Understanding the Role of PBMs in the US Drug Pricing Debate

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Executive Summary

Pharmacy benefit managers (PBMs) exist to provide payers—that is, health insurance plans and large employers—with expertise and services related to prescription drugs. As intermediaries, they play a key role in the US prescription drug marketplace. PBMs have been shown to yield enormous value to the US healthcare system. But recent claims that PBMs are responsible for high drug prices have gained traction, in part due to concerted efforts by others in the supply chain.

This paper explains how and why PBMs function and provide value. It also draws lessons from past efforts to restrict PBMs in order to caution that targeting PBMs' incentives and ability to negotiate lower prices with manufacturers could result in higher total drug spending.

For example, a rule proposed in 2019 would have restricted one function that PBMs perform for their clients—negotiating confidential manufacturer rebates—in Medicare Part D and Medicaid Managed Care Organizations. The proposed rule was estimated to increase both Part D beneficiary premiums and Medicare spending and was ultimately blocked by Congress. But new policies have been proposed that limit PBMs' incentives and ability to negotiate and assume risk on behalf of their customers.

These proposals include mandating transparency from PBMs about aspects of their business, including rebates negotiated with drug manufacturers; "delinking" PBM compensation from list price—that is, prohibiting PBMs from charging fees based on the list price of a drug; and banning spread pricing (an arrangement that PBMs offer to mitigate clients' risk). Lawmakers putting forward these proposals seem to take as given that PBMs bear some blame for high drug prices. However, previous research and analyses have demonstrated otherwise. Indeed, PBMs have been shown to help control healthcare costs, making it unsurprising that some of the new proposals have been estimated to increase healthcare spending.

As Congress ostensibly works to lower drug prices, it has considered a range of policy proposals but seems fixated on PBMs. Ironically, it has at its fingertips the opportunity to pass meaningful policies that address drug prices. Brand drug manufacturers are known to use various tactics to block competition and maintain their monopoly power on lucrative drugs, including manipulating the regulatory system and using strategies known as patent thickets and product hopping. Several bills have been introduced in an attempt to address these tactics. But such legislative reforms have thus far failed to be enacted into law.

While bills that facilitate drug competition are likely to yield savings, those aimed at PBMs risk limiting the effectiveness of existing market-based mechanisms and increasing pharmaceutical spending. It is vital that lawmakers recognize and pursue effective strategies that promote competition and reject policies that could yield the opposite.

Introduction

Recent public opinion data from Pew Research Center (2023) found that the affordability of healthcare was second only to inflation as "a very big problem in the country today." Nearly two-thirds of those surveyed, including a majority of both Democrats and Republicans, agreed with this sentiment. Given voters' concerns about healthcare costs and the government's significant role in regulating and paying for healthcare services, lawmakers have been focused on bringing down healthcare costs, including spending on prescription drugs.

In particular, policymakers are incensed by high drug prices, and recent proposals reflect their attempts to address what they perceive to be the root of the problem. For example, the Inflation Reduction Act of 2022 empowers the Department of Health and Human Services (HHS) to negotiate prices directly with drug manufacturers in Medicare Part D. And members of Congress have introduced a variety of bills intended to target high drug prices, including some that would address tactics drugmakers use to unduly extend monopoly pricing.

While policymakers have proposed or enacted a range of reforms, these policies are not equally well-targeted or effective, and some may have the opposite of the intended effect. For example, proposals that promise to address drug prices by restricting the business practices of pharmacy benefit managers (PBMs) are misguided and may actually increase overall drug spending. Nevertheless, these types of proposals have persisted, in part because of concerted efforts by others in the supply chain to push the claim that PBMs are responsible for high drug prices.

Given the staying power of this claim, this paper returns to basics and explains how and why PBMs function and provide value in the pharmaceutical supply chain and the healthcare system. It also draws lessons from past efforts to restrict PBMs in order to caution that targeting PBMs' incentives and ability to negotiate lower prices with manufacturers could result in higher drug spending.

