



July 2019

MEDICARE PART D

Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization

This Report Is Temporarily Restricted Pending Official Public Release.

GAO Highlights

Highlights of [GAO-19-498](#), a report to congressional requesters

Why GAO Did This Study

Total expenditures for the Medicare Part D drug program exceeded \$100 billion in 2016. Part D plan sponsors may use a PBM to provide drug benefit management services for Part D coverage, such as negotiating drug rebates and other price concessions and paying pharmacy claims. Policymakers have sought a better understanding of PBMs' roles in the drug supply chain and plans' and PBMs' efforts to manage Part D drug spending and use.

GAO was asked to examine the role of PBMs in the Part D program. This report examines, among other objectives, (1) the extent to which Part D plan sponsors use PBMs, (2) trends in rebates and other price concessions obtained by both PBMs and plan sponsors for Part D drugs, and (3) how PBMs earn revenue for services provided to Part D plans.

GAO analyzed Centers for Medicare & Medicaid Services (CMS) data on Part D plan sponsors' use of PBMs in 2016 as well as CMS drug expenditure, pricing, and rebate and other price concession data for all Part D drugs from 2014 through 2016 (the most recent available data at the time of our analysis). GAO reviewed service agreements between Part D plan sponsors and PBMs that were approved by CMS from January 2016 through May 2018 and had the highest enrollment as of June 2018. GAO spoke with CMS officials and 38 stakeholder groups including PBMs, Part D plan sponsors, pharmacy representatives and drug manufacturers.

View [GAO-19-498](#). For more information, contact John Dicken at (202) 512-7114 or dickenj@gao.gov.

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MEDICARE PART D

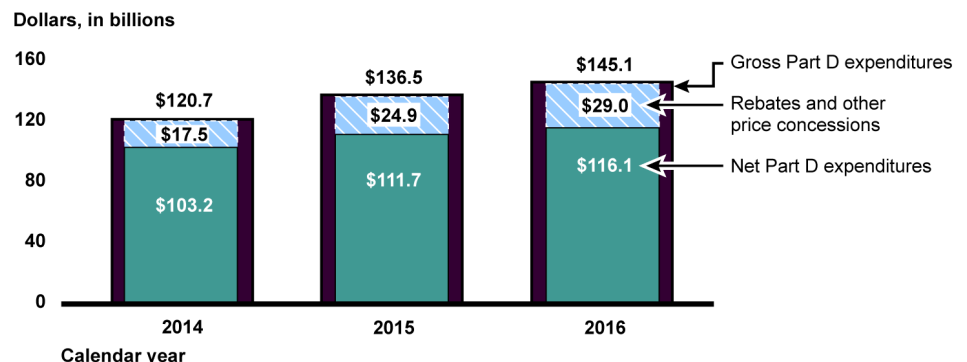
Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization

What GAO Found

Medicare Part D plan sponsors used pharmacy benefit managers (PBM) to provide 74 percent of drug benefit management services and performed the remaining 26 percent of services themselves in 2016—the most recent year of data at the time of our analysis. Plan sponsors are private entities that operate drug plans; PBMs are organizations that help manage drug benefits.

Rebates and other price concessions—discounts generally paid by manufacturers to Part D plan sponsors and PBMs after the sale of a drug at the pharmacy—grew faster than Part D expenditures from 2014 through 2016. Specifically, gross expenditures (the amount paid to pharmacies by plan sponsors, or by the PBM on the sponsor's behalf, and by the beneficiary) increased 20 percent, to \$145.1 billion. During this period, rebates and other price concessions increased 66 percent, to \$29 billion—20 percent of 2016 gross expenditures. Consequently, net expenditures (gross expenditures less rebates and other price concessions) increased only 13 percent, to \$116.1 billion.

Gross Medicare Part D Expenditures, Net Part D Expenditures, and Rebates and Other Price Concessions for All Part D Drugs, 2014-2016 (in billions of dollars)



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-19-498

PBMs primarily earned Part D revenue through a volume-based fee paid by plan sponsors based on PBM-processed claims; a per-member, per-month fee paid by plan sponsors; or a combination of the two. PBMs also earned revenue from the rebates they negotiated with manufacturers for Part D drugs, which accounted for \$18 billion of the \$26.7 billion in rebates in 2016. PBMs retained less than 1 percent of these rebates, passing the rest to plan sponsors. Plan sponsors in turn may use rebates to help offset the growth in drug costs, helping control premiums for beneficiaries.

The Department of Health and Human Services provided technical comments on a draft of this report, which GAO incorporated as appropriate.

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Abbreviations

AWP	average wholesale price
CMS	Centers for Medicare & Medicaid Services
DIR	direct and indirect remuneration
HHS	Department of Health and Human Services
HPMS	Health Plan Management System
ISDR	Ingredient, strength, dosage, and route of administration
NADAC	National Average Drug Acquisition Cost
PACE	Program of All-inclusive Care for the Elderly
PBM	Pharmacy Benefit Manager
PDE	prescription drug event
PDP	prescription drug plan
PSAO	Pharmacy Services Administrative Organization

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July 15, 2019

The Honorable Susan Collins
Chairman
Special Committee on Aging
United States Senate

The Honorable Richard Neal
Chairman
Committee on Ways and Means
House of Representatives

Medicare Part D is the voluntary program that provides outpatient prescription drug coverage for Medicare beneficiaries who enroll in Part D drug plans.¹ Total Part D program expenditures were more than \$100 billion in 2016, the most recent data at the time of our analysis. These expenditures account for the amount paid to pharmacies by Part D plan sponsors, or by a pharmacy benefit manager PBM (PBM) on the sponsors' behalf, and by beneficiaries for Part D drugs. Part D plan sponsors—which are private companies—contract with the Centers for Medicare & Medicaid Services (CMS) to provide this prescription drug coverage to Medicare beneficiaries.² Plan sponsors may have multiple contracts with CMS, with each contract providing one or more distinct drug plans.³ Plans may charge different monthly premiums and have different beneficiary cost-sharing arrangements—such as deductibles and cost-sharing for covered drugs.⁴

¹Beneficiaries may receive Part D coverage through either stand-alone Part D prescription drug plans (PDPs) that supplement traditional Medicare or through Medicare Advantage (Part C) plans that generally must cover all Medicare benefits and usually offer Part D coverage.

²PBMs are organizations that help manage drug benefits.

³For example, a Part D plan sponsor may have contracts covering various regions of the country. Plans covered under the same contract may differ in their benefit structure, the drugs they cover, and the pharmacies they contract with to fill prescriptions. In this report, we refer to a drug plan or plans covered under each sponsor contract with CMS as a “Part D plan sponsor contract.”

⁴A deductible is a fixed dollar amount that beneficiaries must pay before coverage takes effect. Part D plan sponsor payments to pharmacies generally include a portion that the beneficiary pays, known as cost-sharing, which may be a flat amount (copayment) or a percentage of the drug's costs (coinsurance).

There are a number of services associated with providing a drug benefit, including establishing networks of pharmacies and negotiating rebates and other price concessions from manufacturers. One drug benefit management service that is often performed is utilization management, a process to help ensure that the use of drugs and other medical services is based on medical necessity, efficiency, and appropriateness. Part D plan sponsors may perform these drug benefit services themselves or have them performed by PBMs. PBMs have come under scrutiny as policymakers have attempted to better understand their role in the drug supply chain and plan sponsors' and PBMs' efforts to manage Part D drug spending and use.

You asked us to provide an overview of the role of PBMs in the Medicare Part D program. This report examines:

1. the extent to which Part D plan sponsors use PBMs to deliver drug benefit management services to Medicare beneficiaries;
2. how PBMs earn revenue from the services they provide to Part D plan sponsors;
3. trends in rebates and other price concessions obtained by Part D plan sponsors and PBMs from drug manufacturers and others;
4. the extent to which prices for Part D drugs are discounted off of manufacturer list prices; and
5. what is known about savings and other effects of utilization management services commonly used in Part D plans.

To examine the extent to which Part D plan sponsors contract with PBMs to deliver drug benefit management services to Medicare beneficiaries, we analyzed CMS Health Plan Management System (HPMS) data for 2016, the most recent available expenditure and rebate and other price concession data at the time of our analysis. The data identified the entity or entities responsible for performing each of 10 drug benefit management services under plan sponsors' Part D contracts.⁵ According to CMS, these are the key drug benefit management services associated with providing Part D drug coverage and include paying pharmacy claims

⁵HPMS is CMS's web-based system through which Part D plan sponsors report their bids and other contract information to CMS. According to CMS, Part D plan sponsors are to report the entities responsible for performing these services on an ongoing basis.

and negotiating rebates and other price concessions.⁶ CMS provided HPMS data for the 624 Part D plan sponsor contracts that were effective in 2016.⁷ For each contract, we used the HPMS data to determine the extent to which a plan sponsor performed a service itself, contracted with a PBM to perform the service, or performed the service in coordination with a PBM. In this report, we refer to any organization (other than the plan sponsor itself) that provides one of the 10 drug benefit management services to a plan sponsor as a PBM.

To examine how PBMs earn revenue for the services they provide to Part D plan sponsors, we examined 20 service agreements between PBMs and Part D plan sponsors.⁸ These agreements generally contain detailed information on the services that the PBM will provide, how the plan sponsor will pay the PBMs for those services, and the rates pharmacies will be paid for prescription drugs.⁹ The 20 service agreements were those approved between January 2016 and May 2018 that had the highest enrollment in June 2018, the most recent data available at the time of our analysis.¹⁰

We also examined PBM revenue reported to CMS by Part D plan sponsors in their rebates and other price concession data reports—also referred to as direct and indirect remuneration (DIR)—in 2016, the most

⁶The eight other services are: pharmacy network development, enrollment processing, enrollee appeals and grievance process management, customer service, management of a pharmacy and therapeutics committee, coordination with other drug benefit programs, pharmacy technical assistance, and drug benefit administration. Instead of being reported as one of the 10 distinct services, utilization management services may be included under several of the 10 prescription drug benefit services that plan sponsors report to CMS in the HPMS data.

⁷These 624 contracts provided 4,663 unique plans and were operated by 207 Part D plan sponsors in June 2016.

⁸The service agreements and the provisions in those agreements that we examined are not generalizable to all service agreements that are in effect.

⁹One service agreement did not have complete information on the primary way that the PBMs would be paid. CMS told us that payment information between Part D plan sponsors and PBMs may be omitted from information submitted to the agency if the sponsors consider it proprietary.

¹⁰Part D plan sponsors are required to provide CMS their service agreements with PBMs for initial approval by the agency. They are also required to provide CMS with any changes to substantive provisions of the service agreements, such as payment provisions, but do not have to provide CMS with a new service agreement containing the changes. See 42 U.S.C. § 1395w-115(f)(1).

recent data available at the time of our analysis. These data include information on any price concessions made after a drug is purchased from the pharmacy by a beneficiary. One type of price concession is a rebate, which is generally a discount paid by drug manufacturers to a Part D plan sponsor, or by a PBM on the sponsor's behalf, after a beneficiary purchases a drug.¹¹ These discounts may be offered in exchange for better placement on a plan sponsor's list of covered drugs, known as a formulary, which encourages the use of the manufacturer's drugs by assigning them to tiers within the formulary that have lower beneficiary cost sharing.¹² Plan sponsors and PBMs may receive other price concessions that lower the price of a drug. For example, plan sponsors may receive fees from pharmacies based on their performance, which affect prices for certain drugs since the performance fees affect the amount the plan sponsor pays the pharmacy.¹³ The rebate and other price concession reports also include information on any revenue earned by PBMs through their retaining a portion of negotiated rebates. We define the gross price of a drug as the total amount paid to the pharmacy by the Part D plan sponsor, the PBM on the sponsor's behalf, and the beneficiary; gross price less rebates and other price concessions is the net price. The rebate and other price concession reports to CMS also include monies that are not concessions used in the calculation of net price, such as certain sources of PBM revenue, including fees paid by manufacturers to PBMs for certain services, as well as spread pricing—

¹¹Beneficiary cost-sharing is based on the price of the drug at the point of sale. Therefore, if a manufacturer provides a rebate after the point of sale, which, as noted, is generally the case, the beneficiary's cost sharing is not reduced by the amount of the rebate. Other factors may affect the amount of beneficiary cost-sharing, such as beneficiaries paying more for drugs purchased at pharmacies not within the Part D plan sponsor's preferred pharmacy network.

¹²A formulary is a Part D plan sponsor's list of covered drugs. Plan sponsors may assign drugs to different tiers within a formulary that correspond to different levels of beneficiary cost sharing. The tiers with lower cost sharing correspond to more favorable placement in the formulary to encourage beneficiaries to use lower cost drugs. Although rebates and other price concessions do not directly affect the price beneficiaries pay at the pharmacy, which is based on the price before any price concessions are applied, the presence of a rebate may affect their cost-sharing in other ways, such as by placing the drug on a preferred formulary tier with lower cost sharing in exchange for the rebate.

¹³Part D plan sponsors and PBMs may enter into performance arrangements with pharmacies where they either pay a fee or receive a bonus based on their performance, such as a specified percent of prescriptions dispensed for a generic drug (instead of a brand-name drug). The revenue paid to pharmacies is considered an incentive payment and monies received from pharmacies by plan sponsors, or PBMs on their behalf, is considered a price concession.

where PBMs earn revenue by keeping the difference between the amount they charged the pharmacy and the amount they charged the plan for a drug.

To examine trends in rebates and other price concessions obtained by Part D plan sponsors and PBMs from manufacturers and others for Part D drugs, we analyzed plan sponsors' gross and net expenditures for these drugs from 2014 through 2016. For a given drug, gross expenditures reflect what was paid to the pharmacy by the Part D plan sponsor, PBMs on the sponsor's behalf, and the beneficiary. To calculate gross expenditures, we used Medicare prescription drug event (PDE) data to calculate gross brand-name and generic drug expenditures and utilization for all Part D plan sponsors.¹⁴ Net expenditures reflect any rebates and other price concessions obtained by Part D plan sponsors and PBMs after a beneficiary receives a drug. To calculate net expenditures, we obtained rebate and other price concession information and subtracted it from plan sponsors' brand-name and generic gross expenditures. We identified brand-name and generic drugs by grouping expenditure claims with the same active ingredient, strength, dosage form, and route of administration.¹⁵ We also used CMS Part D enrollment data to examine gross and net expenditures per Medicare beneficiary for sponsor contracts in 2016.¹⁶ We also examined differences in the amount

¹⁴Part D plan sponsors—both PDPs and Medicare Advantage drug plans—submit a PDE record to CMS for each time a beneficiary obtains a prescription drug. The PDE record contains information on the beneficiary receiving the drug, the price paid by the plan sponsor to the pharmacy, and applicable beneficiary cost-sharing. We calculated expenditures based on a drug's ingredient cost, dispensing fees, sales tax, and applicable vaccine administration fees for all Part D drugs. We excluded PDE claims billed under Programs of All-Inclusive Care for the Elderly plan contracts because they are exempted from certain Part D requirements, such as charging beneficiaries cost-sharing. We also excluded compounded drugs, which are tailor-made by a pharmacy for a beneficiary and over-the-counter drugs as they are generally not covered by Medicare Part D. We used information from Red Book, a compendium published by Truven Health Analytics, to identify brand-name and generic drugs and to determine drugs' therapeutic class, dose, and route of administration.

¹⁵The dosage form is the physical form in which a drug is produced and dispensed, such as a tablet or capsule; route of administration is the way of administering a drug to a site in a patient, such as taking a drug orally.

¹⁶We used June 2016 data to indicate enrollment, as this month has relatively stable enrollment as it does not fall within an annual open enrollment period where beneficiaries may change their Part D coverage.

of rebates and other price concessions relative to expenditures obtained by Part D plan sponsors that used a PBM, relative to those that did not.¹⁷

To obtain more information on drugs that have the greatest fiscal impact on the Part D program and its beneficiaries, we calculated gross and net expenditures for the brand-name and generic drugs with the highest expenditures, highest utilization, and highest expenditure per utilization in 2016. For both brand-name and generic drugs, we identified the following: the 200 brand-name and 200 generic drugs with the highest expenditures in 2016; the 200 brand-name and generic drugs with the highest utilization in 2016 (based on number of 30-day prescriptions); and the 200 brand-name and generic drugs with the highest expenditures per utilization (i.e., highest expenditure per number of 30-day prescriptions). As a result of overlap in the groups of drugs, these criteria yielded lists of the 444 unique highest expenditure, highest utilization brand-name drugs and the 476 unique highest expenditure, highest utilization generic drugs. Together, these 920 highest expenditure, highest utilization brand-name and generic drugs accounted for 81 percent of Part D expenditures in 2016.¹⁸

To examine the extent to which Part D drug prices are discounted off of manufacturer list prices, we compared the median gross and net prices for the 444 brand-name and 476 generic highest expenditure, highest utilization drugs to (1) list prices established by manufacturers and (2) the cost to pharmacies of acquiring these drugs. For the list price, we used the 2016 average wholesale price (AWP)—which we refer to as manufacturer list price—which reflects the average price manufacturers suggest wholesalers charge pharmacies for a drug.¹⁹ For pharmacy acquisition costs, which reflect the price pharmacies paid to obtain the drug, we used retail community pharmacy acquisition cost data from

¹⁷We determined PBM use through 2016 HPMS data that identified whether a Part D plan sponsor contract used a PBM for rebate and price concession negotiations with manufacturers, pharmacies, or others.

¹⁸Of the 920 highest expenditure, highest utilization brand-name and generic drugs, the 444 brand-name drugs accounted for 65 percent of expenditures, and the 476 generic drugs accounted for 16 percent of expenditures.

¹⁹AWP is a list price and does not reflect the actual price paid by pharmacies or wholesalers for a drug. We obtained AWP information from Truven Analytics' Red Book.

National Average Drug Acquisition Cost (NADAC) data.²⁰ Part D plan sponsors and PBMs acting on the sponsor's behalf may negotiate prices paid to pharmacies that are lower than manufacturers' list price, but higher than pharmacies' acquisition costs. Separately, the plan sponsor or PBM may also receive rebates and other price concessions that are not part of their payments to pharmacies, but are reflected in their net price. We also calculated a gross Part D drug price using 2016 PDE data by dividing gross per unit expenditures for a given drug by the total quantity dispensed for the drug.²¹ To calculate a net Part D price, we subtracted rebates and other concessions per quantity dispensed from the gross per unit price. We separated drugs sold in retail community pharmacies from those sold in specialty pharmacies, as they dispense low-volume and high-cost drugs to patients undergoing intensive therapies for illnesses.²² For each drug, we then determined median pharmacy acquisition costs, median gross Part D prices, and median net Part D prices as a proportion of median manufacturer list prices.

To examine what is known about savings and other effects of utilization management services commonly used in Part D plans, we conducted a literature search for studies that examined the effect of utilization management services in Part D (regardless of whether they were provided by a PBM or another entity) on the following outcomes: (1) financial costs or savings, (2) beneficiaries' health indicators, and (3) beneficiaries' access to clinically appropriate medications or taking their medications as prescribed (adherence). The literature search was performed from April 2018 to July 2018 using keyword searches in bibliographic databases, including ProQuest, EBSCO, and Scopus. We limited our search to peer-reviewed studies published beginning in

²⁰NADAC is obtained from a survey of community retail pharmacies and was developed to provide a national pricing benchmark for states' Medicaid programs. NADAC does not contain data from non-retail pharmacies, such as mail-order or specialty pharmacies.

²¹Quantity dispensed is the unit of measure for the drug such as milliliters or milligrams.

²²We determined whether a drug was sold in retail or specialty pharmacies based on NADAC data. We found that 97 percent of the 444 highest expenditure, highest utilization brand-name drugs that lacked NADAC were listed as specialty drugs on a Part D plan sponsor's formulary. Given this, we refer to drugs that do not have a NADAC price as those sold in specialty pharmacies.

