

Congressional Budget Office
Washington, D.C.

**Incorporating the Effects of the Proposed Rule on
Safe Harbors for Pharmaceutical Rebates in
CBO’s Budget Projections—Supplemental Material for
*Updated Budget Projections: 2019 to 2029***

May 2019

In this document, the Congressional Budget Office describes its analysis of the effects of a proposed rule that the agency expects would result in pharmacies’ charging beneficiaries prices for prescription drugs that reflect manufacturers’ discounts.

The Congressional Budget Office’s baseline budget projections generally include estimates of the effects of actions that the agency anticipates the Administration will take under current law. Lawmakers have expressed particular interest in the effects of a proposed rule that CBO expects would result in pharmacies’ charging beneficiaries prices for prescription drugs that reflect the discounts that pharmacy benefit managers (PBMs) negotiate with manufacturers. This document describes CBO’s analysis of that rule.

Implementing the rule as proposed would, CBO estimates, increase federal spending by about \$177 billion over the 2020–2029 period: Spending for Medicare would increase by about \$170 billion and spending for Medicaid by about \$7 billion.

The effects described below represent the agency’s estimates of the budgetary effects of implementing the rule as proposed. In accordance with CBO’s standard practice for incorporating the effects of proposed rules in its baseline projections, the current baseline projections reflect the assumption that there is a 50 percent chance that the final issued rule will be the same as the proposed one and a 50 percent chance that no new rule like the proposed one will be issued.¹ On the basis of that assumption, CBO projects that the proposed rule would increase mandatory spending by a total of \$89 billion over the 2020–2029 period.

The rule was proposed by the Office of Inspector General of the Department of Health and Human Services (HHS) on January 31, 2019. It would eliminate the existing safe harbor for rebates paid by pharmaceutical manufacturers to health plans and PBMs in Medicare Part D and Medicaid managed care beginning January 1, 2020. (That safe harbor protects those parties from liability or penalty in specific situations defined in regulations implementing the anti-kickback statute, which prohibits offering or accepting payments to induce use of services reimbursable under federal health care programs.) That change would effectively make it illegal for a drug manufacturer to pay rebates to a health plan or PBM in those programs in return for coverage or preferred treatment of the manufacturer’s drug under the PBM’s plan. The rule would replace that safe harbor with two new ones: one related to upfront discounts for prescription drugs and the other to service fees.

The comment period for the proposed rule closed on April 8, as CBO was finishing its work on its current baseline projections. On the basis of the typical timeline for a rule to move from proposal to implementation, CBO does not expect the final rule to be issued before mid-June.

¹ Congressional Budget Office, *Updated Budget Projections: 2019 to 2029* (May 2019), www.cbo.gov/publication/55151. For a discussion of how CBO reflects anticipated administrative actions in its baseline projections, see Congressional Budget Office, letter to the Honorable John M. Spratt (May 2, 2007), www.cbo.gov/publication/18615. After a final version of a rule is promulgated, CBO incorporates the full effects of the final rule in subsequent cost estimates and in future baseline projections.

Proposed Changes in Program Rules

The proposed rule would apply to transactions involving Part D plans in Medicare and managed care organizations (MCOs) participating in state Medicaid programs. When announcing the rule, HHS indicated that its intention was for manufacturers to lower their list prices, replace rebates with discounts, or do both. Under the rule, PBMs could continue to negotiate discounts in return for covering certain medications or giving those medications preferential placement on their formulary (a list of prescription drugs preferred by an insurance plan), but the discounts could not take the form of a rebate paid by the manufacturer to the PBM. Rather, all discounts would need to be directed to the pharmacy and reflected in the final price charged to beneficiaries.

Manufacturers could offer discounts to beneficiaries either by reducing their list price or by making a payment to the pharmacy of the full amount of the negotiated discount (referred to as a chargeback). Under the current system, a Part D beneficiary's cost-sharing obligation is related to the list price of the drug (that is, it does not reflect the rebates paid by the manufacturer to the PBM or plan). Under the system envisioned by HHS, a beneficiary's cost-sharing obligation for a prescription drug for which the manufacturer currently provides a rebate under the safe-harbor rules would instead be based either on a lower list price or on a post-chargeback price.

