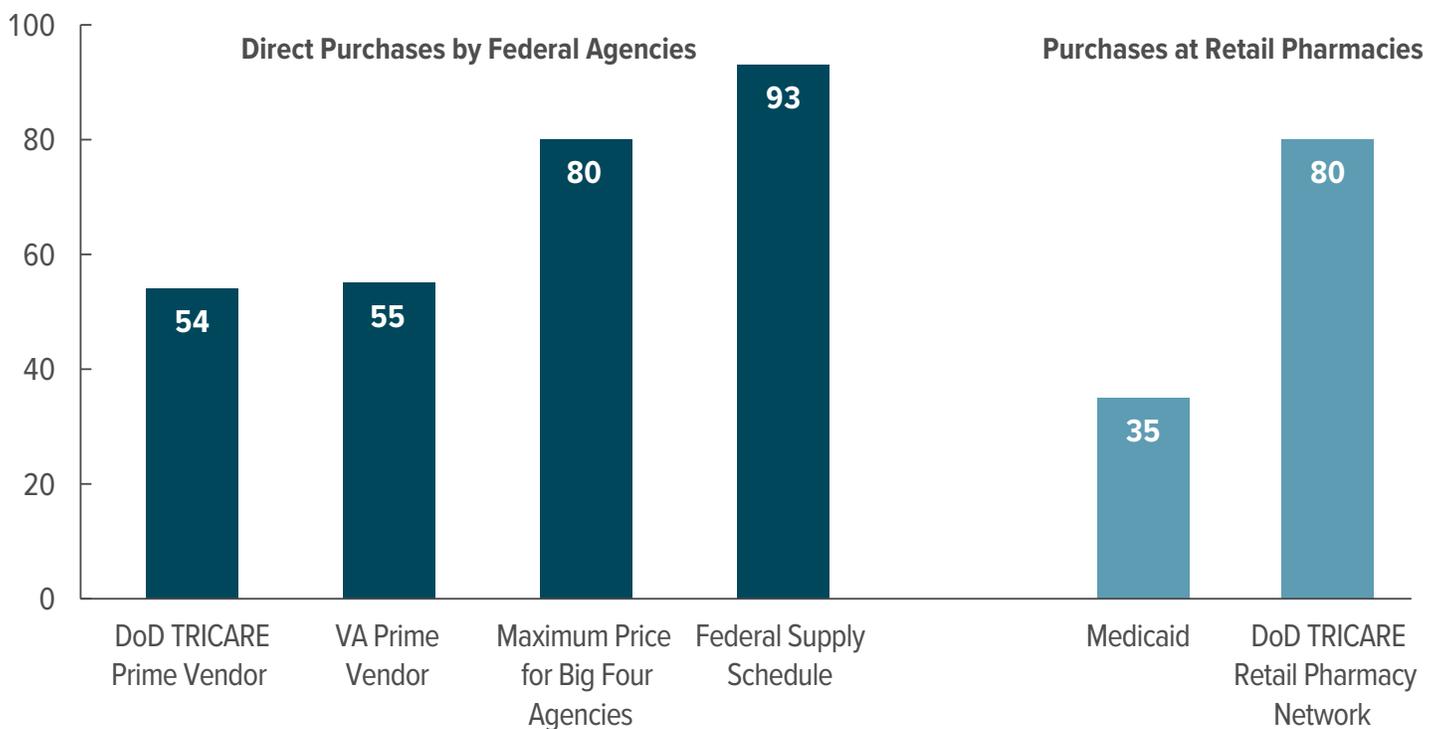




A Comparison of Brand-Name Drug Prices Among Selected Federal Programs

Average Price of Top-Selling Brand-Name Drugs As a Percentage of Their Average Net Price in Medicare Part D, 2017



At a Glance

The federal government is a major purchaser of prescription drugs, both directly through federal agencies, such as the Department of Defense (DoD), and indirectly through federal health insurance programs, such as Medicare Part D. In this report, the Congressional Budget Office describes how the prices of brand-name prescription drugs are determined in different federal programs and compares drug prices among those programs in 2017.

The main analysis focuses on the prices (net of applicable rebates and discounts) of 176 top-selling brand-name drugs in Medicare Part D. CBO computed the average price of those drugs per standardized prescription—a measure that roughly corresponds to a 30-day supply of medication.

- The average price ranged from \$118 in Medicaid to \$343 in Medicare Part D. The much lower net prices in Medicaid are the result of higher manufacturer rebates in that program than in Medicare Part D.
- The Department of Veterans Affairs (VA) and DoD each paid average prices that were between the average prices paid in Medicaid and Medicare Part D.

CBO also compared the prices of specialty drugs (from the sample of top-selling drugs), which treat chronic, complex, or rare conditions, frequently have high prices, and may require special handling or patient monitoring. The average price of specialty drugs ranged from \$1,889 in Medicaid to \$4,293 in Medicare Part D.

Those comparisons of average drug prices among federal programs do not indicate how prices would change if the method of determining prices in one program was extended to other programs. In such a scenario, drug manufacturers would very likely alter their price negotiations with purchasers in ways that could affect the prices in all federal programs and in the private sector.

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As referred to in this report, the Affordable Care Act comprises the Patient Protection and Affordable Care Act (Public Law 111-148), the health care provisions of the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152), and the effects of subsequent judicial decisions, statutory changes, and administrative actions.

In general, the drug prices presented by CBO in this report apply to calendar year 2017. But the nonfederal average manufacturer prices (non-FAMP) reflect sales made during an earlier period—for most drugs, the period beginning on October 1, 2015, and ending on September 30, 2016. Under statutory rules, the non-FAMP calculated on the basis of sales in that earlier period was used to determine the maximum prices paid in 2017 by the Big Four agencies (the Department of Veterans Affairs, the Department of Defense, the Public Health Service, and the Coast Guard, which are the four largest direct federal purchasers of prescription drugs).

The Congressional Budget Office has corrected this report since its original publication. Corrections are listed at the end of the report.



A Comparison of Brand-Name Drug Prices Among Selected Federal Programs

Summary

The federal government is a large purchaser of pharmaceuticals. In 2018, federal spending on outpatient prescription drugs accounted for more than 40 percent of total U.S. expenditures on such drugs that year.¹ Federal spending on prescription drugs consists of direct purchases by federal agencies, such as the Department of Defense (DoD), and indirect purchases through federal health insurance programs, such as Medicare Part D. The prices of prescription drugs in federal programs have important implications for the federal budget, patients, drug manufacturers and distributors, and pharmacies. Federal programs vary greatly in how the prices for prescription drugs are determined, resulting in substantial variation in those prices.

What Programs Did CBO Examine?

In this report, the Congressional Budget Office describes how the prices of brand-name prescription drugs are determined in the following federal programs and compares drug prices among those programs:

- Medicare Part D (the prescription drug program for Medicare beneficiaries);
- Medicaid;
- The Federal Supply Schedule (FSS) for pharmaceuticals program, which establishes prices available to all direct federal purchasers (federal agencies that buy drugs directly from wholesalers or manufacturers and provide their own dispensing services);
- The federal ceiling price (FCP) program, which establishes prices available to the Big Four agencies (the four largest direct federal purchasers)—the Department of Veterans Affairs (VA), DoD, the Public Health Service, and the Coast Guard;

- VA's prime vendor program; and
- DoD's TRICARE program, which consists of both the agency's prime vendor program, in which drugs are dispensed at military treatment facilities (MTFs) or by mail, and the TRICARE retail pharmacy network.

How Are Prices Determined in Those Programs?

The approaches used to determine the prices of brand-name prescription drugs vary greatly among programs.

- In Medicare Part D, private insurers (or pharmacy benefit managers operating on their behalf) and manufacturers negotiate to determine drug prices under market conditions similar to those facing commercial insurers.
- In Medicaid, manufacturer rebates that are specified by federal statute reduce drug prices.
- Prices listed on the FSS, to which direct federal purchasers have access, are determined through a combination of statutory rules and negotiation.
- The Big Four agencies generally pay lower prices than other direct federal purchasers because of a statutory cap on the prices they pay.
- VA and DoD often pay lower prices than the other Big Four agencies for drugs dispensed through their medical facilities or by mail. They obtain those lower prices primarily because they use national formularies (preapproved lists) of preferred drugs, steer patients to lower-cost drugs, and buy drugs in large volumes—all of which increase their leverage with drug manufacturers.

DoD reimburses a network of retail pharmacies for drugs dispensed to TRICARE enrollees. Drugs sold through the TRICARE retail pharmacy network are subject to mandated refunds from manufacturers that are akin to rebates in other programs. However, the prices of drugs dispensed through that network are higher than the

1. Out-of-pocket and state expenditures on outpatient prescription drugs are not included in this figure. See Centers for Medicare & Medicaid Services, "National Health Expenditures by Type of Service and Source of Funds, CY 1960–2018" (accessed June 4, 2020), <https://go.usa.gov/xGhej>.

prices of drugs dispensed through MTFs or by mail. VA also allows veterans to obtain prescription drugs at retail pharmacies through its community care program, but relatively few drugs are dispensed through that program, which is not examined in this report.

Drug manufacturers routinely offer temporary price reductions to direct federal purchasers, which can enable Big Four agencies to purchase drugs at prices below the Big Four prices (the maximum prices those agencies are required to pay) and other agencies to purchase drugs at prices below the FSS prices.

What Data and Measures of Prices Did CBO Use?

CBO compared drug prices (net of applicable rebates and discounts) among programs by computing the weighted-average price for two different samples of brand-name drugs in Medicare Part D: a sample of 176 top-selling drugs and a sample of 64 high-priced drugs. Those two samples accounted for 85 percent and 16 percent, respectively, of total spending on brand-name prescription drugs in Medicare Part D in 2017.

The net prices reflect the amounts paid by federal agencies or insurance programs plus the amounts, if any, paid out of pocket by beneficiaries. CBO also compared prices for the subset of top-selling drugs that are specialty drugs. Such drugs typically treat chronic, complex, or rare conditions, frequently have high prices, and may require special handling or patient monitoring. Because CBO used the *retail price* (the price before accounting for rebates and discounts) to identify the samples of top-selling and high-priced drugs, those samples were not skewed toward drugs with high *net prices* in Medicare Part D.

In each case, CBO computed the average price per standardized prescription—a measure that roughly corresponds to a 30-day supply of medication. The analysis compared prices from 2017, the most recent year for which data were available when the work began.

How Do Prices Compare Among Programs?

Key findings from CBO's analysis of 176 top-selling brand-name drugs include the following:

- The average net price per standardized prescription ranged from \$118 in Medicaid to \$343 in Medicare Part D. The much lower net prices in Medicaid are the result of larger manufacturer rebates in that program than in Medicare Part D.
- The average FSS price was \$317, and the average Big Four price was \$273.
- The average prices for VA and DoD were \$190 and \$184, respectively, for drugs dispensed at the agencies' medical facilities or by mail.
- The average net price in the DoD TRICARE retail pharmacy network was \$272.

Pharmacy dispensing fees are incorporated into the prices in Medicare Part D, Medicaid, and the TRICARE retail pharmacy network. However, the prices for VA and DoD (for drugs dispensed through their medical facilities or by mail) do not include the agencies' costs of dispensing drugs. Adjusting for that difference would not change the finding that the prices of brand-name drugs purchased by VA and DoD are higher than those in Medicaid and lower than those in Medicare Part D, because the best evidence is that pharmacy dispensing fees account for between 3 percent and 6 percent of the price of brand-name drugs. The estimated prices for Medicare Part D and Medicaid also include an amount retained by wholesalers, which averages about 1 percent of the price of brand-name drugs. Both VA and DoD receive discounts from their wholesalers, which are reflected in the prices estimated for this report.

Among the sample of 176 top-selling drugs, the average net price of specialty drugs was much higher than that of other drugs, ranging from \$1,889 in Medicaid to \$4,293 in Medicare Part D. The average net price of the sample of 64 high-priced drugs (most of which were specialty drugs) ranged from \$5,841 in Medicaid to \$11,484 in Medicare Part D.

The comparisons of average drug prices among federal programs in this report do not indicate how prices would change if one program's method of determining prices was extended to other programs. In such a scenario, drug manufacturers would very likely alter their price negotiations in ways that could affect prices in all federal programs and in the private sector.

How Have Price Differences Among Programs Changed Since 2003?

In an earlier report, CBO compared the prices of brand-name drugs among federal programs in 2003, which was before Medicare Part D was implemented.² In that analysis, the average net price in Medicaid for a sample of top-selling drugs was higher than the average prices

2. See Congressional Budget Office, *Prices for Brand-Name Drugs Under Selected Federal Programs* (June 2005), www.cbo.gov/publication/16634.

paid by VA and DoD. CBO used different methods in the previous report, and the agency has not fully analyzed the reasons for the differences in its findings. The increase in Medicaid rebates paid by drug manufacturers is most likely a key reason that net prices in Medicaid are now lower than those paid by VA and DoD.

How Brand-Name Drug Prices Are Determined in Different Federal Programs

There are many different purchasers of prescription drugs within the federal government, and they pay a variety of prices. Those prices reflect several factors, including statutory regulations, whether and how preferred drug formularies are used, and overall conditions in the prescription drug market that affect all purchasers, public or private. The prices of brand-name drugs in Medicare Part D are determined through negotiations between private plans and manufacturers under market conditions similar to those facing commercial insurers. Drug prices in Medicaid are heavily influenced by manufacturer rebates specified by federal statute. Drug prices in other federal programs are determined through a set of statutory rules and negotiations (see Table 1). Medicare Part D is the largest federal prescription drug program (\$88.3 billion in federal expenditures on outpatient prescription drugs in 2018), followed by Medicaid (\$21.8 billion), DoD (\$7.7 billion), and VA (\$7.2 billion).³

3. Where applicable, those estimates are net of manufacturer rebates and other discounts and do not include enrollees' cost-sharing payments. The amount for Medicare Part D, which was estimated by the staff of the Centers for Medicare & Medicaid Services' Office of the Actuary and provided to CBO, reflects gross spending on benefits including enrollees' premiums. That amount was used because the amount for total prescription drug expenditures by Medicare reported in the National Health Expenditure Accounts (NHEA) includes spending on outpatient drugs covered by Part B as well as Part D. Both the Medicare and Medicaid amounts reflect spending in calendar year 2018. The Medicaid amount includes only federal spending for Medicaid and the Children's Health Insurance Program and is taken directly from the NHEA. See Centers for Medicare & Medicaid Services, "National Health Expenditures by Type of Service and Source of Funds, CY 1960–2018" (accessed June 4, 2020), <https://go.usa.gov/xGhej>. Because data on drug spending in the NHEA excluded certain expenditures by VA and DoD, those data were not used to estimate the amounts those agencies spent on drugs. Instead, CBO used amounts reported by DoD and VA for fiscal year 2018. See Department of Defense, *Evaluation of the TRICARE Program: Fiscal Year 2020 Report to Congress* (February 2020), p. 43, <https://go.usa.gov/x7pFU> (PDF, 8.5 MB); and Department of Veterans Affairs, "FY 2020 Budget Submission"

This report estimates the prices of outpatient brand-name prescription drugs that are self-administered and typically obtained at pharmacies, including mail-order pharmacies. The report focuses on brand-name drugs because they generally have much higher prices than generics and have been the main focus of policymakers' concerns about drug prices. In 2017, about three-quarters of total spending on drugs in Medicare Part D (calculated using retail prices) was on brand-name drugs. The prices of physician-administered drugs and drugs purchased and administered in hospitals or other facilities are not included in the analysis.

Medicare Part D

The drug benefit in Medicare Part D is delivered through private insurance plans that compete on the basis of their premiums and benefit design. Two types of Part D plans are available: stand-alone plans, which only cover prescription drugs, and Medicare Advantage prescription drug plans, which cover prescription drugs and provide other Medicare benefits. For each type of plan, drug prices are determined by negotiations between plans (or their pharmacy benefit managers—PBMs) and manufacturers under market conditions similar to those affecting commercial insurers.

Part D beneficiaries obtain prescription drugs from pharmacies, which generally purchase the drugs from wholesalers (see Figure 1 on page 6). Beneficiaries typically pay a portion of the price for a prescription at the point of sale in the form of cost sharing (the amount of which depends on the plan's benefit structure and the phase of coverage the beneficiary is in). Pharmacies receive the rest of the price of a prescription from PBMs, which are private companies that manage prescription drug benefits on behalf of insurance plans (including Part D plans and commercial insurers).⁴ The amount of the payments from PBMs to pharmacies reflects the terms of service agreements that Part D plans negotiate with PBMs.

(Zip file), *Volume II: Medical Programs and Information Technology Programs* (February 10, 2020), p. VHA-167, <https://go.usa.gov/xAa6E> (PDF, 5.2 MB).

