



September 2023

MEDICARE PART D

CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending

GAO Highlights

Highlights of [GAO-23-105270](#), a report to Congressional Requesters

Why GAO Did This Study

Medicare Part D drug expenditures exceeded \$200 billion in 2021. Part D plan sponsors may negotiate rebates from drug manufacturers, where manufacturers offer payments to sponsors in exchange for access to a plan's formulary. Manufacturers may offer higher rebates in exchange for lower beneficiary cost-sharing or facing fewer competitors. Policymakers have sought better understanding of rebates' effects on Part D spending and beneficiary access.

GAO was asked to examine rebates in the Part D program. This report, among other objectives, describes (1) rebate and expenditure information for Part D drugs and (2) implications of rebates on plan sponsors and beneficiaries. GAO also assessed how CMS considers rebate data in its oversight of Part D formularies.

GAO 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 CMS documentation; and spoke with CMS officials, plan sponsors, and manufacturers.

What GAO Recommends

The Administrator of CMS should monitor the effect of rebates on plan sponsor formulary design and on Medicare and beneficiary spending to assess whether rebate practices are likely to substantially discourage enrollment by certain beneficiaries. The Department of Health and Human Services did not concur with GAO's recommendation. GAO believes the recommendation could help ensure compliance with Part D requirements.

View [GAO-23-105270](#). For more information, contact John Dicken at (202) 512-7114 or dickenj@gao.gov.

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What GAO Found

GAO found plan sponsors—private companies that provide voluntary Medicare Part D prescription drug coverage—received \$48.6 billion in rebates from drug manufacturers in 2021. Three therapeutic drug classes accounted for 73 percent of rebates: (1) endocrine metabolic agents, including antidiabetic drugs; (2) blood modifiers, including anti-stroke drugs; and (3) respiratory agents, including anti-asthma drugs.

Beneficiary use of highly rebated drugs had different spending implications for plan sponsors, beneficiaries, and Medicare. In general, rebates may reduce plan sponsor payments for drugs with a higher gross cost to an amount lower than the payment for a competing drug with a lower cost. This may lower Medicare drug spending, as its plan sponsor payments are based on drug costs after rebates. However, rebates do not lower individual beneficiary payments for drugs, as these are based on the gross cost of the drug before accounting for rebates. Thus drugs with higher gross costs generally result in higher beneficiary payments relative to payments for competing drugs with lower gross costs. GAO found payments by beneficiaries were more than plan sponsor payments, after accounting for rebates, for 79 of the 100 drugs receiving the most rebates.

Medicare Part D Expenditures by Beneficiaries and Plan Sponsors, after Rebates, for the 79 Highest-Rebated Drugs Where Beneficiaries Paid More than Plan Sponsors, 2021



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-23-105270

The Centers for Medicare & Medicaid Services (CMS) uses drug rebate data to help ensure its plan sponsor payments are accurate, but CMS officials stated they do not use this data in its oversight of plan formularies. CMS conducts an annual clinical formulary review, which includes reviewing if formularies include commonly prescribed drug classes. GAO found that rebates may influence formulary design in ways that could affect beneficiary access for certain drugs. CMS officials told GAO that an evaluation of rebate information is unnecessary given its clinical formulary review, and that CMS is statutorily prohibited from interfering with drug manufacturer and plan sponsor negotiations. However, monitoring rebate and expenditure data would not require CMS to interfere with negotiations between plan sponsors and manufacturers, and it could provide CMS and Congress insight on the extent to which rebates' influence on formularies could discourage enrollment of certain beneficiaries. Such monitoring of rebates will be particularly important as the agency implements the provisions of the Inflation Reduction Act of 2022, which will change Part D plan sponsor, beneficiary, and Medicare drug spending responsibility and may affect formulary design and rebates.

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Abbreviations

CMS	Centers for Medicare & Medicaid Services
FDA	Food and Drug Administration
FTC	Federal Trade Commission
HHS	Department of Health and Human Services
PBM	pharmacy benefit manager

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September 5, 2023

The Honorable Hakeem Jeffries
Minority Leader
House of Representatives

The Honorable Amy Klobuchar
Chair, Subcommittee on Competition Policy, Antitrust,
and Consumer Rights
Committee on the Judiciary
United States Senate

The Honorable Richard Blumenthal
United States Senate

The Medicare Part D program provides voluntary prescription drug coverage to Medicare beneficiaries. In 2021, approximately 49 million Medicare beneficiaries received Part D coverage with drug expenditures of more than \$200 billion.¹ Part D drug coverage is provided to Medicare beneficiaries through drug plans provided by Part D plan sponsors, private companies who contract with the Centers for Medicare & Medicaid Services (CMS) to provide this drug coverage. Plan sponsors' 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” that vary in their cost-sharing amounts, which 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, where

¹Part D is an optional outpatient prescription drug benefit offered by Medicare—the federally financed health insurance program for persons aged 65 and over, individuals under age 65 with certain disabilities, and individuals with end-stage renal disease. Medicare also has a drug benefit available under Part B—primarily for physician administered drugs—which is outside the scope of this report.

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

manufacturers provide payments to sponsors when a beneficiary purchases a drug in exchange for access to a plan's formulary.³

Rebates may lower spending for Part D drugs because Medicare bases its payments to plan sponsors on the cost they pay for drugs after rebates, and plan sponsors use rebates to reduce the premiums beneficiaries pay for their drug coverage.⁴ We previously reported that manufacturer rebates paid to plan sponsors reduced gross expenditures—the amount paid by plan sponsors and beneficiaries for Part D drugs—by 18.6 percent in 2016.⁵

Policymakers and others have questioned 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. For example, beneficiaries may not directly benefit from rebates as their cost-sharing is based on the gross price of a drug paid to a pharmacy, before any rebates are taken into account.⁶ As a result, beneficiaries who take highly rebated drugs may pay higher cost-sharing, while the rebates subsidize lower premiums for all beneficiaries. Furthermore, higher rebates for established drugs may create an incentive for plan sponsors to give them more preferred placement on their formularies over new drugs entering the market with lower costs, but fewer rebates. The Federal Trade Commission (FTC), one of the federal agencies that enforces antitrust

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).

⁴In addition to rebates, plan sponsors may obtain other price concessions that lower their spending for Part D drugs, including fees from pharmacies for not meeting certain performance metrics.

⁵In 2016, manufacturers paid \$27 billion in rebates for Part D drugs, which lowered Part D gross expenditures from \$145.1 billion to \$118.1 billion. [GAO-19-498](#).

⁶For example, a \$100 drug with 20 percent beneficiary cost-sharing and \$20 rebate would cost a beneficiary \$20 and the plan \$60. Not all beneficiaries pay cost-sharing. Certain beneficiaries may receive low-income subsidy assistance payments, which results in them paying no or minimal cost-sharing payments based on their income.

laws, has noted that rebates may affect competition depending on the circumstances.⁷

Part D plan sponsors have flexibility in developing their formularies, but they are subject to certain laws, regulations, and policies enforced by CMS, which administers the Part D program. For example, federal law requires CMS to review Part D plan sponsor formularies and approve formularies only if they are unlikely to substantially discourage enrollment by different types of beneficiaries.

You asked us to look at the types and function of rebate arrangements in pharmaceutical markets, including their effect on drug spending, utilization, and competition. In this report, we assessed the Medicare Part D program to:

1. describe rebate and expenditure information for Part D drugs;
2. describe the types of rebate arrangements negotiated between selected pharmaceutical manufacturers and Part D plan sponsors;
3. describe the relationship between rebates and Part D formulary placement for competing drugs;
4. describe the implications of rebates on spending by Part D plan sponsors, beneficiaries, and the Medicare program; and
5. examine how, if at all, CMS considers rebate data as part of its oversight of Part D plan formularies.

To describe the extent to which Part D plan sponsors received rebates from manufacturers for Part D drugs, we analyzed 2021 CMS Part D prescription drug expenditure and rebate data, the most recent data available at the time of our analysis. These data provided gross expenditures for Part D drugs (i.e., the amount paid to pharmacies by plan sponsors and beneficiaries—the latter in the form of cost-sharing), the rebate amounts paid by manufacturers, and utilization—based on the

⁷For example, FTC and others have noted certain rebate arrangements may constitute “rebate walls” (sometimes referred to as “rebate traps”) whereby rebate arrangements may stifle competition and innovation. In its May 2021 report on rebate walls, FTC stated “rebate walls refer to a situation in which a dominant pharmaceutical manufacturer uses rebate strategies in its contracts with third party payors to maintain market power, by giving its products preferred status in drug formularies, and to prevent sales of competing products.” Federal Trade Commission, *Report on Rebate Walls*, (Washington, D.C.: May 2021).

number of 30-day supplies for each drug. We analyzed and report drug expenditure and rebate information for brand-name and generic drugs based on their ingredient, strength, and dose form.⁸ We also used Merative’s RED BOOK to determine a drug’s therapeutic class and Food and Drug Administration (FDA) information to identify biologics and biosimilars.⁹ We report gross expenditures, as they provide the basis for applicable beneficiary cost-sharing prior to the application of rebates and are used as the basis for determining beneficiary spending within the Part D benefit (see the background for additional information on beneficiary payment and the Part D benefit). We also subtract rebates from gross expenditures to calculate net expenditures.

To describe the types of rebate arrangements negotiated between selected pharmaceutical manufacturers and Part D plan sponsors, we 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.¹⁰ Our selection of drugs was based on 2020 spending and rebate data, which was the most recent data available when we selected rebate agreements. We selected six of the 25 largest Part D plan sponsors by contract enrollment in 2020 and the six manufacturers of the 24 brand-name drugs. We selected 24 brand-name

⁸For the purposes of our report, we identified brand-name drugs as drugs that have a marketed brand name and biologics, which are products derived from living sources, such as humans, animals, and microorganisms. An approved generic drug is therapeutically equivalent to a corresponding brand-name drug and is generally marketed under a nonproprietary generic name. In some instances, a generic drug may be marketed under a brand name. In other instances, a brand-name drug may be marketed by the brand-name manufacturer, or by another company with the manufacturer’s permission and without the brand name on the label, and is referred to as an “authorized generic.” For the purposes of our report, we identified generic drugs as drugs that are marketed without a brand name, including authorized generics, and biosimilars that are highly similar to an existing biologic licensed by the Food and Drug Administration (FDA).

⁹A “therapeutic class” identifies drugs that are similar in chemical structure, pharmacological effect, or clinical use. RED BOOK, a drug pricing compendium, provides a five-level nested classification for each drug, with the first level being the broadest. We report the first level for Part D drugs, which represented 25 unique therapeutic classes for Part D drugs in 2021.

¹⁰The 24 brand-name drugs represented approximately 100 unique ingredient, strength, and dose combinations. Some of the plan sponsors shared a financial relationship with a PBM (e.g., the plan sponsor and PBM were owned by the same parent organization) or worked with a PBM for services such as negotiating rebate agreements with manufacturers. In these instances, we obtained the rebate agreements directly from the PBM on the plan sponsor’s behalf. For reporting purposes, we report these perspectives as “plan sponsor” perspectives.

drugs based on one or more factors, including: those that had at least one drug formulation that was among the 100 most highly rebated in 2020, were competitors of highly rebated drugs, or were biologics.¹¹ We applied our selection criteria to achieve a unique and unidentifiable mix of plan sponsors, manufacturers, and drugs in order to protect the proprietary and confidential nature of the information in the rebate agreements. We interviewed CMS officials and interviewed or obtained written responses from representatives from three pharmaceutical manufacturers and four Part D plan sponsors, including those associated with a PBM, regarding the types of rebating arrangements that are negotiated between plan sponsors, or PBMs on their behalf, and manufacturers.

To describe the relationship between rebates and Part D formulary placement among competing drugs, we examined 2021 CMS formulary, expenditure, and rebate data. We examined the relationship between rebates and formulary placement from two perspectives in order to address potentially distinct implications for (1) brand-name competitor drugs that accounted for approximately half of rebate dollars in 2021 and (2) brand-name drugs with generic-name counterparts that accounted for approximately 13 percent of rebate dollars in 2021.¹² Specifically, we conducted the following analyses.

- **Competitive groups.** We identified 10 groups of competitor drugs (hereafter, referred to as competitive groups) and assessed the extent to which Part D formularies listed highly rebated brand-name drugs in these groups on a preferred formulary tier relative to available competitor drugs.¹³ We also examined 2021 CMS Part D prescription drug expenditure and rebate data for drugs in the competitive groups to determine the relative costs of highly rebated brand-name and competitor drugs. These 10 competitive groups accounted for \$23.9

¹¹As a result of our selection criteria, some of the selected drugs were also among those that were less rebated in 2020.

¹²While addressing separate perspectives, these analyses overlapped in that certain drugs were represented in both sets of selected drugs.

¹³To select the brand-name drugs included in the 10 competitive groups, we identified the brand-name drugs that were listed in the rebate agreements that we reviewed as competitors to a given manufacturer's drug. We included brand-name drugs that were listed in at least two agreements as competitors for a particular drug. We defined highly rebated brand-name drugs in the 10 competitive groups as brand-name drugs for which rebates accounted for at least 25 percent of expenditures. The average rebate percentage for these drugs was 51 percent. The competitive groups also included lower-rebated drugs that were identified as competitors in the rebate agreements.

billion in rebate dollars, or approximately half of all Part D rebate dollars in 2021.

- **Brand-name drugs and generic-name counterparts.** We assessed the extent to which brand-name drugs that had counterparts marketed under a generic name, (hereafter, referred to as generic counterparts) were rebated, and we reviewed Part D formularies to determine formulary placement for brand-name drugs relative to their generic counterparts. We compared the formulary placement of 40 highly rebated brand-name drugs and generic counterparts to other brand-name drugs with generic counterparts.¹⁴ The 40 selected brand-name drugs accounted for \$6.3 billion in rebate dollars, or approximately 13 percent of all Part D rebates in 2021.

To describe the implications of rebates on spending by Part D plan sponsors, beneficiaries, and the Medicare program, we used 2021 CMS Part D prescription drug expenditure and rebate data to determine (1) the total amount spent by these payers for the 100 highest rebated drugs—those accounting for approximately 80 percent of all Part D rebates—analyzed in our first reporting objective and (2) spending per utilization for the drugs within the 10 selected brand-name competitive groups and 40 selected brand-name drugs with generic counterparts analyzed in our third reporting objective. For these Part D drugs, we calculated gross expenditures by Part D plan sponsors, beneficiaries and others on their behalf, and manufacturers (in the form of discounts provided for applicable beneficiaries in the coverage gap).¹⁵ We subtracted rebates manufacturers paid to Part D plan sponsors from the amount spent by plan sponsors to determine net plan sponsor spending.

To examine how, if at all, CMS considers rebate data as part of its oversight of Part D plan formularies, we interviewed CMS officials on

¹⁴We selected the 40 highly rebated brand-name drugs by identifying the drugs that accounted for the top 98 percent of rebate dollars among Part D brand-name drugs for which we identified generic counterparts.

¹⁵Beneficiary payments are approximate and include payments by beneficiaries and other payers on their behalf, including Medicare's low-income subsidy payments, and third-party payers such as group health plans (e.g., for retired beneficiaries receiving drug coverage through an employer-based plan) and other government payers. In some instances, beneficiary payments may include payments made by plan sponsors. Plan sponsors' spending net of rebates are approximate, as these 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.

oversight related to drug spending and rebate use. We also reviewed applicable Part D statutes and CMS regulations, reporting requirements for plan sponsors, the Medicare Prescription Drug Benefit Manual, and formulary review guidelines. We examined CMS oversight activities in the context of relevant statutes and regulations governing their oversight and relevant internal controls for the federal government.¹⁶ We interviewed FTC officials and reviewed applicable statutes, policy statements, and reports in order to summarize FTC perspectives on rebate arrangements, which are summarized in appendix II.

For all of the data we analyzed, we took steps to assure their reliability, including interviewing knowledgeable officials, conducting data checks for outliers and anomalies, and comparing the data to published information when available. After taking these steps, we determined that the data were sufficiently reliable for the purposes of our reporting objectives. Appendix I provides additional details on our scope and methodology for analyzing drug expenditure and rebate information in findings 1, 3, and 4.

We conducted this performance audit from May 2021 to September 2023 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings based on our audit objectives.

