



Testimony

Before the Subcommittee on Health,
Committee on Energy and Commerce,
House of Representatives

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MEDICARE PART D

CMS Should Monitor Effects of Rebates on Drug Coverage and Spending

Statement of John E. Dicken, Director, Health Care

Chair Guthrie, Ranking Member Eshoo, and Members of the Subcommittee:

I am pleased to be here today as you examine the role of Medicare coverage in providing access to innovative drugs, medical devices, and technology. In particular, Medicare coverage of prescription drugs plays a key role in giving Medicare beneficiaries access to drug treatments, including new innovative prescription drugs, and has profound effects on the program's fiscal sustainability. In 2021, approximately 49 million Medicare beneficiaries received prescription drug coverage through Medicare Part D, with drug expenditures of more than \$200 billion.¹ Medicare provides this drug coverage to Medicare beneficiaries through drug plans provided by Part D plan sponsors, private companies who contract with the Centers for Medicare & Medicaid Services (CMS).

These drug plans vary in their premiums, in their lists of covered drugs—known as formularies—and in associated beneficiary cost-sharing.² Plan sponsors place drugs into different tiers which vary in their cost-sharing amounts and are meant to encourage beneficiaries to use drugs on tiers with lower cost-sharing. Plan sponsors, or pharmacy benefit managers (PBM) on their behalf, may negotiate rebates from drug manufacturers. These manufacturers provide payments to sponsors when a beneficiary purchases a drug in exchange for that drug's inclusion on a plan's formulary.³

Policymakers and others have noted tradeoffs in the effect that rebates may have on Medicare Part D drug spending and beneficiary access to drugs, as well as on competition among prescription drugs. Rebates reduce gross spending for drugs—the total amount paid to pharmacies by

¹Part D is an optional outpatient prescription drug benefit offered by Medicare. Medicare also has a drug benefit available under Part B—primarily for physician administered drugs—which is outside the scope of this statement.

²Beneficiary cost-sharing may include a flat amount (co-payment) or a percentage of a drug's costs (coinsurance).

³Part D plan sponsors may contract with PBMs to provide a variety of pharmacy benefit services, including drug claims adjudication, developing formularies, and negotiating rebates. Some Part D plan sponsors share a financial relationship with their PBM. For example, an entity may own both a plan sponsor and a PBM. GAO found that, in 2016, Medicare Part D plan sponsors used PBMs to provide 74 percent of drug benefit management services and performed the remaining 26 percent of services themselves. GAO, *Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization*, [GAO-19-498](#) (Washington, D.C.: July 15, 2019).

plan sponsors and beneficiaries—and lower premiums for all beneficiaries.

However, beneficiaries may not directly benefit from rebates when they purchase drugs. This is because their cost-sharing is based on the gross price of a drug paid to a pharmacy, before any rebates are taken into account.⁴ As a result, beneficiaries who use highly rebated drugs may pay higher cost-sharing. Furthermore, higher rebates for established drugs may create an incentive for plan sponsors to give them more preferred placement on their formularies (e.g., placing them on a tier with lower cost-sharing) over new drugs entering the market with lower costs, but fewer rebates.

My testimony today summarizes findings and a recommendation from our September 2023 report examining rebates in the Medicare Part D program.⁵ Accordingly, my testimony discusses

1. rebate and expenditure information for Part D drugs;
2. the types of rebate arrangements negotiated between selected pharmaceutical manufacturers and Part D plan sponsors;
3. the relationship between rebates and Part D formulary placement for competing drugs;
4. the implications of rebates on spending by Part D plan sponsors, beneficiaries, and the Medicare program; and
5. the fact that CMS does not consider rebate data as part of its oversight of Part D plan formularies.

To conduct this work, we analyzed CMS drug expenditure and rebate data for Part D drugs in 2021 (the data most recently available at the time of our analysis); reviewed selected rebate agreements between plan sponsors and drug manufacturers; reviewed CMS documentation; and spoke with CMS officials, plan sponsors, and manufacturers. More detailed information on the objectives, scope, and methodology of this work can be found in the issued report.

⁴For example, a \$100 drug with 20 percent beneficiary cost-sharing and a \$20 rebate would cost a beneficiary \$20 and the plan \$60. Not all beneficiaries pay cost-sharing.

⁵See GAO, Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending, [GAO-23-105270](#) (Washington, D.C.: Sep. 5, 2023).

We conducted the work on which this statement is based in accordance with generally accepted government auditing standards.

