TheZetemaProject

What Would be the Impact of Eliminating Drug Rebates?

Key Takeaways

Rebates are cash payments sent back by pharmaceutical manufacturers to PBMs for specific drugs after purchase, of which PBMs then share a portion with the plan sponsor they serve

Drug rebates are currently protected by safe harbor protections that define them as “discounts” and exempt them from federal anti-kickback laws governing Medicare Part D plans and Medicaid managed-care organizations

The contractual terms of rebates are trade secrets, but research has shown that they are mainly used for high-cost, brand-name drugs in cases where there are interchangeable drugs within a therapeutic class

The lack of transparency and flow of cash within the drug supply chain, and rebates in particular, can create price distortions

There are five major stakeholder groups in the drug supply chain impacted by rebates: (1): pharmaceutical manufacturers; (2) PBMs; (3) payers and plan sponsors; (4) wholesalers and pharmacies; and (5) patients

Rebate savings go from drug manufacturers to PBMs, which take a cut and then pass them on to payers and plan sponsors. However, these entities generally use the savings to lower premiums for their customers, rather than passing on the discount to patients at the point of sale.

There is virtual consensus that the elimination of rebates would raise premiums, but plenty of debate regarding whether, by how much, and for which patients costs for drugs would drop

The elimination of rebates as a reform would shift costs and create financial winners and losers, but there is disagreement regarding what this would look like and what the time frame might be for change to be realized

TheZetemaProject

Regardless of how costs might shift, most experts don't believe that eliminating drug rebates will reduce overall drug costs

Introduction

Pharmaceutical rebate dynamics are poorly understood by the general public, many policymakers, and even experts in the healthcare field. Yet the business practice of rebates has come under increased scrutiny in the last year, with administrative action proposed and competing reactions from policymakers, private sector stakeholders, and experts filtering into the public policy debate. This background paper will define and describe the role of drug rebates upon the pharmaceutical supply chain and explore the debate around what the elimination of rebates might mean for the various participants in the drug supply chain.

The Trump Administration's Proposal

"The current rebate-based system rewards higher list prices, enriches middlemen and drives up patients' costs. We are taking action to encourage the industry to shift away from the opaque rebate system and provide true discounts to patients at the point of sale."

- HHS Secretary Alex Azar

In January, the Trump Administration proposed a rule change that would eliminate pharmaceutical rebates in the Medicare and Medicaid managed care markets by January 1, 2020. The proposal would force pharmacy benefit managers (PBMs) and drug makers to deduct any discounts offered from the *list price* of drugs, i.e., the figure that patients' drug copayments are based upon. The idea is to pass money onto patients at the pharmacy counter, departing from the status quo, where rebates are often absorbed by the system to lower health insurance premiums and support plan administration. Rebates for government programs are currently exempt from federal anti-kickback laws; that would change under the new proposal.

Reactions to the proposal were mixed and created some unlikely bedfellows. PBMs, health insurers, and some Democratic lawmakers argued that the move would raise insurance premiums with no guarantees that drug prices would actually drop. Drug manufacturers

were more bullish on the proposal, arguing that it would lower patient costs, create transparency, and demonstrate that they were not responsible - or not wholly responsible - for patients' high drug prices. Patient advocates for specific diseases, such as diabetes and cancer, hailed the proposal as lowering drug costs for chronically ill patients in need of drugs on a regular basis. Financial analysts and policy experts cast doubt upon the timeline of the changes, saying that it is unlikely to be fully implemented by the beginning of 2020.

Whatever the reaction, the administration's move has created increased attention upon and scrutiny of the pharmaceutical rebates.

Drug Rebates: A Primer

Broadly speaking, a **rebate** involves a manufacturer or seller returning a portion of the purchase price of a product to the buyer, creating an overall cost reduction for the product. The original purchase price is known as the **list price**; the total cost to the buyer after the rebate is known as the **net price**. Rebates are not exclusive to the healthcare world: Automobile companies, electronics manufacturers, and other producers and sellers employ rebates as well to incentivize sales of a particular product. What distinguishes prescription drug rebates from other rebates is the complexity of the pharmaceutical supply chain, the opacity of the rebate process, and the ways in which the funds are absorbed or passed through the system.