2006—the year the Part D program began.²³ We identified and reviewed 52 studies that met these criteria.

For all five of our objectives, we obtained the perspectives of stakeholders on Part D plan sponsors' use of PBMs as well as their perspectives on sponsors' efforts to control Part D expenditures and drug utilization. These stakeholders consisted of representatives from 17 small, mid-sized, and large Part D plan sponsors; seven PBMs; three drug manufacturers; a wholesaler and pharmacy services administrative organization; and a patient advocacy organization.²⁴

For all of the data we analyzed, we took steps to assure their reliability, including interviewing knowledgeable officials, conducting data checks, and comparing 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.

We conducted this performance audit from May 2017 to July 2019 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.

²³We analyzed utilization management services provided to Medicare beneficiaries without regard to who provided the service.

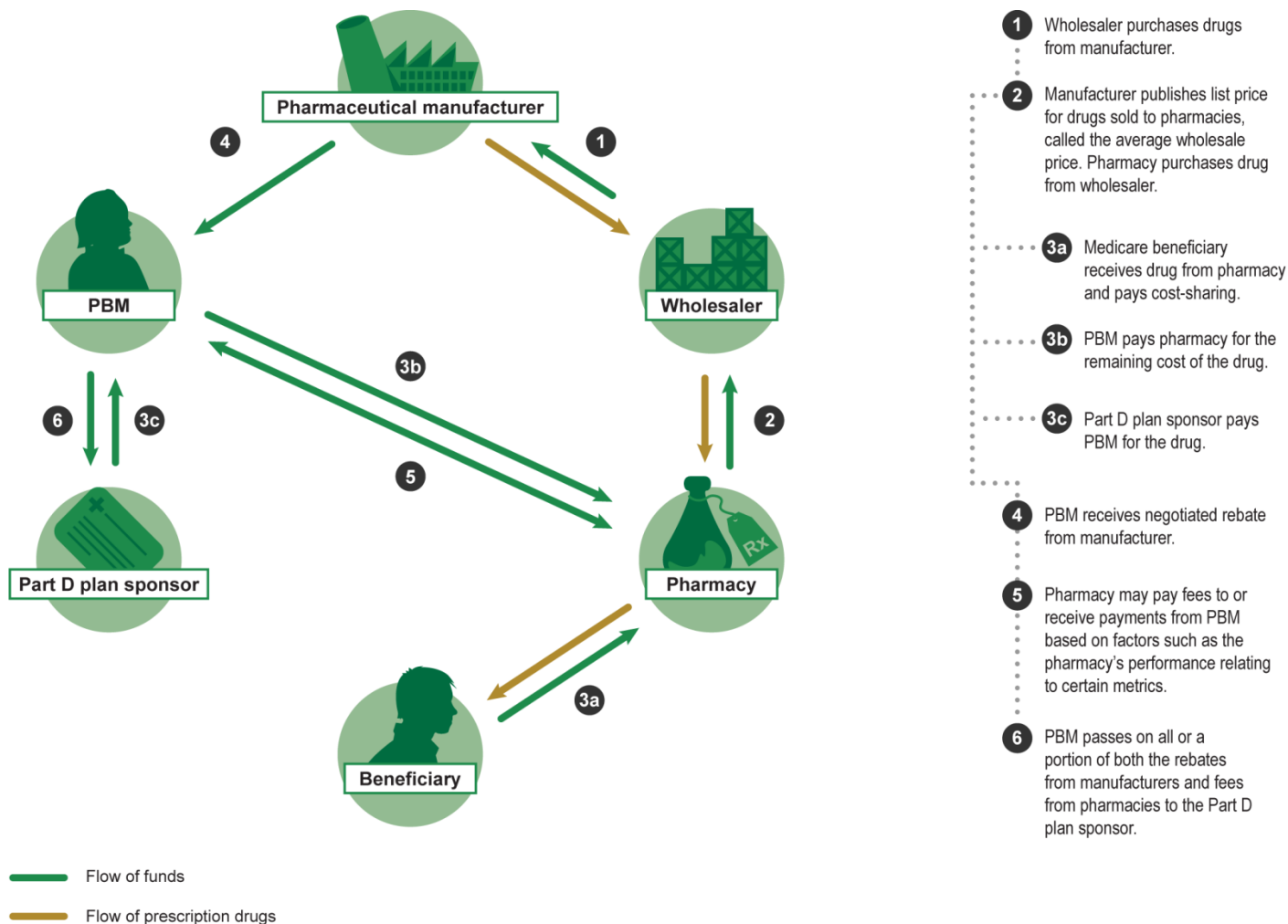
²⁴The 17 Part D plan sponsors consisted of 11 that had the 20 contracts with the largest enrollment in 2016 (enrollment in these contracts accounted for 82 percent of Part D enrollment in 2016); three that had contracts with enrollment at or just below the median 2016 contract enrollment; and three that had three contracts with enrollment at or below the bottom enrollment quartile. We spoke with representatives from the six PBMs that provided the most drug benefit services to Part D plan sponsors in 2016 as identified by our analysis of HPMS data. We also spoke with the PBM that provided the eighth most drug benefit services to Part D plan sponsors.

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 (a system 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. In the Part D program, CMS pays Part D plan sponsors to provide drug coverage, and plan sponsors may charge beneficiaries monthly premiums in exchange for coverage. Plan sponsors and PBMs negotiate reimbursement rates for the drugs provided to beneficiaries. When the beneficiary purchases a drug, the pharmacy is paid by the Part D plan sponsor, or through the PBM on the sponsor's behalf, and by the beneficiary through any applicable cost-sharing. (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 (PBM)



Source: GAO. | GAO-19-498

Note: This flow chart illustrates the use of a PBM by a Medicare Part D plan sponsor to pay prescription drug claims and negotiate rebates and other price concessions with manufacturers and others. In some cases, Part D plan sponsors perform these activities themselves or in conjunction with a PBM. For example, a plan sponsor may use a PBM to pay the pharmacy for a drug, while negotiating rebates directly with the manufacturer. In addition, other funds flow through the prescription drug supply chain. For example, the Centers for Medicare & Medicaid Services (CMS) makes prospective monthly payments to Part D plan sponsors based on plan sponsors' estimates of providing drug coverage to beneficiaries. These payments are reconciled by CMS at the end of the year to ensure that payments reflect actual drug costs minus rebates and other price concessions. Beneficiaries may also pay plan sponsors monthly premiums in exchange for their drug coverage.

Prescription Drug Plan Services

Services associated with developing and managing a prescription drug plan performed by PBMs, Part D plan sponsors, or both, include:

- **Formulary development.** Determining the list of drugs covered under the plan (the formulary), including assignment of covered drugs to tiers that correspond to different levels of beneficiary cost sharing and placing restrictions on drugs included in the formulary. Part D plan sponsors submit formularies for their plans to CMS for review and approval annually.
- **Pharmacy network development.** Creating a network of pharmacies where beneficiaries may fill their prescriptions and negotiating drug prices and reimbursement rates with those pharmacies. 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.²⁵
- **Utilization management services.** Utilization management services include processes such as:
 - **Prior authorization.** A requirement that beneficiaries obtain approval for a drug by the PBM or plan sponsor before obtaining the drug if it is to be covered by the plan.
 - **Step therapy.** A requirement where more expensive drugs are covered only if beneficiaries try less expensive alternatives first and find them not to be effective.
 - **Medication therapy management.** A program required by CMS designed to improve medication adherence and reduce the risk of adverse drug events through discussion with targeted beneficiaries and prescriber intervention.²⁶
 - **Drug utilization review.** A concurrent examination by the PBM or plan sponsor of prescriptions at the time of purchase by the beneficiary to assess safety considerations, such as potential adverse interactions, and compliance with clinical guidelines (including quantity and dose). These reviews can also occur

²⁵See 42 C.F.R. § 423.100 (2018).

²⁶Beneficiaries are automatically eligible for a Part D plan sponsor’s CMS-mandated medication therapy management program if they meet the following criteria: (1) have at least two chronic diseases; (2) are taking at least two Part D drugs; and (3) are likely to incur annual costs for covered Part D drugs greater than or equal to a specified cost threshold. Plan sponsors may include additional beneficiaries in their program, independent of these criteria.

retrospectively to analyze beneficiaries' drug utilization and physicians' prescribing patterns.

- **Negotiation of rebates from manufacturers.** Negotiating rebates for Part D plan sponsors with manufacturers in exchange for driving more utilization of a manufacturer's drug. This can include more favorable placement on the sponsor's formulary. The rebate terms do not have to be disclosed to the public, but plan sponsors must report rebate amounts to CMS.

PBM Revenue

PBMs may earn revenue from providing drug benefit management services to Part D plan sponsors in a number of ways, including: (1) payments from plan sponsors for administering services, such as drug benefits claim processing; (2) retention of a portion of drug rebates that PBMs negotiate on behalf of the plan sponsor and fees for managing and distributing those rebates; (3) spread pricing; and (4) payments from manufacturers for various services. PBMs may provide drug benefit management services to Part D plan sponsors and commercial plans, such as employer-sponsored health plans. Commercial plans may pay PBMs in ways similar to Part D plans (e.g., rebate retention and claims processing fees).

Part D Coverage and Payments

Part D plan sponsors are also required to provide access to all or substantially all drugs covered under certain therapeutic classes of drugs, known as Medicare protected classes: (1) anticonvulsants, (2) antidepressants, (3) antineoplastics, (4) antipsychotics, (5) antiretrovirals, and (6) immunosuppressants for the treatment of transplant. Plans are limited in the formulary restrictions they can apply to these drugs. Additionally, CMS generally requires Part D plan sponsors to provide coverage for at least two drugs in each class.

CMS makes payments prospectively to Part D plan sponsors for beneficiary drug coverage. CMS pays plan sponsors monthly, and these payments are determined through annual bids submitted 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 price concessions that the sponsor expects to receive during the ensuing program year. At the end of the program year, CMS reviews cost data submitted by plan sponsors through PDE 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 or making additional payments. Thus, the final

plan payments by CMS are based on the costs actually incurred by Part D plan sponsors minus rebates and other price concessions that are either passed along to the plan sponsors or retained by the PBMs.

Implications of Rebates and Other Price Concessions

Rebates and other price concessions reduce the cost of the Part D program to beneficiaries and the federal government. In developing their bids, Part D plan sponsors may subtract rebates and other price concessions that are passed along to them from their estimated drug costs.²⁷ When they do, rebates and other price concessions reduce a plan sponsor's estimate of liability that is reflected in bid amounts, which, in turn, reduce beneficiary premiums because they are based, in part, on the bid amount. This downward pressure on premiums is one reason that premiums remained relatively unchanged between 2010 and 2015, according to CMS, even though total gross Part D drug costs grew about 12 percent per year in that period.

Rebates have additional implications for Part D beneficiaries and the Part D program more generally. Since beneficiary cost sharing is calculated based on the price of the drug at the time of purchase (i.e., before rebates are paid), beneficiaries pay higher cost sharing than they would if rebates were paid at the point of sale. In addition, higher pre-rebate drug prices may result in beneficiaries more quickly reaching the catastrophic coverage phase, where the federal government's share of drug costs increases, and the plan sponsors' share decreases.²⁸

²⁷Part D plan sponsor bids may be based on other factors, including estimated drug costs, beneficiary cost sharing, administrative expenses, and profit.

²⁸There are multiple phases in the Part D program that beneficiaries may pass through based on their cost sharing (which do not include premiums). For 2019, after a \$415 deductible is met, beneficiaries enter the initial coverage period, where enrollees cover 25 percent of costs and plans cover 75 percent of costs until drug costs exceed \$3,820, when enrollees reach the coverage gap. In the coverage gap ("donut hole") phase, brand-name drug costs are covered by drug manufacturers (70 percent drug discounts), plan sponsors (5 percent), and beneficiaries (25 percent). For generic drugs, plan sponsors cover 63 percent of costs, and beneficiaries cover 37 percent. In 2019, beneficiaries reach the catastrophic phase when their cost sharing reaches \$5,100. The federal government then covers 80 percent of costs, the plan sponsor covers 15 percent, and the beneficiary covers 5 percent. The coverage gap will be "closed" beginning in 2020, with the beneficiary covering 25 percent of costs for both brand-name and generic drugs. The federal government pays subsidies to Part D plan sponsors that cover about 75 percent of the plan premium and is also responsible for payment 80 percent of costs in the catastrophic phase.

Part D Plan Sponsors Used a PBM to Provide Most Drug Benefit Management Services in 2016, and Use Was Concentrated among Five PBMs

Seventy-four percent of the drug benefit management services provided under 624 Part D plan sponsor contracts were performed by a PBM alone or in conjunction with a Part D plan sponsor in 2016.²⁹ We found that plan sponsors performed the remaining 26 percent of services themselves. In addition, a PBM was used to provide one or more of the 10 key drug benefit management services under nearly all of the 624 Part D plan sponsor contracts (99.7 percent), and the manner in which they used them varied, as summarized below:³⁰

- **Number of drug benefit management services provided.** Part D plan sponsor contracts varied by the number of services provided by PBMs. Eighty-nine percent of Part D plan sponsor contracts used a PBM alone or in conjunction with a plan sponsor for at least half of the 10 drug benefit management services; 15 percent of contracts used a PBM alone or with a plan sponsor for all 10 services.
- **Number of PBMs used.** Part D plan sponsor contracts varied in the number of PBMs used to provide one or more of the 10 drug benefit management services. Fifty-four percent of contracts used one PBM, 35 percent used two or three PBMs, and 11 percent used four or more PBMs.
- **Types of drug benefit management services provided.** Part D plan sponsor contracts varied by the drug benefit management services they used a PBM to provide. PBMs alone or with the plan sponsor more frequently provided claims adjudication (99 percent of Part D plan sponsor contracts), pharmacy network development (92 percent), and rebate and other price concession negotiations (83 percent). In contrast, PBMs alone or with the plan sponsor less frequently provided a pharmacy and therapeutics committee (45 percent),

²⁹We determined the proportion of the 10 drug benefit management services in the HPMS database that was provided by a PBM to the 624 Part D plan sponsor contracts included in our analysis. PBMs were used to perform 4,592 of the 6,240 drug benefit management services (74 percent) provided to the 624 contracts. We counted plan sponsor contracts as using a PBM to provide a drug benefit management service if the PBM provided the service alone or in combination with the plan. We found that that PBMs and Part D plan sponsors together performed 20 percent of drug benefit management services, and PBMs alone performed 54 percent of drug benefit management services.

³⁰Some of the entities used by Part D plan sponsors to provide drug benefit management services may have other lines of business besides PBM services. For example, Xerox, which provides print and digital document services, provided drug benefit management services such as beneficiary customer services in conjunction with a plan sponsor or PBM to 66 plan sponsor contracts.

enrollee appeals and grievance process-management (30 percent), and enrollment processing (34 percent).

Part D plan sponsors mainly used five PBMs in 2016. Of the 103 PBMs that provided at least one drug benefit management service to the 624 Part D plan sponsor contracts in 2016, the following five provided at least one service to 528 (85 percent) plan sponsor contracts in 2016: CVS Caremark, OptumRx, Express Scripts, Medimpact, and Argus.³¹ These five PBMs also provided the largest number of services to Part D plan contracts in 2016.³² For example, CVS Caremark, by itself or with another PBM or plan sponsor, provided 17 percent of services that PBMs provided to Part D plan sponsors' contracts in 2016, the most of any PBM.³³

See appendix II for more information on variation in Part D plan sponsor contracts' use of PBMs, factors that influence sponsors' decision to use a PBM, and additional information on the PBMs used by Part D plan sponsors.

³¹For example, CVS Caremark provided at least one service to 25 percent of contracts, which accounted for 30 percent of total Part D enrollment.

³²The share of the PBMs' total business that Medicare represents varied widely among the top five PBMs. Specifically, the PBMs told us that Part D accounted for between 1 percent and 57 percent of the total number of individuals for whom they provide drug coverage. In addition, the five largest PBMs in the Part D program included in our analysis may vary from sources that do not focus solely only on the Medicare Part D PBM market, or that used a different metric of market share than number of drug benefit management services (e.g., number of prescription claims adjudicated by the PBM).

³³The remaining four PBMs—OptumRx, Express Scripts, MedImpact, and Argus—provided 14 percent, 10 percent, 9 percent, and 5 percent of the drug benefit management services respectively. A Part D plan sponsor may use more than one PBM to provide a drug benefit management service. In this instance, we counted each respective PBM as providing the same service in our summary counts. Argus is known as DST Pharmacy Solutions as of September 2017.

PBMs Primarily Earned Part D Revenue through Fees Paid by Plan Sponsors, Not Rebate Retention, and Reported That This Differed from PBMs' Commercial Plan Revenue

Our review of 20 service agreements between Part D plan sponsors and PBMs found that the primary revenue source for PBMs from services they provided to Part D plans was (1) a volume-based fee paid by plan sponsors based on the number of paid claims that the PBM processed; (2) a flat monthly per-member, per-month fee paid by plan sponsors; or (3) a combination of the two. Nineteen of the 20 service agreements that we reviewed stated that PBMs were to be paid in one of these ways.³⁴ None of the service agreements tied these fees to the price of a drug paid to the pharmacy.³⁵ Representatives we interviewed from all seven of the PBMs confirmed that a Part D plan sponsor-paid fee for the PBM's services was the primary way they earned revenue from their Part D clients.

We also examined PBM revenue reported to CMS by Part D plan sponsors in their rebates and other price concession data—also referred to as direct and indirect remuneration (DIR)—in 2016, the most recent data available at the time of our analysis. These data show that PBMs passed nearly all rebates received from manufacturers through to Part D plan sponsors in 2016. Part D plan sponsors reported to CMS that, of the approximately \$18 billion in rebates that PBMs negotiated with pharmaceutical manufacturers that year, PBMs retained \$74.3 million, or about 0.4 percent, and passed through the remaining 99.6 percent to plan sponsors.³⁶

The small amount of PBM rebate retention in the Part D program was also reflected in the service agreements we examined and in our interviews with PBM representatives. Sixteen of the 20 service agreements that we reviewed included provisions that required the PBM to pass through all rebates to the Part D plan sponsor; one other agreement required at least 95 percent to be passed through to the plan

³⁴The provisions in the remaining service agreement that we reviewed did not include such specific information on how the PBM was to be paid.

³⁵While some service agreements detailed the amount of the fees for the various services that the PBM would provide, it is not possible to tell from the agreements how much revenue those services generated for the PBM because no agreement provided the volume of business for any service.

³⁶PBMs negotiated \$18 billion of the \$26.7 billion in rebates that were negotiated on behalf of Part D plan sponsors. Plan sponsors negotiated \$7.3 billion in rebates. We were unable to determine the entity responsible for negotiating the remaining \$1.3 billion in rebates as we could not determine whether the PBM or plan sponsor negotiated rebates for certain Part D plan sponsor contracts.

sponsor. The other three service agreements that we reviewed either did not include provisions related to rebate retention or redacted such information. Officials we interviewed from four of the seven PBMs told us their PBMs passed through to Part D plan sponsors all rebates obtained from manufacturers. Representatives of one PBM noted that plan sponsors, in turn, may use rebates to help offset the growth in drug costs, helping lower premiums for beneficiaries. Representatives from the other three PBMs noted that the amount of retained rebates was relatively small, consistent with the data reported to CMS.

PBMs and Part D plan sponsors may earn non-rebate revenue from manufacturers for providing certain services. The service agreements we examined included examples of this revenue, including fees for rebate program administration, prescriber education programs, and programs designed to ensure patients adhere to, and comply with, recommendations regarding a particular prescription.³⁷ The full amount that PBMs and Part D plan sponsors earned from manufacturers for non-rebate services in 2016 was \$516.5 million. Although CMS requires these fees to be reported to the agency by plan sponsors, CMS does not break out how much of the money was received by PBMs and how much was received by plan sponsors.