4. The flow of drugs and financial transactions in Part D is similar in many respects to what occurs in the commercial market. The discussion in this section and the summary in Figure 1 focus on the main features and most common arrangements in the market and do not reflect all types of arrangements. For example, some Part D plans (and some private insurers in the commercial market) manage their prescription drug benefits rather than contracting with a PBM. And in some cases, prescription drugs are delivered directly from manufacturers to pharmacies.

Table 1.

Comparison of Selected Federal Programs Providing Outpatient Prescription Drug Coverage

	Medicare Part D	Medicaid	VA Prime Vendor Program	DoD TRICARE Program
Eligibility	People age 65 or older who paid Medicare payroll taxes for at least 10 years; certain younger people who have received Social Security disability benefits for at least two years or who have end-stage renal disease or amyotrophic lateral sclerosis.	States are required to cover certain low-income individuals, including children and their parents, pregnant women, people with disabilities, and people age 65 or older. States may choose to cover other groups, such as low-income adults without dependent children and people receiving home- and community-based services.	Veterans who have served on active duty (including reservists) and who did not receive a dishonorable discharge may be eligible for VA health care benefits. While most such veterans qualify, their length of service, income, and service-connected disabilities may affect their access to VA health care.	Active-duty and retired military and dependents.
Where Prescriptions Are Filled	Private pharmacies, including mail-order pharmacies.	Participating private pharmacies, including mail-order pharmacies.	VA medical facilities or VA mail-order pharmacy. ^a	Military treatment facilities; TRICARE mail-order pharmacy; TRICARE retail network pharmacies; nonnetwork pharmacies.
Covered Drugs	Plan sponsors develop their own list of covered drugs subject to certain requirements. Plans may steer enrollees toward preferred drugs by requiring higher copayments or requiring prior authorization for nonpreferred drugs.	States must cover all drugs made by manufacturers that have entered into a rebate agreement with CMS, except for drugs used for a limited set of conditions specified by federal law. Each state may develop a list of preferred drugs and require prior authorization or higher copayments for drugs not on that list.	VA develops a national formulary with a list of preferred drugs and steers patients toward those drugs by requiring prior authorization and, in some cases, higher copayments for drugs not on that list.	DoD develops a national formulary with a list of preferred drugs and steers patients toward those drugs by requiring prior authorization and, in some cases, higher copayments for drugs not on that list.

Continued

The net prices ultimately paid by Part D plans for prescription drugs dispensed to beneficiaries are greatly affected by rebates that the PBMs and Part D plans receive from drug manufacturers. Those rebates are generally known only to the negotiating parties, though Part D plans must report any rebates and discounts they receive to the Centers for Medicare & Medicaid Services (CMS), the federal agency that administers the Medicare and Medicaid programs. In 2016, manufacturers paid an estimated \$27 billion in rebates to PBMs and Part D plans.⁵ PBMs can secure rebates by including a man-

ufacturer’s drug on a plan’s formulary—that is, the list of drugs covered by the plan—or by placing the drug on a tier within a plan’s formulary that requires lower cost sharing, making it more attractive to beneficiaries than competing drugs. Different tiers usually have varying cost-sharing requirements: Generic drugs typically have the lowest cost-sharing requirements, followed by preferred brand-name drugs (drugs for which the plan has negotiated a rebate in exchange for preferred status), followed by nonpreferred brand-name drugs. When several competing drugs with comparable clinical benefits are available, plans and PBMs have greater leverage to negotiate larger rebates; when a brand-name drug offers unique and substantial clinical benefits, plans and PBMs have less leverage in negotiations, and rebates tend to be smaller.

5. In Medicare Part D, PBMs pass virtually all of the rebates they negotiate with manufacturers to the plans. Under program rules, plans can account for rebates in projecting their costs of delivering the drug benefit, which enables them to reduce their bids and thus reduce the premiums they charge beneficiaries. In contrast, PBMs often retain a portion of the rebates they negotiate on behalf of commercial insurers. See Government Accountability Office, *Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and*

Utilization, GAO-19-498 (July 2019), <https://www.gao.gov/products/GAO-19-498>.



Table 1.

Continued

Comparison of Selected Federal Programs Providing Outpatient Prescription Drug Coverage

	Medicare Part D	Medicaid	VA Prime Vendor Program	DoD TRICARE Program
How Prices Are Determined	Negotiations between Part D plans (or their PBMs) and manufacturers. Plans might receive price concessions in exchange for including preferred drugs in their formularies. Manufacturers are also required to give discounts on brand-name drugs when enrollees are within a specified range of spending on covered drugs.	In fee-for-service systems, state Medicaid agencies set payments to pharmacies; in managed care arrangements, plans typically contract with a PBM to negotiate payment rates with pharmacies. In both cases, net prices are heavily influenced by rebates that drug manufacturers must pay to Medicaid.	Price available to the Big Four (minimum of federal supply schedule price and federal ceiling price) is a starting point for further potential price concessions based on inclusion in preferred drug formularies. ^b	Price available to the Big Four (minimum of federal supply schedule price and federal ceiling price) is a starting point for further potential price concessions based on inclusion in preferred drug formularies. ^b
Total Federal Expenditures in 2018 (Billions of dollars)^c	88.3^d	21.8^e	7.2^f	7.7^g

Data source: Congressional Budget Office. See www.cbo.gov/publication/56978#data.

CMS = Centers for Medicare & Medicaid Services; DoD = Department of Defense; PBM = pharmacy benefit manager; VA = Department of Veterans Affairs.

- a. In certain limited cases, veterans can obtain prescription drugs at retail pharmacies through VA's community care program.
- b. The Big Four are the four largest direct federal purchasers of prescription drugs (VA, DoD, the Public Health Service, and the Coast Guard).
- c. The amount shown for each program represents total federal expenditures on all outpatient prescription drugs, not just expenditures on brand-name drugs. Out-of-pocket expenditures, such as copayments or deductibles, are excluded.
- d. The amount for Medicare Part D is for calendar year 2018 and represents the federal government's gross spending on benefits, including enrollees' premiums. The figure for total prescription drug expenditures by Medicare reported in the National Health Expenditure Accounts includes spending on outpatient drugs covered under Part B as well as Part D. In a personal communication, CMS staff apprised CBO of the amount of spending attributed solely to Part D.
- e. The amount for Medicaid is for calendar year 2018 and includes federal expenditures for the Children's Health Insurance Program. State expenditures on those programs are not included. The amount is based on data from the National Health Expenditure Accounts maintained by CMS.
- f. The amount for VA is for fiscal year 2018. Because data on drug spending in the National Health Expenditure Accounts excluded certain expenditures by VA, those data were not used to estimate the amount the agency spent on drugs. Instead, CBO used amounts reported by VA. See Department of Veterans Affairs, "FY 2020 Budget Submission" (Zip file), *Volume II: Medical Programs and Information Technology Programs* (February 10, 2020), p. VHA-167, <https://go.usa.gov/xAa6E> (PDF, 5.2 MB).
- g. The amount for DoD's TRICARE program is for fiscal year 2018. Because data on drug spending in the National Health Expenditure Accounts excluded certain expenditures by DoD, those data were not used to estimate the amount the agency spent on drugs. Instead, CBO used amounts reported by DoD: See Department of Defense, *Evaluation of the TRICARE Program: Fiscal Year 2020 Report to Congress* (February 2020), p. 43, <https://go.usa.gov/x7pFU>.

Net prices in Part D can also be reduced by discounts that manufacturers are required to provide to beneficiaries on brand-name drug costs incurred in the "coverage gap" of the Part D benefit. Before 2011, the standard Part D benefit did not cover the costs for any drugs purchased in that phase of the benefit, but the Affordable Care Act (ACA) gradually eliminated the gap in coverage, beginning in 2011.⁶ To help finance the phasing out

of the coverage gap, the law required drug manufacturers to provide a 50 percent discount on brand-name drugs purchased by enrollees when their spending on covered drugs placed them in that phase of the Part D benefit.

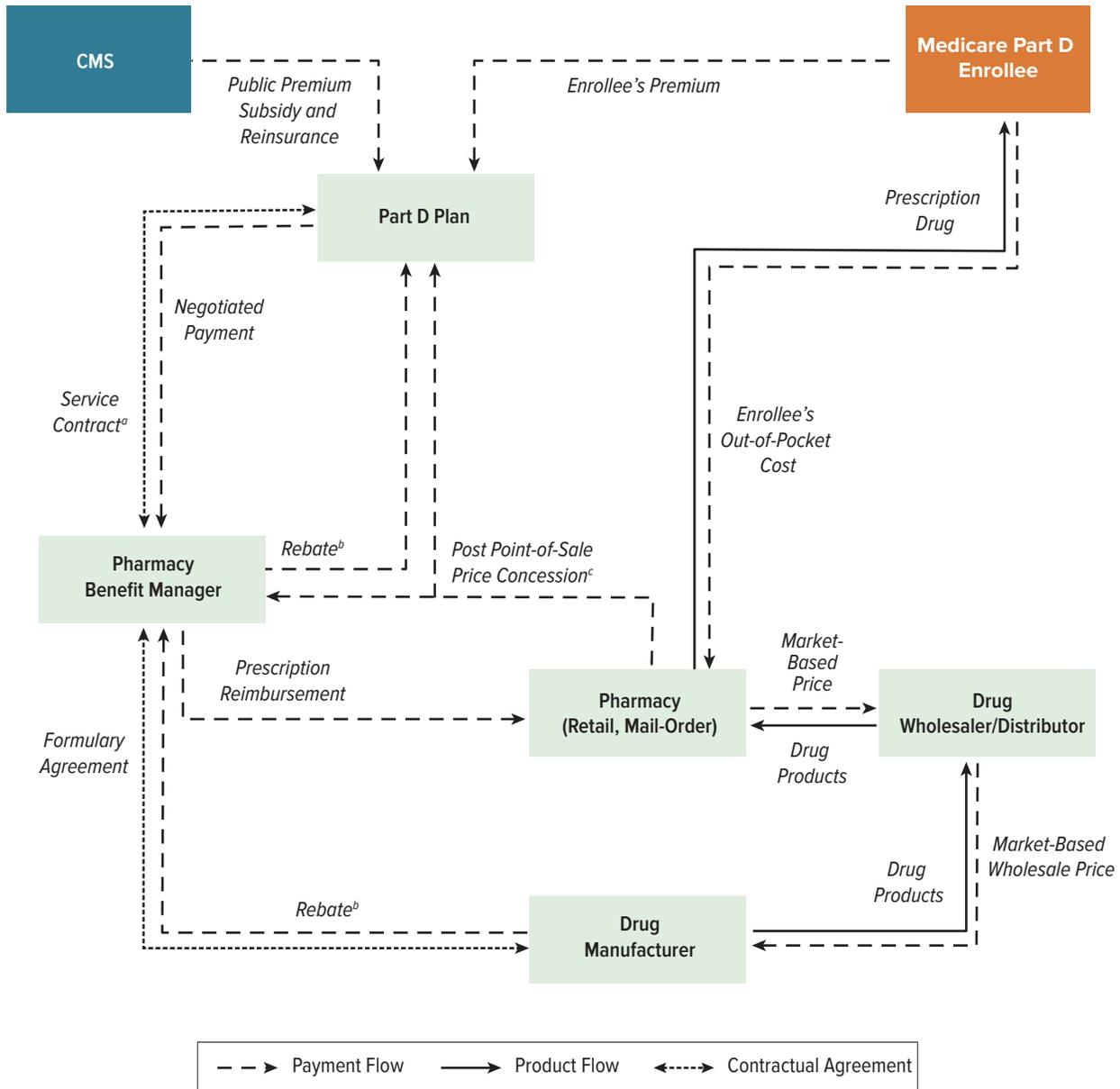
out-of-pocket costs for such spending during the year. Those thresholds are updated annually. The amount of cost sharing required for a given prescription in the coverage gap fell over the 2011 to 2019 period; since 2019, the standard benefit requires enrollees to pay 25 percent of drug costs in the coverage gap. Although the coverage gap has been eliminated, the term *coverage gap* is still defined in federal law to refer to that phase of the benefit.

6. In 2017, the coverage gap began when an enrollee incurred \$3,700 in total covered drug spending (valued at retail prices) and ended when the enrollee had incurred \$4,950 in



Figure 1.

Medicare Part D's System for Purchasing Brand-Name Outpatient Prescription Drugs



Data source: Congressional Budget Office, adapted from Kaiser Family Foundation, *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain* (prepared by Health Strategies Consultancy, March 2005), <https://tinyurl.com/y63m7ck2>.

CMS = Centers for Medicare & Medicaid Services.

- a. Many Part D plans own their pharmacy benefit managers.
- b. A recent analysis found that in 2016, pharmacy benefit managers passed nearly all the rebates they received from manufacturers on to the Part D plans. See Government Accountability Office, *Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization*, GAO-19-498 (July 2019), www.gao.gov/products/gao-19-498.
- c. Price concessions from pharmacies after the point of sale take the form of periodic payments from pharmacies to the plans or to pharmacy benefit managers.

Legislation enacted in 2018 increased the required manufacturer discount from 50 percent to 70 percent.⁷

Furthermore, net prices in Part D are often reduced by price concessions from pharmacies after the point of sale, which take the form of periodic payments from pharmacies to the plans or to PBMs. Pharmacies are frequently willing to make those price concessions in exchange for being included in a plan's preferred pharmacy network.⁸ Price concessions from pharmacies are generally much smaller than manufacturer rebates. In 2016, total pharmacy price concessions after the point of sale amounted to an estimated \$2.1 billion.⁹

The market conditions facing Part D plans differ from those facing commercial insurers in two important ways that have offsetting effects on the net prices that both groups pay. First, Part D plans are subject to more stringent regulations than commercial insurers with respect to the coverage of certain drugs. Specifically, Part D plans are required to cover all drugs in six "protected" therapeutic classes.¹⁰ (A therapeutic class is a group of drugs that treats a common condition.) That requirement increases beneficiaries' access to those drugs, but it also reduces the ability of plans to obtain rebates for them.¹¹ Plans have the greatest leverage to obtain sizeable rebates from drug manufacturers when they can credibly

threaten to exclude a drug from their formulary, but that threat is eliminated for the drugs in the protected classes, which the plans must cover.¹² If Part D plans could exclude more drugs from their formularies, the resulting savings might be passed on to beneficiaries in the form of lower plan premiums as plans competed for enrollees.

The second way in which the market conditions facing Part D plans differ from those facing commercial insurers concerns the rebates required by law under the Medicaid program (discussed below). The Medicaid rebate for a particular drug depends partly on the lowest net price offered to a commercial buyer. That makes it costly for drug manufacturers to extend large rebates to commercial insurers because the same rebate would be applied to purchases in Medicaid. Prices in Part D are not included in the calculation of Medicaid rebates, so it is less costly for a manufacturer to offer a large rebate to a Part D plan than to a commercial insurer. Because of that difference, CBO expects that, on balance, net prices for Part D plans are lower on average than those for commercial insurers for the same set of drugs.

Manufacturers typically sell drugs to wholesalers at a negotiated discount from a list price, known as the wholesale acquisition cost (WAC), that the manufacturers establish. Either the WAC or another list price, the average wholesale price (AWP), serves as the basis for negotiations between wholesalers and pharmacies. The WAC and the AWP are both publicly available, but the prices that wholesalers pay manufacturers and the prices that pharmacies pay wholesalers are known only to the negotiating parties.¹³

The original design of the Part D program gave plans incentives to limit drug utilization and to negotiate low prices for drugs because that enabled them to charge

7. Manufacturers are not required to provide coverage-gap discounts for beneficiaries who receive assistance with their premiums and cost sharing under the Low-Income Subsidy program. For more information on coverage-gap discounts, see Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* (March 2020), Chapter 14, www.medpac.gov/-documents/-reports.
8. See Deana Bell and Tracy Margiott, *Medicare Part D DIR: Direct and Indirect Remuneration Explained*, Milliman White Paper (Milliman, January 2018), <https://tinyurl.com/y2jq4mvw> (PDF, 225 KB).
9. See Government Accountability Office, *Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization*, GAO-19-498 (July 2019), www.gao.gov/products/GAO-19-498.
10. The six classes are immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic (cancer) drugs.
11. According to one study, plans are much less likely to obtain rebates for drugs in the protected classes than for other brand-name drugs. See Nicholas J. Johnson, Charles M. Mills, and Matthew Kridgen, *Prescription Drug Rebates and Part D Drug Costs* (Milliman, July 2018), <https://tinyurl.com/y34aw4lu> (PDF, 138 KB).

12. The same would be true if the federal government itself negotiated with manufacturers. To secure prices that are more favorable than the net prices negotiated by Part D plans, the federal government would need to be able to exclude certain drugs from coverage or have another form of leverage with manufacturers.