The proposed rule deals only with safe-harbor provisions under the purview of HHS's Inspector General and does not incorporate guidance from the Centers for Medicare & Medicaid Services (CMS) for prescription drug programs in Medicare and Medicaid. On April 5, CMS took a first step toward issuing such guidance when it announced a program under which Medicare would absorb nearly all of Part D plans' financial losses during calendar year 2020 if changes in safe-harbor provisions—such as those in the proposed rule—were implemented for that year.

Estimated Effects on Medicare Spending for Part D

CBO consulted with stakeholders and outside experts to understand the likely effects of implementing the rule as proposed. On the basis of those consultations, CBO concluded that with the new safe harbors defined in the proposed rule, pharmaceutical manufacturers would withhold some of the discounts they previously negotiated that could no longer be used under the rule—particularly those based on whether a PBM met targets for the share of prescriptions filled with a manufacturer's drug. Specifically, in the agency's assessment, manufacturers would withhold about 15 percent of the amounts they currently rebate to PBMs in Part D and would negotiate discounts approximately equal to the remaining 85 percent.² CBO expects that rather than

² In its analysis of the proposed rule, CMS's Office of the Actuary estimated that manufacturers would retain 15 percent of current rebates. After discussing that estimate with stakeholders and other experts, CBO concluded that it was reasonable and adopted it for this analysis.

lowering list prices, manufacturers would offer the renegotiated discounts in the form of chargebacks.³

Direct Effects of the Proposed Rule

CBO estimates that the direct effect of implementing the proposed rule would be to increase federal spending on Part D premiums by about \$170 billion over the 2020–2029 period. That increase stems from manufacturers’ withholding 15 percent of current-law rebates, increases in federal subsidies for premiums, changes in the annual thresholds at which beneficiaries’ cost-sharing requirements and other program rules change, and the costs of implementing the chargeback system.

Increases in Premiums. Under current rules, plans may use manufacturers’ rebates to reduce premiums for all beneficiaries. If those rebates were no longer paid directly to plans, Part D premiums would rise. Because the government subsidizes 74.5 percent of the basic beneficiary premium, higher premiums would lead to larger federal subsidies, thus increasing federal spending.⁴

Changes in Cost-Sharing Thresholds. For beneficiaries not enrolled in the low-income subsidy program, the standard Part D benefit defines three annual thresholds:

- A deductible (\$415 in 2019)—the amount that a beneficiary must pay before the plan covers about 75 percent of the cost of prescriptions and the beneficiary about 25 percent;
- An initial coverage limit (\$3,820 in 2019)—the point, measured by total spending (the beneficiary’s deductible and cost sharing plus the plan’s contributions), above which the allocation of spending among the beneficiary, plan, and drug manufacturer depends on whether the prescription is filled with a generic or brand-name drug; and
- A catastrophic threshold (\$5,100 in 2019)—a limit on the beneficiary’s spending (measured as the beneficiary’s out-of-pocket spending plus manufacturers’ discounts but *not* spending by the Part D plan or other supplemental plan) above which the beneficiary is responsible only for a small percentage of the costs of covered drugs.

The thresholds are increased each year by the rate of growth in per capita spending for the program. Both the thresholds and per capita spending are measured using the final prices

³ Reductions in list prices would affect the entire market for prescription drugs, whereas manufacturers could use chargebacks to provide discounts on only those prescriptions covered by Medicare Part D and Medicaid MCOs.

⁴ Some beneficiaries would pay lower prices on their prescription drugs, and for some beneficiaries, those reductions would be greater than their premium increases. For other beneficiaries—namely those who use few drugs or drugs without significant rebates—the premium increase would outweigh the price reductions.

beneficiaries pay at the pharmacy counter, so the calculated rate of growth in per capita spending would decline if those prices began to reflect discounts provided through chargebacks. On the basis of the projection that 85 percent of the rebates would be provided through chargebacks that would reduce the final prices beneficiaries pay, CBO estimates that implementing the rule would ultimately reduce the current thresholds by 14 percent. Because changes in the growth in per capita spending are measured with a lag, that reduction in thresholds would not, in CBO's assessment, be fully realized until 2022 or 2023. Thereafter, thresholds are projected to grow at the same rate as they would under the current safe-harbor rules.

