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Reforming Rebate Contracting will Improve Drug Affordability

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Abstract

The Department of Health and Human Services (HHS) finalized a regulation on November 20, 2020 that removed the safe harbor protections for rebates on prescription drugs paid to pharmacy benefit managers (PBMs) and Part D plans. This analysis evaluates the expected impact from this regulation on Medicare premiums and patient out-of-pocket (OOP) costs.

Based on the data from the California Department of Managed Health Care (DMHC), the loss of manufacturer drug rebates would cause the average insurance premiums to increase by \$40.96 annually. Across the 12.9 million recipients of the Medicare low-income subsidy, this implies an increase in expenditures of \$528.4 million. If OOP costs were to fall by the full share of the concessions paid (as expected from this reform), then patients with high OOP costs (\$3,214 annually according to the Kaiser Family Foundation), could expect to save \$1,451 annually.

These policy trade-offs do not account for the expected improvement in patients' adherence to their medications from lowering their OOP costs. Relying on proxies for these relationships, per patient total health care savings could range between \$381 and \$1,522 depending upon the actual improvement in medication adherence observed. Across the more than 1 million Medicare Part D patients with high OOP costs, total healthcare expenditures for Medicare could decline between \$386.9 million and \$1.5 billion.

Based on the results of the study, the finalized regulation should meaningfully address the drug affordability problem while imposing only minimal increases in individuals' insurance premiums and total Medicare expenditures.

Keywords: Rebates; Rebate reform; Patient; Out-of-pocket costs; Medicare; CBO; PBMs; HHS

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Introduction

On November 20, 2020, the Health and Human Services (HHS) Secretary finalized a regulation that excludes "rebates on prescription drugs paid by manufacturers to pharmacy benefit managers (PBMs) and Part D plans from safe harbor protection under the Anti-Kickback Statute (AKS) [1]." If implemented, this reform would mean that all rebates would need to be passed along to Medicare beneficiaries.

Proponents of the regulation claim that this reform will ensure that patients who are prescribed expensive medicines directly benefit from the large and growing concessions paid by drug manufacturers. Further, by ensuring that patients benefit from the current rebates, the reform will meaningfully address the drug affordability problem. Critics of the reform respond that eliminating the discounts would increase Medicare's costs and

ultimately lead to higher premiums for all other patients because PBMs utilize some of the concessions to reduce plan premiums. This analysis evaluates which of these arguments are consistent with publicly available insurance premium data.

After documenting the rapid growth in concessions relative to the actual transaction prices of drugs, the next section uses data from the California Department of Managed Health Care (DMHC), IQVIA, and the Kaiser Family Foundation (KFF), to estimate whether the proposed rebate reform will meaningfully: (1) reduce out-of-pocket costs (OOP) for patients, (2) increase premium costs, and (3) increase Medicare's expenditures.

Data from DMHC provides a detailed cost breakdown from a sample of health plan premiums. Leveraging these data, coupled with KFF data on the average Medicare Part D premium, the increase in beneficiaries' premiums that should be expected

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from this proposal are calculated. The impact on Medicare is then estimated by extrapolating the increased premium cost per beneficiary to the share of Medicare recipients that receive a low-income subsidy.

KFF and IQVIA provide data on the average costs for patients with high drug OOP spending and the size of the current concessions paid by drug manufacturers, respectively. Based on these data, the expected impact on OOP spending for patients are calculated.

The findings demonstrate that eliminating the manufacturer drug rebates will only marginally increase the average annual premium on a static basis but meaningfully reduce the OOP costs for patients with high drug costs.

The assumption “static basis” refers to the potential impact on patient adherence to their medicines. Because the reforms will create a significant reduction in out-of-pocket costs, rebate reform is expected to improve patients’ adherence to their medications. Greater medication adherence will improve patient health outcomes and generate healthcare savings that will offset the higher premium and Medicare costs estimated in the static analyses.

Taken together, this analysis supports the arguments of the proponents of the reform. The finalized rebate reform regulation will not lead to the large increases in Medicare’s costs or health insurance premiums. Instead, the reforms will meaningfully reduce the drug costs for patients prescribed expensive medications and help reduce overall healthcare expenditures.