13. For more information on the WAC and AWP, see Steven M. Lieberman and Paul B. Ginsburg, *Would Price Transparency for Generic Drugs Lower Costs for Payers and Patients?* (Brookings Institution, June 2017), <https://tinyurl.com/yaztarp8> (PDF, 377 KB); and Kaiser Family Foundation, *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain* (prepared by Health Strategies Consultancy, March 2005), <https://tinyurl.com/y63m7ck2>.

lower premiums and attract more enrollees.¹⁴ Plans are at financial risk for a portion of the drug costs incurred by their enrollees—that is, the plans lose money if the costs they incur are greater than they projected. However, the share of drug costs for which plans are at financial risk has declined over the years, which has reduced the plans' incentives to limit total expenditures, because a greater share of risk is borne by the Medicare program than by the plans. From 2007 to 2017, the share of basic benefit costs for which plans were responsible fell from 53 percent to 29 percent among enrollees without Part D's low-income subsidy and from 30 percent to 19 percent for enrollees receiving that subsidy.¹⁵ The reinsurance provision of the Part D program has contributed to those changes. (Under the reinsurance provision, the Medicare program pays nearly all of the drug costs for a beneficiary after the total drug spending for that person exceeds a specified threshold.)

Medicaid

Medicaid is an entitlement program, jointly funded by the states and the federal government, that pays for health care services on behalf of certain low-income individuals. The states administer the program under broad federal guidelines. Some Medicaid beneficiaries receive drug benefits through fee-for-service systems, and others receive them through private managed care plans, depending on state policy (and in some cases, depending on beneficiaries' choices of whether to enroll in a managed care plan). In both cases, net prices in Medicaid are heavily influenced by the Medicaid drug rebate program, which specifies the rebates that drug manufacturers must pay to state Medicaid agencies.

In Medicaid fee-for-service systems, the flow of drugs is similar to that in Medicare Part D, but some of the financial transactions are much different. Beneficiaries, who pay a modest copayment or none at all, obtain drugs from participating pharmacies, which typically purchase them from wholesalers (see Figure 2). The pharmacies receive payment from a state Medicaid agency based on each state's formula for the cost of acquiring and dispensing the drug.

For Medicaid beneficiaries who receive their drug benefits through a managed care plan, the state Medicaid agency pays a predetermined payment per enrollee to the plan to cover the expected cost of drugs and other benefits. Medicaid managed care plans often contract with a PBM to negotiate payment rates with pharmacies, oversee preferred drug lists, and pay pharmacies for the drugs they dispense. The PBMs are not required to use the same payment rates that the state Medicaid agency uses to pay pharmacies for drugs delivered through a fee-for-service system, although they are required by law to pay pharmacies rates that are high enough to ensure appropriate access for the managed care enrollees.

State Medicaid agencies receive the rebates specified in the Medicaid drug rebate program directly from the manufacturers for drugs delivered through fee-for-service systems and managed care plans. Amounts collected under the federal rebate program are shared by the federal government and states partly on the basis of the federal medical assistance percentage, which is the share of Medicaid spending in each state paid by the federal government.¹⁶

There are two components to the rebate defined in federal statute. The first, called the basic rebate, is the larger of either a flat rebate amount—currently 23.1 percent of the average manufacturer price (AMP) of a brand-name drug—or the difference between the AMP and the “best price” (the lowest net price extended to any private buyer, excluding Part D plans).¹⁷ In other words, if the brand-name drug manufacturer offers certain

14. Part D plans use various utilization management tools to limit spending on drugs, such as prior authorization (in which beneficiaries and their physicians must obtain approval from the plan before it will cover a particular drug) and step therapy (in which beneficiaries must try a less expensive drug first to see if it is effective when a more expensive drug is prescribed).

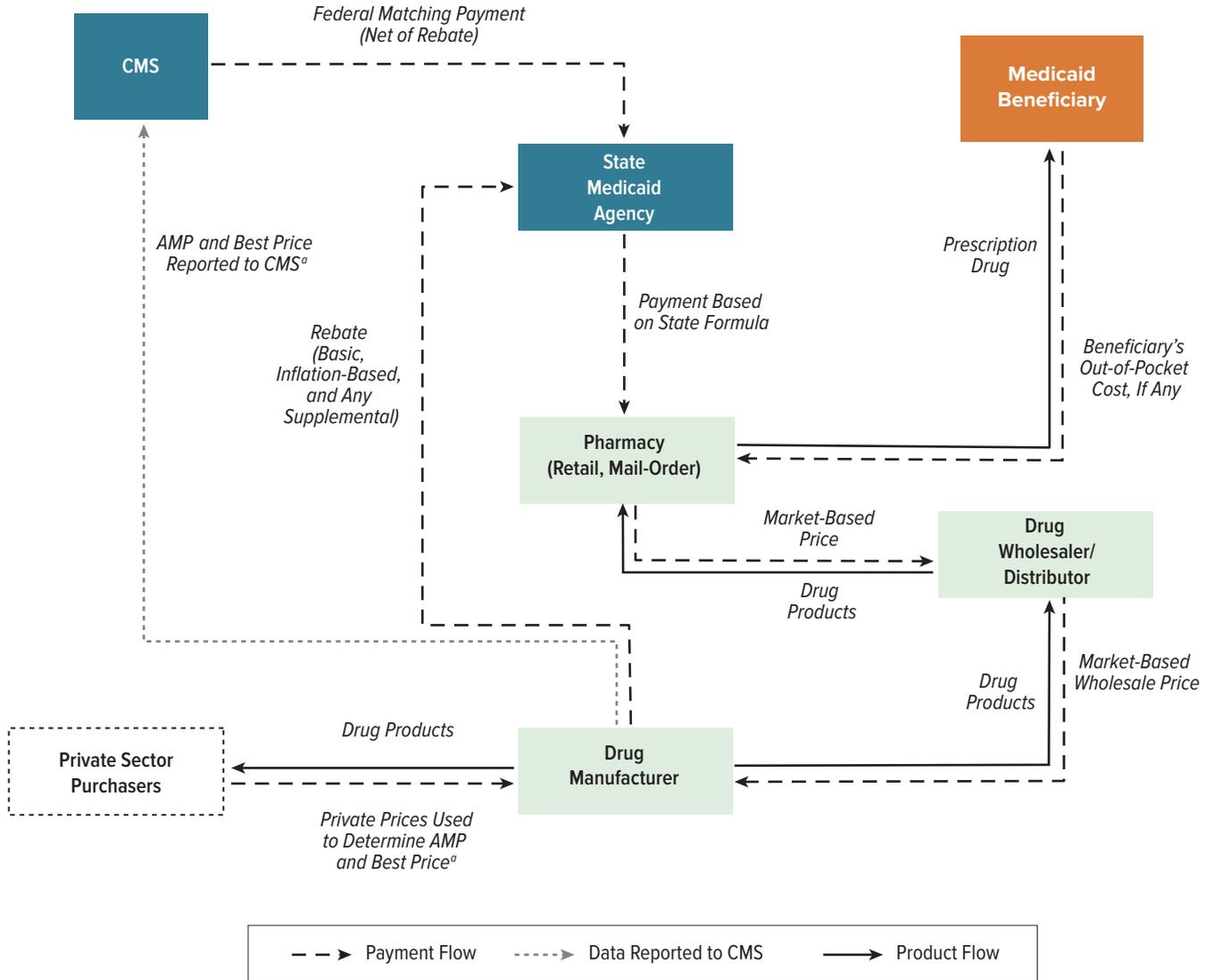
15. See Medicare Payment Advisory Commission, *Report to the Congress: Medicare and the Health Care Delivery System* (June 2020), Chapter 5, www.medpac.gov/-documents-/reports.

16. The federal medical assistance percentage is determined by a formula that gives higher federal payment shares to states with lower per-capita income. The minimum federal share is 50 percent of a state's Medicaid spending. Before the ACA was implemented, states and the federal government split drug rebates under the federal rebate program entirely on the basis of the federal medical assistance percentage. The ACA revised the method used to calculate those rebates by increasing the flat rebate for brand-name drugs and making certain other changes. Increases in the total amount of drug rebates that are attributable to those changes are not shared with the states.

17. As a condition of participation in the Medicaid drug rebate program, drug manufacturers must report the AMP and the best price to CMS on a quarterly basis. The two prices must be reported for each respective dosage form (capsule versus tablet, for example) and strength (10 milligrams versus 20 milligrams, for example) of all prescription drugs purchased on behalf of Medicaid beneficiaries. Those prices, which are not made available to the public, are used to determine manufacturers' rebate obligations. Prices in Medicare Part D plans are not included in the best price.

Figure 2.

Medicaid’s Fee-for-Service System for Purchasing Brand-Name Outpatient Prescription Drugs



Data source: Congressional Budget Office.

This figure depicts the main features of the flow of drug products and payments in a fee-for-service Medicaid system. Many states use pharmacy benefit managers (PBMs) to help administer drug benefits, develop preferred drug lists, and negotiate supplemental rebates with drug manufacturers, though PBMs are not depicted here. In states where Medicaid beneficiaries receive drug benefits through a managed care plan, the purchasing arrangements are different. Many such plans contract with a PBM to negotiate payment rates with pharmacies, negotiate additional rebates with manufacturers (beyond those required by federal statute), develop preferred drug lists, and pay pharmacies for the drugs they dispense.

AMP = average manufacturer price; CMS = Centers for Medicare & Medicaid Services.

a. The best price is the lowest net price at which a drug is offered to any private buyer. It is used to compute rebates in the Medicaid program.

private-sector purchasers a rebate that exceeds 23.1 percent of the AMP, then the basic rebate received by Medicaid is increased to match that larger private-sector rebate.¹⁸ That rebate can make it more costly for manufacturers to offer discounts to buyers in the private sector and can result in higher prices there for some brand-name drugs, particularly those with a large market share in Medicaid.¹⁹

The second part of the Medicaid rebate is based on the rate of increase in the AMP. If the AMP grows faster than overall inflation as measured by the consumer price index for all urban consumers (CPI-U), the excess amount of that growth is owed as an additional rebate.²⁰ That inflation-based rebate ensures that the net prices manufacturers receive for drugs purchased by Medicaid beneficiaries do not increase faster than the rate of inflation. Federal law caps the sum of the basic rebate and the inflation-based rebate at 100 percent of the AMP.²¹

In addition to the basic and inflation-based rebates, states and Medicaid managed care plans may negotiate for supplemental rebates beyond those statutory rebates by using preferred drug lists.²² Medicaid programs cover drugs that are not on preferred drug lists, but they often require step therapy or prior authorization for such drugs. Furthermore, to receive payment for drugs in Medicaid, drug manufacturers must participate in the

340B Drug Pricing Program, which is not included in the analysis in this report (see Box 1).

State Medicaid programs must cover all prescription drugs made by manufacturers that have entered into a rebate agreement with CMS except for drugs that are used for certain conditions specified in federal law. Although most drug manufacturers choose to participate in the Medicaid drug rebate program, they are not obligated to do so. If a manufacturer chooses not to participate, states receive no federal Medicaid payment for any of that company's drugs, and state Medicaid agencies may choose not to cover those drugs.

Direct Federal Purchasers

Some federal health care programs purchase prescription drugs directly from manufacturers or wholesalers and provide their own dispensing arrangements for patients. The four largest direct federal purchasers, collectively known as the Big Four agencies, are VA, DoD, the Public Health Service (including the Indian Health Service), and the Coast Guard. Other direct federal purchasers include the Bureau of Prisons, the Peace Corps, Immigration and Customs Enforcement, the National Aeronautics and Space Administration, and the Department of State. Prices for direct federal purchasers are determined through a combination of statutory rules and negotiation (see Figure 3).

Federal Supply Schedule Prices. All direct federal purchasers have access to prices listed on the FSS, which are publicly reported prices determined by negotiation between VA (on behalf of all direct federal purchasers) and drug manufacturers. The FSS is intended to allow direct federal purchasers to buy brand-name drugs at prices equal to or below the lowest prices negotiated between manufacturers and their most-favored commercial customers, defined as the customers that receive the best discount or price agreement.²³ Drug manufacturers must have their brand-name drugs listed on the FSS to sell them to direct federal purchasers or through the Medicaid program. During a multiyear contract period, an FSS price may not increase faster than the net price charged to the most-favored commercial customer.

18. For generic drugs, manufacturers pay a rebate equal to 13 percent of the AMP, with no associated best price provision.

19. See Mark Duggan and Fiona M. Scott Morton, "The Distortionary Effects of Government Procurement: Evidence From Medicaid Prescription Drug Purchasing," *Quarterly Journal of Economics*, vol. 121, no. 1 (February 2006), pp. 1–30, <http://dx.doi.org/10.1093/qje/121.1.1>.

20. The inflation-based rebate is computed on the basis of the growth of the AMP relative to the CPI-U from a base period, which for each drug is either the quarter in which the drug entered the market or the quarter before the federal drug rebate program began, whichever is later.

21. According to one analysis, the statutory rebate would have exceeded the AMP for nearly 20 percent of brand-name drugs in the fourth quarter of 2015 if not for the cap. See Medicaid and CHIP Payment Access Commission, *Report to Congress on Medicaid and CHIP* (June 2019), pp. 6–7, <https://go.usa.gov/xAaKS>.

22. Supplemental rebates are much smaller than the statutory rebates. CBO did not include supplemental rebates in this analysis, because data are not available on the amount of those rebates for specific drugs.

23. The FSS price does not have to equal the most-favored commercial customer price in all cases. The former is a negotiated price and can be higher or lower than the latter. FSS prices change throughout the year as prescribed in individual FSS contracts.

Box 1.

The 340B Drug Pricing Program

The 340B Drug Pricing Program requires drug manufacturers to give discounts on their outpatient drugs to certain hospitals and health centers, called covered entities, that serve low-income or underserved populations. All drug manufacturers that participate in Medicaid must also participate in the 340B program, which was created by the Veterans Health Care Act of 1992 as Section 340B of the Public Health Service Act.

In 2010, eligibility for the 340B program expanded to include more kinds of facilities, such as critical access hospitals and rural referral centers, that provide health care services to people in remote areas. And because the proportion of Medicaid patients that a facility serves is a factor in determining its eligibility for the 340B program, expansions in Medicaid under the Affordable Care Act have also accelerated the program's growth. Discounts in the 340B program apply to both self-administered drugs and physician-administered drugs, and covered entities can dispense drugs through in-house pharmacies, through community pharmacies with which they have contracts (referred to as contract pharmacies), or both. In 2010, the Department of Health and Human Services' Health Resources and Services Administration (HRSA) changed its guidance to allow covered entities to use multiple contract pharmacies (instead of just one) to provide their 340B drugs.¹ As a result, the number of contract pharmacies has grown substantially. Because of all of those changes, purchases at discounted 340B program prices, known as ceiling prices, have increased rapidly in recent years, from \$12 billion in 2015 to \$24 billion in 2018.²

1. See Medicare Payment Advisory Commission, *Report to the Congress: Overview of the 340B Drug Pricing Program* (May 2015), <https://go.usa.gov/x74Gw> (PDF, 496 KB).

2. For the 2015 estimate, see Department of Health and Human Services, Health Resources and Services Administration, *Fiscal Year 2018:*

The 340B ceiling price is the maximum price a manufacturer can charge for a drug in the 340B program. The ceiling price for each covered outpatient drug is the difference between the drug's average manufacturer price and a rebate amount that is calculated using the Medicaid rebate formula. Covered entities may also negotiate prices lower than the 340B ceiling price. The discounts under the 340B program only affect the prices that covered entities pay manufacturers (that is, they do not directly affect the price paid by the beneficiary).

Discounted prices within the 340B program represent the actual prices at which manufacturers must sell their drugs to covered entities and are intended to subsidize safety-net services, such as uncompensated care; however, covered entities receive those discounts on drugs dispensed to all of their patients, not just their low-income or uninsured ones. There are no restrictions on the prices that covered entities charge insurers, though covered entities are required to make certain that manufacturers are not charged duplicate discounts for drugs dispensed to Medicaid beneficiaries. Although systems are in place to prevent such duplicate discounts, the greater use of contract pharmacies and the larger number of Medicaid beneficiaries in managed care plans have made preventing them difficult. Some critics assert that the 340B program has become too large for HRSA to oversee.³

Justification of Estimates for Appropriations Committees (June 2018), <https://go.usa.gov/xsCp6> (PDF, 3.1 MB). For the 2018 estimate, see Department of Health and Human Services, Health Resources and Services Administration, *Fiscal Year 2021: Justification of Estimates for Appropriations Committees* (June 2020), <https://go.usa.gov/x74Gu> (PDF, 4.5 MB).

3. See Medicaid and CHIP Payment and Access Commission, *The 340B Drug Pricing Program and Medicaid Drug Rebate Program: How They Interact* (May 2018), <https://go.usa.gov/x747C> (PDF, 204 KB).