Background

Prescription Drug Supply Chain

Several entities are involved with, and pay different prices for, prescription drugs as they move from the manufacturer to the beneficiary (this is referred to as the prescription drug supply chain). In general, manufacturers develop and sell their drugs to wholesalers, and wholesalers then sell the drugs to pharmacies. When a beneficiary purchases a drug from a pharmacy, the pharmacy is paid by the Part D plan sponsor—or the PBM on the sponsor’s behalf—and by the beneficiary through any applicable cost-sharing. Manufacturers then

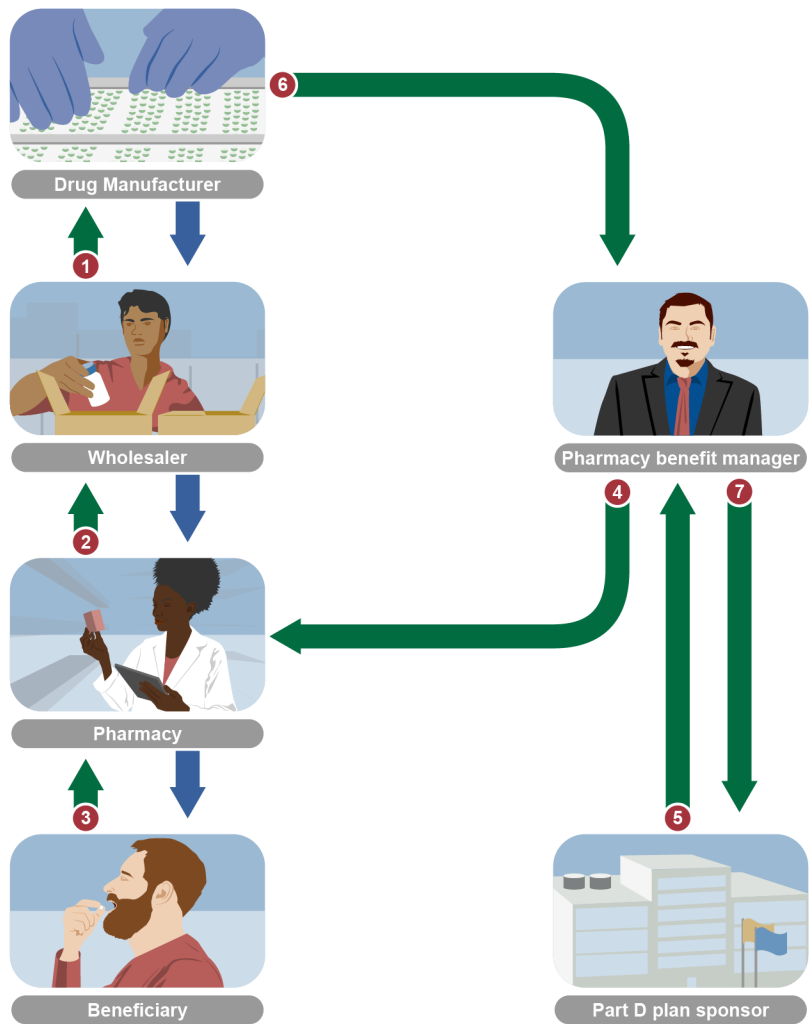
¹⁶GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: Sept. 10, 2014). Internal control is a process effected by an entity’s oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved. We examined CMS oversight relative to Principle 7 which states that management should identify, analyze, and respond to risks related to achieving the defined objectives.

generally pay applicable rebates to the plan sponsor—or PBM on their behalf—after the drug is purchased. (See fig. 1 for a flow chart showing the relationship between certain entities in the prescription drug supply chain when a Part D plan sponsor uses a PBM.)

Figure 1: Example of the Flow of Funds and Prescription Drugs through the Supply Chain When a Medicare Part D Beneficiary Purchases a Drug through a Part D Plan Sponsor Using a Pharmacy Benefit Manager

- 1 Wholesaler purchases drug from manufacturer.
- 2 Pharmacy purchases drug from wholesaler.
- 3 Beneficiary purchases drug from pharmacy and pays applicable cost-sharing.
- 4 Pharmacy benefit manager (PBM) pays pharmacy for remaining cost of drug.
- 5 Part D plan sponsor pays PBM for the drug.
- 6 PBM receives negotiated rebate from manufacturer.
- 7 PBM passes on all or a portion of rebate from manufacturer.

- Flow of funds
- Flow of drugs



Source: GAO; GAO (illustrations). | GAO-23-105270

Medicare Part D Coverage

Medicare beneficiaries receive Part D drug coverage through two types of drug plans: stand-alone Part D prescription drug plans that supplement traditional Medicare with prescription drug coverage, or Medicare Advantage (Part C) plans that generally must cover all Medicare benefits and usually offer Part D coverage. Part D also includes a low-income subsidy that provides assistance with premiums and cost-sharing. Low-income subsidy beneficiaries pay zero or nominal cost-sharing and the subsidy pays for the remainder of cost-sharing. Nearly 13 million individuals with low income and assets—approximately 26 percent of Part D enrollees—received low-income subsidy benefits in 2021.

Part D Formularies

Formularies are lists of drugs covered by Part D plans. Plan sponsors, or PBMs on their behalf, develop formularies by identifying the clinically appropriate drugs to treat conditions within specific therapeutic classes. Plan sponsors then negotiate rebates with manufacturers and negotiate drug prices with pharmacies.¹⁷


In developing their formularies, plan sponsors generally place drugs into different “tiers” on their formularies. Each plan sponsor can divide the tiers on its plan formularies in different ways, with plans generally offering 5-tier formularies. Generally, drugs in a lower-numbered tier cost beneficiaries less than drugs in higher-numbered tiers, with generic drugs on the lowest tier and brand-name and specialty drugs on a higher tier.¹⁸ For example, tier 1 may include most generic prescription drugs, which have the lowest cost-sharing, while tier 5 may include specialty drugs, which include high-cost prescription drugs with the highest cost-sharing. For both generic and brand-name drugs, plans may offer preferred and non-preferred tiers. Drugs in preferred tiers are generally more cost-effective for the plan than drugs in non-preferred tiers. Preferred brand-name and generic drugs also generally have lower cost-sharing than non-preferred brand-name and generic drugs. When beneficiaries use a drug not covered on a plan’s formulary, they can expect to pay full price for the drug. Beneficiaries may file for a coverage exception and ask the plan






¹⁷In negotiating prices with pharmacies, plan sponsors create pharmacy networks where beneficiaries may fill their prescriptions. This can also include developing “preferred networks,” whereby beneficiaries pay lower cost-sharing and pharmacies agree to receive lower prices for drugs in exchange for increased volume of prescriptions purchased.

¹⁸In order for a Part D sponsor to place a Part D drug on a specialty tier in 2021, a Part D drug’s 30-day equivalent ingredient cost must have exceeded \$670. For these drugs, CMS set the maximum allowable cost-sharing at 25 percent if the plan required a deductible for drug coverage and 33 percent if the plan had no deductible. Beginning January 1, 2022, CMS allowed Part D plans to have a second, “preferred” specialty tier with a lower cost-sharing amount than their other specialty tier.

sponsor to cover the drug with cost-sharing. See figure 2 for a hypothetical example of a 5-tier formulary, with different costs associated with drug type and tier placement.

Figure 2: Example of Drug Type and Beneficiary Cost Associated with Medicare Part D Formulary Tiers



Tier	Drug type	Cost to beneficiary
1	 Preferred generics	\$
2	 Generics	\$\$
3	 Preferred brands	\$\$\$
4	 Non-preferred	\$\$\$\$
5	 Specialty	\$\$\$\$\$

Source: GAO; GAO (illustrations). | GAO-23-105270

Note: Plan sponsors generally place drugs into different “tiers” on their plan formularies that correspond to different levels of beneficiary cost-sharing. Each plan can divide its tiers in different ways, with plans generally offering 5-tier formularies. Generally, drugs in a lower-numbered tier cost less for a beneficiary than drugs in a higher tier, with generic drugs on the lowest-numbered tiers and brand-name and specialty drugs on higher-numbered tiers.

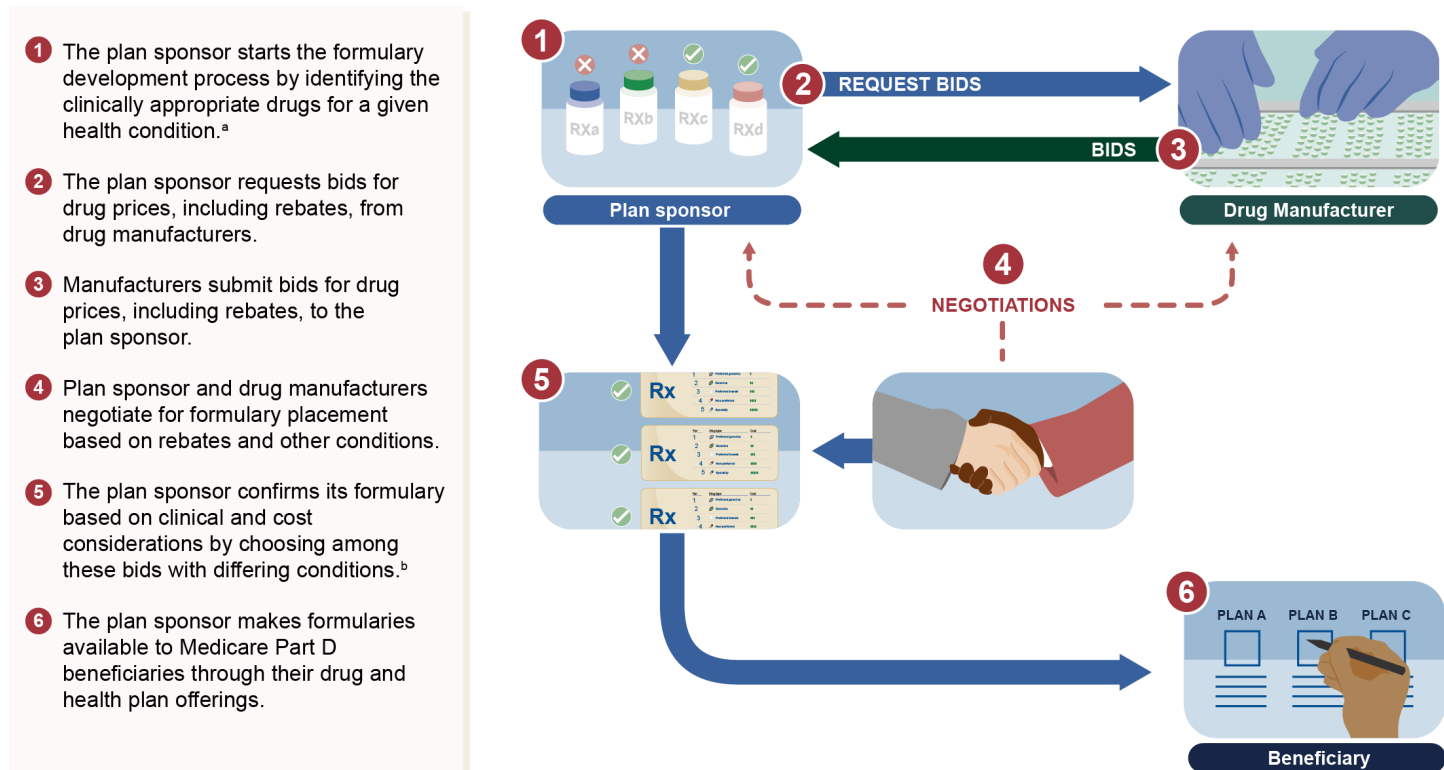
Plan sponsors are required to have utilization management programs to help ensure that the use of drugs and other medical services is based on medical necessity, appropriateness, and cost considerations. Examples of utilization management include the following.

- **Prior authorization.** Plan sponsors may require a beneficiary to obtain the plan sponsor’s approval for a drug, known as prior authorization. Plan sponsors may also require prior authorization when they cover a medication for certain, but not all, medical conditions for which a drug is approved.
- **Step therapy.** Plan sponsors may require a beneficiary to first try a certain, less expensive drug on the plan’s formulary that has been proven effective for most people with a given condition before the beneficiary can move up a “step” to another drug. For example, a plan sponsor may require the use of a generic drug before moving to a similar, more expensive brand-name drug.

Part D plan formularies may vary in their list of covered drugs and cost-sharing amounts but must adhere to certain CMS requirements. Part D

plan sponsors' formularies (1) must provide access to an acceptable range of Part D drug choices; (2) must not be likely to substantially discourage enrollment of certain beneficiaries; (3) cover all or substantially all drugs in the following six therapeutic classes, which are: antineoplastic; antipsychotics; anticonvulsants, antidepressants, immunosuppressants, and antiretrovirals; and (4) include two drugs in each class. See figure 3 for an overview of Part D plan sponsor formulary development.

Figure 3: Example of Medicare Part D Plan Sponsor Formulary Development



Source: GAO; GAO (illustrations). | GAO-23-105270

Notes: Formularies are lists of drugs covered by Medicare Part D plans. In developing formularies, plan sponsors place drugs into different “tiers” with drugs on a lower-numbered tier generally costing beneficiaries less than drugs on a higher-numbered tier

^aPlan sponsors may use a pharmacy benefit manager to develop their formulary.

^bPlan sponsors are subject to formulary requirements. While they are not required to cover all Part D drugs, sponsors’ formularies (1) must provide access to an acceptable range of Part D drug choices, (2) must not be likely to substantially discourage disenrollment of certain beneficiaries, (3) include two drugs in each class of drugs, and (4) cover all or substantially all drugs in the following protected classes: antineoplastics; antipsychotics; anticonvulsants, antidepressants, immunosuppressants, and antiretrovirals.

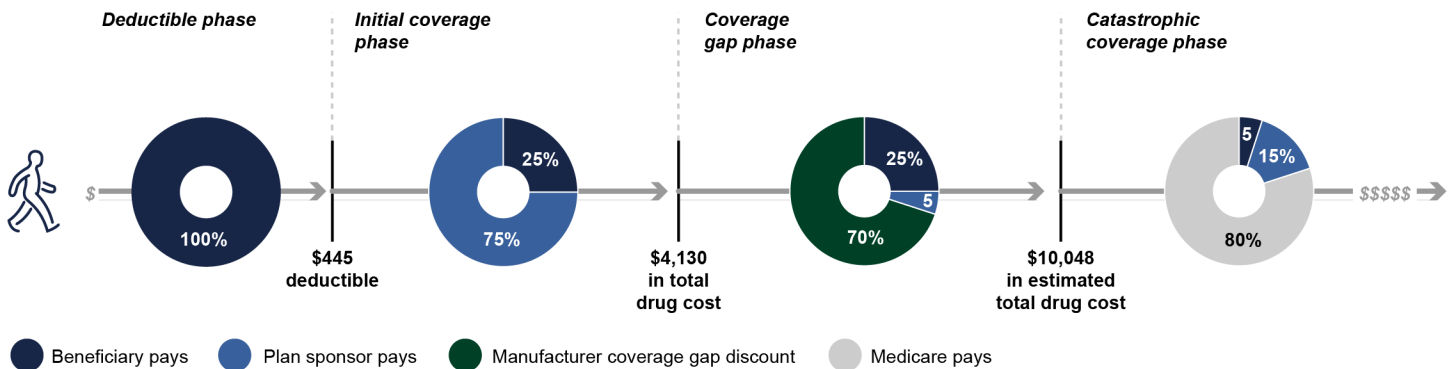
Part D Drug Benefit

Part D plan sponsors must offer a minimum “standard benefit” package by meeting certain statutory requirements. There are four Part D coverage phases in the standard benefit, in which the beneficiary, the Part D plan sponsor, the drug manufacturer, and Medicare pay different amounts. In 2021, the standard benefit had a deductible phase where the beneficiary paid 100 percent of all drug costs up to \$445. Once the \$445 deductible was met, a beneficiary entered the initial coverage phase, in which drug costs were shared between the beneficiary (who paid 25 percent in coinsurance) and the Part D plan sponsor (which paid 75 percent), until total drug spending reached \$4,130 (and beneficiary cost-sharing was approximately \$1,360). After this limit was reached, a beneficiary entered the “coverage gap” phase where the beneficiary, Part D plan sponsor, and drug manufacturer paid 25 percent, 5 percent, and 70 percent, respectively, of brand-name drug costs (the amount paid by the manufacturer—the manufacturer coverage gap discount—was in the form of a discount manufacturers paid on behalf of beneficiaries).¹⁹ The coverage gap lasted until total drug spending reached approximately \$10,048 (and beneficiary cost-sharing was \$6,550). After this point, the beneficiary entered the catastrophic phase, in which Medicare paid 80 percent of costs (referred to as reinsurance), Part D plan sponsors paid 15 percent, and beneficiaries paid 5 percent for all drugs, with no upper limit on beneficiary spending. (See fig. 4.) As described in more detail below, the Inflation Reduction Act of 2022 makes a number of changes to the Part D benefit beginning in 2025, including changes to beneficiary, plan sponsor, and Medicare payment amounts.²⁰

¹⁹Plan sponsors initially paid the manufacturer coverage gap discount to pharmacies on behalf of beneficiaries in the coverage gap. Manufacturers reimbursed plan sponsors for these monies later. In contrast, manufacturers did not pay for generic drugs in this phase, so Part D plan sponsors covered 75 percent of generic costs and beneficiaries covered 25 percent of generic costs. Low-income subsidy beneficiaries did not receive brand discounts from manufacturers in the coverage gap phase. For most low-income subsidy beneficiaries, Medicare paid for all cost-sharing except nominal copayments, thereby including most spending in the coverage gap phase.

