Congressional Budget Office
*Nonpartisan Analysis for the U.S. Congress*

# Prescription Drugs: Spending, Use, and Prices



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# At a Glance

In recent years, policymakers have expressed concerns about the high prices of prescription drugs. Those drugs offer wide-ranging benefits, such as reducing the need for services provided by physicians and hospitals, improving the quality of life, and extending life. However, high prices reduce consumers' access to such medications. They also contribute to higher spending that strains budgets, including the federal budget.

In this report, the Congressional Budget Office examines trends in nationwide spending on prescription drugs over the 1980–2018 period. The report also provides a more detailed analysis of trends in spending, use, and prices in the Medicare Part D and Medicaid programs over the 2009–2018 period.

- **Spending on Prescription Drugs.** After decades of increases, per capita spending on prescription drugs began to level off in real terms (that is, with the effects of economywide inflation excluded) in the mid-2000s. Since that time, such spending has fallen as a percentage of total spending on health care services and supplies. That slower growth in spending is associated with the growing availability of generic drugs, which tend to have much lower prices than their brand-name counterparts.

  The period from 2013 to 2015 was an exception; during that time, spending on prescription drugs increased sharply, both in dollar terms and as a share of total spending on health care services and supplies. Although per enrollee spending in Medicare Part D was fairly stable from 2009 to 2018, per enrollee spending in Medicaid increased somewhat faster than nationwide per capita spending over that period.

- **Use of Prescription Drugs.** Consumers' use of prescription drugs has increased over time. Greater use of generic drugs is a key factor in that increase.

- **Prices of Prescription Drugs.** The average net price of a prescription—that is, the price of a prescription after subtracting the discounts and rebates that manufacturers provide to private insurers and federal programs—fell from $57 in 2009 to $50 in 2018 in the Medicare Part D program and from $63 to $48 in the Medicaid program. That trend reflects the increased use of lower-cost generic drugs, which was partially offset by rising prices for brand-name drugs. The average net price of brand-name prescription drugs increased substantially over that period: from $149 to $353 in Medicare Part D and from $147 to $218 in Medicaid. Average prices for generic drugs in Medicare Part D and Medicaid fell over that period. Nationwide changes in average prices—overall and for both brand-name drugs and generic drugs—probably followed similar patterns.

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# Notes

To remove the effects of general inflation when comparing prices and spending over time, all estimates of drug spending and prices in this report have been adjusted to 2018 dollars using the gross domestic product price index from the Bureau of Economic Analysis.

Unless otherwise indicated, all drug spending totals are based on net prices. Net drug spending and net prices include the total amount paid to a pharmacy less any discounts and rebates that manufacturers and pharmacies provide to "payers" (such as commercial and government-sponsored health insurance plans and the Medicaid program). In the case of Medicare Part D, those rebates and discounts include statutory discounts in the coverage gap. Because the Congressional Budget Office could not obtain data on the rebates and discounts paid for generic drugs in the Medicare Part D program, rebates and discounts for generic drugs were not subtracted from drug spending totals and net prices for that program.

For the analysis underlying this report, CBO used data from the Centers for Medicare & Medicaid Services. Spending totals, prescription counts, and average prices for prescription drugs in the Medicare Part D program were derived from data from the Part D Event File; those data were combined with detailed data on the rebates that Medicare Part D plans receive from manufacturers and pharmacies for brand-name drugs. For the Medicaid program, those values were derived from the State Drug Utilization Data and data on statutory Medicaid rebate amounts. Medicaid spending reflects total program spending, including both federal and nonfederal contributions.

Unless this report specifies otherwise, all discussions about prescription drugs—and all dollar amounts—pertain to drugs purchased in retail settings, such as local pharmacies or mail-order pharmacies, and exclude drugs that are administered in physicians' offices or hospitals. (In some cases, Medicaid's administrative data include drugs that are administered in physicians' offices; those drugs are included in this analysis.)

All prescription counts and average prices for medications obtained through Medicare Part D have been adjusted to reflect standardized 30-day prescriptions. Any prescription for which the number of days supplied is less than or equal to 30 counts as a single standardized prescription; for prescriptions in which the number of days supplied exceeds 30, the number of standardized prescriptions is equal to the number of days supplied divided by 30. For example, a prescription that has a 90-day supply equals three standardized prescriptions. Prescription counts and average prices for medications obtained through Medicaid were not adjusted for duration of supply because that information is not included in the Medicaid data.

CBO has corrected this report since its original publication. Corrections are listed at the end of the report.

# Prescription Drugs: Spending, Use, and Prices


## Summary

Prescription drugs have become an increasingly important part of U.S. health care, as evidenced by the growth in nationwide spending on those drugs from 1980 to 2018.[1] Over that period, such spending increased more than tenfold in real terms (that is, with the effects of economywide inflation excluded). This report by the Congressional Budget Office discusses trends in nationwide spending on prescription drugs in the retail market from 1980 to 2018. It also presents a detailed analysis of trends in spending, use, and prices in the Medicare Part D and Medicaid programs over the 2009–2018 period.

### What Are Recent Trends in Spending for Prescription Drugs?

Nationwide spending on prescription drugs increased from $30 billion in 1980 to $335 billion in 2018. (All estimates of drug spending and prices in this report are expressed in 2018 dollars.) Over that period, real per capita spending on prescription drugs increased more than sevenfold: from $140 to $1,073.[2] That increase in spending was driven by the development and use of many types of drugs that have yielded myriad health benefits. Because of those health benefits, some drugs, such as those that treat cardiovascular conditions, are associated with reductions in spending on services provided by hospitals and physicians.[3] Other types of drugs, such as those that treat multiple sclerosis or cancer, may not offer such compensating savings, but they have improved the lives of those with chronic conditions and have also extended life.

Spending on prescription drugs increased particularly rapidly after the mid-1990s with an increase in the number of drugs that attained "blockbuster" status by generating at least $1 billion in sales annually. Those blockbuster drugs generally treat conditions, such as high cholesterol or high blood pressure, that affect a large segment of the population.

Aside from a pronounced increase between 2013 and 2015, spending on prescription drugs has grown more slowly since the mid-2000s. That slower growth in spending—and the accompanying reduction in per capita spending—is associated with the growing availability of generic drugs, which tend to have much lower prices than their brand-name counterparts. The brief, sharp increase in spending between 2013 and 2015 coincided with the introduction of a particularly expensive class of drugs that treat hepatitis C.

Although per enrollee spending in Medicare Part D—Medicare's pharmaceutical benefit—was fairly stable from 2009 to 2018, per enrollee spending in Medicaid increased somewhat faster than nationwide per capita spending over that period. Per enrollee spending on prescription drugs in Medicare Part D averaged about $2,700 per year. Annual per enrollee spending in Medicaid increased over that period by 20 percent, from $445 to $530, whereas nationwide per capita spending increased by 10 percent.

Differences in average spending among enrollees in Medicare and Medicaid and the nation as a whole most likely stemmed from differences in the health profiles of their respective patient populations and statutory rebates in the Medicaid program. (Those rebates represent payments from drug manufacturers to "payers," such as commercial and government-sponsored health insurance plans and the Medicaid program.) Medicare beneficiaries are more likely to be prescribed medications for various chronic conditions, whereas many Medicaid beneficiaries who have prescription drug coverage through that


1. When CBO conducted its analysis, 2018 was the most recent year for which data were available.

2. In this report, "per capita" is used to describe averages for the nationwide population, whereas "per enrollee" is used to describe averages for enrollees in Medicare Part D or in Medicaid.

3. See David M. Cutler and others, "Explaining the Slowdown in Medical Spending Growth Among the Elderly, 1999–2012," *Health Affairs*, vol. 38, no. 2 (February 2019), pp. 222–229, www.healthaffairs.org/doi/10.1377/hlthaff.2018.05372.

program are younger and healthier and therefore are less likely to have medications prescribed for them on an ongoing basis.

## How Has the Use of Prescription Drugs Changed Over Time?

Nationwide per capita use of prescription drugs has increased in recent years. Per enrollee use of prescription drugs has also increased in Medicare Part D and Medicaid—from an average of 48 prescriptions per year in 2009 to 54 in 2018 in Medicare Part D, and from 7 prescriptions per year to 11 in Medicaid over that period. Increased use of prescription drugs is primarily associated with the increasing availability and use of generic drugs, along with the continued development of new treatments. In addition, the share of spending on prescription drugs that insurers cover has increased substantially: In 1990, consumers paid 57 percent of their prescription drug costs out of pocket, on average. By 2009, that share had fallen to 20 percent; it fell further, to 15 percent, in 2018.

The share of prescriptions for generic drugs has also increased substantially. Nationwide, that share increased from 75 percent in 2009 to 90 percent in 2018. In Medicare Part D, the share of prescriptions for generic drugs increased from 72 percent to 90 percent between 2009 and 2018; in Medicaid, it increased from 70 percent to 87 percent over that period. Increased use of generic drugs is attributable to several factors: their growing availability; their lower prices; and the lower out-of-pocket liability for consumers with health insurance compared with the amount people would pay for brand-name drugs. The share of prescriptions for generic drugs may be less likely to rise in the future, both because the 90 percent dispensing rate for such drugs is already high and because newer brand-name drugs tend to be more costly to manufacture and may be more challenging to replicate as generic drugs.

## How Has the Average Price of a Prescription Changed Over Time?

The average price of a prescription has fallen in both the Medicare Part D and Medicaid programs in recent years: from $57 in 2009 to $50 in 2018 in Medicare Part D and from $63 to $48 in Medicaid over that period. Those decreases were largely driven by the increased use of generic drugs in those programs. The growing use of generic drugs has put downward pressure on the nationwide average price of a prescription in recent years as well.

Brand-name drugs, while accounting for a declining share of prescriptions, have experienced substantial growth in average prices. Over the 2009–2018 period, the average price of a prescription for a brand-name drug more than doubled in the Medicare Part D program and increased by 50 percent in Medicaid. Two key drivers of those increases were higher launch prices for new drugs and growth in the prices of individual drugs already on the market. The growing shift toward specialty drugs among new drug entrants was an important factor in the increased launch prices of new drugs. (Specialty drugs, which treat complex, chronic, or rare conditions—such as different types of cancer, rheumatoid arthritis, or multiple sclerosis—tend to be costly to manufacture, serve relatively small markets, and have high prices. They may also require special handling or patient monitoring.)[4]

Federal policies have also played a role in the pricing patterns for brand-name drugs. For example, Medicaid's statutory rebates create an incentive for manufacturers to negotiate higher prices for commercial insurers as well as higher marketwide launch prices. (However, those rebates also create an incentive for manufacturers to increase prices more slowly over time, which probably mitigates the effect of higher initial prices.) In addition, the increase in the share of overall drug spending that is covered by Medicare and Medicaid may dampen the pressure on manufacturers to restrain prices because patients are more willing to purchase high-priced drugs when they have less exposure to those prices.

Unlike prices for brand-name drugs, average prices for generic drugs have fallen in recent years. From 2009 to 2018, the average price of a prescription for a generic drug fell from $22 to $17 in Medicare Part D and from $27 to $23 in Medicaid. Although the federal government and nearly all of the states have pursued legal action against several generic drug manufacturers for price fixing and other anticompetitive behavior, prices have probably increased for only a minority of generic

4. Different companies and different analysts use varied criteria to define specialty drugs. CBO uses the definition developed by IQVIA Institute for Human Data Science, a health information technology company. For more information on that definition and how CBO has followed it, see Congressional Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* (February 2021), www.cbo.gov/publication/56978.

drugs that represent a relatively small share of spending on prescription drugs.

## Trends in Spending for Prescription Drugs

From 1980 until the mid-2000s, spending on prescription drugs increased steadily—both in dollar terms and as a share of overall health care spending. That growth was driven by increases in the availability and use of different types of new drug therapies along with increasing prices of brand-name drugs. However, after the mid-2000s, the increasing availability and use of generic drugs put downward pressure on spending growth. Nationwide, real per capita spending and the share of overall health care spending attributable to prescription drugs began to decrease in the mid-2000s, with the exception of a sharp increase from 2013 to 2015. That increase coincided with the introduction of a particularly expensive class of drugs that are used to treat hepatitis C. Per enrollee spending was relatively flat in the Medicare Part D program from 2009 to 2018, whereas Medicaid's per enrollee drug spending grew over that period.

### Nationwide Spending on Prescription Drugs

Since 1980, the share of nationwide spending on health care services overall that can be attributed to prescription drugs has nearly doubled, from about 5 percent to almost 10 percent in 2018. Through the 1980s and early 1990s, 5 percent to 6 percent of all spending on health care services and supplies was on prescription drugs obtained in the retail market (that is, from pharmacies—either in stores or by mail order). By 2018, that share was 10 percent (see Figure 1). In comparison, the share of spending on health care services and supplies that was attributable to hospital services fell from 40 percent in 1980 to 31 percent in 2018, and the share attributable to services provided by medical professionals and in clinical settings was about 20 percent over that period.

