



Examining the Inflation Reduction Act's Medicare Part D Inflationary Rebate Guidance

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Executive Summary

- Much attention has been paid to the Inflation Reduction Act's (IRA) Medicare drug pricing "negotiation" provisions, but the IRA contains another set of provisions that will have significant consequences for both drugmakers and seniors: mandates for inflationary rebates in Medicare Parts B and D.
- In the latest rulemaking to implement the IRA's drug pricing provisions, the Centers for Medicare and Medicaid Services (CMS) published revised rebate guidance clarifying that any drug that costs more than \$100 per Medicare Part D beneficiary per year and increases in cost greater than inflation may result in drugmakers being required to pay an inflationary rebate; this guidance will capture almost all medications.
- CMS' framework is likely to undermine the ability of Part D plans through pharmacy benefit managers (PBMs) to negotiate rebates to lower prescription drug costs for seniors by weakening competition between manufacturers and PBMs for sizable rebates; in turn, this guidance will likely increase costs for Part D plans, and these increased outlays will likely be passed on to seniors through larger premiums and out-of-pocket prescription drug expenses.

Introduction

Much attention has been paid to the Inflation Reduction Act's (IRA) Medicare drug pricing "negotiation" provisions. But the IRA contains another set of provisions that will have significant consequences for both drugmakers and seniors: mandates for inflationary rebates in Parts B and D.

In the latest rulemaking to implement the IRA's drug pricing provisions, the Centers for Medicare and Medicaid Services (CMS) [published](#) revised rebate guidance clarifying that any drug that costs more than \$100 per Medicare [Part D](#) beneficiary per year and increases in cost greater than inflation may result in drugmakers being required to pay an inflationary rebate; this guidance will capture almost all medications.

Despite the IRA's vast changes to [Medicare](#), the law's myopic focus on drug [list prices](#) in isolation, rather than on the *net* prices of drugs, does not present an adequate assessment of the prescription drug market and serves as an improper starting point for such provisions. While Congress spent much of 2023 [scrutinizing](#) Part D beneficiary cost-sharing as related to list prices, CMS' guidance could exacerbate the out-of-pocket costs for patients on very expensive specialty medications.

CMS' framework is likely to undermine the ability of Part D plans through pharmacy benefit managers (PBMs) to negotiate rebates (typically to be shared with the plan or plan sponsor) to lower prescription drug costs for seniors, principally by weakening competition between manufacturers and PBMs for sizable rebates. If manufacturers reduce rebate offerings to PBMs to offset the financial risk of inflationary rebates, Part D premiums could potentially increase in two ways. First, plans (without sizable rebates) must then cover a greater

portion of an expensive medication. Second, beneficiary cost-sharing could increase for new branded products launched with high list prices as seniors' [copayment](#) is typically based on list and not the net price.

CMS' IRA guidance will likely increase costs for Part D plans by disincentivizing manufacturers from offering sizable rebates to PBMs, and these increased outlays will be passed on to seniors through larger premiums and out-of-pocket prescription expenses.

For a deeper dive into the IRA's drug pricing provisions, see the American Action Forum's [series](#) page on the subject.

IRA and Inflationary Rebates in Medicare Part B

The IRA requires manufacturers to pay inflationary rebates for drugs in both Medicare Part B (physician-administered drugs) and Part D (pharmacy medications). Yet plan and beneficiary cost-sharing differ significantly under each Medicare part. Under Medicare Part B, beneficiaries are required to pay a 20 percent coinsurance of the drug's price. If a drug under Part B received an inflationary penalty, a beneficiary's coinsurance is reduced to prevent them from paying prices that increased greater than inflation. According to the Department of Health and Human Services (HHS), [47 drugs](#) met the criteria for a Medicare Part B inflationary rebate in 2023. Typically, Part B drugs are reimbursed by Medicare under a "[buy and bill](#)" model without additional rebates or price concessions from manufacturers.

Medicare Part B is based on a very different reimbursement scheme than Medicare Part D. Currently, Part B inflationary rebates are being used to limit seniors' cost-sharing obligations whereas Medicare Part D inflationary rebates are not intended to do so.

IRA and Inflationary Rebates Medicare Part D

[PBMs](#) are contracted by health plans to provide pharmacy benefits to plan sponsors' enrollees. They also offer drug formularies to health plans by negotiating rebates from drug manufacturers. PBMs create pharmacy networks, reimburse pharmacies for dispensing and purchasing a drug, and provide utilization management tools such as prior authorization and step therapy. PBMs use rebate negotiations with drug manufacturers to reduce health plans' overall prescription drug costs, but not the cost of an individual patient's transaction. PBMs only offer products and services to plans and plan sponsors participating in Medicare Part D.