Part D Drug Rebates Were Concentrated Among a Small Number of Brand-Name Drugs and a Few Therapeutic Classes

In September 2023, we reported that rebates were concentrated among a small number of brand-name drugs and in three therapeutic classes. Specifically, we found that in 2021, pharmaceutical manufacturers paid plan sponsors \$48.6 billion in rebates, which accounted for 23 percent of the \$210.6 billion in Part D gross expenditures. These rebates were largely concentrated among a small number of drugs. We found that 84.2 percent (\$40.9 billion) of the rebates were for 100 brand-name drugs, representing 1.3 percent of all Part D drugs.⁶ Of the \$48.6 billion manufacturers paid in Part D rebates in 2021, 73 percent went to drugs within three therapeutic classes:

- endocrine metabolic agents, which include anti-diabetic drugs (e.g., insulins);
- blood modifiers, which include anti-stroke medications; and
- respiratory agents, which include anti-asthma medications.

In addition, these three therapeutic classes combined accounted for 40 percent of gross expenditures and 19 percent of utilization among all Part D drugs. See table 1 for information on rebates, gross expenditures, and utilization by therapeutic class for Part D drugs in 2021.

Table 1: Percentage of Rebates, Gross Expenditures, and Utilization for Medicare Part D Drugs by Therapeutic Class, 2021

Therapeutic class	Percentage of Part D rebates	Percentage of gross Part D expenditures	Percentage of Part D utilization
Endocrine metabolic agents	42	21	13
Blood modifier agents	17	10	3
Respiratory agents	14	9	3
Musculoskeletal agents	5	5	2
Central nervous system agents	4	12	19
Ophthalmologic agents	4	3	2
Cardiovascular agents	4	8	41
Genitourinary agents	3	2	3
Gastrointestinal agents	3	3	6

⁶These 100 drugs accounted for 42.5 percent of gross Part D expenditures and 6.5 percent of utilization. Further, biologics accounted for 27 of the 100 highest rebated drugs, 29.4 percent of the rebates, 23.2 percent of utilization, and 28.8 percent of expenditures.

Therapeutic class	Percentage of Part D rebates	Percentage of gross Part D expenditures	Percentage of Part D utilization
Anti-infective agents	2	6	2
Antineoplastic agents	1	14	1
Immunological agents	1	4	0
Dermatological agents	1	2	1
Other therapeutic classes	0	1	3
Total	100	100	100

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-23-107056

Note: We analyzed 2021 CMS prescription drug expenditure and rebate data for Medicare Part D drugs. Rebates are discounts manufacturers provide to Part D plan sponsors after a drug is purchased. Gross expenditures reflect what was paid to a pharmacy by the Part D plan sponsor and beneficiaries. We identified therapeutic class information using information from the RED BOOK, a drug pricing compendium published by Merative. Totals may not sum to 100 due to rounding.

Selected Part D Plan Sponsor and Manufacturer Rebate Agreements

In our September 2023 report, we found the selected 2020 Part D plan sponsor and manufacturer rebate agreements we reviewed contained a range of conditions intended to increase utilization and market share for a manufacturer's drug in exchange for rebates to plan sponsors.⁷ Key examples of these rebate conditions among the contracts we reviewed, described more fully in our report, include the following:

- **Preferred formulary tier.** All plan sponsors and drug manufacturers had rebate agreements where manufacturer rebates were based on a manufacturer's drug being placed on the formulary tier with the lowest cost-sharing relative to its competitor drugs in exchange for rebates to the plan sponsor.⁸
- **Number of competitors.** All plan sponsors and drug manufacturers had rebate agreements that based rebate amounts in part on the number of manufacturers that had competitor drugs on a preferred tier with the rebated drug. In general, manufacturers offered higher rebates if their drug was on a tier with fewer competing manufacturers.

⁷We reviewed 2020 rebate agreements negotiated between six drug manufacturers and six Part D plan sponsors, or PBMs on their behalf, for 24 brand-name drugs. Our selection of drugs was based on 2020 spending and rebate data, which was the most recent data available when we selected rebate agreements to review.

⁸While described separately, each condition often worked in conjunction with other rebate conditions. For example, some agreements specified that manufacturers would only pay rebates if their drug was on the preferred formulary tier and not subject to any restrictions.

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- **Competitors subject to restrictions.** All plan sponsors and drug manufacturers had rebate agreements where manufacturers offered rebates for their drug based on the condition that competitor drugs be subject to restrictions in order to limit their utilization (e.g., subjecting competitor drugs to utilization management or requiring that a competitor drug be excluded from the formulary).⁹
 - **Bundling.** At least half of the plan sponsors and manufacturers had rebate agreements that included provisions where a manufacturer's rebates for a specific drug were predicated on one or more of its other drugs also being placed on the preferred tier. For example, in some agreements, rebates for the manufacturer's drug were based on plan sponsors including four or more of the manufacturer's drugs on the sponsor's formulary in a preferred position.