Nationwide per capita spending on prescription drugs increased from $140 in 1980 to $1,073 in 2018 (see Figure 2).[5] (Those spending amounts are net of rebates and discounts. For background information on rebates, negotiations, and other attributes of pharmaceutical markets, see Box 1 on page 6.) Per capita spending on prescription drugs roughly doubled every 10 years before slowing down in the mid-2000s.

Although this report focuses on prescription drugs obtained through the retail market, spending on prescription drugs purchased in nonretail settings—such as physicians' offices, clinics, and hospitals—represents a substantial share of overall spending on prescription drugs. A recent estimate suggests that nonretail drugs represented approximately 30 percent of overall net spending on prescription drugs in the United States in 2016.[6] The general pattern of total drug spending over the period studied in this report is similar when those other sources and types of prescription drugs are included.[7]

### Trends in Spending Over the 1995–2013 Period.

Spending on prescription drugs rose particularly rapidly after 1995 as a number of drugs reached blockbuster status.[8] That wave of blockbuster drugs consisted of top sellers that were in high demand because they offered

5. Those spending figures come from the National Health Expenditure Accounts (NHEA), which report total spending on prescription drugs purchased at retail or mail-order pharmacies, minus the rebates that drug manufacturers pay to pharmacy benefit managers and health insurance plans. The spending figures are adjusted to account for inflation using the gross domestic product price index from the Bureau of Economic Analysis and are expressed in 2018 dollars. For more information on how NHEA data are constructed, see National Health Statistics Group, Office of the Actuary, Centers for Medicare & Medicaid Services, *National Health Expenditure Accounts: Methodology Paper, 2020—Definitions, Sources, and Methods* (2020), https://go.usa.gov//xswJJ (PDF, 621 KB).

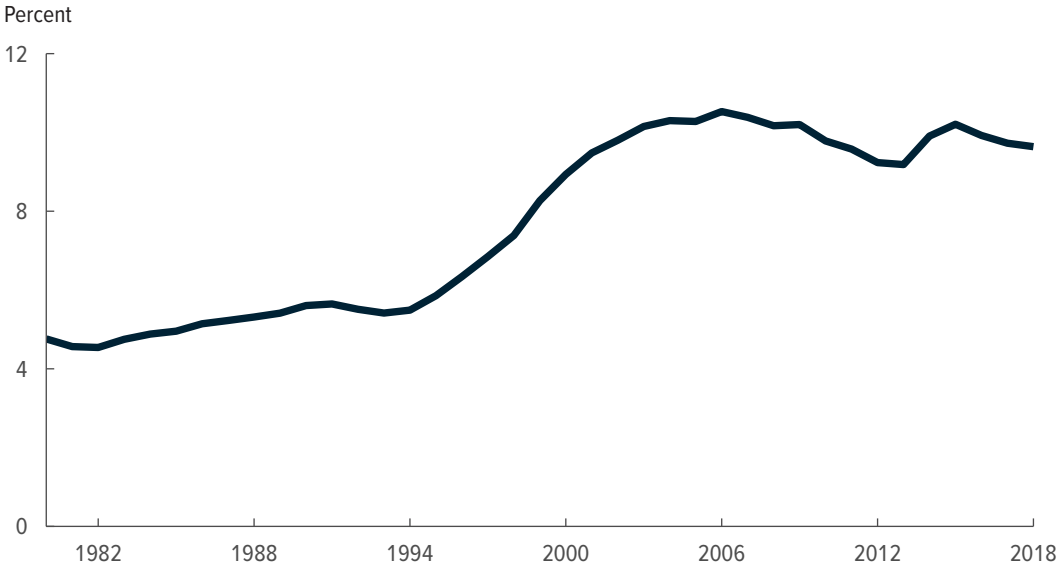
6. In that estimate, gross margins were projected to be the same in retail and nonretail settings—in other words, the percentage difference between a provider's or pharmacy's revenues and invoice costs for prescription drugs was the same, on average, in those two types of settings. See Charles Roehrig, *Projections of the Prescription Drug Share of National Health Expenditures Including Non-Retail* (Altarum, May 2018), https://tinyurl.com/d62yuens (PDF, 1.87 MB).

7. IQVIA is another commonly cited data source for spending on prescription drugs. That company's data report spending on prescription drugs from all channels, including those administered in hospitals and physicians' offices. Those data do not include markups along the distribution chain, such as dispensing fees or wholesalers' markups. As a result, it is difficult to directly compare IQVIA data with NHEA data. For IQVIA's data on prescription drug spending over a recent 10-year period, see IQVIA Institute for Human Data Science, *Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023* (May 2019), https://tinyurl.com/byjnzd7.

8. See Murray Aitkin, Ernst R. Berndt, and David M. Cutler, "Prescription Drug Spending Trends in the United States: Looking Beyond the Turning Point," *Health Affairs*, vol. 27 (2008), pp. w151–w160, https://www.healthaffairs.org/doi/10.1377/hlthaff.28.1.w151.

Figure 1.

## Spending on Prescription Drugs Purchased From Pharmacies as a Share of Total Spending on Health Care Services and Supplies




From 1980 to 2018, the availability and use of different types of new drug therapies, along with rising prices for brand-name drugs, contributed to increases in spending on prescription drugs. At the same time, the availability and use of generic drugs put downward pressure on such spending.

Data source: Congressional Budget Office, using data from Centers for Medicare & Medicaid Services, National Health Expenditure Data, Historical, National Health Expenditures by Type of Service and Source of Funds: Calendar Years 1960 to 2019, entries for "Prescription Drugs" and "Total National Health Expenditures" (accessed December 10, 2021), https://go.usa.gov/xASdV. See www.cbo.gov/publication/57050#data.

Spending on prescription drugs is net of rebates paid by manufacturers to payers, such as commercial and government-sponsored health insurance plans and the Medicaid program.

Data for prescription drug spending exclude spending on drugs that are administered in physicians' offices or hospital settings.

new treatments for relatively common health conditions. The most prominent of those drugs were statins for high cholesterol, ACE inhibitors for high blood pressure, proton-pump inhibitors for acid reflux and gastric ulcers, and antidepressants and antipsychotics for mental illnesses. When the patents on those drugs began to expire—an event often referred to as the patent cliff—lower-priced generic substitutes were introduced and gained market share.[9] In the midst of that shift, the Medicare Part D program was created, which both increased access to prescription drugs for Medicare beneficiaries and contributed to the shift from brand-name drugs to generic alternatives.[10] As a result, per capita spending on prescription drugs leveled off at about $940 in the mid-2000s and then fell to $900 by 2013, and the share of overall health care spending for prescription drugs peaked at 10.5 percent in 2006 and then fell to 9.2 percent in 2013.

**Trends in Spending Since 2013.** Spending on prescription drugs increased again over the 2013–2015 period before leveling off thereafter. A key factor in that increase was the introduction, at the end of 2013, of a class of specialty drugs that treat hepatitis C. The drugs for hepatitis C were introduced at particularly high prices.[11] Insurers and patients may have been willing to pay those prices because of the enormous clinical benefits those drugs offer when compared with older therapies

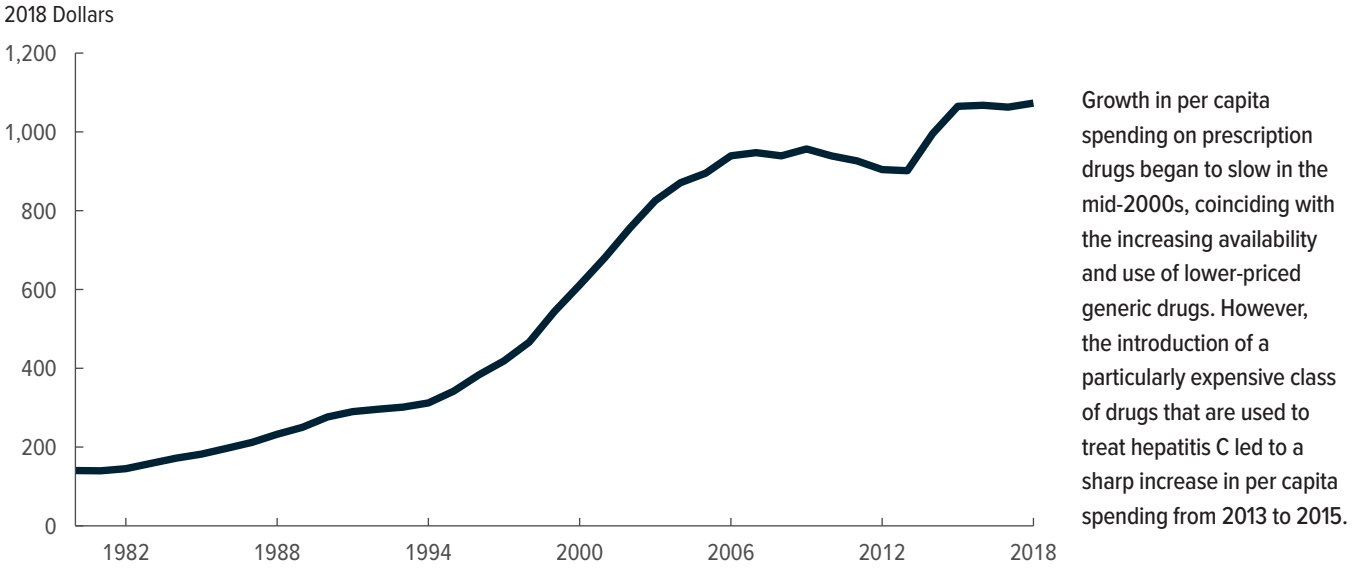
9. Since 1995, U.S. patents have been granted for 20 years from the date of filing. With time for processing the patent application and, in particular, for testing a new drug and gaining approval from the Food and Drug Administration to market it, the effective life of a drug patent is often about 10 years.

10. Most Part D plans have a benefit design that includes lower out-of-pocket costs for generic drugs. See Murray Aitkin, Ernst R. Berndt, and David M. Cutler, "Prescription Drug Spending Trends in the United States: Looking Beyond the Turning Point," *Health Affairs*, vol. 27 (2008), pp. w151–w160, www.healthaffairs.org/doi/10.1377/hlthaff.28.1.w151.

11. For example, Sovaldi was launched in December 2013 with a list price of $84,000 for a standard 12-week regimen, and Harvoni was launched in October 2014 with a list price of $94,500 for a standard 12-week regimen. Viekira Pak was launched soon after, in December 2014, with a list price of $83,319 for a standard 12-week regimen. See Medicaid and CHIP Payment and Access Commission, *High-Cost HCV Drugs in Medicaid: Final Report* (prepared by Brian Bruen and others, January 2017), https://go.usa.gov/xswhd.

Figure 2.

## Total Nationwide Spending, per Capita, on Prescription Drugs Purchased From Pharmacies




Data source: Congressional Budget Office, using data from Centers for Medicare & Medicaid Services, National Health Expenditure Data, Historical, National Health Expenditures by Type of Service and Source of Funds: Calendar Years 1960 to 2019, entries for "Prescription Drugs" and "Population" (accessed December 10, 2021), https://go.usa.gov/xASdV. See www.cbo.gov/publication/57050#data.

Spending on prescription drugs is net of rebates paid by manufacturers to payers, such as commercial and government-sponsored health insurance plans and the Medicaid program.

Data for prescription drug spending exclude spending on drugs that are administered in physicians' offices or hospital settings.

To remove the effects of general inflation when comparing prices and spending over time, estimates of spending on prescription drugs have been adjusted to 2018 dollars using the gross domestic product price index from the Bureau of Economic Analysis.

(they successfully treat about 95 percent of patients with chronic hepatitis C infection) and the stiff demand for that kind of therapy.[12] However, the patient population for that class of drugs is larger than that for many specialty drugs, leading to a larger impact on spending than would have occurred for a similarly priced drug that treats a smaller patient population.

Implementation of the insurance expansions under the Affordable Care Act (ACA) also occurred during this period.[13] Researchers have found that new take-up of Medicaid in states that expanded coverage under the terms of the ACA was associated with greater use of prescription drugs because those benefits reduced out-of-pocket spending for the previously uninsured and also tended to be more generous than previous sources of coverage.[14] Take-up of marketplace health insurance options under the insurance expansions may have been associated with a similar response. However, overall use of prescriptions in the Medicaid program did not grow faster in the years immediately following the insurance expansions than it did in prior years, suggesting that the expansions were not a key driver of the increase in spending on prescription drugs over that period.[15]

12. See Department of Veterans Affairs, "Hepatitis C Medications: An Overview for Patients" (accessed March 16, 2021), https://go.usa.gov/xs7qe.

