

Negative Economic Impact of Restricting Drug Rebates in Medicare Part D

BY ALEX BRILL

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INTRODUCTION

On July 24, President Trump issued an Executive Order on prescription drug rebates that invoked a proposed regulatory change he withdrew a year earlier. Put forward in February 2019 by the Department of Health and Human Services (HHS) Office of Inspector General (OIG), the proposed rule would have restricted drug manufacturer rebates to pharmacy benefit managers (PBMs) in Medicare Part D and Medicaid Managed Care Organizations (MCOs) and instead permitted negotiated point-of-sale discounts to beneficiaries. The government's own actuarial analysis estimated at the time that the policy change would increase spending in Medicare by nearly \$200 billion over a decade (*OACT, 2018*).

In July 2019, a spokesperson for the Trump administration announced, "Based on careful analysis and thorough consideration, the President has decided to withdraw the rebate rule" (*Owens, 2019*). In an about-face, the new Executive Order orders the HHS Secretary to "complete the rulemaking process" to restrict drug rebates in Medicare Part D (without mentioning MCOs), while ensuring that such action "is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs" (*White House, 2020*).

As analyses of the proposed rule have made clear, restricting rebates without prompting an increase in federal spending, premiums, or out-of-pocket costs is infeasible and would defy economic logic even if actuaries can fabricate assumptions to suggest such an outcome. In this paper, I reiterate the expected effects of restricting drug manufacturer rebates in Medicare Part D and discuss new analyses related to this potential policy change.¹ Because the Executive Order claims that "rebates are the functional equivalent of kickbacks," I begin by explaining the legitimate function of drug rebates and why they

have had a safe harbor exception to the anti-kickback statute for more than 30 years.

UNDERSTANDING DRUG REBATES

Safe Harbor for Rebates

The federal anti-kickback statute (*42 USC § 1320a-7b(b)*) codifies the government's longstanding prohibition of remuneration as inducement to provide goods or services that are financed by federal healthcare programs. The government has long understood that price reductions in the form of rebates are not such inducements and has explicitly provided a safe harbor protection for these arrangements.

The statutory and regulatory history of the safe harbor exception to the anti-kickback statute for drug discounts dates back to 1987 legislation (the Medicare and Medicaid Patient and Program Protection Act) and regulations proposed in 1989 and finalized in 1991 (*56 FR 35952*). As OIG noted in the proposed rebate rule, the 1991 safe harbor regulations "recognized that rebates can function like legitimate reductions in price" (*OIG, 2019a*).

Role of Rebates in Lowering Healthcare Costs

Rebates have long been a useful tool in facilitating negotiations between drug manufacturers and large-volume buyers, such as PBMs. They foster competition among drug manufacturers with similar products. And, as economist Fiona Scott Morton has explained, performance-based contracts between PBMs and drug manufacturers – where a PBM is able to negotiate a lower price for a drug by agreeing to shift market share to the drug – lead to lower prices overall. According to Scott Morton (*2019*), "Prices will rise in equilibrium when PBMs cannot condition low prices on achieving certain shares."

¹ For a more comprehensive report on the problems with this policy proposal, see Alex Brill, "Concerns Regarding the Proposed Rule to Restrict Drug Manufacturer Rebates in Medicare Part D and Medicaid MCOs," April 2019, available at www.getmga.com/wp-content/uploads/2019/04/MGA-Report-on-Proposed-Rebate-Restriction-3.pdf.

Rebates also help keep premiums lower across the board, as payors use the savings from rebates to lower premiums for all beneficiaries. While point-of-sale discounts would lower out-of-pocket costs for some patients, evidence presented below demonstrates that these discounts would be lower than the rebates they would supposedly be replacing.

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ESTIMATES OF THE NEGATIVE EFFECTS OF RESTRICTING DRUG REBATES

The Executive Order charges the HHS Secretary with ensuring that restricting rebates in Medicare Part D would not increase federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs. But analyses of the proposed rule at the time it was published estimated increases in all three categories – as well as increased profits for drug manufacturers.

In modeling the impact of the proposed rule, HHS not only relied on its own actuarial analysis by the Centers for Medicare & Medicaid Services Office of the Actuary (OACT), but also contracted with two private-sector firms, Milliman Inc. and Wakely Consulting Group. In this section, I review estimates from these original analyses; in the next section, I present new evidence of the negative economic impact of restricting rebates.

Impact on Federal Spending

OACT (2018) estimates that, over 10 years, the proposed rule would increase federal spending on Medicare Part D by \$196.1 billion and federal spending on Medicaid by \$1.7 billion.

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A key factor underlying OACT's analysis is an expectation that drug manufacturers will keep for themselves a portion of the rebate dollars currently paid to PBMs. Specifically, OACT assumes that drug manufacturers will retain 15 percent of existing Part D rebates. As the proposed rule notes, OACT believes that "consumer discounts provide less return on investment to drug manufacturers than rebates" (OIG, 2019a).

Of the remaining 85 percent of rebate dollars, OACT assumes that 75 percent will materialize as point-of-sale discounts to Medicare beneficiaries and 25 percent as lower list prices. However, it is important to emphasize that, to the extent that the proposed rule's prohibition on rebates does result in lower list prices, overall Medicare spending will increase. This is because a reduction in list price affects both Medicare Part D and non-Medicare plans; if current rebate dollars are repurposed to lower the list price of a drug, then a portion of that price discount accrues to private health plans and their members. Medicare Part D spending is approximately one-third of total drug spending and therefore would capture a minority of the cost savings associated with lower drug prices.