Although prices on the FSS are available to all direct federal purchasers, agencies using the FSS to buy prescription drugs do not necessarily pay those prices. Manufacturers routinely offer direct purchasers discounts called temporary price reductions, which can be extended to a single purchaser, multiple purchasers, or all purchasers that use the FSS.²⁴

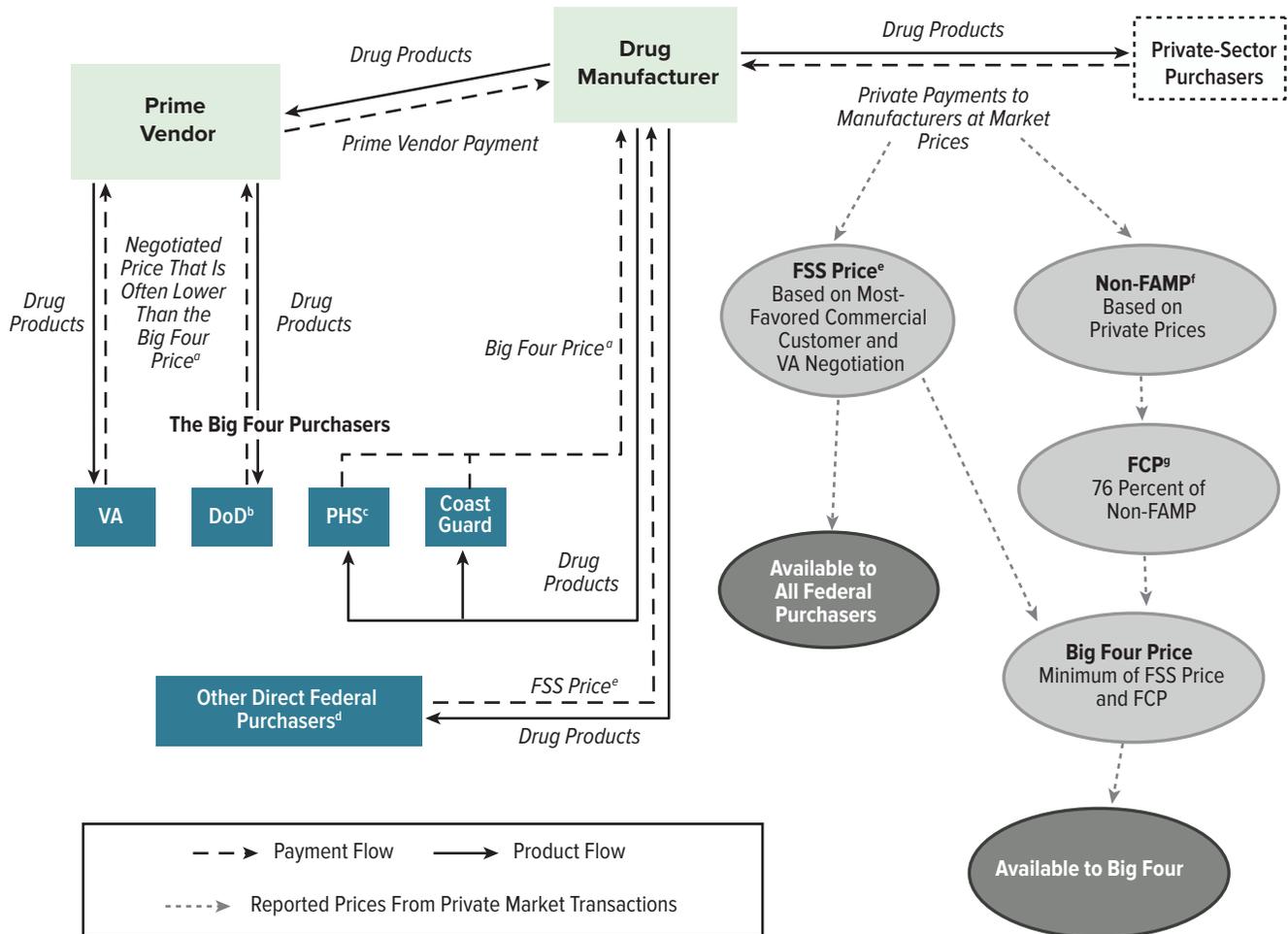
24. See Department of Veterans Affairs, Office of Inspector General, *The Impact of Allowing Government Agencies to Be Excluded*

Big Four Agencies. Under the FCP program, VA, DoD, the Public Health Service, and the Coast Guard can obtain certain statutory discounts that can bring their prices below those on the FSS. Those further discounts are based on prices that manufacturers selling prescription drugs to direct federal purchasers are required to

From Temporary Price Reductions on Federal Supply Schedule Pharmaceutical Contracts, Report 18-04451-06 (October 30, 2019), <https://go.usa.gov/x7cJX>. (PDF, 2.1 MB).

Figure 3.

Direct Federal Purchasers' System for Buying Brand-Name Outpatient Prescription Drugs



Data source: Congressional Budget Office.

- a. The Big Four price is the maximum price a drug manufacturer is allowed to charge the Big Four federal agencies, which are the Department of Veterans Affairs (VA), the Department of Defense (DoD), the Public Health Service (including the Indian Health Service), and the Coast Guard. It is the lower of the Federal Supply Schedule price and the federal ceiling price, minus any additional price concessions. VA and DoD often pay prices that are lower than the Big Four prices, primarily because they use national formularies of preferred drugs, they steer patients to lower-cost drugs, and they buy drugs in large volumes—all of which increase their negotiating leverage with drug manufacturers.
- b. This represents drugs dispensed from DoD military treatment facilities and the TRICARE mail-order pharmacy, but not dispensed through the TRICARE retail pharmacy network.
- c. The Public Health Service (PHS) includes the Indian Health Service.
- d. Included among the other direct federal purchasers are the Bureau of Prisons, the National Aeronautics and Space Administration, the Department of State, and other federal agencies and institutions.
- e. Federal Supply Schedule (FSS) prices are determined through a combination of statutory rules and negotiation between VA and drug manufacturers.
- f. The nonfederal average manufacturer price (non-FAMP) is the average price wholesalers pay manufacturers for drugs distributed to nonfederal purchasers, reflecting discounts but excluding any prices found by the Secretary of the VA to be merely nominal.
- g. The federal ceiling price (FCP) is equal to 76 percent of a drug's non-FAMP in the previous year minus an additional amount if the non-FAMP grew more quickly than inflation as measured by the consumer price index for all urban consumers.

report to VA. The nonfederal average manufacturer price (non-FAMP) is the average price paid to manufacturers by wholesalers for drugs distributed to nonfederal purchasers, reflecting discounts but excluding any prices found by VA to be merely nominal (for example, in the case of drugs delivered to charities).²⁵ The non-FAMP is used to set a cap—the FCP—on how much manufacturers can charge the Big Four. The FCP is equal to 76 percent of a drug’s non-FAMP in the previous year, minus an additional amount if the non-FAMP grew more quickly than the CPI-U during the previous one-year period.

The Big Four price for a particular drug—the maximum price a drug manufacturer is allowed to charge the Big Four agencies—is the lower of the FSS price or the FCP.²⁶ In many cases, the Big Four agencies can pay even lower prices if they benefit from a temporary price reduction of the FSS price or, in the case of VA and DoD, if they use formularies of preferred drugs and other means, as discussed below.

Department of Veterans Affairs. VA purchases prescription drugs directly through a wholesaler, known as a prime vendor, that is selected through a competitive bidding process. VA operates an integrated health care delivery system that generally provides health care benefits directly to enrolled veterans at its medical facilities and also through agreements with community providers. Patients usually obtain their prescription drugs by mail or at pharmacies in VA medical facilities.

VA obtains discounts in many cases that lead to prices lower than the Big Four price. Those discounts result primarily from VA’s use of its national formulary, in which the agency agrees to the preferred or exclusive use of certain drugs, within a class of drugs, on the basis of safety, efficacy, and price. VA has direct administrative influence over health care providers in its integrated system, so in many cases it is well positioned to strongly encourage the use of a preferred drug. Manufacturers are often willing to make major price concessions not only to achieve a higher sales volume from VA but also because VA facilities train many medical residents and fellows, and inclusion on the formulary could influence future prescribing behavior outside VA. In addition to discounts from manufacturers, VA also receives discounts from its prime vendor for prompt payment.

Department of Defense. TRICARE is DoD’s health care program for active-duty service members and their families, military retirees and their families, and certain other beneficiaries. Under the TRICARE program, beneficiaries can fill prescriptions at military treatment facilities, through the TRICARE mail-order pharmacy (TMOP), at pharmacies in the TRICARE retail pharmacy network, or at nonnetwork pharmacies.²⁷ DoD has access to the Big Four prices (as described above). Like VA, it can obtain further discounts by using preferred drug formularies, and its prime vendors are selected through a competitive bidding process.²⁸

DoD is a direct federal purchaser (through its prime vendors) of drugs dispensed through MTFs and TMOP but not of drugs dispensed through the TRICARE retail pharmacy network. In the latter program, DoD reimburses community pharmacies that dispense drugs to TRICARE enrollees. The 2008 National Defense Authorization Act requires drugs dispensed through the TRICARE retail pharmacy network to be treated as if they were purchased by DoD, and therefore they must be priced according to the rules of the FCP program. Drugs sold through that network are subject to

25. The non-FAMP is similar to the AMP, which drug manufacturers are required to report to CMS to have their drugs covered by the Medicaid program, but there are some differences in how the two are defined. First, manufacturers report the AMP to CMS, whereas the non-FAMP is reported to VA. Moreover, the non-FAMP includes several adjustments (to reflect prompt-pay discounts and free goods, for example) that the AMP does not include. Lastly, the AMP considers only drugs sold at retail pharmacies, whereas the non-FAMP has no such restriction. Therefore, the non-FAMP includes drugs that are sold to wholesalers and are eventually dispensed through retail pharmacies, mail-order pharmacies, health care providers, and other non-retail pharmacies.

26. Drug manufacturers sometimes agree to offer all direct federal purchasers a single price for a drug. In those cases, the FSS price and the Big Four price are identical. (For those drugs, the FSS price must be less than or equal to the FCP.) In other cases, often when the FSS price is greater than the FCP, drug manufacturers charge non-Big Four agencies one price and Big Four agencies another price.

27. To fill a prescription at a nonnetwork pharmacy, beneficiaries must pay the full price and file a claim for reimbursement, which is subject to a deductible and out-of-network cost sharing. Spending through nonnetwork pharmacies represented less than 0.2 percent of net retail drug spending within TRICARE in 2017. CBO did not include prices for sales in nonnetwork pharmacies in its analysis, because the agency did not have data on those prices.

28. Drugs sold at TRICARE network and nonnetwork retail pharmacies are not part of the prime vendor program.

mandated refunds from manufacturers. Those refunds, akin to rebates in other programs, are calculated as the difference between the annual non-FAMP and the FCP, plus any further discounts provided by the manufacturer to receive preferred formulary placement for drugs in certain therapeutic classes. However, DoD generally pays higher net prices for drugs dispensed through the TRICARE retail pharmacy network than for those dispensed through MTFs or TMOP. In fiscal year 2017, prescriptions dispensed through TMOP accounted for 50 percent of DoD's total spending on outpatient prescription drugs in TRICARE, compared with 23 percent for prescriptions dispensed through MTFs and 27 percent for prescriptions dispensed through retail pharmacies.²⁹

How Drug Prices in Different Segments of the Market Are Related

The methods used to determine prescription drug prices in federal programs can affect drug manufacturers' decisions about the list prices and rebates they offer in the private sector. Those decisions, in turn, can affect net prices paid in some federal programs. For example, the best-price component of the Medicaid rebate makes it more costly for drug manufacturers to offer large discounts to private payers because the manufacturers would have to offer the same discounts to Medicaid if those discounts exceeded 23.1 percent of the AMP. An analysis by CBO found that the introduction of the Medicaid drug rebate program in 1991 increased the net prices paid by some private payers.³⁰ Another analysis found that the Medicaid drug rebate program raises private payers' prices for drugs when sales through Medicaid are a large share of the drugs' total sales.³¹ The policies that determine prices for direct federal purchasers may have a similar effect on prices in the private sector.

29. The share of spending on prescription drugs dispensed at retail pharmacies is net of the refunds that DoD receives from manufacturers. See Department of Defense, *Evaluation of the TRICARE Program: Fiscal Year 2020 Report to Congress* (February 2020), p. 43, <https://go.usa.gov/x7pFU>.

30. See Congressional Budget Office, *How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry* (January 1996), www.cbo.gov/publication/14944.

31. See Mark Duggan and Fiona M. Scott Morton, "The Distortionary Effects of Government Procurement: Evidence From Medicaid Prescription Drug Purchasing," *Quarterly Journal of Economics*, vol. 121, no. 1 (February 2006), pp. 1–30, <http://dx.doi.org/10.1093/qje/121.1.1>.

The inflation-based component of the Medicaid rebate discourages drug manufacturers from raising the AMP faster than the CPI-U once a drug is on the market. It also encourages them to set higher prices for new drugs than they otherwise would.

The price comparisons in this report do not indicate what prices would result if one federal program adopted the pricing approach currently used by another program, because changes to current laws or regulations could alter manufacturers' overall pricing choices. To analyze the effects of such changes in law, CBO would account for likely changes in manufacturers' pricing decisions.

How Brand-Name Drug Prices Vary Among Federal Programs

The prices of brand-name prescription drugs vary greatly by program. Among the federal programs in this analysis, the lowest average net prices were paid in Medicaid because of the large rebates obtained from manufacturers, as specified by law. Direct federal purchasers such as VA and DoD, whose prices are determined by a combination of statutory rules and negotiations, generally paid higher net prices than those in Medicaid. The highest net prices were paid in Medicare Part D, which relies primarily on market forces similar to those in the commercial market to determine prices.

CBO compared prices among programs for two samples of brand-name drugs: 176 top-selling drugs and 64 high-priced drugs. The agency also analyzed prices separately for specialty and nonspecialty drugs among the sample of top-selling brand-name drugs. Specialty drugs typically treat chronic, complex, or rare conditions, frequently have high prices, and may require special handling or patient monitoring. CBO analyzed the prices of specialty drugs separately because they have accounted for a growing share of new drugs introduced to the market in recent years and they are generally introduced at much higher prices than nonspecialty drugs.³²

For each program, CBO constructed prices per standardized prescription, which roughly corresponds to a 30-day supply of medication. For each sample of drugs, the agency computed a weighted-average price for each

32. For a discussion of the data and methods used in this report, including the definition of specialty drugs, see the appendix. For more information on specialty drugs, see Congressional Budget Office, *Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid* (March 2019), www.cbo.gov/publication/54964.

program by using quantities sold in Part D as a common set of weights.

Federal Programs in Which Drugs Are Dispensed at Retail Pharmacies

In 2017, average net prices of drugs in Medicare Part D were higher than those in DoD's TRICARE retail pharmacy network, and average net prices of drugs in both programs were substantially higher than those in Medicaid.³³

Top-Selling Drugs. The average net price per standardized prescription for the sample of 176 top-selling brand-name drugs was \$343 in Medicare Part D, which was nearly three times higher than the average net price (\$118) in Medicaid and 26 percent higher than the average net price (\$272) in the DoD TRICARE retail pharmacy network (see Table 2). The average retail price was similar in Medicare Part D and Medicaid, but the average *net* price was much higher in Medicare Part D because the rebates and discounts in that program were smaller than those in Medicaid. Rebates and discounts for the sample of top-selling drugs averaged 35 percent of the retail price in Medicare Part D. In Medicaid, rebates totaled 77 percent of the retail price—split roughly evenly between the basic rebate and the additional inflation-based rebate.³⁴ Net prices in the TRICARE retail pharmacy network were lower than in Medicare Part D because the former is subject to Big Four pricing and receives additional refunds.³⁵

Prices were much higher for specialty drugs than for nonspecialty drugs in each program. For example, among the sample of top-selling drugs, the average net price per standardized prescription in Medicare Part D was \$4,293 for specialty drugs and \$184 for nonspecialty drugs. The average net price for both categories of drugs was greater in Medicare Part D than in the TRICARE retail pharmacy network, and it was substantially lower in

Medicaid than in either of those programs. For specialty drugs, the average net price per standardized prescription was more than twice as high in Medicare Part D as in Medicaid (\$4,293 versus \$1,889). For nonspecialty drugs, the difference in average net price between the two programs was nearly fourfold (\$184 in Medicare Part D versus \$47 in Medicaid).

Rebates and discounts constituted a smaller percentage of retail prices for specialty drugs than for nonspecialty drugs in both Medicare Part D and Medicaid, although in each case those percentages were much smaller in Part D than in Medicaid. In Medicare Part D, rebates and discounts averaged 12 percent of the retail price for specialty drugs and 47 percent of the retail price for nonspecialty drugs. That large difference is attributed to negotiations between Part D plans and manufacturers that generally result in greater rebates when drugs have multiple close substitutes, which occurs more frequently for nonspecialty drugs.