²⁰Pub. L. No. 117-169, tit. I, subtit. B, 136 Stat. 1818, 1833-1905.

Figure 4: Overview of the Medicare Part D Standard Benefit for Brand-Name Drugs, 2021



Source: GAO analysis of Medicare Part D standard benefit parameters; GAO (illustration). | GAO-23-105270

Note: This figure describes the phases of the Medicare Part D standard drug benefit for beneficiaries not receiving low-income subsidy assistance, including the amount spent by plan sponsors, beneficiaries, manufacturers, and Medicare. Part D plan sponsors are required to offer a standard benefit, but may provide alternative benefit structures that are actuarially equivalent to the standard benefit. In 2021, beneficiaries paid 100 percent of drug costs in the deductible phase. In the coverage gap phase, plan sponsors initially paid the manufacturer coverage gap discount to pharmacies on behalf of beneficiaries, and manufacturers reimbursed plan sponsors for these monies later. For generic drugs, beneficiaries in the coverage gap phase paid 25 percent and plan sponsors paid 75 percent of drug costs. Manufacturers did not provide discounts for low-income subsidy beneficiaries in the coverage gap phase. For most low-income subsidy beneficiaries, Medicare paid for all cost-sharing except nominal copayments, thereby including most spending in the coverage gap phase.

Plan sponsors may follow this standard benefit structure in developing their plans, or they may offer alternative benefit structures. That is, they may offer a benefit that is actuarially equivalent to the standard benefit structure subject to some constraints but adjust certain cost-sharing features, while covering the same share of drug spending for beneficiaries, on average, as the benefit outlined above.²¹

Medicare Part D Payment to Plan Sponsors and Beneficiary Premiums

Medicare makes two primary payments to plan sponsors, as follows.

- **Prospective monthly payments.** Medicare pays plan sponsors a monthly payment to cover the estimated costs of providing beneficiary drug coverage. These payments are determined through annual bids submitted by plan sponsors in June of the preceding program year, which runs from January 1 through December 31. Those bids reflect the plan sponsors' estimates of program costs and rebates and other

²¹In addition to the basic benefit, some plans offer supplemental coverage for which beneficiaries pay an additional premium. Those plans are sometimes referred to as enhanced plans. Benefits offered by enhanced plans may include additional coverage in the coverage gap, lower cost-sharing, or a lower deductible.

price concessions that the sponsor expects to incur and receive during the ensuing program year.

- **Reinsurance.** Medicare pays plan sponsors for 80 percent of drug spending in the catastrophic phase of the drug benefit, which was spending above approximately \$10,048 in 2021.²²

At the end of the program year, CMS reviews cost data submitted by plan sponsors through Prescription Drug Event records and their submission of rebate and other price concession data and compares estimated payments with actual costs incurred, with CMS either reclaiming some funds from or making additional payments to plan sponsors. Thus, Medicare's final payments to plan sponsors are based on the costs actually paid by sponsors minus rebates and other price concessions.

In addition to a deductible and cost-sharing, most Part D plan sponsors charge beneficiaries monthly premiums for their drug coverage, which vary by plan. Beneficiary premiums are based on the average bids submitted by participating sponsors for standard benefits each year and are adjusted to reflect the difference between the standardized bid amount of the plan the beneficiary enrolls in and the nationwide average bid. Rebates help lower plan premiums, as they are based on the estimated cost of providing drug coverage net of rebates and other price concessions.

Payment for Part D Drugs

There are multiple payers involved when a Medicare beneficiary purchases a drug from a pharmacy, including plan sponsors, beneficiaries, drug manufacturers, and the Medicare program. When a beneficiary purchases a drug, the pharmacy is paid by the plan sponsor and by the beneficiary through any applicable cost-sharing (the total amount paid to the pharmacy reflects gross expenditures).²³ For beneficiaries in the coverage gap phase, manufacturers provide a discount of 70 percent of brand-name drug costs for beneficiaries not receiving low-income subsidy assistance (manufacturer coverage gap discounts). For beneficiaries in the catastrophic phase, Medicare pays

²²In addition, Medicare establishes symmetric risk corridors separately for each plan to limit a plan sponsor's overall losses or profits. Under risk corridors, Medicare limits a plan sponsor's potential losses (or gains) by financing some of the higher-than-expected costs (or by recouping excessive profits). Also, Medicare pays plan sponsors that enroll low-income beneficiaries most of their enrollees' cost sharing and premiums (known as the low-income subsidy).

²³Beneficiary cost-sharing varies by their total spending within the Part D drug benefit.

plan sponsors for a portion of beneficiary spending (referred to as reinsurance). After a drug is purchased, plan sponsors may receive monies that lower their payment for Part D drugs, including rebates from manufacturers as well as other price concessions from pharmacies. Plan payments minus rebates results in net plan expenditures.²⁴

Rebates

Plan sponsors' use of formularies—through tier placement, cost-sharing, and utilization management—creates incentives for manufacturers of drugs within a similar therapeutic class to compete with one another to provide discounts to plan sponsors in the form of rebates for drugs, often in exchange for more favorable formulary placement. Part D plan sponsors may enter into rebate agreements with drug manufacturers, whereby plan sponsors seek rebates based on a number of factors including formulary placement, the number of competitors the drug will compete against, and whether the drug will be subject to any utilization management.

Rebates also have implications for competition. FTC has noted that rebate arrangements may be both competitive and anticompetitive depending on the circumstances. FTC stated that manufacturers, PBMs, and plan sponsors may enter into rebate agreements that deliver value to plans and patients.²⁵ However, rebates may incentivize plan sponsors to favor higher cost drugs over less expensive alternatives, which can lead to increased costs to beneficiaries. FTC also noted that rebates may shift costs and misalign incentives in a way that ultimately increases beneficiaries' costs and stifles competition from lower-cost drugs, especially when generics and biosimilars are excluded from or disfavored on formularies. See appendix II for additional information on FTC's oversight of rebating agreements in the pharmaceutical marketplace.

The Inflation Reduction Act of 2022

The Inflation Reduction Act of 2022 made a number of changes to the Medicare drug benefit beginning in October 2022.²⁶ Implementation of these provisions may change rebate incentives and change the effects

²⁴CMS also takes into account other price concessions (e.g., discounts from pharmacies) in addition to rebates in its calculation of net plan spending for purposes of confirming the accuracy of its payments to Part D plan sponsors.

²⁵Federal Trade Commission, *Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products*, (Washington, D.C.: June 2022).

²⁶Pub. L. No. 117-169, tit. I, subtit. B, 136 Stat. at 1833-1905.

rebates have on spending for the Medicare program, plan sponsors, and beneficiaries.²⁷ For example, the act capped beneficiary out-of-pocket spending for insulin at \$35 starting in 2023. Beginning in 2025, the act will cap total Medicare Part D out-of-pocket spending for beneficiaries at \$2,000. At this time, a number of changes will also occur within the Part D standard benefit, including the reduction of Medicare responsibility in the catastrophic phase from 80 to 20 percent of the costs for brand-name drugs, biologics, and biosimilars and from 80 to 40 percent of costs for generic drugs.²⁸ The act replaces the 70 percent coverage gap discount with a new discount in 2025, where manufacturers will provide a 10 percent discount for brand-name drugs, biologics, and biosimilars to beneficiaries who exceed the deductible phase but have not reached the catastrophic threshold and a 20 percent discount on drugs dispensed to enrollees who reach the catastrophic threshold.²⁹ In addition, the act established the Medicare Drug Price Negotiation Program, which requires the Department of Health and Human Services (HHS) to negotiate prices for selected high-cost drugs beginning in 2026.³⁰

²⁷The Congressional Budget Office estimated the effects of the Inflation Reduction Act of 2022 prescription drug-related provisions, including their effects on rebates in the Part D program. See Congressional Budget Office, *How CBO Estimated the Budgetary Impact of Key Prescription Drug Provisions in the 2022 Reconciliation Act*, (Washington, D.C.: February 2023).

²⁸Plan sponsors' share of drug costs in the catastrophic phase will increase from 15 to 60 percent.

²⁹The discount is to be phased in gradually for certain manufacturers that account for a small share of Part D spending.

³⁰The Inflation Reduction Act of 2022 authorizes Medicare to begin negotiating prices for selected Part D and Part B drugs, starting in 2023. The Secretary of Health and Human Services is authorized to negotiate the prices for 10 Part D drugs in 2026, 15 Part D drugs in 2027, 15 total drugs from Parts D and B in 2028, and 20 drugs from Parts D and B in 2029 and beyond. Parts D and B drugs must meet the following criteria to qualify for negotiation: (1) be among the highest expenditure, (2) be single-source prescription drugs (e.g., those lacking generic competition), and (3) 7 or more years since FDA approval for chemical drugs and 11 or more years for biologic drugs. As of July 2023, multiple organizations had filed lawsuits challenging aspects of the Medicare Drug Price Negotiation Program. See *Merck & Co. v. Becerra*, No. 23-cv-01615 (D.D.C. filed June 6, 2023); *Dayton Area Chamber of Commerce v. Becerra*, No. 23-cv-00156 (S.D. Ohio filed June 9, 2023); *Bristol Myers Squibb Co. v. Becerra*, No. 23-cv-03335 (D.N.J. filed June 16, 2023); *Nat'l Infusion Ctr. Ass'n v. Becerra*, No. 23-cv-00707 (W.D. Tex. filed June 21, 2023); *Astellas Pharma US, Inc. v. Becerra*, No. 23-cv-04578 (N.D. Ill. filed July 14, 2023); *Janssen Pharm., Inc. v. Becerra*, No. 23-cv-03818 (D.N.J. filed July 18, 2023).

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

In 2021, manufacturer rebates for Part D drugs were concentrated among drugs in three therapeutic classes. Rebates were also largely concentrated among a small number of brand-name drugs in 2021.

Part D Rebates Were Concentrated among Drugs in Three Therapeutic Classes

Rebates were concentrated among drugs in three therapeutic classes. 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. Of the \$48.6 billion manufacturers paid in Part D rebates in 2021, 73 percent went to drugs within three therapeutic classes: (1) endocrine metabolic agents, which include anti-diabetic drugs (e.g., insulins); (2) blood modifiers, which include anti-stroke medications; and (3) respiratory agents, which include anti-asthma medications. Among all Part D drugs, these three classes combined accounted for 73 percent of rebates, 40 percent of gross expenditures, and 19 percent of utilization. See appendix III for additional information on rebates, expenditures, and utilization for all Part D drugs.

Rebates and Price Concessions from Manufacturers and Pharmacies

Part D plan sponsors, or pharmacy benefit managers (PBM) on their behalf, frequently obtain rebates and other price concessions from manufacturers and pharmacies after a Part D beneficiary obtains a prescription. These monies lower Part D plan sponsors' costs for drugs and are reported to the Centers for Medicare & Medicaid Services (CMS) for use in paying plan sponsors for their drug coverage. In 2021, Part D plan sponsors, or PBMs on their behalf, obtained \$62.1 billion in rebates and other price concessions.

Rebates paid to plan sponsors by manufacturers accounted for the largest proportion of these monies—78.2 percent—or \$48.6 billion.

Pharmacy-related price concessions accounted for the second-largest amount—20.3 percent—or \$12.6 billion. These include bonuses paid by plan sponsors or PBMs to pharmacies, or fees paid by the pharmacies to plan sponsors or PBMs, based on how well the pharmacy met certain agreed-upon performance metrics, such as the generic dispensing rate. In 2021, pharmacies paid \$14.3 billion to plan sponsors and received \$1.7 billion.

Other price concessions, totaling 1.5 percent of all rebates and price concessions, included administrative fees paid by manufacturers to plan sponsors (\$843 million) and monies retained by PBMs (\$103 million).

Source: GAO analysis of CMS data. | GAO-23-105270

- **Endocrine metabolic agents.** These accounted for 42 percent of rebates, 21 percent of gross expenditures, and 13 percent of utilization. Anti-diabetic agents accounted for 97 percent of rebates for endocrine metabolic agents.
- **Blood modifier agents.** These accounted for 17 percent of rebates, 10 percent of gross expenditures, and 3 percent of utilization. Anticoagulant agents, which are used to prevent strokes, accounted for 97 percent of rebates for blood modifier agents.
- **Respiratory agents.** These accounted for 14 percent of rebates, 9 percent of gross expenditures, and 3 percent of utilization. Antiasthma agents accounted for 89 percent of rebates for respiratory agents.

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
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-23-105270

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 calculated utilization based on the number of 30-day supplies for each drug. We excluded compounded drugs, which are tailor-made by a pharmacy for a beneficiary; over-the-counter drugs, as they are generally not covered by Medicare Part D; and drugs associated with Part D plans that do not have a formulary. We identified therapeutic class information using information from the RED BOOK, a drug pricing compendium published by Merative. We consolidated rebates, expenditures, and utilization information for therapeutic classes that had rebates accounting for less than 1 percent of all Part D rebates into “other therapeutic classes.” Totals may not sum to 100 due to rounding.

While rebates were concentrated within three therapeutic classes, the relative amount of rebates as a proportion of gross expenditures varied by therapeutic class. For example, drugs in some therapeutic classes—endocrine metabolic agents, blood modifier agents, respiratory agents, ophthalmologic agents, and genitourinary agents—all received rebates that accounted for more than 30 percent of their gross expenditures. In contrast, rebates accounted for five percent or less of gross expenditures for immunological and antineoplastic agents, with drugs in these classes having higher expenditures per utilization than drugs receiving higher amounts of rebates. For example, antineoplastic drugs, which are

medications used to treat cancer, had gross expenditures per utilization of \$2,099 and net expenditures per utilization of \$2,057. In contrast, endocrine metabolic agents had gross expenditures per utilization of \$137 and net expenditures per utilization of \$73. See table 2 for additional information on expenditures and rebates by therapeutic class.

Table 2: Rebates and Gross and Net Costs per Utilization by Therapeutic Class for Medicare Part D Drugs, 2021

Therapeutic Class	Rebates as a proportion of gross expenditures	Gross costs per utilization	Net costs per utilization
Endocrine metabolic agent	47%	\$137	\$73
Blood modifier agent	39%	\$260	\$158
Respiratory agent	37%	\$218	\$137
Musculoskeletal agent	21%	\$258	\$203
Central nervous system agent	8%	\$54	\$50
Ophthalmologic agent	34%	\$108	\$71
Cardiovascular agent	10%	\$18	\$16
Genitourinary agent	31%	\$62	\$43
Gastrointestinal agent	19%	\$49	\$40
Anti-infective agent	6%	\$326	\$305
Antineoplastic agent	2%	\$2,099	\$2,057
Immunological agent	5%	\$2,046	\$1,937
Dermatological agent	8%	\$147	\$136

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-23-105270

Notes: We analyzed 2021 CMS Medicare Part D expenditure and rebate information for Part D drugs and identified therapeutic class information using information from the RED BOOK, a drug pricing compendium published by Merative. Rebates are discounts manufacturers provide to Part D plan sponsors after a drug is purchased. Rebates as a percentage of gross expenditures reflect rebates as a proportion of what was paid to a pharmacy by the Part D plan sponsors and the beneficiary. Gross costs account for the average expenditures paid by plan sponsors and beneficiaries for a 30-day supply of a drug and net costs account for the average expenditures paid by plan sponsors and beneficiaries after accounting for rebates. We omitted drugs in therapeutic classes that accounted for less than 1 percent of all rebates in 2021. In total, these classes accounted for 1 percent of expenditures and 3 percent of utilization in 2021.

A Relatively Small Number of Brand-Name Drugs Received the Majority of Rebates

Rebates were largely concentrated among a small number of brand-name drugs in 2021. Of the \$48.6 billion in rebates in 2021, 84.2 percent—\$40.9 billion—were for 100 Part D drugs, 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.³¹ (See table 3.)

³¹Of the 100 highest rebated drugs, all were brand-name drugs, with biologics accounting for 27 of the drugs, 29.4 percent of the rebates, 23.2 percent of utilization, and 28.8 percent of expenditures.

Furthermore, the 10 drugs with the highest rebates accounted for 32.1 percent of rebates, 15.0 percent of gross expenditures, and 2.6 percent of utilization.