PBMs earned little Part D revenue from spread pricing—keeping the difference between the amount the PBM paid the pharmacy for a drug and the amount the PBM charged the plan for the drug, from 2014 through 2016. PBMs earned about \$300,000 from spread pricing in 2016, according to CMS rebate and other price concession data. CMS data also show that PBMs earned no revenue from spread pricing in either 2014 or 2015. PBMs generally earn more from spread pricing and rebate retention from commercial plans than they do from Part D, according to officials from three PBMs. Officials from two of these PBMs said CMS reporting requirements have removed much of the incentive in Part D for PBMs to earn revenue from spread pricing because of the complexity of the requirements and the criticism from health care providers when reports to CMS containing these amounts are publicized.

See appendix III for more information on Part D plan sponsor reporting to CMS of the amounts of revenue—other than rebates and discounts—that

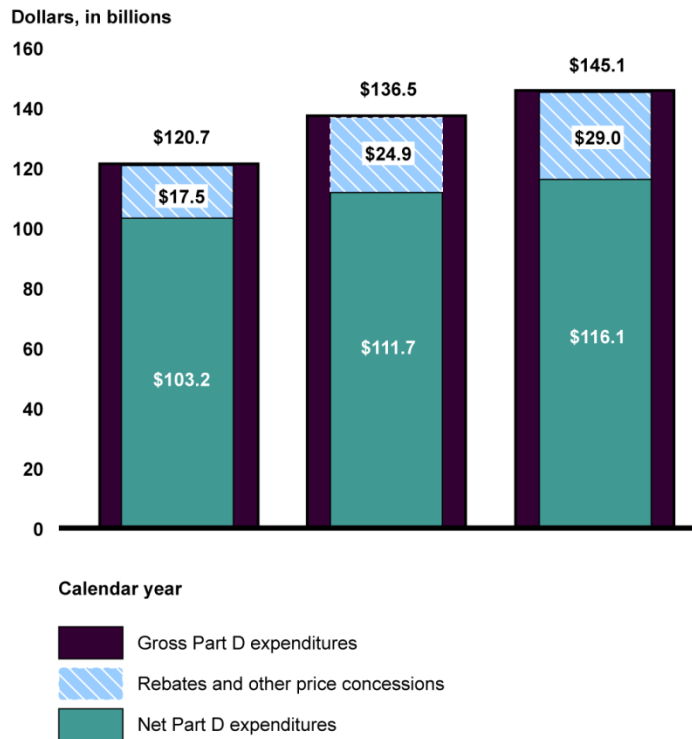
³⁷We were unable to determine the amount of revenue that PBMs obtained from these services because the volume of usage of services was not contained in any service agreements.

manufacturers provide to their PBMs; and on PBM and Part D plan sponsor perspectives on PBM revenue earned from spread pricing, the effect of CMS requirements on spread pricing revenue, and differences between PBMs' Part D and commercial business lines.

Rebates and Other Price Concessions Grew Faster Than Part D Expenditures from 2014 through 2016

Growth in the amount of rebates and other price concessions provided by manufacturers and others to Part D plan sponsors and PBMs outpaced growth in gross and net Part D expenditures for all brand-name and generic drugs from 2014 through 2016. Gross expenditures reflect what was paid to the pharmacy by the Part D plan sponsor—or the PBM on the sponsor's behalf—and by the beneficiary for a given drug. Net expenditures reflect any rebates and discounts obtained by plan sponsors and PBMs after a beneficiary receives a drug. During this time, gross Part D expenditures increased 20 percent, from \$120.7 billion in 2014 to \$145.1 billion in 2016. The amount of rebates and other price concessions obtained for these drugs increased 66 percent during the same period, from \$17.5 billion to \$29 billion. As a result, rebates and other price concessions as a proportion of gross expenditures increased from 14 percent of gross expenditures in 2014 to 20 percent in 2016. This resulted in an increase in net Part D expenditures of 13 percent, from \$103.2 billion in 2014 to \$116.1 billion in 2016 (see fig. 2).

Figure 2: Gross Medicare Part D Expenditures, Net Part D Expenditures, Rebates and Other Price Concessions for All Part D Drugs, 2014-2016 (in billions of dollars)



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-19-498

Notes: We used CMS data to analyze brand-name and generic drug expenditures for Part D contracts from 2014 through 2016. We excluded expenditures from contracts that participated in the Medicare Program of All-Inclusive Care because they are exempted from Part D requirements, such as charging beneficiaries cost-sharing. We also excluded expenditures for compounded drugs which are tailor-made by a pharmacy for a beneficiary and over-the-counter drugs as they are generally not covered by Medicare Part D.

Gross expenditures reflect what was paid to the pharmacy by the Part D plan sponsor, pharmacy benefit managers on the sponsor's behalf, and the beneficiary for a given drug. Net expenditures reflect any rebates and other price concessions obtained by plan sponsors and PBMs after a beneficiary receives a drug as reported in the direct and indirect remuneration data.

Rebates accounted for most of the total of rebates and other price concessions obtained for Part D drugs from 2014 through 2016. Rebates are generally paid by manufacturers to Part D plan sponsors, or PBMs on sponsors' behalf, after a drug is purchased from a pharmacy. In 2016, rebates accounted for 92 percent (\$27 billion) of the \$29.1 billion in rebates and other price concessions. The proportion was generally consistent in 2014 and 2015, with rebates accounting for 93 and 91 percent of total rebates and other price concessions, respectively.

Pharmacy-related price concessions, which include any monies obtained by plan sponsors and PBMs from a pharmacy after a beneficiary purchases a drug, accounted for nearly all the rest of rebates and other price concessions—7 percent—in 2016.³⁸ The amount of pharmacy-related price concessions increased 295 percent from 2014 through 2016 (\$538 million to \$2.1 billion).

The 444 highest expenditure, highest utilization brand-name drugs accounted for the majority of expenditures and received the vast majority of rebates and other price concessions in 2016. These drugs accounted for 65 percent of the \$145 billion in Part D expenditures and received 90 percent of the \$29.1 billion in rebates and other price concessions obtained for Part D drugs.³⁹ Of the 444 highest expenditure, highest utilization brand-name drugs in 2016, the 200 highest utilization and the 200 highest expenditure drugs received a greater amount of rebates and other price concessions than the 200 highest expenditure per utilization drugs.⁴⁰ (See table 1.) Furthermore we found that brand-name drugs received greater amounts of rebates and other price concessions than generic drugs.⁴¹ Specifically, among the 444 highest expenditure, highest

³⁸According to CMS, pharmacy-related price concessions includes payments to and from pharmacies that affect the net price of the drug purchased by the Part D plan sponsor after the point-of-sale. These include reconciling any differences between the contracted payment rate by the PBM or Part D plan sponsor to the pharmacy and the rate paid to the pharmacy at the point-of-sale. They also include bonuses paid by the plan sponsor or PBM to the pharmacy or fees paid by the pharmacy to the plan sponsor or PBM based on how well the pharmacy met certain agreed upon performance metrics, such as the generic dispensing rate. In 2016, payments from pharmacies to plan sponsors totaled \$2.3 billion and payments from plan sponsors to pharmacies totaled \$211 million. The net of these payments—\$2.1 billion—is reported as pharmacy-related price concessions.

³⁹We analyzed Part D expenditure and rebate and other price concessions data from the prescription drug event and DIR data sets for three groups of brand-name drugs: the 200 drugs with the highest expenditures, the 200 drugs with the highest utilization, and the 200 drugs with the highest expenditures per utilization. This resulted in a group of 444 unique brand-name drugs across the three groups. We focused our analysis on brand-name drugs, as they received the majority of rebates and other price concessions in 2016.

⁴⁰There was a strong correlation between the amount of rebates and other price concessions with expenditures (correlation coefficient of 0.91) and utilization (correlation coefficient of 0.74) for the 444 highest expenditure, highest utilization brand-name drugs. The correlation coefficient is a statistical measure of association, ranging in value from negative 1 to positive 1, with negative 1 indicating a perfect negative correlation, 0 an absence of correlation, and positive 1 a perfect positive correlation.

⁴¹Rebates are used more frequently for drugs where there is competition and for which there are therapeutic substitutes and are rarely available for generic drugs. See G. Dieguez, M. Alston, and S. Tomicki, *A Primer on Prescription Drug Rebates: Insights Into Why Rebates Are A Target For Reducing Prices* (Milliman, Inc. May 2018).

utilization brand-name drugs and the 476 highest expenditure, highest utilization generic drugs, brand-name drugs received 98 percent of rebates and other price concessions in 2016.

Table 1: Rebates and Other Price Concessions and Expenditures for the Highest Expenditure, Highest Utilization Brand-Name Medicare Part D Drugs, 2016

Brand-Name Drug category	Gross Part D expenditures (billions of dollars)	Rebates and other price concessions (billions of dollars)	Net expenditures (billions of dollars)	Rebates and other price concessions as a proportion of gross expenditures (percent)	Median number of beneficiaries receiving each drug
200 Highest-expenditure	85.3	24.6	60.7	29	52,847
200 Highest-utilization	62.7	22.6	40.1	36	95,852
200 Highest-expenditure per utilization	20.3	2.3	17.9	12	301

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-19-498

Note: We analyzed CMS Part D expenditure and rebate and other price concession data from the prescription drug event and direct and indirect remuneration data sets for three groups of brand-name drugs: the 200 drugs with the highest expenditures, the 200 drugs with the highest utilization, and the 200 drugs with the highest expenditures per utilization. We identified drugs that had common ingredients, strengths, dose, and route of administration and combined them. This resulted in a group of 444 unique brand-name drugs across the three groups.

Gross expenditures reflect what was paid to the pharmacy by the Part D plan sponsor, pharmacy benefit managers on the sponsor's behalf, and the beneficiary for a given drug. Net expenditures reflect any rebates and discounts obtained by plan sponsors and PBMS after a beneficiary receives a drug.

Consistent with the results for all Part D drugs, from 2014 through 2016 rebates and other price concessions outpaced growth in gross and net expenditures for the three groups of highest expenditure, highest utilization brand-name drugs in our analysis (see table 2 for information on these brand-name drugs). The three groups of brand-name drugs generally had higher percent changes in rebates and other prices concessions and in gross and net expenditures than did all Part D drugs, which includes generics. For example, from 2014 through 2016, net expenditures for the 200 highest expenditure brand-name drugs increased 27 percent compared to a 13 percent increase for all Part D drugs. Of the three groups, the 200 drugs with the highest expenditure per utilization had the largest percentage increases in expenditures and rebates and other price concessions. However, these drugs had relatively

low gross expenditures, rebates and other price concessions, and utilization compared with the other two groups.⁴² Increases in expenditures for the three groups of drugs in our analysis were primarily accounted for by increases in the price per drug rather than changes in utilization, as indicated by the growth in expenditures exceeded growth in their utilization.

Table 2: Percentage Change in Rebates and Other Price Concessions and Expenditures for the Highest Expenditure, Highest Utilization Brand-Name Medicare Part D Drugs, 2014-2016

Drug group	Median percentage growth, 2014-2016			
	Gross expenditures (percent)	Rebates and other price concessions (percent)	Net expenditures (percent)	Utilization (percent)
200 Highest-expenditure	38	92	27	1
200 Highest-utilization	29	61	13	-1
200 Highest-expenditure per utilization	61	302	59	24

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-19-498

Notes: We analyzed CMS expenditure and rebate and other price concession information, known as direct and indirect remuneration, for the following groups of brand-name drugs: the 200 with the highest expenditures, the 200 with the highest utilization, and the 200 with the highest expenditures per utilization. We identified drugs that had common ingredients, strengths, dose, and route of administration and combined them. This resulted in a group of 444 unique brand-name drugs across the three groups.

Gross expenditures reflect what was paid to the pharmacy by both the Part D plan sponsor, pharmacy benefit managers on the sponsor's behalf, and the beneficiary for a given drug. Net expenditures reflect any rebates and other price concessions obtained by plan sponsors and PBMS after a beneficiary receives a drug.

Net expenditures per beneficiary were similar if a Part D plan sponsor used a PBM for rebate negotiations or if it conducted its own negotiations. Specifically, in 2016, median net expenditures per enrollee were similar for plan sponsors using a PBM and those that did not at \$2,557 and \$2,570, respectively. Rebates and other price concessions accounted for a median of 12 percent of gross Part D expenditures for plan sponsors using a PBM for their negotiations and a median of 10 percent for plan

⁴²The highest expenditure per utilization drugs had a median of 300 beneficiaries receiving them in 2016, compared to a median of 53,000 and 96,000 beneficiaries for the highest expenditure drugs and the highest utilization drugs, respectively.

sponsors that did not.⁴³ The majority—82 percent—of plan sponsors used a PBM to obtain rebates and other price concessions on their behalf.⁴⁴ The plan sponsors that performed their own negotiations generally had higher enrollment than those that used a PBM—a median of approximately 47,000 beneficiaries, compared to approximately 13,000 beneficiaries (see table 3).

Table 3: Rebates and Other Price Concessions Received by Medicare Part D Plan Sponsors That Used a Pharmacy Benefit Manager (PBM) for Rebate Negotiations and Those That Did Not, 2016

	Part D plan sponsors				
	Number of Part D sponsors ^a	Median Part D sponsor enrollment	Rebates and other price concessions as percentage of gross Part D expenditures (median)	Median gross Part D expenditures per enrollee (dollars)	Median net Part D expenditures per enrollee (dollars)
PBM-performed	177	12,526	12	3,042	2,557
Plan-performed	20	46,860	10	3,031	2,570

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-19-498

Note: We analyzed CMS Part D expenditure and rebate and other price concessions from the prescription drug event and direct and indirect remuneration data for 2016 to determine the amount of rebates and other price concessions relative to gross expenditures, which reflect the amount paid to the pharmacy by the Part D plan sponsor, PBMs on the sponsor's behalf, and the beneficiary for a given drug. Net expenditures reflect any rebates and discounts obtained by plan sponsors and PBMs after a beneficiary receives a drug.

^aExcluded are 20 Part D plan sponsors for which we were unable to determine the entity performing their rebate and price concession negotiations.

See appendix IV for additional information on expenditures and rebates and other price concessions obtained for the 444 highest expenditure, highest utilization brand-name Part D drugs in 2016. The appendix also contains information on expenditures and rebates and other price concessions obtained by the Part D plan sponsors whose representatives we interviewed.

⁴³Of the 217 Part D plan sponsors, 177 plan sponsors, accounting for 54 percent of Part D enrollment in 2016, used a PBM to conduct their rebate and price concession negotiations. Twenty plan sponsors, accounting for 39 percent of enrollment, performed their own rebate and price concession negotiations. The remaining 20 sponsors, for which we could not determine the entity conducting the negotiations, accounted for 7 percent of the enrollment.

⁴⁴This calculation reflects PBM use by plan sponsors. Each sponsor may have more than one contract that offers Part D coverage. Our analysis of plan sponsor use of PBMs for their individual Part D found that 82 percent of contracts used a PBM, either alone or in conjunction with the plan sponsor, for rebate and price concession negotiations.

Part D Drug Prices Were Significantly Lower Than List Prices for Brand-Name Drugs in Retail Pharmacies; Drugs Sold in Specialty Pharmacies Received Fewer Discounts

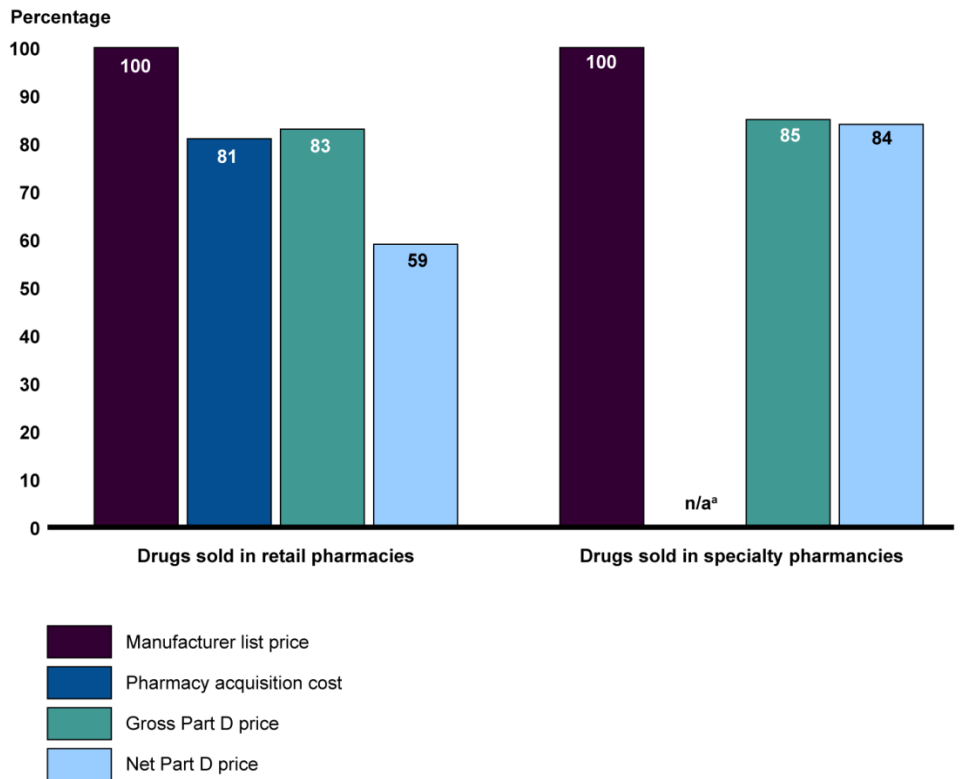
In 2016, the highest expenditure, highest utilization brand-name drugs sold in retail pharmacies received discounts off of manufacturer list prices that were significantly higher than those sold in specialty pharmacies.⁴⁵ Of the 444 highest expenditure, highest utilization brand-drugs in our analysis, 244 were sold in retail pharmacies. For this group, gross Part D prices—those paid to the pharmacy by the Part D plan sponsor, PBMs on the sponsor's behalf, and the beneficiary—were 17 percent lower than manufacturer list prices for these drugs. When rebates and other price concessions were accounted for, net Part D prices were 41 percent lower than manufacturer list prices.⁴⁶ In contrast, the 200 drugs sold in specialty pharmacies received fewer discounts off of manufacturer list prices. For these drugs, median gross and net prices were 15 percent and 16 percent, respectively, lower than manufacturer list prices (see fig. 3).⁴⁷ As a result, drugs sold in retail pharmacies received median discounts (41 percent) that were 2.5 times larger than those sold in specialty pharmacies (16 percent).

⁴⁵We separated drugs sold in retail community pharmacies from those sold in specialty pharmacies, as the latter dispense low-volume and high-cost drugs to patients undergoing intensive therapies for illnesses.

⁴⁶Pharmacy acquisition cost, which reflects the price pharmacies paid to obtain the drug, was 19 percent lower than manufacturer list prices for drugs sold in retail pharmacies.

⁴⁷Of the 200 brand-name drugs sold in specialty pharmacies, 187 were among the 200 Part D drugs with the highest expenditure per utilization Part D drugs in 2016. As noted earlier, these drugs had lower utilization and received fewer rebates than drugs with higher utilization and higher expenditures.

Figure 3: Medicare Part D Median Drug Prices as a Percentage of Manufacturer List Prices for Highest Expenditure and Highest Utilization Brand-Name Drugs, 2016



n/a = not applicable

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data and data from Truven Health Analytics. | GAO-19-498

Notes: Brand-name drugs sold in retail pharmacies had a gross median per unit price of \$11.75, while the gross median per unit price for brand-name drugs sold in specialty pharmacies was \$315.54.