In theory, inflationary penalties intend to prevent the pharmaceutical industry from setting higher and higher list prices, yet such regulations overlook the role [rebates](#) play in reducing the amount a payer (public or private) pays for medicines. Typically, for brand name drugs, drug manufacturers offer substantial rebates to receive PBM-preferred tiering placement on a drug formulary. Many rebate agreements between the PBM and the manufacturer are based on [formulary access](#), [tiering](#), [volume](#), and [other metrics](#).

For some medications, fluctuations in pricing can occur even if the drug's list price never changes, potentially creating a scenario under CMS' guidance in which a manufacturer owes an inflationary rebate to CMS greater than the net sales of the product. Recent data [analysis](#) highlights that net prices (the actual amount paid after accounting for rebates) fell by 7 percent, even though list prices increased in 2023. For example, one 2023 [analysis found](#) that weighted average prices (in this case using wholesale acquisition cost) on brand name drugs has declined since 2012. Thus, list price alone is not reflective of cost for payers in either the private or public sector.

Recently, the Congressional Budget Office [updated](#) its [score](#) of the IRA's inflationary penalties, estimating that "average net prices of drugs in both Part B and Part D will be 2 percent lower in 2031 than they would have been without the inflation-rebate provisions and that overall, those provisions will reduce the federal budget deficit by \$8 billion in that year." Future [inflationary rebates](#) under Part D paid by manufacturers will be added to the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund. Non-compliant manufacturers face civil monetary penalties of [125 percent of required rebate amounts](#). CMS [intends](#) to send out inflationary rebate invoices to manufacturers in 2025 based on data submitted from 12-month applicable periods beginning October 1, 2022, and October 1, 2023.

Poor Incentives in Medicare Part D

IRA Plan Incentives

The IRA limits the amount Part D plans can increase their premiums to [6 percent](#) per year between 2024 to 2029. Following 2029, the HHS secretary will determine the plan's premium growth limit. Starting in 2024, Part D beneficiaries will have a \$2,000 out-of-pocket maximum set. American Action Forum research highlighted that the [potential impacts](#) on Part D beneficiaries the IRA changes to the catastrophic drug expenses and low-income-subsidy population may have on Medicare Part D stand-alone plans and Medicare Advantage plans. In November 2023, a [study](#) projected that average premiums would increase between 42 percent and 57 percent in 2024 in the five states with highest Medicare population (California, Florida, Texas, New York, and Pennsylvania). Furthermore, the study found that "approximately 25 percent of retirees are expected to exceed the \$2,000 limit, around 75 percent will face higher premiums with no reduction in co-pays due to the lower catastrophic limit." The structural changes to Medicare Part D plan cost and beneficiary cost-sharing liability appear to be increasing costs for the majority of seniors as savings from the IRA broadly are [not likely](#) to be used by CMS to reduce beneficiary costs. As American Action Forum [research](#) pointed out, "Medicare savings are simply another means of financing the IRA's \$670 billion in clean energy tax credits and other spending on energy and the environment." With no federal requirement to use the Medicare savings from the IRA for Medicare beneficiaries, CMS enforcement of inflationary penalties is a small but punitive mechanism to accumulate additional funds for the program.

IRA Manufacturer Incentives

In Medicare Part D, PBMs have historically assisted plans in keeping [costs low](#) for seniors by negotiating competitive formularies and obtaining sizable rebates. CMS implementation of inflationary rebates is likely to disincentivize manufacturers from offering PBMs rebates as manufacturers will prioritize higher list prices at launch as well as limiting rebate offerings over the lifecycle of product. This shift could see price increases for products that have only one manufacturer or for products found within Medicare's [six protected classes](#). In MedPac's [June 2023 Report to Congress](#), the commission noted that from 2015 to 2021: "While rebates vary considerably across drug classes and over time, we observed large rebates in classes that had strong brand rivalries but lacked generic or biosimilar entry. In contrast, for protected classes of drugs in which virtually all drugs must be covered, price competition was weakened, hindering plans' ability to negotiate rebates, and allowing gross and net prices of single-source drugs in many protected classes to grow faster than for drugs in

other classes.” Inflationary rebates are likely to be [another factor](#) in decreasing drug pricing competition and increasing costs for seniors.

Conclusion

CMS’ revised guidance on Medicare Part D inflationary rebates is likely to weaken competition between manufacturers and PBMs for sizable rebates. Indeed, through this process, the IRA is establishing incentives that will ultimately increase costs to seniors by undercutting market competition, as its focus on drugs’ list price rather than their net price is misguided. CMS’ new rule is establishing mandates and regulations without fully factoring in the role rebates play in the reduction of Part D premiums. This will likely cause unnecessary disruptions and increase costs for seniors in the long-term.