13. 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.

14. See Ausmita Ghosh, Kosali Simon, and Benjamin D. Sommers, "The Effect of Health Insurance on Prescription Drug Use Among Low-Income Adults: Evidence From Recent Medicaid Expansions," *Journal of Health Economics*, vol. 63 (January 2019), pp. 64–80, https://doi.org/10.1016/j.jhealeco.2018.11.002.

15. See IQVIA Institute for Human Data Science, *Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021* (May 2017), Chart 8, https://tinyurl.com/32ea3225.

Box 1.

## The Flow of Payments and Products in Prescription Drug Markets

Markets for prescription drugs purchased at pharmacies in the United States are served by a complex supply chain, with payment flows involving multiple actors, including intermediaries (such as pharmacy benefit managers, or PBMs, which negotiate prices but do not distribute or dispense the products). The supply process begins with pharmaceutical manufacturers selling their output to wholesale distributors. The distributors resell those drugs to pharmacies, at prices that may have been negotiated by group-purchasing organizations on behalf of members, including pharmacies. Pharmacies package the drugs into prescriptions and sell them a third time, to consumers. As a result, the concept of "price" differs depending on the entity that is receiving payment—or paying—for a prescription.

### Payments That Pharmacies Receive

The retail price of a drug at the pharmacy counter is determined by negotiations between pharmacies and insurers (or their PBMs) and reflects both wholesale and retail markups. Those markups compensate the wholesaler and pharmacy, respectively, for the services they provide and for their inventory costs. The retail price of a given drug is probably similar for most payers.[1] (Payers are the entities that pay for prescription drugs, namely commercial insurers and federal health care programs, as well as individuals without insurance coverage for prescription drugs.) Consumers who have not yet satisfied their insurance plan's annual deductible pay that retail price or possibly much less if the manufacturer has a coupon program for that drug and the consumer is eligible for the program. (A deductible is the amount of spending an enrollee incurs before an insurer begins covering expenses.) Consumers with health insurance who have met their deductible pay only a portion of the retail price, as specified by their plan's copayment or coinsurance schedule; the remainder is paid by their plan or its PBM. (A copayment is a specified dollar amount that an enrollee pays at the time a drug is purchased. Coinsurance is cost sharing in the form of a set percentage of the drug's cost.) Consumers without insurance may pay a pharmacy's "usual and customary" price—which tends to be higher than the retail prices paid by other payers—or may pay a discounted amount using a coupon program such as GoodRx.[2]

### Prices That Insurers Pay

For insurance plans, a drug's retail price bears little relation to the plan's costs for prescription drug claims, especially in the case of brand-name drugs. The actual price to the insurer is largely determined by the rebate, the negotiated payment it later receives from the manufacturer. (Manufacturers of generic drugs generally do not offer rebates to insurance plans, although they pay rebates to pharmacies.)[3] The size of the rebate, which varies by drug, health insurance plan, and enrollees' total purchases of the drug in that plan, is negotiated in advance by the insurer or the insurer's PBM. (That process is described below in the section titled "Negotiations With Manufacturers.")

For brand-name drugs, the PBM may achieve its markup by retaining a small portion of the manufacturer's rebate, with the remainder going to the insurer or payer. The insurer, in turn, shares most of the rebate with its enrollees in the form of lower premiums or more generous benefits on its insurance coverage.[4] For generic drugs, there is generally no rebate to share; consequently, the PBM may mark up the net prices of those drugs or may instead charge the plans higher fees for its administrative services.

**Negotiations With Manufacturers.** The process by which net prices are negotiated is similar for most insurance plans,

1. The Congressional Budget Office found that retail prices for a given basket of drugs were very similar for Medicare and Medicaid. See Congressional Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* (February 2021), www.cbo.gov/publication/56978.

2. See Adam J. Fein, "How GoodRx Profits From Our Broken Pharmacy Pricing System" (blog entry, August 31, 2020), https://tinyurl.com/2dh6hxyw.

3. Unlike rebates for brand-name drugs, those rebates do not reduce net costs to plans because they are paid to pharmacies or wholesalers rather than to plans or PBMs. See Steven M. Lieberman and Paul B. Ginsburg, *Would Price Transparency for Generic Drugs Lower Costs for Payers and Patients?* (Leonard D. Schaeffer Center for Health Policy and Economics and the Center for Health Policy at Brookings, June 2017), https://tinyurl.com/2mczpcxs.

4. PBMs have recently reported that 90 percent of rebates are passed through to insurers and plan sponsors, though small insurers and employers have reported that they receive smaller shares of rebates. See Elizabeth Seeley and Aaron S. Kesselheim, *Pharmacy Benefit Managers: Practices, Controversies, and What Lies Ahead* (Commonwealth Fund, March 2019), https://tinyurl.com/b7xh8vup (PDF, 405 KB).

Continued

Box 1. Continued

## The Flow of Payments and Products in Prescription Drug Markets

although the net prices themselves can vary widely across those plans. A PBM bargains with a manufacturer for a larger rebate on a drug in exchange for preferred placement of that drug in a plan's formulary (or list of covered drugs). Those negotiations may also include stronger restrictions on—or exclusion of—competing drugs as well as "price protection" rebates that protect the PBM and plan against large price increases during the benefit year.

For drugs in the preferred tier of a plan's formulary, enrollees typically have a lower copayment or coinsurance rate and may face fewer restrictions—such as the requirement that a beneficiary obtain prior authorization before purchasing a drug. The opposite is true for drugs in nonpreferred tiers. (Drugs in nonpreferred tiers generally have higher cost-sharing requirements or more restrictions on utilization than drugs in preferred tiers.) Net prices for the Medicaid program are heavily influenced by rebates determined by statutory rules, though smaller supplemental rebates may be negotiated by states through a similar process in exchange for placement on a preferred drug list.[5]

That process generally does not extend to drugs that must be administered by a physician. In such cases, the insurer often reimburses the administering physician who provided the drug rather than purchasing it from a pharmacy. Those drugs tend to be covered by an insurance plan's medical benefit rather than its pharmacy benefit. For that reason, the pricing for physician-administered drugs mostly relies on the prices that physicians pay to purchase those drugs.

Manufacturers tend to offer larger rebates on drugs that face competition from other products. (In the absence of competition, a pharmaceutical company may offer only minimal or no rebates.) That applies to rebates for commercial insurance plans as well as to those provided to Medicare Part D, which is administered by private insurers. A large share of rebates provided to Medicaid, by contrast, are not directly negotiated, although they partly depend on the rebates negotiated by commercial insurers. Specifically, Medicaid receives the greater of the largest rebate paid to any commercial insurer or a statutory minimum rebate (currently 23.1 percent of the average manufacturer price, or AMP—the average price that wholesalers have paid for drugs they sell to retailers or that retailers paid directly to manufacturers).

**Payments From Pharmacies.** Pharmacies are another source of post-sale payments to PBMs and plans that reduce the net prices they have paid for prescription drugs. Such payments, which generally take the form of fees that pharmacies pay to PBMs and plans, are much smaller than those from manufacturers and can apply to purchases of both brand-name and generic drugs.[6] Those fees are generally related to inclusion of a pharmacy in a plan's network of preferred pharmacies or to discounts associated with prompt payment.[7]

**Additional Rebates Paid to Medicaid and Other Federal Payers.** Rebates paid to Medicaid are also subject to the inflation-adjustment provision described in the section of the report titled "Comparing Prices Among Payers." Most states also negotiate with manufacturers for supplemental Medicaid rebates in exchange for providing beneficiaries easier access to the drugs associated with those rebates. Other federal payers negotiate discounts that make the prices paid by those programs substantially lower than net prices in Part D but somewhat higher than those paid by Medicaid.[8] Although manufacturers of generic drugs do not generally pay a negotiated rebate to insurers, Medicaid receives a statutory minimum rebate, currently 13 percent of the AMP plus an inflation-based rebate, on generic drugs.

5. The Medicaid price and spending figures in this report do not include those supplemental rebates because CBO does not have information about such rebates.

6. The size of those fees in the Part D program has been growing in recent years. By one estimate, post-sale discounts accounted for 18 percent of all rebates and discounts collected by Part D plans in 2019. See Adam J. Fein, "Pharmacy DIR Fees Hit a Record $9 Billion in 2019—That's 18% of Total Medicare Part D Rebates" (blog entry, February 13, 2020), https://tinyurl.com/5xsuhua3.

7. See Deana Bell and Tracy Margiott, *Medicare Part D DIR: Direct and Indirect Remuneration Explained* (Milliman, January 2018), https://tinyurl.com/p7r5dp9v.

8. See Congressional Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* (February 2021), www.cbo.gov/publication/56978.

## Medicare and Medicaid Spending on Prescription Drugs

Measured in 2018 dollars, spending on prescription drugs grew from $74 billion in 2009 to $120 billion in 2018 in the Medicare Part D program and from $18 billion to $32 billion in Medicaid. Those programs account for a large share of all U.S. spending on retail prescription drugs. Together, beneficiaries in those programs were responsible for about 45 percent of nationwide spending on retail prescription drugs in 2018 as measured in the National Health Expenditure Accounts. The analysis in this section covers a shorter period than the period examined for nationwide spending because Medicare Part D was not implemented until 2006, and early data were not representative of the program's spending because it took time for enrollees to adapt to the new program. This was particularly true for people who were dually eligible for Medicare and Medicaid and whose prescription drug coverage transitioned from Medicaid to Medicare Part D.[16] CBO therefore decided to focus on the most recent 10-year period for which data were available for both programs. (Those totals reflect amounts spent by insurers and patients, less rebates and discounts for brand-name drugs.)

For the purposes of making comparisons between different populations, it is most meaningful to compare patterns in per capita or per enrollee spending. Changes in spending per person reflect a variety of factors, such as changes in average health status—both at the population level and the program level—and changes in prices. For example, the aging of members of the baby-boom generation most likely increased nationwide per capita spending over the 2009–2018 period because of the corresponding increase in the average age of the population.[17] At the same time, that trend probably put downward pressure on per enrollee spending in Medicare Part D because it corresponded to a larger relative increase in the younger Medicare population. Changes in total spending are also affected by population and enrollment growth—and enrollment in Medicare Part D and Medicaid grew much faster than the nationwide population over the study period.[18] For Medicare Part D, net per enrollee spending on prescription drugs remained relatively stable, averaging about $2,700 from 2009 to 2018. Medicaid's per enrollee spending grew by about 20 percent over that period, starting from $445 per enrollee in 2009 and reaching $530 in 2018.[19] Over the same period, nationwide per capita spending grew by nearly 10 percent—from $957 to $1,073.

The greater increase in Medicaid's per enrollee spending may partly relate to new specialty drugs that treat conditions, such as HIV or hepatitis C, with a higher prevalence in the Medicaid population than in the Part D population.[20] Another key factor is a greater increase in per enrollee use of prescription drugs in Medicaid than in Medicare Part D, as demonstrated below. The role of the Medicaid expansions in those trends is unclear, depending on the average usage patterns of the newly eligible Medicaid population compared with the previously eligible population. One study found that increases in prescription volume were similar to increases in enrollment in states that expanded Medicaid, suggesting that the impact on per enrollee spending depends on the average prices for drugs used by the newly eligible population compared with the previously eligible population.[21]

16. See Kaiser Family Foundation, *The Transition of Dual Eligibles to Medicare Part D Prescription Drug Coverage: State Actions During Implementation* (2006), https://tinyurl.com/2v4crsf8.

17. The baby-boom generation is the cohort born between 1946 and 1964.

18. In Medicare Part D, enrollment grew by about 60 percent—about the same amount as for spending—whereas the number of people who received coverage for prescription drugs from the Medicaid program grew by about 50 percent. In comparison, the nationwide population grew by less than 10 percent.

19. For the purposes of this analysis, beneficiaries who are dually enrolled in Medicare and Medicaid are counted as Medicare enrollees because their prescription drug use is covered by the Medicare Part D benefit. In addition, some Medicaid-only enrollees are eligible only for limited benefits. The calculations of per enrollee Medicaid spending and prescription drug use in this report incorporate CBO's estimate of the number of people with Medicaid coverage for prescription drugs. For more details, 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. 32, www.cbo.gov/publication/55011.

20. See Kaiser Family Foundation, "Medicaid and HIV" (October 1, 2019), https://tinyurl.com/y53tecc8; and Haley Bush and others, "Impact of Hepatitis C Virus and Insurance Coverage on Mortality," *American Journal of Managed Care*, vol. 25, no. 2 (February 2019), pp. 61–67, https://tinyurl.com/2t4t2prk.