Moreover, disallowing Medicare Part D rebates while permitting point-of-sale discounts will compress discounts across all plans, resulting in higher average net prices in Medicare Part D (Brill, 2019). It also will encourage tacit collusion among manufacturers. As the Federal Trade Commission (FTC) has explained:

Whenever PBMs have a credible threat to exclude pharmaceutical manufacturers from their formulary, manufacturers have a powerful incentive to bid aggressively. Willingness to bid aggressively,

however, is affected by the degree of transparency with respect to the terms that pharmaceutical companies offer PBMs. Whenever competitors know the actual prices charged by other firms, tacit collusion – and thus higher prices – may be more likely. (*FTC, 2004*)

In the scenario with assumptions most like those made by OACT, Milliman (*2019a*) predicts that, from 2020 to 2029, total government costs will increase by \$139.9 billion. All but one of Milliman’s non-static scenarios confirm large increases in federal spending on Part D. But PBMs already have ample incentive to pursue these strategies.

Impact on Medicare Premiums and Out-of-Pocket Spending

According to the OACT (*2018*) analysis, Medicare Part D premiums will increase by \$58 billion and beneficiary cost sharing will decline by \$83.2 billion; the net impact will be –\$25.2 billion. In the scenario with assumptions most like those made by OACT, Milliman (*2019a*) predicts that, over the period 2020–2029, total beneficiary costs will rise by \$12.3 billion, as the projected increase in premiums (\$44.9 billion) is larger than the projected decrease in out-of-pocket costs (\$32.6 billion).

As noted above, drug rebates are used to lower premium costs across all beneficiaries. Shifting from rebates to point-of-sale discounts would effectively redistribute these savings to beneficiaries who use discounted drugs. According to the Wakely (*2018*) analysis, savings will accrue to only 30 percent of non-low-income beneficiaries while the remaining 70 percent will see their out-of-pocket costs rise. Milliman (*2019b*) estimates that only 9 percent of Medicare beneficiaries will experience net savings.

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Manufacturer Profits

Drug manufacturers represent one group that seems to benefit unequivocally from restricting rebates in Medicare Part D. As discussed above, OACT (*2018*) assumes that drug manufacturers will retain 15 percent of current rebates. And OACT notes that “pharmaceutical manufacturers would benefit from the proposed rule overall, even as list prices were reduced.” In all scenarios considered by Milliman (*2019a*), the proposed rule is estimated to decrease drug manufacturers’ costs. Estimates for this decrease range from \$17.1 billion to \$29.5 billion.

Drug company revenues also are predicted to rise. OACT (*2018*) reports that total drug spending will surge by \$137 billion.

NEW EVIDENCE RELATED TO DRUG REBATES

The negative effects of the proposed rule were well-documented at the time it was issued. Since the comment period for the proposed rule closed, additional analyses related to drug rebates in Medicare Part D have been released. Here, I highlight three studies from government agencies, including one from HHS OIG, which previously put forward the proposed rule.

CBO: Proposed Rule Would Increase Federal Spending

In May 2019, the Congressional Budget Office (CBO) provided a budget estimate for the proposed rule because of the level of interest in the policy change among lawmakers. CBO estimated that restricting rebates would increase federal spending by \$177 billion over 10 years: \$170 billion in Medicare spending and \$7 billion in Medicaid spending (*CBO, 2019*).

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Like OACT (2018), CBO assumed that manufacturers would keep 15 percent of rebates, “particularly those based on whether a PBM met targets for the share of prescriptions filled with a manufacturer’s drug.” CBO expects drugmakers to target remaining rebate dollars toward discounts on Medicare and Medicaid drugs, rather than lowering the list prices of drugs for the whole market. Nevertheless, the proposed rule would still result in increased premiums for beneficiaries and increased spending for the federal government.

GAO: Rebates Are Passed on to Plan Sponsors

At the request of members of Congress, the Government Accountability Office (GAO) in July 2019 released a report on the role of PBMs in Medicare Part D. GAO found that drug rebates in Part D provide savings to both beneficiaries and the government. Between 2014 and 2016, the growth of rebates outpaced the growth of Part D spending (*GAO, 2019*).

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GAO also reported that “PBMs retained less than 1 percent of these rebates, passing the rest to plan sponsors.” Indeed, PBMs kept only 0.4 percent of manufacturer rebates. This finding is particularly significant in light of the Executive Order’s assertion that Medicare beneficiaries “pay more than they should for drugs while the middlemen collect large ‘rebate’ checks.”

OIG: Rebates Lead to Savings in Part D

Also at the request of Congress, the OIG itself released a report in September 2019 on drug rebates in Part D. The report noted that, while Part D spending on brand drugs increased during the period analyzed (2011–2015), “rebates substantially reduced the growth in total Part D spending” during that time (*OIG, 2019b*).

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OIG found that 55 percent of brand drugs reimbursed under Part D had rebates every year between 2011 and 2015. According to the report, “Total Part D reimbursement for brand-name drugs increased by 19 percent from 2011 to 2015, versus a 4-percent increase in rebate-adjusted reimbursement for these drugs over the 5 years reviewed.”

Conclusion

President Trump's recent Executive Order targeting drug rebates revives a proposed rule that would restrict an important tool for providing savings to the federal government and Medicare Part D beneficiaries. Moreover, net drug costs and drug company revenues would rise significantly if the Medicare Part D safe harbor for rebates is eliminated. Numerous analyses have shown that it would not be possible to fulfill the Executive Order's mandate not to increase federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs.

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ABOUT THE AUTHOR

Alex Brill is the CEO of Matrix Global Advisors, an economic policy consulting firm. He is also a resident fellow at the American Enterprise Institute. Previously, he was chief economist and policy director to the House Ways and Means Committee.

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