Table 3: Percent of Rebates, Gross Expenditures, and Utilization for 100 Highest-Rebated Part D drugs Compared to All Other Part Drugs, 2021

	100 highest rebated drugs	All other Part D drugs
Percent of Part D drugs	1.3%	98.7%
Percent of rebates	84.2%	15.8%
Percent of gross expenditures	42.5%	57.5%
Percent of utilization	6.3%	93.7%

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-23-105270

Notes: We analyzed 2021 CMS Medicare Part D expenditure and rebate information for Part D drugs based on their rebates—discounts manufacturers provide to Part D plan sponsors after a drug is purchased. We identified the 100 drugs that received the highest rebates in 2021 and compared them to all other Part D drugs. Gross expenditures reflect what was paid to a pharmacy by Part D plan sponsors and beneficiaries. Utilization reflects the number of unique 30-day supplies for a drug.

Selected Part D Plan Sponsor and Manufacturer Rebate Agreements and Perspectives

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. These conditions included preferred formulary tier placement, limits and restrictions on competitor drugs, and removal of rebates in the case of market entry of a competing generic drug. Representatives of Part D plan sponsors and drug manufacturers provided additional perspectives on aspects of Part D rebate negotiations and rebate agreements.

Selected Rebate Agreement Conditions

Part D Drug Rebate Amounts by Type, 2021

The Centers for Medicare & Medicaid Services (CMS) requires Medicare Part D plan sponsors to report information on the amount of rebates obtained from drug manufacturers across six rebate categories. These six categories represented \$47.1 billion (97 percent) of the \$48.6 billion in rebates in 2021. Of the \$47.1 billion in rebates, plan sponsors reported receiving:

- 92.7 percent of their rebates for providing manufacturers with formulary access and tier placement,
- 2.7 percent of their rebates for rebate guarantee amounts from pharmacy benefit managers,
- 2.4 percent of their rebates in CMS's "other rebates" category,
- 2.1 percent of their rebates for drug prices exceeding price inflation thresholds,
- 0.02 percent of their rebates for meeting market share targets, and
- 0.01 percent of their rebates for volume targets.

Source: GAO analysis of CMS data. | GAO-23-105270

Part D plan sponsor and manufacturer rebate agreements contained conditions intended to increase utilization and market share for a manufacturer's drug in exchange for rebates. The selected 2020 rebate agreements we reviewed for six selected plan sponsors and manufacturers contained the formulary and rebate conditions manufacturers and Part D plan sponsors would agree to meet for 24 selected brand-name drugs. The rebate percentages manufacturers actually paid to plan sponsors depended on the plan sponsors' final formulary decisions. For example, the rebate percentages in the agreements were generally tied to formulary placement of the drug in combination with other conditions, such as the number of competitor drugs on the same formulary tier and the extent to which the drug was subject to utilization management requirements like prior authorization. There was variation in the number and type of conditions in the rebate agreements we reviewed.

Conditions found in rebate agreements for each of the six plan sponsors and manufacturers. The following conditions were present in at least one rebate agreement for all the selected plan sponsors and manufacturers. While described separately, each condition below 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.

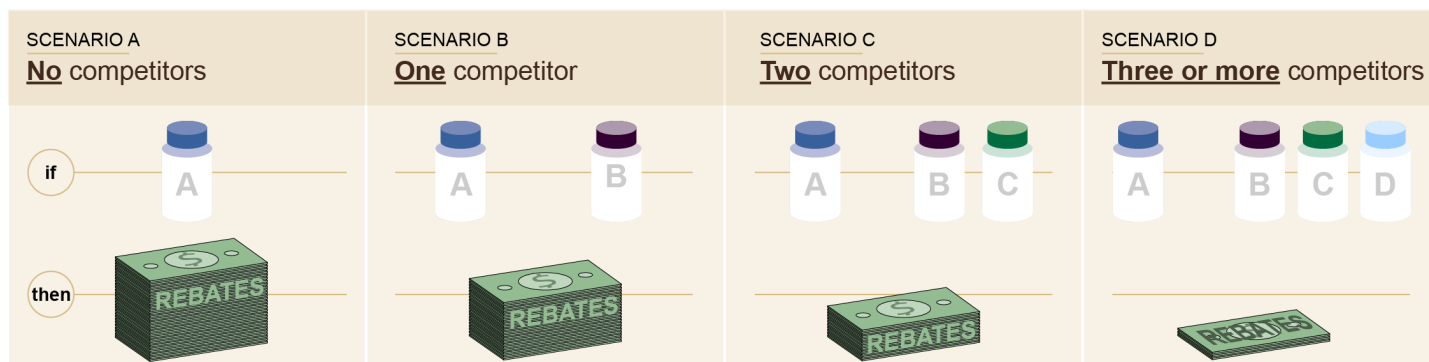
- **Preferred formulary tier.** All plan sponsors and drug manufacturers had rebate agreements where manufacturer rebates were based on a manufacturer's drug being placed on the formulary tier with the lowest cost-sharing relative to its competitor drugs in exchange for rebates to the plan sponsor.³² While manufacturers generally offered rebates in exchange for more preferred formulary placement to drive utilization and access to the manufacturer's drug, there were instances where manufacturers agreed to provide rebates for having their drugs listed anywhere on a plan sponsor's formulary.
- **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

³²The rebate agreements defined competitor drugs by brand name or more generally as drugs that compete against each other within the same therapeutic category.

manufacturers. For example, manufacturers agreed to pay higher rebates if their drug was either the only preferred drug in a given competitive group of drugs or was one of two manufacturers with preferred drugs in the group. If the plan sponsor added additional competitor drugs to the same tier on the formulary as the manufacturer's drug, the manufacturer would provide lower or no rebates. See figure 5 for an illustration of how manufacturer rebate percentages may vary based on the number of competitor drugs.

Figure 5: Illustrative Examples of Rebate Offerings Based on the Number of Competitors on the Preferred Formulary Tier

The following scenarios describe manufacturer rebate offerings based on the number of competitor drugs covered by a plan sponsor's formulary on the preferred brand tier.



Source: GAO analysis of selected rebate contracts between manufacturers and Medicare Part D plan sponsors; GAO (illustrations). | GAO-23-105270

Note: GAO reviewed 2020 rebate agreements negotiated between six drug manufacturers and six Medicare Part D plan sponsors for 24 brand-name drugs.

- **No restrictions for the rebated drug.** All plan sponsors and drug manufacturers had rebate agreements where manufacturers offered rebates to plan sponsors if their drug was not restricted or disadvantaged on a plan sponsor's formulary relative to its competitor drugs. That is, the agreements included rebate conditions that disincentivized plan sponsors from applying policies that can restrict utilization, such as prior authorization and step therapy, to a manufacturer's drug.³³
- **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. The agreements

³³There were also instances where manufacturers agreed to provide rebates even when their drug was subject to restrictions such as utilization management.

included a range of conditions that could limit access to competitor drugs in exchange for rebates, including subjecting competitor drugs to utilization management (e.g., prior authorization or step therapy) or requiring that a competitor drug be excluded from the formulary and otherwise not covered by the plan sponsor, except in cases of medical need.³⁴

- **No generic equivalents.** All plan sponsors and drug manufacturers had rebate agreements where manufacturer rebates were based on the absence of competing generic drugs. Specifically, some agreements stated that the rebate agreements would cease when an applicable generic entered the market while others stated rebate agreements would cease when an applicable generic was placed on the same or a more preferred tier on the formulary.

Additional rebate conditions that varied in frequency. The rebate agreements we reviewed contained other conditions that would increase utilization for a manufacturer's drug while restricting competitor drugs' access to formularies in exchange for rebates. These conditions were included in at least one rebate agreement for at least half of the selected plan sponsors and half of the selected manufacturers, unless otherwise noted.

- **Bundling.** At least half of the selected plan sponsors and selected 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.
- **Specifying a competitor drug.** At least half of the selected plan sponsors and selected manufacturers had rebate agreements that included provisions where manufacturers offered higher rebates for one drug conditional on an agreement that only specified drugs would be placed on the same tier as the manufacturer's drug. For example, these manufacturer rebates were predicated on the manufacturer's

³⁴Beneficiaries, through their prescribers, may request a formulary exception for the plan sponsor to cover an excluded drug. According to CMS, a beneficiary's prescriber must provide support to the plan sponsor that the non-formulary drug is necessary for treating a beneficiary's condition because all covered Part D drugs on any tier would not be as effective or would have adverse effects.

drug being one of two competitor drugs on a preferred tier, with the other competitor drug explicitly named.

- **Targeting number of beneficiaries covered.** At least half of the selected plan sponsors and selected manufacturers had rebate agreements that included provisions where manufacturers offered rebates based in part on the number of beneficiaries in a plan using the formulary. For example, some rebate agreements conditioned rebates on a specified number of beneficiaries to which a manufacturer's drug would be made available to ensure coverage on formularies used by higher-enrollment plans.
- **Beneficiaries must try rebated drug before competitors.** At least half of the selected plan sponsors and selected manufacturers had rebate agreements that included provisions where rebates were conditioned on the manufacturer's drug's status in the line of drugs subjected to step therapy, such that a beneficiary must first try the rebated drug before being eligible to try other drugs in the same therapeutic class. For example, some agreements stated that the manufacturer's drug must be first in the line of step therapy, and that all other drugs in the class, other than those produced by preferred manufacturers, must be subject to prior authorization.
- **Rebates based on sales.** Some rebate agreements based manufacturer rebates on plan sponsors reaching a certain dispensing threshold, either in market share or volume, for the rebated drug. This provision was included in agreements for more than half of the manufacturers and less than half of the plan sponsors. For example, certain agreements based manufacturer rebates on sales for their drug reaching a specified proportion of utilization for all drugs within the relevant therapeutic category.

Selected Part D Plan Sponsor and Manufacturer Perspectives

In our interviews with representatives of four of the six selected Part D plan sponsors, which included those associated with PBMs, and of three of the six selected manufacturers, representatives provided additional perspectives and context regarding Part D drug rebate negotiations. These representatives provided a range of perspectives with respect to negotiating manufacturer rebates. While the perspectives varied, the following issues were described by representatives of at least one manufacturer and plan sponsor, unless otherwise noted.

- **Manufacturer goals in rebate negotiations.** Representatives of manufacturers and plan sponsors we interviewed told us that manufacturers place rebate value on obtaining the least restricted formulary access for their drug and restricting or excluding competitor

drugs on the formularies, with the goal of maintaining or increasing beneficiary access to and use of the rebated drug.³⁵ However, manufacturer representatives noted that a PBM's ability to potentially exclude drugs from formularies that cover a large percentage of enrollees may force manufacturers into a "winner takes all" rebate strategy, where manufacturers need to offer increasingly higher rebates in order to remain on plan sponsors' formularies.

- **Plan sponsor goals in rebate negotiations.** Representatives of manufacturers and plan sponsors stated that plan sponsors' goals in negotiating rebates are to obtain drugs at the lowest possible net cost, which reflects what plan sponsors pay after accounting for rebates. They noted that plan sponsors prefer to focus on obtaining rebates and using them to lower premiums for all beneficiaries.³⁶ For example, representatives of a PBM associated with a plan sponsor told us that, in their experience, plan sponsors were interested in using rebates to lower premiums rather than other options, such as point-of-sale rebates, that could lower beneficiary cost-sharing for specific drugs. Representatives of a manufacturer noted that, as a result of obtaining rebates to lower premiums rather than negotiating lower drug prices, rebates for higher-cost drugs—typically those prescribed to sicker beneficiaries—are used to subsidize lower premiums for other beneficiaries.
- **Drugs that receive rebates.** Representatives of manufacturers and plan sponsors reported that manufacturer rebates were based on factors including the number of competitor drugs within a therapeutic class of drugs, the presence of generics, and Part D policies. Plan sponsor representatives noted that manufacturers generally offer fewer rebates for drugs without market competition; however, where

³⁵Rebates may also be used to increase market share of other drugs. For example, representatives of a manufacturer noted that they may seek bundled rebates—which condition a rebate for one drug on preferred formulary placement of additional drugs—when they have difficulty obtaining market share in one drug category but have significant volume or market share in another category. Bundled rebates may encourage the plan sponsor to provide access to the lesser-used drug. Representatives of another manufacturer said that they may seek bundled rebates to ensure broad access to their products and limit the extent to which products are excluded or unaffordable.

³⁶For example, plan sponsor representatives stated that in the Medicare Part D program, rebates are used to lower costs for Medicare beneficiaries. One sponsor noted that the savings contributed to reductions in Part D basic premiums, from \$34.70 in 2017 to \$30.50 in 2021. In addition, another sponsor noted that rebates lower the costs to the Medicare program as rebates lower sponsors' estimated costs of providing coverage—on which Medicare bases its prospective payments—and are used in determining the accuracy of Medicare reinsurance and risk-sharing payments.

there are competitor drugs, plan sponsors can leverage their control of formulary tier placement for drugs to secure rebates from manufacturers, which plan sponsors noted lowers the cost of these drugs. For example, manufacturer representatives noted that, in drug classes with competition, PBMs can potentially block out manufacturers, which results in manufacturers providing higher rebates for drugs in these classes. Plan sponsor representatives also noted that there are Medicare policies in place that prevent sponsors from obtaining rebates from manufacturers in some situations. For example, plan sponsors are generally unable to obtain rebates for drugs within Medicare protected classes, as manufacturers know plans must cover all of their products within these classes.³⁷

- **Effects on new entrants and competition.** Representatives of manufacturers and plan sponsors stated that rebates do not prevent a new generic or brand-name drug from entering the market. For example, representatives of manufacturers and plan sponsors said that the entry of a new generic at a lower price typically changes the market dynamics because utilization will likely shift to the lower-cost generic drug, which would likely be placed on a more preferred formulary tier. However, plan sponsor representatives noted that, if the generic drug does not have a lower cost, the manufacturer of the brand-name drug may still offer rebates so that the drug may remain competitive after accounting for rebates. For example, in some cases the price of a new generic drug may not be that much less than the brand-name drug. Plan sponsors may continue to prefer the brand-name drug in this instance as the rebates on the brand-name drug result in the plan sponsor obtaining the drug at a lower net cost than the generic. Representatives of a manufacturer, however, also noted that plan sponsors' focus on obtaining rebates disadvantages drugs with lower gross prices as these drugs are associated with lower rebate dollars.
- **Rebate agreement process.** Representatives of manufacturers and plan sponsors stated that the conditions in the rebate agreements reflect a variety of formulary and rebate options, and that the final decision around formulary design was that of the plan sponsors. Manufacturer representatives stated that PBMs generally provide expectations on rebate amounts and options, and seek a variety of rebate offers from manufacturers that they can offer to plan sponsors. However, it is ultimately up to the plan sponsor to determine what

³⁷Additionally, plan sponsor representatives cited Medicare's requirement that plan sponsors cover at least two drugs in each therapeutic class as a limit to plan sponsors' ability to obtain rebates.

option to choose based on how the plan sponsor wants to design their formulary and the extent to which they opt to provide formulary access in exchange for rebates. For example, representatives of a manufacturer noted that bundled rebate arrangements—in which rebates are conditioned on formulary placement of additional manufacturer drugs—help ensure a manufacturer’s formulary access for its entire portfolio of drugs, and they noted it is up to plan sponsors or PBMs to decide whether or not to accept such an offer. Plan sponsor representatives noted they prefer to avoid bundled rebates as these rebates restrict a plan sponsor’s ability to manage its formularies.

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

Part D plan sponsors frequently gave preferred formulary placement to highly rebated, relatively higher-gross-cost brand-name drugs on their formularies compared to lower-gross-cost competitor drugs, which generally had lower rebates. In addition, generic counterparts for 40 highly rebated brand-name drugs were less likely to be included or given preferred placement over the brand-name drug on Part D plan sponsor formularies compared to generic counterparts for other brand-name drugs.

Part D Plan Sponsors Frequently Gave Highly Rebated Drugs Preferred Formulary Placement among 10 Competitive Drug Groups

Part D plan sponsor formularies more frequently preferred highly rebated, relatively higher-gross-cost brand-name drugs compared to lower-gross-cost competitor drugs in the 10 groups of competitor drugs we reviewed (referred to hereafter as competitive groups).³⁸ Plan sponsors generally

³⁸For purposes of this report, we considered a drug to have preferred placement on a formulary if it was (1) on the lowest cost-sharing formulary tier relative to other drugs within the competitive group (not necessarily the lowest possible Part D tier), and (2) had similar or fewer utilization management requirements relative to other drugs within the competitive group. We refer to drugs that had preferred placement on a formulary as “preferred drugs.” Plan sponsors may use more than one Part D formulary. Gross cost refers to gross expenditures, or the amount paid by plan sponsors and beneficiaries (or other payers on their behalf) to pharmacies, per utilization—defined as a 30-day supply—before accounting for rebates. We refer to drugs with a rebate percentage of at least 25 percent as highly rebated. 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. We included brand-name drugs that were listed in at least two agreements as competitors for a particular drug and also included additional drugs that shared the same ingredient, strength, and dose form as another drug in the competitive group. We refer to drugs within the same competitive group as competitor drugs.

paid less for these higher-gross-cost drugs, after accounting for rebates, than for lower-gross-cost drugs within the groups.³⁹

- In the majority of competitive groups—seven of the 10—more formularies preferred relatively higher-gross-cost, highly rebated drugs than preferred the lowest-gross-cost drug in the group. In general, rebates lowered the plan sponsors’ net costs for the higher-gross-cost drugs in the group below that of the lower-gross-cost drugs. Moreover, in three of these 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.
- In the remaining three of the 10 competitive groups we reviewed, more formularies preferred the lowest-gross-cost drug than the relatively higher-gross-cost, highly rebated drugs in the group. In two of these three competitive groups, net plan sponsor payments for the lowest-gross-cost drugs remained lower than their net payments for the higher-gross-cost, highly rebated drugs.⁴⁰ Conversely, in one of these three competitive groups, net plan sponsor payments were lower for higher-gross-cost drugs than for the lowest-cost drug in the group after accounting for rebates. (See table 4.)