21. See Ausmita Ghosh, Kosali Simon, and Benjamin D. Sommers, "The Effect of Health Insurance on Prescription Drug Use Among Low-Income Adults: Evidence From Recent Medicaid Expansions," *Journal of Health Economics*, vol. 63 (January 2019), pp. 64–80, https://doi.org/10.1016/j.jhealeco.2018.11.002.

Differences in the amounts of per enrollee spending in Medicare Part D and Medicaid and in per capita spending in the United States as a whole are stark. They are most likely driven by a combination of differences in average health status and statutory rebates in the Medicaid program. Per enrollee spending in Medicare is much higher than the national average, probably because many Medicare beneficiaries have chronic health conditions and may fill several prescriptions per month. By contrast, lower per enrollee spending in Medicaid is probably attributable to a combination of the statutory rebates in that program—which lead to lower net prices—and the fact that many Medicaid beneficiaries with prescription drug coverage are relatively healthy adults or children. That offsets higher average spending by the less healthy disabled population in the Medicaid program.

## Trends in the Use of Prescription Drugs

Utilization of prescription drugs nationwide has increased in recent years, both because the prevalence of chronic conditions has increased with the aging of the U.S. population and because new therapies and generic drugs have become available.[22] Over the past several decades, consumers, health care providers, and insurers have witnessed the emergence of blockbuster therapies that treat common conditions, such as high blood pressure, high cholesterol, anxiety, and depression; and the emergence of generic alternatives for those drugs has improved access to such treatments by offering lower-cost options. In addition, consumers' share of spending on prescription drugs has fallen substantially as the combined share of spending covered by federal programs and private health insurance has increased over time.

Use of prescription drugs among those enrolled in Medicare Part D and Medicaid increased as well. Administrative data about Medicare Part D show that from 2009 to 2018 the average number of standardized prescriptions per beneficiary rose from 48 to 54 per year—a 13 percent increase. (Standardized prescriptions are adjusted to 30-day equivalents for more than a 30-day supply.) According to administrative data about Medicaid, the number of prescriptions per person with Medicaid coverage for prescription drugs rose from an average of 7 to 11 per year over that same period—an increase of 57 percent. (The administrative data on Medicaid drug use and spending do not include information on days supplied and thus are unadjusted.) As with per enrollee spending, the variation in per enrollee use of prescription drugs between those two programs reflects differences in the health status of their beneficiaries.

### Underlying Drivers of Increased Use

The reduction in consumers' out-of-pocket costs for prescription drugs is one key factor that explains the increased use of prescription drugs. In 1990, consumers' share of spending on prescription drugs was 57 percent. By 2009, that share had fallen to 20 percent. It continued to fall thereafter, declining to 15 percent in 2018. That long-term decline is largely explained by a gradual increase in the share of spending covered by the Medicare and Medicaid programs, which grew from 13 percent in 1990 to 36 percent in 2018.[23]

Some of that increase is attributable to the creation of Medicare Part D in 2006. In that year, the share of spending covered by Medicare and Medicaid increased to 25 percent, up from 19 percent in 2005. That share has steadily increased since 2006. More recent increases were partly attributable to the increased generosity of the Part D benefit that was mandated by both the ACA in 2010 and the Bipartisan Budget Act of 2018, as well as to the Medicaid expansions that were encouraged by the ACA.[24]

The role of private health insurance in paying for prescription drugs has also increased since 1990. Its share of spending was 26 percent in 1990 and 44 percent in 2018, although the share covered by private health

22. See, for example, IQVIA Institute for Human Data Science, *Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021* (May 2017), https://tinyurl.com/32ea3225.

23. Those spending figures, along with the ones in the next two paragraphs, are from Centers for Medicare & Medicaid Services, National Health Expenditure Data, Historical, NHE Tables, Table 16: "Retail Prescription Drugs Expenditures; Levels, Percent Change, and Percent Distribution, by Source of Funds: Selected Calendar Years, 1970–2018," https://go.usa.gov/xASdV.

24. The Affordable Care Act required that cost sharing in the Part D coverage gap gradually fall from 100 percent of retail prices in 2010 to 25 percent in 2020. (Also known as the donut hole, the coverage gap represents a range of spending for which beneficiaries were originally required to pay the full cost of their prescription drugs. Although the coverage gap was eliminated in 2019, the term is still defined in federal law to refer to that phase of the benefit.) The Bipartisan Budget Act accelerated that change by setting maximum cost sharing for brand-name drugs dispensed in the coverage gap to 25 percent in 2019. (That provision also applied to biosimilars, which are drugs that contain the same active molecule as a drug made from a living organism—referred to as a biologic drug.)

insurance was highest in the early 2000s, ranging from 47 percent to 50 percent. That share has since fallen.

Greater access to generic drugs in those programs may be another key factor that explains the increased use of prescription drugs: Lower-cost options make it easier for people to purchase their prescribed medications. Nationwide, the share of standardized prescriptions dispensed for generic drugs was 75 percent in 2009 and reached 90 percent by 2018.[25] In Medicare Part D, the number of standardized prescriptions dispensed for generic drugs more than doubled from 2009 through 2018, whereas the number of standardized prescriptions dispensed for brand-name drugs declined by a third. In Medicaid, the number of generic prescriptions roughly tripled over that time, whereas the number of brand-name prescriptions was essentially unchanged (see Figure 3). As a result, the share of prescriptions for generic drugs in Medicare Part D increased from 72 percent in 2009 to 90 percent in 2018; that share increased from 70 percent to 87 percent in Medicaid over the same period. Increased use of generic drugs also helps explain why per enrollee spending in federal programs rose more slowly than the increase in overall use of prescription drugs in those programs.

## Factors Contributing to Changes in the Use of Generic Drugs

One of the primary factors contributing to the increased use of generic drugs over the 2009–2018 period was the availability of generic equivalents for a growing number of brand-name drugs as their patents expired or were successfully challenged by manufacturers of generic drugs. That process accelerated in the first decade of the 2000s when the blockbuster drugs of the previous decade began losing their sales-exclusivity rights. In addition, insurers have used a variety of tools to steer patients toward generic drugs.

However, the rate of increase in the share of prescriptions for generic drugs has slowed in recent years. That reduced growth coincides with the leveling off of two former sources of growth: First, the share of prescriptions for which a generic option is available has equaled 92 percent since 2016. Second, since 2013, 97 percent of prescriptions that have both a brand-name option and a generic option have been dispensed as generic drugs.[26] Also, going forward, further availability of generic drugs may be somewhat limited if newer and more complex brand-name drugs are less likely to attract generic competition. That could be the case if those drugs treat conditions that affect fewer patients and are more challenging to replicate.

**Factors that Increase the Use of Generic Drugs.** Health insurers use a variety of methods to encourage the use of generic drugs when they are available. A common tool is to charge lower out-of-pocket costs for generics than for brand-name alternatives. For example, employment-based insurance plans required a copayment—that is, a specified dollar amount that an enrollee pays at the time a drug is purchased—of $11, on average, in 2019 for prescription drugs in their first tier, which is usually largely restricted to generic drugs.[27] Average copayments for drugs in the second and third tiers ranged from $33 to $59; those tiers tend to include preferred and nonpreferred brand-name drugs.[28] Plans often require lower cost sharing for drugs with "preferred" formulary placement and higher cost sharing for drugs with "nonpreferred" formulary placement. (A formulary is the plan's list of covered prescription drugs.) Plans typically require even higher cost sharing for specialty drugs, which are less likely to have generic alternatives.

Similarly, median copayments for generic drugs ranged from no cost for preferred generics to $3 for nonpreferred generics among stand-alone Medicare Part D plans in 2020. (The median copayment divides copayment amounts into two equal groups; that is, half of enrollees in stand-alone Part D plans paid nothing for preferred generics and no more than $3 for nonpreferred generics,

25. See Ernst R. Berndt and Murray L. Aitken, "Brand Loyalty, Generic Entry, and Price Competition in Pharmaceuticals in the Quarter Century After the 1984 Waxman-Hatch Legislation," *International Journal of the Economics of Business*, vol. 18, no. 2 (August 2011), pp. 177–201, https://doi.org/10.1080/13571516.2011.584423; and IQVIA Institute for Human Data Science, *Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023* (May 2019), https://tinyurl.com/2byjnzd7.

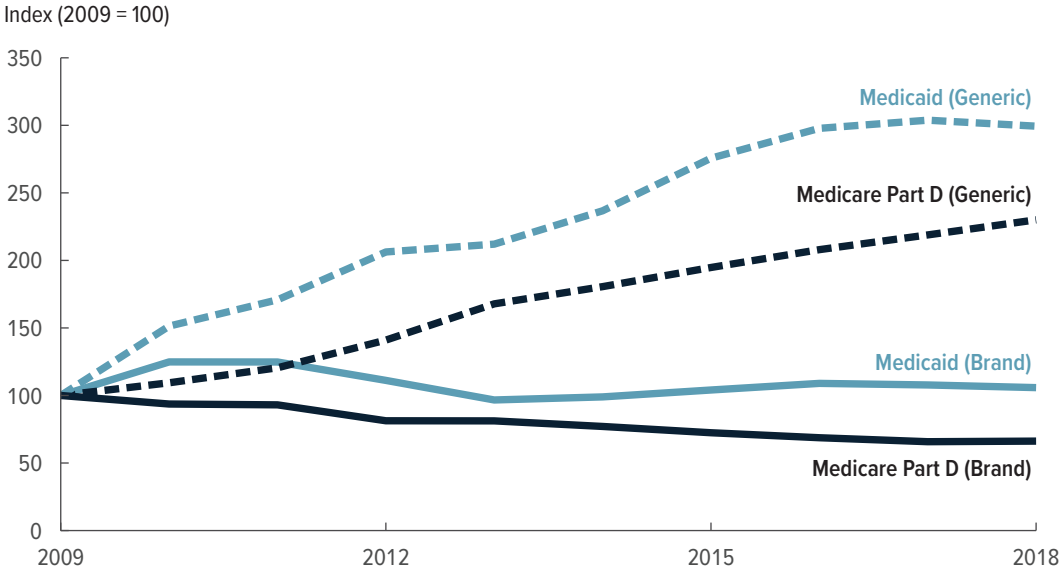
26. See IQVIA Institute for Human Data Science, *Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023* (May 2019), https://tinyurl.com/2byjnzd7.

27. Tiered formularies allow insurance plans to cover less expensive options more generously and more expensive options less generously. Generic drugs often require the lowest amount of cost sharing, whereas very expensive drugs or those for which plans have negotiated smaller rebates tend to have higher cost-sharing requirements.

28. See Kaiser Family Foundation, *2019 Employer Health Benefits Survey* (September 25, 2019), https://tinyurl.com/wc9smxep.

Figure 3.

## Changes in the Number of Brand-Name and Generic Prescription Drugs Dispensed Through Medicare Part D and Medicaid




Although the use of generic drugs grew over the 2009–2018 period, the use of brand-name drugs did not. Two factors account for that difference: Generic equivalents for a growing number of brand-name drugs became widely available, and insurers increasingly steered patients toward generic drugs.

Data source: Congressional Budget Office, using administrative data for Medicare Part D and Medicaid. See www.cbo.gov/publication/57050#data.

and the other half paid no less than those amounts.) Copayments for generic drugs topped out at $10 that year, and the median copayment for preferred brand-name drugs was $42.[29] In general, cost sharing for non-preferred brand-name drugs and specialty drugs tended to be set at a percentage of retail prices—the prices that plans pay to pharmacies, which do not account for rebates provided by manufacturers.[30]

Other tools are used to manage utilization directly: For the most part, the Medicaid program requires that generic versions of a drug be dispensed when available, and most Medicare Part D plans exclude the brand-name version of a drug from its formulary when a generic alternative is available.[31]

When consumers pay the full amount for a prescription drug out of pocket, the difference in the amount they pay for a generic drug versus a brand-name alternative is generally larger than the differences described above. That leads to a greater incentive to choose a generic substitute over a brand-name drug. Consumers may have to pay the full amount for a drug for three reasons: They lack health insurance (or their plan does not include coverage for prescription drugs); their prescribed drug is not covered by their plan; or they have not met their insurance plan's annual deductible (if any) for prescription drugs. (A deductible is the amount of spending an enrollee incurs before an insurer begins covering expenses.) In the first two cases, consumers may pay a pharmacy's "usual and customary" price—which tends to be higher than the retail prices paid by other federal health care programs and commercial insurers—or they may pay a discounted amount using a coupon program such as GoodRx.[32] In the third case, the

29. Some people are enrolled in a Medicare Advantage plan for services provided in hospitals and by physicians and then enroll in a connected Part D plan provided by the same Medicare Advantage insurer. Those who are not enrolled in Medicare Advantage enroll in a stand-alone Part D plan.