A brief primer on the current drug pricing system

The list prices announced by drug manufacturers – which are also referred to as wholesale acquisition cost (WAC) – are often mistaken for the market price, but they are not the effective market price. These list prices do not account for the hundreds of billions of dollars in concessions that are paid each year in the form of discounts, rebates, fees and chargebacks. These concessions have been growing quickly. According to *Drug Channels*, between 2015 and 2019, concessions grew an average of 11.5 percent annually [2]. The list price minus the value of these concessions equals the net price, which is the actual market price [3].

Comparing the growth in gross and net prices on medicines as measured by IQVIA to the growth in inflation for overall medical care as measured by the Bureau of Labor Statistics (BLS) demonstrates that the growth in the market price of drugs has been less than the growth in overall medical care inflation [4]. Specifically, medical care inflation increased 14.5 percent between 2014 and 2019, but the net price (e.g. the actual market price) increased 8.9 percent. Drug list prices that are often confused for the market price but do not reflect all of the concessions paid, increased 41.5 percent.

The current drug rebate system incentivizes these trends. Since PBMs retain a percentage of the concessions, they are incentivized to encourage fast growing gross prices that are offset by fast growing concessions because such a system generates more revenues for these firms. Plan sponsors benefit because they use

a large share of these revenues to offset the costs of premiums for all policyholders. Meanwhile, manufacturers’ revenues depend on the ever-shrinking net price, but compete based on the size of the concessions. Ultimately the accumulation of these systemic incentives encourages fast growing gross prices and concessions, but slow growing net, or actual market, prices.

Unlike plan sponsors, patient OOP costs do not depend on the net price of medicines, or the actual market price, because the typical insurance benefit design bases patient OOP costs on the list prices of medicines when they pay their co-insurance costs or deductibles. As a result, the excessive growth in list prices is driving up drug costs for patients, especially those who rely on expensive medications. This has led to the untoward outcome that patients who are prescribed expensive medicines face rising costs despite the fact that the market price of drugs is actually growing slower than overall medical inflation

Drug rebates are a small share of health insurance premiums

The California Department of Managed Health Care (DMHC) produces an annual report that “looks at the impact of the cost of prescription drugs on health plan premiums” [5]. Table 1 summarizes the DMHC’s findings from the 2018 report with respect to the share of premiums associated with different categories of healthcare spending. Table 1 demonstrates that both in 2017 and 2018, approximately three-quarters of the health insurance premiums were used to cover medical expenses. Netting out the impact of drug rebates, which were the equivalent of around 1.5 percent of premiums) net drug spending accounted for 11.5 percent of total health insurance premiums in 2017 and 11.2 percent of total health insurance premiums in 2018 (**Table 1**).

Leveraging these data, the estimated impact on the average Medicare Part D premium from the proposed rebate rule can be calculated, see Table 2. The first row of Table 2 presents the average Medicare Part D premium for all Medicare Part D plans in 2019, which was \$29.20 per month or \$350.40 annually [6]. Based on the DMHC analysis, these costs account for 12.7 percent of the total health insurance premium. These data imply that the equivalent total health insurance premium for these patients should be approximately \$230 monthly, or \$2,761 annually.

Table 1 Share of Health Insurance Premiums by Expenditure Category 2017 and 2018.

	Percentage of Premium	
	2017	2018
Health plan expenditures on prescription drugs	12.9%	12.7%
Medical Expenses	76.8%	74.3%
Manufacturer Drug Rebates	-1.4%	-1.5%
Administrative Expenses	5.0%	5.0%
Commissions	2.4%	2.2%
Profit	1.5%	3.9%
Taxes and Fees	2.8%	3.5%
Total Health Plan Premium	100.0%	100.0%
Net Pharmaceutical Expenditures	11.5%	11.2%

Source: California Department of Managed Health Care

The DMHC study also provides the size of the rebates relative to the total insurance premium, which was 1.5 percent as of 2018 [7]— this is reflected as a negative in Table 2 to denote that these are revenues for the insurer. Based on a monthly health insurance premium of \$230, the loss of the premium subsidy implies that if the insurer wanted to maintain its current revenues, it would have to increase premiums by \$3.41 per month, or by \$41 annually. This implies that the total Medicare Part D premiums would rise from \$350 annually to \$391 annually (Table 2).

