Addressing High Drug Prices by Reforming Pharmacy Benefit Managers

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Abstract: Recently, Congress has focused on reforms to address pharmacy benefit managers' (PBMs) role in high drug prices for patients. Congress must not excessively restrict PBMs' ability to negotiate with manufacturers; alternatively, reforms could be paired with other policies that address the high prices of brand-name drugs.

Excessive prices for brand-name prescription drugs in the U.S. harm patients. One in four U.S. adults reports having difficulty affording their medications, and three in ten report not picking up prescriptions or skipping doses due to high cost.[1] Even among those with insurance, patients frequently owe high out-of-pocket costs that limit access to essential medications. Patients with higher out-of-pocket costs are less likely to pick up prescriptions for new medications[2] and are less likely to stay on medications for chronic diseases like diabetes and cardiovascular disease.[3] When patients cannot afford prescription medications to control symptoms or treat or prevent disease, their health suffers.

In 2022, Congress passed several major policies to address the high costs of prescription drugs as part of the Inflation Reduction Act. These policies included allowing Medicare to negotiate drug prices for some drugs, adding penalties for drug manufacturers for raising prices on existing medications, and lowering out-of-pocket costs for those with Medicare Part D prescription drug coverage.[4]

On the heels of this momentous policy achievement, in 2023, several Congressional committees have turned their attention to the role that pharmacy benefit managers (PBMs) play in high drug costs for patients. Several different reforms are being considered, many of which have bipartisan support.[5] To contextualize these reform efforts, this review explores the role of PBMs in the U.S. pharmaceutical market, identifies how PBMs might contribute to high drug costs, and makes recommendations about how to optimally tailor policies to address the key problems with PBM business practices.

Origins of High Drug Prices

In the U.S., new brand-name drugs are granted patents and other statutory protections that prevent direct competition from generic and biosimilar manufacturers during periods of market exclusivity. Often, companies add layers of additional patents that prevent competition for longer than anticipated.[6] These periods of protection against competition typically last 12–17 years,[7] during which drug companies are free to set and raise prices at will.[8] As a result of this dynamic, prices for brand-name drugs have skyrocketed. The median launch price for newly marketed brand-name drugs has been increasing by approximately 20% per year, from $2,115 per year in 2008 to $180,007 per year in 2021.[9] After drugs are introduced, manufacturers frequently have hiked prices each year above the

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rate of inflation, without any evidence that the drugs are becoming safer or more effective. These price increases averaged 4.5% per year from 2007 to 2018.[10] For example, the price of adalimumab (Humira), an anti-inflammatory medication used to treat rheumatoid arthritis and several other conditions, increased by 470% from 2003 to 2021.[11]

Compared with the U.S., other developed countries have far more sensible policies for regulating brand-name drug prices. Most countries systematically evaluate new drugs, negotiate fair prices that are aligned with drugs' benefits to patients, and have mechanisms to lower prices over time.[12] As a result, average prices for brand-name drugs are twice as high in U.S., compared to peer countries.[13] For the first time, the Inflation Reduction Act of 2022 will allow Medicare to begin negotiating prices for certain drugs with substantial Medicare spending. This policy is a landmark achievement, although the scope is limited; manufacturers will still be free to set prices for at least nine years after FDA approval, and negotiated prices will only apply to Medicare, not the many Americans with private insurance plans.[14]

Currently, the most important strategy for controlling high drug prices in the U.S. is ensuring timely generic competition after market exclusivity periods expire. Effective generic competition can lower prices by 80% or more.[15] This direct competition is effective because states allow pharmacists to automatically substitute generics in place of the brand-name drug.[16] Generics account for 97% of prescriptions among drugs for which they are available.[17] Generic competition saved the U.S. health care system an estimated $8.8 billion in 2017 alone.[18]

