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Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid: An In-Depth Analysis

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Abstract

In this working paper, the Congressional Budget Office examines the prices paid for specialty drugs and spending on those drugs in Medicare Part D and Medicaid from 2010 to 2015. Specialty drugs treat chronic, complex, or rare conditions, frequently have high prices, and may require special handling or monitoring of patients. The retail prices paid to pharmacies for brand-name specialty drugs are similar in Medicare Part D and Medicaid, but net prices are much higher in Medicare Part D because rebates from manufacturers are substantially lower than in Medicaid. In 2015, the weighted average net price for 50 top-selling brand-name specialty drugs in Medicare Part D was $3,600 per "standardized" prescription—a measure that roughly corresponds to a 30-day supply of medication—whereas the weighted average net price for the same set of drugs in Medicaid was $1,920. In Medicare Part D, net spending on specialty drugs rose from $8.7 billion in 2010 to $32.8 billion in 2015. In Medicaid, net spending on specialty drugs roughly doubled over the same period, reaching $9.9 billion in 2015. For beneficiaries in the Medicare Part D program who took brand-name specialty drugs, average annual net spending on such drugs per beneficiary (in 2015 dollars) increased from $11,330 in 2010 to $33,460 in 2015.

Keywords: Medicare Part D, Medicaid, specialty drugs

JEL Classification: I10, I11, I13, I18

Notes

Unless otherwise indicated, all estimates of drug prices and per capita spending in 2010 have been adjusted to 2015 dollars to remove the effects of general inflation when comparing those results with estimates for 2015.

The estimates of total drug spending have not been adjusted for inflation in order to facilitate comparison with budgetary figures published on drug spending in Medicare and Medicaid.

Net drug spending in this paper includes the total amount paid to the pharmacy less any discounts and rebates. Those spending estimates include cost sharing as well as the amount covered by the drug benefit.

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Summary

In recent years, the prices paid for certain types of drugs—referred to as specialty drugs—have received considerable attention from the media and policymakers. Specialty drugs typically treat chronic, complex, or rare conditions, frequently have high prices, and may require special handling or monitoring of patients. From 2010 through 2015, such drugs accounted for a growing share of new drugs introduced to the market, and they were introduced at much higher prices than nonspecialty drugs. In 2015, brand-name specialty drugs accounted for about 30 percent of total net spending on prescription drugs in both Medicare Part D and Medicaid, although they accounted for only about 1 percent of all prescriptions dispensed in each program.

New drug development has emphasized specialty drugs and contributed to the increased spending on such drugs. For example, 60 percent of the brand-name drugs approved by the Food and Drug Administration over the 2011–2015 period that were covered by Medicare Part D were specialty drugs. Furthermore, specialty drugs accounted for about three-quarters of the sales of all such newly approved brand-name drugs in Medicare Part D and Medicaid in 2015.

Net prices for specialty drugs (after accounting for rebates from manufacturers and other discounts) are substantially higher in Medicare Part D than in Medicaid. In 2015, the weighted average net price for 50 top-selling brand-name specialty drugs in Medicare Part D was $3,600 per "standardized" prescription—a measure that roughly corresponds to a 30-day supply of medication—whereas the weighted average price for the same set of drugs in Medicaid was $1,920. That difference was attributable to the much higher rebates on drug purchases in Medicaid. By comparison, the average net price for 50 top-selling brand-name nonspecialty drugs in Medicare Part D in 2015 was $150 per standardized prescription, and the average net price of those drugs in Medicaid was $55.

Because Medicare Part D and Medicaid are two large purchasers of prescription drugs, increases in spending for those drugs could have important implications for the federal budget (as well as state budgets in the case of Medicaid). In response to a request from the Chairman of the House Committee on Ways and Means, the Congressional Budget Office undertook an analysis of the prices of specialty drugs and spending on those drugs over the 2010–2015 period. The results of that analysis are presented in a companion report titled *Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid*.[1] This paper provides a deeper examination of the topic and a more detailed discussion of the data and methods that CBO used in its analysis.

The agency adopted a definition of specialty drugs that captures the main features that are typically associated with such drugs. That definition includes both brand-name and generic

[1] See Congressional Budget Office, *Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid* (March 2019), www.cbo.gov/publication/54964.

drugs, although over 90 percent of net spending on specialty drugs in both Medicare Part D and Medicaid has been on brand-name drugs. This paper focuses on specialty drugs that are primarily purchased through pharmacies, including specialty pharmacies. Most of the specialty drugs examined in this paper are self-administered, although some physician-administered specialty drugs are also covered by Medicaid's pharmacy benefit.

What Prices Are Paid for Specialty Drugs in Medicare Part D and Medicaid?

The prices of specialty drugs—and indeed all prescription drugs—are determined much differently in Medicare Part D than in Medicaid. The drug benefit in Medicare Part D is delivered by private plans, which negotiate with pharmacies over the retail prices of drugs and with drug manufacturers over rebates on drug purchases. (In this paper, the price paid to the pharmacy before considering any rebates or other discounts is referred to as the retail price.) The net prices paid by the plans are the retail prices less the rebates and any other discounts. The design of the Part D program is intended to give plans an incentive to manage the benefit efficiently and to negotiate low net prices for drugs because that enables them to charge lower premiums and thus encourage beneficiaries to enroll. However, certain factors (which are discussed later in this paper) dampen that incentive—particularly for specialty drugs.

In Medicaid, beneficiaries can receive drug benefits through a fee-for-service (FFS) system or through managed care plans. In either case, net prices are heavily influenced by two statutory rebates tied to prices paid in the private sector. The first statutory rebate is a specified percentage of the average price that manufacturers earn on sales to pharmacies for each drug (that percentage is larger for drugs that have greater discounts for private-sector purchasers). The second statutory rebate ensures that the prices Medicaid pays to drug manufacturers do not increase faster than general inflation.

Retail prices for brand-name drugs are similar in Medicare Part D and Medicaid, but net prices are much higher in Medicare Part D because the rebates are substantially lower than in Medicaid. In Medicare Part D, the weighted average retail price per standardized prescription for 50 top-selling brand-name specialty drugs was $4,380 in 2015, which was nearly identical to the weighted average retail price for the same drugs in Medicaid. (In that comparison, the "mix" of drugs—or the share of total standardized prescriptions attributed to each drug—was held constant between the two programs, using Medicare's mix.) The average retail price of those 50 drugs varied greatly, ranging from $250 to almost $43,000 per standardized prescription.

The average rebate paid by manufacturers for those 50 drugs in Medicare Part D was 13 percent of the retail price, resulting in an average net price of $3,800 per prescription. In addition, in 2015 manufacturers were required to offer a 50 percent discount on purchases of brand-name drugs within a specified range of spending for beneficiaries who did not qualify for low-income subsidies. When that 50 percent discount was also applied, the rebates plus discounts amounted to 18 percent of the average retail price, resulting in an average net price of $3,600. In Medicaid,

the rebates for those 50 drugs averaged 56 percent of the retail price (again holding the mix of drugs constant between the two programs), and the weighted average net price was $1,920—or just over half the average net price in Medicare Part D.

The average net price of a prescription for brand-name specialty drugs increased more rapidly from 2010 to 2015 in Medicare Part D than in Medicaid, growing at an average annual rate of 22 percent in Medicare Part D and 12 percent in Medicaid. (Like all estimates of drug prices in this paper, those estimates have been adjusted to remove the effects of general inflation.) In each program, that increase was largely attributable to a shift toward use of higher-priced drugs—especially new drugs that were introduced after 2010. The slower net price growth in Medicaid was attributable primarily to differences in the mix of specialty drugs used in the two programs.

The much higher prices of specialty drugs as compared with nonspecialty drugs was attributable to the higher prices at which those drugs were introduced, not to more rapid growth in prices following their introduction. Focusing on the annual increases in drug prices beyond general inflation over time after drugs were introduced to the market, the average net price of brand-name specialty drugs in Medicare Part D increased at an average annual rate of 5.8 percent from 2010 to 2015, compared with an average annual increase of 7.4 percent for brand-name nonspecialty drugs.

What Are Recent Trends in Net Spending on Specialty Drugs in Medicare Part D and Medicaid?

Specialty drugs accounted for a growing share of total net drug spending in Medicare Part D and Medicaid from 2010 to 2015. On the basis of past trends and information on recent drug approvals and drugs under development, CBO expects that trend to continue.

Medicare Part D. In Medicare Part D, net spending on specialty drugs rose from $8.7 billion in 2010 to $32.8 billion in 2015, whereas net spending on nonspecialty drugs rose from $59.6 billion to $72.6 billion. By 2015, specialty drugs accounted for 31 percent of total net spending in Medicare Part D, up from 13 percent in 2010. (All estimates of total drug spending in this paper are in nominal terms—that is, they have not been adjusted to remove the effects of general inflation. CBO expressed spending totals in that way to facilitate comparison with budgetary estimates published by CBO and other government agencies. By contrast, all estimates of per capita drug spending are expressed in 2015 dollars to remove the effects of general inflation.)

On a per capita basis, the increase in specialty drug spending in Medicare Part D was largely offset by a decline in spending on nonspecialty drugs. Net per capita spending on specialty drugs in Medicare Part D grew from $330 in 2010 to $830 in 2015, whereas net spending on nonspecialty drugs fell from $2,290 to $1,830. Overall, per capita drug spending remained nearly flat over the period. The growth in net per capita spending on specialty drugs, at an average annual rate of 20 percent, was almost entirely attributable to spending growth on brand-name

specialty drugs, which in turn was the result of an increase in the average net price of a standardized prescription for such drugs.

Average annual net spending per enrollee on brand-name specialty drugs among Part D enrollees who took such drugs increased from $11,330 in 2010 to $33,460 in 2015 (in 2015 dollars). Among Part D enrollees who used a brand-name specialty drug and did not receive assistance with their cost sharing—either through the low-income subsidy program or through an employer-sponsored plan—the average out-of-pocket cost for such drugs (in 2015 dollars) increased from $1,750 in 2010 to $3,540 in 2015. Out-of-pocket costs for specialty drugs accounted for nearly 90 percent of total out-of-pocket costs under Part D for those beneficiaries in 2015. Net spending on specialty drugs and out-of-pocket costs for those drugs varied greatly across beneficiaries.

Some experts have raised concerns about the rapid increase in spending in the "catastrophic phase" of the Medicare Part D benefit, in which the federal government reimburses Part D plans directly for about 80 percent of drug costs and beneficiaries pay 5 percent of drug costs. (In 2015, beneficiaries entered the catastrophic phase of the Part D benefit after incurring out-of-pocket costs of $4,700.) From 2010 to 2015, brand-name specialty drugs accounted for just over 80 percent of the growth in net spending per beneficiary in that phase of the Part D benefit.

Medicaid. In Medicaid, net spending on specialty drugs roughly doubled from 2010 to 2015, rising from $4.8 billion to $9.9 billion, whereas net spending on nonspecialty drugs rose from $14.5 billion to $18.6 billion. By 2015, specialty drugs accounted for 35 percent of drug spending in Medicaid, up from 25 percent in 2010.

