare coverage to prescription drugs dispensed by a pharmacy. Often proponents of government negotiation will lament the lack of negotiation in the Part D program, and progressives have long chafed under the law’s “noninterference” provision. The claim that there is no negotiation in Part D is inaccurate, however. Negotiations between drug plan sponsors, drug manufacturers, and pharmacy benefit managers (PBMs) are a hallmark of the program and have been one driver of the program’s low premiums. The noninterference provision simply blocks the Secretary of HHS from interfering in those negotiations.

Nevertheless, many policy experts and lawmakers on the left have advocated for the federal government to negotiate drug prices directly with manufacturers on behalf of all Medicare beneficiaries. For the HHS Secretary to drive steep discounts on behalf of all beneficiaries, one of two things would have to occur. Either the secretary would have to implement a single program-wide formulary—in effect eliminating all the choice beneficiaries currently have between different plans, thereby restricting their access to some medications—or the secretary would simply be using the power of the government to set prices for a privately produced good. In the former instance every coverage decision would become a political problem to be appealed directly to Congress, ultimately undermining the secretary’s ability to negotiate. In the later, the government would be abandoning any pretense of market capitalism.

Proponents of government negotiation recognize that, in the absence of either approach, the secretary would lack leverage to drive down prices, and that’s where arbitration comes in. Under this scenario, the secretary would seek to negotiate discounts on drugs for the Part D program, but if manufactures were unwilling to negotiate or if the government and manufacturers could not come to terms, the government could initiate a final-offer style arbitration process similar to what MedPAC has outlined for Part B.

Many proponents, including health economist Richard Frank of Harvard Medical School, recognize that negotiations and arbitration would be administratively complex.^[7] Therefore, most proposals suggest focusing on a subset of drugs. Like in the Part B case, the exact criteria are typically not spelled out, but a combination of price and competition are most commonly suggested as triggers. Some policymakers have floated an arbitrary number of drugs that HHS would be required to negotiate prices for each year, establishing a floor, though not a ceiling, with which HHS would need to comply.^[8]

IMPLEMENTATION QUESTIONS

Within these scenarios there remain myriad questions with dramatic implications for the ultimate outcome.

How Would the Arbitrator Be Chosen?

Would the arbitrator be mutually agreed upon by both the manufacturer and the government, or would the government be able to appoint any arbitrator it chooses? Frank has suggested that arbitrators be selected in consultation between industry, HHS, and the American Arbitration Association.^[9] News reports have indicated that the Part D arbitration proposal being developed by Speaker of the House Nancy Pelosi would designate the Government Accountability Office (GAO) as the arbitrator, after progressive members of the House Democratic Caucus objected to a neutral third party being selected.^[10] Under such a scenario, the government and a drug manufacturer would go to arbitration after failed price negotiations—with the government also serving as arbitrator. If it is the government deciding between the government-proposed price and the industry-proposed price, that scenario begins to look like thinly veiled government price setting. In both its 2017 recommendation and 2019 report, MedPAC argues that neutrality on the part of the arbitrator would be crucial. MedPAC did suggest a possible role for GAO in recommending a slate of potential arbitrators and giving both the secretary and the manufacturer the ability to strike a limited number of candidates, not unlike the process of jury selection in a trial.

What Drugs Would Be Eligible for Arbitration, and How Would It Be Triggered?

As briefly discussed above, there seems to be some consensus that the negotiation and arbitration route might be best utilized for a subset of drugs, as opposed to all medications (though any such limitation certainly has not been decided). The question then becomes, which drugs? Most focus has been on specialty drugs with limited competition, notably high prices, and a limited target patient population. Ultimately, however, it matters how these eligibility criteria are spelled out. What constitutes a high price? Would it be an arbitrary dollar amount for all drugs, or would clinical effectiveness, cost-benefit, and other factors be taken into account, leading to a more nuanced but also non-uniform trigger? Similarly, what would constitute limited competition for a particular drug? How many competitors is enough? How similar do the competitor products need to be? What if there are a number of competitors, but they are not all approved for exactly the same indications?

Assuming agreement on a set of criteria for making a drug eligible for arbitration, what would trigger the arbitration process? In MedPAC's 2017 proposal, arbitration would be triggered after a failure of negotiations between MedPAC's proposed Part B DVP vendors and a manufacturer. In its broader 2019 consideration of arbitration, MedPAC discussed empowering the HHS Secretary to initiate arbitration for drugs exceeding a certain price threshold and explored the possibility of bypassing direct negotiation altogether and simply moving directly to arbitration.

In the Part D program, arbitration would likely follow a stalemated negotiation between the secretary and a manufacturer. What would constitute a reasonable period for negotiation to be attempted prior to arbitration? Would either the government, the manufacturer, or both parties have to demonstrate a good faith effort was made at negotiation before moving to arbitration?

What About Proprietary Data?

A huge consideration—one not fully analyzed at this juncture of the debate—relates to manufacturers' proprietary data. What types of data would the government and manufacturer be required to submit to the arbitrator with their proposed payment rate? Would manufacturers be required to turn over proprietary data about manufacturing, R&D, advertising, and even compensation costs? What about internal documents surrounding decisions about the delivery mechanism for a drug and implications thereof for coverage under Part B or D, patent applications, or failure rates? What about pricing concessions and other private contract details of arrangements with other independent parties such as PBMs, employer-sponsored insurance plans, or other private market insurance plans? Would there be any restrictions on what the arbitrator can require from the manufacturer?