Part D Plan Sponsors Frequently Gave Highly Rebated Drugs Preferred Formulary Placement

Our analysis in our September 2023 report showed that Part D plan sponsors frequently gave preferred formulary placement to highly rebated, relatively higher-gross-cost brand-name drugs compared to lower-gross-cost competitor drugs, which generally had lower rebates. Specifically, in seven of the 10 groups of competitor drugs we reviewed, we found that Part D plan sponsor formularies more frequently preferred highly rebated, relatively higher-gross-cost brand-name drugs compared to lower-gross-cost competitor drugs.¹⁰ Plan sponsors generally paid less for these higher-gross-cost drugs, after accounting for rebates, than for lower-gross-cost drugs within the groups. Moreover, in three of these seven groups, plan sponsors received more in rebates than they paid for the higher-gross-cost, highly rebated drugs, resulting in a net profit with respect to these specific drugs based only on the rebates received.

⁹Beneficiaries, through their prescribers, may request a formulary exception for the plan sponsor to cover an excluded drug.

¹⁰Gross cost refers to gross expenditures, or the amount paid by plan sponsors and beneficiaries (or other payers on their behalf) to pharmacies, per 30-day supply—before accounting for rebates. We defined competitive groups based on the drugs that were listed as competitors to a given manufacturer's drug in the rebate agreements we reviewed. The higher and lower-gross-cost drugs refer to drugs that had a higher- or lower-gross-cost relative to other drugs in the competitive group, not relative to all Part D drugs.

Implications of Part D Rebates on Plan Sponsor, Beneficiary, and Medicare Spending

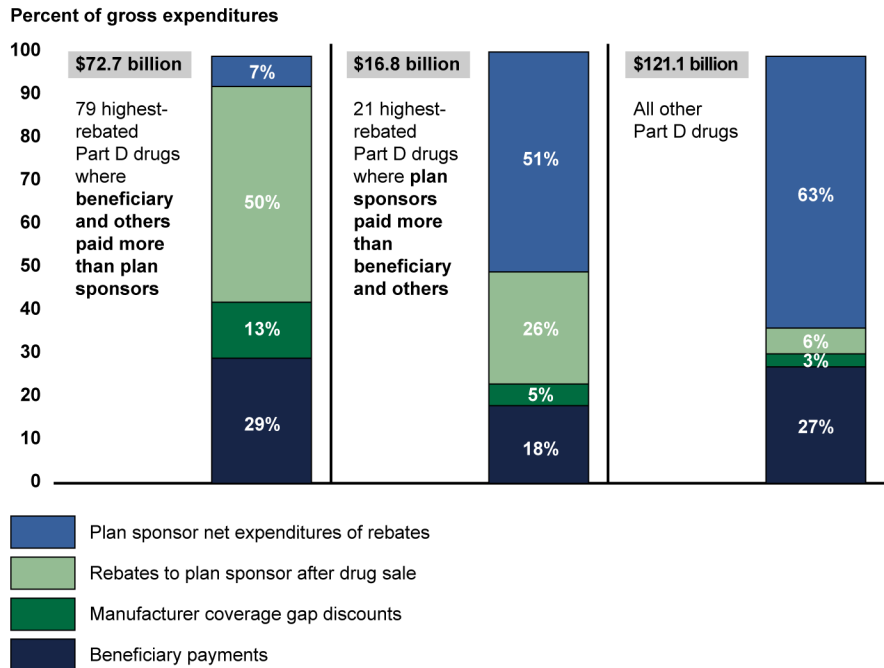
In our September 2023 report we found plan sponsors' formulary preference for and beneficiary use of highly rebated drugs had different implications for spending by plan sponsors, beneficiaries, and Medicare. In general, rebates may reduce plan sponsor payments (i.e., plan sponsors' net spending after accounting for rebates) for higher-gross-cost drugs to an amount below what the payment would be for lower-gross-cost, competitor drugs. Rebates, however, do not lower beneficiary payments for prescription drugs, which are based on the gross cost of the drug before accounting for rebates. Therefore, higher-gross-cost drugs generally result in higher beneficiary payments relative to beneficiary payments for lower-gross-cost competitor drugs. While rebates do not reduce costs for individual beneficiaries that are prescribed highly rebated drugs, rebates may lower the cost of premiums for Part D beneficiaries in the aggregate and for the Medicare program—which subsidizes approximately 75 percent of the cost of premiums—because premiums are set based on anticipated net drug costs after accounting for rebates.