Prices are the 2016 median per unit prices for the brand-name drugs that met the following criteria: the 200 drugs with the highest expenditures, the 200 drugs with the highest utilization, and the 200 drugs with the highest expenditures per utilization. We identified drugs that had common ingredients, strengths, dose, and routes of administration. This resulted in a group of 444 unique brand-name drugs across the three groups because some drugs met multiple criteria and therefore appeared in more than one group. Of these 444 brand-name drugs, 244 were drugs sold in retail pharmacies, and 200 were drugs sold in specialty pharmacies.

Manufacturer list price is the median average wholesale price. Pharmacy acquisition cost reflects prices reported in surveys of community retail pharmacies in the National Average Drug Acquisition Cost data set. Gross Part D prices reflect median unit prices paid to pharmacies by Part D plan sponsors, pharmacy benefit managers on the sponsor's behalf, and the beneficiary and net Part D prices account for rebates and other price concessions obtained by plan sponsors for these drugs.

^aPharmacy acquisition cost data are unavailable for drugs sold in specialty pharmacies, as these pharmacies are not surveyed by CMS.

See appendix V for more information on prices for the highest expenditure, highest utilization brand-name drugs and for information on prices for selected generic drugs.

Utilization Management Was Generally Associated with Financial Savings and Improved Health Indicators, but Its Effect on Medication Adherence and Access Was Less Clear

Our review of 52 peer-reviewed studies indicates that utilization management services were associated with financial savings or improved beneficiary health indicators. However, the effects on ensuring that beneficiaries take their medication as prescribed (adherence) and access to clinically appropriate prescriptions were less clear.⁴⁸ The studies examined the effects of 10 different types of utilization management services in three areas: (1) financial savings; (2) beneficiary health indicators; and (3) beneficiary medication adherence and access:⁴⁹

- **Financial savings.** Twenty-seven of the 36 studies we reviewed that examined financial savings found that utilization management services were associated with savings for the Medicare program, Part D plans, or beneficiaries. For example, all eight studies that examined the relationship between generic substitution and financial savings found savings.⁵⁰ Of the 10 studies that did not find financial savings, five found no statistically significant impact of the utilization management service on savings, three found the utilization management service was associated with a decrease in savings, and two found both an increase and decrease in savings for different types of utilization management services.
- **Beneficiary health indicators.** Twelve of the 20 studies that examined beneficiary health indicators found that utilization management services were associated with improvement, such as a reduction in adverse drug events. Ten of the 12 studies that found improvement examined either medication therapy management programs or comprehensive medication reviews. The other two studies that found improvement looked at drug utilization reviews, which examine a beneficiary's prescriptions to identify safety considerations, such as potential adverse interactions with other

⁴⁸The studies used a range of health indicators, such as appropriateness of medications for older adults, cholesterol values, and reductions in adverse drug events.

⁴⁹Some studies examined the effect of utilization management services on more than one outcome. For example, one study examined both step therapy and prior authorization.

⁵⁰Generic substitution is switching a generic drug for its bioequivalent, brand-name counterpart.

drugs and compliance with clinical guidelines.⁵¹ Of the eight studies that found no improvement, one found that a health indicator worsened, and four found improvement in at least one health indicator and a decline in at least one other indicator.

- **Beneficiary medication adherence and access.** Of the 15 studies that examined the effect of utilization management services on beneficiaries' medication adherence or access to clinically appropriate drugs, 10 examined medication therapy management programs or comprehensive medication reviews. Seven of these 10 found improvement in medication adherence.⁵² In contrast, the other five studies that examined adherence and access found negative, mixed, or no effects associated with prior authorization and step therapy. For example, two studies examined the effect of prior authorization and step therapy and found that these utilization management services resulted in increased access problems. Two other studies examined the relationship of prior authorization and step therapy adherence and found a mixed impact. The remaining study examined the relationship of only prior authorization with the time needed to access medications and found no clinically significant impact.

Stakeholders we interviewed generally agreed that utilization management services resulted in financial savings but differed in their views regarding the effect of utilization management services on beneficiaries' medication adherence and access to clinically appropriate drugs. In interviews with representatives from PBMs, Part D plan sponsors, and a manufacturer trade association, these stakeholders generally agreed that utilization management services resulted in financial savings. While representatives from most Part D plan sponsors and PBMs told us that utilization management services have resulted in no adverse impact on medication adherence and access to prescriptions, representatives of the three drug manufacturers we interviewed told us that utilization management services limit medication adherence and access to medications by, for example, delaying therapy to needed drugs.

⁵¹ A comprehensive medical review, which can be part of a medication therapy management program, is a systematic process of assessing medications to identify problems, such as a change in a drug's effect when taken with another drug, and creating a plan to resolve them.

⁵² The remaining three studies found that the utilization management service had no statistically significant impact on adherence.

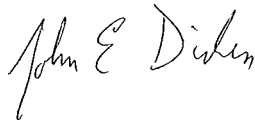
See appendix VI for more information about the effects of utilization management services from the peer-reviewed studies we examined and the stakeholders we interviewed. See appendix VII for the articles included in our literature review.

Agency Comments

The Department of Health and Human Services provided technical comments on a draft copy of this report, which GAO incorporated as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the appropriate congressional committees and the Secretary of Health and Human Services. 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@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 VIII.



John E. Dicken
Director, Health Care

Appendix I: Objectives, Scope, and Methodology

This appendix provides details on our scope and methodology in addressing each of our five reporting objectives: (1) the extent to which Part D plan sponsors contract with pharmacy benefit managers (PBM) to deliver drug benefit management services to Medicare beneficiaries; (2) how PBMs earn revenue from the services they provide to Part D plan sponsors; (3) trends in rebates and other price concessions obtained by Part D plan sponsors and PBMs from manufacturers and others for Part D drugs; (4) the extent to which prices for Part D drugs are discounted off of manufacturer list prices; and (5) what is known about savings and other effects from utilization management services commonly used in Part D. In addition, the appendix describes the steps we took to assure the reliability of the data we analyzed.

Interviews

For all our objectives, we obtained the perspectives of stakeholders on Part D plan sponsors' use of PBMs as well as information on sponsors' efforts to control Part D expenditures and drug utilization. We spoke to representatives from 17 small, mid-sized, and large Part D plan sponsors: Aetna, Anthem, Banner Health, Cambia Health, Cigna, CVS, Express Scripts, Kaiser, Health Care Service Corp, Health Plan of San Mateo, Henry Ford Health System, Humana, Missouri Highways and Transportation Commission, Rite Aid, United Health Care, University of Pittsburgh Medical Center, and WellCare.¹ We spoke with seven PBMs: Argus, CVS Caremark, EnvisionRx, Express Scripts, MedImpact, Prime Therapeutics, and OptumRx.² To obtain other drug industry perspectives, we spoke with representatives from three drug manufacturers: Eli Lilly, Gilead, and Amgen. We also spoke with one entity that is both a wholesaler and pharmacy services administrative organization: AmerisourceBergen. Additionally, we spoke with other industry and advocacy organizations, including groups representing drug

¹The 17 Part D plan sponsors consisted of 11 sponsors that had the 20 contracts with the largest enrollment in 2016 (enrollment in these contracts accounted for 82 percent of Part D enrollment in 2016); three plan sponsors that had contracts with enrollment at or just below the median 2016 contract enrollment; and three plan sponsors that had three contracts with enrollment at or below the bottom enrollment quartile. In this report, we refer to a drug plan or plans covered under each sponsor contract with the Centers for Medicare & Medicaid Services (CMS) as a "Part D plan sponsor contract."

²Argus is known as DST Pharmacy Solutions as of September 2017. We spoke with representatives from the six PBMs that provided the most drug benefit management services to Part D plan sponsors in 2016 as identified by our analysis of HPMS data. We also judgmentally selected an additional PBM that provided the eighth most drug benefit management services to Part D plan sponsors.

manufacturers, Part D plan sponsors, pharmacies, and PBMs: America's Health Insurance Plans, Biotechnology Innovation Organization, Community Oncology Alliance, National Association of Chain Drug Stores, National Association of Specialty Pharmacies, National Community Pharmacists Association, Patients for Affordable Drugs, Pharmacy Benefit Management Institute, Pharmaceutical Care Management Association, and Pharmaceutical Research and Manufacturers of America.

The Extent to Which Part D Plan Sponsors Contract with PBMs to Deliver Drug Benefit Management Services to Beneficiaries

To determine the extent to which PBMs provided services to Part D plan sponsors, we analyzed the Centers for Medicare & Medicaid Services' (CMS) Health Plan Management System (HPMS) data that identified the entity or entities responsible for performing each of 10 key drug benefit management services for plan sponsors' Part D contracts in 2016, the most recent available expenditure and rebate and other price concession data at the time of our analysis.³ CMS provided HPMS data for the 624 Part D plan sponsor contracts that were effective in 2016.⁴ The data contained the entity or entities reported by each plan sponsor as performing each service. Using this information, we identified for each contract whether the plan sponsor performed a service itself; contracted with a PBM to perform the service; or performed the service in coordination with a PBM. For a given contract, we counted as being a PBM any entity that was not the plan sponsor that performed one or more drug benefit management services. We manually reviewed those PBMs against a list of PBM members from a PBM trade organization. We used

³HPMS is the communication portal through which Part D plan sponsors report information to CMS. According to CMS, Part D plan sponsors are required to report the entities responsible for performing these 10 drug benefit management services on an ongoing basis: claims adjudication, rebate and other price concession negotiations, pharmacy network development, enrollment processing, enrollee appeals and grievance process-management, customer service, management of a pharmacy and therapeutics committee, coordination with drug benefit programs, pharmacy technical assistance, and drug benefit administration.

⁴Plan sponsors contract with CMS to provide Part D coverage through individual contracts that each offer one or more unique drug plans. Part D coverage is offered through contracts providing stand-alone Part D prescription drug plans (PDPs) that supplement traditional Medicare or through Medicare Advantage (Part C) plans that cover all Medicare benefits, including Part D drug coverage. CMS provided us with HPMS data for all PDP and Part C plan sponsor contracts. They excluded Program of All-inclusive Care for the Elderly (PACE) Part D plans, as they are exempted from Part D requirements, such as charging beneficiaries cost-sharing. These 624 contracts provided 4,663 unique plans and were operated by 207 Part D plan sponsors in June 2016.

internet searches to confirm the entity was not the plan sponsor in instances when it was not listed in the trade organization's member directory. In doing so, we also identified whether the plan sponsor shared common ownership with the PBM responsible for providing the drug benefit management service. For example, there were instances where the plan sponsor and PBM were sister organizations owned by the same parent company. In this situation, we counted the PBM as a separate entity from the plan.

In addition, we analyzed PBM use by plan sponsor contract enrollment size using CMS contract enrollment information from June 2016.⁵ Additionally, we used HPMS data to examine plan sponsor contracts' variation in the number of PBMs used, the types of services that PBMs provided, and the use of PBMs by contract enrollment size. We also identified the PBMs that provided the most services and described the services they provided. Last, we interviewed Part D plan sponsor representatives to understand the considerations that influenced their decision about how and whether to use a PBM.

How PBMs Earn Revenue from the Services They Provide to Part D Plan Sponsors

To determine how PBMs earned revenue from services they provide to Part D plan sponsors, we relied on four information sources. First, we reviewed selected service agreements between PBMs and Part D plan sponsors. The service agreements generally contain detailed information on the services that the PBM will provide, how the plan sponsor will pay the PBM for those services, and the rates that pharmacies will be paid for Part D drugs. We asked CMS for a list of all service agreements it approved between January 2016 and May 2018 that were in effect as of June 2018. CMS provided us with a list of 119 service agreements. Using June 2018 Part D publicly available enrollment data from CMS, we obtained from CMS the 20 service agreements for Part D plans sponsors with the largest enrollment in June 2018. While most of the service agreements included sufficient information to determine how the PBMs were paid, some did not, and, where appropriate, we noted these instances in our findings.

Second, we examined PBM revenue reported to CMS by Part D plan sponsors in their rebates and other price concession data—also referred

⁵We used June 2016 data to indicate enrollment, as this month has relatively stable enrollment as it does not fall within the annual open enrollment period where beneficiaries may change their Part D coverage.

to as direct and indirect remuneration (DIR)—for 2014, 2015, and 2016. These rebate and other price concession submissions contain information on the various sources of revenue and expenses incurred by PBMs and plan sponsors.⁶

Third, we reviewed applicable CMS regulations and guidance on the reporting of PBM and Part D plan sponsor revenue and expenses.

Fourth, we interviewed PBM representatives about the extent to which PBMs retained rebates or passed them through to plan sponsors and, in some cases, the reasons for this decision. We also asked certain PBM representatives whether their revenue sources for Part D, specifically rebate retention and spread pricing, differed from PBMs' and plan sponsors' commercial business and, if so, the reasons for any differences.

Rebates and Other Price Concessions Obtained by Part D Plan Sponsors and PBMs from Manufacturers and Others for Part D Drugs

To examine rebates and other price concessions obtained by Part D plan sponsors and PBMs from manufacturers and others for Part D drugs, relative to overall Part D expenditures, we analyzed plan sponsors' gross and net expenditures for Part D drugs for 2014 through 2016, the most recent data available at the time of our analysis. Gross expenditures reflect what was paid to the pharmacy by the plan sponsor, PBMs on the sponsor's behalf, and the beneficiary for a given drug. Net expenditures reflect any rebates and other price concessions obtained by Part D plan sponsors and PBMs after a beneficiary receives a drug. To calculate gross expenditures, we used Medicare prescription drug event (PDE) data to calculate gross brand-name and generic drug expenditure and utilization information for all Part D plan sponsors' contracts.⁷ We used

⁶We reviewed Part D plan-sponsor-filed DIR data, which contains information on rebates and other price concessions, along with additional breakdowns of other revenue sources, including monies retained by PBMs for non-rebate services they provided to manufacturers and spread pricing—the difference between what the PBM paid the pharmacy and charged the Part D plan sponsor for a drug.

⁷Part D plan sponsors—both PDPs and Medicare Advantage drug plans—must submit a PDE record to CMS each time a beneficiary obtains a prescription drug. The PDE record contains information on the beneficiary receiving the drug, the price paid by the plan sponsor to the pharmacy, and applicable beneficiary cost-sharing. We excluded PDE claims billed under PACE contracts because they are exempted from certain Part D requirements, such as charging beneficiaries cost-sharing. We also excluded compounded drugs, which are tailor-made by a pharmacy for a beneficiary, and over-the-counter drugs as they are generally not covered by Medicare Part D.

Red Book, a compendium published by Truven Health Analytics, to determine whether drugs were brand-name or generic.⁸ We then identified individual brand-name and generic drugs by grouping expenditure claims with the same active ingredient, strength, dosage form, and route of administration (known as ISDR).⁹ We calculated brand-name and generic drug expenditures based on a drug's ingredient cost, dispensing fees, sales tax, and applicable vaccine administration fees. We used PDE data to calculate gross expenditures for all Part D plan sponsors at both the contract and plan sponsor level.¹⁰ We used DIR data to determine the amount of rebates and other price concessions and subtracted this amount from this data to calculate net expenditures.¹¹ We also obtained plan sponsor enrollment data using publicly available CMS data for June 2016, which allowed us to calculate gross per beneficiary expenditures.¹²

We also examined differences in the amount of rebate and other price concessions obtained relative to expenditures for Part D plan sponsors that used a PBM relative to those that did not. We determined PBM involvement in rebate and other price concession negotiations for individual plan sponsors using 2016 HPMS data. We specifically looked at each entity listed in HPMS as negotiating rebates and other price concessions with drug manufacturers and others. We were able to determine whether a PBM or plan sponsor performed this service for 197 plans sponsors. However, there were 20 Part D plan sponsors where a

⁸Generic drugs may have more than one manufacturer, and we grouped these drugs together regardless of whether they were produced by more than one manufacturer.

⁹The dosage form is the physical form in which a drug is produced and dispensed, such as a tablet or capsule; route of administration is the way of administering a drug to a patient, such as taking a drug orally. We used the Red Book to determine drugs' therapeutic class, dose, and route of administration.

¹⁰Part D plan sponsors may have one or more unique contracts that each offer one or more unique drug plans. We collapsed all sponsors' respective contract expenditure information, which resulted in a list of 217 unique plan sponsors in 2016.

¹¹Rebates are a form of price concession paid by a drug manufacturer to the plan sponsor or the PBM working on the plan's behalf generally after a drug was purchased by a beneficiary. Plan sponsors may receive other price concessions that lower the price of a drug. For example, plan sponsors may receive fees from pharmacies based on their performance.

¹²We used June 2016 data to indicate enrollment because this month has relatively stable enrollment as it does not fall within an annual open enrollment period where beneficiaries may change their Part D coverage.

PBM or plan was not solely listed as performing the rebate and other price concession service. In these instances, we could not identify which entity negotiated rebates and other price concessions and therefore excluded them from this analysis.¹³

To obtain more information on drugs that have the greatest fiscal impact on the Part D program and beneficiaries, we calculated gross and net expenditures for the brand-name and generic drugs with the highest expenditures, highest utilization, and highest expenditure per utilization in 2016. For both brand-name and generic drugs, we identified the following: the 200 brand-name and 200 generic drugs with the highest expenditures in 2016; the 200 brand-name and generic drugs with the highest utilization in 2016 (based on number of 30-day prescriptions); and the 200 brand-name and generic drugs with the highest expenditures per utilization (i.e., highest expenditure per number of 30-day prescriptions). As a result of overlap in the groups of drugs, these criteria yielded two groups: the 444 highest expenditure, highest utilization brand-name drugs and the 476 unique highest expenditure, highest utilization generic drugs. These 920 drugs accounted for 81 percent of total Part D expenditures in 2016.¹⁴ We used drug-level rebate and other price concessions data to calculate net drug prices for these drugs by subtracting rebate and other price concessions for each drug from gross expenditures.¹⁵

¹³We excluded instances in which the plan sponsor and PBM were listed as performing this service together because we wanted to isolate any differences in expenditures and the amount of rebates and other price concessions based on whether the plan sponsor or PBM performed the service. This differs from our analysis of Part D plan sponsors' use of PBMs in the Part D program, where we examined the extent to which PBMs were involved in providing these services, regardless of whether the PBM performed alone in conjunction with the plan sponsor.

¹⁴Of the 920 highest expenditure, highest utilization brand-name and generic drugs, the 444 brand-name drugs accounted for 65 percent of total drug expenditures and the 476 generic drugs accounted for 16 percent of expenditures.

¹⁵In addition to plan sponsor-level DIR data, Part D plan sponsors submit drug-level DIR data to CMS. This contains information on the amount of rebates and other price concessions, but does not include the additional breakdowns included in the plan sponsor-level data (e.g., information on retained rebates).

The Extent to Which Prices for Part D Drugs Are Discounted Off of Manufacturer List Prices

To determine the extent to which Part D drug prices are discounted off of manufacturer list prices, we compared the median gross and net prices for the 444 brand-name and 476 generic highest expenditure, highest utilization drugs to (1) list prices established by manufacturers, and (2) the cost to pharmacies of acquiring these drugs. For list prices, we used 2016 average wholesale price (AWP) data from Truven Health Analytics' Red Book.¹⁶ AWP is a common benchmark drug price used in the negotiation of payment rates between Part D plan sponsors and pharmacies.¹⁷ Because AWP is updated on an ongoing basis, we calculated a day-weighted per unit price that takes into account the number of days that the reported price was in effect in 2016. We then determined the median AWP price for each drug product based on the ISDR.¹⁸ We refer to the median price as the manufacturer list price.

For pharmacy acquisition costs, which reflect the price pharmacies paid to obtain the drug, we used retail community pharmacy acquisition cost data from National Average Drug Acquisition Cost (NADAC) data. NADAC does not contain data from non-retail pharmacies, such as mail-order or specialty pharmacies. For our groups of 444 brand-name and 476 generic drugs, we separated drugs sold in retail community pharmacies from those sold in specialty pharmacies. If a drug did not have pharmacy acquisition cost data from NADAC, we considered that drug to be sold in specialty pharmacies and, thus, a specialty drug.¹⁹

We used 2016 PDE data to determine the gross per unit Part D price for a drug by dividing the gross expenditures for the drug by the total quantity

¹⁶We analyzed 2016 AWP data, as this was the most recent data for which both PDE and DIR data were available at the time of our analysis.