CBO was not able to estimate net per capita spending on specialty drugs as precisely for Medicaid as for Medicare Part D because of data limitations. However, the agency was able to determine that net per capita spending on specialty drugs grew at a much slower rate from 2010 to 2015 in Medicaid than in Medicare Part D and that net per capita spending on both specialty drugs and nonspecialty drugs was much lower in Medicaid than in Medicare Part D. The lower net per capita spending on specialty drugs in Medicaid was the result of lower utilization in the Medicaid population, differences in the mix of drugs used, and the lower net prices in Medicaid.

What Are Specialty Drugs?

Researchers and industry stakeholders define specialty drugs in varying ways. Some researchers have relied on price alone to define a specialty drug.[2] Others rely on specialty drug lists developed by pharmacy benefit managers (companies that manage and administer drug benefits

[2] For example, see Stacie B. Dusetzina, "Share of Specialty Drugs in Commercial Plans Nearly Quadrupled, 2003–14" *Health Affairs*, vol. 35, no. 7 (July 2016), pp. 1241–1246, www.healthaffairs.org/doi/full/10.1377/hlthaff.2015.1657.

for health plans) to identify such drugs.[3] A useful definition of specialty drugs encompasses a broad set of characteristics that helps to distinguish them from nonspecialty drugs. For this paper, CBO relied on a definition of specialty drugs developed by IQVIA (formerly known as IMS Health).[4] That definition of specialty drugs requires that all such drugs treat a chronic, complex, or rare condition and have at least four of the following seven characteristics:

- Cost at least $6,000 per year,
- Be initiated or maintained by a specialist,
- Be administered by a health care professional,
- Require special handing in the supply chain,
- Be associated with a patient payment assistance program,
- Be distributed through nontraditional channels (such as a specialty pharmacy), or
- Require monitoring or counseling either because of significant side effects or because of the type of disease being treated.

On the basis of that definition, "orphan" drugs, biologic products, and drugs that treat cancer, multiple sclerosis, and human immunodeficiency virus (HIV) are frequently considered to be specialty drugs.[5] However, high-cost drugs used to treat acute conditions are generally not considered to be specialty drugs under IQVIA's definition.[6]

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[3] For example, see Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, "Observations on Trends in Prescription Drug Spending" (March 2016), https://go.usa.gov/xEHZU. See also James D. Chambers and others, "Despite High Costs, Specialty Drugs May Offer Value for Money Comparable to That of Traditional Drugs," *Health Affairs*, vol. 33, no. 10 (October 2014), pp. 1751–1760, www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.0574.

[4] The list of specialty drugs on the market in 2015 was purchased from IQVIA and is proprietary.

[5] Orphan drugs are approved for a health condition that affects fewer than 200,000 people in the United States. Companies that develop such drugs receive a tax credit equal to 50 percent of their clinical investigation expenses. Orphan drugs are eligible for seven years of market exclusivity. (In cases in which drugs are approved for multiple indications, that exclusivity period applies only to indications that meet the orphan drug criteria.) For more information, see Food and Drug Administration, Center for Drug Evaluation and Research, "Orphan Drugs," *Small Business Chronicles* (July 2012), https://go.usa.gov/xE2pf (PDF, 119 KB).

[6] Also, IQVIA does not consider insulin used to treat diabetes to be a specialty drug.

IQVIA provided CBO with a list of specialty drugs that were on the market in 2015, and the $6,000 threshold applies to the annual cost of those drugs in 2015. That comprehensive definition of specialty drugs allowed CBO to analyze trends in the pricing of and spending on such drugs over the 2010–2015 period.[7] (When this project was first undertaken, 2015 was the most recent year for which data were available.)

Spending on specialty drugs has been a key driver of the growth in total spending on prescription drugs in recent years. According to IQVIA, overall spending on specialty drugs in the United States increased from $82 billion to $151 billion between 2011 and 2015. (Those estimates are based on wholesale prices and include all drug spending in the United States through all distribution channels, such as pharmacies and hospitals.) IQVIA's analysis found that two-thirds of the increase in total drug spending between 2011 and 2015 could be attributed to specialty drugs and that specialty drugs accounted for 30 percent of total drug spending in the United States by 2015. Spending in five therapeutic classes amounted to 80 percent of overall specialty drug spending in the United States in 2015: oncology, autoimmune treatments, viral hepatitis, multiple sclerosis, and HIV antiretrovirals.[8]

Since 2015, spending on specialty drugs has continued to grow faster than spending on nonspecialty drugs. Between 2015 and 2016, spending on specialty drugs grew by almost 18 percent, reaching $178 billion.[9] Over the same period, spending on nonspecialty drugs remained flat and may even have declined slightly after accounting for rebates and discounts. Patent expirations tended to lower spending for nonspecialty drugs but have had much less effect on spending for specialty drugs. In addition, most sales of new brand-name drugs are for specialty drugs. For example, of the $12 billion in new brand-name drugs sales in 2017, $9.8 billion (about 80 percent) was for specialty drugs.[10]

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[7] Both brand-name drugs and their generic counterparts, when available, are included on the specialty drug list. IQVIA's definition of specialty drugs has many features in common with the criteria used by the pharmacy benefit managers Express Scripts and Prime Therapeutics (such as treating a chronic, complex, or rare condition, having a high price, or requiring special handling or administration). CBO's estimates of the share of drug spending in Medicare Part D and Medicaid that can be attributed to specialty drugs are similar to those reported by Express Scripts for those programs in recent years.

[8] See IMS Institute for Healthcare Informatics, *Medicines Use and Spending in the U.S.: A Review of 2015 and Outlook to 2020* (April 2016) and similar reports from prior years.

[9] See IQVIA Institute for Human Data and Science, *Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021* (May 2017), https://tinyurl.com/y2ldg5ox Like the sales figures reported in the previous paragraph, the estimated sales for 2016 are valued at wholesale prices. Between 2016 and 2017, sales of brand-name specialty drugs valued at wholesale prices net of rebates grew by 9 percent.

[10] See IQVIA Institute for Human Data and Science, *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022* (April 2018), https://tinyurl.com/ydatt7bx, and a similar report for 2016. The 2018 report considered brand-name drugs introduced within the past two years to be new drugs.

Although generic versions of some brand-name specialty drugs are available on the market, most sales of brand-name specialty drugs from 2010 to 2015 were for products that benefited from patent protection (and thus had no generic versions available on the market). Many brand-name specialty drugs are biologic products (such as sugars, proteins, cells, or tissues derived from living material) or other complex molecules. Drug manufacturers can now develop "biosimilar" versions of brand-name biologic drugs (which have similar therapeutic effects as their brand-name counterparts); however, that process is generally more challenging and time-consuming than developing generic versions of small-molecule, chemically synthesized drugs. Currently, no biosimilar version of a brand-name specialty drug primarily covered by Medicare Part D is available on the market.[11]

This report focuses primarily on specialty drugs that are purchased from a pharmacy. Such drugs are covered by Medicare Part D and Medicaid's prescription drug benefit. Some specialty drugs are administered by physicians or other health care professionals. Those drugs are usually covered by Medicare Part B (Medical Insurance) and Medicaid's medical benefit.[12] However, under Medicaid, claims for drugs that are administered by a physician or other health care professional are sometimes submitted under Medicaid's prescription drug benefit rather than the medical benefit.[13] In 2015, just over 20 percent of net specialty drug spending in Medicaid's prescription drug benefit was for drugs usually administered by a health care professional. In Medicare Part D, less than 5 percent of specialty drug spending was for such drugs. That difference is one of several factors that cause the composition of specialty drug spending under Medicaid's prescription drug benefit to differ from that under Medicare Part D.

CBO investigated how the estimates of prices for and spending on specialty drugs presented in this paper would change if physician-administered drugs were excluded from the analysis. The findings of that additional analysis, presented in the Appendix, are very similar to the findings presented in the main text of this paper.

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[11] An abbreviated pathway for the approval of biosimilar versions of brand-name biological products was established in 2009 by the Biologics Price Competition and Innovation Act. However, only one biosimilar drug (Zarxio) had been approved by 2015, and it was primarily covered by Medicare Part B, not Medicare Part D. A biosimilar version of Procrit is now available on the market. Although this drug has some sales in Medicare Part D, it is primarily covered by Medicare Part B.

[12] In 2015, the Medicare Part B program and Medicare beneficiaries combined paid $25.8 billion for drugs purchased under the program. See Medicare Payment Advisory Commission, *June 2018 Data Book: Health Care Spending and the Medicare Program* (July 2018), p. 147, http://medpac.gov/-documents-/data-book. Data are not readily available to estimate spending on physician-administered drugs paid for under Medicaid's medical benefit.

[13] Medicaid payment policies for physician-administered drugs vary by state and sometimes by drug as well.

How Are Prescription Drug Prices Determined in Medicare Part D and Medicaid?

Medicare Part D and Medicaid are the two largest government programs that purchase prescription drugs. The Medicare Part D drug benefit is delivered by private drug plans. Under Part D, drug prices are determined primarily through negotiations between Part D plans and providers (such as pharmacies and drug manufacturers).[14] Under Medicaid, some beneficiaries receive their benefits through an FFS program whereas other beneficiaries are enrolled in managed care plans that deliver health care benefits (including drug benefits). Although some negotiations over drug pricing occur within Medicaid, the main factors that determine brand-name drug prices are large statutory rebates tied to private-sector prices and general inflation. (Manufacturers also pay statutory rebates on generic drugs in Medicaid. However, those rebates have a much smaller effect on the final net prices paid for drugs because generic versions have relatively low prices, and the rebates for those drugs are much lower in relation to retail prices than is the case for brand-name drugs.)

CBO estimates that total net spending on prescription drugs covered under Medicare Part D in 2015 amounted to $106 billion—constituting one-third of total outpatient drug spending in the United States.[15] (Unless noted otherwise, all estimates of net spending on drugs in this paper are equal to the total amount paid to the pharmacy for the prescription, including any patient cost-sharing amount less any rebates or discounts.) Additionally, net spending on prescription drugs covered under Medicaid amounted to $32 billion in 2015, accounting for about 10 percent of total outpatient drug spending in the United States.[16]

Beneficiaries covered by Medicare Part D are age 65 or older, disabled, or have end-stage renal disease, whereas beneficiaries covered by Medicaid's prescription drug benefit are children and nondisabled adults under age 65 in low-income households as well as some elderly and disabled people who do not qualify for Medicare. Some of the most costly beneficiaries in terms of average drug spending were moved out of Medicaid's drug benefit and into the Medicare Part D drug benefit when the latter program first began in 2006. Those people are eligible for both Medicare and full Medicaid benefits. In 2015, such beneficiaries, referred to as full dual-eligible beneficiaries, accounted for 19 percent of Medicare Part D beneficiaries and about one-third of

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[14] A pharmacy-benefit management company such as Express Scripts or CVS–Caremark may administer and manage the drug benefit on behalf of a Part D plan sponsor. In such cases, the pharmacy-benefit manager will negotiate prices with drug manufacturers and pharmacies.

[15] According to the National Health Expenditure Accounts, total net spending on outpatient drugs was $324 billion in 2015.

[16] Those totals do not include spending on over-the-counter drugs, which are sometimes covered by Medicare Part D and Medicaid and account for less than 1 percent of net drug spending in those programs. The estimate of net Medicaid drug spending comes from the National Health Expenditure Accounts and includes both state and federal spending. CBO estimated net drug spending under the Medicare Part D program for 2015.