Targeting PBMs' incentives and ability to negotiate lower prices with manufacturers could result in higher drug spending.

PBMs' Role in the Pharmaceutical Supply Chain

PURPOSE AND VALUE OF PBMS

Private healthcare payers—that is, health insurance plans and large employers—typically cover prescription drugs for their members. This requires payers to design and manage their pharmacy benefits and affords them the opportunity to negotiate with drug manufacturers for lower prices in exchange for the promise of higher utilization of a product. It has become common practice for manufacturers to give price concessions (usually in the form of confidential rebates) for placement on a payer's formulary, which is a list of drugs associated with incentives to steer members to the most cost-effective among clinically appropriate options.

Given the burdens and complexities of managing a pharmacy benefit, most payers opt to hire a PBM, which also allows payers (and by extension their members) to benefit from the leverage in price negotiations that PBMs gain from representing multiple payers. But PBMs do not merely offer leverage. As one expert explained, "Creating value requires both scale and expertise. . . . PBMs use techniques and programmes that have been researched and reported in the peer-reviewed literature as being effective—that is, have demonstrated value," including evidence-based formulary design, strategies for reaching high-risk members, and retrospective analysis of drug utilization (*Lyles, 2017*). PBMs also provide data to customers and manufacturers and perform services related to pharmacy benefit claims, including processing member claims and reimbursing pharmacies for drug acquisition and dispensing costs.

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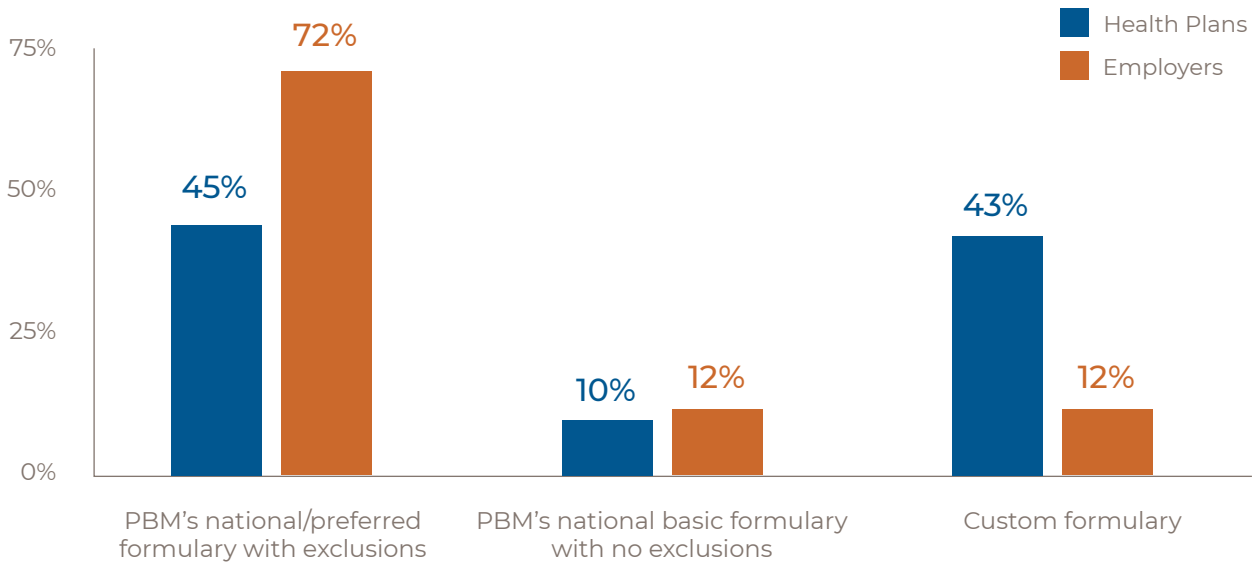
PBMs have been shown to yield enormous value to the US healthcare system. This value arises in the form of lower net prices and premiums, greater medication adherence, and incentives for pharmaceutical innovation, among others (*Mulligan, 2022*). PBMs generate an estimated $145 billion in societal value annually, compared to a market with no PBM services (*ibid.*). And this value is specific to PBMs—should plans perform PBM services themselves, they would lose an estimated 40 percent of the net value, or $58 billion (*ibid.*).