30. See Juliette Cubanski and Anthony Damico, *Medicare Part D: A First Look at Prescription Drug Plans in 2020* (Kaiser Family Foundation, November 2019), http://tinyurl.com/8kw9x2ts.

31. See Kaiser Family Foundation, *How State Medicaid Programs Are Managing Prescription Drug Costs* (2020), https://tinyurl.com/vuee3xz3; and Stacie B. Dusetzina and others, "Medicare Part D Plans Rarely Cover Brand-Name Drugs When Generics Are Available," *Health Affairs*, vol. 39, no. 8 (August 2020), pp. 1326–1333, www.healthaffairs.org/doi/full/10.1377/hlthaff.2019.01694.

32. See Adam J. Fein, "How GoodRx Profits From Our Broken Pharmacy Pricing System" (blog entry, August 31, 2020), https://tinyurl.com/2dh6hxyw.

consumer pays the retail price that the plan negotiated with the pharmacy. In 2019, 13 percent of people with employment-based insurance were enrolled in a plan with a deductible specific to prescription drugs, up from 10 percent in 2005.[33]

**Constraints on Further Increases in the Use of Generic Drugs.** The use of generic drugs may not increase much further for two reasons: First, generic drugs are used extensively. (Those drugs represent 90 percent of all prescriptions.) Second, newer drugs are more likely to be biologics (drugs that are produced from living organisms). Those drugs are more complex and harder to manufacture or replicate than small-molecule drugs. Consequently, there may be fewer generics developed from them when their patents expire.

Manufacturing a biologic with the same active molecule—called a biosimilar—introduces an additional layer of complexity compared with small-molecule drugs. Biosimilars are necessarily created from different cell lines than the originals, so they are not identical at the molecular level. As a result—unlike for generic versions of small-molecule drugs—noninnovator firms (that is, manufacturers of generic or biosimilar drugs) typically need to run clinical trials to demonstrate that their biosimilars are not meaningfully different from the reference biologic product. For certain biologic drugs that have small markets, the difficulty that prospective imitators might face is compounded. The lower potential revenues from sharing a small market, at lower prices, may increase the risk that firms producing biosimilars will fail to recover their higher development costs from imitating a complex drug.[34] As a result, future competition from noninnovators may be less robust in some cases as the patents for today's newer drugs expire.

In addition, drug manufacturers have been able to partly neutralize insurance plans' ability to steer their enrollees toward generic drugs by issuing coupons directly to consumers. Drug coupons make expensive therapies more affordable and increase manufacturers' unit sales. However, coupons interfere with insurers' cost-control efforts: Specifically, by covering some or all of an enrollee's copayment or coinsurance (cost sharing in the form of a set percentage of the drug's cost), coupons reduce or eliminate the cost difference between a more expensive drug and a cheaper generic or preferred alternative. When a coupon induces an enrollee to choose a brand-name drug over a generic, it increases the cost to insurers because they then must cover the more expensive brand-name drug for that enrollee. (Coupons also provide a discount for consumers who have not yet met their deductible or who lack insurance coverage.)

Coupon programs offered by manufacturers have become more prevalent over time: Whereas in 2009 manufacturers issued coupons for fewer than 100 brand-name drugs, by 2015 more than 700 drugs were covered by coupons.[35] Some policymakers have taken steps to limit the use of those coupons. For example, California has banned their use for brand-name drugs that have generic equivalents. By one estimate, that ban affects about 20 percent of the drugs covered by coupons.[36] Other states are considering similar legislation. In addition, coupons for brand-name drugs cannot be used by Medicare and Medicaid beneficiaries because they constitute a violation of the anti-kickback statute.[37]

## Trends in the Average Price of a Prescription

Nationwide data on the average prices of prescription drugs are not readily available, but it is unlikely that the average net price of a prescription has increased considerably in recent years. Nationwide per capita spending on prescription drugs has generally held steady or declined since the mid-2000s—other than the increase from 2013 to 2015—whereas use of prescription drugs has most likely increased over that period. Further, a recent

33. See Kaiser Family Foundation, *2019 Employer Health Benefits Survey* (September 25, 2019), https://tinyurl.com/wc9smxep.

34. This difficulty remains even though the price discounts associated with biosimilars are generally smaller than those associated with generic drugs. See IQVIA Institute for Human Data Science, *Biosimilars in the United States 2020–2024: Competition, Savings, and Sustainability* (September 2020), https://tinyurl.com/ydsjhc6y.

35. See Karen Van Nuys, Geoffrey Joyce, and Rocio Ribero, "Prescription Drug Coupons: A One-Size-Fits-All Policy Approach Doesn't Fit the Evidence" (Health Affairs blog entry, February 16, 2018), www.healthaffairs.org/do/10.1377/hblog20180215.988517/full/.

36. Ibid.

37. Certain copayment assistance programs are available for Medicare Part D enrollees to use, as long as they are sponsored by a bona fide independent charity. See Office of Inspector General, Department of Health and Human Services, Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg., no. 104 (May 30, 2014), 31120–31123, https://go.usa.gov/xsfqF.

industry analysis shows that reductions in spending resulting from losses of exclusivity and generic pricing reductions nearly offset the growth in spending resulting from the entry of new drugs and price growth among other brand-name drugs.[38]

Changes in average prices in the Medicare and Medicaid programs also support that assessment. In Medicare Part D, the average net price of a prescription (measured in 2018 dollars) fell from $57 in 2009 to $50 in 2018. The decline was greater in Medicaid; in that program, net prices fell from $63 in 2009 to $48 in 2018 (see Figure 4).[39]

Changes in the average net price of a prescription are driven by two opposing trends: increases in the use of lower-cost generic drugs and increases in the prices of brand-name drugs. The share of prescriptions for generic medications that people have purchased at retail pharmacies has grown to 90 percent. That shift toward generic drugs has put considerable downward pressure on the average price of the prescription drugs that people have purchased. However, average prices of brand-name drugs—which constitute the remaining 10 percent of prescriptions—have increased considerably over time. Those increases in average prices represent the combined effect of price increases for drugs already on the market and prices for new drugs, which tend to be higher than prices for drugs already on the market.

## Comparing Prices Among Payers

Underlying the overall trends are differences in the prices paid by various payers. (Payers are the entities that pay for prescription drugs, namely commercial insurers and federal health care programs, as well as individuals without prescription drug coverage.) One key factor that drives those differences is that manufacturers provide different rebate amounts to different payers for a given drug. Another key factor is that people with different sources of coverage tend to use different sets of drugs that have different average prices.

**Comparisons Between Medicare and Medicaid.** The similarity in the net prices for drugs covered by Medicare and Medicaid masks large differences in average retail prices—that is, the prices paid to pharmacies—for the drugs that beneficiaries of those programs purchase. The average retail price of a prescription covered by Medicaid is much higher than that of a prescription covered by Medicare. In 2018, that average price was $98 for Medicaid beneficiaries—about 40 percent higher than the average of $69 that Medicare beneficiaries incurred that year. Because retail prices for a given drug tend to be similar in Medicare and Medicaid, those differences primarily reflect differences in the mix of drugs used in the two programs.[40]

The differences in average retail prices are most likely attributable to differences in the two populations' underlying health care needs. Medicare beneficiaries tend to use less complex drugs that treat chronic conditions. Those drugs tend to have lower retail prices. By contrast, the prescriptions that Medicaid-only beneficiaries fill are more likely to be costly drugs that treat complex conditions. (Such drugs include psychotherapeutic drugs and HIV treatments.) Nevertheless, per enrollee spending on prescription drugs is lower in Medicaid than in Medicare because Medicaid beneficiaries tend to use fewer drugs.

In addition, Medicaid beneficiaries tend to have low cost-sharing requirements—and sometimes none at all—and any cost sharing is generally not tied to the price of a drug. Therefore, Medicaid beneficiaries may be more likely to fill prescriptions for more expensive medications

38. See IQVIA Institute for Human Data Science, *Medicine Spending and Affordability in the U.S.: Understanding Patients' Costs for Medicines*, Exhibit 3: "Net Manufacturer Revenues and Growth 2014–2019, All Channels, US$Bn" (August 2020), https://tinyurl.com/3y7s33rd.

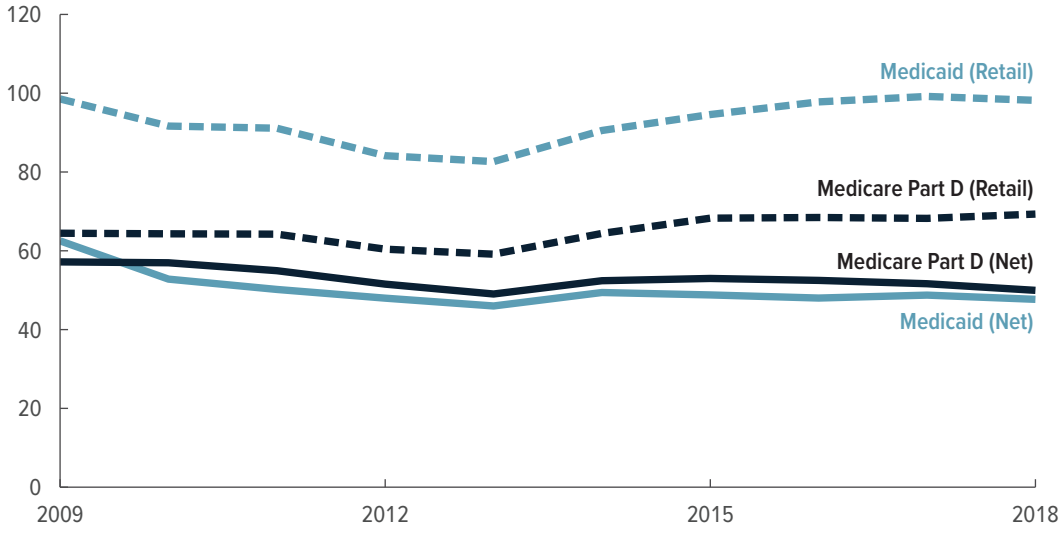
39. The average net prices of a prescription for Medicare Part D and Medicaid that are discussed in this section are calculated by dividing total spending, net of rebates and discounts, by the total count of prescriptions. In the case of Medicare Part D, the denominator is standardized prescriptions, whereas it is the simple count of prescriptions in the case of Medicaid. In addition, rebates and discounts in the Medicare Part D program reflect only those received for brand-name drugs. Average prices for brand-name and generic drugs are calculated using the same approach, stratified by brand status; average retail prices are calculated using total spending at retail prices, rather than netting out rebates and discounts.

40. The comparisons in this report differ from those of a recent CBO report on the prices paid for brand-name drugs in federal programs. See Congressional Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* (February 2021), www.cbo.gov/publication/56978. This report documents the average prices for prescriptions filled in each program; the other report examined price differences for a set basket of prescriptions. That is, the average price differences in this report reflect not only price differences for given drugs, but also differences in the mix of drugs used by people in the two programs.

Figure 4.

## Average Price of a Prescription Drug Obtained Through Medicare Part D and Medicaid

2018 Dollars




Despite increases in the use of lower-cost generic drugs over the 2009–2018 period, the average price of a prescription drug did not fall significantly, because of increases in the prices of brand-name drugs. Variations in prices between Medicare Part D and Medicaid reflect differences in the types of drugs that physicians prescribed for enrollees and differences in the two programs' post-sale rebates and discounts.

Data source: Congressional Budget Office, using administrative data for Medicare Part D and Medicaid. See www.cbo.gov/publication/57050#data.

Net prices reflect the rebates and fees paid by manufacturers and pharmacies to payers, such as government-sponsored health insurance plans and the Medicaid program, for brand-name drugs. Rebates and fees paid for generic drugs are not included because CBO's access to those data is restricted.

The data in these series reflect the average price of prescriptions filled each year and exclude drugs that are administered in physicians' offices or hospital settings.

To remove the effects of general inflation when comparing prices and spending over time, estimates of prices for prescription drugs have been adjusted to 2018 dollars using the gross domestic product price index from the Bureau of Economic Analysis.

than Medicare beneficiaries, whose cost sharing is more directly tied to the price of a drug.

Another CBO report indicated that Medicare beneficiaries tend to use less expensive drugs within a therapeutic class than do Medicaid beneficiaries.[41] Medicare beneficiaries also tend to use generic drugs to a slightly greater degree than Medicaid beneficiaries do. The remaining difference in retail prices stems from differences in average prices for the sets of brand-name and generic drugs used by the two populations.