Part D drug spending.[17] That difference in the types of beneficiaries covered by each program partly explains why drug spending tends to be much higher in Medicare Part D than in Medicaid even though fewer beneficiaries receive drug benefits through Medicare Part D than through Medicaid.[18] Beneficiaries in Medicare Part D take, on average, about five times as many prescription drugs per year as Medicaid beneficiaries.

Medicare Part D

Two categories of plans participate in Medicare Part D: stand-alone prescription drug plans, which enroll beneficiaries who receive their other Medicare coverage through the traditional FFS program, and Medicare Advantage prescription drug plans. The plans compete for enrollees on the basis of premiums, benefit design, specific drugs covered, and quality of services.

Overview of the Drug Benefit. The standard drug benefit in Medicare Part D had the following features in 2015:

- A deductible of $320;
- Coverage for 75 percent of spending between the deductible and an initial coverage limit of $2,960;
- Limited coverage for generic and brand-name drugs when spending was between the initial coverage limit and a catastrophic limit on out-of-pocket costs of $4,700 (a range of spending sometimes referred to as the coverage gap);[19] and
- Coverage for 95 percent of spending above the catastrophic limit. As is the case today, Part D plans paid 15 percent of drug costs, and federal reinsurance payments covered about 80 percent of drug costs in that phase of the benefit. Beneficiaries paid for 5 percent of costs, and there was no limit on out-of-pocket costs.[20]

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[17] Medicaid's statutory rebates no longer applied to their drug purchases once those beneficiaries were shifted into the Medicare Part D program in 2006.

[18] Almost 40 million beneficiaries received drug benefits through Medicare Part D in 2015 compared with close to 60 million in Medicaid.

[19] In 2015, Part D plans covered 35 percent of generic drug spending and 5 percent of brand-name drug spending in that phase of the benefit.

[20] Reinsurance payments are equal to about 80 percent of spending valued at retail prices in the catastrophic phase of the benefit less an average rebate amount. (For additional details, see the section titled "Reinsurance.") Those amounts are calculated across all drug spending at the plan level.

The plans' share of spending and beneficiaries' share of spending under the Part D benefit are linked to the retail price—that is, the price that the Part D plan has negotiated with the pharmacy.[21] Thus, beneficiaries' cost sharing in the catastrophic phase is equal to 5 percent of the retail price of the prescription. The retail price is the total amount received by the pharmacy for the prescription when it is dispensed and does not account for any price concessions such as rebates from drug manufacturers, which are reported separately by the Part D plan to the Centers for Medicare & Medicaid Services (CMS). Usually, the retail price is the sum of any beneficiary cost-sharing amount plus the amount paid by the plan, but it can also include payments from other sources.

Part D plans may offer alternative benefit designs as long as they cover the same share of drug spending by enrollees, on average, as the standard benefit described above. (This is referred to as coverage that is actuarially equivalent.) Most plans offer such alternative benefit designs, which often specify a lower deductible than the standard benefit and use flat copayments rather than coinsurance, especially for preferred drugs. In addition to the basic benefit, some plans offer supplemental coverage for which beneficiaries pay an additional premium. [22]

The federal government subsidizes about 75 percent of the cost of the basic benefit in Medicare Part D. In 2015, federal spending on those subsidies came to $53 billion. Cost-sharing and premium subsidies provided to low-income Part D beneficiaries added an additional $26 billion to federal spending. Thus, total federal spending on Medicare Part D was $79 billion in 2015—about 12 percent of total Medicare spending.[23] In addition, Part D beneficiaries paid $11.5 billion in premiums and $15.1 billion in cost sharing in 2015.

Since 2011, drug manufacturers have been required to offer a discount of 50 percent on purchases of brand-name drugs in the coverage gap for all beneficiaries who do not have sufficiently low income to qualify for cost-sharing subsidies. The coverage gap closed in 2019. Part D plans now cover 5 percent of spending for brand-name drugs and 63 percent of spending for generic drugs in that phase of the benefit. The discount offered by manufacturers also

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[21] The retail price does not account for price concessions—such as rebates from drug manufacturers—received by the Part D plan after the prescription is dispensed. That retail price (or "negotiated price" in CMS's regulations) is the total amount paid to the pharmacy for the prescription. The total amount paid to the pharmacy is equal to what the plan pays for the prescription plus any beneficiary cost-sharing amount. There are sometimes other sources of payments that cover part of the cost of the prescription, such as cost-sharing assistance beyond the standard benefit offered by employer-sponsored Part D plans, which restrict enrollment to the employer's retirees.

[22] For additional details on the Part D benefit structure and program, see Medicare Payment Advisory Commission, *Payment Basics: Part D Payment System* (October 2018), https://go.usa.gov/xEA8B.

[23] See Medicare Payment Advisory Commission, *Report to Congress: Medicare Payment Policy* (March 2017), Chapter 14, pp. 383 and 413, http://medpac.gov/docs/default-source/reports/mar17_entirereport.pdf (3.3 MB). That does not include $1.4 billion paid by the federal government to subsidize employers that offer drug coverage to their retirees outside of the Medicare Part D benefit.

increased from 50 percent to 70 percent on brand-name drugs in 2019. Beneficiaries now pay 25 percent of the cost of brand-name drugs and 37 percent of the cost of generic drugs.[24]

Beneficiaries who qualify for and enroll in the low-income subsidy (LIS) program have most of their Part D out-of-pocket costs covered by Medicare. For such beneficiaries, the federal government pays for most drug costs between the initial coverage limit and the catastrophic limit through cost-sharing subsidies. LIS beneficiaries make only modest copayments until they reach the catastrophic limit, at which point copayments are zero for most of those beneficiaries.[25] The federal government also provides subsidies that cover most of their premiums. LIS enrollees accounted for about 30 percent of Part D beneficiaries and about half of total drug spending under the program in 2015.

How Part D Plans Manage Drug Costs. A key factor that helps Part D plans lower drug costs are rebate payments that Part D plans negotiate with manufacturers of brand-name drugs. Medicare Part D plans also negotiate with community pharmacies and specialty pharmacies over the retail prices paid for drugs. (Specialty pharmacies distribute drugs that require special handling and patient support.)[26] The net price paid for a drug in Medicare Part D is equal to the retail price paid to the pharmacy, less any rebate that Part D plans receive subsequently from the drug manufacturer, less the 70 percent manufacturer discount (which was 50 percent over the 2010–2015 period examined in this paper) when that applies.

To further lower drug costs, each Part D plan sponsor also creates a formulary—a list of covered drugs that places drugs in different tiers partly on the basis of their cost-effectiveness. The tiers with the lowest cost-sharing requirements are for generic drugs and preferred brand-name drugs. Nonpreferred brand-name drugs are placed in a tier with higher cost-sharing requirements. Manufacturers often are willing to pay a rebate to a Part D plan in exchange for more favorable treatment—such as being placed in a lower cost-sharing tier. CBO estimates that in 2015, manufacturer rebates and other discounts averaged 29 percent of spending on brand-name drugs under Medicare Part D at retail prices.

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[24] The Bipartisan Budget Act of 2018 increased the manufacturer discount from 50 percent to 70 percent starting in 2019.

[25] For a small subset of LIS beneficiaries, copayments are 15 percent of drug costs until the catastrophic limit is reached, at which point only modest copayments are required. Still, that could mean over $1,600 in out-of-pocket costs for such beneficiaries in 2015 if they reached the catastrophic threshold by taking a brand-name specialty drug.

[26] In 2015, drugs distributed through specialty pharmacies accounted for 23 percent of spending for brand-name specialty drugs in Medicare Part D. Community pharmacies accounted for 65 percent of spending for brand-name specialty drugs valued at retail prices, mail-order pharmacies accounted for 5 percent, home infusion providers accounted for 2 percent, pharmacies associated with managed care organizations accounted for 2 percent, and long-term care facilities accounted for 2 percent.

Most Part D plans also have a "specialty" tier in which cost sharing can vary from 25 percent to 33 percent of the drug's retail price. Because brand-name specialty drugs have such high prices, those cost-sharing amounts can be over $1,000 for a single prescription (until the beneficiary reaches the catastrophic phase of the benefit).[27] In order to be placed in a specialty tier, regulations under the Part D program require that the drug cost at least $670 per month.[28] (The drugs that are placed in a specialty tier vary considerably across Medicare Part D plans, and they may not necessarily meet the specialty drug criteria defined by IQVIA.)

Medicare Part D plans are required to cover all drugs in six protected classes. Those six classes include antiretrovirals (used to treat HIV), antidepressants, antipsychotics, antineoplastics (used to treat cancer), anticonvulsant agents (used to treat epilepsy), and immunosuppressants (when used to prevent organ rejection in patients who have received an organ transplant). Specialty drugs fall primarily within three of those protected classes (antiretrovirals, antineoplastics, and immunosuppressants). Those three classes together accounted for about one-third of specialty drug spending in Medicare Part D in 2015. Although that requirement facilitates beneficiaries' access to needed drugs, it also probably increases Part D spending in those classes. That occurs because the ability of Part D plans to negotiate effectively for rebates is hampered in the protected classes because the plans are not permitted to exclude drugs in those classes from their formularies (although they are permitted to place drugs within those classes in different cost-sharing tiers). As a result, sponsors of Part D plans have less leverage in their negotiations with drug manufacturers to obtain the largest possible rebates.[29]

Part D plans have an incentive to manage drug costs partly because that enables them to charge lower premiums and attract more beneficiaries to enroll in their plan.[30] However, some analysts have observed that plans have limited incentive to manage the drug costs of enrollees once they exceed the catastrophic threshold because the plans are responsible for only about 15 percent of the costs incurred in that phase of the benefit.[31] Between 2010 and 2015, the share of total drug spending by Part D beneficiaries (valued at retail prices) that occurred in that phase of the benefit grew from 20 percent to 38 percent.

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[27] In 2015, the average retail prescription price of a brand-name specialty drug in Medicare Part D (using IQVIA's definition) was $4,170.

[28] Over the 2010–2015 period studied in this paper, the threshold was $600 per month.

[29] See for example, Fiona Scott Morton and Lysle Boller, *Enabling Competition in Pharmaceutical Markets*, Hutchins Center Working Paper 30 (Brookings, May 2017), p. 19, https://tinyurl.com/yxhc5ebm (PDF, 892 KB).

[30] Beneficiaries' premiums are set through a competitive bidding process in which the bid largely reflects a plan's estimated cost for providing drug benefits to Part D beneficiaries. The difference in premiums between two Part D plans is equal to the difference in their bids.

[31] Medicare Payment Advisory Commission, *Report to the Congress: Medicare and the Health Care Delivery System* (June 2016), Chapter 6, http://medpac.gov/-documents-/reports.

Reinsurance. The federal government covers about 80 percent of drug spending in the catastrophic phase of the Part D benefit through reinsurance payments. Those payments are calculated by taking 80 percent of aggregate spending in the catastrophic phase of the benefit (valued at retail prices) and subtracting an amount that accounts for the average rebate that the plan collects across all drug spending by its beneficiaries.[32] For example, if total spending in the catastrophic phase of the benefit was $1 million for a particular plan, and the average amount of rebates and other price concessions was 20 percent of all drug spending (valued at retail prices), then the reinsurance payments would be 80 percent of $1 million less $200 million. That would be 80 percent of $800,000, or $640 million.

