radically pragmatic





In searching for ways to satisfy public demand for lower drug prices, President Trump has found rare common ground with Democrats. The White House recently released a plan to reform the way pharmacy benefit managers (PBMs) negotiate prices with drugmakers on behalf of health insurance companies. Specifically, the proposal takes aim at special discounts or rebates negotiated by PBMs that create a perverse incentive for drugmakers to push up the list price of their products.

The idea is to get rid of these incentives in order to bring down drug prices, which would mean lower out-of-pocket expenses for patients.

Democrats like Senator Ron Wyden have long pushed for changes to the rebate structure. However, Trump's plan has drawn fire from critics who say it could become a boon for big drug companies by shifting more costs to the federal government.

The truth is, the rebate proposal is a good first step to help Medicare beneficiaries at the drug counter; but, without further action to increase transparency around drug pricing and encourage competition, costs could be shifted from drug companies to taxpayers.



WHAT DOES THE PROPOSED RULE CHANGE?

The proposed rule, issued by the Department of Health and Human Services (HHS), attempts to unlink the price of drugs from the way PBMs are paid. PBMs are intermediaries between health plans and drug companies that negotiate discounts and manage drug formularies. PBMs take a cut of the discounts (called "rebates") that they negotiate from drug companies as a part of their payment. The rule takes aim at what is essentially a kickback scheme between drugmakers and PBMs by eliminating the existing legal safe harbor for rebates from the Medicare prescription drug program (Part D) and Medicaid managed care plans. However, the rule proposes adding two more narrow safe harbors - one for rebates that would directly benefit patients at the point of sale and one for flat fees paid to PBMs in exchange for their services. If finalized, the proposed changes would go into effect January 1, 2020.

The proposed regulation points in the right direction. It would lower out-of-pocket costs for people enrolled in Part D and reduce perverse incentives for drug companies to raise the list prices of their drugs. But there's a hitch: the Trump proposal could also put the federal government on the line for more of the nation's drug costs.

HOW DOES THE CURRENT SYSTEM WORK?

To understand how Trump's idea works, you have to understand how convoluted the current market is – as outlined in my paper, *The Problem with PBMs*. PBMs evolved in the late 1960s and early 1970s when the number of drugs reaching the market was hard for health plans to manage. PBMs negotiate with drugmakers to determine drug formularies (the list of covered prescription drugs and the co-pays) for health plans as well as process drug benefit claims.

If a market is working correctly, PBMs have incentives to structure a formulary around value. Drugs on a formulary are typically grouped into tiers that determine a patient's portion of the drug cost. A typical formulary includes 3-4 tiers, with the first being the lowest cost-sharing and the last being the highest — meaning low-cost, highly effective drugs would be covered with little to no co-pays (tier 1) and expensive, less-effective drugs would have higher cost-sharing (tier 4). This model encourages patients to take the most cost-effective drugs and keeps down health care spending. However, the market evolved to incorporate rebates, which means formularies are no longer based on value.

WHAT'S THE MATTER WITH REBATES?

Rebates have distorted market incentives. In exchange for a preferred tier on a formulary, drugmakers give PBMs discounts off of the list price, known as "rebates." These rebates are passed along to the client – the health plan – after PBMs take a percentage for themselves. This means that the larger the gap between the list price and discount, the more revenue the PBM acquires. The discounts are not considered at the point of purchase, however. Medicare beneficiaries typically have co-pays based on the artificially high list price of the drug rather than on the negotiated net price.

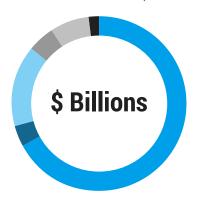
The proposed rule seeks to get rid of the incentive to increase list prices in order to give PBMs large rebates in exchange for a preferred spot on the formulary. It remains to be seen how PBMs will design formularies if this rule goes into effect, but it seems to reason that they will once again have financial incentive to steer patients toward high-value drugs rather than drugs where they get the largest rebates.