GLOSSARY OF TERMS

Rebate: a price reduction for specific drugs offered by manufacturers to pharmacy benefit managers, which then share a portion with the health insurer they serve.
List Price: The original purchase price of a product
Net Price: The total cost to the buyer after the rebate
PBM: A third-party administrator of prescription drug programs
Safe Harbor Protections: An exclusion to liability under the Federal anti-kickback statute, allowing rebates to be paid by drug makers to PBMs as "discounts"

Drug rebates are generally paid by a pharmaceutical manufacturer to a pharmacy benefit manager (**PBM**), a third-party administrator of prescription drug programs. Rebates are

also occasionally made by pharmaceutical manufacturers to wholesalers or pharmacies, or by pharmacies to PBMs or payers. But in large part, rebates are best understood as a price reduction for specific drugs offered by manufacturers to PBMs, which then share a portion with the payer or plan sponsor they serve. Drug rebates are fully legal and are currently protected by **safe harbor protections** that define them as “discounts” and exempt them from federal anti-kickback laws governing Medicare Part D plans and Medicaid managed-care organizations.

The specific terms of rebate contracts are trade secrets not available to the public or policymakers. Yet studies have estimated that drug makers pay $89 billion annually in rebates split across private health plans ($23 billion), Medicare Part D plans ($31 billion), Medicaid ($32 billion), and other payers ($3 billion), creating a total 21 percent difference between the total list price and total net price of drugs in the US [1]. Rebates are used mainly for high-cost, brand-name drugs [2]. They are found most often in cases where there are interchangeable drugs within a therapeutic class, as the price reduction is intended to make the products more attractive to the PBMs and payers. Additionally, the drug companies strike deals for their rebated products to be included within their formulary with preferred tier placement, making the copayment for the manufacturer's drug smaller than those of similar medications, increasing consumer demand for that drug. Yet patients’ copayments for prescribed medications are generally based upon the formulary tier of a drug, not the net price. This can lead to price distortions, where the patient’s cost is lower for a more expensive drug than its less expensive counterpart, as is demonstrated in the below table.

TheZetemaProject

Hypothetical Case of Rebates Distorting the Market

Drugs in a similar therapeutic class	**List price**	**Rebate**	**Net Price to PBM**	**Formulary Tier**	**Patient co-pay**
Drug A (with rebate contract)	$200	$150	$50	2nd (preferred)	$25
Drug B (without rebate contract)	$150	$0	$150	3rd (non-preferred)	$50

There are five major stakeholder groups affected by rebates:

(1) pharmaceutical manufacturers;

(2) PBMs;

(3) payers and plan sponsors;

(4) wholesalers and pharmacies; and

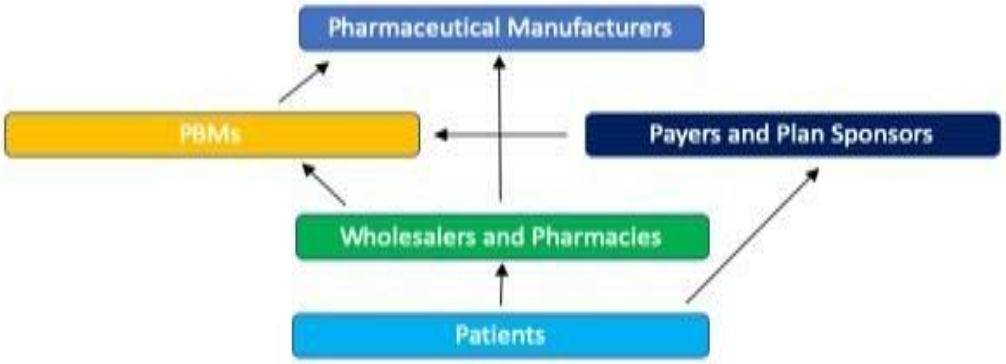
(5) patients.

Below is a diagram of the ways these stakeholders interact in terms of product flow, payment flow and rebate flow:

TheZetemaProject

Product Flow

Payment Flow



Rebate Flow

As the above chart notes, the savings from rebates are passed from drug manufacturers to PBMs, which take a cut and then pass on the reduced costs to payers and plan sponsors. However, these entities generally use the savings to lower health insurance premiums for their members, rather than passing on the discount to the patient at the point of sale. This results in lower costs for patients as a cohort in their premiums, but little to no reduction for the more specific patients purchasing the rebated drugs. Were rebates to be eliminated, the payers and plan sponsors argue, premium costs would increase for all, with little guarantee that list prices would go down.