Part D plans can evaluate their net costs at the individual drug level when negotiating for rebates with manufacturers. Because reinsurance payments are not calculated at the individual drug level, the larger the rebate paid to the Part D plan for a particular drug, the lower the share of the drug's net costs that the plan is responsible for in the catastrophic phase of the benefit. Therefore, the design of the catastrophic phase does not substantially reduce Part D plans' incentives to negotiate for higher rebates on brand-name specialty drugs that have a large share of spending in that phase of the benefit. The Part D plan covers 15 percent of any increase in the retail price for such drugs but retains almost all of any increase in the rebate that it is able to negotiate for such drugs.

For example, suppose that the retail price of a brand-name specialty drug was $1,000 per prescription. In addition, suppose that the prescription fell within the catastrophic phase of the benefit. In that case, the beneficiary's out-of-pocket payment would be 5 percent of that amount or $50 (see Table 1). The federal reinsurance payment would be 80 percent of $1,000 (or $800), less an average rebate amount. If the average rebate collected by the plan across all drug spending was 18 percent (as it was for the Part D program in 2015), then the $800 would be reduced by 18 percent (or $144), and the total reinsurance payments from the government to the plan would be $656. If the rebate amount negotiated between the plan sponsor and the manufacturer was 12 percent, then the net cost of the drug would be $880 ($1,000, less a rebate of $120). The plan's liability for the drug would be $880, less the federal reinsurance payment of $656 and further reduced by $50 in out-of-pocket payments (or low-income cost-sharing subsidies), which is equal to $174. The plan would end up paying 17 percent of the retail cost of the drug and an even higher share of the net cost of the drug. (Note that many brand-name specialty drugs have relatively low rebates, in which case the Part D plan ends up paying for more than 15 percent of its net costs in the catastrophic phase of the benefit.) If, however, the

[32] If the average rebate on drug spending in the catastrophic phase of the benefit is close to the average rebate across all drug spending and across all phases of the benefit, then reinsurance payments received by the plan are roughly equal to 80 percent of net drug spending in the catastrophic phase of the benefit. In 2015, the average rebate across all drug spending in Part D was 18 percent, and the average rebate across all drug spending in the catastrophic phase of the benefit was 16 percent.

rebate on the drug was 30 percent (or $300), then the amount collected by the plan in reinsurance payments plus the beneficiary's out-of-pocket payment would come to $706 while the net cost of the drug would be only $700. The plan would actually earn a small profit of $6 on the prescription.

Benefit Design in the Catastrophic Phase and Pricing of Specialty Drugs. The design of the Part D benefit in the catastrophic phase creates an incentive for drug manufacturers to charge higher prices to pharmacies for brand-name specialty drugs that have a significant share of spending in that phase of the benefit. That in turn leads to higher costs to the federal government. The incentive for manufacturers to charge higher prices exists because Part D plans and beneficiaries cover only a small share of spending (about 15 percent and 5 percent, respectively) in the catastrophic phase of the benefit whereas the federal government, which has no influence on purchasing decisions, covers about 80 percent of spending through reinsurance payments. Because Part D plans and beneficiaries pay for only a small share of any increase in the retail price for such drugs, manufacturers have a greater incentive to raise their prices than would be the case if Part D plans and beneficiaries covered a larger share of spending. That incentive for a manufacturer of a brand-name specialty drug to charge a higher price primarily exists when the average beneficiary taking the drug is expected to end up in the catastrophic phase of the Part D benefit. The incentive is even greater when the sales of the drug to Medicare Part D beneficiaries are large relative to the drug's total U.S. sales.

Medicaid

States administer the Medicaid program and receive federal subsidies that cover 63 percent of all Medicaid drug spending on average, with states covering the remaining costs. (The federal subsidy amount varies across states.) Medicaid outpatient pharmacy benefits may be delivered by Medicaid FFS, wherein states directly reimburse pharmacies for prescription drugs. Alternatively, states may contract with private managed care plans to administer the drug benefits together with medical benefits. Under the Medicaid program, beneficiaries generally have low cost sharing for prescription drugs. According to CMS, the federal share of Medicaid drug spending on outpatient pharmacy benefits, net of rebates, was $21 billion in 2015.[33]

The primary factors that determine the final net prices paid by Medicaid for brand-name prescription drugs are two statutory rebates that are tied to private-sector prices. First, manufacturers must pay a basic statutory rebate under Medicaid for brand-name drugs that is equal to at least 23.1 percent of the average price manufacturers earn on sales to pharmacies for those drugs. However, if the manufacturer offers certain private-sector purchasers a rebate that exceeds 23.1 percent, then the basic rebate received by Medicaid is increased to match that larger

[33] See the National Health Expenditure Accounts of the Centers for Medicare & Medicaid Services for 2015, https://go.usa.gov/xEA8J. Those figures include spending for drugs under the Children's Health Insurance Program.

private-sector rebate.[34] Second, manufacturers must pay an additional rebate to Medicaid for a drug equal to the amount by which increases in its average manufacturer price have exceeded the rate of general inflation. (The average manufacturer price, or AMP, is the average price received by manufacturers on sales to pharmacies before accounting for any rebates paid subsequently to insurers or pharmacy benefit managers. For brand-name drugs, the AMP is about 95 percent of the retail price.) CBO estimates that, in 2015, those combined statutory rebates for brand-name drugs in the Medicaid program averaged 67 percent of the average manufacturer price, with about half of that amount attributable to the inflation rebate.

Generic manufacturers are required to pay a statutory rebate equal to 13 percent of the average price manufacturers earn on sales to pharmacies—plus an additional rebate when their prices increase faster than general inflation. Because generic drug prices are usually much lower than brand-name drug prices, the rebate amounts paid by manufacturers on generic drug purchases represent a very small share of total rebate revenues collected by states in Medicaid.

Beyond those statutory rebates, states may negotiate for supplemental rebates using preferred drug lists.[35] Supplemental rebates negotiated by the states represented about 4 percent of Medicaid FFS drug spending at retail prices in 2015. (Some states also negotiate for supplemental rebates on drug purchases within Medicaid managed care plans. Such rebates represented a smaller share of retail drug spending within those plans.)[36] The net price paid by Medicaid for a drug is equal to the retail price paid to the pharmacy, less the statutory rebates and any supplemental rebates. Because data on supplemental rebates are not available by drug, they are not accounted for in the estimates presented in this paper.

Medicaid managed care plans are paid by the states on a capitated basis (a fixed amount per beneficiary) for the cost of providing drug benefits and other health care benefits to Medicaid beneficiaries.[37] Medicaid managed care plans negotiate payment rates with pharmacies. Since 2010, manufacturers have been required to pay Medicaid statutory rebates on drug purchases made by Medicaid beneficiaries in managed care plans. Managed care plans may also negotiate additional rebates beyond the statutory rebates and any supplemental rebates negotiated by the state, but data on those additional rebates are not available. Consequently, for this paper, CBO

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[34] This is sometimes referred to as the best price provision. That provision tends to increase the prices paid by certain private-sector purchasers that are able to negotiate the lowest net prices and thus determine the best price.

[35] If a brand-name manufacturer's drug is not on the preferred drug list, then the state may require the beneficiary to obtain prior authorization before the drug is dispensed. Some manufacturers pay a supplemental rebate to the state in addition to the statutory rebate that is already required in order for their drug to be included on the preferred drug list.

[36] CMS's Medicaid expenditure reports contain information on total supplemental rebates collected by states for FFS Medicaid and also Medicaid managed care plans. However that information is not available by drug.

[37] Capitated payments are determined in advance and do not depend on the actual costs incurred by the plan in the year for which the payments are made.

estimated net prices for drugs purchased through Medicaid managed care plans in the same way it estimated net prices for drugs purchased through FFS Medicaid—namely, as the retail price paid to the pharmacy less the statutory rebates. Over the 2010–2015 period, CBO estimates, the share of Medicaid outpatient drug spending covered through Medicaid managed care plans grew from about 10 percent to roughly half.[38]

By statute, cost-sharing amounts in Medicaid are very low—usually no more than $1 to $4 per prescription in 2015.[39] Furthermore, those cost-sharing amounts are waived by the pharmacy if the Medicaid beneficiary is unable to pay those amounts. Still, for a small group of beneficiaries that receive their drug benefits through Medicaid, the amount of cost sharing requested by the pharmacy can be high. For beneficiaries with incomes above 150 percent of the federal poverty guidelines (commonly referred to as the federal poverty level), cost sharing can be as high as 20 percent of the retail price for nonpreferred brand-name drugs. However if the nonpreferred drug is medically necessary, the preferred cost-sharing amount applies. Thus, beneficiaries in Medicaid are largely shielded from the high prices of brand-name specialty drugs.

What Data and Methods Did CBO Use in Its Analysis?

To estimate drug prices and spending in Medicare Part D, CBO used beneficiary-level claims data on the entire Part D population to estimate total spending at retail prices and the number of units (such as tablets, capsules, or milliliters) and prescriptions dispensed over the 2010–2015 period by drug. CBO also used confidential data on the rebates and discounts obtained by Part D plans from manufacturers by drug during that period to estimate net drug prices and spending by drug. For Medicaid, CBO used publicly available data on utilization and spending by National Drug Code (NDC) as well as confidential data on statutory rebate amounts over the 2010–2015 period to estimate net prices and spending. CBO merged the Medicare Part D and Medicaid data with Red Book data (by NDC code), which include drug product characteristics, and with a list of specialty drugs on the market in 2015 provided by IQVIA.[40]

For the analysis of Medicare Part D, CBO constructed prices per "standardized" prescription, which the agency defined to control for differences across prescriptions in the number of days

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[38] When a beneficiary is enrolled in a Medicaid managed care plan, states have a choice of whether to offer the drug benefit through the plan or through FFS Medicaid. After the statutory rebates became available on drug purchases by Medicaid managed care plans in 2010, states shifted more drug spending out of FFS Medicaid and into Medicaid managed care. In addition, the proportion of Medicaid beneficiaries enrolled in managed care has increased over time.

[39] Cost-sharing amounts for nonpreferred drugs can reach $8 per prescription.

[40] The Food and Drug Administration assigns NDC codes to drugs that can be used to identify the manufacturer, chemical entity, dosage form, strength, and package size. Red Book, a product of IBM Micromedex, provides pricing data as well as certain characteristics of the drug by NDC code, including a numerical code that can be used to match all drugs with the same active ingredients or molecular entity. That latter numerical code was used to identify all drugs by NDC code that matched the drugs on the specialty drug list provided by IQVIA.

supplied. (CBO defined a prescription in which the number of days supplied is less than or equal to 30 as one standardized prescription. For a prescription in which the number of days supplied exceeded 30, the agency defined the number of standardized prescriptions as the number of days supplied divided by 30. Thus, for example, a prescription for a 90-day supply was defined as three standardized prescriptions for the analysis of Medicare Part D prices.) Because of data limitations, CBO did not construct standardized prescriptions for most of the analysis of Medicaid prices.[41]

A potential concern with this analysis is that one of the seven criteria for a drug to be classified as a specialty drug is that it cost at least $6,000 in 2015, which is the last year in the analysis period. Specifically, if some drugs are classified as specialty drugs for this analysis only because their price increased by enough to exceed the $6,000 threshold in 2015, that feature of the definition might lead to higher estimated increases in prices and spending for specialty drugs over the 2010–2015 period than would otherwise be the case. That is because the list of specialty drugs used for this analysis could include some drugs that tended to have higher price increases causing them to cross the $6,000 threshold during that period (but those drugs would not otherwise have been included on the 2015 list of specialty drugs). CBO examined this question and found that less than $0.5 billion out of $36.7 billion in spending on specialty drugs at retail prices in 2015 under Medicare Part D was on such drugs (that is, drugs that crossed the $6,000 threshold during the 2010–2015 period and might not have met the definition of a specialty drug in 2015 had they not crossed that cost threshold). Because that $0.5 billion represents only 1 percent of spending for brand-name specialty drugs in 2015, the issue of drugs' crossing the cost threshold during the study period did not significantly affect the results presented in this paper.