The rebates in Medicaid, as a percentage of retail prices, were smaller for specialty drugs than for nonspecialty drugs (60 percent versus 86 percent) for two reasons that relate to the two components of the Medicaid rebate. First, the inflation-based component of the Medicaid rebate was, on average, lower (as a percentage of the retail price) for specialty drugs than for nonspecialty drugs. The inflation-based component of the rebate averaged 31 percent of the retail price in Medicaid for specialty drugs and 43 percent for nonspecialty drugs. That difference partly reflects the fact that most specialty drugs were introduced after nonspecialty drugs. Second, the basic rebate is also lower as a percentage of the retail price for specialty drugs (averaging 29 percent) than for nonspecialty drugs (averaging 43 percent).³⁶ That difference reflects the fact that rebates for private payers tend to be lower for specialty drugs than for nonspecialty drugs, for the reason given above. As a result, the

33. In this report, the term *retail pharmacy* refers to pharmacies that dispense self-administered drugs to the general public, including mail-order pharmacies.

34. CBO did not include supplemental rebates paid by manufacturers to state Medicaid programs or Medicaid managed care plans, because data on those supplemental rebates are not available for specific drugs.

35. CBO did not estimate retail prices (without subtracting refunds and discounts) or refunds in the TRICARE retail pharmacy network, because only prices net of refunds were provided by DoD.

36. Each drug's total rebate in Medicaid is capped at the level of the AMP. In the data used for this analysis, the basic and inflation-based rebates are reported for each drug before the cap is applied. Therefore, for some drugs, the sum of the two components of the rebate exceeds the AMP. In those cases, before calculating the average basic and inflation-based rebates, CBO first rescaled those components for each drug so that their sum was equal to the drug's total rebate and each component's proportion of the total was preserved. For example, if the basic and inflation-based rebates in the data were 40 percent and 80 percent of the AMP, respectively, CBO rescaled those components so that they were 33.3 percent and 66.7 percent of the AMP, respectively.

Table 2.

Average Prices per Standardized Prescription for Brand-Name Drugs in Selected Federal Programs, 2017

Dollars

Program	Top-Selling Drugs			High-Priced Drugs
	Total	Specialty	Nonspecialty	Total
Purchases at Retail Pharmacies				
Medicare Part D				
Retail price	525	4,902	349	12,832
Net price	343	4,293	184	11,484
Rebates and discounts as a percentage of retail price	35	12	47	11
Medicaid				
Retail price	517	4,752	346	12,515
Net price	118	1,889	47	5,841
Rebates and discounts as a percentage of retail price	77	60	86	53
DoD TRICARE retail pharmacy network (Net price)	272	2,846	169	7,849
Direct Purchases by Federal Agencies				
Federal Supply Schedule	317	3,377	194	9,951
Big Four ^a	273	2,804	171	8,138
VA prime vendor	190	2,002	117	5,848
DoD prime vendor (MTFs and TMOP)	184	2,094	107	6,131
Intermediate Prices Used to Determine Medicaid Prices				
AMP	509	4,632	343	12,378
Best price ^b	298	3,533	168	9,954
Ratio of best price to AMP	0.59	0.76	0.49	0.80
Intermediate Prices Used to Set Big Four Prices				
Non-FAMP ^c	458	4,191	307	11,300
FCP	273	2,750	173	7,881
Reference List Prices				
AWP	670	6,172	448	15,971
WAC	558	5,143	374	13,309
Number of Drugs	176	68	108	64

Data source: Congressional Budget Office, using data from the Centers for Medicare & Medicaid Services, the Department of Veterans Affairs, the Department of Defense, and Truven Health Analytics (now part of IBM Watson Health). See www.cbo.gov/publication/56978#data.

AMP = average manufacturer price; AWP = average wholesale price; DoD = Department of Defense; FCP = federal ceiling price; FSS = Federal Supply Schedule; MTF = military treatment facility; non-FAMP = nonfederal average manufacturer price; TMOP = TRICARE mail-order pharmacy; VA = Department of Veterans Affairs; WAC = wholesale acquisition cost.

- The Big Four are the four largest direct federal purchasers of prescription drugs (VA, DoD, the Public Health Service, and the Coast Guard).
- The best price is the lowest net price at which a drug is offered to any private buyer. It is used to compute rebates in the Medicaid program.
- For most drugs, the annual non-FAMP was calculated on the basis of sales between October 2015 and September 2016 and was used to set the FCP and the Big Four price for 2017.

difference between the AMP and the best price is smaller for specialty drugs than for nonspecialty drugs, so the basic rebate for specialty drugs is less likely to exceed 23.1 percent of the AMP. For the sample of top-selling drugs, the best price was, on average, 24 percent lower than the AMP for specialty drugs and 51 percent lower than the AMP for nonspecialty drugs.

The average value of the AMP among the sample of 176 top-selling drugs was \$509 (slightly less than their average retail price), and the average best price for those drugs was \$298. The AMP is intended to reflect the average price manufacturers receive for prescription drugs, but because of details about how the AMP is calculated, it may not always do so. For example, sales to mail-order pharmacies and prompt-pay discounts that manufacturers give to wholesalers are excluded from the calculation. In addition, the regulations specifying how manufacturers should compute the AMP and the best price are complex, and manufacturers have used varying assumptions in following them.³⁷

The average wholesale acquisition cost for the sample of 176 top-selling brand-name drugs was \$558 per standardized prescription—6 percent higher than the average retail price of those drugs in Medicare Part D. As discussed previously, wholesalers typically purchase drugs from manufacturers at a negotiated discount from the amount of the WAC. The AWP, another list price that is sometimes used as a starting point in business-to-business negotiations in the pharmaceutical industry, averaged \$670 for the 176 top-selling brand-name drugs—28 percent higher than the average retail price of those drugs in Medicare Part D.

High-Priced Drugs. The average net price for the sample of high-priced drugs was \$11,484 per standardized prescription in Medicare Part D, which was nearly double the average net price in Medicaid (\$5,841) and 46 percent higher than the average net price in the TRICARE retail pharmacy network (\$7,849). The average retail price for those drugs was similar in Medicare Part D and in Medicaid, but the average net price was much higher in Part D because the rebates and discounts in that program averaged 11 percent of the retail price, whereas rebates in Medicaid averaged 53 percent of the retail

price. The Medicaid rebates for high-priced drugs consisted of basic rebates averaging 29 percent of the retail price and inflation-based rebates averaging 24 percent of the retail price. CBO did not analyze specialty drugs separately for the sample of high-priced drugs, because 56 of the 64 drugs included in that sample were specialty drugs.

Direct Federal Purchasers

The prices that direct federal purchasers pay for brand-name prescription drugs also vary considerably by program. FSS prices in 2017 were higher than the Big Four prices, and both of those prices were substantially higher than those in VA's and DoD's prime vendor programs (the latter including drugs dispensed at MTFs and through TMOP but not those dispensed through the TRICARE retail pharmacy network or nonnetwork retail pharmacies).

Top-Selling Drugs. The average FSS price for the sample of 176 top-selling brand-name drugs was \$317 per standardized prescription. The average Big Four price for those drugs was \$273, 14 percent lower than the average FSS price. The average FSS price was \$3,377 for specialty drugs and \$194 for nonspecialty drugs. The average Big Four price was \$2,804 for specialty drugs (17 percent lower than the average FSS price) and \$171 for nonspecialty drugs (12 percent lower than the average FSS price).

In the VA prime vendor program, the average price among the sample of top-selling brand-name drugs was \$190, which was similar to the average prices paid for drugs dispensed by DoD at MTFs and through TMOP (\$184). Those average prices were about a third lower than the average Big Four price. As described above, VA and DoD can negotiate lower prices than the Big Four prices for their direct purchases. That is mainly because of the large volume of drugs they buy and their ability to influence which drugs are prescribed by physicians they employ. The average price for specialty drugs in the VA prime vendor program was \$2,002; it was \$117 for nonspecialty drugs. Each of those prices was about 30 percent lower than the respective average Big Four price. Similarly, the average price for specialty drugs dispensed at MTFs and through TMOP was \$2,094; it was \$107 for nonspecialty drugs.

The average non-FAMP for the sample of 176 top-selling drugs was \$458, about 10 percent lower than the

37. Department of Health and Human Services, Office of Inspector General, *Reasonable Assumptions in Manufacturer Reporting of AMPs and Best Prices* (September 2019), <https://oig.hhs.gov/oei/reports/oei-12-17-00130.asp>.

average AMP for those drugs (\$509). The non-FAMP and the AMP are each intended to reflect the average price received by manufacturers, but they differ because they reflect sales during different periods and because of differences in how they are calculated.

High-Priced Drugs. The average FSS price for the sample of 64 high-priced brand-name drugs was \$9,951, and the average Big Four price was \$8,138 (18 percent lower than the FSS price). The average price for those drugs in the VA prime vendor program was \$5,848 (72 percent of the Big Four price), and DoD's average price for drugs dispensed through its prime vendor program (at MTFs and through TMOP) was \$6,131 (75 percent of the Big Four price).

Considerations for Comparing Prices Among Programs

The average prices reported for the direct federal purchasers are not directly comparable with the average prices reported for programs in which drugs are dispensed at retail pharmacies for two reasons. First, the prices for the latter set of programs include the amounts retained by pharmacies to cover their costs of dispensing drugs plus their profits on those transactions. In contrast, the average FSS and Big Four prices, as well as those for the VA and DoD prime vendor programs, do not include the costs of dispensing drugs. Adjusting the estimates to account for that difference would not change the finding that the average prices in the VA and DoD prime vendor programs are higher than the average net price in Medicaid and lower than the average net price in Medicare Part D. The best available evidence indicates that the amount retained by pharmacies accounts for between 3 percent and 6 percent of retail spending on brand-name prescription drugs.³⁸ If those estimated amounts retained by pharmacies are removed from the average net price in Medicare Part D (to make that estimate more comparable with the estimated direct purchaser prices), that price is reduced by between 5 percent

and 9 percent, resulting in an average net price ranging from \$311 to \$327 for the sample of top-selling drugs. Removing the amount retained by pharmacies from the average net price in Medicaid would reduce that price and widen the gap between the average price in Medicaid and the average prices paid by VA and DoD.

The second reason that the estimated prices for the two sets of federal programs are not directly comparable is that the prices at which drugs are dispensed at retail pharmacies include the amount retained by wholesalers, which is generally about 1 percent of retail spending on brand-name prescription drugs.³⁹ VA and DoD have negotiated so-called negative distribution fees with their prime vendors, which are, in effect, discounts based on the costs of ordered drugs.⁴⁰ Those discounts are incorporated in the estimated prices presented in this report, so no adjustment is needed to make the prices for the VA and DoD prime vendor programs comparable with the other prices.

Comparing Relative Prices Among Federal Programs

Expressing the average price in each program (net of applicable rebates and discounts) relative to the average net price in Medicare Part D illustrates the degree of variation in prices among programs. For top-selling drugs, the average net price in Medicaid was 35 percent of the average net price in Medicare Part D, and the average price in the VA and DoD prime vendor programs was about 55 percent of the average net price in Medicare Part D (see Figure 4). (The estimates in Figure 4 have not been adjusted to account for the fact that markups by pharmacies and wholesalers are included in some prices but not in others.)⁴¹ The average FSS price

38. For evidence that the amount retained by pharmacies is 3 percent of retail spending on brand-name drugs, see Neeraj Sood and others, *The Flow of Money Through the Pharmaceutical Distribution System* (USC Schaeffer Center for Health Policy & Economics, June 2017), <https://tinyurl.com/rvzq5xj> (PDF, 500 KB). For evidence that the amount retained by pharmacies is 6 percent of retail spending on brand-name drugs, see Aaron Vandervelde and Eleanor Blalock, *The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized by Stakeholders* (Berkeley Research Group, 2017), <https://tinyurl.com/y293n34s> (PDF, 1.1 MB).

39. See Neeraj Sood and others, *The Flow of Money Through the Pharmaceutical Distribution System* (USC Schaeffer Center for Health Policy & Economics, June 2017), <https://tinyurl.com/rvzq5xj> (PDF, 500 KB); and Aaron Vandervelde and Eleanor Blalock, *The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized by Stakeholders* (Berkeley Research Group, 2017), <https://tinyurl.com/y293n34s> (PDF, 1.1 MB).

40. See Congressional Budget Office, *The Department of Veterans Affairs' Pharmaceutical Prime Vendor Program* (attachment to a letter to the Honorable Kent Conrad, February 25, 2009), www.cbo.gov/publication/20496.

41. CBO did not make such an adjustment, because the agency expects that pharmacy and wholesaler markups are greater for specialty drugs than for nonspecialty drugs (because specialty drugs often require special handling in the supply chain and are often distributed through specialty pharmacies), but the agency has no information on the size of that difference.

for top-selling drugs, which is similar to the lowest net price offered to commercial buyers, was 93 percent of the average net price in Medicare Part D.

In DoD's TRICARE program, the average price paid for drugs dispensed at MTFs or through TMOP was about one-third lower than the average price for drugs sold through the TRICARE retail pharmacy network. That difference in price might be largely attributable to the fact that DoD has greater control over the variety of medications dispensed at MTFs and through TMOP than through the retail pharmacy network, and therefore has greater leverage when negotiating direct purchase prices. Another factor contributing to the difference in average prices is that DoD receives a discount from its prime vendors in the form of a negative distribution fee for drugs dispensed at MTFs or through TMOP but receives no such discount for drugs dispensed at retail pharmacies. The average retail pharmacy price was also very close to the average Big Four price. Because retail pharmacy prices include pharmacy and wholesaler mark-ups but Big Four prices do not, that finding suggests that manufacturers are paid slightly less than the Big Four price, on average, for drugs dispensed in the TRICARE retail pharmacy network.

Distributions of Selected Prices Relative to Medicare Part D and Big Four Prices

Two-thirds of the drugs in the sample of top-selling drugs had an estimated net price in Medicaid that was less than half of their net price in Medicare Part D. Nearly a quarter of the drugs in the sample had an estimated net price in Medicaid that was between zero and 5 percent of the net price in Medicare Part D (see Table 3). The large number of drugs with net prices near zero in Medicaid reflects the unique characteristics of the Medicaid rebate, which rises both with growing differences between list and net prices in the commercial market and with increasing list prices over time. Drug manufacturers that have made pricing decisions that resulted in a net price close to zero in Medicaid for a particular drug have calculated that the increased revenue from other payers more than offsets the loss in revenue from Medicaid. Prices do not approach zero in other programs, either because they are negotiated by the manufacturer or because, in the case of the Big Four price, they are set by a formula that prohibits the price from being zero.

The distributions of relative prices were different for other federal programs. Prices in DoD's TRICARE retail pharmacy network, FSS prices, and Big Four prices were less than half of the corresponding net price in Medicare Part D for between 9 percent and 11 percent of the drugs in the sample of top-selling drugs. And although Medicare Part D had the highest average net prices among the programs that CBO studied, the FSS price exceeded those prices for 36 percent of the drugs in the sample, as did the price in DoD's TRICARE retail pharmacy network for 28 percent of drugs in the sample, and the Big Four price for 27 percent of them. Relative to the net price in Medicare Part D, the distributions of prices paid by VA and DoD through their direct purchases (that is, through their prime vendor programs) mostly fell between the distribution of prices in Medicaid and the distribution of Big Four prices. DoD's direct purchase prices were between one-quarter and three-quarters of the net price in Medicare Part D for 70 percent of the drugs in the sample, and prices paid by VA fell within that range for 61 percent of the drugs in the sample.

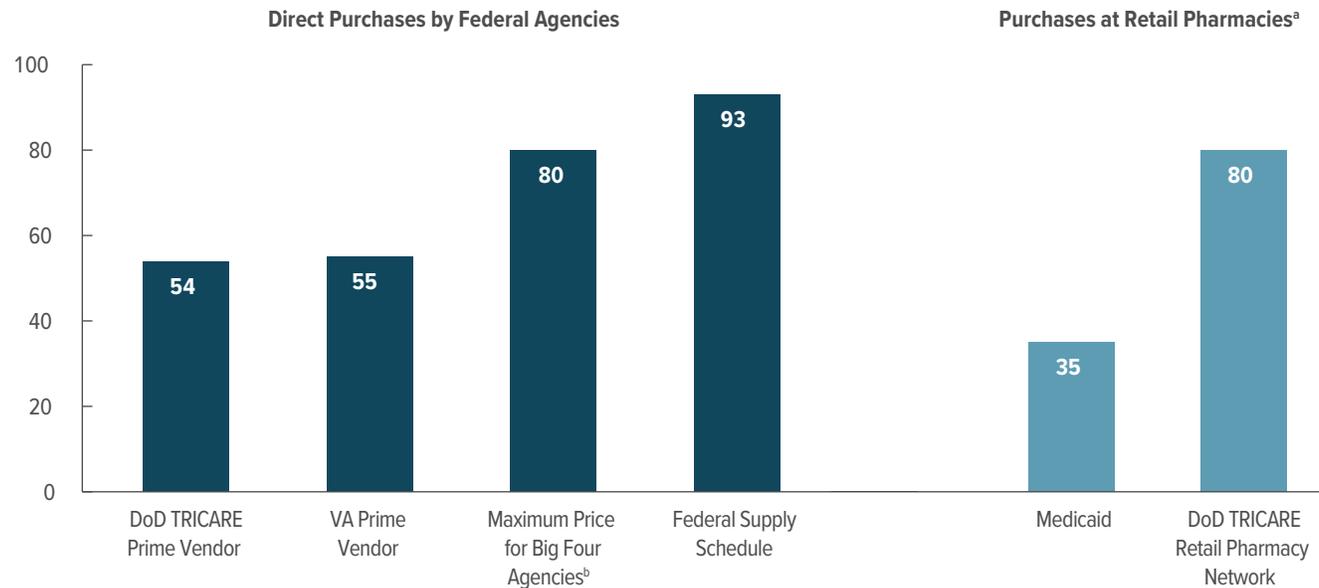
CBO also analyzed the ratio of VA and DoD direct purchase prices to the Big Four price. As Big Four agencies, both VA and DoD are entitled to buy drugs at the Big Four price, but as discussed above, they paid average prices that were between 67 percent and 70 percent of the average Big Four price for top-selling drugs. However, the distributional analysis reveals that for the majority of drugs in the sample of top-selling drugs, those agencies actually paid prices for their direct purchases that were closer to the Big Four price than the comparison of average prices would suggest. The price paid by VA exceeded three-quarters of the Big Four price for 73 percent of the drugs in the sample, as did the average price paid by DoD for 67 percent of those drugs.