PBMS IN CONTEXT

Among the more than 300 million Americans with health insurance, 275 million have their prescription drug coverage managed by a PBM (*Visante, 2023a*). There are 73 PBMs operating in the United States (*Pharmaceutical Care Management Association, 2023*), with three (CVS Caremark, Express Scripts, and OptumRx) representing nearly 80 percent of the market (*Fein, 2023*).

FIGURE 1. PAYER FORMULARY PREFERENCES



Source: PSG (2023).

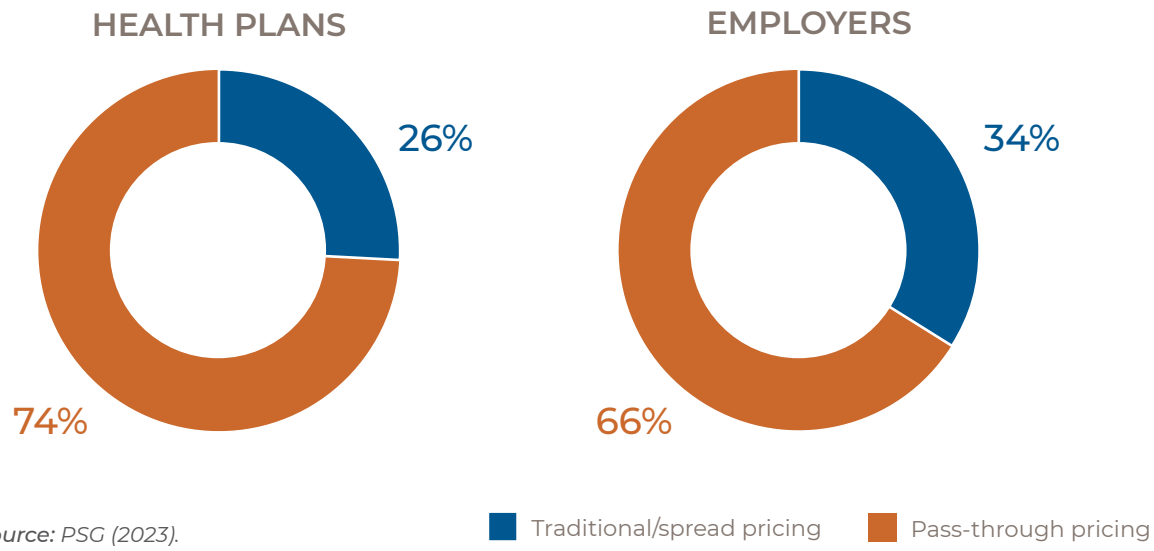
Given that PBMs exist to provide payers with expertise and services, it is important to understand not only PBMs but also their customers. Some payers choose to band together to negotiate PBM contracts. In a recent survey conducted by Pharmaceutical Strategies Group (PSG), 34 percent of health plans and large employers indicated that they participate in coalitions or collaboratives to negotiate PBM contracts (*PSG, 2023*).

The PSG survey covers a range of payer preferences for various arrangements with PBMs, including types of formularies, rebate-sharing, and pricing structures. The majority of employers (72 percent) opted for their PBM's national/preferred formulary with exclusions while health plans were evenly split (43 percent and 45 percent, respectively) between a custom formulary and their PBM's national/preferred formulary with exclusions (**see Figure 1**).

Payers also have different preferences for pharmacy reimbursement in their PBM contracts. Most employers and health plans (66 percent and 74 percent, respectively) prefer pass-through pricing, while a smaller share prefers traditional or "spread" pricing (**see Figure 2**). Under pass-through pricing, payers are responsible for actual pharmacy costs, while spread pricing involves a fixed payment per prescription from the payer to the PBM regardless of the terms the PBM ends up negotiating.