To remove the effects of general inflation, the estimates of *drug prices* and *per capita spending* presented in this paper have been adjusted to 2015 dollars using the price index for personal consumption expenditures (PCE). The estimates of *total drug spending* have not been adjusted for inflation in order to provide a better comparison with budgetary figures published on drug spending in Medicare and Medicaid.

What Prices Are Paid for Specialty Drugs in Medicare Part D and Medicaid?

The retail prices paid to pharmacies under Medicare Part D and Medicaid for the same brand-name specialty drug are very similar. However, after accounting for the rebates paid by drug

[41] CBO constructed standardized prescriptions for an analysis of Medicaid prices for 50 top-selling brand-name specialty drugs. Because substantial additional effort would have been required, CBO did not construct standardized prescriptions for its analysis of Medicaid prices per prescription across all specialty drugs.

manufacturers and holding the mix of drugs constant between the two programs, CBO estimates that the average net price for a specified set of top-selling brand-name specialty drugs in 2015 was almost twice as high in Medicare Part D as in Medicaid. In addition, the average price of a prescription for brand-name specialty drugs increased more rapidly in Medicare Part D than in Medicaid from 2010 to 2015 because of differences in the mix of drugs used in the two programs.

Retail Prices for the Top 10 Specialty Drugs in Each Program

Of the 10 specialty drugs with the highest spending under Medicare Part D in 2015, two had an average retail price in that year of over $20,000 per standardized prescription (see Table 2). Both of those drugs (Harvoni and Sovaldi) treat hepatitis C. The average annual spending per user at retail prices for those two drugs in 2015 was about $90,000. Those drugs, taken alone or in combination with other hepatitis C drugs, usually cure hepatitis C, a progressive liver disease that, if left untreated, can lead to cirrhosis and liver failure. The treatment period is about 12 weeks (though it varies by drug and circumstance). Among the other eight top-selling specialty drugs in Medicare Part D, the average retail price per standardized prescription ranged from about $3,000 to about $10,000, and the average annual spending per user at retail prices for those drugs ranged from about $27,000 to $81,000. Those eight drugs treat various types of cancer, anemia, rheumatoid arthritis, Crohn's disease, plaque psoriasis, and multiple sclerosis. The weighted average retail price per prescription for all brand-name specialty drugs in Medicare Part D in 2015 was about $4,200, whereas the weighted average retail price of all brand-name nonspecialty drugs was about $260.

Those prices do not reflect the amounts actually paid for the drugs under Part D because they do not capture rebates and discounts, which reduce the prices paid by the plans.[42] However, beneficiaries' cost sharing for brand-name specialty drugs is typically specified as a percentage of the retail price, not the net price, so the estimates in Table 2 are relevant for determining the amounts paid by beneficiaries.

Total retail spending in Medicare Part D in 2015 on the 10 top-selling specialty drugs was $18.5 billion, or 14 percent of the total Part D retail spending in that year. (Those estimates of drug spending are valued at retail prices—that is, before the receipt of any rebates from manufacturers.) Total Part D spending at retail prices exceeded $1 billion for seven of the 10 top-specialty drugs: Harvoni, Revlimid, Humira, Enbrel, Copaxone, Sovaldi, and Gleevec.

Six of the 10 specialty drugs with the highest spending in Medicaid were not among the 10 top-selling specialty drugs in Medicare Part D. Five of those top-selling specialty drugs in Medicaid

[42] CBO is not able to present average prices for specific drugs net of rebates because the data on rebates are confidential. Estimates of net prices in Part D and Medicaid are presented below for groups of drugs; in that way, the confidentiality of the rebates for specific drugs is maintained.

treat HIV, and the other drug treats hemophilia (see Table 3). Three of the top 10 specialty drugs in Medicaid had an average retail price in 2015 of over $20,000 per prescription. [43] Those three drugs were Advate, which treats hemophilia, and Harvoni and Sovaldi, which treat hepatitis C.[44] The remaining top-selling specialty drugs in Medicaid had average retail prices ranging from about $1,300 to $3,700 per prescription. The weighted average retail price per prescription for all brand-name specialty drugs in Medicaid in 2015 was about $2,360, whereas the weighted average retail price of all brand-name nonspecialty drugs was $280.

Harvoni was the only drug with sales of over $1 billion in the Medicaid program in 2015 (valued at retail prices). The remaining nine top-selling specialty drugs in Medicaid had spending (valued at retail prices) between $300 million and about $800 million. With spending valued at retail prices, total spending on the top 10 specialty drugs in Medicaid amounted to almost $7 billion, which comprised 12 percent of total Medicaid drug spending in 2015.

Average Retail and Net Prices of 50 Top-Selling Brand-Name Specialty Drugs

CBO compared the prices paid by Medicare Part D for 50 top-selling brand-name specialty drugs in that program with the prices paid by Medicaid for the same drugs. The weighted average retail price per standardized prescription in 2015 for those drugs was $4,380 in Medicare Part D, which was very similar to the average price in Medicaid (see Table 4).[45] The average retail price per standardized prescription for those 50 drugs varied greatly, ranging from $250 to almost $43,000. Net of rebates and discounts, the average price per standardized prescription in Medicare Part D in 2015 was $3,600—almost twice as much as in Medicaid ($1,920). That estimate for Medicare Part D includes the manufacturer discount of 50 percent for prescriptions dispensed between the initial coverage limit and the catastrophic threshold. Manufacturers were required to pay that discount for beneficiaries who do not receive low-income subsidies. In the absence of that discount, the average net price for the 50 drugs in Medicare Part D was $3,800.[46]

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[43] Unlike the analysis of the top 10 drugs in Medicare Part D, CBO did not have the claims data available to estimate average annual spending among users of each specialty drug within Medicaid.

[44] Within Medicare, hemophilia clotting factors such as Advate are covered by Medicare Part B rather than Medicare Part D.

[45] Those estimates are the weighted average retail price per standardized prescription, with each drug weighted by the number of standardized prescriptions in Medicare Part D (when calculating both the average price under Medicare Part D as well as under Medicaid). CBO used the Part D claims data to determine the average number of units per standardized prescription for each drug and used that information to convert units to standardized prescriptions in the Medicaid data.

[46] CBO's analysis was based on the average rebates paid by manufacturers for each drug across the entire Part D program. That approach did not account for the fact that the rebates manufacturers pay for the same drug may differ depending upon whether the Part D plan has greater or smaller concentrations of LIS beneficiaries. Rebates for the top 50 drugs analyzed here are about 2 percentage points higher on average for beneficiaries who receive low-income subsidies compared with those that do not. A similar differential was found for the 50 top-selling nonspecialty drugs analyzed.

Prices net of rebates are much lower in Medicaid than in Medicare Part D because the rebates in Medicaid are much higher. The statutory rebates in Medicaid averaged 56 percent of retail prescription costs for the 50 top-selling brand-name specialty drugs.[47] By contrast, the rebates paid by drug manufacturers to Medicare Part D drug plans averaged just 18 percent of the retail price for those top-selling brand-name specialty drugs when the 50 percent manufacturer discount is included. When that discount is excluded, rebates average 13 percent of the retail price for Medicare Part D.[48]

CBO conducted analogous comparisons for the 50 top-selling brand-name nonspecialty drugs in Medicare Part D. The average retail price per standardized prescription for those drugs in 2015 was $300 in Medicare Part D, which was very similar to the average price in Medicaid. Net of rebates and discounts (including the 50 percent manufacturer discount), the weighted average price per standardized prescription for those 50 drugs in Medicare Part D in 2015 was $150—almost three times as much as in Medicaid ($55). Manufacturer rebates are substantially higher for nonspecialty drugs than for specialty drugs in each program (as a percentage of the retail price), for reasons discussed below. For both types of drugs, the rebates are substantially higher in Medicaid than in Medicare Part D.

Price Growth for Brand-Name Specialty Drugs in Each Program

CBO used two different approaches to measure the price growth of brand-name specialty drugs between 2010 and 2015. In the first approach, CBO examined the change in the average net price of a prescription over time. In the second approach, CBO used a price index to examine the average annual increase in drug prices over time after they were introduced. The first approach captures both increases in the prices of individual drugs over time as well as shifts in the mix of drugs used between years. The second approach captures average price increases for individual drugs between consecutive years while holding the mix of drugs constant between years. The first approach yields a much higher estimate of price growth because it incorporates not only the growth captured by the price-index approach but also the shift toward the use of higher-priced drugs—including new drugs—during the period examined.

Change in the Average Net Price of a Prescription. The average net price of a prescription for brand-name specialty drugs increased more rapidly from 2010 to 2015 in Medicare Part D than in Medicaid.

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[47] Those estimates do not include any supplemental rebates negotiated by state Medicaid agencies or Medicaid managed care plans. In Medicaid FFS, such rebates average about 4 percent of brand-name drug sales but are probably lower for brand-name specialty drugs, which have fewer competitors in the market.

[48] The manufacturer discount of 50 percent in the coverage gap has a relatively small effect on the average net price of brand-name specialty drugs because over 80 percent of spending on such drugs is in the catastrophic phase of the benefit, where that discount does not apply.

Medicare Part D. The average net price of a standardized prescription for brand-name specialty drugs under Medicare Part D rose from $1,310 in 2010 to $3,590 in 2015, an average annual increase of 22 percent (all estimates are in 2015 dollars; see the top panel of Table 5). That increase was partly attributable to the use of new specialty drugs introduced after 2010, which accounted for 40 percent of net spending on brand-name specialty drugs in 2015. Those newer specialty drugs had a substantially higher average net price in 2015 than specialty drugs that were older (and had already been introduced by 2010). In particular, in 2015, the newer brand-name specialty drugs had an average net price per standardized prescription in Medicare Part D that was more than three times the average net price for older brand-name specialty drugs ($8,680 versus $2,570).[49] CBO's analysis suggests that the shift toward use of new brand-name specialty drugs could have accounted for over 40 percent of the total increase in the average prescription price of a brand-name specialty drug between 2010 and 2015.[50]

Among older brand-name specialty drugs (those already on the market by 2010), the average net price of a standardized prescription (in 2015 dollars) rose from $1,310 in 2010 to $2,570 in 2015, an average annual increase of 14.4 percent. About 40 percent of that increase was attributable to

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[49] For this analysis, only new molecular entities or biologic products that appeared on the list of novel drug approvals published by the Food and Drug Administration from 2011 to 2015 were included in the category of new brand-name drugs.