Moreover, one of the reasons VA and DoD paid less than the Big Four price is that those agencies receive discounts from their prime vendors in the form of negative distribution fees. Those discounts are applied to the contract prices negotiated between those agencies and the manufacturers. In addition to the prices they paid to their prime vendor, VA reported the amount of the negative distribution fee for each drug to CBO. Using that information, CBO calculated the contract prices negotiated between VA and the manufacturer and found that VA's contract price was actually equal to the Big Four price for 104 of the 176 drugs in the sample of top-selling drugs. Although CBO does not know the amount of the

Figure 4.

Average Price of Top-Selling Brand-Name Drugs As a Percentage of Their Average Net Price in Medicare Part D, 2017

Percent



Data source: Congressional Budget Office, using data from the Centers for Medicare & Medicaid Services, the Department of Veterans Affairs, the Department of Defense, and Truven Health Analytics (now part of IBM Watson Health). See www.cbo.gov/publication/56978#data.

DoD = Department of Defense; VA = Department of Veterans Affairs.

- a. The estimates shown for Medicaid and the DoD TRICARE retail pharmacy network are based on net prices in each program.
- b. The Big Four are the four largest direct federal purchasers of prescription drugs (the Department of Veterans Affairs, the Department of Defense, the Public Health Service, and the Coast Guard).

negative distribution fee that applied to DoD's direct purchases, it is likely that in many cases the negotiated contract price is equal to the Big Four price in that program as well. For 102 of the drugs in the sample of 176 top-selling drugs, DoD paid its prime vendors between 85 percent and 95 percent of the Big Four price.

An examination of the price distributions among the sample of high-priced drugs in Medicare Part D reveals some of the same patterns observed in the sample of top-selling drugs. One significant difference between the samples of top-selling and high-priced drugs is that prices in the latter were less dispersed relative to the net price in Medicare Part D. For example, the FSS price was greater than the net price in Medicare Part D for 13 percent of the drugs in the sample of high-priced drugs, compared with 36 percent of the drugs in the sample of top-selling drugs. Another difference is that

only 5 percent of drugs in the sample of high-priced drugs had net prices in Medicaid that were less than 5 percent of their corresponding prices in Medicare Part D, compared with 23 percent of drugs in the sample of top-selling drugs.

Comparison With Earlier Estimates of Drug Prices in Selected Federal Programs

This report is an update to a report published by CBO in 2005, which compared drug prices in selected federal programs using a sample of the top-selling brand-name prescription drugs in 2003.⁴² Although the methods used to estimate the 2003 drug prices differ somewhat from those used in this report, they are similar enough to

42. See Congressional Budget Office, *Prices for Brand-Name Drugs Under Selected Federal Programs* (June 2005), www.cbo.gov/publication/16634.

Table 3.

Distribution of the Ratios of Drug Prices to the Net Price in Medicare Part D and to the Big Four Price

Percent

Ranges of Ratios by Sample	Ratios of Program Prices to Net Prices in Medicare Part D				Ratios of Program Prices to the Big Four Price ^a	
	Medicaid Net Price	DoD TRICARE Retail Price ^b	FSS Price	Big Four Price	VA Prime Vendor Price	DoD Prime Vendor Price ^c
Top-Selling Drugs						
0 to 0.05	23	0	0	0	0	0
0.06 to 0.25	19	1	0	0	7	5
0.26 to 0.50	25	10	9	10	9	13
0.51 to 0.75	21	35	24	46	11	16
0.76 to 1.00	9	27	31	16	73	66
1.01 to 1.25	3	11	14	16	0	1
1.26 to 1.50	0	11	11	7	0	0
1.51 or higher	1	5	11	3	0	0
High-Priced Drugs						
0 to 0.05	5	0	2	2	0	0
0.06 to 0.25	11	5	0	3	3	0
0.26 to 0.50	25	5	5	5	2	2
0.51 to 0.75	41	53	30	66	8	11
0.76 to 1.00	17	36	52	22	86	81
1.01 to 1.25	2	0	9	0	2	5
1.26 to 1.50	0	2	2	3	0	0
1.51 or higher	0	0	2	0	0	2

Data source: Congressional Budget Office, using data from the Centers for Medicare & Medicaid Services, the Department of Veterans Affairs, the Department of Defense, and Truven Health Analytics (now part of IBM Watson Health). See www.cbo.gov/publication/56978#data.

Percentages indicate the fraction of products in each sample for which the indicated ratio is within the indicated range.

The sample of top-selling drugs contains 176 drugs, and the sample of high-priced drugs contains 64 drugs.

DoD = Department of Defense; FSS= Federal Supply Schedule; VA = Department of Veterans Affairs.

- a. The Big Four price is the price available to the Big Four agencies (the four largest direct federal purchasers), consisting of VA, DoD, the Public Health Service, and the Coast Guard. That price is the minimum of the FSS price and the federal ceiling price. VA and DoD often pay lower prices than the other Big Four agencies because they use formularies (preapproved lists) of preferred drugs, they steer patients to lower-cost drugs, and they buy drugs in large volumes.
- b. The DoD TRICARE retail price refers to the average net price of drugs dispensed through the TRICARE retail pharmacy network.
- c. The DoD prime vendor price refers to the average price of drugs dispensed at military treatment facilities and through the TRICARE mail-order pharmacy.

illustrate how the price differences among the various federal programs have changed since then.⁴³

43. In both analyses, the prices for direct federal purchasers reflect the prices paid to manufacturers (or to wholesale distributors in some cases). However, net prices in Medicaid were estimated differently for the two years. For 2003, net prices were estimated by subtracting rebates from average manufacturer prices; for 2017, net prices were estimated by subtracting rebates from retail prices. Because retail prices include amounts retained by pharmacies and wholesalers, the estimates of net Medicaid prices in this report are somewhat higher than the estimates that would have been obtained if CBO had used the approach from the

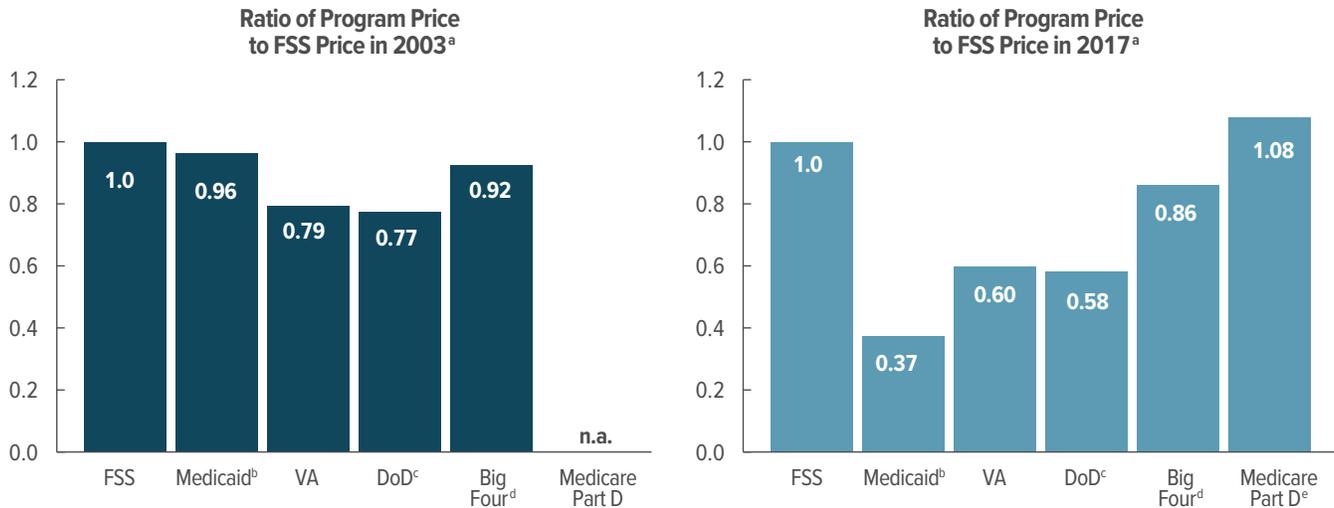
Because the FSS price is present in both this report and the report published in 2005, it can be used to compare their results. In 2017, the average net price in Medicaid was by far the lowest in all the federal

previous report. Also, the two analyses are based on different drugs. The previous analysis was based on a sample of 130 brand-name drugs that accounted for about half of all sales through retail pharmacies in the United States in 2003, whereas the main analysis in the current report is based on a sample of 176 brand-name drugs that accounted for 85 percent of total spending on brand-name drugs in Medicare Part D in 2017.



Figure 5.

Average Prices of Brand-Name Outpatient Prescription Drugs in Selected Federal Programs As a Ratio of the Federal Supply Schedule Price



Data sources: For 2017 estimates, Congressional Budget Office, using data from the Centers for Medicare & Medicaid Services, the Department of Veterans Affairs, the Department of Defense, and Truven Health Analytics (now part of IBM Watson Health); for 2003 estimates, Congressional Budget Office, *Prices for Brand-Name Drugs Under Selected Federal Programs* (June 2005), www.cbo.gov/publication/16634. See www.cbo.gov/publication/56978#data.

Estimates for 2003 are based on a sample of 130 top-selling brand-name drugs in that year; estimates for 2017 are based on a sample of 176 top-selling brand-name drugs in that year. Medicare Part D was not fully implemented until 2006, so no estimate is available for 2003.

- Federal Supply Schedule (FSS) prices are determined through a combination of statutory rules and negotiation between the Department of Veterans Affairs (VA) and drug manufacturers.
- Net prices in Medicaid were estimated differently for the two years. For 2003, net prices were estimated by subtracting rebates from average manufacturer prices; for 2017, net prices were estimated by subtracting rebates from retail prices.
- The 2003 estimate for the Department of Defense (DoD) is based on drugs dispensed at military treatment facilities; the 2017 estimate includes drugs dispensed at military treatment facilities and through the TRICARE mail-order pharmacy. For both years, the estimate excludes prices paid for drugs purchased at network or nonnetwork retail pharmacies.
- The estimate represents the prices available to the Big Four agencies (the four largest direct federal purchasers), consisting of VA, DoD, the Public Health Service, and the Coast Guard. That price is the minimum of the FSS price and the federal ceiling price. VA and DoD often pay lower prices than the other Big Four agencies because they use formularies (preapproved lists) of preferred drugs, they steer patients to lower-cost drugs, and they buy drugs in large volumes.
- The estimate for Medicare Part D is based on net prices in that program.

programs examined: 37 percent of the average FSS price (see Figure 5). The next lowest prices were those paid by DoD (58 percent of the FSS price) and VA (60 percent) in their prime vendor programs.⁴⁴ By contrast, in 2003, the average net price in Medicaid was only slightly lower than the FSS price (96 percent of that price), and the

lowest average prices were paid by DoD (77 percent of the FSS price) and VA (79 percent). Another difference is that the prices paid by VA and DoD in their prime vendor programs were lower relative to the Big Four price in 2017 than in 2003.

CBO has not fully analyzed the factors underlying those differences. However, increases in the amounts of Medicaid rebates paid by drug manufacturers are likely an important reason that net prices in Medicaid are now lower than prices paid by VA and DoD. In 2003, the average Medicaid rebate on brand-name drugs was

44. The 2003 estimate for DoD is based on drugs dispensed at military treatment facilities; the 2017 estimate includes drugs dispensed at military treatment facilities and through the TRICARE mail-order pharmacy. The DoD retail channel is not used for this comparison.

35 percent of the AMP.⁴⁵ In 2017, the average Medicaid rebate for the sample of top-selling brand-name drugs included in this report was 78 percent of the AMP. During the intervening period, the basic and inflation-based rebates for brand-name drugs both increased, on average. The increase in the average basic rebate is partly attributable to a change in law. In 2003, the basic Medicaid rebate for a brand-name drug was the larger

of the flat rebate of 15.1 percent of the AMP or the difference between the AMP and the best price extended to any private buyer. The ACA increased the flat rebate amount to 23.1 percent of the AMP, reducing average net prices paid by Medicaid. The average inflation-based rebate increased because the AMP of brand-name prescription drugs grew faster than the CPI-U.⁴⁶

45. See Congressional Budget Office, *Prices for Brand-Name Drugs Under Selected Federal Programs* (June 2005), p. 11, www.cbo.gov/publication/16634.

46. For additional information on the increase in the basic and inflation-based rebates in Medicaid, see Anna Anderson-Cook, Jared Maeda, and Lyle Nelson, *Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid: An In-Depth Analysis*, Working Paper 2019-02 (Congressional Budget Office, March 2019), p. 24, www.cbo.gov/publication/55011.

Appendix: Data and Methods Used in This Report

The Congressional Budget Office used a variety of data sources to compare the prices paid for brand-name prescription drugs among the federal programs included in this report. The agency compared the average prices among programs for a sample of top-selling brand-name drugs and a sample of high-priced brand-name drugs. CBO compared prices in 2017, the most recent year for which data were available when the analysis began. In identifying the samples of top-selling drugs and high-priced drugs from Medicare Part D data, the agency used retail prices. That way, the samples were selected using a pricing measure that did not depend on the size of the rebates and discounts for drugs in Part D.¹

CBO counted all drugs with the same root product name as a single drug. For example, Novolog, Novolog Penfill, and Novolog Mix 70/30 Flexpen are considered the same drug (Novolog). A National Drug Code (NDC) defines a drug at the most granular level by its manufacturer, product name, dosage form, strength, route of administration, and package size. Each drug can have multiple NDCs.

Data Sources

The data CBO used for this analysis vary by program and include individual-level claims, manufacturer rebate data, and publicly available price data.

CBO used the Part D Drug Event File, which contains data on individual claims for all Medicare Part D beneficiaries, to estimate retail prices for brand-name drugs. (In this report, the price paid to the pharmacy before considering any rebates or other discounts is referred to as the

retail price. It includes the amount paid by the insurer and the amount paid by the beneficiary as cost sharing. The net price is the retail price minus rebates and other discounts.) Those data include the total amount paid to the pharmacy for each prescription valued at retail prices and the number of units (such as tablets) dispensed for each claim. CBO also used NDC-level data on the rebates and discounts that each Part D plan obtained from manufacturers and pharmacies during the year to estimate the net price of each drug.² The information on rebates and discounts is not publicly available and is typically known only to the parties involved in a transaction, such as drug manufacturers, plans, and pharmacy benefit managers (PBMs), in the case of manufacturer rebates. However, Part D plans are required to submit data to the Centers for Medicare & Medicaid Services (CMS) on the rebates and discounts they receive from drug manufacturers and pharmacies, and CMS is required by federal law to give CBO access to those data.

CBO used data it obtained from CMS to compute retail and net prices at the NDC level in Medicaid. The data from CMS included information on drug utilization and spending in Medicaid, which CBO used to compute retail prices, and information on statutory Medicaid rebate amounts, which CBO used to compute net prices.³ For each NDC, the data from CMS also included the average manufacturer price (AMP) and best price (the lowest net price extended to any private buyer, excluding Part D plans), both of which are used

1. CBO included both single-source and multi-source brand-name drugs in the analysis. Single-source brand-name drugs are marketed or sold by one manufacturer or labeler and are protected under patent exclusivity. Multi-source brand-name drugs are marketed or sold by two or more manufacturers or labelers and are no longer protected under patent exclusivity, and there are therapeutically equivalent generic drugs available to be substituted for them.

2. The Medicare Part D net price was calculated as the retail price minus manufacturer rebates, coverage gap discounts, and price concessions from pharmacies to pharmacy benefit managers that occur after the point of sale.