These additional premium costs on a static basis pale in comparison to the reduction that the small number of patients who take expensive medicines could expect from this reform. Based on the IQVIA data, total drug spending measured at list prices was \$671 billion in 2019, with concessions equaling \$303 billion or 45.2 percent of the value of the drugs at list prices (excluding retail coupons that directly benefit patients) [8]. If patients’ OOP share was the same percentage as currently, but based on these net prices rather than the current list prices, then 2019 total OOP expenditures would have been \$45 billion, or \$37 billion less than the actual cost of \$82 billion. The majority of these cost reductions would benefit the patients with high out-of-pocket costs (high OOP) that, in 2017, averaged \$3,214 [9].

Applying the 45.2 percent reduction to the average expenses for high OOP patients provides perspective on the policy trade-off involved. If the average expenses for high OOP patients were to fall by the full share of the concessions paid, then the average costs for high OOP patients would fall by \$1,451 to \$1,763. By this measure, on a static basis, the policy trade-off is a \$1,451 reduction in costs for the patients bearing the brunt of the affordability crisis in exchange for a \$41 increase in annual premiums for all Medicare Part D enrollees.

If the expected impact on premiums from rebate reform is \$41 annually, and assuming that Medicare will pay for all of the extra costs for the 12.9 million recipients of the low-income subsidy, then the expected additional annual expenditures from the reform will be \$528.4 million. This budgetary impact is significantly less than the \$13.5 billion in costs that the Centers for Medicare and Medicaid Services (CMS) estimated when evaluating this reform, see Table 3 [10]. These estimated expenditures are calculated on a static basis, and do not account for the dynamic impacts the reforms will have on patient behavior (Table 3).

Before discussing the dynamic impacts, an important side note is worth mentioning. Even if the CMS calculations were correct,

Table 2 Estimated Impact on Average Medicare Part D Premium from Mandating Rebates Benefit Patients (based on 2019 premium costs).

	Monthly Premium	Annual Premium
Medicare Part D Premium	\$29.20	\$350.40
Pharmaceutical Expenditure	12.7%	12.7%
Implied Healthcare Premium	\$230.11	\$2,761.31
Percentage Drug Rebate	-1.5%	-1.5%
Dollar Value of Drug Rebate	\$(3.41)	\$(40.96)
Medicare Part D Premium Excluding Drug Rebates	\$32.61	\$391.36

Sources: Author calculations based on data from the Kaiser Family Foundation and California Department of Managed Health Care

Table 3 Estimated Impact on Federal Costs from Mandating Patients Who Are Prescribed the Medicines Receive the Rebates (based on 2019 premium costs).

	Annual Federal Cost
Medicare Part D Premium Increase Due to Drug Rebates	\$40.96
Low-income subsidy recipients	12.9 million
Federal Government Increased Subsidy Costs	\$528,375,791

Sources: Author calculations based on data from the Kaiser Family Foundation and California Department of Managed Health Care

these additional expenditures do not necessarily undermine the justification for the reform. The purpose of insurance is to spread the financial costs associated with a risk across a wide population, with those people who did not experience the adverse event subsidizing the costs of those people who did. Since the current rebate system increases costs on patients who are prescribed expensive medicines in order to lower the premiums for everyone else, it is the antithesis of actual insurance. Fixing this system that imposes large financial costs on patients when they are most vulnerable is a worthy goal regardless of the impacts on premiums and Medicare’s costs. However, there are reasons to be suspicious that rebate reform would meaningfully increase premium costs or Medicare’s costs.

Better drug adherence will save money

The previous cost trade-offs are estimated on a static basis. However, there are many studies that have documented a link between reduced OOP expenditures on drugs and greater adherence to medicines [11]. Further, greater adherence has been linked to reduced expenditures on other healthcare services. Therefore, overall health insurance premium costs will benefit from a decline in overall healthcare costs. The Congressional Budget Office, in its analysis of this issue, found that policy changes that influence Medicare beneficiaries’ use of prescription drugs, such as those altering the cost-sharing structure of the Part D prescription drug benefit, probably affect federal spending on their medical services. After reviewing recent research, the Congressional Budget Office (CBO) estimates that a 1 percent increase in the number of prescriptions filled by beneficiaries would cause Medicare’s spending on medical services to fall by roughly one-fifth of 1 percent [12].