[50] It is challenging to determine how much of the growth in the average price per prescription for brand-name specialty drugs between 2010 and 2015 was attributable to the introduction of new brand-name specialty drugs because of uncertainty about the way in which the introduction of those new drugs affected the net prices and market shares of older specialty drugs. CBO developed an estimate using the average net prescription price in 2015 for older brand-name specialty drugs as an approximation of what older brand-name specialty drugs would have cost had the new brand-name specialty drugs not been introduced. That method of approximating the counterfactual average prescription cost for older brand-name specialty drugs in 2015 suggests that the higher average prices of the new brand-name specialty drugs contributed 45 percent of the total increase in the average price of a brand-name specialty drug between 2010 and 2015. New specialty brand-name drugs accounted for 16.6 percent of prescriptions dispensed for specialty brand-name drugs in 2015. The calculation is as follows: (8,680 – 2,570)*16.6 percent is equal to 1,014 which is 45 percent of the total change in the average price of a brand-name specialty drug prescription over the 2010–2015 period of $2,280.

Other researchers have recently found that the average cost of a prescription for an oral solid specialty drug increased at an average annual rate of 20.6 percent over the 2008–2016 period and that new drugs accounted for 71 percent of that cost increase. (For injectable specialty drugs, those amounts were 12.5 percent and 52 percent, respectively.) Those results were based on list prices (wholesale acquisition costs) and weighted by the prescriptions covered by a large private-sector health insurer. That paper did not use a price-index approach. The estimated average rate of cost increase captures both changes in drug mix as well as year-over-year price increases over time. That paper tends to find a larger contribution of new drugs to cost growth partly because their definition of "new drugs" was much broader (as it also includes new dosage forms and combination products). In addition, their approach to apportioning cost increases between new and existing drugs differed from the approach taken here. See Inmaculada Hernandez and others, "The Contribution of New Product Entry Versus Existing Product Inflation in the Rising Cost of Drugs," *Health Affairs*, vol. 38, no. 1 (2019), pp. 76–83, https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2018.05147.

an increase in the net prices of individual drugs over time, and the remainder was the result of a change in the mix of drugs toward those with higher prices within that group of drugs.[51]

The average net price of a standardized prescription for brand-name nonspecialty drugs under Medicare Part D rose at a much slower average annual rate from 2010 to 2015 than the aforementioned rate for brand-name specialty drugs (4.5 percent versus 22.3 percent). The introduction of new drugs after 2010 had a much smaller effect on the growth of the average net price of brand-name nonspecialty drugs than was the case for specialty drugs. Partly for that reason, the average net price of brand-name nonspecialty drugs grew at a much slower rate from 2010 to 2015 than was the case for specialty drugs.

Medicaid. The average net price per prescription for brand-name specialty drugs under Medicaid's prescription drug benefit rose from $700 in 2010 to $1,220 in 2015, an average annual increase of 11.7 percent (all estimates are in 2015 dollars; see the bottom panel of Table 5).[52] As was true for Medicare Part D, that increase was largely attributable to the introduction of new specialty drugs after 2010 that had a substantially higher average net price in 2015 than those that had been introduced previously. In 2015, the newer brand-name specialty drugs had an average net price in Medicaid that was more than four times that of older brand-name specialty drugs ($4,660 versus $900). Those price levels are substantially lower than the corresponding estimates for Medicare Part D because of the much higher rebates under Medicaid and differences in the mix of drugs used in the two programs.

Among older brand-name specialty drugs, the average net price per prescription (in 2015 dollars) rose from $700 in 2010 to $900 in 2015, an average annual increase of 5.1 percent. That increase was partly attributable to an increase in the net prices of individual drugs and partly the result of a change in the mix of drugs toward those with higher prices. The net prices of specialty drugs grew at a slower rate in Medicaid than in Medicare Part D partly because the inflation rebate constrains the growth of drug prices paid by Medicaid.

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[51] Some older brand-name specialty drugs that were on the market in 2010 and used by Medicare Part D enrollees in that year were largely replaced by newer specialty drugs available by 2015, which accounts for part of the change in the mix of drugs. In the absence of such changes, CBO estimates that the net prices for the set of older brand-name specialty drugs purchased in 2010 and also available in 2015 would have increased at an average annual rate of 6.8 percent per year, or from $1,311 in 2010 to $1,822 in 2015 (using a Laspeyres price-index approach). Thus, the amount of the increase attributed to year-over-year price growth for individual drugs can be estimated as: ($1,822 – $1,311)/($2,572 – $1,311) = 40 percent.

[52] If drugs administered by a physician are excluded from the analysis, the average price of a brand-name specialty drug grows a bit more quickly over the period in both Medicaid and Medicare Part D. However, the basic conclusions regarding the comparison between Medicare Part D and Medicaid do not change markedly if physician-administered drugs are excluded from the calculations. In addition, the average net price of a brand-name specialty drug is still much lower in Medicaid than in Medicare Part D when physician-administered drugs are excluded from the analysis. See the Appendix for details.

Although the average net price for brand-name specialty drugs under Medicaid grew at a considerable rate from 2010 to 2015, the average net price for brand-name nonspecialty drugs declined during that period, from $80 to $70 (in 2015 dollars). The increase in the weighted average statutory rebate from just over 60 percent to almost 80 percent contributed to the decline in the average net prescription price of nonspecialty brand-name drugs in Medicaid.

Average Annual Increase in Net Drug Prices Using a Price Index. Using a price-index approach, CBO estimates that the prices of brand-name specialty drugs grew somewhat more slowly on average over the 2010–2015 period than the prices of brand-name nonspecialty drugs. To conduct that analysis, CBO constructed a price index to measure the change in prices for each consecutive pair of years in the period, in each case holding the mix of drugs constant at the shares in the first of the two years, and then computed the average annual increase in prices for each consecutive pair of years over the 2010–2015 period.[53] As before, all prices were expressed in 2015 dollars. Using that approach, CBO estimated that the retail prices of brand-name specialty drugs increased at an average annual rate of 8.5 percent from 2010 to 2015, compared with an average annual increase of 10.4 percent for brand-name nonspecialty drugs, and that the net prices of brand-name specialty drugs increased at an average annual rate of 5.8 percent, compared with an average annual increase of 7.4 percent for brand-name nonspecialty drugs. The 5.8 percent average annual increase in the net price of brand-name specialty drugs is much smaller than the 22.3 percent average annual increase in the average net price of a standardized prescription for such drugs over that period, indicating that much of the latter increase was attributable to changes in the mix of drugs used—particularly the use of new drugs (those introduced after 2010).

Because of data limitations, CBO was not able to apply the price-index approach that was used for Medicare Part D to examine the growth in prices for brand-name specialty drugs and brand-name nonspecialty drugs in Medicaid.[54] However, because of the inflation rebate in Medicaid, CBO expects that the growth of net prices would have been lower in Medicaid than in Medicare Part D.

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[53] CBO used a chained Laspeyres price-index approach, which enabled the agency to gradually incorporate new brand-name specialty drugs introduced during the 2011–2014 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.

[54] Although it is straightforward for a pharmacy to report the number of capsules or tablets dispensed on a claim, the unit-count variable can be less reliable in both the Medicare Part D and Medicaid data for certain types of dosage forms that are more common amongst specialty drugs, such as injectable or infusible drugs. For Medicare Part D, CBO was able to use the number of days supplied in the Part D claims data to standardize the size of a prescription and undertake the price-index analysis. The number of days supplied by each prescription is not available in the Medicaid drug utilization files posted on CMS's website.

Change in Rebates. Rebates as a percentage of spending at retail prices increased for both brand-name specialty drugs and brand-name nonspecialty drugs over the 2010–2015 period in Medicare Part D and Medicaid. In Medicare Part D, the average manufacturer rebate for brand-name specialty drugs rose from 2.6 percent of retail spending in 2010 to 10.5 percent in 2015 (see the top panel of Table 6). That increase could suggest that manufacturers of some brand-name specialty drugs faced greater competition by 2015. After including the other discounts available under Medicare Part D (such as the 50 percent manufacturer discount on certain purchases), total rebates and discounts for brand-name specialty drugs were 14.0 percent of retail spending in 2015. Average manufacturer rebates under Medicare Part D were substantially higher for brand-name nonspecialty drugs than for brand-name specialty drugs. For brand-name nonspecialty drugs, manufacturer rebates grew from 17.4 percent of retail spending in 2010 to 28.4 percent in 2015, and total rebates and discounts in 2015 were 37.3 percent of retail spending. The negotiations between Part D plan sponsors and manufacturers over drug pricing generally result in greater rebates when drugs have multiple close substitutes available, which occurs more frequently for nonspecialty drugs.

In Medicaid, the average total rebate for brand-name specialty drugs grew from 42.1 percent of the average manufacturer price in 2010 to 50.0 percent in 2015 (see the bottom panel of Table 6). In both 2010 and 2015, the basic rebate for specialty drugs was about 5 percentage points higher than the inflation rebate. The average total rebate for brand-name nonspecialty drugs grew from 61.9 percent in 2010 to 79.1 percent in 2015. The basic rebate and the inflation-based rebate for nonspecialty drugs were nearly equal in 2010 (at about 31 percent), but in 2015 the inflation rebate was higher (48.2 percent versus 40.6 percent).[55] The rebates in Medicaid for brand-name specialty drugs and nonspecialty drugs are substantially higher than the rebates in Medicare Part D.

The rebates and discounts on both specialty and nonspecialty brand-name drugs in the Medicare Part D program increased by a larger amount in percentage-point terms than those in Medicaid over the period (11.4 percentage points compared with 7.9 percentage points for brand-name specialty drugs). That can be explained partly by the manufacturer discount in the coverage gap that began in Medicare Part D in 2011. There are also many other factors involved, such as the floor on Medicaid's basic rebate of 23.1 percent and differences in the mix of drugs used by the two programs.

[55] The sum of the weighted average basic rebate and additional rebate was 89.9 percent in 2015. However, the statutory rebates cannot exceed 100 percent of the AMP for a given drug. After accounting for this upper limit on statutory rebates, the weighted average statutory rebate owed on sales of brand-name nonspecialty drugs was 79.3 percent in 2015.

What Are Recent Trends in Net Spending on Specialty Drugs in Medicare Part D and Medicaid?

Total spending on specialty drugs net of rebates increased substantially from 2010 to 2015 in both Medicare Part D and Medicaid, although the rate of spending growth was much greater in Medicare Part D. Net spending on specialty drugs in Medicare Part D also increased substantially when measured on a per capita basis, an occurrence that was primarily the result of an increase in the average net price per prescription for brand-name specialty drugs. Because of data limitations, CBO conducted a much more limited analysis of per capita spending on specialty drugs in Medicaid. Still, CBO was able to determine that net per capita spending on specialty drugs grew at a much slower rate in Medicaid than in Medicare Part D.