WITHOUT THESE REBATES, WILL DRUG PRICES DROP DRAMATICALLY?

So far, so good. It's important to note, however, that PBMs have contracts that allow them to get paid in a number of ways other than rebates. There are fees for administration services, performance incentives, and pharmacy dispensing fees at specialty pharmacies. It is possible that, without making parts of the business more transparent, they could also increase costs without using the rebate model.

It is important to maintain perspective. Though this is the first step to helping some consumers, PBMs account for only a small portion of drug costs – roughly \$23 billion of a roughly \$480 billion market. In fact, total U.S. spending on Humira, an arthritis drug that is the top selling drug in the U.S., is greater than total U.S. spending on PBMs annually.²

FIGURE 1: Retained Revenue across U.S. Pharmaceutical Sector in 2016 (\$ billions)



Manufacturers	\$323
Wholesalers	\$18
Pharmacies	\$73
PBMs	\$23
Providers	\$35
Insurers	\$9

Source: Nancy Yu, Preston Atteberry and Peter Bach, "Spending on Prescription Drugs in the US: Where Does All The Money Go?," Health Affairs, July 2018.

HOW WOULD THIS AFFECT PART D PREMIUMS?

The administration's proposed changes would also affect drug pricing in other ways. The administration predicts that reducing costs at the point of sale would increase premiums across all beneficiaries. In other words, instead of patients who need the most expensive drugs bearing most of the costs at the counter, the costs would be distributed across all enrollees of a plan through increased premiums. This benefits those who need help paying for expensive drugs the most.

HOW WOULD THIS AFFECT FEDERAL SPENDING?

The rule may have unintended consequences on federal spending. Because the federal government pays a significant portion of premiums for every Medicare Part D beneficiary, if costs are shifted to premiums, it will likely drive up federal spending. The proposed rule notes that there is lot of uncertainty around how this could impact the market depending on how PBMs and consumers respond to the changes. Without any change in consumer or PBM behavior, the proposed rule analysis shows that net drug spending, accounting for all discounts and rebates, would increase more than \$20 billion over 10 years: \$34.8 billion more in federal spending and a \$14.5 billion decrease in beneficiary spending. In other words, Trump's proposal may not lower U.S. drug spending; it may simply shift that spending from seniors on Medicare to taxpayers.

And there's another complicated wrinkle – this one involving the notorious "doughnut hole." Under Part D, there is a deductible that beneficiaries must meet and then an initial coverage period where the enrollee pays part and the plan pays part of the cost of drugs.



However, there is an "initial coverage limit" that then pushes beneficiaries into the doughnut hole where Medicare beneficiaries must pay for prescription drugs out of pocket. Drug companies are required to give a 70 percent discount during this coverage gap before beneficiaries reach an out-of-pocket maximum and the government coverage kicks back in, at 95 percent. Because the rule would reduce out of pocket spending, it seems likely that fewer beneficiaries would make it to the doughnut hole threshold and, therefore, fewer drug companies would have to provide the 70 percent discount of their drugs and share in the responsibility of covering drug costs.

WHAT ARE THE REACTIONS TO THE PROPOSAL?

That's why the White House proposal is earning mostly mixed praise. It would clearly benefit sicker Medicare beneficiaries with high drug out-of-pocket costs. Additionally, it would reduce perverse incentives to set high list prices for drugs and encourage drug companies to compete on the value of their product rather than their kickback to the PBM.

That being said, policymakers need to consider how the rule will change formulary design, PBM payments, and the Part D coverage gap. While it provides a more transparent, equitable way of subsidizing high-cost drugs for beneficiaries, Democrats are right to point out that it also shifts costs to taxpayers. The proposed rule acknowledges there is a lot of ambiguity around the changes and it is unsure how the market will respond. Progressives should closely monitor the impact, continue to push for transparency in the market, and think creatively about new ways to put downward pressure on prescription drug prices.

References

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