Accounting for the expected cost reductions for other medical services that are enabled by greater patient adherence to their drugs, the net increase in federal government expenditures would be even lower. Based on Optum Rx’s experience with drug adherence and overall medical costs, it is possible to provide a sense of the potential savings [13-15].

An Optum white paper in 2012 linked improved rates of medication adherence to increased expenditures on drugs but even larger decreases in expenditures on other health care services for patients living with diabetes [16]. On net, the study found that as patients’ adherence with their medications improved, overall drug costs increased but total medical costs decreased by a larger amount. Based on the difference in spending between the top and bottom adherence categories from the Optum study, a

1 percentage point increase in diabetes patients' adherence with their medications decreases overall spending by \$95.14.

According to a United Healthcare analysis, reducing patients' out-of-pocket costs improves their adherence rates.

United Healthcare data analytics demonstrate that when consumers do not have a deductible or large out-of-pocket cost, medication adherence improves by between 4 and 16 percent depending on plan design, contributing to better health and reducing total health care costs for clients and the health system overall [17].

Applying Optum's adherence-to-cost relationship (\$95.14 decrease in costs per 1 percentage point increase in adherence) to the broader patient population, and UnitedHealth Group's range of improved adherence due to lower out-of-pocket costs (between 4 percent and 16 percent), yields an estimated range of the per patient reduction in total healthcare spending due to greater medication adherence that is between \$381 and \$1,522. Across the more than 1 million Medicare Part D patients who the Kaiser Family Foundation documented as having high out of pocket expenditures [18], total healthcare expenditures for Medicare could decline between \$386.9 million and \$1.5 billion due to the improved medication adherence enabled by the rebate reform proposal, see **Table 4**.

These savings are only indicative of the potential, and a more precise methodology would need to account for the specific adherence-to-cost impact across all of the medicines driving the high out-of-pocket cost for Medicare Part D patients. These estimates are important for demonstrating that by not considering the financial benefits from improving drug adherence, the CMS grossly overestimates the costs of this program on the federal budget. In fact, instead of being a cost, it is possible that the rebate reform will actually decrease overall Medicare spending.

Conclusion

The current drug concession system is raising patient costs. This perverse outcome is why reforms are needed. Mandating that all drug concessions must benefit the patients purchasing the medicines is a positive reform that meaningfully addresses this

Table 4 Estimated Systemic Savings and Medicare Savings Due to Increased Medication Adherence.

	Percentage Improvement in Medication Adherence	
	4.0%	16%
Medical Savings per patient	\$381	\$1,522
High cost Medicare Part D Patients	1,016,660	1,016,660
Medicare Savings	\$386,889,963	\$1,547,559,852

Source: Author calculations

problem and reduces the excessive costs that Medicare Part D patients are inappropriately bearing.

The reform will not meaningfully increase costs for the government as some critics of the policy assert. Even without accounting for the beneficial impacts on improved medicine adherence, the impact on policyholder premiums is a fraction of the cost reduction that patients who require expensive medications will receive. From an insurance perspective, this trade-off seems warranted. But, this trade-off is also overstated.

When patients fail to properly adhere to their prescribed medicines, they suffer worse health outcomes, and the health care system endures higher overall costs. Studies have found that high out-of-pocket costs discourage patients from adhering to their medicines. Reducing these out-of-pocket costs improves overall patient adherence. Beyond the important benefits for patient health, improved adherence generates broader healthcare savings that offsets the higher premium costs. These positive dynamics further the arguments in favor of rebate reform.

Ultimately, addressing the drug affordability problem requires targeted reforms that identifies which patients are bearing the high costs, and the policy inefficiencies driving these unwanted outcomes. In this case, patients who are prescribed expensive medicines are facing excessive costs because the current concession system is unacceptably forcing an improper share of the costs on to them. Reforming the system is, consequently, an important policy that will meaningfully improve the broader pharmaceutical system in the U.S.

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