¹⁷AWP is the manufacturer's suggested price for a drug sold by a wholesaler to a pharmacy and does not reflect the actual price charged by a wholesaler.

¹⁸A drug with the same proprietary name may have more than one ISDR. For example, Amitiza, which is lubiprostone, has separate ISDR for 8 microgram and 24 microgram capsules.

¹⁹We determined whether a drug was sold in retail or specialty pharmacies based on NADAC data. We found that 97 percent of the 444 highest expenditure, highest utilization brand-name drugs that lacked NADAC were listed as specialty drugs on a Part D plan sponsor's formulary. Given this, we refer to drugs that do not have a NADAC price as those sold in specialty pharmacies.

dispensed of it.²⁰ For example, a drug that had 1,000 units prescribed to Medicare beneficiaries and \$5,000 in gross expenditures would have a gross per unit price of \$5. We determined net per unit Part D prices for the drugs in our two study groups by dividing the amount of rebates and other price concessions for each drug by the quantity dispensed of it and then subtracting the amount of rebates and other price concessions per quantity from the gross Part D price for each drug.

For each drug, we then determined the median pharmacy acquisition cost (if available), median gross Part D price, and median net Part D price as a proportion of median manufacturer list price by dividing each price by the median manufacturer list price. We then reported the median value for these pricing points for the highest expenditure, highest utilization drugs in our analysis.

Analysis of Literature on Effect of Utilization Management Services

To determine what is known about the impact of utilization management services that PBMs commonly provide to Part D plan sponsors, or that plan sponsors may perform themselves, we conducted a literature search for studies that examined the effect of utilization management services in Part D (regardless of whether they were provided by a PBM or another entity) on the following outcomes: (1) financial costs or savings, (2) beneficiaries' health indicators, and (3) beneficiaries' access to clinically appropriate medications or taking their medications as prescribed (adherence).²¹ The literature search was performed from April 2018 to July 2018 using keyword searches in bibliographic databases, including ProQuest, EBSCO, and Scopus. We limited our search to studies published beginning in 2006—the year the Part D program began.

For our searches, we developed a list of search terms for our literature review by reviewing relevant background documentation and several database searches. The search terms included: “utilization management,” “prior authorization,” “quantity limits,” “step therapy,” “generic substitution,” “drug utilization review,” “quantity edit,” “medication therapy management,” and “comprehensive medication review,” combined with

²⁰Quantity dispensed is measured in units such as milliliters or milligrams. For a given drug, we summed the total number units given to Medicare beneficiaries and divided it by the gross expenditures for the drug.

²¹Utilization management services may be included under various combinations of the 10 prescription drug benefit management services, instead of being a distinct service that Part D plan sponsors report to CMS in its HPMS database.

“access,” “adherence,” “health benefit,” “clinical outcome,” “generic use,” “cost effectiveness,” “savings,” “costs,” and “Medicare.”

The literature search generated 700 studies. We reviewed this list by examining the abstracts for those studies that addressed the effects of utilization management services in Part D and were published in peer-reviewed journals. We identified 48 studies that met our criteria then added four more that met the criteria from several literature reviews we examined, resulting in a final group of 52 peer-reviewed studies that we analyzed. We analyzed these studies to group them by type of utilization management service evaluated and type of outcome measured. We documented any methodological limitations of these studies but did not exclude any of them on this basis. See the bibliography in Appendix VII for a list of the 52 studies in our review.

We also interviewed PBMs, plan sponsors, and drug manufacturers to obtain their views regarding the impact of utilization management services in Part D plans and asked them to recommend additional studies on utilization management services. We did not assess the methodology or data reliability of the studies provided to us by these drug supply chain stakeholders; none of them met our criterion of being published in peer-reviewed journals. We used these studies to better understand stakeholder perspectives.

Data Reliability

To ensure the data used to produce this report were sufficiently reliable, we took several steps. We performed data reliability checks on the HPMS data by reviewing the data for missing values and errors, checking the information against other publicly available sources, and interviewing knowledgeable agency officials. We performed data reliability checks on the PDE and DIR data by reviewing relevant documentation, checking the data for outliers and errors, and interviewing knowledgeable agency officials. We performed data reliability checks of the AWP and NADAC data sets by testing the data for missing data and outliers and reviewing relevant documentation. After taking these steps, we determined the data were sufficiently reliable for the purposes of our reporting objectives.

We conducted this performance audit from May 2017 to July 2019 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.

Appendix II: Medicare Part D Plan Sponsors' Use of Pharmacy Benefit Managers (PBM)

This appendix provides additional detail on the use of PBMs by Part D plan sponsors to provide prescription drug benefit management services to Medicare beneficiaries.

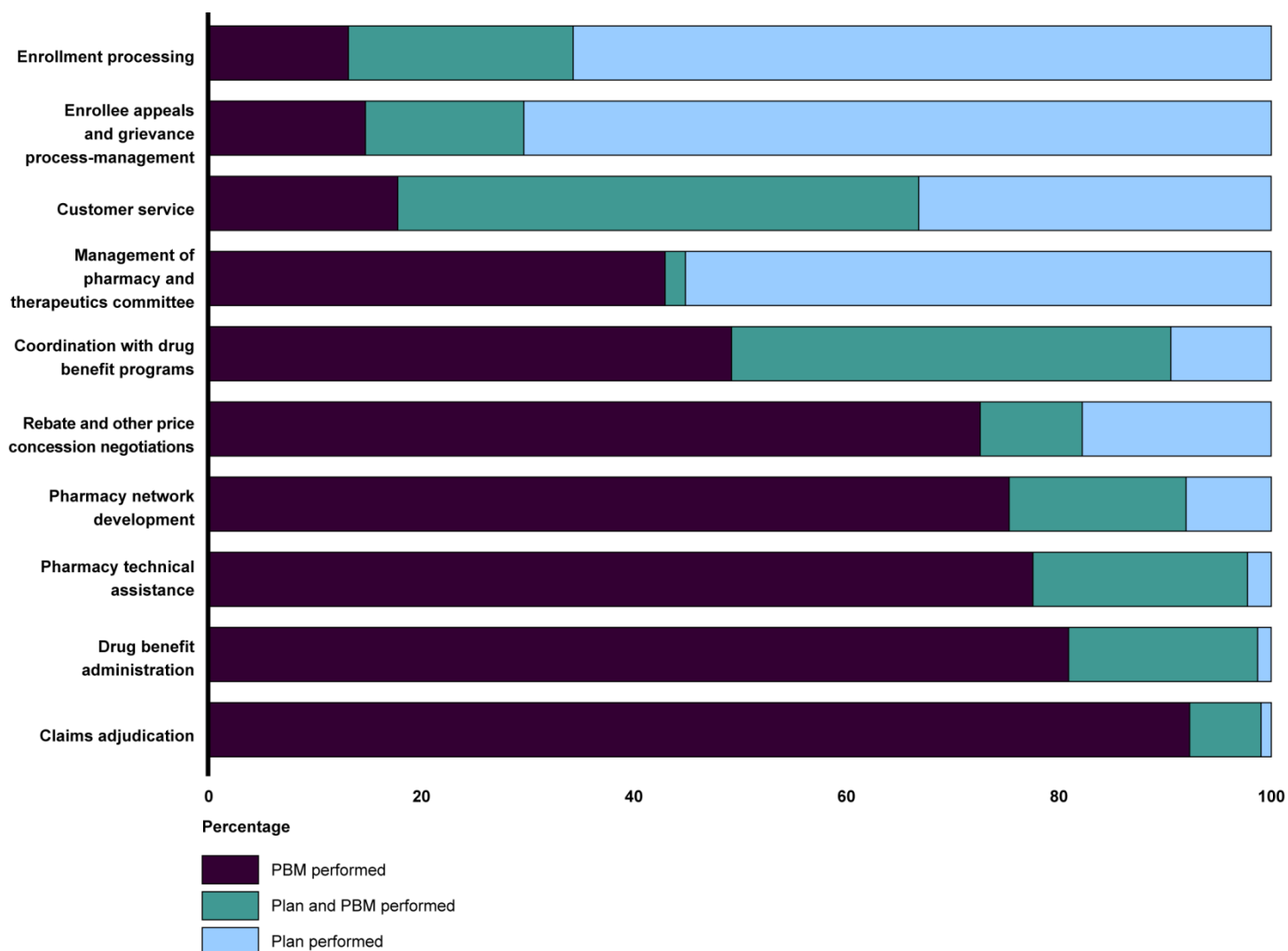
Part D Plan Sponsors' Use of PBMs

We examined Centers for Medicare & Medicaid Services' (CMS) data to identify the 10 key drug benefit management services provided by PBMs under 624 Part D plan sponsor contracts in 2016, the most recent available expenditure and rebate and other price concession data at the time of our analysis, and found the following variation in plan sponsor use of PBMs:¹

- **Services provided by PBMs.** Part D plan sponsors' contracts varied by the services provided by PBMs in 2016. Plan sponsors' use of a PBM for drug benefit services—either alone or with the plan sponsor—for their 624 contracts varied from 30 percent for enrollee appeals and grievance process-management to 99 percent for claims adjudication. For seven of the 10 drug benefit management services, PBMs—either alone or in conjunction with the plan sponsor—provided services to more than half the sponsor contracts (see fig. 4).

¹In this report, we refer to a drug plan or plans covered under each sponsor contract with CMS as a "Part D plan sponsor contract."

Figure 4: Medicare Part D Plan Sponsor Contract Use of Pharmacy Benefit Managers (PBM) for 10 Drug Benefit Management Services, by Percent of Contracts, 2016

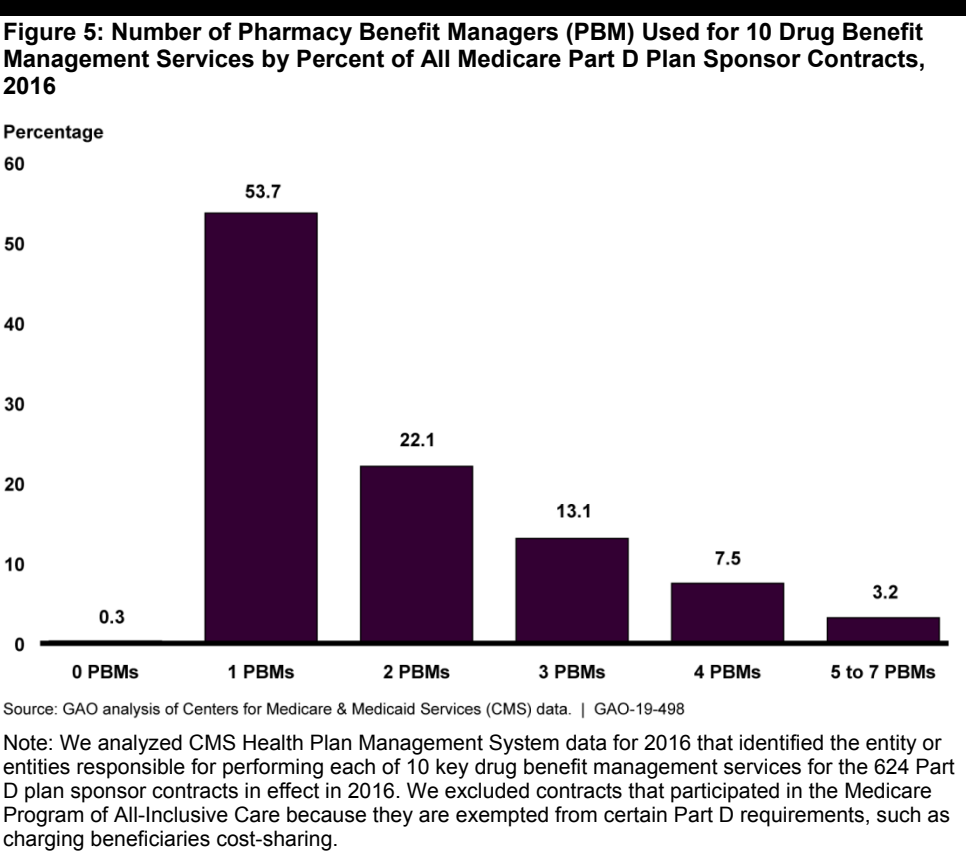


Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-19-498

Note: We analyzed CMS Health Plan Management System data for 2016 that identified the entity or entities responsible for performing each of 10 key drug benefit management services for the 624 Part D plan sponsor contracts in effect in 2016. We excluded contracts that participated in the Medicare Program of All-Inclusive Care because they are exempted from Part D requirements such as charging beneficiaries cost-sharing.

- **Number of PBMs used.** Part D plan sponsor contracts varied in the number of PBMs used to provide one or more of the 10 drug benefit management services. For example, 54 percent of plan sponsors'

contracts used a single PBM, while 11 percent used four or more PBMs (see fig. 5).



- **Use of PBMs by enrollment.** Smaller Part D contracts—those with contract enrollment below the median enrollment of all Part D contracts—used a PBM more often than larger contracts—those with enrollment at or above the median. For instance, 87 percent of smaller Part D plan sponsor contracts used a PBM alone or with the plan sponsor for rebate and price concession negotiations, compared to 77 percent of larger contracts. Similarly, 54 percent of smaller Part D contracts used a PBM alone or with a plan for a pharmacy and therapeutics committee, compared to 35 percent of larger contracts.
- **Use of financially related PBMs.** Part D plan sponsors’ contracts varied by their use of PBMs with which they were related by common

ownership—either as a subsidiary or a sister company.² In 2016, plan sponsors used a PBM with which they were related by common ownership for 17 percent of the 624 Part D plan sponsors contracts. Larger contracts—those with enrollment at or above the median—were more likely to use a PBM related by common ownership than smaller contracts. Larger contracts used a financially related PBM for 24 percent of drug benefit management services, compared to 10 percent of drug benefit management services provided to smaller contracts.

Factors Influencing Plans' Decisions to Use a PBM

The Part D plan sponsor representatives with whom we spoke noted several considerations that influenced their decision about how and whether to use a PBM. One plan sponsor noted that small plans may lack the resources to conduct their own rebate negotiations and, therefore, may use a PBM instead. Three other plan sponsors noted they switched from conducting their own rebate negotiation with manufacturers to using a PBM. Two plan sponsors said this switch was due to PBMs' ability to obtain larger rebates than the plan sponsor could, and the third determined a PBM would help it achieve the best value and quality, while meeting Part D's regulatory requirements.

In contrast, representatives of three other Part D plan sponsors noted advantages of performing drug benefit management services themselves. For example, one plan sponsor noted that it performs almost all drug benefit management services internally, as it believes doing so improves quality through better communication and care coordination with pharmacies. Another plan sponsor noted the decision not to contract out certain services to a PBM may be influenced by a desire for more customization over formulary management and greater control over prior authorization. Representatives of one plan sponsor noted that their plan does not use a PBM because they believe they are more effective in developing formularies with better utilization management and greater use of generic drugs than are PBMs.³

²For example, UnitedHealth Group owns UnitedHealthcare—which operates Part D plans—and OptumRx—a PBM.

³Greater use of generic drugs is associated with financial savings, as generics are generally less expensive than brand-name drugs.

Variation in the Number of Services Provided by PBMs to Part D Plan Sponsors

Our analysis of CMS data for the 624 Part D plan sponsor contracts found that the five PBMs that provided the largest number of services to Part D plan sponsors' contracts in 2016 also generally provided a full range of PBM services to them. Four of the top five PBMs provided all 10 drug benefit management services to plan sponsors' contracts while the fifth PBM conducted claims adjudication but used an intermediary to conduct rebate negotiations.⁴ (See table 4). Furthermore, the top five PBMs provided a high proportion of the services that Part D plan sponsors most commonly used a PBM to provide. For example, CVS Caremark provided claims adjudication to 144 (23 percent) of Part D plan sponsor contracts, and OptumRx provided this service to 138 (22 percent).

Table 4: Number of Medicare Part D Plan Contracts That Used Top Five Pharmacy Benefit Managers (PBM) for Drug Benefit Management Services, 2016

Drug benefit management service	Number of contracts that used each PBM for the service (n=624)				
	CVS Caremark	OptumRx	Express Scripts	MedImpact	Argus ^a
Claims adjudication	144	138	93	73	74
Drug benefit administration	145	134	92	73	73
Coordination with drug benefit programs	137	120	89	67	61
Customer service	91	87	30	49	9
Pharmacy network development	142	130	93	73	29
Enrollment processing	14	3	3	8	0
Management of a pharmacy and therapeutics committee	79	18	21	50	0
Rebate and price concession negotiation	119	120	86	59	3
Enrollee appeals and grievance management	44	11	17	25	0
Pharmacy technical assistance	124	132	91	69	66

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-19-498

Note: We analyzed CMS Health Plan Management System data for 2016 that identified the entity or entities responsible for performing each of 10 key drug benefit management services for the 624 Part D plan sponsor contracts in effect in 2016. We excluded contracts that participated in the Medicare Program of All-Inclusive Care because they are exempted from Part D requirements, such as charging beneficiaries cost-sharing. In some instances, a Part D plan sponsor used more than one PBM to provide a drug benefit management service. In these instances, multiple PBMs were counted as providing the same service in our summary counts.

^aArgus is known as DST Pharmacy Solutions as of September 2017.

⁴This PBM did not provide enrollment processing or appeals and grievance process-management.

In contrast, we found that Part D plan sponsors used a large number of PBMs to provide a limited range of drug benefit management services. For example, 48 percent of PBMs provided only one type of drug benefit management service to plan sponsors' contracts, and 22 percent of PBMs provided only one service to only one plan sponsor contract. For instance, there were 10 unique entities counted as PBMs in our analysis that provided only customer service support to one plan sponsor contract. One PBM representative noted in an interview that it is relatively common for plan sponsors and PBMs to contract with other vendors to provide additional assistance with drug benefit management services. One plan sponsor told us, for example, that its PBM uses a vendor to manage customer service calls.

Appendix III: Information on Pharmacy Benefit Manager (PBM) Revenue Earned from Manufacturers and from Spread Pricing

This appendix provides additional detail on (1) non-rebate revenue that PBMs may earn for services provided to manufacturers and Medicare Part D plan sponsors, and (2) PBM perspectives on Centers for Medicare & Medicaid Services (CMS) policies relating to spread pricing in Part D.

Non-rebate Revenue That PBMs May Earn for Services Provided to Manufacturers and Part D Plan Sponsors

PBMs and Part D plan sponsors may earn non-rebate revenue from manufacturers for providing certain services. Even though this money is reported to CMS as part of the rebate and other price concession submission, not all of it is considered rebates or other price concessions, which will lower plan liability in determining bids and thereby lower premiums. Of the \$516.5 million in non-rebate revenue paid by manufacturers in 2016, \$440 million, or about 85 percent, represented the amount paid for the services that exceeded the fair market value of the service and is considered rebates and other price concessions. These may be used to reduce the drug costs incurred by the plan sponsor. Therefore, this revenue factors into bid determinations and may be used to reduce premiums.

The remaining \$78.6 million in payments from manufacturers were considered “bona fide service fees”—fees paid by manufacturers to Part D plan sponsors and PBMs for services that the manufacturer would otherwise perform, or contract for, and that represented the fair market value of those services. Such fees do not reduce the plan sponsor’s drug costs and, therefore, could not factor into reducing premiums.¹ The determination of a bona fide service fee as reported to CMS is made by the drug manufacturer and the Part D plan sponsor and is not routinely evaluated by CMS, agency officials told us. However, CMS requires that the PBM and manufacturer have information documenting the fair market value of the service.