This dynamic is particularly true in government markets. In Medicare Part D, rebates are shared between the Medicare Part D plans and the government. Rebates lower the Part D plan's overall costs, yet they do not affect patient cost sharing, which can be as high as 50 percent for non-preferred prescription drugs. HHS predicts a 14 to 19 percent increase in Medicare Part D premiums if rebates were to be eliminated, though the agency also believes that systemic adaptations to the new rule would mean lower premium increases over time [3]. Whatever the exact figure, there is consensus that Part D premiums would rise. There is debate over whether or by how much patients would benefit at the point of sale were rebates to be removed, and if this benefit outweighs the burden of increased premiums.

A Post-Rebate World: Who Wins and Loses?

Pharmaceutical Manufacturers

Though there is some debate regarding what the elimination of rebates would mean for drug makers, it would vary greatly by company. Generics could become even more attractive than branded drugs in the same therapeutic class without rebates to reduce the price differential and facilitate favorable formulary status. Some smaller drug makers may find the shake-up more troubling, depending on specific market dynamics. One financial analyst predicted that "There are small companies that will go out of business were [the administration's proposal] to be implemented."

The picture is significantly rosier for larger and more diversified drug companies. At least at first, the elimination of rebates as a whole would mean a tremendous financial windfall for them, as drug makers currently pay approximately $89 billion a year for them [1]. With net costs plummeting for manufacturers without rebates, the question then becomes: By how much and how soon will list prices be lowered, either through discounts or through downward competitive pressure in a more transparent free market? Pharmaceutical manufacturers tend to say that list prices will drop immediately given the newly more transparent market environment. Financial analysts predict that - at the very least - there will be a multi-year lag between the end of rebates and major changes to list prices. PBMs suspect that drug manufacturers will simply pocket the money they formerly spent on rebates to increase their profits.

The pharmaceutical industry supports the administration's proposal, which probably would increase industry profits. CMS's Office of the Actuary (OACT) modeled the proposed rule's effect on Medicare Part D. OACT concludes that drug manufacturers would retain 15 percent of the rebate payments they currently send to PBMs, spending the remaining 85 percent between lower list prices (21 percent) and point-of-sale discounts (64 percent) [4]. Yet that 15 percent that the drug makers would "keep" equals approximately $4.65 billion annually, given the Altarum estimate of $31 billion spent on rebates for Part D [1]. And this analysis does not include the $32 billion Medicaid rebate space or the $23 billion commercial rebate marketplace that would be eliminated in a post-rebate world.

> "PBMs negotiate on behalf of consumers, and are able to keep a lid on overall costs for prescription drugs with market-based tools that encourage competition among drug makers and drugstores, and incentivize consumers to take the most cost-effective and clinically appropriate medication,"
>
> - The Pharmaceutical Care Management Association, the PBMs industry's trade group

Pharmacy Benefit Managers (PBMs)

It's unclear exactly how eliminate of rebates would affect PBMs, though they are strongly opposed to the potential change. While PBMs indisputably profit from drug rebates, the degree to which this is true is not well known due to contract secrecy. PBM executives claim that they reward themselves little for negotiating

rebates, with the Pharmaceutical Care Management Association, the trade association representing PBMs, stating that "Typically, PBMs pass along more than 90 percent" of rebate savings to payers and plan sponsors [5]. Still, 10 percent of an $89 billion annual market is significant.

Yet it is also important to remember that PBMs serve critical functions beyond the rebate system. PBMs are responsible for developing and maintaining drug formularies, contracting with pharmacies, and handling the administrative processing and paying of prescription drug claims. PBMs are tasked with maintaining or reducing the pharmacy expenditures of their payer and plan sponsor customers while concurrently trying to improve healthcare outcomes for members. None of these roles go away in a post-rebate world.

However, PBMs vociferously oppose eliminating rebates. They claim that, while they have been vilified as "self-serving middlemen," what they give in value to their payer and plan sponsor customers far exceeds their costs. Many also state that the focus on rebates is a distraction, as 90 percent of US prescriptions are for generics and thus do not qualify for rebates. PBM executives are emphatic that rebates do not significantly benefit *their* bottom lines, particularly in the Medicare Part D space [6]. Yet if this is the case, why are PBMs opposed to eliminating rebates?