Payers who opt for spread pricing typically prefer predictability in their expenses and protection from unanticipated costs. According to the Chamber of Commerce (*2023*), "Risk-mitigation pricing (also referred to as spread-pricing) provides employers a definitive price for prescription drug benefit payments to pharmacies, and transfers the risks associated with daily fluctuations in drug prices onto the . . . PBM."

FIGURE 2. PAYER PRICING PREFERENCES

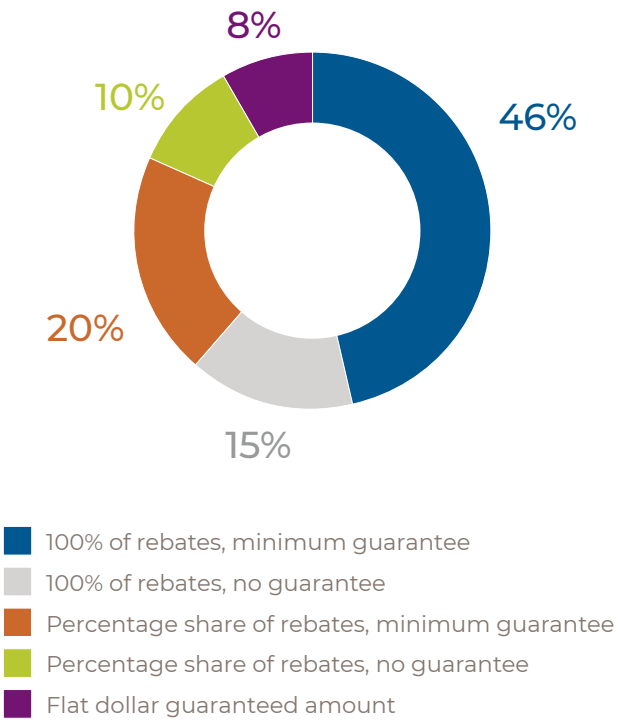


Source: PSG (2023).

Payers also have a variety of contract arrangements when it comes to rebates, ranging from a guaranteed flat dollar amount to 100 percent of rebates passed through from the PBM (**see Figure 3**). As Northwestern University economist Craig Garthwaite (*2022*) explains, "The split of the rebate between the PBM and the payer is dictated by a contract that is the result of a bilateral negotiation between those firms."

In short, PBMs work on behalf of their customers to develop drug coverage for patients with an eye toward keeping premiums affordable and helping manage risk, and their customers have a range of options when it comes to pharmacy benefit contracts. However, some on the outside have begun criticizing PBMs and their business practices. Specifically, drug manufacturers and pharmacists —and now many lawmakers—allege that PBMs leverage their position to encourage manufacturers to raise list prices and limit reimbursement to independent community pharmacists, among other criticisms. However, as Garthwaite (*2022*) notes, "Much of the furor at PBMs over increasing list prices, rebates, and cost sharing may be aimed at the wrong target."

FIGURE 3. REBATE PASS-THROUGH ARRANGEMENTS



Source: PSG (2023).

PROPOSED REFORMS AND PAST EFFORTS TO LIMIT PBMS

So far in 2023, Congress has held 11 hearings and introduced numerous bills to impose limits or new requirements on PBMs. State lawmakers have also introduced PBM legislation, ostensibly to address high drug prices. Proposals include mandating transparency from PBMs about aspects of their business, including rebates negotiated with drug manufacturers; "delinking" PBM compensation from list price—that is, prohibiting PBMs from charging fees based on the list price of a drug; and banning spread pricing (an arrangement, described above, that PBMs offer to mitigate clients' risk).

These proposals seem to take as given that PBMs bear some blame for high prices. However, previous research and analyses have demonstrated that PBM practices do not drive up drug prices.[1] To the contrary, PBMs have been shown to help control healthcare costs.[2] In fact, a recent effort to restrict one function that PBMs perform for their clients—negotiating confidential manufacturer rebates—would have resulted in an increase in both premiums and healthcare spending.