³⁹The 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. For the higher-gross-cost drugs, 51 percent of drug costs were rebated back to plan sponsors, on average, and in total all the drugs in the 10 competitive groups accounted for approximately half—\$23.9 billion—of all Part D rebates for 2021. For this analysis, we summarized expenditure, rebate, and payment information for drugs at the brand-name level by calculating a weighted average of the individual drug formulations based on the number of prescriptions.

⁴⁰In one of these groups, the lowest-gross-cost drug was also the more highly rebated drug.

Table 4. Percentage of Medicare Part D Formularies Where Selected Drugs Were Preferred and Listed in 10 Competitive Drug Groups, 2021

Competitive drug group	Percentage of Part D formularies where drug was preferred		Percentage of Part D formularies where drug was listed		Lower net cost to plan sponsor, of the two drugs	
	Highest-gross-cost, highly rebated drug	Lowest-gross-cost drug	Highest-gross-cost, highly rebated drug	Lowest-gross-cost drug	Highest-gross-cost, highly rebated drug	Lowest-gross-cost drug
1	92%	5%	100%	53%	X	
2 ^a	91%	23%	100%	65%	X	
3	89%	4%	100%	62%	X	
4 ^a	84%	13%	96%	68%	X	
5	66%	49%	97%	82%	X	
6	64%	1%	95%	65%	X	
7 ^a	64%	67%	96%	94%		X
8	56%	0%	91%	63%	X	
9	54%	74%	75%	91%		X
10	20%	58%	90%	93%	X	
Average	68%	29%	94%	74%		

Legend: X = drug with lowest net cost to plan sponsor of the two drugs.

Source: GAO analysis of Centers for Medicare & Medicaid Services data. | GAO-23-105270.

Notes: Gross cost refers to gross expenditures per utilization, or the amount paid by plan sponsors and beneficiaries, or other payers on their behalf, to pharmacies for a 30-day supply of the drug before accounting for rebates. We summarized gross cost at the brand-name level by calculating the weighted average gross cost of the individual drug formulations based on the number of prescriptions. The highest-gross-cost, highly rebated drug in each competitive group refers to the drug with the highest gross cost in the group among those with a rebate percentage of at least 25 percent. These percentages may equal more than 100 because plans may have more than one preferred drug on their formularies per group, and because there were additional drugs in the competitive groups besides the highest- and lowest-gross-cost drugs that could be preferred. We considered a drug to have preferred placement on a formulary if it was (1) on the lowest cost-sharing formulary tier relative to other drugs within the competitive group (not necessarily the lowest possible Part D tier), and (2) had similar or fewer utilization management requirements relative to other drugs within the competitive group.

^aThe lowest-gross-cost drug in the competitive group also had a rebate percentage of at least 25 percent.

In addition, we found that most rebates for drugs in the 10 competitive groups were paid to plan sponsors that limited the number of preferred drugs to one or two brand-name manufacturers. Across these 10 groups, 28 percent of utilization was associated with formularies that limited the number of manufacturers of preferred drugs in the competitive group to one, while an additional 49 percent was associated with formularies that limited manufacturers of preferred drugs in the competitive group to two. Overall, 83 percent of the \$23.9 billion in rebate dollars for drugs in the 10

competitive groups were tied to plan sponsors that limited preferred drugs to one or two manufacturers.

Generic Counterparts for Highly Rebated Drugs Were Less Frequently Listed on Formularies than Generic Counterparts for Other Drugs

Generic counterparts for the 40 selected, highly rebated brand-name drugs were less frequently listed or preferred over the brand-name drug on Part D formularies compared to generic counterparts for other brand-name drugs.⁴¹ In general, rebates were uncommon among most brand-name Part D drugs with competition from a generic counterpart.⁴² However, there were substantial rebate dollars—\$6.4 billion—concentrated among relatively few brand-name drugs that commonly had authorized generic counterparts, which are brand-name drugs marketed by the brand-name manufacturer, or by another company with the brand-name manufacturer’s permission, without the brand-name label.⁴³ Manufacturers paid the majority of rebates for the 40 highly rebated brand-name drugs to plan sponsors when the sponsors did not list the generic counterpart for the brand-name drug on the formulary.

Among Part D formulary placements for 40 highly rebated brand-name drugs and their generic counterparts, 27 percent listed the generic counterpart and not the brand-name drug, 24 percent listed the brand-name drug but not the generic counterpart, and 20 percent listed the brand-name drug on the same tier as the generic counterparts.⁴⁴ Most rebate dollars—78 percent—among the highly rebated brand-name drugs

⁴¹These 40 brand-name drugs were those that accounted for the top 98 percent of the \$6.4 billion in rebate dollars among 1,633 Part D brand-name drugs for which we identified generic counterparts—approximately 13 percent of total Part D rebates for 2021. The other 1,593 Part D brand-name drugs that had generic counterparts accounted for \$130 million in rebate dollars. The 40 brand-name drugs included multiple formulations of the same brand-name and represented 22 brand-names in total.

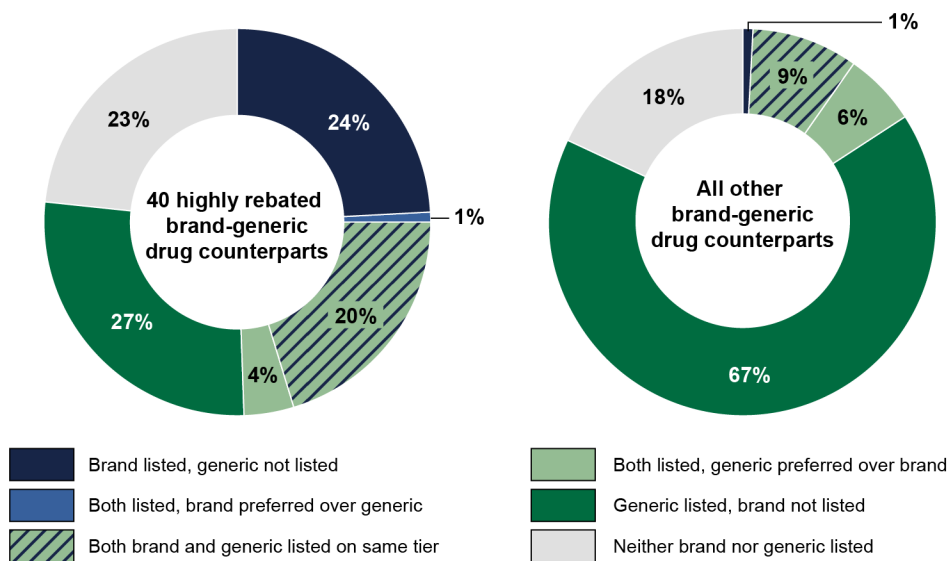
⁴²For purposes of this report, we refer to the following as generic counterparts: (1) non-branded drugs that shared the same ingredient, strength, and dose form as brand-name drugs, which included both authorized generics and generic drugs produced by competing manufacturers, and (2) biosimilars for reference biologics. We did not include generic drugs that were marketed under a brand name, and we only included generic counterparts that were listed on CMS’s archived 2020 Part D formulary reference file.

⁴³The HHS Office of Inspector General also reported that in 2020, some Part D plans did not cover authorized generics for certain higher cost brand-name drugs, limiting beneficiary access to less costly options. See Department of Health and Human Services, Office of Inspector General, *Part D Plan Preference for Higher-Cost Hepatitis C Drugs Led to Higher Medicare and Beneficiary Spending*, OEI-BL-21-00200 (Washington, D.C.: August 2022).

⁴⁴An additional 4 percent listed the generic counterpart on a more preferred tier than the brand-name drug, while 1 percent listed the generic counterpart on a less preferred tier than the brand-name drug.

were paid to plan sponsors that did not list the generic counterpart on the formulary. An additional 18 percent of rebates were paid to plan sponsors that listed the generic counterpart on the same formulary tier as the highly rebated brand-name drug. In contrast, for all other brand-name drugs and generic counterparts that were not highly rebated, the majority of formularies preferred the generic counterpart over the brand or did not list the brand and less commonly listed the brand while not listing the generic. (See fig. 6.)

Figure 6. Percentage of Formulary Placements among 40 Highly Rebated Brand-Name Drugs with Generic Counterparts Compared to Other Brand-Name Drugs with Generic Counterparts in Medicare Part D Formularies



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-23-105270

Note: The 40 highly rebated brand-name drugs were those that accounted for the top 98 percent of the \$6.4 billion in rebates among Medicare Part D brand-name drugs for which we identified generic counterparts in 2021. For all other brand-name drugs and generic counterparts, the formulary placement type “both listed, brand preferred over generic” is not shown as it accounted for 0.1 percent of formulary placements. For purposes of this analysis, we included drugs marketed under a brand name and biologics as brand-name drugs, and we included the following as generic counterparts: (1) non-branded drugs that shared the same ingredient, strength, and dose form as brand-name drugs, which included both authorized generics and generic drugs produced by competing manufacturers and (2) biosimilars for reference biologics. Percentages do not total 100 percent due to rounding.

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

Plan sponsors' formulary preference 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.

Consistent with these dynamics, we found different implications for beneficiary and plan sponsor spending in each of the three groups of drugs identified in finding 1 and finding 3 in this report: the 100 highest rebated Part D drugs (as reported by their total spending), the 10 competitive groups (as reported by their spending per utilization, defined as a 30-day supply), and the 40 highly rebated brand-name drugs with generic counterparts (as reported by their spending per utilization, defined as a 30-day supply).

100 highest rebated Part D drugs. We found beneficiary payments—paid by beneficiaries or other payers on their behalf—were more than plan sponsor payments for the majority of the 100 highest rebated Part D drugs discussed previously after accounting for rebates (see finding 1). Medicare payments for low-income subsidy beneficiaries accounted for the majority of beneficiary payments.⁴⁵ Specifically, for 79 of the 100 highest rebated Part D drugs in 2021, beneficiaries, or other payers on their behalf, spent \$21.0 billion and plan sponsors spent \$41.9 billion, which translated to \$5.3 billion in plan sponsor spending after accounting

⁴⁵The 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.

for rebates.⁴⁶ For the 79 drugs where beneficiaries, or other payers on their behalf, spent more than plan sponsors, we found the following.

- Of the \$72.7 billion paid to pharmacies for the purchase of these drugs, beneficiaries, or other payers on their behalf, spent \$21.0 billion and manufacturers provided \$9.8 billion in coverage gap discounts.⁴⁷ Medicare low-income subsidy payments accounted for 59 percent of the \$21.0 billion spent by beneficiaries, or other payers on their behalf.
- Manufacturers paid plan sponsors \$36.6 billion in rebates for these drugs, which resulted in net plan sponsor spending of \$5.3 billion, down from \$41.9 billion in gross plan sponsor spending.

For the other 21 highest-rebated drugs, plan sponsor payments were greater than beneficiary payments. Beneficiaries spent \$3.0 billion and plan sponsors spent \$13.0 billion, which translated to \$8.7 billion in plan sponsor spending after accounting for rebates. For these 21 drugs, we found the following.

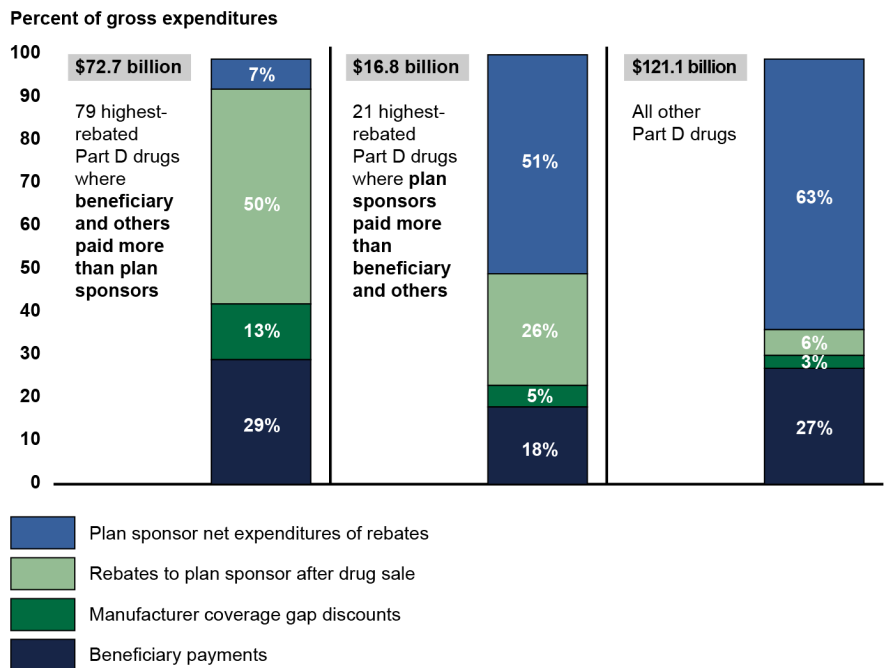
- Of the \$16.8 billion paid to pharmacies for the purchase of these drugs, beneficiaries, or other payers on their behalf, spent \$3.0 billion, and manufacturers provided \$841 million in coverage gap discounts. Medicare low-income subsidy payments accounted for 50 percent of the \$3.0 billion spent by beneficiaries or other payers on their behalf.

⁴⁶Beneficiary payments are approximate and include payments by beneficiaries and other payers on their behalf, including Medicare's low-income subsidy payments, and third-party payers such as group health plans (e.g., for retired beneficiaries receiving drug coverage through an employer-based plan) and other government payers. In some instances, beneficiary payments may include payments made by plan sponsors. Plan sponsors' spending net of rebates is approximate, as these 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.

⁴⁷MedPAC has noted that beneficiaries receiving low-income subsidies have weaker financial incentives to choose cheaper alternatives as they have limited cost-sharing for their drugs. For example, beneficiaries receiving low-income subsidies have no financial incentive to choose preferred drugs over an alternative drug on a non-preferred tier or a drug not on the formulary. MedPAC recommended that Congress establish a higher co-payment for low-income subsidy beneficiaries receiving non-preferred drugs and drugs not covered on a formulary. MedPAC, *Report to the Congress: Medicare and the Health Care Delivery System* (Washington, D.C.: June 2020).

- Manufacturers paid plan sponsors \$4.3 billion in rebates for these drugs, which resulted in net plan sponsor spending of \$8.7 billion, down from \$13.0 billion in gross plan sponsor spending.
- Plan spending being greater than beneficiary spending is consistent with expenditures for all other Part D drugs, where plan sponsors paid \$84.0 billion, beneficiaries, or other payers on their behalf, spent \$33.2 billion, and manufacturers provided \$3.9 billion in coverage gap discounts. Manufacturers paid \$7.7 billion in rebates to plan sponsors, which resulted in net plan sponsor spending of \$76.3 billion for these drugs, down from \$84.0 billion in gross plan sponsor spending (See fig. 7.)