3. CBO calculated the Medicaid net price by subtracting statutory rebates (the basic rebate and inflation-based rebate) from the retail price. The agency does not account for the supplemental state-based rebates or rebates to managed care plans, because data are not available on the amounts of those rebates for specific drugs. Those supplemental rebates account for only a small percentage of total rebates in Medicaid.

to determine statutory rebates in Medicaid (see the glossary). Drug manufacturers are required to submit NDC-level data to CMS on the AMP and the best price for each drug. Those data are not publicly available, but they were included in the data CBO obtained from CMS.

The Department of Veterans Affairs (VA) provided much of the data used to estimate the prices paid by direct federal purchasers. CBO used publicly available prices from Federal Supply Schedule (FSS) and Big Four price contracts on VA's website. Furthermore, CBO used invoice-level claims data from VA's prime vendor program to estimate prices paid to the prime vendor for brand-name drugs. VA also provided data on the nonfederal average manufacturer price (non-FAMP) and the federal ceiling price (FCP) for each NDC, which are used to determine the Big Four price (the maximum price that any Big Four agency is required to pay). Drug manufacturers are required to submit data to VA on the non-FAMP for each NDC, which is used to compute the FCP. Those data are not publicly available.

The Department of Defense (DoD) provided data on total units purchased and total spending at the NDC level to estimate prices paid to its prime vendors for brand-name drugs dispensed at military treatment facilities (MTFs) and through the TRICARE mail-order pharmacy (TMOP). CBO combined the data on prices for drugs dispensed through those two distribution channels because prices for the two are very similar, and prices are available for fewer drugs dispensed through TMOP than at MTFs.⁴ DoD also provided CBO with similar data to estimate net prices of drugs dispensed through the TRICARE retail pharmacy network.⁵

4. A wider range of drugs is dispensed at MTFs than through TMOP because the latter is used primarily for drugs taken over an extended period of time to treat chronic conditions. As discussed below, CBO conducted its analysis on drugs for which prices were available for all of the programs included in this report. By combining the data on prices for drugs dispensed at MTFs and through TMOP, CBO was able to include more drugs in the analysis than would have been the case had it computed estimates separately for those two distribution channels. In a preliminary analysis of drugs for which prices were available for both distribution channels, CBO found that the average prices for the two distribution channels differed by less than 2 percent for the sample of top-selling drugs and by less than 1 percent for the sample of high-priced drugs.
5. The net price of drugs dispensed through the TRICARE retail pharmacy network is equal to the retail price, which includes pharmacy dispensing fees, minus refunds from manufacturers.

CBO merged the data provided by CMS, VA, and DoD with Red Book data from Truven Health Analytics (now part of IBM Watson Health). Those data include drug characteristics, such as how the drug is administered (for example, orally) and its product category (for example, generic), as well as the wholesale acquisition cost (WAC) and the average wholesale price (AWP) for each NDC.

Methods

To conduct the analyses presented in this report, CBO constructed samples of top-selling and high-priced drugs, estimated annual prices for certain NDCs for which multiple prices were reported during the year, and estimated average prices for each program from NDC-level prices. The agency used a definition of specialty drugs developed by IQVIA (formerly IMS Health).

Constructing the Samples of Top-Selling and High-Priced Drugs

To construct the samples of brand-name drugs included in this report, CBO began with the 200 top-selling drugs and the 200 highest-priced drugs in Medicare Part D in 2017. The agency then removed physician-administered drugs from the samples, excluded drugs for which a price was not available for all other programs included in this report, and excluded drugs that appeared to have invalid prices. Applying those steps resulted in a final sample of 176 top-selling drugs and 64 high-priced drugs. Those two samples included 30 of the same drugs. CBO constructed prices per standardized prescription to control for differences among prescriptions in the number of days a medication was supplied.⁶

The sample of 176 top-selling drugs accounted for 85 percent of total spending on brand-name drugs and

Those refunds include mandatory refunds as well as voluntary discounts provided by manufacturers based on formulary placement. DoD did not provide CBO with data on the retail price or the amounts of the refunds.

6. CBO defined a standardized prescription as a prescription in which a medication was supplied for a number of days equaling 30 or less. For a prescription in which a medication was supplied for more than 30 days, CBO defined the number of standardized prescriptions as the number of days supplied divided by 30. For example, a prescription for a 93-day supply of a medication was defined as 3.1 standardized prescriptions. Using the Medicare Part D claims data, the agency computed the number of units (such as tablets) per standardized prescription for each drug. Then, the number of units per standardized prescription in Medicare Part D was applied to the other federal programs to determine prices per standardized prescription in those programs.

80 percent of brand-name standardized prescriptions in Medicare Part D in 2017. The sample of 64 high-priced drugs accounted for 16 percent of total spending on brand-name drugs and only 0.6 percent of brand-name standardized prescriptions.⁷ (In this appendix, all such calculations use spending valued at retail prices.)

Identifying the Initial Samples. CBO identified the initial samples of brand-name prescription drugs by isolating the 200 drugs with the highest retail spending (before accounting for rebates and discounts) and the 200 drugs with the highest retail prices per standardized prescription. The agency achieved that by first summing standardized prescriptions and spending at retail prices among the Medicare Part D claims that involve the same NDC. After calculating the price per standardized prescription (by dividing total spending at retail prices by the number of standardized prescriptions for each NDC), the data were aggregated to the drug level using standardized prescriptions as weights to determine the price for each drug. CBO sorted drugs from highest to lowest in terms of retail prices (to determine the 200 highest-priced drugs) and in terms of total spending at retail prices (to determine the 200 top-selling drugs).

Removing Physician-Administered Drugs. This report is concerned with the prices paid for brand-name, self-administered prescription drugs. In most cases, physician-administered drugs are covered under the medical benefits, rather than the pharmacy benefits, of the federal programs included in this analysis. In Medicare, physician-administered drugs are covered under Part B. CMS specifies which drugs are covered under Part D and which are covered under Part B. As a result, most spending for physician-administered drugs occurs outside the Part D benefit. Sometimes, however, physician-administered drugs are billed through Part D, and it is unclear why that occurs. Because the purpose of this report is to compare the prices paid for self-administered drugs among different federal programs, CBO removed physician-administered drugs from its analysis.⁸

After removing physician-administered drugs, 194 top-selling drugs and 134 high-priced drugs remained (see Table A-1). Thus, many more of the original 200 highest-priced drugs were classified as physician-administered drugs than was the case for the top-selling drugs. The data show that drugs with the highest prices in Medicare Part D are more likely to be drugs that are administered through intravenous therapy, infusion, or health professional-aided subcutaneous injection, such as highly expensive cancer therapies. The samples of drugs obtained after removing physician-administered drugs are regarded as the complete samples for the remainder of this appendix (that is, they are the complete samples of self-administered drugs to which additional sample selection criteria were applied).

The sample of 194 top-selling drugs corresponded to 1,020 NDCs, and the sample of 134 high-priced drugs corresponded to 397 NDCs. Thus, each top-selling drug was represented by an average of 5.3 NDCs, whereas each high-priced drug was represented by an average of 3.0 NDCs.

Excluding NDCs for Which Some Prices Were Missing.

CBO excluded any NDC for which the price was missing in any federal program included in this report. In that step, 373 NDCs were excluded from the sample of top-selling drugs, reducing the number of drugs included in that sample by 16. Additionally, 263 NDCs were excluded from the sample of high-priced drugs, reducing the number of drugs in that sample by 67. The NDCs that were excluded represented 7 percent of total Part D spending for the complete sample of top-selling drugs and 28 percent of total Part D spending for the complete sample of high-priced drugs. CBO did not exclude a drug from the sample unless all NDCs associated with that drug were excluded.

drug. If the drug is administered intravenously or intravesically, infused, or administered as an intramuscular or intrathecal injection, it is regarded as a physician-administered drug. If a drug is injected subcutaneously, it is considered self-administered if the patient can be trained to inject the drug at home. Otherwise, it is considered a physician-administered drug. CBO determined whether patients could be trained to take a subcutaneously injected drug at home on the basis of information posted on the Mayo Clinic's website (www.mayoclinic.org). CBO applied a similar method in a 2019 report on specialty drugs. For additional information, see Anna Anderson-Cook, Jared Maeda, and Lyle Nelson, *Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid: An In-Depth Analysis* (Congressional Budget Office, March 2019), www.cbo.gov/publication/55011.

7. The 176 top-selling drugs accounted for 62 percent of total spending on brand-name drugs in Medicaid in 2017, and the 64 high-priced drugs accounted for 10 percent of total spending on brand-name drugs in that program. CBO did not have the data necessary to compute analogous estimates for direct federal purchasers.

8. The method for identifying drugs primarily administered by a physician or other health professional was as follows. If the drug is administered orally, it is considered to be a self-administered

Table A-1.

Complete Medicare Samples, Excluded NDCs, and Final Analytical Samples for Top-Selling and High-Priced Drugs

	NDCs	Drugs	Number of Standardized Prescriptions (Millions)	Total Part D Spending (Billions of dollars)
Sample of Top-Selling Drugs				
Complete Sample of Top-Selling Drugs in Medicare	1,020	194	198.6	102.6
Excluded Because at Least One Price Is Missing	373	16	13.2	6.8
<i>Percentage of Complete Medicare Sample</i>	37	8	7	7
Excluded Because at Least One Price Appears Invalid	32	2	3.8	1.7
<i>Percentage of Complete Medicare Sample</i>	3	1	2	2
Final Analytical Sample	615	176	181.5	94.1
<i>Percentage of Complete Medicare Sample</i>	60	91	91	92
Sample of High-Priced Drugs				
Complete Sample of High-Priced Drugs in Medicare	397	134	1.9	23.9
Excluded Because at Least One Price Is Missing	263	67	0.5	6.7
<i>Percentage of Complete Medicare Sample</i>	66	50	29	28
Excluded Because at Least One Price Appears Invalid	5	3	*	0.3
<i>Percentage of Complete Medicare Sample</i>	1	2	1	1
Final Analytical Sample	129	64	1.3	16.9
<i>Percentage of Complete Medicare Sample</i>	32	48	70	71
Pooled Top-Selling and High-Priced Samples				
Complete Pooled Medicare Sample	1,254	286	198.7	105.0
Excluded Because at Least One Price Is Missing	552	72	13.3	8.0
<i>Percentage of Complete Medicare Sample</i>	44	25	7	8
Excluded Because at Least One Price Appears Invalid	36	4	3.8	1.8
<i>Percentage of Complete Medicare Sample</i>	3	1	2	2
Final Analytical Sample	666	210	181.6	95.2
<i>Percentage of Complete Medicare Sample</i>	53	73	91	91
Memo: Sample of Top-Selling Specialty Drugs				
Complete Sample of Top-Selling Specialty Drugs in Medicare	296	80	7.6	39.2
Excluded Because at Least One Price Is Missing	130	11	0.6	5.6
<i>Percentage of Complete Medicare Sample</i>	44	14	7	14
Excluded Because at Least One Price Appears Invalid	10	1	0.1	0.4
<i>Percentage of Complete Medicare Sample</i>	3	1	2	1
Final Analytical Sample	156	68	6.9	33.3
<i>Percentage of Complete Medicare Sample</i>	53	85	91	85
Memo: Sample of Top-Selling Nonspecialty Drugs				
Complete Sample of Top-Selling Nonspecialty Drugs in Medicare	724	114	190.9	63.3
Excluded Because at Least One Price Is Missing	243	5	12.6	1.3
<i>Percentage of Complete Medicare Sample</i>	34	4	7	2
Excluded Because at Least One Price Appears Invalid	22	1	3.7	1.3
<i>Percentage of Complete Medicare Sample</i>	3	1	2	2
Final Analytical Sample	459	108	174.6	60.8
<i>Percentage of Complete Medicare Sample</i>	63	95	91	96

Data source: Congressional Budget Office, using data from the Centers for Medicare & Medicaid Services, the Department of Veterans Affairs, the Department of Defense, and Truven Health Analytics (now part of IBM Watson Health). See www.cbo.gov/publication/56978#data.

An NDC defines a drug at the most granular level by its manufacturer, product name, dosage form, strength, route of administration, and package size.

Physician-administered drugs have been removed from all the samples in this table.

Total spending in Medicare Part D is reported at retail prices.

NDC = National Drug Code; * = less than 0.05 million.

Excluding NDCs With Invalid Prices. CBO then removed NDCs for which the prices appeared to be invalid for at least one program. In this step, the agency excluded 32 NDCs from the sample of top-selling drugs and 5 NDCs from the sample of high-priced drugs (thereby excluding two drugs from the sample of top-selling drugs and three drugs from sample of high-priced ones). Those excluded NDCs represent 2 percent and 1 percent, respectively, of total Part D spending for the complete Medicare samples of the two sets of drugs. The invalid prices could have resulted from errors in the data on either the payment per prescription or the number of units of the drug that was dispensed.

CBO assessed the validity of the prices in the data by comparing them with certain publicly reported prices. First, the agency excluded NDCs from the samples if either the average Part D retail price or the average Medicaid retail price differed significantly from the WAC, which is a list price that is used as a starting point in business-to-business transactions in the prescription drug market. For the final sample of top-selling drugs included in the analysis, the average retail prices in Part D and Medicaid were 94 percent and 93 percent of the WAC, respectively. NDCs were excluded from the final samples if either the Part D or Medicaid retail price was below 75 percent of the WAC or above 105 percent of the WAC. CBO arrived at those cutoff values upon finding that nearly all NDCs had Part D and Medicaid retail prices within that range, and that values outside that range most often appeared to be outliers. Those checks caused 32 NDCs to be excluded from the sample of top-selling drugs—25 because of the comparison with the price in Medicaid alone, 4 because of the comparison with the Part D price, and an additional 3 because of comparisons with both prices. From the sample of high-priced drugs, 5 NDCs were excluded as a result of comparing the price in Medicaid with the WAC, and no NDCs were excluded as a result of comparing the price in Part D with the WAC.

As a final check, CBO then identified observations for which any associated federal price was higher than the AWP. Because the AWP is akin to a “sticker price” and is widely considered the highest price assigned to a drug, any prices that are higher than the AWP are probably the result of an error in the reporting of that price or the quantity of units dispensed. CBO identified nine NDCs from the sample of top-selling drugs and three NDCs from the sample of high-priced drugs that had

an associated federal price that exceeded the AWP, but all of those NDCs also had a Medicaid retail price that diverged from the WAC. Therefore, no NDCs were excluded from either sample as a result of that check that would not otherwise have been excluded as a result of comparing the retail price in Medicaid with the WAC.

Comparing the Final Samples With the Initial Samples of Outpatient Drugs. After excluding physician-administered drugs, CBO began with a set of 1,020 NDCs representing the top-selling drugs in Medicare Part D and 397 NDCs representing the high-priced drugs in Medicare Part D. CBO analyzed 615 of the NDCs in the sample of top-selling drugs after removing observations for which prices were missing or were likely to be incorrect. Those 615 NDCs accounted for 91 percent of standardized prescriptions and 92 percent of total spending for the original 1,020 NDCs. From the 397 NDCs representing the high-priced drugs in Medicare Part D, CBO analyzed 129 NDCs that accounted for 70 percent of standardized prescriptions and 71 percent of total spending for those original NDCs.

For both the samples of top-selling drugs and high-priced drugs, prices were least likely to be available in VA’s prime vendor program (see Table A-2). Of the 1,020 NDCs in the initial sample of top-selling drugs, prices in that program were available for only 723 of them. However, those 723 NDCs represented 99 percent of the standardized prescriptions and 95 percent of the total Part D spending in the initial sample. Prices in VA’s prime vendor program were available for about 40 percent of the NDCs in the sample of high-priced drugs (166 out of 397). Those 166 NDCs accounted for 74 percent of the standardized prescriptions and 74 percent of the spending in the initial sample of high-priced drugs.

Missing prices for drugs in DoD’s prime vendor program—dispensed at military treatment facilities or through TMOP—also caused drugs to be excluded from the final samples. Of the initial sample of top-selling drugs, prices for drugs in the DoD prime vendor program were available for only 767 NDCs. However, those NDCs represented nearly all of the standardized prescriptions and 97 percent of the total Part D spending in the initial sample. DoD prime vendor prices were available for 50 percent of the NDCs in the sample of high-priced drugs. Those NDCs accounted for 86 percent

Table A-2.