Brand-name manufacturers have developed numerous strategies to delay generic competition and extend their periods of monopoly protection.[19] For example, companies protect their drugs with thickets of patents related to the manufacturing, formulation, and use of the drug; generic drug makers must dispute these patents, and the resulting litigation can delay generic market entry. In other cases, brand-name drug makers introduce and heavily market slightly modified versions of their drug with additional patent protection, just before the original drug nears the end of its exclusivity period; this strategy is known as product hopping.[20] In one example, the drug maker Teva introduced a new version of the multiple sclerosis medication glatiramer acetate (Copaxone) that could be injected three times weekly instead of once a day; this maneuver delayed effective generic competition by more than two years, costing $4–6 billion in additional health care spending in the U.S.[21]

Congress could expand the Medicare negotiation provisions in the Inflation Reduction Act to include drugs closer to the date of approval and expand these negotiated prices to protect those with private insurance. They could also promote greater scrutiny of pharmaceutical patents granted by the U.S. Patent and Trademark Office to prevent drug companies from obtaining dozens of irrelevant patents to extend their market exclusivities. Congress could also encourage the U.S. Federal Trade Commission to investigate and prosecute anti-competitive behaviors that delay competition and result in higher prices for consumers.

The most important policies Congress can enact to lower prescription drug costs are those that address high brand-name drug prices set by manufacturers and encourage timely generic competition. For example, Congress could expand the Medicare negotiation provisions in the Inflation Reduction Act to include drugs closer to the date of approval and expand these negotiated prices to protect those with private insurance. They could also promote greater scrutiny of pharmaceutical patents granted by the U.S. Patent and Trademark Office to prevent drug companies from obtaining dozens of irrelevant patents to extend their market exclusivities. Congress could also encourage the U.S. Federal Trade Commission to investigate and prosecute anti-competitive behaviors that delay competition and result in higher prices for consumers.

The Role of Pharmacy Benefit Managers

To manage their prescription drug plans, most health insurers in the U.S. contract with pharmacy benefit managers (PBMs). To control spending, PBMs typi-

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cally create a tiered formulary and impose utilization management rules to steer patients toward lower-cost medications and away from more expensive ones. Tiered formularies mean that patients pay lower out-of-pocket costs for drugs on preferred tiers. In 2022, 84% of workers with private insurance had pharmacy coverage with three or more tiers, and average copayments ranged from $11 in the lowest tier to $116 in the fourth tier.[22]

In addition to tiered formularies, another cost-containment strategy used by PBMs involves limiting access to expensive medications with utilization management tools. One such tool is prior authorization, which requires insurance approval before a medication can be covered. A recent study found that two out of three new brand-name drugs had a prior authorization requirement by at least one of the eight largest health insurers administering Medicare Part D plans, and 40% of these prior authorizations imposed requirements that were more strict than the FDA-approved labeling.[23] Another utilization management tool, called step therapy, requires patients to try a less expensive medication before a more expensive medication is covered.

Tiered formularies and utilization management tools can be frustrating for clinicians and patients, particularly when they prevent or delay the use of medications that are appropriate and aligned with evidence and standard clinical practice. Prior authorizations can be burdensome and time-consuming, adding to already busy clinical practices, and variations in these policies among plans can be confusing and difficult to navigate. By one estimate, physicians devote $27 billion worth of time each year navigating utilization management tools.[24]

Although these formulary management strategies are frustrating and costly, they are currently essential tools used by PBMs and health plans to negotiate lower prices from drug manufacturers. Brand-name drug manufacturers rely on adequate coverage by PBMs and insurers for patients to be able to access and use their expensive medications. As a result, PBMs can sometimes negotiate discounts from manufacturers in exchange for preferred formulary placement.

This negotiation process means that patients who need expensive medications sometimes face high out-of-pocket costs or restricted access. For legislators, it can be tempting to enact rules that protect patients from this process, such as capping out-of-pocket costs or preventing step therapy restrictions. However, enacting such policies will inevitably impede PBMs' abilities to negotiate discounts, thereby resulting in higher net spending on some medications. As a result, any such policies must be accompanied by other policies that address high prices set by drug manufacturers.