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LESSONS NOT LEARNED: THE REBATE RULE

This effort came in the form of a proposed rule, issued in February 2019 by the HHS Office of Inspector General (OIG), that would have restricted drug manufacturer rebates to PBMs and instead permitted point-of-sale discounts to beneficiaries in Medicare Part D and Medicaid Managed Care Organizations (*OIG, 2019a*).

In its analysis of the proposed rule's impact, the Centers for Medicare and Medicaid Services (CMS) Office of the Actuary (OACT) estimated that the rule would increase Part D beneficiary premiums and increase spending in Medicare by nearly $200 billion over a decade (*OACT, 2018*).[3] Importantly, OACT assumed that drug manufacturers would keep 15 percent of rebates they otherwise would have provided. In May 2019, the Congressional Budget Office (CBO) estimated that the proposed rule would increase federal spending by $177 billion over 10 years (*CBO, 2019*).[4]

In July 2019, President Trump withdrew the proposed rule but issued an Executive Order the following July instituting the same policy changes (*White House, 2020*).[5]

In 2022, Congress blocked implementation of the rule, but not before it gave an illuminating look at both the role of PBMs in lowering drug costs and a vision of what Medicare—and by extension the US healthcare system—might look like without PBMs. That is, a system with higher premiums, higher spending, and more revenue for drug manufacturers.

[1] *See, for example, Visante (2017) and Brill (2022).*

[2] *See, for example, Roehrig (2018), OIG (2019b), and Visante (2023b).*

[3] *HHS also hired two private actuarial firms (Wakely Consulting Group and Milliman Inc.) to analyze the proposed rule. Wakely estimated that CMS payments would increase and net out-of-pocket (OOP) expenses would be lower for 30 percent of non–low income beneficiaries and higher for 70 percent as a result of the proposed rule (Wakely, 2019). (The impact to low-income beneficiaries was negligible.) Milliman modeled multiple scenarios. In the scenario most closely resembling the OACT analysis, Milliman estimated that, over a decade, government spending would increase nearly $140 billion, beneficiary OOP expenses would increase more than $12 billion, and drug manufacturers would retain more than $17 billion (Milliman, 2019).*

[4] *See Brill (2019a) for a more thorough exploration of the consequences of the rebate rule.*

[5] *See Brill (2020a) for consideration of the Executive Order and government sources issued after April 2019.*

Indeed, a Government Accountability Office analysis in July 2019 found that PBMs kept only 0.4 percent of manufacturer rebates (*GAO, 2019*). And an OIG report in September 2019 determined that "rebates substantially reduced the growth in total Part D spending" during the period analyzed (2011–2015) (*OIG, 2019b*).

Studies have also shown that rebates are not correlated with increasing list prices (*Visante, 2017*) and that prices generally increase at comparable rates whether drugs are rebated or not (*Brill, 2022*). Despite the evidence, policymakers continue to believe the narrative about PBMs and have been persistent in their efforts to restrict PBMs' functions.

IMPACT OF PROPOSED REFORMS

Like the rebate rule, recent legislative proposals targeting other aspects of the PBM business model could have unintended negative outcomes for healthcare spending and premiums. As University of Chicago economist Casey Mulligan (*2023*) explains:

> Even if regulations succeeded at enhancing PBM competition . . . the net regulatory gains through the competition channel are at best small because PBM net revenues are dwarfed by the value they deliver clients and the industry overall. . . . A greater risk is that regulation stifles competition among PBMs and significantly reduces the value of benefit management.

The new proposals—including those aimed at transparency, delinking, and spread pricing—generally limit PBMs' ability to negotiate and assume risk on behalf of their customers. The result of this government interference in contracting arrangements would be a reduction in both customers' choices and PBMs' incentives to provide services.