Specialty drugs are used to treat a similar set of health conditions in Medicare Part D and Medicaid, although the distribution of spending by condition differs between the two programs because of substantial differences in the characteristics of the covered populations. In Medicare Part D, the three conditions that accounted for the most spending on specialty drugs in 2015 were hepatitis C and cancer (each of which accounted for 24 percent of spending on specialty drugs valued at retail prices) and multiple sclerosis (12 percent). In Medicaid, the three conditions that accounted for the most spending on specialty drugs valued at retail prices were HIV (22 percent), hepatitis C (17 percent), and cancer (13 percent). Because retail prices tend to be similar across the two programs, the differences in the share of total spending at retail prices reflect differences in drug utilization.

The estimates of total drug spending presented below are in nominal amounts (that is, they have not been adjusted to account for the effects of general inflation), which facilitates comparison with budgetary estimates published by CBO and other government agencies. However, estimates of per capita drug spending were converted to 2015 dollars using the PCE price index.

Medicare Part D

Net spending on specialty drugs in Medicare Part D increased almost fourfold from 2010 to 2015—rising from $8.7 billion to $32.8 billion, an average annual increase of 31 percent (see Figure 1). During that period, net spending on nonspecialty drugs in Medicare Part D rose from $59.6 billion to $72.6 billion, an average annual increase of 4 percent. Specialty drugs accounted for a growing share of net spending in Medicare Part D, rising from 12.7 percent in 2010 to 31.1 percent in 2015. Some of the increase in net spending in Medicare Part D can be attributed to growth in Part D enrollment, which increased at an average annual rate of 7 percent from 2010 to 2015. CBO removed that effect by analyzing trends in per capita spending in Part D.

Net per Capita Spending on Specialty Drugs in Medicare Part D. Between 2010 and 2015, a large percentage increase in net per capita spending on specialty drugs was nearly offset by a decline in net per capita spending on nonspecialty drugs. The result was that overall net per capita spending on drugs in Medicare Part D remained almost flat over the period. From 2010 to

2015, net per capita spending on specialty drugs in Medicare Part D increased from $330 to $830, an average annual increase of 20.1 percent, whereas net per capita spending on nonspecialty drugs decreased from $2,290 to $1,830, an average annual decrease of 4.3 percent (all of those estimates are in 2015 dollars; see Table 7). Net per capita spending on all drugs in Medicare Part D increased only slightly from $2,620 to $2,660 during that period, an average annual increase of 0.3 percent.

Per capita spending on brand-name nonspecialty drugs fell largely because of patent expirations that occurred over the period. That caused overall net per capita spending on all brand-name drugs to decline slightly, from $1,870 to $1,840, as the increase in spending on brand-name specialty drugs was not sufficient to offset the decline in per capita spending on brand-name nonspecialty drugs.

Brand-Name Specialty Drugs. The growth in net per capita spending on specialty drugs was almost entirely attributable to spending growth on brand-name specialty drugs, which accounted for about 95 percent of total net spending on specialty drugs in Medicare Part D in both 2010 and 2015. (The remaining 5 percent was for spending on generic specialty drugs.) All of the recent growth in net per capita spending on brand-name specialty drugs in Medicare Part D was the result of an increase in the average net price of a standardized prescription for such drugs, which grew (in 2015 dollars) from $1,310 in 2010 to $3,590 in 2015 (see Table 5). During that time, the average annual number of prescriptions for brand-name specialty drugs per Part D enrollee fell slightly from 0.24 to 0.22, and the share of Part D enrollees taking a brand-name specialty drug declined slightly from 2.8 percent to 2.4 percent.[56] (Over the same period, the average annual number of prescriptions for all drugs per Part D enrollee per year increased from 50 to 53.) Brand-name specialty drugs accounted for only about 0.5 percent of all prescriptions in Part D in both 2010 and 2015.

Brand-Name Specialty Drugs Introduced After 2010. Much of the growth in net per capita spending on brand-name specialty drugs in Medicare Part D from 2010 to 2015 was attributable to spending on drugs that were introduced after 2010. Those newer drugs accounted for 63 percent of the increase in net per capita spending on brand-name specialty drugs from 2010 to

[56] Although the percentage of Part D enrollees who took a brand-name specialty drug declined slightly from 2010 to 2015, the average number of prescriptions for brand-name specialty drugs among enrollees who took such drugs increased slightly from 8.6 to 9.3. CBO did not determine the reasons for those trends. The decline in the share of Part D enrollees who took a brand-name specialty drug could be explained partly by changes in the characteristics of those enrollees. For example, as discussed below, the share of Part D enrollees who received subsidies through the LIS program declined during that period, and LIS enrollees are more likely than other Part D enrollees to use brand-name specialty drugs. In addition, there may have been changes in the share of beneficiaries with a condition that can be treated by a specialty drug. Increases in out-of-pocket costs could also have contributed to a smaller share of beneficiaries' taking a brand-name specialty drug for those beneficiaries who did not receive assistance with enrollment in either the LIS program or an employer-sponsored plan.

2015, and they accounted for 40 percent of total net spending on such drugs in Medicare Part D in 2015.[57]

Generic Specialty Drugs. Net per capita spending on generic specialty drugs in Medicare Part D (in 2015 dollars) grew from $20 in 2010 to $30 in 2015.[58] That increase was attributable to an increase in both the average net price of a prescription for generic specialty drugs and the average number of prescriptions per enrollee for such drugs. From 2010 to 2015, the average net price of a prescription for generic specialty drugs in Medicare Part D (in 2015 dollars) increased from $56 to $78, and the average number of prescriptions for such drugs per Part D enrollee increased from 0.33 to 0.42. Generic specialty drugs accounted for 0.7 percent of all prescriptions in 2010 in Medicare Part D and that share increased to 0.8 percent in 2015. So, in 2015, about twice as many prescriptions were dispensed for generic specialty drugs as for brand-name specialty drugs, but generic specialty drugs accounted for only 1 percent of net Part D spending.

Nonspecialty Drugs. The decline in net per capita spending on nonspecialty drugs in Medicare Part D from 2010 to 2015 was driven by a decrease in net per capita spending on brand-name nonspecialty drugs (from $1,550 to $1,040 in 2015 dollars), which was only partially offset by an increase in net per capita spending on generic nonspecialty drugs (from $730 to $790 in 2015 dollars). Those changes were partly attributable to patent expirations on some top-selling nonspecialty drugs, which resulted in many patients' shifting from brand-name drugs to lower-cost generics. From 2010 to 2015, the average number of prescriptions for brand-name nonspecialty drugs per Part D enrollee fell from 12 to 6, and the average net price of a prescription for such drugs in Medicare Part D increased from $130 to $165 (in 2015 dollars). Per capita spending across all brand-name drugs (specialty and nonspecialty) actually declined slightly (by $30) because the increase in spending on brand-name specialty drugs was not sufficient to fully offset the decline in spending on brand-name nonspecialty drugs. During that period, the average number of prescriptions for generic nonspecialty drugs per Part D enrollee increased from 37 to 46, and the average net price of a prescription for such drugs in Part D fell from $20 to $17 (in 2015 dollars).

The increase in generic market share helped to hold per capita drug spending nearly flat over the 2010–2015 period. As the generic share of all prescriptions dispensed grew from about

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[57] In Medicare Part D, net per capita spending on brand-name specialty drugs that were on the market in 2010 rose from $290 in 2010 to $480 in 2015. Net per capita spending on newer drugs in 2015 was $320.

[58] Some generic versions of brand-name drugs meet the criteria established for the definition of specialty drugs. Examples of generic specialty drugs include hydroxychloroquine sulfate, methotrexate sodium, and leflunomide, which reduce inflammation in patients with autoimmune diseases such as rheumatoid arthritis; fluorouracil, which is a chemotherapy drug; exemestane, which treats breast cancer; entecavir, which treats hepatitis B; and Glatopa, which treats multiple sclerosis.

75 percent to just over 85 percent, the net average prescription price across all types of drugs in Medicare Part D fell slightly, from $53 to $50 between 2010 and 2015. Per capita drug spending still increased slightly because the number of prescriptions dispensed per beneficiary increased.[59]

Net Spending in the Medicare Part D Catastrophic Phase. In the catastrophic phase of the Part D benefit, total net spending for all drugs tripled from 2010 to 2015, rising from $14 billion to $43 billion. Net spending on brand-name specialty drugs in the catastrophic phase of the benefit increased from $5.4 billion to $26.1 billion. Part D plans were reimbursed on a cost basis (through reinsurance payments) for 46 percent of the total cost of the basic benefit in 2015. That was up from about 30 percent in 2010. Furthermore, the share of reinsurance payments in basic benefit costs has continued to increase and is expected to reach 58 percent in 2018.[60] That is attributable to the fact that plans have less incentive to invest in managing drug costs efficiently under cost-based reimbursement.[61]

That growth in drug spending in the catastrophic phase of the benefit can be largely explained by increased spending on brand-name specialty drugs. Among all Part D enrollees, total net spending per capita on all drugs in the catastrophic phase (in 2015 dollars) doubled from $550 in 2010 to $1,080 in 2015. Net per capita spending on brand-name specialty drugs in the catastrophic phase increased (in 2015 dollars) from $200 to $660, accounting for just over 80 percent of the total growth in net per capita spending in the catastrophic phase in Medicare Part D between 2010 and 2015. The share of net spending in the catastrophic phase accounted for by brand-name specialty drugs increased from almost 40 percent in 2010 to about 60 percent in 2015.[62]

Net Spending and Out-of-Pocket Costs Among Medicare Part D Enrollees Who Take Specialty Drugs. Average annual net spending on brand-name specialty drugs among Part D enrollees who took such drugs increased from $11,330 in 2010 to $33,460 in 2015 (all estimates

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[59] Per capita drug spending increased slightly even as the average price of a prescription fell because the number of prescriptions dispensed per Medicare Part D beneficiary increased from 50 to 53, or by 6.5 percent.

[60] On the basis of plan bids, the total cost of the basic benefit in 2018 is expected to be $137 per beneficiary on average (which includes expected reinsurance payments). Of that amount, reinsurance costs are expected to be $79, or about 58 percent. See Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* (March 2018), Figure 14-5, p. 421, http://medpac.gov/-documents-/reports.

[61] The Medicare Payment Advisory Commission has recommended reducing the share of drug spending in the catastrophic phase that is covered through reinsurance payments. See Medicare Payment Advisory Commission, *Report to Congress: Medicare and the Health Care Delivery System* (June 2016), Chapter 6, http://medpac.gov/-documents-/reports.

[62] A separate analysis, which is based on retail prices, has found that high-priced drugs that cost $1,000 or more per month made up one-third of spending in the catastrophic phase in 2010; that amount increased to two-thirds by 2015. See Department of Health and Human Services, Office of Inspector General, *High-Price Drugs Are Increasing Federal Payments for Medicare Part D Catastrophic Coverage*, OEI-02-16-00270 (January 2017), https://oig.hhs.gov/oei/reports/oei-02-16-00270.asp.

in this section are in 2015 dollars; see Table 8). Most of that increased spending per beneficiary fell in the catastrophic phase of the benefit. CBO analyzed net spending and out-of-pocket costs separately for three subgroups of Part D beneficiaries: non-LIS enrollees not enrolled in an employer-sponsored plan, beneficiaries enrolled in an employer-sponsored plan that is also a Part D plan, and LIS enrollees.[63] The first group generally receives no assistance with cost sharing, the second group usually receives help with cost sharing from a former employer, and the third group receives substantial cost-sharing subsidies from the federal government.