The answer PBMs give is two-fold. First, the absence of rebate value they are able to pass onto payers and plan sponsors would raise premiums dramatically. The elimination of rebates in Medicare Part D would raise premiums (which currently average at $33 monthly) by about 25 percent, according to one PBM expert. HHS predicts a more modest increase in Part D premiums, from 14 to 19 percent, and likely much lower than that due to expected changes the system will make in response to the implementation of the administration's proposal [3]. Nevertheless, there is consensus that Part D premiums, as well as commercial premiums, would rise in a post-rebate world.

The second point PBMs make is that - as the clients of millions of aggregated businesses and other payers and plan sponsors - they are the only entities with enough leverage to keep net drug prices lower than drug makers would like. PCMA said in a statement "These

rebates are used by payers to reduce premiums and out-of-pocket costs for patients. Getting rid of rebates would leave patients and payers, including Medicaid and Medicare, at the mercy of drug manufacturer pricing strategies" [7]. This position was echoed by House Speaker Nancy Pelosi, who stated “Under the Trump Administration's proposal, Big Pharma could see even bigger profits and even less restraint on what they charge seniors” [8].

Yet it is clear that PBMs are feeling pushed toward reform, with pressure to return more of the rebates they achieve to patients at the point of sale. The below case study examines a recent move by UnitedHealthcare and OptumRx to do just that.

CASE STUDY: UnitedHealthcare to Pass On Rebate Saving to Patients in the Commercial Market

UnitedHealthcare opposes the administration’s proposal to eliminate rebates from the Medicare Part D market, stating that it would dramatically raise premiums for older people. Yet the health insurance giant, in partnership with its sibling PBM company OptumRx (both companies are owned by UnitedHealth Group), have taken steps to push rebate savings directly to patients at the pharmacy counter in the commercial market. In 2018, the companies implemented a point-of-sale discount for fully-insured members, lowering out-of-pocket costs for patients filling prescriptions for branded drugs by an average of $130 per eligible prescription. More than five million members are potentially eligible for these discounts. Furthermore, the companies in March announced that all new employer-sponsored plans must participate in this program beginning in January 2020.

OptumRx CEO and Zetema Project Panelist John Prince testified before the Senate Subcommittee on Finance, “We have heeded the call for change by taking direct action to ensure that the discounts we obtain directly lower consumers’ out-of-pocket costs at the pharmacy counter.” Other experts call the move political. Max Nisen, a Bloomberg opinion columnist, wrote that the move “smartly preempts Trump administration efforts to reform rebates, and shows that the industry can make needed changes ahead of pushes for an even bigger government-led overhaul of the way they do business.” Whatever the impetus, it is clear that industry is beginning to take steps within the commercial market to pass on net savings to patients making drug purchases.

Payers and Plan Sponsors

Payers and plan sponsors are broadly defined here as those who pay for health insurance that covers patients' drug costs. They include health plans, employers, unions, and government programs. These entities are largely opposed to the removal of rebates and arguably have the most to lose were rebates to be eliminated. Payers and plan sponsors use the money saved by rebates to subsidize their premiums. Already under fire for their high rates, it is clear that - in a post-rebate world - premiums would rise dramatically, both for Medicare Part D plans and in the private commercial marketplace.

America's Health Insurance Plans (AHIP), the national association whose members provide coverage for health care and related services, has come out fighting against the administration's proposal. It claims that this policy will starkly raise premiums and inflate government spending. Matt Eyles, president and CEO of AHIP, stated, "…the focus on rebates has been a distraction from the real issue – the problem is the price."

Payers and plan sponsors have allied themselves with PBMs to defend the existing rebate system, claiming that savings lost from rebates will end up boosting profits for drug makers rather than reaching patients. AHIP released its own projections based on CMS's Office of the Actuary (OACT) work described above, but instead of using the 15 percent figure that the OACT predicts pharmaceutical manufacturers will retain in the absence of rebates, AHIP suggests 50 percent [9].

Aside from how eliminating rebates would affect drug makers, payers are opposed to the change due to its impact on premiums. From their perspective, rebate savings should be pooled to benefit *all* members through lower premiums, not reserved for patients prescribed the rebated medications. Thus the debate boils down to less of a financial one and more of a philosophical one: Should drug rebates benefit all members in the form of lower premiums, or be more specifically targeted at savings for the patients prescribed the rebated medication? This question is explored in greater detail below.