Figure 7: 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-23-105270

Notes: We examined CMS expenditure and rebate information for Medicare Part D drugs in 2021. The plan sponsor and beneficiary payment amounts are approximate. In order to calculate plan sponsor net expenditures, we subtracted rebates, which manufacturers pay plan sponsors after a beneficiary purchases a drug, from the amount plan sponsors paid. Beneficiary payments include payments by beneficiaries and other payers on their behalf, including Medicare's low-income subsidy payments, and third-party payers such as group health plans (e.g., for retired beneficiaries receiving drug coverage through an employer-based plan) and other government payers. In some instances, beneficiary payments may include payments made by plan sponsors. Plan sponsors' spending amounts net of rebates are approximate, as these 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

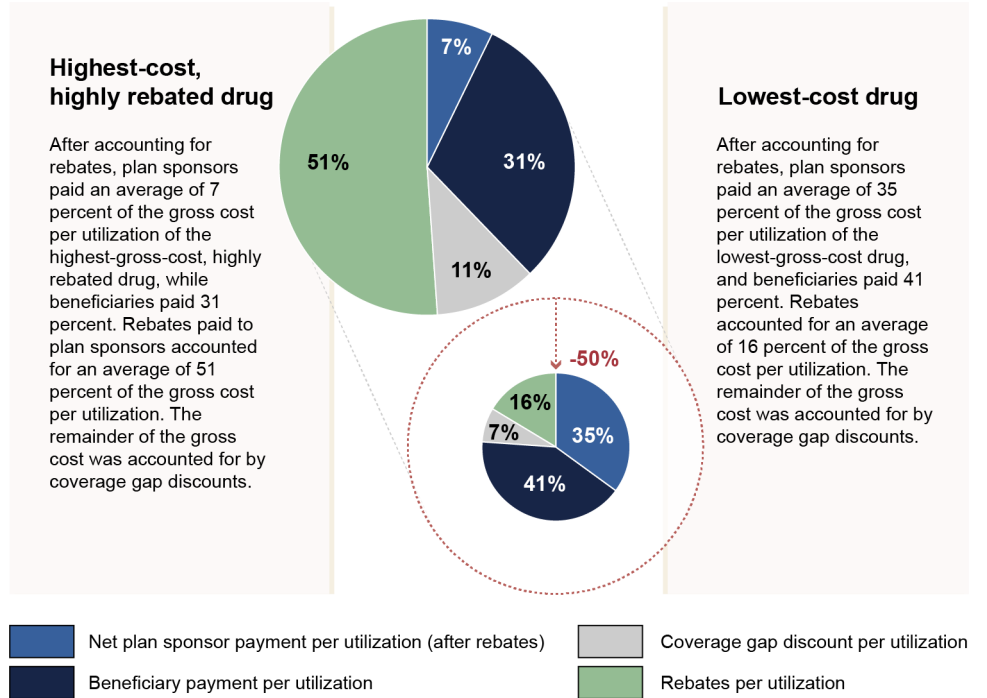
Part D benefit. In the coverage gap phase of the Part D benefit, plan sponsors initially paid the manufacturer coverage gap discount to pharmacies on behalf of beneficiaries, and manufacturers reimbursed plan sponsors for these monies later. These monies do not include manufacturer rebates.

Competitive drug groups. For the 10 competitive groups discussed previously (see finding 3), we found that net plan sponsor payments per utilization (after accounting for rebates) were lower for higher gross-cost, highly rebated drugs than for lower-gross-cost drugs in 8 of the 10 groups. In contrast, beneficiary payments per utilization generally remained higher for the highly rebated, higher gross-cost drugs than for lower-gross-cost drugs because rebates did not lower beneficiary payments.⁴⁸ Generally, beneficiaries more frequently used the higher gross-cost drugs, meaning that beneficiary payments were higher for these drugs in total as well as on a per-utilization basis.

See figure 8 for more information on the average net plan sponsor payments per utilization and beneficiary payments per utilization for the highest-cost, highly rebated drug in the ten competitive groups compared to the lowest-cost drug in each group.

⁴⁸In one of the competitive groups, beneficiary payments per utilization were slightly lower for the highest- than for the lowest-gross cost drugs, which were relatively similar in cost.

Figure 8. Medicare Part D Net Plan Sponsor Payment, Beneficiary Payment, Rebate, and Coverage Gap Discount Amounts per Utilization for Higher- and Lower-Gross-Cost Drugs, On Average across 10 Selected Competitive Groups, 2021



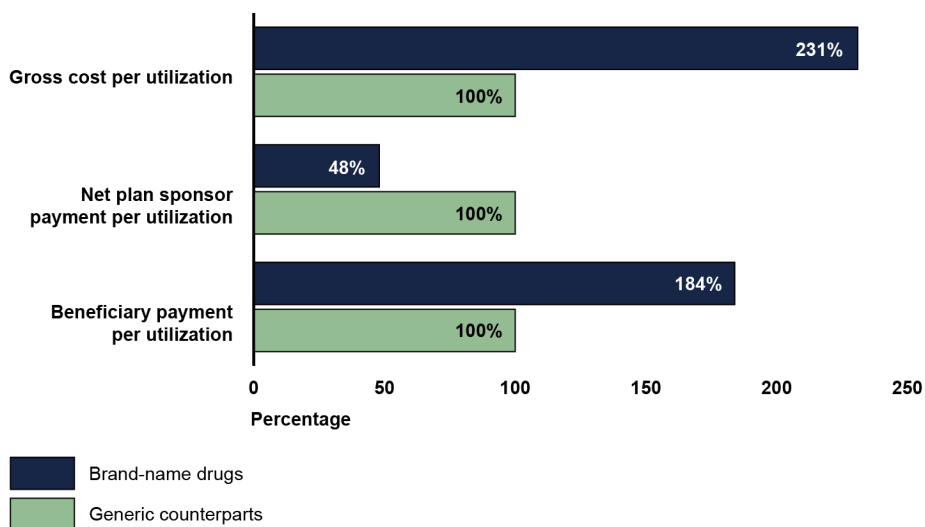
Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-23-105270

Notes: We analyzed expenditures, utilization, and rebates for 10 selected groups of competitor drugs. 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. We included brand-name drugs that were listed in at least two agreements as competitors for a particular drug and also included additional drugs that shared the same ingredient, strength, and dose form as another drug in the competitive group. The highest-cost drug refers to the highest-gross-cost, highly rebated drug within each competitive group; the lowest-cost drug reflects the drug with the lowest gross cost, irrespective of rebates. Gross cost refers to gross expenditures, or the amount paid by plan sponsors and beneficiaries, or other payers on their behalf, to pharmacies per utilization, defined as a 30-day supply for the drug, before accounting for rebates. We calculated the weighted average gross cost per utilization, net plan sponsor payment (after accounting for rebates) per utilization, rebate amount per utilization, and beneficiary payment per utilization for drugs at the brand-name level, weighted based on the number of prescriptions.

Brand-name drugs and generic counterparts. Among the 40 highly rebated brand-name drugs with generic counterparts discussed previously (see finding 3), gross drug costs and beneficiary payment per utilization were higher, on average, for the brand-name drugs compared to their generic counterparts, while net plan sponsor payments per utilization were lower, on average, after accounting for rebates. See figure 9. This resulted from rebates lowering the plan sponsor payment amounts

for the brand-name counterparts, while not lowering beneficiary payment amounts.

Figure 9: Average Difference in Gross Cost, Net Plan Sponsor Payment, and Beneficiary Payment per Utilization for 40 Highly Rebated Brand-Name Drugs and Generic Counterparts, 2021



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-23-105270

Notes: Gross cost refers to gross expenditures (the amount paid by plan sponsors and beneficiaries, or other payers on their behalf, to pharmacies) per utilization, defined as a 30-day supply, before accounting for rebates. Beneficiary payment per utilization refers to payments made by or on behalf of beneficiaries per utilization. Net plan sponsor payment per utilization refers to payments made by plan sponsors per utilization after accounting for rebates. We calculated the average gross cost, beneficiary payment, and net plan payment amounts per utilization for 40 highly rebated brand-name drugs and their generic counterparts. The 40 highly rebated brand-name drugs were those that accounted for the top 98 percent of the \$6.4 billion in rebate dollars among Medicare Part D brand-name drugs in 2021 for which we identified generic counterparts. For purposes of this analysis, we included drugs marketed under a brand name and biologics as brand-name drugs, and we included the following as generic counterparts: (1) non-branded drugs that shared the same ingredient, strength, and dose form as brand-name drugs, which included both authorized generics and generic drugs produced by competing manufacturers and (2) biosimilars for reference biologics.

There were a small number of instances where plan sponsors paid more for brand-name drugs after accounting for rebates than for generic counterparts—that is, plan sponsor payments per utilization were higher both on a gross and net basis for the brand-name drugs than for their generic counterparts. We looked at cases where at least 25 percent of formularies listed the highly rebated brand-name drug and not the generic counterpart, or preferred the brand-name drug over the generic counterpart. Among these cases, there were three brand-name drugs for which plan sponsor payments per utilization were higher than for their generic counterparts even after accounting for rebates. Although

infrequent, such cases involve higher costs for both beneficiaries and plan sponsors, as well as for the Medicare program.

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

Although CMS uses Part D drug rebate data in its oversight process for ensuring the accuracy of its prospective payments to plan sponsors for providing Medicare Part D drug coverage, CMS officials stated the agency does not use rebate data as part of its review of Part D plan formularies.⁴⁹

Requirements for CMS's oversight of Part D plan formularies are set forth in statute, agency regulations, and agency guidance. Under 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.⁵⁰

CMS officials stated their review of Part D plan formularies includes an annual "clinical review" of formularies, the basis of which is to ensure sponsors meet program requirements and beneficiaries have access to drugs. 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 beneficiary enrollment. As described in the Medicare Prescription Drug Benefit Manual and by CMS officials, CMS does the following in this review.

⁴⁹CMS makes prospective monthly payments to plan sponsors based on plan sponsors' estimates of providing drug coverage to beneficiaries. Plan sponsors report rebates to CMS after the conclusion of the contract year. CMS uses rebate data to ensure its prospective payments reflect actual drug costs throughout the drug benefit year. In addition, CMS provides the Internal Revenue Service rebate information related to requirements under the Patient Protection and Affordable Care Act, which imposed an annual fee on each covered entity engaged in the business of manufacturing or importing branded prescription drugs. Pub. L. No. 111-148, § 9008, 124 Stat. 119, 859 (2010). CMS officials stated they periodically review a judgmental sample of Part D plan sponsor contracts to ensure the completeness and correctness of the rebate data.

⁵⁰42 U.S.C. § 1395w-111(e)(2)(D) and 42 C.F.R. § 423.272(b)(2)(i) (2022).

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- Reviews formularies to determine if they include commonly prescribed drug classes for the Medicare population and all commercially available vaccines.⁵¹
 - Reviews formularies to determine whether utilization management requirements follow industry best practices.
 - Analyzes formularies to identify what are termed “outliers.” For example, CMS guidance states the agency will identify benefit features that are outliers from industry best practices and may ask sponsors to provide written clinical justification for these unusual benefit features. Agency officials stated outliers could include practices such as a sponsor subjecting all drugs within a class to prior authorization. To the extent that plan sponsors’ formulary arrangements contain outliers, CMS will conduct an additional review to ensure they are not discriminatory.⁵²

CMS officials stated they do not review or consider expenditure or drug rebate information as part of the agency’s review of plan formularies to determine whether the formulary is likely to substantially discourage enrollment by certain Part D eligible individuals. CMS officials told us that, given the agency’s clinical review of formularies, an evaluation of expenditure or rebate information is not necessary to ensure that a formulary is not likely to substantially discourage enrollment. Additionally, CMS officials told us that the statutory non-interference clause, which prohibits CMS from interfering with the negotiations between drug manufacturers and Part D plan sponsors or requiring a particular formulary or price structure, prevents them from considering plan rebate arrangements as part of the agency’s formulary review.⁵³

However, CMS could take steps that would help gain insight into these issues that do not involve interfering with negotiations between plan sponsors and manufacturers or requiring a particular formulary.

⁵¹According to CMS guidance, these drug classes cover common diseases and conditions and allow CMS to ensure that sponsors cover the most widely used medications, or therapeutically similar medications, for the most common conditions. Agency officials stated they also ensure that formularies meet other requirements, including the requirement that sponsors include two drugs from each class on their formulary.

⁵²CMS’s review of potentially discriminatory practices includes looking for a lack of appropriate drug classes to treat certain diseases, a lack of sufficient drugs in a therapeutic class, inappropriate tier placement that would discriminate against a group of beneficiaries, or missing drugs that could discourage certain types of beneficiaries from enrolling in the plan.

⁵³See 42 U.S.C. § 1395w-111(i).

Specifically, CMS could monitor aggregated rebate and expenditure data from prior years to gain insight into rebate practices that influence formulary design in ways that could affect beneficiary access for certain Part D drugs and may not be identified by a clinical formulary review. For example, as described in findings 3 and 4, we found instances where plan sponsors preferred rebated brand-name drugs with higher costs to beneficiaries over lower-cost alternatives. Such practices may result in certain beneficiaries not having access to 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).⁵⁴ Monitoring of rebate and expenditure data could provide the agency, Congress, and others with information on whether formulary practices are likely to discourage enrollment of certain beneficiaries. In addition, such monitoring would be consistent with federal internal control standards, which call for agencies to identify, analyze, and respond to risks related to achieving its defined objectives.⁵⁵

Conclusions

Overall, rebates may reduce Part D drug spending because they lower Medicare's monthly payments to plan sponsors, and plan sponsors use rebates to lower beneficiary premiums. However, there are implications for plan sponsors, beneficiaries, and the Medicare program to the extent rebates encourage plans to place higher-gross-cost, highly rebated drugs on their formularies over lower-cost alternatives. We found that beneficiary spending was higher than plan sponsor spending after accounting for rebates for drugs with high rebates, and beneficiaries generally paid more for higher-gross-cost highly rebated drugs than for lower cost alternatives. This also affected Medicare spending as the

⁵⁴HHS's Office of the Assistant Secretary of Planning and Evaluation and MedPAC both found that high cost-sharing for drugs may create access barriers. In March 2021, MedPAC reported that its review of beneficiary access and quality information for Medicare Part D found that, while beneficiaries may be less likely to encounter access issues for most drugs, high cost-sharing for beneficiaries receiving expensive therapies may be a barrier to accessing these drugs. A 2022 HHS Office of the Assistant Secretary of Planning and Evaluation report found that the high cost and out-of-pocket expenses of drugs may cause many Americans—particularly those with chronic conditions such as diabetes and chronic obstructive pulmonary disease—to delay or skip taking needed treatments. MedPAC, *Report to the Congress: Medicare Payment Policy*, (Washington, D.C.: March 2021) and Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation Office of Health Policy, *Data Point: Prescription Drug Affordability among Medicare Beneficiaries*, HP-2022-03, (Washington, D.C: January 19, 2022).

⁵⁵[GAO-14-704G](#).

program was responsible for a large proportion of beneficiary cost-sharing for beneficiaries receiving low-income subsidy assistance. CMS conducts a clinical review of plan formularies to ensure plan sponsors meet program requirements. Monitoring the effects of rebates would not require CMS to interfere with negotiations between plan sponsors and drug manufacturers and would provide CMS, Congress, and others additional insight on the extent to which rebates' influence on formularies could discourage enrollment of certain beneficiaries. This monitoring would also provide CMS with important information as a number of provisions under the Inflation Reduction Act of 2022—including those related to drug price negotiation for selected high-cost drugs and limits beneficiary out-of-pocket spending, may change rebate incentives and change the effects rebates have on formulary design and spending.

Recommendation for Executive Action

The Administrator of CMS should monitor the effect of rebates on plan sponsor formulary design and on Medicare and beneficiary spending to assess whether rebate practices are likely to substantially discourage enrollment by certain beneficiaries.

Agency Comments

We requested comments on a draft of this report from HHS and FTC. HHS provided comments, which are reprinted in appendix IV. HHS and FTC also provided technical comments, which we incorporated as appropriate. For example, HHS noted that current guidance on Part D drugs and formulary requirements does not include mention of ensuring that beneficiaries receive clinically appropriate medications at the lowest possible cost. We therefore removed reference to this language in the report and our recommendation.

HHS responded that it did not concur with our recommendation. HHS stated it already performs a Part D formulary review to ensure compliance with Part D requirements and does not consider the evaluation of expenditure or rebate information necessary to ensure that a formulary is not likely to substantially discourage enrollment. HHS added that any analysis of the current rebate structure would not be reflective of the future Part D benefit design, due to impending changes to the Part D program as required under the Inflation Reduction Act of 2022.

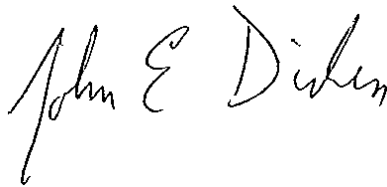
As discussed in our report, rebate practices may influence formulary design in ways that could affect beneficiary access for certain Part D drugs and may not be identified by a clinical formulary review. For example, we found instances where plan sponsors gave preferred formulary placement to rebated, brand-name drugs with higher costs to beneficiaries over lower-cost alternatives; this may affect beneficiary

access to 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). CMS's monitoring of the effects of rebates using available rebate information could provide CMS, Congress, and others with increased visibility into the extent to which rebate and formulary practices are likely to substantially discourage enrollment of certain beneficiaries. For example, CMS could use previous years' rebate information to help target areas for additional focus in its formulary reviews.