In recent congressional testimony, Northwestern professor Craig Garthwaite (*2022*) cautioned:

> Some have proposed policies where PBMs are not allowed to have contracts in which they are compensated based on the size of the rebate or the list price of a product. While this would certainly eliminate any perverse incentives for large rebates, it would also diminish the incentives for PBMs to push for large discounts. If the primary motivation for such policies is an underlying concern about the competitiveness of the PBM market, eliminating the ability for firms to sign incentive compatible contracts could have meaningful unintended consequences.

Some of the consequences of these limitations have been quantified in terms of healthcare spending and other effects.

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Cost of PBM Transparency Mandate

According to the actuarial firm Milliman Inc., bills that mandate PBM transparency could result in drug manufacturers offering fewer price concessions. Using OACT's prediction that manufacturers would keep 15 percent of rebates when rebates are not confidential, Milliman (*2023*) estimates that PBM disclosure bills could increase federal healthcare spending by 10 percent ($134 billion) over a decade.

Similarly, Mulligan (*2023*) estimates the cost of transparency mandates and finds that they would result in increased premiums of $10.2 billion–$13.3 billion annually; increased net costs in the supply chain of $1.9 billion–$3.4 billion annually; and increased external effects (nondrug health costs, tax distortions, and foregone innovation) of $4.6 billion–$5.7 billion per year.

Addressing High Drug Prices

While Congress remains fixated on PBMs, it has at its fingertips the opportunity to pass meaningful policies that address drug prices. Brand drug manufacturers are known to use various tactics to block competition and maintain their monopoly power on lucrative drugs, including manipulating the regulatory system and using strategies known as patent thickets and product hopping (*Brill, 2019b*).

A patent thicket comprises follow-on patents to the original patent filed for the purpose of making it difficult for competitors to enter the market when the original patent expires. These secondary patents are incidental to the product patents and cover areas like formulation, indication, dosage, and route of administration (*Brill and Robinson, 2021*). The most well-known example of this misuse of the patent system is Humira, the top-selling drug in the world that faced competition for the first time this year after being shielded for 20 years by more than 100 patents.

Patent thickets cost the healthcare system billions of dollars. Estimated lost savings from patent thickets around five drugs totaled $7.6 billion from 2012 to 2018 (*Biosimilars Council, 2019*). Another analysis estimates a one-year cost ranging from $1.8 billion to $7.6 billion for drugs with patent thickets shielding them from competition (*Brill and Robinson, 2023*).

Product hopping also drives use of high-priced drugs. This term describes brand drug manufacturers' strategy of waiting until the end of a product's exclusivity on the market to introduce a modified version of the product that has remaining exclusivity. The drugmaker then works to move patients to the new product, thereby protecting market share from competition. Product hopping was estimated to have a one-year cost of $4.7 billion for five products (*Brill, 2020b*).

Senators have written to the Food and Drug Administration and the Patent and Trademark Office about their concerns over brand drugmakers' anticompetitive practices. Several bills, including the Affordable Prescriptions for Patients Act of 2023, have been introduced in an attempt to address these tactics. CBO (*2022*) estimated that an earlier version of this bill would save $836 million over 10 years. But thus far there has been no definitive legislative action.

While Congress remains fixated on PBMs, it has at its fingertips the opportunity to pass meaningful policies that address drug prices.

Conclusion

PBMs exist to provide payers with expertise and services related to prescription drugs. These intermediaries play a key role in the US prescription drug marketplace, providing data insights to customers; utilizing clinical expertise to design formularies; leveraging their scale to constrain aggregate spending on pharmaceuticals; and facilitating the terms and cost-sharing responsibilities between patients, payers, drug manufacturers, and pharmacies.

As Congress ostensibly works to lower drug prices, it has considered a range of policy proposals but seems fixated on PBMs. Well-targeted proposals would facilitate drug competition—for example, by ending drugmakers' anticompetitive tactics like patent thickets and product hopping. But proposals aimed at PBMs—such as delinking or a ban on spread pricing—do nothing to address drug prices. In fact, they risk limiting the effectiveness of existing market-based mechanisms and increasing pharmaceutical spending. It is vital that lawmakers recognize and pursue effective strategies that promote competition and reject policies that could yield the opposite.

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