Wholesalers and Pharmacies

It is less clear what impact the elimination of drug rebates would have on pharmaceutical suppliers and sellers. Higher premiums and lower point-of-sale costs could conceivably increase adherence rates, benefitting both wholesalers and retail pharmacies. However, this effect is likely to be minimal. It's notable that the trade associations for these groups haven't come out with strong support for or opposition to the administration's proposed rule.

Patients

Patients very widely in their needs, drug use, financial capacity, and exposure to healthcare costs based on their coverage profile. The effect of rebates upon patients' drug costs are equally varied. Broadly speaking, rebates are generally used to lower premiums for patients, whether they are covered through Medicare, Medicaid, or private insurance. This amounts to a "pooling" of drug spending that creates financial winners (people who benefit from rebates in the form of reduced premiums without needing much help at the point-of-sale) and losers (people suffering from chronic and/or serious conditions whose point-of-sale costs dwarf that of their premiums).

There is no single "spokesperson" for patients; patient advocacy groups are often disease- or demographic-specific. Unsurprisingly, these groups hold different opinions about rebates. Organizations that represent patients with chronic and/or severe conditions tend to support the administration's proposal; groups focused on keeping premiums low tend to oppose it. Other reactions by patient advocates have been more mixed. AARP expressed concerns about the potential for increased premiums and uncertainty about whether and how discounts would be transferred to the point-of-sale, ultimately urging CMS to conduct a thorough analysis assessing the impact on premiums and out-of-pocket costs.

In the end there may be no way to avoid this tradeoff: lower premiums for all, or cheaper drugs for the sickest. Either way, and even if the proposed rule is implemented, it seems unlikely that total drug costs will decline substantially.

TheZetemaProject

Discussion Questions

How will the elimination of rebates impact drug makers?

If a post-rebate world means that immense sums of money being issued by manufacturers are no longer being spent, why wouldn't the drug makers simply pocket the money to increase profits?

What mechanisms or potential policies might be needed to incentivized to push down list prices or offer point-of-sale discounts?

What would be the lag time for drug makers to reduce their list prices to be better in line with current net prices?

How will the elimination of rebates impact PBMs?

If rebates provide PBMs with little additional profit, as they claim, why are they fighting so hard to preserve them?

Payers and plan sponsors use rebate savings to push down premiums for all members, but leave chronically and/or severely ill patients with the burden of paying a portion of list price for their life-saving drugs, even when they are rebated. Is this a good or a bad thing? What are the trade-offs and moral implications? If eliminating drug rebates generally would make many expensive medications cheaper for individual patients but would raise premiums for all, is that desirable?

Given that eliminating rebates is unlikely to reduce overall drug costs, is this initiative a distraction from the larger issue?

TheZetemaProject

References

[1] Roehrig, Alan. “The Impact of Prescription Drug Rebates on Health Plans and Consumers.” Alatrum. 2018-04.

[2] “Maintaining the Affordability of the Prescription Drug Benefit: How Managed Care Organizations Secure Price Concessions from Pharmaceutical Manufacturers.” Academy of Managed Care Pharmacy.

[3] “Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees.” Federal Register, The Daily Journal of the United States Government. 2019-02-06.

[4] “Proposed Safe Harbor Regulation.” Office of the Actuary, Centers for Medicare and Medicaid Services. 2018-08-30.

[5] “New Data: Rebates are Unrelated to Drugmakers’ Pricing Strategies.” Pharmaceutical Care Management Association. 2018-08-15.

[6] Morse, Susan. “Health insurance tax, not rebates, greatest threat to affordability, UnitedHealth Group CEO says.” Healthcare Finance. 2019-04-16.

[7] Luhby, Tami. “Just who gets those big drug rebates?” CNN Business. 2018-05-07.

[8] “Pelosi Statement on Trump Administration’s Proposed Prescription Drug Rebate Rule.” Nancy Pelosi, Speaker of the House, Newsroom. 2019-02-01.

[9] “Press Release: Costs for Taxpayers Could Skyrocket Under Proposed Rebate Rule.” America’s Health Insurance Plans. 2019-04-08.