Implementation Costs. As noted above, CBO expects that manufacturers would provide discounts in the form of chargebacks to pharmacies rather than reduce their list prices. After talking with stakeholders and experts in the prescription drug market, the agency concluded that no current system could both meet the proposed rule's standards and facilitate chargebacks. Implementing a system that could meet both of those objectives would require additional time. The resources needed to create and operate chargeback systems would increase premiums by about 1 percent of the amount of the chargebacks, CBO estimates.

Effect of Changes in Utilization

Lower prices on prescription drugs reduce beneficiaries' out-of-pocket costs. Beneficiaries who do not fill some of their prescriptions because their current out-of-pocket expenses are high would be more likely to fill them and to better adhere to their prescribed drug regimens if their costs were lower, as they would be under the proposed rule. In CBO's estimate, the additional Part D utilization stemming from implementing the proposed rule would increase federal spending for beneficiaries who are not enrolled in the low-income subsidy program over the 2020–2029 period by a total of about 2 percent, or \$10 billion. However, the increase in the number of beneficiaries following their drug regimens would also reduce spending for services covered under Parts A and B of Medicare, such as hospital and physician care, by an estimated \$20 billion over that period.⁵ On net, those effects are projected to reduce Medicare spending by \$10 billion over the 2020–2029 period.

Effect of the Loss-Absorption Program

In the additional guidance issued on April 5, CMS instructed plans to submit bids based on the status of the final rule on June 3, the day bids are due. A final rule is unlikely to be promulgated before that deadline, and CBO does not expect plans' bids to reflect the effects of the final rule. CMS stated that if there was a change to the safe-harbor rules in 2020, it would establish a voluntary two-year program in which the government would absorb 95 percent of any losses in 2020 (that is, amounts by which the costs that a plan actually incurred exceeded a target amount

⁵ For more on CBO's estimate of the medical effects of increased spending on prescription drugs, see Congressional Budget Office, *Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services* (November 2012), www.cbo.gov/publication/43741.

based on its bid) beyond the first 0.5 percent. If the proposed rule was implemented, that program would increase federal spending by \$10 billion, CBO estimates. The federal payments for those losses would probably occur in fiscal year 2022 because the payment amounts would be determined through a reconciliation process that is typically settled in November of the calendar year after the benefit year.

Estimated Effects on Federal Spending for Medicaid

Pharmaceutical manufacturers that voluntarily participate in Medicaid are required to pay rebates to states for prescription drugs. Those statutory rebate amounts are calculated on the basis of the average manufacturer price (AMP), which is the average price received by manufacturers for sales to retail pharmacies before any rebates later paid to insurers or PBMs are accounted for. It is unclear if the new chargebacks in Part D that would occur if the proposed rule was implemented would be excluded from the AMP calculation. Without additional guidance from CMS, CBO estimates that there is a 50 percent probability that the chargebacks would be included in the AMP calculations, which would decrease the federal government's share of rebate collections for Medicaid by about \$6 billion over the 2020–2029 period.

In addition, the changes in safe-harbor rules would apply to the managed care organizations that furnish benefits to enrollees in many state Medicaid programs. Under current law, MCOs (or PBMs acting on behalf of MCOs) negotiate rebates with manufacturers in return for giving the manufacturer's drugs priority on the plan's formulary or providing other preferential treatment. Those rebates are in addition to the statutory rebates mentioned above and equal a much smaller share of spending on brand name drugs in Medicaid than similar rebates negotiated in Part D. Given the minimal cost-sharing requirements in Medicaid, the prices that beneficiaries pay cannot be much lower than they are currently, so it is unclear how manufacturers could deliver substantial new discounts to Medicaid beneficiaries covered by MCOs and still comply with the rule.

Because of the minimal cost-sharing requirements, CBO expects manufacturers to withhold 75 percent of the rebates they negotiated with MCOs under current law, increasing costs to states and the federal government. Although MCOs are projected to raise their per capita rates in response to that increase, CBO estimates that state Medicaid programs would recoup 75 percent of the lost rebates over several years by, for example, carving out drug benefits for MCO enrollees and subjecting them to the rules that apply to enrollees in fee-for-service Medicaid, including the use of a preferred drug list. (The agency does not expect all states to use such approaches, which is the primary reason that less than 100 percent of the lost rebates are estimated to be recouped.) On net, those changes would increase federal spending by about \$1 billion over the 2020–2029 period, CBO estimates.