**Comparisons With Commercial Plans.** Although CBO does not have data on per capita drug use or average prices for the rest of the U.S. population, it is plausible that both average use and average retail prices for that group are between the Medicare and Medicaid averages. The average age of people without public insurance (most of whom have commercial insurance) and the average health status of that population are probably between those of the Medicaid population (which has a large proportion of younger parents and children) and the Medicare population (which consists mostly of elderly people and disabled people). In addition, the fact that the nationwide share of prescriptions for generic drugs is about the same as the share of such prescriptions in Medicare suggests that the generic share among commercially insured people is closer to Medicare's percentage (90 percent) and higher than Medicaid's percentage (87 percent).

Average net prices for commercial plans most likely differ from net prices in Medicare and Medicaid not only because of differences in the set of drugs those plans' enrollees take, but also because of differences in how those prices are determined. In CBO's assessment, retail prices for a given drug are generally similar across payers. However, the net price of a given drug is generally

41. See Congressional Budget Office, *Competition and the Cost of Medicare's Prescription Drug Program* (July 2014), p. 31, www.cbo.gov/publication/45552.

lower for Medicaid than for commercial plans or for Medicare Part D because of rebates that manufacturers are required to pay to Medicaid plans—particularly for brand-name drugs. Medicaid programs are entitled by law to receive the greater of 23.1 percent of the drug's average manufacturer price (AMP) or the largest rebate that the manufacturer gives to any payer (excluding certain government programs, such as Medicare Part D) for all brand-name drugs.[42] The rebate also includes an additional component that is determined on the basis of growth in the drug's AMP relative to inflation.[43] For generic drugs, Medicaid's rebate includes a basic rebate (equal to 13.0 percent of the drug's AMP) and the same inflation-based component as Medicaid's rebate for brand-name drugs.[44]

In CBO's judgment, the average net price of a given brand-name drug is probably lower in Medicare Part D than in commercial plans. The Medicare Part D benefit is administered by private insurers who also provide commercial insurance plans, and rebate negotiations by both types of plans are handled in similar fashion, perhaps even by the same negotiators. Those negotiations operate under the same general set of incentives for both Part D plans and private plans in that the availability of therapeutic alternatives—and a plan's willingness to steer enrollees toward a particular drug—increases the amount that manufacturers are willing to provide to that plan in the form of a rebate (see Box 1 on page 6).

The primary difference in bargaining leverage between commercial plans and Medicare Part D plans is that the largest rebate that a manufacturer offers to a commercial plan also has to be made available to Medicaid, which reduces the size of the largest rebate that manufacturers would otherwise be willing to pay. In contrast, rebates that manufacturers pay to Part D plans do not directly affect Medicaid prices. Therefore, manufacturers may be willing to pay larger rebates to Part D plans than to commercial insurance plans.

However, another difference is that Part D plans must, by statute, cover all available drugs in each of six "protected" therapeutic classes.[45] That puts Part D plans at a disadvantage when negotiating rebates on those drugs because their pharmacy benefit managers (PBMs) cannot credibly threaten to exclude such drugs from the Part D formularies they manage if the manufacturer does not offer a sufficient rebate.[46] (PBMs are intermediaries who manage prescription drug benefits for insurance plans or other payers.) Although there may be some variation in the extent of price differences for a given drug across therapeutic classes, CBO believes that the link between Medicaid's "best price" requirements and the rebates paid to commercial plans outweighs the impact of the protected classes in Part D because the best price requirement applies to all brand-name drugs.

### Prices for Brand-Name Drugs

Net prices for brand-name drugs reflect the competitive landscape for a given drug. In cases in which therapeutic alternatives are limited, the manufacturer tends to have greater leverage, particularly for drugs that offer larger benefits to patients than other treatment options. In those cases, manufacturers have considerable monopoly power to exercise, particularly given that insured patients often pay a small share of the total price of a brand-name drug and that plans may feel considerable pressure to cover those drugs in order to retain market share. Similarly, as employers make decisions about the generosity of their employment-based plans, they may feel pressure to provide coverage for such drugs in order to retain employees. In situations in which there are therapeutic alternatives, payers and PBMs tend to have greater leverage to negotiate for lower net prices. In those cases, net prices would probably be set lower—or grow more slowly—because manufacturers typically accept lower prices in exchange for greater formulary access (or reduced formulary access for their competitors).

42. The AMP is 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.

43. For more details about how prices for brand-name drugs differ between Medicare Part D and Medicaid, see Congressional Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* (February 2021), www.cbo.gov/publication/56978.

44. Those minimum rebate percentages were set in 2010 with the enactment of the Affordable Care Act. Before then, the minimum rebate was 15.1 percent for brand-name drugs and 11.0 percent for generic drugs.

45. The protected classes are anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants.

46. Part D plans retain other forms of negotiating leverage. For instance, even for those protected classes, PBMs can still use "steering tools," such as utilization management or formulary-tier placements, to encourage beneficiaries to choose one drug over another.

Since 2008, Medicare and Medicaid have both experienced substantial increases in the prices they pay for brand-name drugs. For Medicare Part D, the average net price of a prescription for a brand-name drug (measured in 2018 dollars) more than doubled between 2009 and 2018, from $149 to $353. For Medicaid, the average net price increased by about 50 percent, from $147 to $218 (see Figure 5). Retail prices have increased even more dramatically. Between 2009 and 2018, the average retail price of a prescription for a brand-name drug in Medicare Part D more than tripled, from $175 to $547. For Medicaid, the average retail price more than doubled, from $262 to $584. (For more detail on the divergence between retail and net prices, see Box 2.)

**Factors Underlying Rapid Increases in Prices for Brand-Name Drugs.** Growth in average prices reflects a combination of several factors. For example, the composition of brand-name prescriptions that people fill has shifted from less expensive drugs toward more expensive drugs. One key factor in the shift toward more expensive drugs is that newer drugs tend to be more expensive than older drugs. In addition, prices for drugs already on the market tend to grow faster than inflation. Finally, federal policies influence manufacturers' pricing strategies and lead to higher prices in certain circumstances.

*The Role of Launch Prices.* Newer drugs are often launched at higher prices than those paid for drugs currently on the market. For example, in the Medicare Part D program, the average net price in 2015 for brand-name drugs that were launched after 2010 was nearly four times the average net price for brand-name drugs already on the market in 2010. And in 2017, the average net price for new drugs launched after 2015 was 12 times the average net price for brand-name drugs already on the market in 2015.[47] As a result, the combination of take-up of new brand-name drugs and shifting from older brand-name drugs to generic alternatives has led to higher average prices for brand-name drugs.

The phenomenon of increasingly high launch prices for new drugs is partly driven by the rising number of specialty drugs. Specialty drugs tend to be more complex to develop and manufacture than nonspecialty drugs, and they generally have much higher prices because of the larger benefits to health and well-being that they tend to confer on their patients. In 2015, they accounted for 78 percent of spending on new drugs (launched after 2010) in Medicare Part D and 8 percent of prescriptions for new drugs. In 2017, specialty drugs accounted for 88 percent of that spending and 39 percent of prescriptions for new drugs (those launched after 2015). Although prices for a given drug vary across payers, the rising influence of specialty drugs on spending—and therefore on usage-weighted average prices—probably plays a role for all payers. An industry report supports that idea, noting that specialty drugs represented the largest share of new drugs over the 2014–2018 period and that specialty drugs have "far higher" costs per patient than nonspecialty drugs.[48]

*The Role of Price Growth.* Another key component of the growth in average net prices for brand-name drugs is year-over-year price growth for a given drug, though the importance of that factor may differ substantially among payers. Using a price index approach, CBO found that net prices for brand-name drugs increased by an average of 6.3 percent per year from 2010 to 2017 in the Medicare Part D program, after removing the effects of general inflation.[49] In contrast, using a similar approach, recent research on nationwide drug spending patterns found that *nominal* net prices (that is, net prices with no adjustments for inflation) for brand-name drugs grew by an average of only 3 percent per year over the 2012–2017 period. CBO estimates that nominal price growth for brand-name drugs in Medicare Part D was an average of 7.3 percent per year over the 2012–2017 period, although the two calculations are not directly comparable because they consist of somewhat different sets of drugs. In addition, the net prices in the nationwide study are net of all discounts along the supply chain—including discounts provided to distributors or directly to patients as well as rebates that payers

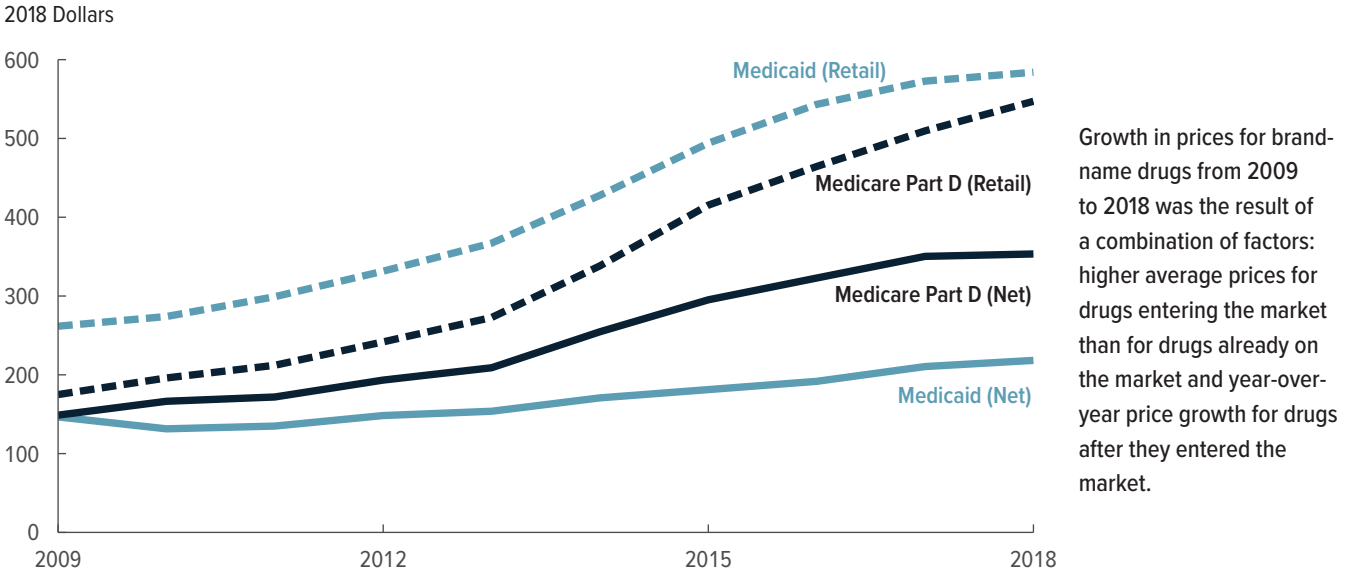
47. Calculations in this section are based on an extension of the analysis in the following paper: Anna Anderson-Cook, Jared Maeda, and Lyle Nelson, *Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid: An In-Depth Analysis*, Working Paper 2019-02 (Congressional Budget Office, March 2019), www.cbo.gov/publication/55011.

48. See IQVIA Institute for Human Data Science, *Medicine Use and Spending in the U.S.: A Review of 2018 and Outlook to 2023* (May 2019), p. 21, https://tinyurl.com/2byjnzd7.

49. CBO used a chained Laspeyres price index approach, which enabled the agency to gradually incorporate new brand-name specialty drugs introduced over the 2011–2016 period into the price index. An initially high launch price for a new drug does not affect that measure. Instead, it captures only the percentage increase in a drug's price between two consecutive years after it is already on the market.

Figure 5.

## Average Price of a Brand-Name Prescription Drug Obtained Through Medicare Part D and Medicaid




Data source: Congressional Budget Office, using administrative data for Medicare Part D and Medicaid. See www.cbo.gov/publication/57050#data.

Net prices for brand-name drugs reflect rebates and fees paid by manufacturers and pharmacies to payers, such as government-sponsored health insurance plans and the Medicaid program.

The data in these series reflect the average price of brand-name prescriptions filled each year and exclude drugs that are administered in physicians' offices or hospital settings.

To remove the effects of general inflation when comparing prices and spending over time, estimates of prices for prescription drugs have been adjusted to 2018 dollars using the gross domestic product price index from the Bureau of Economic Analysis.

received—whereas the net prices in CBO's analysis account only for the rebates that payers received.[50]

However, the large difference does suggest that prices paid by Part D over the 2012–2017 period grew more quickly than the prices paid by other payers, on average. That difference may have been driven by slower price growth in Medicaid, stemming from the statutory rebates that Medicaid receives. In addition, enrollees in commercial insurance plans may have been more likely to use drugs that face therapeutic competition than enrollees in Part D, which may have also led to slower growth in prices paid by commercial plans.