Stakeholder Perspectives on PBM Revenue Earned from Spread Pricing, Rebate Retention, and Differences from the Commercial Sector

CMS requires Part D plan sponsors to report revenue earned from rebates retained by the PBM. This revenue increases the plan’s liability, which increases the amount of plan bids and, therefore, result in higher premiums. In contrast, rebate revenue passed through by PBMs to Part D plan sponsors lowers the plan’s liability, reduces plans bids, and, therefore, lowers beneficiary premiums.

¹See 74 Fed. Reg. 1494, 1512 (Jan. 12, 2009) (preamble, II.B.4.a.).

Some PBMs earn more revenue from spread pricing in their commercial business than in Part D, officials from three PBMs told us. Officials from two of these PBMs noted that CMS requirements create a disincentive to engage in spread pricing that is not present in the commercial sector. Beginning in 2010, CMS required that plan sponsors base the amount of beneficiary cost-sharing on the amount received by the pharmacy for a drug—known as the “pass-through price.”² CMS also required that an estimate of rebates or other price concessions be included in the administrative costs submitted by the plan sponsor for bid determinations.³ Part D plan sponsors can still agree to pay the PBM based on the higher price of the drug without accounting for rebates, known as the lock-in price. However, the difference between that amount and the pass-through price would increase the bid determination and ultimately increase the premiums that plans charge beneficiaries.⁴ Because there are no similar requirements pertaining to the commercial prescription drug benefit market, spread pricing is more common there, CMS officials told us.

²See 74 Fed. Reg. 1505, 1543 (Jan. 12, 2009) (preamble, II.B.3.b.) (codified at 42 C.F.R. § 423.100) (2018) (amending definition of “negotiated prices” upon which cost sharing is based to include reductions due to price concessions).

³See 74 Fed. Reg. 1512, 1513, 1544 (Jan. 12, 2009) (preamble II.B.4.a., b.) (codified at 42 C.F.R. § 423.308 (2018)) (amending definitions of “actually paid” and “administrative costs” to provide that rebates or price concessions are administrative costs, which will be included in the determination of bid amounts).

⁴See 42 C.F.R. §§ 423.265 (c) (2018) (costs included in bids).

Appendix IV: Expenditures and Rebate and Other Price Concession Information for Medicare Part D Drugs

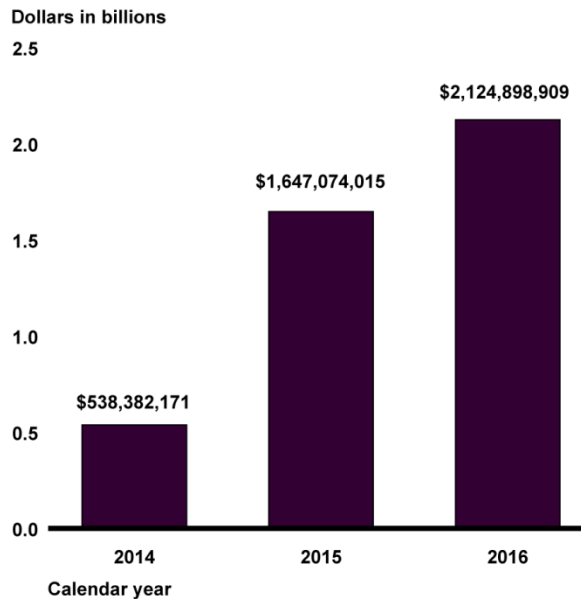
This appendix provides information on (1) pharmacy-related price concessions for all Medicare Part D drugs and (2) expenditure and rebate and other price concession information for the 444 highest expenditure, highest utilization brand-name Part D drugs in 2016. The appendix also contains additional information on expenditures and rebates and other price concessions obtained by the 16 Part D plan sponsors whose representatives we interviewed.

Pharmacy-Related Price Concessions for All Part D Drugs

The amount of pharmacy-related price concessions obtained by Part D plan sponsors, or pharmacy benefit managers (PBM) on plan sponsors' behalf, increased 295 percent from 2014 through 2016, from \$538 million to \$2.1 billion (see fig. 6). These monies account for any adjustments to the price of the drug paid to the pharmacy after the point sale, such as a pharmacy returning money that was overpaid by the plan sponsor or vice versa. It can also include monies paid based on pharmacies' performance in meeting agreed-upon performance metrics—for example, fees a pharmacy pay plan sponsors, or bonuses pharmacies receive from plan sponsors, based on their performance.¹ In 2016, Part D plan sponsors received \$2.3 billion from pharmacies and paid out \$211 million, for a net of \$2.1 billion in pharmacy-related price concessions.

¹An example of a performance metric is a specified percent of prescriptions dispensed for a generic drug (instead of a brand-name drug).

Figure 6: Pharmacy-related Price Concessions, 2014-2016



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-19-498

Note: We analyzed 2014 through 2016 price concession data contained in the direct and indirect remuneration data submitted by Medicare Part D plan sponsors to CMS. Specifically, we analyzed monies paid to, and received from, pharmacies that affect the price of a drug paid by a Part D plan sponsor and pharmacy benefit manager on its behalf following the purchase from a pharmacy.

Five of the seven PBMs and seven of the 12 Part D plan sponsors whose representatives we interviewed said they have performance-based arrangements with pharmacies. One plan sponsor noted that its performance agreement involves paying bonuses to pharmacies that exceed performance measures, while charging fees to pharmacies that did not meet the measures. The sponsor said this is part of an attempt to move from paying for volume to paying for value. Another plan sponsor told us there has been an improvement in pharmacy performance as a result of the program.

Representatives from pharmacy industry groups said these pharmacy-related fees have put increasing pressure on pharmacies. For example, one group noted there is no standardization across measures with each plan sponsor using its own measures, and it is difficult for pharmacies to tie a fee to a specific pharmacy location or claim. Another group noted that fees may be imposed on pharmacies for performance measures not directly applicable to the pharmacy. For example, the group said specialty

pharmacies have been assessed fees for beneficiary lack of adherence to maintenance medications, such as blood pressure medications, that these pharmacies do not commonly provide.

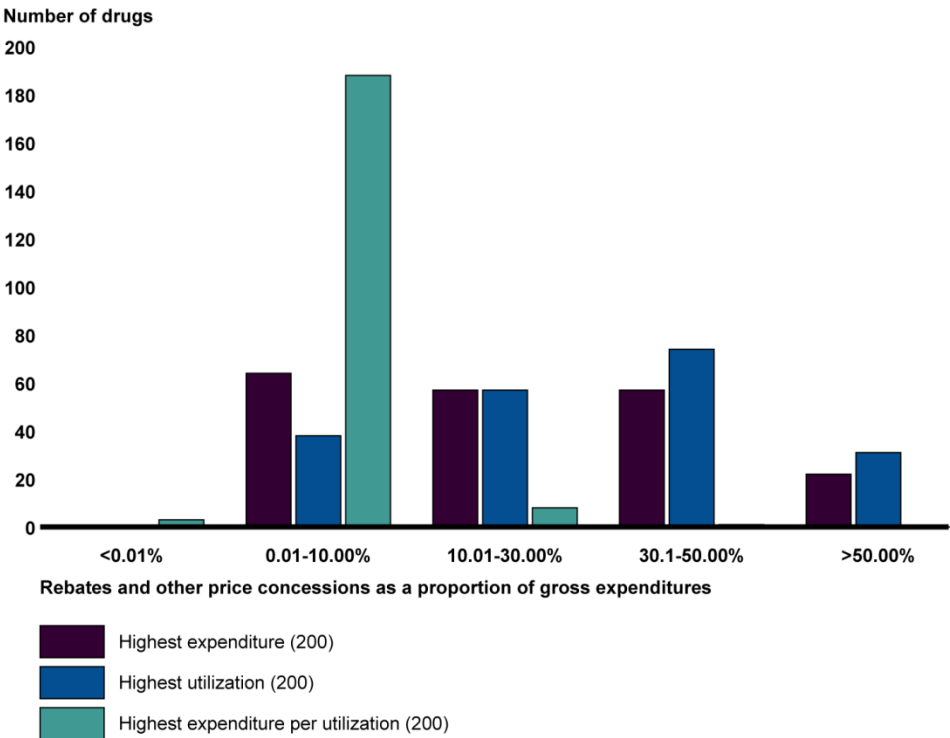
Expenditure and Rebate
and Other Price
Concession Information
for 444 Highest
Expenditure, Highest
Utilization Brand-Name
Drugs

PBMs and Part D plan sponsors obtained rebates and other price concessions for 441 (99 percent) of the 444 highest-expenditure, highest-utilization brand-name drugs in 2016. The amount of rebates and other price concessions for each drug ranged from \$1,300 to \$1.8 billion in 2016, with a median of \$3.3 million.² Rebates accounted for \$24.5 billion of the \$26 billion in rebates and other price concessions (94 percent) obtained by plan sponsors and PBMs for these 444 drugs. As a proportion of gross Part D expenditures—the amount paid by plan sponsors, or the PBM on the sponsors’ behalf, and by beneficiaries—for the 444 drugs ranged from -0.5 percent to 70.5 percent.³ (See fig. 7.)

²Three of the 444 drugs had “negative rebates and other price concessions” ranging from -\$10,000 to -\$37,000 in 2016. According to CMS, negative rebate and other price concession amounts may occur when, for example, risk-sharing arrangements between a plan sponsor and a physician network resulted in more in bonuses paid to the network for reducing drug costs than was received from manufacturers in rebates.

³Gross expenditures do not account for rebates and other price concessions. Generic drugs received few rebates and other price concessions compared to brand-name drugs. In 2016, all 476 generic drugs in our analysis received rebates and other price concessions, ranging from \$48 to \$8.9 million for a drug. The amount of rebates and other price concessions obtained for these drugs accounted for 2.3 percent (\$547 million) of the \$23.9 billion spent on these drugs in 2016. Of the 476 generic drugs, 379 received rebates, which ranged from \$1 to \$2 million for a drug. Across the 920 highest expenditure, highest utilization brand-name and generic drugs in our analysis, generic drugs received 0.13 percent of the \$24.6 billion in rebates and 26 percent (\$515 million) of the \$2 billion in price concessions.

Figure 7: Rebates and Other Price Concessions Received for the Highest-Expenditure, Highest-Utilization Medicare Part D Brand-Name Drugs as a Proportion of Their Gross Expenditures, 2016



Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-19-498

Note: We analyzed CMS expenditure and rebate and other price concession data from the prescription drug event and direct and indirect remuneration DIR data sets for three groups of brand-name drugs: the 200 with the highest expenditures, the 200 with the highest utilization, and the 200 with the highest expenditures per utilization (i.e., highest expenditure per number of 30-day prescriptions). We identified drugs that had common ingredients, strengths, dose, and route of administration and combined them. This resulted in a group of 444 unique brand-name drugs across the three groups.

**Expenditures and Rebates
and Other Price
Concessions for the 444
Highest Expenditure,
Highest Utilization Part D
Brand-Name Drugs, by
Therapeutic Drug Class,
2016**

Expenditures and rebates and other price concessions varied by therapeutic class for the 444 highest expenditure, highest utilization drugs in 2016. Among those with 10 or more drugs in their class, gross expenditures ranged from \$2.9 billion to \$21.2 billion, and rebates and other price concessions ranged from \$170 million to \$8.7 billion (see table 5). Four classes—endocrine metabolic agents, anti-infective agents, respiratory agents, and central nervous system agents—accounted for 54 percent of the gross Part D expenditures, and 62 percent of rebates and other price concessions for the 444 highest expenditure, highest utilization drugs.⁴ When accounting for rebates and other price concessions, these drugs accounted for 51 percent of net Part D expenditures.

Table 5: Expenditures and Rebates and Other Price Concessions for the 444 Highest Expenditure, Highest Utilization Medicare Part D Brand-Name Drugs, by Therapeutic Class, 2016

Therapeutic class	Drugs	Expenditures (in dollars)	Rebates and other price concessions (in dollars)	Rebates and other price concessions as proportion of expenditures (percent)
Endocrine metabolic agent	69	21,159,397,592	8,706,047,671	41
Anti-infective agent	34	11,225,406,324	2,217,176,860	20
Respiratory agent	31	9,886,018,944	3,175,329,544	32
Central nervous system agent	57	8,505,550,786	1,910,305,516	22
Antineoplastic agent	81	8,371,964,875	169,735,568	2
Cardiovascular agent	51	8,002,376,936	3,064,718,411	38
Immunological agent	28	6,307,238,469	256,298,135	4
Blood modifier agent	19	5,392,226,626	1,444,676,699	27
Genitourinary agent	14	3,561,199,830	1,406,975,264	40
Musculoskeletal agent	10	3,515,156,333	589,240,842	17

⁴Part D plans are required to provide access to all drugs covered under certain therapeutic classes of drugs, known as Medicare protected classes: (1) anticonvulsants, (2) antidepressants, (3) antineoplastics, (4) antipsychotics, (5) antiretrovirals, and (6) immunosuppressants for the treatment of transplant. Antineoplastic and immunological drugs, which are part of Medicare's protected classes, received the lowest amount of direct and indirect remuneration (DIR) relative to their gross Part D expenditures. Because the therapeutic class information in Truven Health Analytics' Redbook does not align with Medicare's protected classes, we were unable to determine which of the 444 highest expenditure, highest utilization drugs fell in under the protected classes. Furthermore, it is unclear if antineoplastic and immunological drugs received relatively few rebates and other price concessions as result of the protected class requirement or other factors.

Appendix IV: Expenditures and Rebate and Other Price Concession Information for Medicare Part D Drugs

Therapeutic class	Drugs	Expenditures (in dollars)	Rebates and other price concessions (in dollars)	Rebates and other price concessions as proportion of expenditures (percent)
Gastrointestinal agent	17	3,077,243,117	1,430,029,308	46
Ophthalmologic agent	14	2,930,528,225	1,332,099,094	45

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data and data from Truven Health Analytics. | GAO-19-498

Notes: We analyzed CMS expenditure and rebate and other price concession information, known as direct and indirect remuneration, for the following groups of brand-name drugs: the 200 drugs with the highest expenditures, the 200 drugs with the highest utilization, and the 200 drugs with the highest expenditures per 30-day prescription. We identified drugs that had common ingredients, strengths, dose, and route of administration. This resulted in a group of 444 unique brand-name drugs across the three groups of drugs. We identified therapeutic class information using information from Red Book, a compendium published by Truven Health Analytics.

We omitted the six therapeutic classes in our analysis with fewer than 10 drugs in their class: nasal agents, dermatological agents, antidotes, nutritive agents, dependency agents, and diagnostic agents.

Gross and Net Part D Expenditures Varied among Selected Part D Plan Sponsors in 2016

Rebates and other price concessions as a proportion of gross expenditures varied from 4 percent to 27 percent in 2016 for the 17 Part D plan sponsors whose representatives we interviewed. Gross Part D expenditures per beneficiary ranged from \$1,772 to \$5,583, and net Part D expenditures per beneficiary ranged from \$1,687 to \$4,837 (see table 6).

Table 6: Gross and Net Expenditure Information for the 17 Medicare Part D Plan Sponsors GAO Interviewed, 2016

Part D Sponsor	2016 Rebates and other price concessions as a percentage of gross Part D expenditures (percent)	2016 Gross Part D expenditures per Beneficiary (dollars)	2016 Net Part D expenditures per beneficiary (dollars)
Sponsor A	27	4,609	3,359
Sponsor B	27	4,262	3,125
Sponsor C	25	3,640	2,728
Sponsor D	18	3,412	2,801
Sponsor E	17	2,800	2,312
Sponsor F	17	3,350	2,777
Sponsor G	17	3,031	2,529
Sponsor H	16	4,132	3,468
Sponsor I	16	5,503	4,618
Sponsor J	16	4,398	3,709
Sponsor K	13	2,753	2,385
Sponsor L	13	5,583	4,837
Sponsor M	11	3,379	3,004

Appendix IV: Expenditures and Rebate and Other Price Concession Information for Medicare Part D Drugs

Part D Sponsor	2016 Rebates and other price concessions as a percentage of gross Part D expenditures (percent)	2016 Gross Part D expenditures per Beneficiary (dollars)	2016 Net Part D expenditures per beneficiary (dollars)
Sponsor N	11	4,521	4,039
Sponsor O	10	2,597	2,347
Sponsor P	5	1,772	1,687
Sponsor Q	4	2,806	2,700

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data. | GAO-19-498

Notes: We analyzed CMS expenditure and rebate and other price concession information, known as direct and indirect remuneration, for the following groups of brand-name drugs: the 200 with the highest expenditures, the 200 with the highest utilization, and the 200 with the highest expenditures per 30-day prescription. We identified drugs that had common ingredients, strengths, dose, and route of administration. This resulted in a group of 444 unique brand-name drugs across the three groups of drugs.

Gross expenditures reflect what was paid to the pharmacy by the Part D plan sponsor, pharmacy benefit managers on the sponsor’s behalf, and the beneficiary for a given drug. Net expenditures reflect any rebates and discounts obtained by plan sponsors and pharmacy benefit managers after a beneficiary receives a drug.

Appendix V: Information on Discounts Off Manufacturer List Prices for Brand-Name and Generic Medicare Part D Drugs

This appendix contains additional information on the gross and net discounts for the highest expenditure, highest utilization brand-name and generic Medicare Part D drugs in 2016.

Information on the Extent to Which Brand-Name Part D Drugs Were Discounted Off Manufacturer List Prices

The amount of discounts in 2016 for the 444 highest expenditure, highest utilization brand-name drugs varied by whether they were sold in retail or specialty pharmacies. Discounts also varied by whether the brand-name drugs were highest expenditure, highest utilization or highest expenditure per utilization drugs.¹ Of the 444 highest expenditure, highest utilization brand-name drugs, 244 were sold in retail pharmacies and 200 were sold in specialty pharmacies.²

- **Brand-name retail drugs.** The three groups of drugs all had pharmacy acquisition costs that were 81 percent of manufacturer list prices and gross Part D prices that were between 83 and 84 percent of manufacturer list prices in 2016. However, the net prices varied, ranging from 55 percent of manufacturer list price for the highest utilization drugs to 77 percent for the highest expenditure per utilization drugs (see table 7).³
- **Brand-name specialty drugs.** The 38 highest expenditure drugs and 187 highest expenditure per utilization drugs sold in specialty pharmacies had median gross prices that were between 84 and 85

¹Prices are the 2016 median prices for the brand-name drugs that met the following criteria: the 200 drugs with the highest expenditures, the 200 drugs with the highest utilization, and the 200 drugs with the highest expenditures per 30-day prescription. We identified drugs that had common ingredients, strengths, dosages, or routes of administration. This resulted in a list of 444 unique brand-name drugs across the three groups because some drugs met more than one criterion and therefore appeared in more than one group.

²We determined whether a drug was sold in retail or specialty pharmacies based on National Drug Acquisition Cost (NADAC data). We found that 97 percent of the 444 highest expenditure, highest utilization brand-name drugs that lacked NADAC were listed as specialty drugs on a Part D plan sponsor's formulary. Given this, we refer to drugs that do not have a NADAC price as those sold in specialty pharmacies.

³Manufacturer list price is the median average wholesale price—the list price manufacturers suggest wholesalers charge pharmacies for a drug. Pharmacy acquisition cost reflects prices reported in surveys of community retail pharmacies in the NADAC data set. Gross Part D prices reflect median unit prices paid to pharmacies by Part D plan sponsors, pharmacy benefit managers (PBM) on the sponsor's behalf, and the beneficiary, and net Part D prices account for rebates and other price concessions obtained by plan sponsors for these drugs as reported in the direct and indirect remuneration (DIR) data set.

