VIEWPOINT

HEALTH POLICY

Prescription Drugs—List Price, Net Price, and the Rebate Caught in the Middle

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Pharmacy benefit managers (PBMs), such as Express Scripts, CVS Caremark, and Optum Rx, are some of the larger companies that administer the Medicare Part D prescription drug benefit. These companies facilitate access to prescription drugs for beneficiaries, and because each company generally has millions of enrollees, they leverage their size to extract price concessions from pharmaceutical manufacturers. Because Medicare is not permitted to negotiate drug prices directly, the program and beneficiaries rely on PBMs to negotiate on their behalf.

Although the federal Medicare program bears most of the costs of the Part D benefit, Medicare beneficiaries also pay for Part D through monthly premiums and out-of-pocket payments when they obtain prescription medications (ie, deductibles, co-insurance, or co-payments). Although monthly premiums have stayed relatively unchanged over the past several years, Medicare spending on drugs has increased, even as PBMs have reported effectively containing drug costs.[1] The divergent developments have brought the primary mechanism by which PBMs achieve lower prices under scrutiny. The PBMs do not obtain upfront discounts on most drugs, but instead receive rebates from manufacturers after the point-of-sale.

Rebates paid to PBMs are distinct from rebates routinely encountered with other consumer products because these rebates are paid to the PBM and Medicare (Part D plan) instead of the patient. Furthermore, patients paying deductibles or co-insurance overpay when obtaining prescription drugs that have large rebates because patients' out-of-pocket costs are calculated based on the pre-rebated price ("list price"). For example, a patient with a $1000 drug deductible filling a prescription for a drug that has a list price of $400 and a net price of $300 (rebate of 25%) would pay $400 initially. Similarly, if the patient had 25% co-insurance for prescriptions, the price to the patient would be based on the pre-rebate price ($100 out-of-pocket instead of $75). In recent years, pharmaceutical manufacturers have consistently increased the list prices of their products, while the amount of rebates has also increased. Average manufacturer rebates in Part D increased from 10.4% of drug costs in 2008 to a projected 26.1% in 2019.[2] Despite these savings, list price increases have moved more beneficiaries into catastrophic coverage under Part D, where the Medicare program (ie, taxpayers) pays for 80% of drug spending.[3,4]

> To be certain, the current rebate system contains perverse incentives within the supply chain and increases costs for patients and taxpayers.

On January 31, 2019, US Health and Human Services Secretary Alex Azar proposed to change rules that would effectively eliminate rebates in Medicare Part D and in Medicaid managed care programs. Those rules would classify payments from drug manufacturers to PBMs as "kickbacks," making them illegal under the new proposal.[1] The secretary suggested that removing rebates would lower out-of-pocket spending at the pharmacy counter for Medicare beneficiaries, noting the average rebate for branded drugs is 26% to 30% of the drug's list price. It is hoped that if a proposal is enacted that eliminates rebates, pharmaceutical manufacturers will discount their products directly. That change, keeping all else the same, could reduce out-of-pocket costs for some patients by lowering the drug list price on which their deductibles or co-insurance are calculated. However, the effect the change would have on Medicare program spending is less clear.

This apparent benefit for beneficiaries rests on 2 key assumptions: that beneficiaries will save a meaningful amount of money at the pharmacy counter, and that pharmaceutical manufacturers will voluntarily discount list prices if they no longer pay rebates. Neither assumption may be true.

Rebates are generally offered to PBMs by pharmaceutical manufacturers so that the manufacturer's product can obtain preferred formulary placement over the products of competitors. As such, in competitive markets, rebates are sizable because Part D plans can elect to cover some products and not others. In these cases, the presence of multiple manufacturers with head-to-head competitors in categories such as insulins and drugs to treat hepatitis C have class-level rebates of 66% and 62%, respectively, across all payers.[5] In 2016, leading products in these classes had total pre-rebate spending in Part D of $2.5 billion (Lantus Solostar) and $4.4 billion (Harvoni).[2] For an individual patient, this would reduce list prices on which their deductibles and co-insurance are calculated from $417 to $142 for patients filling a 1-month supply for Lantus Solostar and from $92 648 to $35 206 for patients filling an 84-day course of treatment with Harvoni, assuming class-level rebates applied to these products.

On the other hand, rebates are far less effective at lowering net prices for drugs that either lack relevant competitors or for which Medicare requires formulary inclusion due to "protected class" status. Some

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treatments for cancer offered under Medicare Part D are quite expensive, their prices increase steadily, and there are few to no price concessions. For example, lenalidomide (Revlimid) had a list price of more than $21 000/mo in 2018 and had Medicare pre-rebate spending of nearly $2.7 billion in 2016.[2] Rebates average less than 12% in this category.[5] Under Medicare Part D, patients using lenalidomide currently pay more than $15 000 per year out-of-pocket for this drug. The same is true for many high-priced, novel drugs in other categories that lack competition. Under the new proposal, even if manufacturers converted their rebates to upfront discounts, only those patients who are taking drugs in competitive classes would realize savings, while patients taking some of the most expensive medications would not.

The second assumption, that pharmaceutical manufacturers will voluntarily reduce list prices, may prove even more problematic. There is little reason to expect that manufacturers would discount their prices as much as needed to maintain current levels of drug spending (26%-30% off list prices on average across all products). Instead, the manufacturers may stop paying rebates, make modest reductions to list prices, and end up increasing their profits. In the proposal this issue is acknowledged: total drug spending, and thus total costs of Part D, are projected to increase across the various scenarios evaluated.[1]

The increased costs of Part D under the new rule could be managed, but it would require focusing on the prices of branded drugs more directly and imparting greater formulary flexibility for the Part D plans for drugs with limited competition. But perhaps more important, the structure of Part D needs to be reexamined. As in virtually every other type of insurance, health insurance should be designed to collect resources from many people to protect the few against financial catastrophe. That is precisely how home and car insurance work. Today Medicare Part D works in reverse, with individuals who need expensive drugs that have limited competition facing unlimited out-of-pocket costs.[4]

Under a system with targeted use of pass-through rebates or conversion of rebates to discounts, some beneficiaries taking medications in competitive categories would benefit, but premiums would likely increase for all beneficiaries. Savings would also not be available across all categories of expensive drugs and there is no guarantee that prices will be lowered substantially.

A more extensive restructuring should be considered. First, as recommended under the proposed rule, supply chain members—PBMs, wholesalers, and pharmacies—should be paid on a fee basis that is unrelated to the list price of the drug or the size of the rebate achieved. This would be appropriate for the reimbursement of Part B drugs as well. Patients who are prescribed preferred drugs should have more predictable costs, something that could be achieved were formularies required to have at least one product in each category under a co-payment (flat fee) arrangement. Tools such as reference pricing, value-based pricing, or arbitration could be used to ensure that preferred drugs and drugs that have limited competition are priced appropriately and could help ensure affordability for patients whose treatment options are limited.[6]

Second, the administration should consider capping out-of-pocket spending on Medicare Part D for patients reaching the catastrophic coverage limit and increasing incentives (or penalties) to encourage manufacturers to charge appropriate list prices and limit price increases.[7]

To be certain, the current rebate system contains perverse incentives within the supply chain and increases costs for patients and taxpayers.[3] Requiring companies to compete for formulary coverage and placement based on actual prices could be a step in the right direction. However, discarding rebates without including other checks to pharmaceutical firms' pricing may simply increase the cost of the Part D program for taxpayers and patients. Meanwhile the current proposal[1] will fail to help a large share of beneficiaries who take medications that are either required to be on every formulary or face no direct competition.

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