Our analyses of the 100 highest rebated Part D drugs (as reported by their total spending) illustrated these considerations for beneficiaries, plans, and the Medicare program. We found that total beneficiary payments—paid by or on behalf of beneficiaries—were more than total plan sponsor payments for the majority of the 100 highest rebated Part D drugs in 2021, after accounting for rebates.¹¹ Specifically:

- Beneficiaries, or others on their behalf, spent \$21.0 billion on these 79 drugs, whereas plan sponsors spent \$5.3 billion after accounting for \$41.9 billion in rebates.
- For the remaining 21 of the 100 highest-rebated drugs, plan sponsor payments were greater than beneficiary payments. Specifically, beneficiaries, or others on their behalf, spent \$3.0 billion on these drugs, whereas plan sponsors spent \$8.7 billion after accounting for \$4.3 billion in rebates.
- Plan spending is also greater than beneficiary spending for all other Part D drugs. Specifically, plan sponsors paid \$84.0 billion for these drugs, while beneficiaries, or other payers on their behalf, spent \$33.2 billion. (See fig. 1.)

¹¹The 100 Part D drugs that received the most rebates accounted for 84.2 percent—\$40.9 billion—of the \$48.6 billion in rebates in 2021. Representing 1.3 percent of all Part D drugs, these 100 drugs accounted for 42.5 percent of gross Part D expenditures and 6.5 percent of utilization.

Figure 1: Medicare Part D Expenditures and Rebates by Payer Type for the 100-Most Rebated Drugs and All Other Part D Drugs, 2021



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-23-107056

Notes: We examined CMS expenditure and rebate information for Medicare Part D drugs in 2021. The plan sponsor and beneficiary payment amounts are approximate. To calculate plan sponsor net expenditures, we subtracted rebates from the amount plan sponsors paid. Beneficiary payments include payments by beneficiaries and other payers on their behalf. Plan sponsors' spending amounts do not include fees plan sponsors may have received from pharmacies and others to reduce their drug spending and may include reinsurance payments, which Medicare provides to plan sponsors in the catastrophic phase of the Part D benefit. In the coverage gap phase of the Part D benefit plan sponsors initially paid the manufacturer coverage gap discount to pharmacies on behalf of beneficiaries and manufacturers reimbursed plan sponsors for these monies later. Coverage gap monies do not include manufacturer rebates.

CMS Does Not Consider Rebate Data as Part of Oversight of Part D Plan Formularies

In our September 2023 report, we found that CMS uses Part D drug rebate data to help ensure the accuracy of its prospective payments to plan sponsors for providing Medicare Part D drug coverage. However, we also found that CMS does not use rebate data as part of its review of Part D plan formularies. CMS officials stated their review of Part D plan formularies includes an annual "clinical review" of formularies. This review is intended to determine whether: (1) formularies include commonly prescribed drug classes for the Medicare population and all commercially available vaccines; (2) utilization management requirements follow industry best practices; and (3) formularies contain benefit features that

are “outliers” from industry best practices by, for example, subjecting all drugs within a class to prior authorization. CMS officials explained that the agency approves plan design and formularies based on what they termed as the agency’s “anti-discrimination” authority to ensure that the formulary is not likely to substantially discourage enrollment of certain beneficiaries.¹²

We found instances where plan sponsors preferred rebated brand-name drugs with higher beneficiary costs over lower-cost alternatives. Such practices may result in certain beneficiaries not having access to the lower-cost alternatives. Further, because drugs receiving the highest rebates were concentrated in three therapeutic classes, these rebate and formulary practices can particularly affect certain beneficiaries with chronic conditions treated by drugs in these classes (e.g., diabetes and chronic obstructive pulmonary disease).

In our September 2023 report, we recommended that the Administrator of CMS monitor the effect of rebates on Part D plan sponsor formulary design and on Medicare and beneficiary spending. Such monitoring would allow CMS to assess whether rebate practices are likely to substantially discourage enrollment of certain beneficiaries. CMS disagreed with our recommendation, in part because the agency stated that it already reviews formularies. CMS also noted that rebate practices may change in the future once the Part D program changes as required under the Inflation Reduction Act of 2022.

However, monitoring the effect of rebates as we recommended would provide CMS with important information on whether formulary practices are likely to discourage enrollment of certain beneficiaries. In fact, such information could be particularly valuable as a number of provisions under the Inflation Reduction Act of 2022 may change rebate incentives and the effects rebates can have on formulary design and spending. These provisions include drug price negotiation for selected high-cost drugs and limits on beneficiary out-of-pocket spending. In addition, monitoring of aggregated rebate and expenditure data from prior years could give the agency insight into rebate practices that influence formulary design in

¹²Under the Social Security Act and implementing regulations, CMS may approve a Part D plan only if the plan design and benefits, including the formulary structure, are not likely to substantially discourage enrollment by certain Part D eligible individuals. 42 U.S.C. § 1395w-111(e)(2)(D) and 42 C.F.R. § 423.272(b)(2)(i) (2022).

ways that could adversely affect beneficiary access for certain Part D drugs and may not be identified by a clinical formulary review.

Chair Guthrie, Ranking Member Eshoo, and Members of the Subcommittee, this concludes my prepared statement. I would be pleased to respond to any questions that you or other members of the committee may have at this time.

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