**Appendix V: Information on Discounts Off
Manufacturer List Prices for Brand-Name and
Generic Medicare Part D Drugs**

percent of manufacturer list price and net prices that were 84 percent of manufacturer list price in 2016.⁴

Table 7: Medicare Part D Median Unit Drug Part D Prices as a Percentage of Manufacturer List Prices for the Highest Expenditure, Highest Utilization Brand-Name Drugs Sold in Retail and Specialty Pharmacies, 2016

	Brand-name retail drugs				Brand-name specialty drugs			
	Count (number of drugs)	Pharmacy acquisition cost (percent)	Gross Part D price (percent)	Net Part D price (percent)	Count (number of drugs)	Pharmacy acquisition cost (percent) ^a	Gross Part D price (percent)	Net Part D price (percent)
Median 200 highest expenditure	162	81	83	59	38	n/a	85	84
Median 200 highest utilization	199	81	83	55	1	n/a	n/a ^b	n/a ^b
Median 200 highest expenditure per utilization	13	81	84	77	187	n/a	84	84

Legend: n/a = not applicable

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data and data from Truven Analytics. | GAO-19-498

Notes: Prices are the 2016 median prices for the brand-name drugs that met these criteria: the 200 drugs with the highest expenditures, the 200 drugs with the highest utilization, and the 200 drugs with the highest expenditures per utilization (i.e., highest expenditure per number of 30-day prescriptions). We identified drugs that had common ingredients, strengths, dosages, and routes of administration. This resulted in a group of 444 unique brand-name drugs across the three groups because some drugs met multiple criteria and appeared in more than one group. Of these 444 brand-name drugs, 244 were drugs sold in retail pharmacies, and 200 were drugs sold in specialty pharmacies.

Manufacturer list price is the median average wholesale price. Pharmacy acquisition cost reflects prices reported in surveys of community retail pharmacies in the National Average Drug Acquisition Cost data set. Gross Part D prices reflect median unit prices paid to pharmacies by Part D plan sponsors, pharmacy benefit managers on the sponsor's behalf, and the beneficiary and net Part D prices account for rebates and other price concessions obtained by plan sponsors for these drugs as reported in the direct and indirect remuneration data set.

^aPharmacy acquisition cost data are unavailable for drugs sold in specialty pharmacies, as these pharmacies are not surveyed by CMS.

^bOnly one of the highest utilization drugs was sold in specialty pharmacies; therefore, we omitted pricing data on that drug.

We also found variation in brand-name prices across therapeutic classes for the 244 highest expenditure, highest utilization Part D drugs sold in

⁴Pharmacy acquisition cost data are unavailable for drugs sold in specialty pharmacies, as non-retail pharmacies are not surveyed by the Centers for Medicare & Medicaid Services (CMS). Only one of the highest utilization drugs was sold in specialty pharmacies; therefore, we omitted pricing data on that drug.

retail pharmacies.⁵ In 2016, median gross Part D prices for the brand-name drugs sold in retail pharmacies were similar across the nine therapeutic classes we analyzed, ranging from 81 percent to 84 percent of the manufacturer list price.⁶ However, there was a much wider range among median net prices, from 43 percent to 83 percent of manufacturer list price. Anti-infective agents had the lowest percentage point changes in their prices from gross to net (1 percentage point), while endocrine metabolic agents, cardiovascular agents, respiratory agents, ophthalmologic agents, and genitourinary agents had the largest changes, with declines from gross to net of greater than 30 or more percentage points (see table 8).

Table 8: Medicare Part D Median Unit Drug Prices as a Percentage of Manufacturer List Prices by Therapeutic Class for the Highest Expenditure, Highest Utilization Brand-name Drugs Sold in Retail Pharmacies, 2016

Therapeutic Class	Count	Pharmacy acquisition cost (percent)	Gross Part D price (percent)	Net Part D price (percent)
Endocrine metabolic agent	48	81	82	52
Central nervous system agent	39	80	84	60
Cardiovascular agent	27	81	81	50
Respiratory agent	26	81	83	51
Anti-infective agent	22	81	84	83
Ophthalmologic agent	14	81	83	43
Gastrointestinal agent	13	80	84	56
Genitourinary agent	13	81	83	44
Blood modifier agent	12	81	83	60

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data and data from Truven Health Analytics. | GAO-19-498

Notes: Prices are the 2016 median prices for the 244 brand-name drugs that were sold in retail pharmacies and were among the following three groups of drugs which included drugs sold in retail and specialty pharmacies: the 200 drugs with the highest expenditures, the 200 drugs with the highest utilization, and the 200 drugs with the highest expenditures per 30-day prescription. We identified drugs that had common ingredients, strengths, dosages, and routes of administration. This resulted in a group of 444 unique brand-name drugs across the three groups because some drugs met multiple criteria and appeared in more than one group. Of these 444 brand-name drugs 244 were drugs sold in retail pharmacies, and 200 were drugs sold in specialty pharmacies.

⁵Of the 244 highest expenditure, highest utilization brand-name drugs sold in retail pharmacies, 19.7 percent were endocrine metabolic agents; 16 percent were central nervous system agents; 11.1 percent were cardiovascular agents; and 10.7 percent were respiratory agents.

⁶We omitted the eight therapeutic classes in our analysis with fewer than 10 drugs in their class: antidotes, antineoplastic agents, dermatological agents, dependency agents, immunological agents, musculoskeletal agents, nasal agents, and nutritive agents; these accounted for 30 brand-name drugs sold in retail pharmacies.

We omitted the eight therapeutic classes in our analysis with fewer than 10 drugs in their class: antidotes, antineoplastic agents, dermatological agents, dependency agents, immunological agents, musculoskeletal agents, nasal agents, and nutritive agents; these accounted for 30 brand-name drugs sold in retail pharmacies. We identified therapeutic class information using information from Red Book, a compendium published by Truven Health Analytics.

Manufacturer list price is the median average wholesale price—the list price manufacturers suggest wholesalers charge pharmacies for a drug. Pharmacy acquisition cost reflects prices reported in surveys of community retail pharmacies in the National Average Drug Acquisition Cost data set. Gross Part D prices reflect median unit prices paid to pharmacies by Part D plan sponsors, pharmacy benefit managers on the sponsor's behalf, and the beneficiary and net Part D prices account for rebates and other price concessions obtained by plan sponsors for these drugs as reported in the direct and indirect remuneration data set.

In contrast, there was little variation in both median gross and net prices across all therapeutic classes for brand-name drugs sold in specialty pharmacies. The range in median gross prices as a proportion of manufacturer list prices across the six therapeutic classes was 83 percent to 86 percent, and the range in median net prices as a proportion of manufacturer list prices was 80 percent to 84 percent.⁷

**Information on the Extent
to Which Generic Part D
Drugs Were Discounted
Off Manufacturer List
Prices**

In 2016, discounts off of the manufacturer list price varied by whether the generic drug was sold in retail pharmacies or in specialty pharmacies. Of the 476 highest expenditure, highest utilization generic drugs in our analysis, the 367 sold in retail pharmacies had a median gross and net Part D price that were 66 percentage points lower than the manufacturer list price, and 13 percentage points higher than the pharmacy's cost of acquiring the drugs.⁸

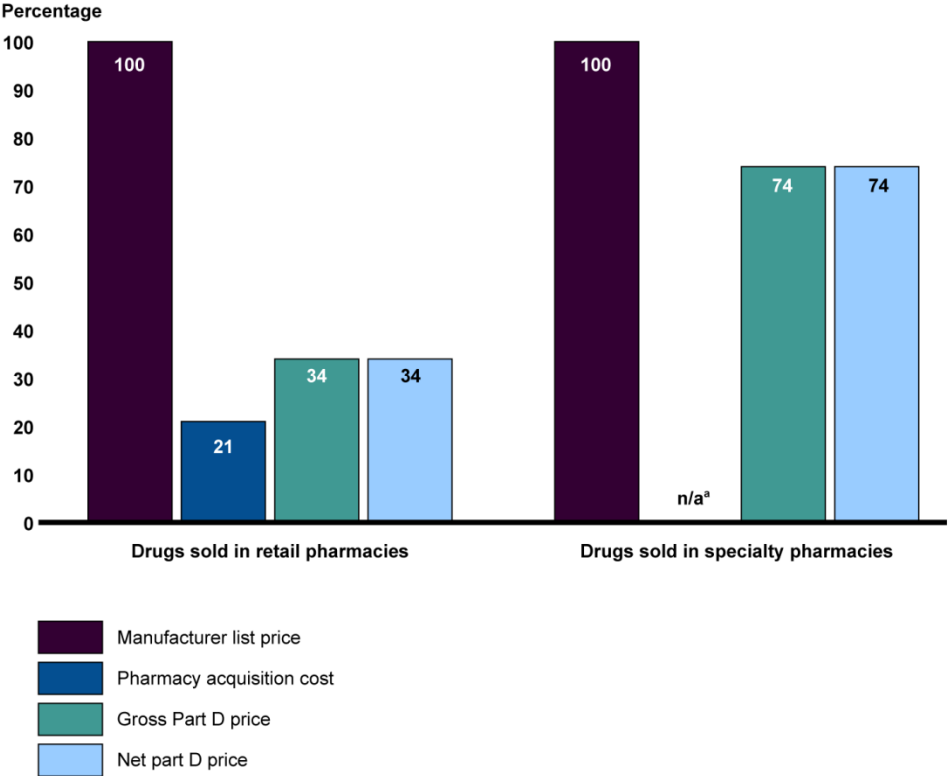
The 109 generic drugs sold in specialty pharmacies received far fewer discounts off of manufacturer list price than drugs sold in retail

⁷Four therapeutic classes accounted for approximately 71 percent of the 200 brand-name drugs sold in specialty pharmacies: 39 percent were antineoplastic agents; 12 percent were cardiovascular agents; 11 percent were immunological agents; and 11 percent were endocrine metabolic agents. Anti-infective agents, blood modifier agents, central nervous system agents, and respiratory agents each accounted for less than 10 percent of the 200 drugs. We omitted one drug without a therapeutic class identified and the eight therapeutic classes with fewer than 10 drugs in the class from our analysis: blood modifier agents, dermatologic agents, diagnostic agents, gastrointestinal agents, genitourinary agents, musculoskeletal agents, respiratory agents, and antidotes.

⁸Prices are the 2016 median prices for the generic drugs that met these criteria: the 200 drugs with the highest expenditures, the 200 drugs with the highest utilization, and the 200 drugs with the highest expenditures per 30-day prescription. We identified drugs that had common ingredients, strengths, dosages, and routes of administration. This resulted in a list of 476 unique brand-name drugs across the three groups, drugs some drugs met more than one criterion and, therefore, appeared in more than one group.

pharmacies. Median gross and net prices for those drugs sold in specialty pharmacies were both 26 percentage points lower than manufacturer list prices (see fig. 8). Therefore, generic drugs sold in retail pharmacies received median discounts (66 percent below manufacturer list prices) that were 2.5 times larger than those generic drugs sold in specialty pharmacies (26 percent below manufacturer list prices).

Figure 8: Medicare Part D Drug Prices as a Percentage of Manufacturer List Prices for the Highest Expenditure, Highest Utilization Generic Drugs Sold in Retail and Specialty Pharmacies, 2016



n/a = not applicable
Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data and data from Truven Health Analytics. | GAO-19-498

Notes: Generic drugs sold in retail pharmacies had a gross median per unit price of \$0.64, while the gross median per unit price for generic drugs sold in specialty pharmacies was \$22.66.

Prices are the 2016 median prices for the generic drugs that met the following criteria: the 200 drugs with the highest expenditures, the 200 drugs with the highest utilization, and the 200 drugs with the highest expenditures per 30-day prescription. We identified drugs that had common ingredients, strengths, dose, and route of administration. This resulted in a group of 476 unique generic drugs across the three groups because some drugs met multiple criteria and appeared in more than one group. Of these 476 generic drugs, 367 were drugs sold in retail pharmacies and 109 were drugs sold in specialty pharmacies.

Manufacturer list price is the median average wholesale price. Pharmacy acquisition cost reflects prices reported in surveys of community retail pharmacies in the National Average Drug Acquisition

Cost data set. Gross Part D prices reflect median unit prices paid to pharmacies by Part D plan sponsors, pharmacy benefit managers on the sponsor's behalf, and the beneficiary and net Part D prices account for rebates and other price concessions obtained by plan sponsors for these drugs as reported in the direct and indirect remuneration data set.

^aPharmacy acquisition cost data are unavailable for drugs sold in specialty pharmacies, as these pharmacies are not surveyed by CMS.

We also found pricing variation by whether the generic drugs were in the 200 highest expenditure, 200 highest utilization group, or the 200 highest expenditures per utilization group.

- **Generic retail drugs.** Of the 367 generic drugs sold in retail pharmacies, 200 were in the group of the 200 highest utilization generic drugs, 198 were in the group of the 200 highest expenditure generic drugs, and 91 were in the group of the 200 generic drugs with the highest expenditure per utilization.⁹ We found that the gross Part D price for the highest utilization drugs was 14 percent of the manufacturer list price, while the gross price for the highest expenditure drugs was 34 percent of the manufacturer list price. However, the Part D gross price for the highest expenditure per utilization drugs was 63 percent of the manufacturer list price. The difference in gross and net Part D price as a percentage of manufacturer list price was one percentage point or less for all three groups of drugs (see table 9).
- **Generic specialty drugs.** Of the 109 generic drugs sold in specialty pharmacies, none was in the group of the 200 highest utilization generic drugs, two were in the group of the 200 highest expenditure generic drugs, and all 109 were in the group of the 200 highest expenditure per utilization generic drugs.¹⁰ The gross Part D price for the highest expenditure per utilization drugs sold in specialty pharmacies was 74 percent of the manufacturer list price, and these drugs received no additional rebates and other price concessions.

⁹Drugs may be included in more than one of our three groups. For example, some drugs are included in both the group of 200 highest expenditure brand-name drugs sold in retail pharmacies and the group of 200 highest expenditure per utilization drugs.

¹⁰The two generic drugs sold in specialty pharmacies that were in the group of 200 highest expenditure generic drugs were also in the group of the 200 highest expenditure per utilization drugs.

Appendix V: Information on Discounts Off
Manufacturer List Prices for Brand-Name and
Generic Medicare Part D Drugs

Table 9: Medicare Part D Median Unit Drug Prices as a Percentage of Manufacturer List Prices for the Highest Expenditure, Highest Utilization Generic Drugs Sold in Retail and Specialty Pharmacies, 2016

	Generic retail drugs as a percentage of manufacturer list price				Generic specialty drugs as a percentage of manufacturer list price			
	Count (number of drugs)	Pharmacy acquisition cost (percent)	Gross Part D price (percent)	Net Part D Price (percent)	Count (number of drugs)	Pharmacy acquisition cost (percent) ^a	Gross Part D price (percent)	Net Part D price (percent)
Median 200 highest expenditure	198	20	34	33	2	n/a	n/a ^b	n/a ^b
Median 200 highest utilization	200	6	14	14	0	n/a	n/a ^b	n/a ^b
Median 200 highest expenditure per utilization	91	60	63	62	109	n/a	74	74

Legend: n/a = not applicable

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data and data from Truven Health Analytics. | GAO-19-498

Notes: Prices are the 2016 median prices for the generic drugs that met these criteria: the 200 drugs with the highest expenditures, the 200 drugs with the highest utilization, and the 200 drugs with the highest expenditures per 30-day prescription. We identified drugs that had common ingredients, strengths, dose, and route of administration. This resulted in a group of 476 unique generic drugs across the three groups because some drugs met multiple criteria and appeared in more than one group. Of these 476 generic drugs, 367 were drugs sold in retail pharmacies and 109 were drugs sold in specialty pharmacies.

Manufacturer list price is the median average wholesale price. Pharmacy acquisition cost reflects prices reported in surveys of community retail pharmacies in the National Average Drug Acquisition Cost data set. Gross Part D prices reflect median unit prices paid to pharmacies by Part D plan sponsors, pharmacy benefit managers on the sponsor's behalf, and the beneficiary and net Part D prices account for rebates and other price concessions obtained by plan sponsors for these drugs as reported in the direct and indirect remuneration data set.

^aPharmacy acquisition cost data are unavailable for drugs sold in specialty pharmacies, as these pharmacies are not surveyed by CMS.

^bOnly two of the highest expenditure generic drugs and none of the highest utilization generic drugs were sold in specialty pharmacies; therefore, we omitted pricing data for these drugs.

There was variation in generic drug pricing across the eight therapeutic classes for generic drugs sold in retail pharmacies. Median gross Part D prices for generic retail drugs ranged from 14 percent of manufacturer list prices for cardiovascular agents to 56 percent of manufacturer list prices for dermatological agents (see table 10). However, there was little difference between in median gross and net Part D prices as a percentage of manufacturer list price for generic retail drugs in any

therapeutic class, with the percentage difference ranging from 0 percent to 2 percent.¹¹

Table 10: Medicare Part D Median Unit Drug Prices as a Percentage of Manufacturer List Prices by Therapeutic Class for the Highest Expenditure, Highest Utilization Generic Drugs Sold in Retail Pharmacies, 2016

Therapeutic class	Count	Pharmacy acquisition cost (percent)	Gross Part D price (percent)	Net Part D price (percent)
Central nervous system agent	127	17	30	29
Cardiovascular agent	88	6	14	14
Endocrine metabolic agent	33	46	54	52
Anti-infective agent	22	43	51	51
Gastrointestinal agent	20	32	46	45
Dermatological agent	18	49	56	55
Blood modifier agent	15	25	38	38
Genitourinary agent	10	30	40	39

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data and data from Truven Analytics. | GAO-19-498

Notes: Prices are the 2016 median prices for the 367 generic drugs that were sold in retail pharmacies and were among the following three groups of drugs which included drugs sold in retail and specialty pharmacies: the 200 drugs with the highest expenditures, the 200 drugs with the highest utilization, and the 200 drugs with the highest expenditures per 30-day prescription. We identified drugs that had common ingredients, strengths, dose, and route of administration. This resulted in a group of 476 unique generic drugs across the three groups because some drugs met multiple criteria and appeared in more than one group. Of these 476 generic drugs, 367 were drugs sold in retail pharmacies and 109 were drugs sold in specialty pharmacies.

We omitted one drug without therapeutic class information and the eight therapeutic classes in our analysis with fewer than 10 drugs in their class: antineoplastic agents, antidotes, immunologic agents, musculoskeletal agents, nasal agents, nutritive agents, ophthalmologic agents, and respiratory agents; these accounted for 33 generic drugs sold in retail pharmacies. We identified therapeutic class information using information from Red Book, a compendium published by Truven Health Analytics.

Manufacturer list price is the median average wholesale price—the list price manufacturers suggest wholesalers charge pharmacies for a drug. Pharmacy acquisition cost reflects prices reported in surveys of community retail pharmacies in the National Average Drug Acquisition Cost data set. Gross Part D prices reflect median unit prices paid to pharmacies by Part D plan sponsors, pharmacy benefit managers on the sponsor's behalf, and the beneficiary and net Part D prices account for rebates and other price concessions obtained by plan sponsors for these drugs as reported in the direct and indirect remuneration data set.

There was little variation in median gross and net prices across the therapeutic classes for generic drugs sold in specialty pharmacies. The

¹¹We omitted one drug without therapeutic class information and the eight therapeutic classes in our analysis with fewer than 10 drugs in their class: antineoplastic agents, antidotes, immunologic agents, musculoskeletal agents, nasal agents, nutritive agents, ophthalmologic agents, respiratory agents; these accounted for 33 generic drugs sold in retail pharmacies.

range in median gross prices as a percentage of manufacturer list prices was 73 to 75 percent (see table 11). There was little difference between median gross and Part D net prices as a percentage of manufacturer list price, with the percentage difference between median gross and net prices 1 percent or less for all classes.¹²

Table 11: Medicare Part D Median Unit Drug Prices as a Percentage of Manufacturer List Prices by Therapeutic Class for the Highest Expenditure, Highest Utilization Generic Drugs Sold in Specialty Pharmacies, 2016

Therapeutic class	Count	Pharmacy acquisition cost ^a	Gross Part D price (percent)	Net Part D price (percent)
Anti-infective agent	42	n/a	73	72
Central nervous system agent	27	n/a	75	75
Antineoplastic agent	16	n/a	74	74

Legend: n/a = not applicable

Source: GAO analysis of Centers for Medicare & Medicaid Services (CMS) data and data from Truven Analytics. | GAO-19-498

Notes: Prices are the 2016 median prices for the 109 generic drugs that were sold in specialty pharmacies and were among the following three groups of drugs which included drugs sold in retail and specialty pharmacies: the 200 drugs with the highest expenditures, the 200 drugs with the highest utilization, and the 200 drugs with the highest expenditures per 30-day prescription. We identified drugs that had common ingredient, strengths, dose, and route of administration. This resulted in a group of 476 unique generic drugs across the three groups because some drugs met multiple criteria and appeared in more than one group. Of these 476 generic drugs, 367 were drugs sold in retail pharmacies and 109 were drugs sold in specialty pharmacies.