We acknowledge the changes to the Part D benefit under the Inflation Reduction Act of 2022 may change rebate incentives and the effects of rebates on formulary design and spending. We believe monitoring rebate information in light of changes to the Part D benefit could help the agency ensure formulary practices moving forward are unlikely to discourage enrollment of certain beneficiaries. CMS's monitoring could be used both to identify patterns of interest and tailored to account for program changes. We therefore maintain that our recommendation to CMS could help ensure compliance with Part D requirements.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, and the Chair of the Federal Trade Commission. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or dickenj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix V.



John E. Dicken
Director, Health Care

Appendix I: Scope and Methods

This appendix provides details on our scope and methodology in addressing the following reporting objectives: (1) rebate and expenditure information for Part D drugs; (2) the relationship between rebates and Part D formulary placement for competing drugs; and (3) implications of rebates on spending by Part D plan sponsors, beneficiaries, and the Medicare program.

To assess the extent to which Part D plan sponsors received rebates from manufacturers for Part D drugs, we analyzed 2021 Centers for Medicare & Medicaid Services (CMS) Part D prescription drug expenditure and rebate data, the most recent data available at the time of our analysis.¹ We analyzed and report drug expenditure and rebate information for brand-name and generic drugs based on their ingredient, strength, and dose form based on a drug's unique RxNorm concept identifier, known as an RxCUI.² For example, for acetaminophen, a nonprescription, over-the-counter drug not included in our results, we would have separately analyzed and reported spending and rebate information for the following two drug formulations: acetaminophen 650mg tablets and acetaminophen 325mg tablets. We used Merative's RED BOOK, a drug pricing compendium, to determine a drug's

¹We analyzed drug expenditure information using CMS's Prescription Drug Event data and rebate information using CMS's Direct and Indirect Data Remuneration data. We excluded compounded drugs, which are tailor-made by a pharmacy for a beneficiary; over-the-counter drugs, as they are generally not covered by Medicare Part D; and drugs associated with Part D plans that do not have a formulary. In addition to rebates, we analyzed additional price concessions plan sponsors received that lowered their spending for Part D drugs, including fees from pharmacies for not meeting certain performance metrics.

²RxNorm is a standardized nomenclature for clinical drugs produced by the National Library of Medicine within the National Institutes of Health. For the purposes of our analysis, we identified brand-name drugs as drugs that have a marketed brand name and biologics, which are products derived from living sources, such as humans, animals, and microorganisms. An approved generic drug is therapeutically equivalent to a corresponding brand-name drug and is generally marketed under a nonproprietary generic name. In some instances, a generic drug may be marketed under a brand name. In other instances, a brand-name drug may be marketed by the brand-name manufacturer, or by another company with the manufacturer's permission without the brand name on the label, and is referred to as an "authorized generic." For the purposes of our analysis, we identified generic drugs as drugs that are marketed without a brand name, including authorized generics, and biosimilars, that are highly similar to an existing biologic licensed by the FDA.

therapeutic class and Food and Drug Administration (FDA) information to identify biologics and biosimilars.³

We identified Medicare Part D drugs based on CMS's 2021 Prescription Drug Event data.⁴ Using this data, we calculated the amount paid to pharmacies for Part D drugs—referred to as total, or gross, drug expenditures.⁵ This included payments by Part D plan sponsors, beneficiaries, and manufacturers (in the form of discounts provided for applicable beneficiaries in the coverage gap).⁶ We also used the Prescription Drug Event data to calculate the number of unique beneficiaries receiving each drug and the drug's utilization—based on the number of 30-day supplies for each drug.⁷ To calculate net expenditures, we identified rebates paid by manufacturers to plan sponsors using CMS's Direct and Indirect Remuneration data and subtracted this from gross expenditures.⁸ We also calculated net plan sponsor expenditures by subtracting rebates from plan expenditures. These amounts are approximate, as these 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.

³A "therapeutic class" identifies drugs that are similar in chemical structure, pharmacological effect, or clinical use. RED BOOK, a drug pricing compendium, provides a five-level nested classification for each drug, with the first level being the broadest. We report the first level for Part D drugs, which represented 25 unique therapeutic classes for Part D drugs in 2021.

⁴Part D plan sponsors submit a prescription drug event record to CMS for each time a beneficiary obtains a prescription drug. The prescription drug event record contains information on the beneficiary receiving the drug, the price paid by the plan sponsor to the pharmacy, and applicable beneficiary cost-sharing.

⁵We calculated gross expenditures based on a drug's ingredient cost, dispensing fees, sales tax, and applicable vaccine administration fees for all Part D drugs.

⁶Plan sponsors initially paid the manufacturer coverage gap discount to pharmacies on behalf of beneficiaries in the coverage gap phase, and manufacturers reimbursed plan sponsors for these monies later. Manufacturers did not provide discounts for generic drugs or low-income subsidy beneficiaries in the coverage gap phase.

⁷To measure drug utilization, we created a weighted number of 30-day supplies. For example, if a drug claim was for a 90-day supply, we counted the number of 30-day prescriptions as three. Similarly, if a drug claim was for a 10-day supply, we counted the number of 30-day supplies as 0.3.

⁸This does not include other price concessions that plan sponsors may receive from manufacturers and pharmacies.

To describe the relationship between rebates and Part D formulary placement for competing drugs, we conducted two distinct analyses using 2021 CMS Part D formulary, expenditure, and rebate data: (1) an analysis of expenditures, rebates, and formulary placement for brand-name and competitor drugs, and (2) an analysis of expenditures, rebates, and formulary placement for brand-name drugs with counterparts that were marketed under a generic name.⁹ Specifically, we conducted the following analyses.

Competitive groups. We identified 10 groups of competitor drugs (hereafter, referred to as competitive groups) and assessed the extent to which Part D plan sponsors placed highly rebated brand-name drugs in these groups on a preferred formulary tier relative to available competitor drugs within the groups. These selected competitive groups accounted for \$23.9 billion in rebates, or approximately half of total rebates in 2021.

- **Identification of competitive groups.** To identify the competitive groups, we reviewed rebate agreements for 24 selected brand-name drugs and identified additional drugs that were listed as competitors to a given manufacturer's drug in the agreements.¹⁰ Using the selected brand-name drugs from the rebate agreements and their listed competitor brand-names, we identified 10 competitive groups of drugs that each included three to five brand-name manufacturers. Each competitive group included all brand-name drugs that were listed in at least two rebate agreements as competitors for a particular drug for purposes of determining rebate percentages based on the number of preferred competitors. The competitive groups also included any additional drugs that shared the same ingredient, strength, and dose form as one of the other drugs within a competitive group.
- **Preferred formulary placement of drugs in the competitive groups:** We used CMS's Approved Formulary Submission Extract to

⁹While addressing separate perspectives, these analyses overlapped in that certain drugs were represented in both sets of selected drugs.

¹⁰We reviewed 2020 rebate agreements negotiated between six drug manufacturers and six Part D plan sponsors for 24 brand-name drugs, which represented approximately 100 unique ingredient, strength, and dose combinations. We selected six of the 25 largest Part D plan sponsors by contract enrollment in 2020 and the six manufacturers of the 24 brand-name drugs. The 24 brand-name drugs were selected based on one or more factors, including: those that had at least one drug formulation that was among the 100 most highly rebated in 2020, were competitors of highly rebated drugs, or were biologics. Our selection of drugs was based on 2020 spending and rebate data, which was the most recent data available when we selected rebate agreements.

determine which drugs in each selected competitive group were preferred drugs on 508 Part D formularies as of December 2021.¹¹

We considered a drug to have preferred placement on a formulary if it was (1) on the lowest cost-sharing formulary tier relative to other drugs within the competitive group and (2) had similar or fewer utilization management requirements relative to other drugs within the competitive group.¹² We assessed the extent to which drugs in the selected competitive groups had preferred placement on each formulary, as well as whether the drugs were listed at all or not listed on each formulary.¹³

- **Comparison of highly rebated, higher-gross-cost drugs and lower-gross-cost drugs.** We reported on formulary placement of highly rebated higher-gross-cost drugs compared to lower-gross-cost drugs in the competitive groups. We used a weighted average based on the number of prescriptions to summarize rebates, gross expenditures, and net plan sponsor payment per utilization for different formulations of the drugs in the competitive groups at the brand-name level. We identified relatively higher-gross-cost, highly rebated brand-name and lower-gross-cost drugs in each competitive group based on their gross expenditures per utilization, defined as a 30-day supply. We defined highly rebated brand-name drugs as those with a rebate percentage of at least 25 percent.¹⁴

Brand-name drugs with generic-name counterparts. We used 2021 CMS formulary, expenditure, and rebate data to assess the extent to which brand-name drugs that had counterparts marketed under a generic

¹¹The 508 formularies included December 2021 formularies other than non-Part D formularies and formularies associated with Program of All-Inclusive Care for the Elderly contracts and demonstration plans, both of which we excluded due to differences in applicable requirements and payment models.

¹²We compared the presence or absence of types of utilization requirements (prior authorization, step therapy, and quantity limits) separately. For example, within each formulary, if one drug in a competitive group was subject to any type of utilization management that other drugs drug in the same group and formulary was not subject to, we did not categorize the drug as preferred.

¹³Plan sponsors may use more than one Part D formulary and each formulary may be used across multiple plans belonging to the plan sponsor. That is, individual formularies reflected a specific plan sponsor's Part D drug formulary placement for some or all of its plans.

¹⁴The average rebate percentage for these drugs was 51 percent. We identified the lowest gross-cost drug in the group based on gross-cost per utilization regardless of rebate percentage.

name, (hereafter, referred to as generic counterparts) received rebates and their Part D formulary placement.

- **Identification of brand-name drugs with generic counterparts.** In order to focus the analysis on brand-name and generic counterpart drugs that were on the market prior to 2021, and were typically covered under Part D, we excluded any drugs that were not listed on CMS's archived 2020 Part D formulary reference file. We identified generic counterparts for brand-name drugs by matching the ingredient, strength, and dose form of the brand-name drugs to those of non-branded drugs. This included authorized generics for brand-name drugs and generic-name equivalents of brand-name drugs produced by competing manufacturers.¹⁵ We also identified biosimilars for biologic drugs and included them as generic counterparts for the reference biologic drugs. Other than biosimilars, we did not include generic drugs that were marketed under a brand-name as generic counterparts. These steps identified 1,633 brand-name drugs with generic counterparts that accounted for \$6.4 billion in rebates, approximately 13 percent of all Part D rebates for 2021.
- **Identification of highly rebated brand-name drugs.** We identified the brand-name drugs that accounted for the top 98 percent of the \$6.4 billion in rebates among all 1,633 Part D brand-name drugs for which we identified generic counterparts, resulting in 40 selected brand-name drugs that accounted for \$6.3 billion in rebates. These 40 highly rebated brand-name drugs included multiple formulations of the same brand name and represented 22 unique brand names in total.
- **Identification of formulary placement types:** We used CMS's Approved Formulary Submission Extract to determine the formulary placement of brand-name drugs relative to their generic counterparts. We reviewed the formulary placements of the 40 highly rebated brand-name drugs and generic counterparts compared to other brand-name drugs with generic counterparts on 508 Part D formularies as of

¹⁵Authorized generics refer to brand-name drugs that are marketed without the brand name on the label and may be sold at a lower cost than the brand-name drug. Authorized generics may be marketed by the manufacturer of the brand-name drug or by another company with the manufacturer's permission.

December 2021. We examined the following formulary placement types:¹⁶

- **Brand listed, generic not listed.** The generic counterpart was not listed on the formulary, while the brand-name drug was listed.
- **Both listed, brand preferred over generic.** The brand-name drug was listed on a more preferred (lower cost-sharing) tier than the generic counterpart.
- **Both listed, brand and generic on the same tier.** The brand-name drug and generic counterpart were listed on the same formulary tier.
- **Both listed, generic preferred over brand.** The brand-name drug was listed on a less preferred (higher cost-sharing) tier than the generic counterpart.
- **Generic listed, brand not listed.** The brand-name drug was not listed on the formulary, while the generic counterpart was listed.
- **Neither brand nor generic listed.** Neither the brand-name drug nor its generic counterpart were listed on the formulary.
- **Multiple placement types.** In some cases, there was more than one brand-name drug or generic counterpart that shared the same ingredient, strength, and dose form. We treated such cases as one brand-generic counterpart, and evaluated whether there were multiple formulary placement types, such as one brand-name drug preferred over a generic counterpart with a second brand-name drug counterpart on the same tier as the generic counterpart. Multiple placement types represented less than one half of a percent of cases, and we did not report them separately.

To describe the implications of rebates on spending by Part D plan sponsors, beneficiaries, and the Medicare program, we used 2021 CMS Part D prescription drug expenditure and rebate data to determine the amount spent by these payers for (1) the highest rebated drugs—those accounting for approximately 80 percent of all Part D rebates—analyzed in our first reporting objective and (2) the drugs within the 10 selected

¹⁶In some cases, multiple brand-name drugs shared the same ingredient, strength, and dose form as a generic counterpart. We report the number of brand-name drugs for which we identified a generic counterpart; for purposes of reviewing formulary placements we treated such cases as one brand-generic counterpart. We also evaluated any differences in utilization management, and found that generic counterparts rarely had more restrictive utilization requirements compared to the brand-name drug.

competitive groups and 40 selected brand-name drugs with generic counterparts analyzed in our third reporting objective.

- **Highest-rebated drugs.** We identified the highest-rebated drugs in 2021 as the 100 drugs receiving the highest rebates in 2021, as described in our first reporting objective. For these drugs, we calculated the amount of gross expenditures spent by Part D plan sponsors, beneficiaries and other payers on their behalf, and discounts manufacturers provided for applicable beneficiaries in the coverage gap (referred to as coverage gap discounts).¹⁷ We subtracted rebates manufacturers paid Part D plan sponsors from the amount spent by plan sponsors to determine net plan sponsor payments.
- **Competitive groups.** We identified competitor drugs within 10 competitive groups, as described in our third reporting objective above. We used a weighted average based on the number of prescriptions to summarize gross cost, rebates, coverage gap discounts, beneficiary payment, and net plan sponsor payment per utilization for different formulations of the drugs in the competitive groups at the brand-name level in the aggregate for the Part D formularies identified in the third reporting objective.
- **Brand-name drugs and generic counterparts.** We identified 40 highly rebated brand-name drugs with generic counterparts, as described in our third reporting objective above. We calculated gross cost per utilization, beneficiary payment per utilization, and net plan sponsor payment per utilization for the 40 highly rebated brand-name drugs and their generic counterparts in the aggregate for the Part D formularies identified in the third reporting objective.

¹⁷Beneficiary payments are approximate and include payments by beneficiaries and other payers on their behalf, including Medicare's low-income subsidy payments, and third-party payers such as group health plans (e.g., for retired beneficiaries receiving drug coverage through an employer-based plan) and other government payers. In some instances, beneficiary payments may include payments made by plan sponsors. Plan sponsors' spending net of rebates are approximate, as these amounts do not include fees plan sponsors may have received from pharmacies and others to reduce their drug spending and may include reinsurance payments.

Appendix II: Recent Federal Trade Commission Activities Related to Pharmaceutical Rebates

The Federal Trade Commission (FTC) enforces federal antitrust laws and works to protect the public against anticompetitive behavior, including in the pharmaceutical marketplace.¹ According to FTC, any antitrust concerns relating to pharmaceutical manufacturers' rebate practices would focus on their potential to create or maintain the market power of an incumbent pharmaceutical product.² In its June 2022 policy statement, FTC noted it has several legal authorities that could apply to pharmaceutical rebating practices, including section 5 of the Federal Trade Commission Act, section 3 of the Clayton Act, section 2 of the Robinson-Patman Act, and the Sherman Act.³

FTC has authority to investigate pharmaceutical competition, including competition in the Medicare Part D program.⁴ FTC officials stated the agency often initiates investigations in response to complaints, congressional and attorney general inquiries, and issues reported in the press. The agency has also held workshops with various agency officials, academics, and others to discuss anticompetitive issues or concerns in the health care marketplace, including several workshops that included a discussion of drug pricing practices.⁵

¹To summarize recent FTC activities related to rebate arrangements, we interviewed FTC officials and reviewed applicable statutes, policy statements, and reports.

²Federal Trade Commission, *Report on Rebate Walls*, (Washington, D.C.: May 2021).

³See Federal Trade Commission, *Policy Statement of the Federal Trade Commission on Rebates and Fees in Exchange for Excluding Lower-Cost Drug Products*, (Washington, D.C.: June 2022). The Federal Trade Commission Act bans unfair methods of competition and unfair or deceptive acts or practices. See 15 U.S.C. §§ 41-58. The Sherman Act prohibits agreements that unreasonably restrain competition as well as monopolization, attempted monopolization, and conspiracies to monopolize. See 15 U.S.C. § 1-7. The Clayton Act addresses certain practices not clearly prohibited under the Sherman Act, such as certain distribution practices that tend to lessen competition. See 15 U.S.C. §§ 12-27. The Robinson-Patman Act generally prohibits large franchises from engaging in price discrimination against smaller businesses. See 15 U.S.C. § 13.