Problems with Rebates

Although negotiation by PBMs is an important strategy for combating the rising prices set by drug manufacturers, the negotiation process does not always ensure that medications are affordable for patients. Rather than directly negotiating for lower drug prices, PBMs traditionally negotiate rebates that are paid retrospectively by drug manufacturers after the point-of-sale.[25] Most of these rebates are passed on to the plan sponsor, and can be used to lower premiums or provide more generous pharmacy benefits, such as lower cost-sharing or broader coverage. However, PBMs are not transparent about the size of these rebates and can have business arrangements with insurers in which they are able to keep a portion of the rebates they negotiate as their own profit.

Additionally, rebates do not directly lower the out-of-pocket costs for patients using expensive medications; these costs are based on list prices set by manufacturers, even in cases when PBMs have negotiated substantial rebates. This is particularly true when plans require patients to pay deductibles (i.e., paying the full cost of medications up to a threshold) or coinsurance (i.e., a percentage of a drug's cost). In a study of commercially insured patients using one of 79 brand-name drugs, 58% paid coinsurance or deductibles; for these patients, their out-of-pocket costs increased when manufacturers raised drug prices.[26]

In the past few years, increasing rebates negotiated by PBMs have partially offset the striking growth in manufacturer list prices. This has resulted in a widening gap between the list prices set by manufacturers and the net prices paid by health insurers after rebates. In Medicare Part D, for example, the share of brand-name drug spending offset by rebates and other discounts increased from 25% in 2014 to 37% in 2018.[27] The ability of PBMs to negotiate rebates varies widely by drug. For brand-name drugs for which there are multiple competitors in the same therapeutic class, PBMs can negotiate steep discounts by offering preferred formulary position to only one drug in the medication class. For example, many insulin products have average rebates exceeding 60%.[28]

In some cases, however, PBMs have limited leverage to negotiate rebates. This can occur either when a drug lacks therapeutic alternatives, or when federal or state law requires insurance companies to cover the drug. For example, Medicare Part D plans are required to cover all medications that fall into six

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protected classes, which limits plans' ability to negotiate rebates for drugs in these classes.[29] One of the protected classes is cancer drugs, which had Medicare Part D rebates averaging less than 10% in 2021.[30]

There is also variation in the ability of PBMs to negotiate rebates. For example, in Colorado, average rebates negotiated by commercial insurers in 2018 ranged from 2% to 27% of gross prescription drug spending.[31] Presumably, this is because PBMs have greater leverage to negotiate rebates when they contract with larger insurers with greater market share.

Given the growth of rebates in recent years, it is reasonable for Congress to seek to protect patients from the widening gap between the list prices set by drug manufacturers and the net post-rebate prices paid by insurers. For example, Congress could prohibit PBMs and insurers from tying patient out-of-pocket costs to pre-rebate manufacturer list price. Such a policy would protect patients and likely would result in lower out-of-pocket costs for some brand-name drugs; however, insurers may need to raise premiums to pay for this more generous coverage. At the very least, Congress could require PBMs to pass the rebates they receive along to the insurance plan sponsor so that rebates can be used to lower premiums and offer more generous prescription drug coverage, although the benefits to patients from such a policy would be less direct.

Concerns about PBM business practices

While there are dozens of PBMs, the three largest — Express Scripts, CVS Caremark, and Optum — control approximately 80% of the market.[32] This consolidation has raised concern among regulators and legislators. However, PBMs argue that their large market share affords them greater leverage to negotiate lower drug prices from manufacturers. In other words, consolidation by PBMs may not be inherently problematic, and, in fact, could help lower drug costs by providing a greater counterweight to pharmaceutical industry market power.

Beyond general concerns about consolidation, however, two legitimate concerns have been raised about the way PBMs conduct business. The first centers around how PBMs contract with health plan sponsors. In some cases, PBMs use a strategy called spread pricing, in which they charge plan sponsors more than they pay pharmacies, allowing the PBM to pocket the difference. This pricing model misaligns financial incentives, allowing PBMs to profit from higher reimbursed prices. If the spread is large, patients may also end up overpaying for medications. In an infamous example, PBMs charged Ohio's Medicaid managed care organizations a "spread" of 31% for generic drugs, which amounted to $208 million of excess spending in one year.[33]