We omitted the 9 therapeutic classes in our analysis with fewer than 10 drugs in their class: antidotes, blood modifier agents, cardiovascular agents, dermatological agents, endocrine metabolic agents, gastrointestinal agents, immunological agents, nutritive agents, and respiratory agents; these accounted for 24 generic drugs sold in specialty pharmacies. We identified therapeutic class information using information from Red Book, a compendium published by Truven Health Analytics.

Manufacturer list price is the median average wholesale price—the list price manufacturers suggest wholesalers charge pharmacies for a drug. Pharmacy acquisition cost reflects prices reported in surveys of community retail pharmacies in the National Average Drug Acquisition Cost data set. Gross Part D prices reflect median unit prices paid to pharmacies by Part D plan sponsors, pharmacy benefit managers on the sponsor’s behalf, and the beneficiary and net Part D prices account for rebates and other price concessions obtained by plan sponsors for these drugs as reported in the direct and indirect remuneration data set.

^aPharmacy acquisition cost data are unavailable for drugs sold in specialty pharmacies, as they are not surveyed by CMS.

¹²We omitted the nine therapeutic classes in our analysis with fewer than 10 drugs in their class: antidotes, blood modifier agents, cardiovascular agents, dermatological agents, endocrine metabolic agents, gastrointestinal agents, immunological agents, nutritive agents, and respiratory agents; these accounted for 24 generic drugs sold in specialty pharmacies.

Appendix VI: Studies and Stakeholders' Views on Effects of Utilization Management Services

This appendix contains additional details on our review of 52 peer-reviewed studies on the effects of utilization management services on (1) financial savings, (2) beneficiary health indicators, and (3) beneficiary medication adherence and access, as well as stakeholders' views on these effects.

Effect of Utilization Management Services on Financial Savings

Of the 36 studies that examined the effect of utilization management services on financial savings, 18 examined medication therapy management programs and eight examined generic substitution.¹ The two groups of studies found the following:

- **Medication therapy management programs or comprehensive medical reviews.** Thirteen of the 18 studies that examined the relationship between a medication therapy management program or comprehensive medical review and financial savings found an increase in savings.² For example, one study found that a medication therapy management program conducted by telephone decreased beneficiary drug costs by \$682 per beneficiary for participants, compared to an increase of \$119 for those not in the program.³
- **Generic and therapeutic substitution and generic dispensing rate.** Of the 8 studies that examined the relationship between generic and therapeutic substitution and financial savings, all found an

¹The other 10 studies examined the effect of various combinations of step therapy, prior authorization and medicine quantity limits on financial savings. Six of these studies found an increase in financial savings and four found no impact, a mixed impact, or a decrease in financial savings.

²The Centers for Medicare & Medicaid Services (CMS) requires medication therapy management programs for covered drugs furnished through a Part D plan. These programs are generally designed to reduce the risk of adverse drug events through discussion with targeted beneficiaries and prescriber intervention. A comprehensive medical review is a systematic process of assessing medications to identify problems, such as a change in a drug's effect when taken with another drug, and creating a plan to resolve them.

³L.R. Moczygemba, J. C. Barner, J. C. Brannier, and E. R. Gabrillo, "Outcomes of a Medicare Part D Telephone Medication Therapy Management Program," *Journal of the American Pharmacists Association*, vol. 52, no. 6 (2012): e144-e152. Nonparticipants in the program were matched to medication therapy management program participants by the beneficiary's number of chronic diseases and Part D drugs. Because this study reports outcomes from a regional Part D telephone medication therapy management program, the results may not be generalizable to all Part D plans or face-to-face medication therapy management programs.

increase in savings.⁴ For example, a 2013 study examined the potential financial savings to beneficiaries and Part D plan sponsors of generic and therapeutic substitution of commonly prescribed drugs.⁵ The study estimated that in 2007, generic and therapeutic substitutions could have resulted in an average annual savings of \$127 and \$389 per person, respectively.⁶

Additionally, eight of these 36 studies examined the generic dispensing rate, and all eight found that utilization management led to an increase in the rate.⁷ The generic dispensing rate—the percent of prescriptions dispensed with a generic drug instead of a brand-name drug—represents a source of financial savings through a reduction in the use of brand-name drugs, which are generally more expensive than generics. For example, a 2017 study analyzed 2012 Part D data to examine the impact of prior authorization and step therapy on generic use among low-income subsidy beneficiaries.⁸ This study found that those randomly assigned to

⁴Studies generally calculated potential savings by estimating the difference between the amount paid for brand-name drugs with the amount that would have been paid if generic drugs had been used.

⁵O.K. Duru, S. L. Ettner, N. Turk, C. M. Mangione, A. F. Brown, J. Fu, L. Simien, and C.W. Tseng, "Potential Savings Associated with Drug Substitution in Medicare Part D: The Translating Research Into Action for Diabetes (TRIAD) Study," *Journal of General Internal Medicine*, vol. 29, no. 1 (2014): 230-236. Generic substitution is switching a generic drug for its bioequivalent, brand-name counterpart. Therapeutic substitution is switching a generic drug for a brand-name drug that is not bioequivalent but is within the same therapeutic class.

⁶The authors noted this study may overestimate potential savings as it assumes that all beneficiaries make every substitution, which in the case of therapeutic substitution is not always medically appropriate.

⁷Of the eight studies, three looked at the effect of medication therapy management, two looked at step therapy, and three looked at the effect of both prior authorization and step therapy. The generic dispensing rate was generally measured as annual days of supply for generics divided by annual total days of supply for all drugs in the class.

⁸X. Shen, B. C. Stuart, C. A. Powers, S. E. Tom, L. S. Magder, and E. M. Perfetto, "Impact of Formulary Restrictions on Medication Use and Costs," *The American Journal of Managed Care*, vol. 23, no. 8 (2017): e265-e274. Low-income subsidy beneficiaries with annual incomes under 135 percent of the federal poverty level, and who meet other criteria, qualify for a 100 percent premium subsidy and reduced cost sharing, among other cost reductions. Prior authorization is a requirement that beneficiaries obtain approval for a drug by the pharmacy benefit manager or plan before obtaining the drug if it is to be covered by the plan. Step therapy is a requirement where more expensive drugs are covered only if beneficiaries try less expensive alternatives first and find them not to be effective.

a plan using both prior authorization and step therapy had an increased generic dispensing rate of 3 to 15 percentage points for all three classes of drugs examined.

Effect of Utilization
Management Services on
Beneficiary Health
Indicators

Twelve of the 20 studies that examined beneficiary health indicators found that utilization management services were associated with improved indicators, while the other eight found a mixed impact, no impact, or a decline.⁹ Examples of studies that looked at the association of utilization management services with beneficiary health indicators include:

- A study analyzing data from three Part D plan sponsors, which found there was a nearly 50 percent reduction in the use of potentially harmful drugs by beneficiaries 6 months after the implementation of a retrospective drug utilization review program.¹⁰
- A randomized trial of medication therapy management for Part D beneficiaries found a nearly 60 percent reduction in beneficiaries' drug therapy problems over time among two groups after the medication therapy management intervention.¹¹

⁹Studies used a range of health indicators, including reducing medications inappropriate for older adults, improved cholesterol values, and reductions in adverse drug events.

¹⁰C.I. Starner, S. A. Norman, R. G. Reynolds, and P. P. Gleason, "Effect of a Retrospective Drug Utilization Review on Potentially Inappropriate Prescribing in the Elderly," *The American Journal of Geriatric Pharmacotherapy*, vol. 7, no. 1 (2009): 11-19. This study did not use a control group, so the results may not be interpreted as the causal effect of the utilization management service. A drug utilization review program is a concurrent examination by the pharmacy benefit manager and plan sponsor of prescriptions at the time of purchase by the beneficiary to assess safety considerations, such as potential adverse interactions, and compliance with clinical guidelines (including quantity and dose).

¹¹The study examined Part D beneficiaries at three academic medical center community pharmacies and family medical clinics at three sites between December 2007 and January 2010. Examples of drug therapy problems include: incorrect dose, drug interactions, or taking the wrong drug for a beneficiary's condition. D.R. Touchette, A. L. Masica, R. J. Dolor, G. T. Schumock, Y. K. Choi, Y. Kim, and S. R. Smith, "Safety-Focused Medication Therapy Management: A Randomized Controlled Trial," *Journal of the American Pharmacists Association*, vol. 52, no. 5 (2012): 603-612.

Effect of Utilization Management Services on Beneficiary Medication Adherence and Access

Fifteen studies examined the effect of utilization management services on beneficiary medication adherence and access. Seven of the 10 studies that examined the effect of either medication therapy management programs or comprehensive medication reviews on beneficiaries' medication adherence (taking medication as prescribed) found improvement.¹² For example, a 2016 study used data from Part D and the U.S. Renal Data System to examine the relationship of medication therapy management eligibility with immunosuppressant drug adherence 12 months after beneficiaries received a kidney transplant.¹³ The study found that medication therapy management-eligible transplant recipients were 14 percent more likely to have improved adherence than transplant recipients who were not eligible. The other three studies that examined medication therapy management programs or comprehensive medication reviews found no statistically significant impact on adherence.

The effect of two other utilization management services—prior authorization and step therapy—on beneficiary medication adherence and access (the ability to obtain clinically indicated prescriptions) is unclear, according to the studies we reviewed.¹⁴ The two studies that examined the relationship of prior authorization and step therapy with adherence both found a mixed impact. For example, one study examined the impact of a health plan requiring either prior authorization or step

¹²Studies varied by the design of the programs and the definitions of medication adherence. For example, studies had varying eligibility criteria for participation—some used opt-in enrollment (eligible beneficiaries must choose to participate), while others used opt-out enrollment (eligible beneficiaries are automatically enrolled unless they decline to participate). Studies also used various measures of adherence, such as surveys of beneficiaries who reported if they stopped their medications. Other studies measured adherence using the medication possession ratio—the proportion of days' supply obtained during a time period, and considered beneficiaries above a certain proportion of days covered (e.g., 75 percent) as adherent.

¹³M.A. Chisholm-Burns, C. A. Spivey, E. A. Tolley, and E. K. Kaplan, "Medication Therapy Management and Adherence among US Renal Transplant Recipients," *Patient Preference and Adherence*, vol.10 (2016): 703-709. Immunosuppressant adherence was defined as a medication possession ratio of at least 80 percent.

¹⁴Studies used various measures of access, such as the time for medications to receive prior authorization approval or surveys of physicians on whether their patients were unable to access needed medications. Also, some studies calculated the combined effect of prior authorization and step therapy and others examined them individually.

therapy on medication use among dual-eligible nursing home residents.¹⁵ The study found that some residents whose new plan required prior authorization or step therapy for their current medication were more likely to have gaps in medication use than those without for two of six classes of drugs in 2006, but no gaps for any of the classes for in 2007 and 2008.¹⁶

The two studies that examined the relationship of prior authorization and step therapy with access found an increase in medication access problems, but they did not focus exclusively on the Medicare population.¹⁷ For example, one study used 2006 data from a random sample of psychiatrists surveyed about their patients to examine the relationship of prior authorization and step therapy with medication access problems among dual-eligible psychiatric patients. The study found that patients in plans with prior authorization and step therapy requirements were 2.8 and 1.8 times more likely, respectively, to have experienced medication access problems than patients in plans without these requirements.¹⁸ This study examined the transition of dual-eligible beneficiaries from Medicaid drug coverage to Medicare Part D when the program began in 2006, so the results may not be generalizable to the entire Medicare population at present.

¹⁵Dual-eligible beneficiaries are eligible for both Medicare and Medicaid. H.A. Huskamp, D. G. Stevenson, A. J. O'Malley, S. B. Dusetzina, S. L. Mitchell, B. J. Zarowitz, M. E. Chernew, and J. P. Newhouse, "Medicare Part D Plan Generosity and Medication Use among Dual-Eligible Nursing Home Residents," *Medical Care*, vol. 51, no. 10 (2013): 894-900.

¹⁶The two classes that were more likely to have gaps in medication use for some residents were antipsychotics and opioids. The other four classes of drugs were angiotensin receptor blockers, cholinesterase inhibitors, osteoporosis medications, and antidepressants.

¹⁷Another study that examined the relationship of only prior authorization with the time needed to access medications found no clinically significant impact.

¹⁸J.C. West, J. E. Wilk, D. S. Rae, I. L. Muszynski, M. Rubio-Stipec, C. L. Alter, K. E. Sanders, S. Crystal, and D. A. Regier, "First-Year Medicare Part D Prescription Drug Benefits: Medication Access and Continuity among Dual Eligible Psychiatric Patients," *The Journal of Clinical Psychiatry*, vol. 71, no. 4 (2010): 400-410.

Stakeholder Perspectives
on the Effect of Utilization
Management on Financial
Savings, Beneficiary
Health, Medication
Adherence and Access to
Clinically Appropriate
Medications

Most representatives of pharmacy benefit managers (PBM), Part D plan sponsors, and a manufacturer trade association we interviewed generally agreed that utilization management services resulted in financial savings by requiring the use of generic drugs. Representatives of 10 of 14 plan sponsors and six of eight PBMs we interviewed stated that utilization management services generally resulted in financial savings.¹⁹ Representatives of one Part D plan sponsor stated that its utilization management services resulted in annual savings of approximately 3 percent.

However, representatives of one Part D plan sponsor and one PBM noted that not all utilization management services result in savings. For example, they noted that improving care with medication therapy management programs may increase drug costs through increased utilization. Additionally, representatives of one Part D plan sponsor noted the savings from utilization management services in commercial plans may be greater than in Part D because the use of manufacturers' copay coupons are prohibited in federal health care programs, including Part D.²⁰ While the coupons reduce or eliminate beneficiaries' out-of-pocket co-payments for certain brand-name drugs, thereby encouraging their use, the coupons do not affect the amount that the plans pay for drugs. Therefore, to the extent that beneficiaries in their commercial plans use coupons, Part D plan sponsors have a greater incentive to employ utilization management services in these plans to reduce the use of more expensive brand-name drugs.

Representatives of Part D plan sponsors and PBMs we interviewed differed with manufacturers and, in some cases, with each other on the effects of utilization management services on various non-financial aspects of drug utilization:

- **Beneficiary health.** Representatives from all three manufacturers we interviewed stated that utilization management services negatively

¹⁹An industry-sponsored study provided to us by a PBM estimated that in 2018, PBMs would save the Part D program \$19 billion (or \$35.15 per member per month) by promoting the use of generic drugs. Actuarial Practice of Oliver Wyman, commissioned by the Glover Park Group on behalf of the Coalition for Affordable Prescription Drugs, *Savings Generated By Pharmacy Benefit Managers in the Medicare Part D Program* (June 2017). The study did not specify how the financial savings from the estimated 5 percent increase in the generic dispensing rate due to PBMs was calculated.

²⁰42 U.S.C. § 1320a-7b.

affected beneficiary health by reducing their access to necessary medications. In contrast, seven of the 11 Part D plan sponsors and four of the five PBMs that discussed the effect of utilization management services on beneficiary health stated that utilization management services generally resulted in improved beneficiary health.²¹ Representatives of certain PBMs and one Part D plan sponsor provided us examples of the ways utilization management services have improved their beneficiaries' health, such as through opioid quantity limits. One Part D plan sponsor noted that point-of-sale utilization management services warn pharmacies of therapeutic duplications, toxicities across multiple prescriptions, or interactions of certain drugs with health conditions.

- **Medication access.** Representatives from all three drug manufacturers noted that utilization management services impose limits on beneficiaries' access to drugs, while seven of nine Part D plan sponsors and three of the four PBMs who discussed this stated utilization management services had no significant restrictions on beneficiaries' access to necessary medications. Representatives from one plan sponsor noted there are appeals processes to ensure beneficiaries' access is not adversely impacted by utilization management services.
- **Medication adherence.** Representatives from all three manufacturers told us that utilization management services limit beneficiaries' adherence to their medications, such as by causing delays in therapy, while seven of eight Part D plan sponsors and all four PBMs who discussed this stated utilization management services had no adverse impact on beneficiaries' adherence to their medications. Representatives from one plan sponsor and two PBMs stated that utilization management services may have a positive impact on adherence, such as by lowering copays through generic substitution.
- **Medicare protected classes and utilization management.** Representatives from Part D plan sponsors, PBMs, and manufacturers differed in their views on the effect of Part D utilization management services restrictions on protected class drugs on beneficiary health. Representatives of two PBMs told us the effect was positive, as beneficiaries who use these drugs do not experience disruptions in therapy. Representatives of two other PBMs said there was no effect, and one said there was a negative effect—as plan

²¹ Representatives we interviewed from four other Part D plan sponsors and one PBM said utilization management services have no effect on beneficiaries' health.

sponsors were required to cover certain less effective drugs. Representatives of one PBM said that, for example, patients in commercial health plans do not have any problems accessing protected class drugs that are subject to utilization management. These representatives noted that the Centers for Medicare & Medicaid Services provides for adequate access. However, one manufacturer told us that utilization management services for HIV drugs are rightly restricted in Part D, as these services may cause disruptions in therapy, which can lead to drug resistance and poorer health outcomes.

Representatives of five Part D plan sponsors said Medicare's restrictions on the use of utilization management services for protected class drugs have had a negative impact on beneficiary health because, for example, they limit plans' ability to ensure that a prescribed drug is appropriate, such as ensuring that a cancer drug is appropriate for a beneficiary's weight. Another plan sponsor representative told us the restrictions may have a positive impact by reducing increases in medical costs, while another plan sponsor said the restrictions have had no impact.

Appendix VII: Bibliography of Peer Reviewed Studies Used in GAO's Literature Review

Abbass, I. M., E. O. Caplan, D. B. Ng, R. Kristy, C. R. Schermer, P. Bradt, J. M. Collins, W. Man, M. Chan, and B. T. Suehs. "Impact of Overactive Bladder Step Therapy Policies on Medication Utilization and Expenditures among Treated Medicare Members." *Journal of Managed Care & Specialty Pharmacy*, vol. 23, no. 1 (2017): 27-37.

Agarwal, A., R. A. Freedman, F. Goicuria, C. Rhinehart, K. Murphy, E. Kelly, E. Mullaney, M. St. Amand, P. Nguyen, and N. U. Lin. "Prior Authorization for Medications in a Breast Oncology Practice: Navigation of a Complex Process." *Journal of Oncology Practice*, vol. 13, no. 4 (2017): e273-e282.

Almodovar, A. S., D. R. Axon, A. M. Coleman, T. Warholak, and M. C. Nahata. "The Effect of Plan Type and Comprehensive Medication Reviews on High-Risk Medication Use." *Journal of Managed Care & Specialty Pharmacy*, vol. 24, no. 5 (2018): 416-422.

Alston, G., and C. Hanrahan. "Can a Pharmacist Reduce Annual Costs for Medicare Part D Enrollees?" *The Consultant Pharmacist*, vol. 26, no. 3 (2011): 182-189.

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Appendix VIII: GAO Contact and Staff Acknowledgments

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Staff Acknowledgements

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