⁴The Department of Justice, and not FTC, enforces the Sherman Act. However, the Supreme Court has held that violations of the Sherman Act also violate the Federal Trade Commission Act. Therefore, FTC can bring cases under the Federal Trade Commission Act against the same kinds of activities that violate the Sherman Act. See *Fed. Trade Comm'n v. Cement Inst.*, 333 U.S. 683, 691-92 (1948).

⁵For example, the effects of rebates on competition were discussed at the joint Food and Drug Administration and FTC *Workshop on a Competitive Marketplace for Biosimilars*, March 9, 2020 and at FTC's November 2017 workshop, *Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics*.

Since 2021, FTC has issued two reports on rebates and announced the start of a study of pharmacy benefit manager (PBM) practices, which includes looking at the competitive implications of rebating.

- **May 2021 rebate walls report.** In response to a congressional request, FTC issued a report describing rebate walls.⁶ The report defined a rebate wall as a situation in which a dominant pharmaceutical manufacturer uses rebate strategies in its contracts with third-party payers to both maintain market power by giving its products preferred status in drug formularies and to prevent sales of competing products. The agency noted that some rebate agreements may become “traps” or “walls.” For example, a “rebate trap” might exist when a manufacturer conditions rebates on formulary access or market share. If a plan sponsor offers a competitor drug access to the formulary, the manufacturer would stop providing the rebate, thereby requiring the plan sponsor to pay the full, non-rebated cost of the drug. Such actions may create “rebate walls” which prevent plan sponsors from introducing lower-cost medicines to their beneficiaries.⁷
- **June 2022 policy statement on rebates.** FTC issued a policy statement explaining how it applies competition and consumer protection laws in the area of drug rebates. FTC noted that rebate agreements may steer patients to higher-cost drugs over less expensive alternatives which could lead to increased costs for both patients and plan sponsors, including increased out-of-pocket costs at the point-of-sale.⁸ The statement raised concern about the implications of rebates and high list prices for insulins. It also noted FTC has legal authorities to investigate those practices that stifle and foreclose competition, including the following.
 - Exclusionary rebates that foreclose competition from less expensive alternatives may constitute unreasonable agreements in restraint of trade under section 1 of the Sherman Act; unlawful

⁶Federal Trade Commission, *Report on Rebate Walls*.

⁷In addition to defining rebate walls, the report noted that application of antitrust laws to such dealing is highly fact-specific. Relevant factors may include market definition and relative market power, the extent of market foreclosure, contract duration, anticompetitive effects and lack of potential countervailing procompetitive justifications, and a customer’s practical ability to terminate agreements.

⁸FTC noted that the statement was intended to “put drug companies and prescription drug middlemen on notice that paying rebates and fees to exclude competitors offering lower-cost drug alternatives can violate competition and consumer protection laws.” Federal Trade Commission, *Policy Statement on Rebates and Fees*.

monopolization under section 2 of the Sherman Act; or exclusive dealing under section 3 of the Clayton Act.

- Inducing PBMs or other intermediaries to place higher-cost drugs on formularies instead of less expensive alternatives in a manner that shifts costs to payers and patients may violate the prohibition against unfair methods of competition or unfair acts or practices under section 5 of the Federal Trade Commission Act.
- Finally, paying or accepting rebates or fees in exchange for excluding lower-cost drugs may violate section 2(c) of the Robinson-Patman Act, which prohibits payments to agents, representatives, and intermediaries who represent another party's interests in connection with the purchase or sale of goods.

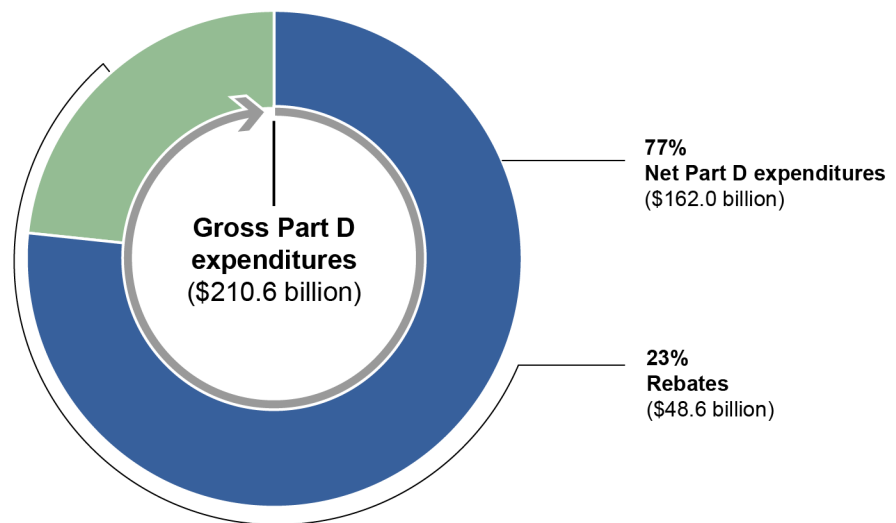
In June 2022, FTC announced it was undertaking an inquiry on PBM practices. In addition to examining the effect of PBM fees and use of PBM-owned pharmacies, FTC stated the inquiry would look at topics such as fees from drug manufacturers, the effects of rebates on formulary design, and the costs of prescription drugs to payers and patients. As of May 2023, FTC officials did not provide an estimated timeline for completion of the inquiry.⁹

⁹In May and June 2023, FTC announced it was expanding its inquiry into PBM practices to include three group purchasing organizations that negotiate rebates on behalf of PBMs.

Appendix III: Expenditure, Utilization, and Rebate Information for Medicare Part D Drugs

Pharmaceutical manufacturers paid plan sponsors \$48.6 billion in rebates in 2021, which accounted for 23.1 percent of the \$210.6 billion in Part D gross expenditures.¹ Accounting for rebates resulted in \$162 billion in net expenditures in 2021. (See fig. 10.)

Figure 10: Gross Medicare Part D Expenditures, Rebates, and Net Part D Expenditures for All Part D Drugs, 2021



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-23-105270

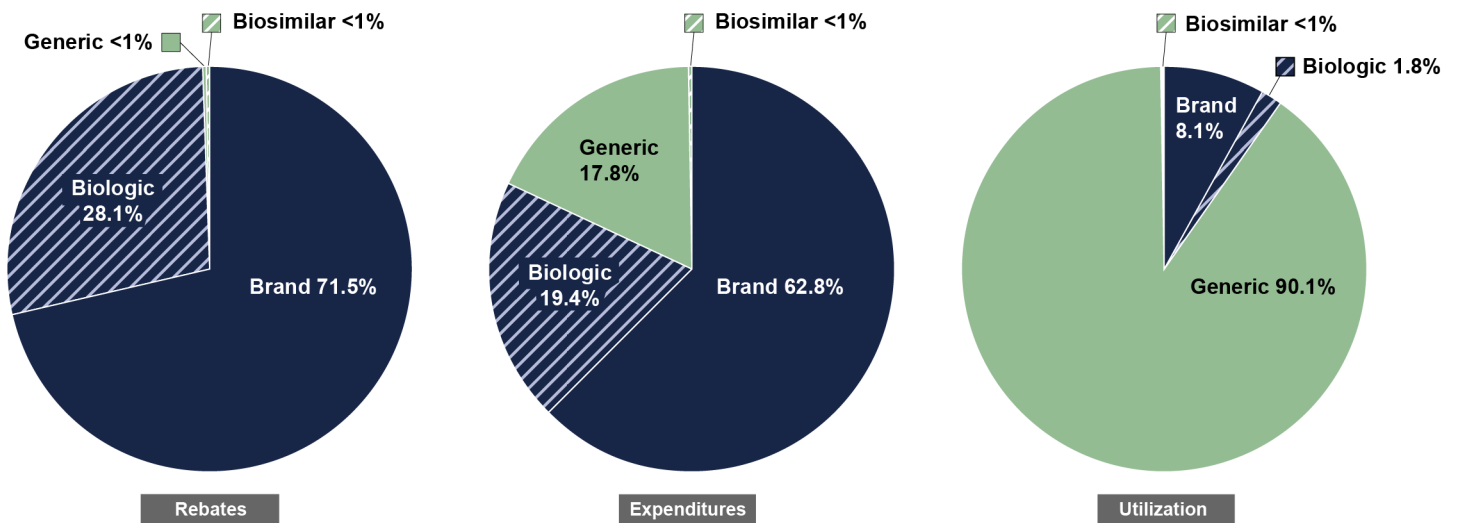
Note: We analyzed 2021 CMS Medicare Part D prescription drug expenditure and rebate data. Gross expenditures reflect what was paid to a pharmacy by Part D plan sponsors and beneficiaries. Rebates are discounts manufacturers provide Part D plan sponsors after a drug is purchased. Net expenditures reflect gross expenditures minus rebates.

¹The \$210.6 billion in Part D expenditures, referred to as gross expenditures, reflects what was paid to pharmacies by plan sponsors and beneficiaries, or other payers on the beneficiary's behalf, and does not include rebates manufacturers generally paid to sponsors after a drug was purchased. Pharmacy benefit managers (PBM) may earn revenue for the services they provide plan sponsors by retaining a portion of the rebates they negotiate from manufacturers on a sponsor's behalf. However, our analysis of Centers for Medicare & Medicaid Services (CMS) rebate information indicated that PBMs retained less than 1 percent of the rebates paid by manufacturers in 2021. GAO previously reported that, in 2016, rebates totaled \$27 billion—18.6 percent—of the \$145.1 billion in Part D drug expenditures. 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).

Brand-name drugs, including biologics, had higher rebates and gross expenditures, but lower utilization, than generic drugs, including biosimilars.

- Brand-name drugs and biologics.** These drugs accounted for 99.6 percent of the \$48.6 billion in rebates paid by manufacturers to Part D plan sponsors. Brand-name drugs accounted for 71.5 percent of total Part D rebates, 62.8 percent of expenditures, and 8.1 percent of utilization. Biologics accounted for 28.1 percent of rebates, 19.4 percent of expenditures, and 1.8 percent of utilization.
- Generic drugs and biosimilars.** These drugs accounted for less than 1 percent—0.4 percent—of the \$48.6 billion in rebates paid by manufacturers to Part D plan sponsors. These drugs accounted for the majority of utilization—90.1 percent—but the minority of expenditures and rebates, at 17.8 percent and 0.4 percent, respectively. Generic drugs accounted for over 90 percent of all utilization, expenditures, and rebates for generics and biosimilars. There were relatively few biosimilars on the market, and they accounted for less than 1 percent of total Part D utilization, expenditures, and rebates. (See fig. 11.)

Figure 11: Rebates, Expenditures, and Utilization for Medicare Part D Drugs, 2021



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-23-105270

Note: We analyzed 2021 CMS Medicare Part D prescription drug expenditure and rebate data for both brand-name and generic drugs. For the purposes of our analysis, we identified brand-name drugs as drugs that have a marketed brand name and biologics, which are products derived from living sources, such as humans, animals, and microorganisms. An approved generic drug is therapeutically equivalent to a corresponding brand-name drug and is generally marketed under a

**Appendix III: Expenditure, Utilization, and
Rebate Information for Medicare Part D Drugs**

nonproprietary generic name. For the purposes of our analysis, we identified generic drugs as drugs that are marketed without a brand name, including authorized generics, and biosimilars, which are highly similar to an existing biologic licensed by the Food and Drug Administration (FDA). Expenditures reflect gross expenditures—what was paid to a pharmacy by the Part D plan sponsors and beneficiaries. Rebates are discounts manufacturers provide to Part D plan sponsors after a drug is purchased. Utilization is based on the number of 30-day supplies for each drug. We excluded compounded drugs, which are tailor-made by a pharmacy for a beneficiary; over-the-counter drugs, as they are generally not covered by Medicare Part D; and drugs associated with Part D plans that do not have a formulary.

Appendix IV: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

August 4, 2023

John E. Dicken
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Dicken:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, **"Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending"** (GAO-23-105270).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Melanie Anne Egorin

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: MEDICARE PART D: CMS SHOULD MONITOR EFFECTS OF REBATES ON PLAN FORMULARIES AND BENEFICIARY SPENDING (GAO-23-105270)

The Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on this draft report. HHS is committed to ensuring that Medicare beneficiaries have access to high quality and affordable health care while, at the same time, working to preserve the Medicare Trust Funds. Recognizing that Medicare can play a large role in promoting the use of more affordable drugs, HHS is committed to continuing to promote competition, support increased utilization of generic drugs, reduce the federal government's spending on drugs, and achieve greater equity in drug access and affordability for beneficiaries, within the authorities granted by statute.

Plan sponsors, private companies that provide voluntary Medicare Part D prescription drug coverage, must submit their drug formularies to HHS for approval each contract year. Among other criteria, HHS reviews formularies to ensure that they provide access to an acceptable range of Part D drug choices, include sufficient drugs in each category and class, and that tier placement and utilization management restrictions do not substantially discourage enrollment by certain beneficiaries. HHS also analyzes formularies to determine whether appropriate access is afforded to drugs or drug classes addressed in widely accepted treatment guidelines. While understanding that plan sponsors will not provide identical coverage of all drug classes, HHS' robust review process focuses on ensuring that sponsors offer a balanced, clinically appropriate formulary.

In addition to reviewing the completeness and structure of each plan's formulary, HHS also reviews each plan's utilization management restrictions, and compares all sponsors' formulary submissions to analyze the comparative use of utilization management tools. When outliers are identified, HHS will analyze whether such restrictions may create problems of access, and if so, will request that plan sponsors present reasonable clinical justifications. Sponsors may be asked to make modifications to their benefit structure or formulary tiering if the submitted justification is not accepted.

Because tier placement affects beneficiary cost-sharing, HHS expects drug tier labels to be representative of the drugs that make up that tier. HHS evaluates the brand/generic composition of the non-preferred brand tier, while affording Part D sponsors the flexibility to determine the cost-sharing structure that is most appropriate for their benefit design, including the ability to mix brand and generic drugs within the non-preferred brand tier.

The formulary review that HHS conducts is designed to ensure that formulary structure does not substantially discourage enrollment by certain beneficiaries, and that beneficiaries receive clinically appropriate medications in compliance with the cost-sharing structure defined by statute.¹

In addition, as noted by GAO, the Inflation Reduction Act of 2022 (IRA) instituted various changes to the Part D program, including with respect to the allocation of financial responsibility for prescription drug costs between plan sponsors, manufacturers, beneficiaries, and the Medicare program. Some of these changes have already taken effect, while others will be implemented in the coming years. For example, the IRA will eliminate beneficiary cost-sharing

¹ Sections 1860D-11(e)(2)(D) and 1860D-2(b)-(c) of the Social Security Act

in the catastrophic phase starting in 2024 and, in 2025, will cap beneficiary annual out-of-pocket spending at \$2,000. Additionally, the IRA established a new Medicare Drug Price Negotiation Program under which HHS will negotiate maximum fair prices on behalf of the Medicare program for certain high expenditure, single source drugs. The maximum fair prices for the first cohort of selected drugs will take effect beginning in 2026.

GAO's recommendations and HHS' responses are below.

GAO Recommendation

The Administrator of CMS should monitor the effect of rebates on plan sponsor formulary design and on Medicare and beneficiary spending to assess whether rebate practices are likely to substantially discourage enrollment by certain beneficiaries and whether beneficiaries receive clinically appropriate medications at the lowest possible cost.

HHS Response

HHS does not concur with GAO's recommendation. As stated above, HHS-already performs Part D formulary review to ensure compliance with Part D requirements, and does not consider the evaluation of expenditure or rebate information necessary to ensure that a formulary is not likely to substantially discourage enrollment. In addition, any analysis of the current rebate structure will not be reflective of future Part D benefit design, due to impending changes to the Part D program, as required under the IRA, which includes implementation of the new Medicare Drug Price Negotiation Program, under which HHS will negotiate maximum fair prices on behalf of the Medicare program for certain high expenditure, single source drugs. As such, we recommend that GAO remove this recommendation.

HHS thanks GAO for their efforts on this issue and looks forward to working with GAO on this and other issues in the future.

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

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Staff Acknowledgements

In addition to the contact named above, Robert Copeland, Assistant Director; William Crafton, Analyst-in-Charge; Ling Guo, Emily Beller Holland, Dan Lee, and Fatima Sharif made key contributions to this report. Also contributing were Kaitlin Farquharson, Laurie Pachter, Ravi Sharma, and Ethiene Salgado-Rodriguez.

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