Further, once the data and documentation required is determined, who will have access to it before, during, and after the arbitration process? Will the government (in the form of HHS) be allowed access to this information, and will the government be able to modify its own bid based on this data? Will the arbitrator be allowed to bring in third-party experts, and will such experts have access to proprietary data? What limitations will be placed on future use of the data after the arbitration process is over? Will there be penalties associated with unallowed release of the data? And what if the arbitrator is, in fact, a government entity like GAO? What restrictions would there be on sharing of information between government entities? The issue of data and private contracts, and the degree to which those details would have to be shared with the government, is particularly problematic and could represent a concerning shift in the government's approach to private companies.

How Broadly Will the Arbitrated Price Be Applied?

So far, we've considered arbitration in the context of Medicare Parts B and D, but MedPAC has raised the possibility of arbitration-determined prices being applied in Part A, and it has even considered its possible implications for private insurance. In fact, some policymakers have suggested that government-negotiated Part D prices should be applied to the entire U.S. health care system—in effect implementing government price setting for private insurance as well as federal programs.^[11] Any policy implementing arbitration would need to explicitly state how broadly the arbitrated price applies.

Even if the arbitrated price is not imposed on the rest of the health care system, it would be important to consider what implications it would have on other agreements. Would prices rise elsewhere, in response to lower prices for the government? What spillover effects might occur in the private market? Further, for how long would the negotiated or arbitrated price apply? One year? In perpetuity? If it is the latter, would it be inflation adjusted? What about competing drugs? Would the price be applied to all drugs with similar indications? What about new competitors that enter the market after the price has been set? Finally, would the manufacturer be required to continue producing the drug for the price that had been set, or could it choose to discontinue the product if the price was too low?

THE IMPLICATIONS OF ARBITRATION

While the specifics of arbitration for Medicare drugs remain undetermined, a few implications are clear. First, it's important to recognize that countries that are aggressively prescriptive in their approaches to drug prices often lack access to many innovative therapies.

Second, this policy would reshape the federal government's relationship to the market and to its citizens. Depending on how arbitration is structured, it would either skirt or completely obliterate the idea that the federal government should not capriciously set prices for private sector goods because of either popular opinion or federal budget constraints. Some argue that the U.S. health care market is not much of a free market to begin with, and certainly that federal health programs operate outside of a traditional market dynamic. These assertions are to some degree true, but this policy would set a trajectory for other policies that is largely at odds with how the government understands and relates to markets. Do we believe that markets work generally, and that market forces lead to better outcomes? Or, aware of the flaws of markets, do we seek a command economy directed by government bureaucrats? The fact that the health care market is not a completely free market does not mean we should actively erode market forces. Government-directed arbitration would involve bureaucrats essentially making decisions about what the value of a prescription drug is for an entire class of patients, an approach that the United States has avoided to date.

Third, this policy would likely reduce revenue for pharmaceutical companies, which could impact the future development of life-saving drugs. Though it is out of style to mention it, drug development is a costly and risky proposition. The United States leads the world in the development of new therapies in part because we do not restrict prices based on government priorities. MedPAC argues in its June 2019 report that arbitration could have a positive effect on innovation by ensuring a process that rewards "products likely to have substantial added benefits over those with smaller added benefits."^[12] Of course the recipients of the benefit, who determines the value, and which metrics will be used remain open questions. Policymakers should consider how even moderate changes to Medicare payment policies may change the incentives for research into various therapies. If high launch prices are targeted indiscriminately, policymakers risk discouraging research into orphan diseases and curative treatments for diseases impacting small populations. Do we want new, life-altering therapies, or slightly improved versions of existing maintenance drugs?

THE CURRENT SITUATION

The current state of play on arbitration is unclear. While the idea has been gaining attention among some segments of the left, other progressives have derided arbitration as being insufficient to the challenge of high drug costs. Some policymakers would prefer more aggressive approaches, such as compulsory licensure, when direct government negotiations fail. These divisions have delayed the expected legislation that Speaker Pelosi is developing. At the same time, negotiations between the White House and House Democrats over a potential agreement on drug prices are either ongoing, close to an agreement, or completely collapsed depending on the day of the week.

Amid this flux and uncertainty, policymakers would do well to remember several things. An arbitration approach would bring many uncertainties to the drug market, as outlined here. Further, the private-market competition within the Part D program has worked quite well for over a decade, and repealing noninterference could undo Part D's success. Arbitration is being framed as a middle ground at the moment, but it is in fact a stark departure from the government's policy approach to pharmaceuticals to date. As such, it merits cautious

and thorough consideration.

- [1] <https://www.americanactionforum.org/comments-for-record/comments-to-cms-on-proposed-international-pricing-index-for-medicare-part-b-drugs/>
- [2] https://www.americanbar.org/groups/dispute_resolution/resources/DisputeResolutionProcesses/arbitration/
- [3] <http://m.mlb.com/glossary/transactions/salary-arbitration>
- [4] <https://www.americanactionforum.org/research/primer-medicare-part-b-drug-payment-system/>
- [5] http://www.medpac.gov/docs/default-source/reports/jun19_medpac_reporttocongress_sec.pdf?sfvrsn=0
- [6] http://medpac.gov/docs/default-source/reports/jun17_ch2.pdf
- [7] <https://nchc.org/3-r-frank-issues-in-drug-price-negotiation-using-binding-arbitration-3/>
- [8] <https://www.politico.com/story/2019/06/06/democrats-prescription-drug-prices-1497676>
- [9] <https://nchc.org/3-r-frank-issues-in-drug-price-negotiation-using-binding-arbitration-3/>
- [10] <https://www.politico.com/story/2019/06/06/democrats-prescription-drug-prices-1497676>
- [11] <https://www.politico.com/story/2019/06/06/democrats-prescription-drug-prices-1497676>
- [12] http://www.medpac.gov/docs/default-source/reports/jun19_medpac_reporttocongress_sec.pdf?sfvrsn=0