*The Role of Federal Policies.* Federal policies may have contributed to the growth in drug prices. Medicaid is entitled to the largest rebate that a manufacturer provides to any payer. (That requirement does not apply to the rebates provided to certain government programs, such as Medicare Part D.) That probably has increased average net prices for commercial payers more broadly. Similarly, the additional statutory rebate provided to Medicaid for drugs whose retail prices rise faster than inflation may have contributed to the higher launch prices of new drugs.[51] However, that rebate requirement may also have dampened price growth over time; as a result, average

50. In particular, the other analysis excluded drugs that might be more likely to have faster price growth, such as oncology products, other injectables, and drugs approved with an orphan indication. (An orphan drug treats a rare disease or condition.) See Pragya Kakani, Michael Chernew, and Amitabh Chandra, *Rebates in the Pharmaceutical Industry: Evidence From Medicines Sold in Retail Pharmacies in the U.S.*, Working Paper 26846 (National Bureau of Economic Research, March 2020), www.nber.org/papers/w26846.

51. See Fiona M. Scott Morton, "The Interaction Between a Most-Favored-Customer Clause and Price Dispersion: An Empirical Examination of the Medicaid Rebate Rules of 1990," *Journal of Economics and Management Strategy* (Spring 1997), vol. 6, no. 1, pp. 151–174, https://onlinelibrary.wiley.com/doi/10.1111/j.1430-9134.1997.00151.x; and Fiona M. Scott Morton, "The Strategic Response by Pharmaceutical Firms to the Medicaid Most-Favored-Customer Rules," *RAND Journal of Economics*, vol. 28, no. 2 (Summer 1997), pp. 269–290, www.jstor.org/stable/2555805.

Box 2.

## Diverging Trends in Retail and Net Prices

The divergence between net and retail prices coincides with sizable increases in the rebates that "payers"—such as commercial insurers and federal health care programs—receive from manufacturers. For Medicare Part D, the average rebate on a brand-name drug, as a fraction of its retail price, has more than doubled since 2009, increasing from 15 percent to 35 percent of the program's spending for brand-name drugs at retail prices in 2018. For Medicaid, the rebate percentage increased from 44 percent in 2009 to 63 percent in 2018. Recent research has found that, on a nationwide basis, average rebates for brand-name drugs have increased as well, from 32 percent in 2012 to 48 percent in 2017.[1] In general, consumer cost sharing is not directly affected by those increases in rebates. Instead, rebates tend to be shared among all enrollees in a given plan through reductions in premiums.

### Factors That Increase Rebates

Some of those increases can be traced to statutory requirements. In the Medicare Part D program, manufacturers have been required since 2011 to provide a discount known as the coverage gap discount. That discount constitutes a substantial portion of the retail prices paid by beneficiaries on the manufacturers' brand-name drugs while they are within the coverage gap. (Also known as the donut hole, the coverage gap represents a range of spending for which beneficiaries were required to pay the full cost of their prescription drugs. Although the coverage gap was eliminated by legislation in 2019, the term is still defined in federal law to refer to that phase of the benefit.) The discount was originally set at 50 percent of the retail price and was increased to 70 percent in 2019. In the Medicaid program, rebates have increased both as a consequence of the additional statutory rebate provided to Medicaid for drugs whose retail prices rise faster than inflation and because of the increase in the minimum rebate as required by the Affordable Care Act. However, the adjustment is limited by a cap on the total rebate Medicaid receives for a drug: It cannot exceed the drug's average manufacturer price.[2] (The average manufacturer price is 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.)

Rebates may also have grown as a consequence of increased competition. The availability of substitute drug therapies gives insurance plans leverage they can use to negotiate larger rebates from manufacturers—for instance, by threatening to favor another manufacturer's drug by offering it to beneficiaries for a smaller copayment. The Medicaid program benefits indirectly from that leverage because commercial insurance plans use it to negotiate larger rebates for themselves, and the Medicaid rebate on brand-name drugs is partially based on the largest rebate received by any of those plans. Many Medicaid programs also engage in negotiation with manufacturers on a smaller scale, bargaining over supplemental rebates they would receive in exchange for placing a drug on a preferred drug list.[3]

### How Rebates Affect Consumers' Costs

Net prices are usually a better measure than retail prices of what consumers and insurance plans actually pay for a drug. In

1. See Pragya Kakani, Michael Chernew, and Amitabh Chandra, *Rebates in the Pharmaceutical Industry: Evidence From Medicines Sold in Retail Pharmacies in the U.S.*, Working Paper 26846 (National Bureau of Economic Research, March 2020), www.nber.org/papers/w26846.

2. That cap will be removed beginning on January 1, 2024, as a result of the American Rescue Plan Act of 2021 (Public Law 117-2). For more information on the rebate cap, see Medicaid and CHIP Payment and Access Commission, *Next Steps in Improving Medicaid Prescription Drug Policy* (June 2019), Chapter 1, pp. 1–15, https://go.usa.gov/xsfdY.

3. The Medicaid price and spending figures in this report do not include those supplemental rebates because CBO does not have information on such rebates.

Continued

prices may have approached the level they would have without the policy.

Likewise, Medicare's minimum formulary requirements may contribute to higher net drug prices in that program. In addition to the requirement that Part D plans cover all drugs in the six protected classes, plans are also required to cover at least two drugs in all other therapeutic classes. Those requirements diminish the leverage that PBMs bring to their negotiations with manufacturers over drug prices for Part D plans.

Manufacturers may also feel less pressure to constrain prices because of the increase in the share of overall drug spending that is covered by insurers. That reduction in consumers' exposure to high prices increases their

Box 2. Continued

## Diverging Trends in Retail and Net Prices

particular, net prices reflect manufacturers' net revenues and the effect of drug spending on insurance premiums. However, there are several exceptions. For example, consumers enrolled in a plan with a deductible for prescription drugs pay the retail price of a drug until they meet that deductible. (A deductible is the amount of spending an enrollee incurs before an insurer begins covering expenses.) In addition, in plans with a coinsurance requirement, enrollees pay a percentage of the drug's retail price rather than making a copayment of a fixed dollar amount. (Coinsurance is cost sharing in the form of a set percentage of the drug's cost. A copayment is a specified dollar amount that an enrollee pays at the time a drug is purchased.) Furthermore, average cost sharing for Medicare Part D beneficiaries is required to be based on retail prices—which means that beneficiaries pay for a larger share of net drug spending as rebate percentages grow.

Consumers do not get the rebates directly. But with competitive forces in insurance markets and regulatory medical loss ratio (MLR) requirements, consumers probably receive a substantial fraction of those rebates—in the form of lower premiums or more generous benefits. The MLR provisions require insurers to devote at least 80 percent of their enrollees' premium payments—85 percent for large group plans—to paying claims or making quality improvements. Failing that, they must provide a rebate equal to the difference between that requirement and what the plan actually paid in claims to their enrollees.[4] As a result, rebates benefit all enrollees in a plan, regardless of the number or type of prescription drugs they purchase.

Some enrollees make higher out-of-pocket payments that are based on the prices their plans pay to pharmacies, rather than on net prices that account for manufacturers' rebates. That is particularly true of enrollees in Part D plans because their benefit designs are required to be actuarially equivalent to a plan with the standard benefit design. (The standard benefit calls for a coinsurance rate of 25 percent once the deductible is met—until the catastrophic threshold is reached.) In addition, cost sharing in the coverage gap tends to take the form of coinsurance rather than a flat copayment. When competition from other drugs leads to larger rebates and lower net prices, that 25 percent coinsurance constitutes a larger share of the net price than for drugs with net prices that are closer to retail prices—that is, for drugs with less competition (or generic drugs). As a result, enrollees who are more likely to use brand-name drugs that face competition from other drugs pay a greater share of net drug costs than enrollees who primarily use generic drugs or brand-name drugs without therapeutic competition.

That dynamic was one of the factors that led CBO to estimate in 2019 that premiums for the Medicare Part D benefit would increase under the Proposed Rule on Safe Harbors for Pharmaceutical Rebates.[5] CBO anticipated that the rule would result in pharmacies' charging beneficiaries prices for prescription drugs that reflect the discounts that pharmacy benefit managers negotiate with manufacturers. Enrollees who use brand-name drugs that face greater competition and have larger rebates would benefit from the lower cost sharing that results from rebates being applied when the prescription is purchased. However, directing part of those rebates toward reducing cost-sharing payments would reduce the amount of rebate dollars that could be used toward reducing premiums for all enrollees, leading to higher premiums.

4. See Rachel Fehr and Cynthia Cox, "Data Note: 2019 Medical Loss Ratio Rebates" (Kaiser Family Foundation, September 26, 2019), https://tinyurl.com/2wu295ke.

5. See Congressional Budget Office, "Incorporating the Effects of the Proposed Rule on Safe Harbors for Pharmaceutical Rebates in CBO's Budget Projections" (supplemental material for *Updated Budget Projections: 2019 to 2029*, May 2019), www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf (286 KB).

willingness to purchase high-priced drugs. Manufacturers may interpret that phenomenon as a higher overall "willingness to pay" and set higher prices, or increase their prices faster, as a result. Policymakers and stakeholders have pointed to the high and rising prices of prescription drugs as a reason to question whether the profits of brand-name drug manufacturers are excessive. (For a brief overview of the profitability of the pharmaceutical industry, see Box 3.)

**Factors That Constrain Growth in the Prices of Brand-Name Drugs.** The availability of therapeutic substitutes provides insurance plans and PBMs with leverage to negotiate lower prices. When alternatives are limited,

Box 3.

## The Profitability of Manufacturers of Brand-Name Drugs

Policymakers and stakeholders often express concern that the profits of manufacturers of brand-name drugs are excessive—particularly given the high and rising prices of many brand-name drugs and the budgetary pressures posed by rising health care costs. That concern may stem from the observation that brand-name prescription drugs are often priced at levels that greatly exceed the immediate costs of manufacturing and distributing them.[1]

However, the profitability of pharmaceutical manufacturers depends on long-term comparisons of revenues versus spending—that is, spending for research and development (R&D) and for production of the firm's entire portfolio of potential products. In general, studies that make those longer-range comparisons find that the profitability of the pharmaceutical industry is similar to that of other industries, whereas shorter-range comparisons find that the profitability of the pharmaceutical industry exceeds that of other industries.

### Factors Underlying the Profitability of Pharmaceutical Manufacturers

Understanding the profitability of the pharmaceutical industry requires distinguishing the revenues and short-run costs of producing a drug once it is approved from the much larger long-run costs of drug development and gaining approval for sale. Small-molecule brand-name drugs tend to have incremental production costs of just pennies per pill. Production costs are often higher for biological drugs, which might require more complex and costlier manufacturing processes. But those costs still tend to be low when compared with the prices that such brand-name prescription drugs often command. Meanwhile, the process of developing and testing a new drug and bringing it to market is risky, costly, and time-consuming.

Brand-name drugs generally command high prices once they are approved, because of the market power that manufacturers of brand-name drugs often have.[2] To encourage R&D, manufacturers of a brand-name drug are granted exclusive rights to produce and market that drug through a combination of patents (granted by the U.S. Patent and Trademark Office) and exclusivity periods (set by statute, depending on the type of drug and the population it treats). Depending on factors such as the timing of a manufacturer's patent application and how long a drug spends in clinical trials, those rights might be in force for a decade or more following the drug's approval by the Food and Drug Administration. During that time, the manufacturer is the sole producer of that drug, although it may face competitive pressure if there are other, similar drugs available in the same therapeutic class. When the market-exclusivity period expires, other firms typically introduce generic versions of that drug, and those generic drugs are often sold at much lower prices than the brand-name drug. The period of exclusive sales rights can be highly profitable for the manufacturer, particularly when a drug confers substantial clinical benefits and few or no therapeutic alternatives are available.

However, from the firm's perspective, profitability reflects its expenditures for all of the drugs in its portfolio of R&D activity, as well as its revenue streams and production costs for drugs that have reached the market. Decisions about whether to undertake the necessary laboratory research and clinical trials for any particular compound must be made in the face of uncertainty about its ultimate clinical value. Most drug compounds yield no significant therapeutic results; of those that enter clinical trials, only about 12 percent make it to market.[3]

1. Generic drug prices are usually close to their unit cost of production, particularly when many generic versions of a drug are available.

2. Another factor underlying brand-name drug prices is that insured patients are insulated from the full cost of their prescription drug choices, with the result that consumers are less sensitive to prices than they otherwise would be.

3. See Joseph A. DiMasi, Henry G. Grabowski, and Ronald W. Hansen, "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," *Journal of Health Economics*, vol. 47 (May 2016), p. 25, https://doi.org/10.1016/j.jhealeco.2016.01.012.