Estimated Effects on Federal Spending for Other Health Programs and on the Private Sector

CBO consulted with stakeholders and industry experts to assess whether implementing the proposed changes in the safe-harbor rules would affect spending for other federal programs or the prices of prescription drugs in the private sector. For the reasons discussed below, CBO concluded that changing the rule would not have a significant effect on spending for prescription drugs by Part B of the Medicare program, other federal programs, or private purchasers.

Medicare Part B

Medicare also covers drugs administered by physicians and other practitioners in an office setting or an outpatient hospital department. Payment for such drugs is generally made through Part B of Medicare rather than through Part D, although in some circumstances, a drug might be covered by both Part B and Part D. Manufacturers do not, in CBO's assessment, provide significant rebates on drugs that are covered by both Part B and Part D, so implementing the proposed rule is not projected to have a significant effect on spending for drugs under Part B. Moreover, if CBO is correct in its assessment that manufacturers would not lower their list prices in response to the proposed rule, implementing the rule would not change Medicare Part B's payments for prescription drugs.⁶

Other Federal Programs

Implementing the proposed rule would not, in CBO's assessment, affect spending for any other federal health programs that provide prescription drug coverage. The rule explicitly applies only to Medicare Part D and Medicaid MCOs. CBO does not anticipate that manufacturers would make any broader changes in prescription drug prices in response to implementing the proposed rule that would flow through to other federal programs.

The Private Sector

As drafted, the proposed changes to safe harbors apply only to Medicare and Medicaid MCOs, not to the larger pharmaceutical market. There would be effects on the larger market only if prescription drug manufacturers changed their list prices, and as discussed above, CBO does not expect them to do so.

Comparison With Other Estimates

CBO's assessment of the effects of the proposed rule is in line with results for some scenarios from other published analyses, although directly comparing results is difficult because various studies have evaluated different policy scenarios. Also, some of the analyses were completed

⁶ Payment for drugs covered under Part B is based on manufacturers' average sales price, which is the average of prices at which manufacturers sell to various purchasers, including wholesalers and group purchasing organizations.

before the formal proposal was published, and they therefore may rely on different assumptions about the policies.

CMS's Office of the Actuary estimated that the proposed rule would increase federal spending for Medicare Part D by about \$196 billion on net over the 2020–2029 period: That amount includes estimates of both the increase in direct subsidies for higher Part D premiums and the reduction in spending for catastrophic benefits and for subsidies for beneficiaries with low incomes.⁷ In addition, CMS estimated that manufacturers would eliminate about 15 percent of their current rebates in Part D; of the remaining 85 percent of rebates that were renegotiated, the agency anticipated that three-quarters would be in the form of chargebacks and one-quarter would be reflected in lower list prices. CMS assumed there would be no change in Part D utilization.

The proposed rule would, according to CMS's estimates, increase federal spending in Medicaid by \$1.7 billion over the 2020–2029 period—the net effect of increased costs in managed care and lower list prices. CMS estimated that 85 percent of rebates paid to MCOs would be withheld and that states would eventually recoup about 50 percent of those rebates, resulting in a net increase in federal spending of \$1.3 billion during the period. In addition, decreases in list prices would reduce Medicaid payments to pharmacies and rebates paid by manufacturers to Medicaid programs, resulting in a net increase in federal costs for Medicaid of \$0.5 billion over the period. Implementing the rule would not, in CMS's assessment, affect Medicaid beneficiaries' rates of prescription drug use.

The consulting firm Milliman also estimated the effects of the proposed rule. It analyzed several scenarios in which stakeholders responded to the proposed rule's safe-harbor changes in different ways. Milliman's estimates for those different scenarios spanned a wide range, from a reduction in federal spending of almost \$100 billion to an increase of about \$139 billion over the 2020–2029 period.⁸

⁷ Centers for Medicare & Medicaid Services, Office of the Actuary, memorandum regarding proposed safe-harbor regulation (August 28, 2018), www.regulations.gov/document?D=HHSIG-2019-0001-0004.

⁸ Department of Health and Human Services, *Impact of Potential Changes to the Treatment of Manufacturer Rebates* (prepared by Milliman, Inc., January 2019), www.regulations.gov/document?D=HHSIG-2019-0001-0002.