Availability of Price Data for Top-Selling and High-Priced Drugs in Medicare Part D in Different Federal Programs

	Pooled Top-Selling and High-Priced Drugs			Top-Selling Drugs			High-Priced Drugs		
	NDCs	Standardized Prescriptions	Total Part D Spending	NDCs	Standardized Prescriptions	Total Part D Spending	NDCs	Standardized Prescriptions	Total Part D Spending
Complete Medicare Sample	1,254	198.7 Million	\$105.0 Billion	1,020	198.6 Million	\$102.6 Billion	397	1.9 Million	\$23.9 Billion
NDCs With Reported Price, by Program		Percentage of Complete Sample			Percentage of Complete Sample			Percentage of Complete Sample	
Medicaid	1,145	94	100	934	94	100	365	100	100
DoD TRICARE retail pharmacy network	1,023	100	100	838	100	100	325	100	99
Federal Supply Schedule	1,092	100	100	879	100	100	361	100	99
FCP and non-FAMP	1,066	94	99	850	94	99	362	97	98
VA prime vendor	804	99	94	723	99	95	166	74	74
DoD prime vendor (MTFs and TMOP)	868	100	97	767	100	97	198	86	88
NDCs Appearing in All Programs	702	93	92	647	93	93	134	71	72
Final Analytical Sample	666	91	91	615	91	92	129	70	71

Data source: Congressional Budget Office, using data from the Centers for Medicare & Medicaid Services, the Department of Veterans Affairs, the Department of Defense, and Truven Health Analytics (now part of IBM Watson Health). See www.cbo.gov/publication/56978#data.

An NDC defines a drug at the most granular level by its manufacturer, product name, dosage form, strength, route of administration, and package size.

Physician-administered drugs have been removed from all the samples in this table.

Total spending in Medicare Part D is reported at retail prices.

DoD = Department of Defense; FCP = federal ceiling price; MTF = military treatment facility; NDC = National Drug Code; non-FAMP = nonfederal average manufacturer price; TMOP = TRICARE mail-order pharmacy.

of the standardized prescriptions and 88 percent of the spending in the initial sample.

Calculating NDC-Level Prices When Multiple Prices Are Reported During the Year

Some of the prices in this analysis are reported multiple times during the year; therefore, additional calculations are required to estimate a single price for each NDC. Some of the prices studied are published in a publicly available list and are in effect for a specified period of time. Those include the AWP, the WAC, the price listed on the FSS, and the Big Four price. CBO used values from the first quarter of 2018 in the Red Book produced by Truven Health Analytics (now part of IBM Watson Health) to represent the AWP and the WAC for drugs

in 2017. VA published updated complete lists of FSS and Big Four prices twice each month in 2017 (24 data releases in total). To estimate a single FSS price for each NDC in 2017, CBO calculated the average of the FSS prices reported for that NDC in VA's 24 data releases that year. The Big Four prices were estimated the same way. For NDCs whose FSS or Big Four price changed during 2017, CBO's approach is equivalent to calculating a weighted average of the different prices for each NDC, so that each price is weighted by the number of data releases in which it appeared.

Other prices are based on sales to private-sector purchasers over a given quarter and are reported to the federal government by manufacturers. Typically, those prices



are not publicly available. Under the Medicaid rebate program, manufacturers report quarterly AMPs and best prices, by NDC, to CMS. CBO calculated the average AMP and best price for each NDC in 2017 by weighting quarterly reported AMPs and best prices by the corresponding number of units dispensed for that NDC in that quarter in Medicaid. Under the FCP program, manufacturers report the non-FAMP, by NDC, to VA on a quarterly basis. VA calculates the FCP annually on the basis of the non-FAMP. VA supplied CBO with 2017 annual values for the FCP, as well as the annual non-FAMP values used to calculate them.

Calculating Average Program Prices

After calculating each of the federal prices for all NDCs included in the analysis, CBO followed a two-step procedure to calculate weighted-average prices at the federal program level for four groups of prescription drugs: a sample of high-priced drugs, a sample of top-selling drugs, the set of specialty drugs among the sample of top-selling drugs, and the set of nonspecialty drugs among the sample of top-selling drugs. In the first step, CBO calculated weighted-average prices at the drug level using the quantity of Medicare Part D standardized prescriptions corresponding to each NDC as weights.⁹ That calculation used only the NDCs that were included in the final sample. In the second step, the weighted-average price for each drug was used to calculate a weighted-average price at the program level. That calculation used the total number of standardized prescriptions for each drug in the complete sample of self-administered drugs as weights.¹⁰ In both steps, CBO used the following formula to calculate weighted-average prices:

$$\text{Weighted-Average Price}_{k,s} = \frac{\sum_{i \in S_s} (P_{i,k}) * (Q_i)}{\sum_{i \in S_s} (Q_i)}$$

In both the first and second steps, the subscript k indexes the federal program whose price is being calculated, Σ denotes summation, and P is the price per standardized

prescription. Other terms have different interpretations in the first and second steps: In the first step, i indexes an NDC, s indexes the drug to which NDC i corresponds, S_s is the set of all NDCs that comprise drug s , and Q_i is the number of standardized prescriptions for NDC i . In the second step, i indexes a drug, s denotes one of the groups of drugs for which average prices are calculated (such as the set of high-priced drugs), S_s is the set of all drugs included in group s , and Q_i is the number of standardized prescriptions for drug i (also representing NDCs that were not included in the first step). A consequence of following this two-step procedure is that the exclusion of NDCs in the sample selection process described above did not affect the weights assigned to drugs in the calculation of program-level average prices. That ensured that drugs were weighted by the number of standardized prescriptions in the complete Part D sample.¹¹

To examine whether the results presented in this report would have been significantly different if CBO had used the number of standardized prescriptions in a program other than Medicare Part D as the weights, the agency reestimated the average prices in each program using the number of standardized prescriptions in Medicaid as the sample weights. The relative levels of the average prices among programs did not vary significantly on the basis of whether Medicaid or Medicare Part D quantities were used as weights.

Defining Specialty Drugs

Researchers and industry stakeholders define specialty drugs in varying ways. Some rely on price alone to define a specialty drug.¹² However, for this report, CBO used a definition of specialty drugs, developed by IQVIA (formerly IMS Health), that encompasses a broader set of characteristics that those drugs share. For an earlier report, CBO purchased from IQVIA a list of all specialty drugs on the market in 2015.¹³ For this report, CBO reused that list of specialty drugs and also applied IQVIA's definition to identify specialty drugs among brand-name drugs that were newly approved by the Food

9. Certain programs provided the price per unit for each drug; therefore, that value was converted to price per standardized prescription by multiplying price per unit by the average number of units per standardized prescription in Medicare Part D for each drug at the NDC level. Other programs, such as VA, provided price per package; therefore, CBO converted that value to price per unit using a variable for package size (the total number of units per package) in VA's data and then to price per standardized prescription.

10. The complete sample referred to here is the sample obtained after excluding physician-administered drugs, which is represented by a pooled sample of 1,254 top-selling and high-priced NDCs.

11. The results are not meaningfully different if NDCs that are excluded in the sample selection process are excluded from the calculation of the drug-level weights.

12. For example, CMS allows Medicare Part D plans to place a drug on their specialty tier if its net price to the plan exceeds a specified threshold (\$670 per month in 2017).

13. The list of specialty drugs in 2015 that CBO obtained from IQVIA (formerly IMS Health) is proprietary. It identifies specialty drugs at the NDC level.

and Drug Administration (FDA) in 2016 and 2017.¹⁴ That definition of specialty drugs requires that they treat a chronic, complex, or rare condition and satisfy at least four of the following seven criteria:

- They cost more than \$6,000 per year;
- They are initiated (that is, prescribed) or maintained (that is, monitored) by a specialist;
- They are administered by a health care professional;
- They require special handling in the supply chain;
- They are associated with a patient payment assistance program;
- They are distributed through nontraditional channels (such as a specialty pharmacy); or
- They require monitoring or counseling either because of significant side effects or because of the type of disease being treated.

CBO applied those criteria to identify specialty drugs among brand-name drugs that were newly approved by the FDA in 2016 and 2017 as follows.

Cost Threshold. CBO classified a drug as exceeding the \$6,000 threshold if the annual median retail spending for the drug (without removing rebates and discounts) per Medicare beneficiary exceeded \$6,000 in 2017 among beneficiaries who obtained at least one prescription for the drug during that year.¹⁵

Initiated or Maintained by a Specialist. CBO's assessment of whether a drug was initiated or maintained by a specialist was based on the prevalence of the disease that the drug treated and the specificity of the organ system affected by that disease.

Administration by a Health Care Professional. CBO's assessment of whether a drug was administered by a health care professional was based on whether the Mayo Clinic website (www.mayoclinic.org) indicated that patients could be trained to take the drug at home.

Special Handling. CBO's assessment of whether a drug required special handling in the supply chain was based on whether the FDA label for the drug designated that it must be refrigerated or shipped frozen. In addition, if a drug was a chemotherapy medication and, therefore, subject to chemotherapy precautions, or if a drug was biohazardous according to the National Institute for Occupational Safety and Health's *NIOSH List of Antineoplastic and Other Hazardous Drugs in Health Care Settings, 2018*, it was also considered to require special handling.

Patient Assistance Program. CBO's assessment of whether a drug was associated with a patient payment assistance program was based on whether the NeedyMeds website (www.needymeds.org) indicated that a patient payment assistance program existed for that drug.

Distribution Through Nontraditional Channels. CBO's assessment of whether a drug was distributed through nontraditional channels was based on whether the drug was present in at least two of the following three specialty pharmacy drug lists: the January 2020 CVS Specialty Pharmacy Distribution Drug List, the January 2019 Cigna Specialty Drug List for Wisconsin, and the 2019 OptumRx Specialty Drug Management Program List. Those three lists are publicly available, are often in unison in identifying specialty drugs among drugs approved in 2016 and 2017, and represent three large specialty pharmacies.

Monitoring or Counseling Required. CBO's assessment of whether a drug required monitoring or counseling was based on whether the drug had considerable side effects that warranted additional monitoring or counseling (such as a required Risk Evaluation and Mitigation Strategy) or whether the disease being treated required additional monitoring for other reasons.¹⁶ Those criteria were often affirmed by checking the FDA label for each drug.

14. CBO regarded the drugs that were designated as specialty drugs in 2015 as having retained that status in 2017.

15. That approach was very similar to IQVIA's method, which specified the threshold as a "list price in excess of \$6,000 per year." If the list price that IQVIA used was the WAC, the annual median per capita spending in Medicare would probably closely approximate the yearly list price. If the list price that IQVIA used was the AWP, IQVIA's criterion would probably be more conservative than CBO's; however, if a drug from 2016 and 2017 was on the edge of specialty status (which was very rare), CBO consulted the drug lists of several specialty pharmacies to ascertain whether the drug was included on them. If there was conclusive evidence that a drug on the "edge" of specialty status was dispensed through several specialty pharmacies, then it was considered to be a specialty drug.

16. A Risk Evaluation and Mitigation Strategy is a pharmaceutical safety program that the FDA may require for certain drugs with considerable safety issues to assist in ensuring that the benefits of the drug outweigh its risks.

Glossary: Key Terms Related to Federal Drug Pricing

340B ceiling price: The maximum price a manufacturer can charge covered entities (certain hospitals and health centers that serve low-income or underserved populations) for a drug in the 340B program. The 340B ceiling price is equal to the difference between the drug's average manufacturer price (AMP) and a rebate amount that is calculated using the Medicaid rebate formula. Covered entities may also negotiate prices lower than the 340B ceiling price.

average manufacturer price (AMP): The average price paid to a manufacturer for a drug distributed to retail pharmacies, either through wholesalers or through sales directly from manufacturers to pharmacies. The AMP does not include the prices of drugs distributed to pharmacies that dispense prescription drugs primarily through the mail. It is not adjusted to account for rebates or other price concessions that manufacturers extend to pharmacy benefit managers or health insurers. Manufacturers report the AMP for each drug to the Centers for Medicare & Medicaid Services (CMS). The AMP is used to calculate the Medicaid basic and inflationary rebates and is not publicly available.

average wholesale price (AWP): The list price that represents the highest possible price assigned to a drug and that is used as a base price for business-to-business negotiations in the drug industry. The AWP is calculated using the wholesale acquisition cost (WAC)—often with a standard markup of approximately 20 percent—and is publicly available.

basic rebate: A rebate provided by manufacturers to Medicaid programs. For most brand-name drugs, it is equal to the greater of 23.1 percent of the AMP or the difference between the AMP and the best price.

best price: The lowest price for a drug available to any private-sector purchaser (not including Medicare Part D plans). The best price reflects discounts, rebates, and other pricing adjustments. Manufacturers report the

best price for each drug to CMS. Data on the best price are not publicly available and are used to calculate the Medicaid basic rebate.

Big Four price: The maximum price a drug manufacturer is allowed to charge the “Big Four” federal agencies, which are the Department of Veterans Affairs (VA); the Department of Defense (DoD); the Public Health Service (PHS, including the Indian Health Service); and the Coast Guard. The Big Four price is the lower of the Federal Supply Schedule (FSS) price and the federal ceiling price (FCP), minus any additional price concessions.

federal ceiling price (FCP): The cap used to determine the maximum price charged to the Big Four agencies (VA; DoD; PHS, including the Indian Health Service; and the Coast Guard), equal to 76 percent of a drug's previous year nonfederal average manufacturer price (non-FAMP) minus an additional amount if the non-FAMP grew more quickly than inflation, as measured by the consumer price index for all urban consumers. To receive payment for any drugs purchased by federal agencies and sold under the Medicaid program, manufacturers must provide brand-name drugs to the Big Four agencies at a price not to exceed the FCP.

Federal Supply Schedule (FSS) price: The price negotiated between manufacturers and VA (on behalf of all direct federal purchasers) that is available to all direct federal purchasers of pharmaceuticals, including VA, DoD, PHS, the Coast Guard, the Bureau of Prisons, the National Aeronautics and Space Administration, the Department of State, and other federal agencies and institutions. FSS prices for brand-name drugs are based on the lowest prices negotiated for brand-name drugs between manufacturers and their most-favored commercial customers. During a multiyear contract period, the FSS price may not increase faster than the net price charged to the most-favored commercial customer. FSS price lists are publicly available.

inflation-based rebate: An additional rebate provided by manufacturers to Medicaid if the AMP for a particular drug grows faster than overall inflation as measured by the consumer price index for all urban consumers. The rebate is equal to the excess amount of that growth.

most-favored commercial (MFC) customer price: The price paid by the private purchaser of a prescription drug who receives the best discount or price agreement from a manufacturer. When negotiating with manufacturers to set FSS prices, VA is required by federal regulations to attempt to achieve an FSS price that is equal to or lower than the MFC price. The MFC price is not publicly available. It is analogous to the best price, which is used to determine Medicaid rebates.

National Drug Code (NDC): A numeric identifier that uniquely identifies a specific drug product at its most granular level of distinction, reflecting its manufacturer, product name, dosage form, strength, route of administration, and package size. Each drug can have multiple NDCs if, for example, it is dispensed at different strengths or in different package sizes.

net price: The price of a drug after discounts, rebates, and other price concessions are subtracted.

nonfederal average manufacturer price (non-FAMP): The average price paid to manufacturers by wholesalers for drugs distributed to nonfederal purchasers, reflecting discounts but excluding any prices found by VA to be merely nominal (for example, in the case of drugs delivered to charities). The non-FAMP does not reflect rebates paid by the manufacturer to third-party payers (such as insurance companies or pharmacy benefit management companies). The non-FAMP is reported to VA and is not publicly available. It is analogous to the AMP, which is used to determine Medicaid rebates.

retail price: The price of a drug sold through retail channels without subtracting any discounts, rebates, or other price concessions.

wholesale acquisition cost (WAC): The list price for a drug sold to wholesalers or other direct purchasers that is used as a base price for business-to-business negotiations in the drug industry. The WAC is publicly available.

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About This Document

This report was prepared at the request of the Chairman of the Senate Budget Committee. In keeping with the Congressional Budget Office's mandate to provide objective, impartial analysis, the report makes no recommendations.

Colin Baker, Scott Laughery, and Yash Patel (formerly of CBO) wrote the report with guidance from Lyle Nelson. Scott Laughery and Yash Patel designed and conducted the data analysis. Christopher Adams, Elizabeth Bass, Ann Futrell, Sebastien Gay, Heidi Golding, Tamara Hayford, Leo Lex, Lara Robillard, Matt Schmit, John Skeen, Julie Topoleski, Ellen Werble, Chapin White, and Katherine Young provided useful comments. Anna Anderson-Cook (formerly of CBO) contributed to the initial development of this report. Rebecca Sachs and Jordan Trinh fact-checked the report.

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CBO continually seeks feedback to make its work as useful as possible. Please send any comments to communications@cbo.gov.



Phillip L. Swagel
Director
February 2021

Corrections

The Congressional Budget Office has corrected this report since its original publication. Both the PDF and online versions were corrected, but for ease of reference, this list indicates the locations of the corrections in the PDF.

The following changes were made on April 9, 2024:

The Notes page: The note beginning “In general, the drug prices presented” was added.

Page 16, Table 2: Footnote c was added.

Page 18, left-hand column, first partial paragraph: “that manufacturers receive for brand-name drugs, but they differ because of differences in the details of how they are calculated” was changed to “received by manufacturers, but they differ because they reflect sales during different periods and because of differences in how they are calculated.”

Page 31, left-hand column, first partial paragraph: The final sentence, “VA provided annual values for the FCP and the non-FAMP to CBO,” was changed to “VA supplied CBO with 2017 annual values for the FCP, as well as the annual non-FAMP values used to calculate them.”