Continued

such as when a new drug is the first to treat a particular condition, then insurance plans and PBMs have limited leverage to negotiate lower prices. As competing products enter the market, payers gain the flexibility to exclude a given drug or to limit patients' use of that drug through higher cost sharing or other utilization management tools.

Consolidation within the pharmacy-benefit-management industry has also increased the leverage that PBMs wield in negotiating on behalf of their client insurers. In the 1980s, the industry consisted of many small PBMs, which, for the most part, simply processed pharmacy claims. Since then, the industry has evolved and now develops and administers many insurance plans' drug

Box 3. Continued

## The Profitability of Manufacturers of Brand-Name Drugs

So, for a firm with 100 products in development and 12 that make it to market, profitability depends on the revenues from the 12 marketed products and the cost of all 100 products in development. Even in those few cases in which a manufacturer successfully develops a new product, it sees no revenue for years following the various decisions about whether to proceed with the requisite stages of development.

Investment capital that is committed to drug R&D could have been invested instead in other activities that are less risky yet still profitable. Because of the relatively high risk of failure in drug development, investors in R&D for those drugs tend to require, in compensation, a high return on their investment if drug development is successful. The investment decisions of manufacturers of brand-name drugs are informed by that same mechanism. A recent report by the Congressional Budget Office found that both total spending on R&D by manufacturers of brand-name drugs and the fraction of their revenues devoted to spending on R&D have increased in recent years.[4] Accordingly, the opportunity costs of that investment capital—the returns that could have been earned through other investments—are an important component of a manufacturer's total costs and must be taken into account when measuring the company's profitability over the long term.

### Estimates of Pharmaceutical Firms' Profits

Estimating the long-term profits that manufacturers of brand-name drugs realize requires examining the entire life cycle of development of a portfolio of drugs and the sales of those drugs. In CBO's assessment, those costs (including long-term capital costs) and revenues constitute the most comprehensive measures of profitability. Estimates of such measures present challenges, and the results can be sensitive to the methods used. Some analyses that have made such an adjustment have found that, compared with other industries, the pharmaceutical industry does not have unusually high profits. A pair of recent studies found that when capital costs and financial risks are taken into account, the pharmaceutical industry's profits are close to—or just below—the middle of the distribution of all industries and might be trending downward.[5]

Some estimates of the pharmaceutical industry's profitability reflect profits earned during a specific period, such as a year or a quarter. Such estimates often indicate that profit margins are higher for manufacturers of brand-name drugs than they are for many other firms.[6] An annual profit estimate provides a glimpse of a drug manufacturer's performance during a given year, but because it does not reflect the long-term opportunity costs and risks associated with R&D investment choices, it does not provide a complete assessment of the profitability of that firm's drug development activity. A full discussion of the profitability of the pharmaceutical industry is beyond the scope of this report.

4. See Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* (April 2021), www.cbo.gov/publication/57025.

5. See Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* (October 2006), www.cbo.gov/publication/18176; Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks, and Rewards*, OTA-H-522 (February 1993); Richard Manning and Saurav Karki, *Economic Profitability of the Biopharmaceutical Industry*, Bates White Policy Brief (September 2018); www.bateswhite.com/newsroom-insight-219.html; and Richard Manning and Saurav Karki, *Economic Profitability of the Biopharmaceutical Industry: 2020 Update*, Bates White Policy Brief (May 2020), https://tinyurl.com/h736mvj8.

6. See Fred D. Ledley and others, "Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies," *JAMA*, vol. 323, no. 9 (March 2020), pp. 834–843, https://doi.org/10.1001/jama.2020.0442; and Government Accountability Office, *Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals*, GAO-18-40 (November 17, 2017), www.gao.gov/products/GAO-18-40.

formularies. In addition, the PBM industry has come to be dominated by just a few large firms. A 2015 merger between the third- and fourth-largest firms left the three largest PBMs handling more than 70 percent of the industry's prescription drug claims. That market power helps those large PBMs negotiate bigger rebates and steeper discounts because they represent a larger share of the patient population. However, their market power remains limited when negotiating net prices of drugs without direct substitutes.

Nevertheless, greater consolidation within the PBM industry also has implications for plans' costs. For example, PBMs probably use their increased leverage when negotiating with insurance plans over contract terms to charge higher fees to plans (which could take the form of PBMs keeping a larger fraction of rebates). The insurance plans then pass some share of those higher costs on to consumers in the form of higher premiums. In addition, over time, there has been an increase in consolidation between PBMs and insurers, as well as between PBMs

and pharmacies, including mail-order and specialty pharmacies. Although that type of consolidation can increase efficiency and reduce plans' costs, the extent to which reduced costs are passed on to enrollees depends on the amount of competition in the market. In addition, to the extent that insurers, PBMs, and pharmacies negotiate with entities outside their ownership group, there may be an incentive to charge higher fees to rival companies.[52]

### Prices for Generic Drugs

As with brand-name drugs, the competitive landscape for generic drugs has a great deal of influence over prices for those drugs. Unlike brand-name drugs, however, generic drugs often face direct competition because the same drug is often manufactured by several companies. Although new generic drugs may have higher prices when they first enter the market, those prices tend to fall as competitors enter the market.

As a result, in contrast with the growth observed in the average prices of brand-name drugs, average prices of generic drugs have tended to fall in real terms in recent years. In Medicare Part D, the average price of a generic prescription was $22 in 2009 and gradually fell to $17 in 2018.[53] For Medicaid, the average price of a generic prescription fell from $27 in 2009 to $23 in 2018 (see Figure 6). A 2016 federal review found that, from mid-2013 to mid-2014, nearly 65 percent of prescriptions for generic drugs in the Medicaid program were for drugs whose prices had declined over that time, even before accounting for rebates to the Medicaid program. That review, by the Department of Health and Human Services (HHS), also cited a finding from Express Scripts, a PBM: Specifically, Express Scripts indicated that for the top 80 percent of generic drugs (by unit sales), the average prescription price fell in 2014 by 20 percent. HHS concluded that generic prices are not a key driver of high spending on prescription drugs.[54] Other recent evidence suggests that year-over-year prices for generic drugs have fallen in the past several years, on average.[55]

Even so, price increases for some generic drugs have raised concerns for policymakers. For example, there are ongoing criminal and civil proceedings related to anticompetitive behavior that led to higher prices.[56] In addition, HHS has found that for about one-fourth of generic drugs with the highest spending in the Medicaid program, prices in recent years have increased faster than the rate of inflation (before accounting for Medicaid's rebates). However, HHS also found that the set of drugs with particularly large price increases represents a very small share of the market and that those price increases did not have a sizable impact on overall spending.[57] More generally, increases in the prices of specific generic drugs—whether facilitated by anticompetitive behavior or by the exercise of market power, or simply reflecting

52. See Rachel Schmidt, Principal Analyst, Medicare Payment Advisory Commission, "Vertical Integration and Medicare Payment Policy" (presentation at a public meeting, October 2, 2020), https://go.usa.gov/xtxAK (PDF, 293 KB); and Medicare Payment Advisory Commission, transcript of a public meeting (October 1, 2020), pp. 83–86, https://go.usa.gov/xtxAR (PDF, 927 KB).

53. The magnitude of this reduction is much smaller than what the Medicare Payment Advisory Commission (MedPAC) found in a recent study. However, the MedPAC analysis used a price index approach that does not reflect the introduction of new products or changes in the mix of products. The figures reported in this publication are simple averages of the price of generic drugs that Part D enrollees purchased. Because the first generic for a particular drug tends to enter at a higher price, which also leads to a natural shift toward more expensive generic drugs upon entry, the difference in results is unlikely to represent an inconsistency between the two analyses. See Medicare Payment Advisory Commission, *July 2021 Data Book: Health Care Spending and the Medicare Program* (July 2021), Section 10, Chart 10-25, https://go.usa.gov/xta3x.

54. See Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, *Understanding Recent Trends in Generic Drug Prices*, ASPE Issue Brief (January 2016), https://go.usa.gov/xsfPp.

55. See Richard G. Frank, Andrew Hicks, and Ernst R. Berndt, *The Price to Consumers of Generic Pharmaceuticals: Beyond the Headlines*, Working Paper 26120 (National Bureau of Economic Research, July 2019), www.nber.org/papers/w26120.

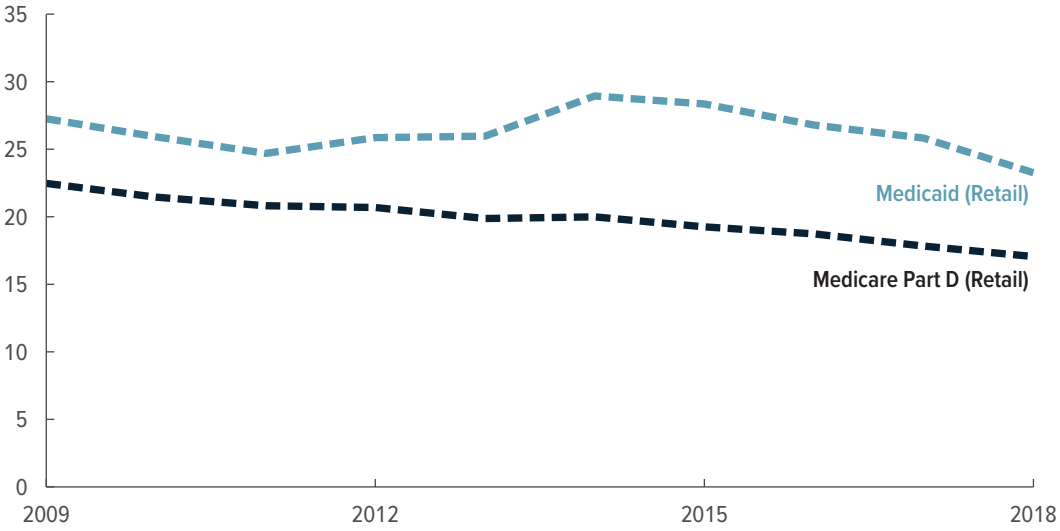
56. See Department of Justice, "Sixth Pharmaceutical Company Charged in Ongoing Criminal Antitrust Investigation: Fifth Company to Admit It Fixed Prices of Generic Drugs" (press release, July 23, 2020), https://go.usa.gov/xsfEx; and Office of the Attorney General of Connecticut, "Drug Price-Fixing Complaint Unsealed: Unredacted Emails Provide Evidence of Conspiracy to Inflate Prices and Hinder Competition, Obstruct Justice" (press release, June 24, 2019), https://tinyurl.com/5r2sks7p.

57. See Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, *Understanding Recent Trends in Generic Drug Prices*, ASPE Issue Brief (January 2016), https://go.usa.gov/xsfPp. (The price here is the average manufacturer price, or AMP, which is the average price paid by wholesalers for drugs distributed to the retail class of trade, net of customary prompt-pay discounts.)

Figure 6.

## Average Price of a Generic Prescription Drug Obtained Through Medicare Part D and Medicaid

2018 Dollars




Whereas the average prices of brand-name drugs tend to rise over time, the opposite is true for generic drugs. Average prices for generic drugs tend to fall over time as competitors enter the market, which has led to a decline in the average prices of generic drugs in recent years.

Data source: Congressional Budget Office, using administrative data for Medicare Part D and Medicaid. See www.cbo.gov/publication/57050#data.

The data in these series reflect the average price of generic prescriptions filled each year and exclude drugs that are administered in physicians' offices or hospital settings.

To remove the effects of general inflation when comparing prices and spending over time, estimates of prices for prescription drugs have been adjusted to 2018 dollars using the gross domestic product price index from the Bureau of Economic Analysis.

shifts in supply or demand—affect total drug spending only to the extent that those drugs are sold in large quantities. Nevertheless, those price increases could have a substantial impact on consumers who use drugs that have increased in price, especially if those consumers' out-of-pocket costs are based on the price of the drug.

# List of Figures

**Figures**

# About This Document

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

Tamara Hayford and David Austin prepared the report with guidance from Joseph Kile, Lyle Nelson (formerly of CBO), and Julie Topoleski. Ru Ding contributed to the analysis. Anna Anderson-Cook (formerly of CBO), Colin Baker, Elizabeth Bass, Julia Christensen, Ryan Greenfield, Stuart Hammond, Lara Robillard, Asha Saavoss, Ellen Werble, Chapin White, and Kate Young provided useful comments. Joshua Varcie fact-checked the report.

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

Phillip L. Swagel
Director
January 2022

CBO has corrected this page since the report was originally published. Corrections are listed at the end of the report.

# 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 notice indicates the location of the correction in the PDF.

**The following change was made on January 21, 2022:**

Page 25, third paragraph: The list of external reviewers was amended to add a missing name.