A second problem is that PBMs have become more vertically consolidated. Each of the major PBMs has now merged with or is operated by a health insurance company.[34] Perhaps more concerningly, the major PBMs each own or are affiliated with their own mail-order and specialty pharmacies, and some with retail pharmacies. Increasingly, PBMs are steering patients to purchase drugs at these PBM-owned pharmacies. This practice raises concerns about conflict of interest; PBMs are supposed to negotiate the lowest prices possible for health plans and consumers, but PBM-owned pharmacies profit from high reimbursement by health insurers that exceeds the cost of acquiring medications from wholesalers or manufacturers. The problems with this vertical consolidation seem to be particularly pronounced among specialty pharmacies. In a recent analysis of Florida's Medicaid managed care plans, the five largest specialty pharmacies — all of which were owned by or affiliated with PBMs — accounted for 0.4% of dispensed claims but 28% of prescription drug profits in 2018.[35]

These two issues — spread pricing and vertical consolidation — may be leading PBMs to overcharge patients and health plans for some medications. The problem seems particularly prominent for generic drugs, for which competition by multiple generic manufacturers is supposed to result in lower prices for patients. Evidence for this has come from comparing average generic drug prices in Medicare Part D with prices for the same drugs at two pharmacies that sell generic medications directly to patients. Medicare Part D plans could have saved more than $3 billion on 108 generic drugs by paying the prices available from the Mark Cuban Cost Plus Drug Company.[34] Similarly, Part D plans could have saved more than 20% on 184 common generics by purchasing these drugs at Costco pharmacy prices.[36] These two examples highlight the problem of overpayment for generics. However, it is unreasonable to expect patients to shop around at multiple retail pharmacies to find the best prices for generic medications; PBMs should be doing this work on patients' behalf.

One notorious example is the cancer medication imatinib (Gleevec), used to treat chronic lymphocytic leukemia. After the brand-name version's market exclusivity ended in 2016, three generic competitors entered the market. By the end of 2017, however, the average prices paid by commercial insurers had only fallen 10%, far less than expected based on that degree of competition.[37] Medicare Part D plans paid an average of $2500 for a 90-day supply of generic

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imatinib; in 2023, the Mark Cuban Cost Plus Drug Company began selling a generic version of imatinib for 20 times less, with a current price of under $100 per 90-day supply.[38]

This degree of overpayment for generic drugs has fueled calls for PBM reform. Congress could take actions to expose and regulate these practices to ensure that patients are not being over-charged for generic medications. For example, Congress could prohibit PBMs from engaging in spread pricing or collecting fees that depend on the prices of medications.[39] Congress could also ask the Government Accountability Office to investigate the impact of vertical consolidation between PBMs and pharmacies, and require PBMs to disclose markups on medications that are filled at PBM-owned pharmacies.

It is important to remember that even with these problems, generics account for only 20% of U.S. prescription drug spending, despite representing more than 90% of filled prescriptions.[40] As a result, policies that target these PBM practices will not lower spending as much as policies that address high manufacturer prices for brand-name drugs.

Conclusions

Lowering drug costs is a high priority for U.S. patients. In Congress, following passage of major reforms in the Inflation Reduction Act of 2022, attention has now focused on the role of PBMs, the middlemen that negotiate lower drug prices from manufacturers on behalf of insurers and consumers. There are several PBM business practices that contribute to high costs for consumers, such as negotiating confidential rebates that do not lower the out-of-pocket costs for patients who use expensive medications, contracting with insurers in ways that link PBM profits with list prices, and vertical consolidation between PBMs and pharmacies that affects competition.

To address these concerns, Congress could prohibit PBMs and insurers from charging patients out-of-pocket costs based on the list prices of medications, regulate and monitor the contracts between PBMs and insurers to ensure that these arrangements do not raise prices for patients, and support investigations into how vertical consolidation between PBMs and pharmacies may be impeding competition. However, any policies targeting PBMs must consider the potential unintended consequences from restricting the leverage PBMs have to negotiate lower prices from drug manufacturers. If members of Congress are serious about lowering drug costs for Americans, PBM reforms should be paired with additional policies that tackle the root cause of the problem: high brand-name drug prices set by drug manufacturers.

Note

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