Non-LIS Enrollees Not Enrolled in an Employer-Sponsored Plan. In 2015, 53 percent of Part D enrollees (or 21 million beneficiaries) were not enrolled in either the LIS program or an employer-sponsored plan and thus generally had no help with cost sharing—a similar share as in 2010. Some 1.4 percent of those beneficiaries (or about 300,000) used a brand-name specialty drug in 2015, compared with 1.9 percent in 2010. Among the enrollees in that group who used a brand-name specialty drug, the average annual net spending on such drugs increased from $8,970 in 2010 to $36,730 in 2015, and their average annual out-of-pocket cost for those drugs increased during that period from $1,750 to $3,540. (The average out-of-pocket cost for all drugs in Part D for such beneficiaries averaged just over $4,000 in 2015. Thus, among beneficiaries who used a brand-name specialty drug in 2015 and who generally had no help with cost sharing, their out-of-pocket costs for specialty drugs accounted for nearly 90 percent of their total out-of-pocket costs under Part D.) The increase in out-of-pocket costs for brand-name specialty drugs from 2010 to 2015 would have been even greater had it not been for the introduction of the 50 percent manufacturer discount in the Part D coverage gap in 2011. In 2015, that discount on brand-name specialty drugs averaged $1,480 for beneficiaries who took such drugs.[64]

Although the average out-of-pocket cost for brand-name specialty drugs more than doubled from 2010 to 2015 for enrollees who generally had no help with cost sharing, those beneficiaries' out-of-pocket costs fell as a share of total net spending for brand-name specialty drugs from 20 percent to 10 percent over that period. Enrollees' out-of-pocket costs constituted a declining share of total net spending for brand-name specialty drugs because a growing portion of the net

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[63] Some beneficiaries receive drug coverage from employer-sponsored plans that are outside of the Medicare Part D program. Spending by such beneficiaries is not included in this analysis. Employers that offer drug coverage outside of the Part D program receive "retiree drug subsidies" from the government.

[64] One study found that total out-of-pocket costs for beneficiaries who took certain brand-name specialty drugs (and who were not eligible for low-income subsidies) decreased slightly over the 2008–2012 period because of the 50 percent manufacturer discount in the coverage gap that started in 2011. The increase in out-of-pocket costs in the catastrophic phase of the benefit over that period did not completely offset the decline in out-of-pocket costs that was attributed to the 50 percent discount. See Erin Trish, Jianhui Xu, and Geoffrey Joyce, "Medicare Beneficiaries Face Growing Out-Of-Pocket Burden for Specialty Drugs While in Catastrophic Phase," *Health Affairs*, vol. 35, no. 9 (September 2016), pp. 1564–1571, https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2016.0418. By contrast, CBO's analysis indicates that by 2015, out-of-pocket costs for beneficiaries who took brand-name specialty drugs had increased since 2010 because the 50 percent discount offered in the coverage gap was not sufficient to offset the higher out-of-pocket costs in the catastrophic phase of the benefit.

spending for those drugs occurred in the catastrophic phase of the Part D benefit, in which about 80 percent of spending is covered by federal reinsurance payments, 15 percent is covered by the plans, and 5 percent is paid by enrollees. Among the group of enrollees who used a brand-name specialty drug, the share of total net spending for those drugs that fell above the catastrophic threshold grew from 67 percent in 2010 to 91 percent in 2015.[65]

Total net spending and out-of-pocket costs for brand-name specialty drugs varied greatly across beneficiaries who used such drugs. Among users of such drugs who generally had no help with cost sharing, 10 percent (or 30,000 beneficiaries) had total net spending on those drugs of at least $90,000 in 2015. In addition, the out-of-pocket costs for brand-name specialty drugs reached at least $7,150 for 10 percent of beneficiaries who took such drugs.[66] For another 10 percent of those users of brand-name specialty drugs, total net sending on those drugs was no more than $1,000, and their out-of-pocket costs were no more than $100 in 2015.[67]

Enrollees in an Employer-Sponsored Plan. In 2015, approximately 16 percent of Part D enrollees (or 6.2 million beneficiaries) were enrolled in an employer-sponsored plan, up from 9 percent in 2010. Part D plans sponsored by employers are available only to Medicare enrollees who are retirees of those employers; they typically provide substantial assistance with cost sharing. The share of enrollees in an employer-sponsored plan who used a brand-name specialty drug fell from 2.8 percent in 2010 to 2.3 percent in 2015. Among enrollees in such plans who used brand-name specialty drugs, the average net spending on such drugs more than tripled from 2010 to 2015, rising from $9,140 to $30,700, whereas the average out-of-pocket cost for such drugs rose only slightly, from $560 to $570. As a share of total net spending on brand-name specialty drugs, those enrollees' out-of-pocket costs fell from 6 percent to 2 percent. The average amount of assistance with cost sharing provided by the employer for brand-name specialty drugs among enrollees who used such drugs rose over that period from $5,408 (59 percent of total net spending for those drugs) to $16,140 (53 percent).

Because employers cover such a high percentage of the cost-sharing amount for their beneficiaries in the coverage gap, those beneficiaries reach the catastrophic threshold at a higher level of total drug spending than all other types of beneficiaries. Therefore, the total share of spending on brand-name specialty drugs that occurs in the catastrophic phase is smaller for those

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[65] The exact dollar amount of total drug spending when a beneficiary enters the catastrophic phase depends on the share of his or her spending on brand-name and generic drugs.

[66] CBO examined the distribution of total net spending on brand-name specialty drugs and out-of-pocket costs for those drugs separately, so not all of the beneficiaries in the top 10 percent of the distribution of total net spending were in the top 10 percent of the distribution of out-of-pocket costs, and vice versa.

[67] For 25 percent of users of brand-name specialty drugs, out-of-pocket costs for those drugs were no higher than $720. Half of those users of brand-name specialty drugs had out-of-pocket costs for those drugs of $3,260 or more. For 25 percent of users of brand-name specialty drugs, out-of-pocket costs for those drugs reached $5,400 or more.

beneficiaries. Nevertheless, much of the increase in the average spending per beneficiary who took a specialty drug occurred in the catastrophic phase. The total share of net spending that fell in the catastrophic phase increased from 13 percent in 2010 to 47 percent in 2015 for those beneficiaries.

LIS Enrollees. In 2015, approximately 31 percent of Part D enrollees (or 12.1 million beneficiaries) were enrolled in the LIS program, down from 37 percent in 2010. The share of LIS enrollees who used a brand-name specialty drug was close to 4 percent in both 2010 and 2015. Among LIS enrollees who used brand-name specialty drugs, the average net spending on such drugs rose from $13,340 in 2010 to $32,300 in 2015, whereas the average out-of-pocket cost for such drugs rose slightly from $57 to $58. As a share of total net spending on brand-name specialty drugs, LIS enrollees' out-of-pocket costs fell from 0.4 percent to 0.2 percent. From 2010 to 2015, the average federal cost-sharing subsidy for brand-name specialty drugs among LIS enrollees who used such drugs (in 2015 dollars) rose from $3,070 (23 percent of total net spending for those drugs) to $4,830 (15 percent).[68]

As was the case for enrollees with no cost-sharing subsidies, a large share of spending for brand-name specialty drugs fell above the catastrophic threshold for LIS beneficiaries, and that share increased significantly over the 2010–2015 period. That occurred for two reasons: Both types of beneficiaries saw a large increase in average annual spending on brand-name specialty drugs, and they reached the catastrophic threshold at a similar amount of drug spending.[69] The share of total net spending on brand-name specialty drugs for LIS enrollees that fell above the catastrophic threshold grew from 71 percent in 2010 to 88 percent in 2015.

Medicaid

Net spending on prescriptions for specialty drugs in Medicaid roughly doubled from 2010 to 2015, rising from $4.8 billion to $9.9 billion, an average annual increase of 16.1 percent (see Figure 2).[70] That increase in net spending on specialty drugs was far lower than the nearly fourfold increase in such spending in Medicare Part D. During that time, net spending on nonspecialty drugs in Medicaid rose from $14.5 billion to $18.6 billion, an average annual increase of 5.1 percent. Specialty drugs accounted for a growing share of net spending on drugs

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[68] Because spending in the catastrophic phase of the benefit increased for brand-name specialty drugs, that also increased the LIS cost-sharing subsidies—which cover nearly 5 percent of drug costs in the catastrophic phase—between 2010 and 2015. (Most LIS beneficiaries pay no out-of-pocket costs in the catastrophic phase; some pay a few dollars.) At the same time, because cost-sharing subsidies represent only a small share of net spending in the catastrophic phase of the benefit, the LIS cost-sharing subsidy as a share of total net spending declined.

[69] In 2015, LIS beneficiaries reached the catastrophic threshold once their total drug spending amounted to about $7,060.

[70] With physician-administered drugs excluded, specialty drug spending in Medicaid grew slightly faster but still much more slowly than in Medicare Part D. See the Appendix for more details.

in Medicaid, rising from 25 percent in 2010 to 35 percent in 2015.[71] On the basis of the evidence (discussed below) regarding the share of recently approved drugs and drugs under development that are specialty drugs, CBO expects that trend to continue.

Net per Capita Spending on Specialty Drugs in Medicaid. CBO was not able to estimate net per capita spending on specialty drugs as precisely for Medicaid as for Medicare Part D because of data limitations. However, the agency was able to determine that net per capita spending on specialty drugs grew at a much slower rate from 2010 to 2015 in Medicaid than in Medicare Part D and that in each year, net per capita spending on both specialty drugs and nonspecialty drugs was much lower in Medicaid than in Medicare Part D.

To compute per capita drug spending in Medicaid, CBO divided total drug spending in the program each year by an estimate of the average monthly number of people with prescription drug coverage under Medicaid. CBO computed the latter figure by starting with the average monthly Medicaid enrollment in each year and then subtracting the number of enrollees who did not have drug coverage through the program. The agency first subtracted dual-eligible beneficiaries from the Medicaid enrollment totals because those beneficiaries receive drug coverage under Medicare Part D rather than Medicaid. Then, CBO subtracted an estimate of the number of Medicaid beneficiaries each year who had partial benefits, since those people typically have no drug coverage or very limited drug coverage under Medicaid.[72] That resulted in an estimate for each year of the number of Medicaid beneficiaries with prescription drug coverage under Medicaid.

Using that approach, CBO found that net per capita spending on specialty drugs in Medicaid grew at an average annual rate from 2010 to 2015 of roughly 9 percent, about half the average annual growth of 20 percent estimated for Medicare Part D. The agency also found that net per capita spending on nonspecialty drugs in Medicaid declined at an average annual rate of about 2 percent during that period. By comparison, net per capita spending on nonspecialty drugs in Medicare Part D fell at an average annual rate of 4.3 percent during that period.

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[71] Excluding physician-administered drugs from the analysis reduces the share of Medicaid drug spending accounted for by specialty drugs by roughly 5 percentage points in 2010 and 2015. See the Appendix for more details.

[72] Medicaid beneficiaries with partial benefits include those who are eligible only for family-planning services or emergency services. CBO used individual-level data from the Medicaid Analytic eXtract (MAX) for 2011 to estimate the percentage of enrollees who were eligible for partial benefits among enrollees who were not dual-eligible beneficiaries. (The agency used 2011 data because it was the most recent year for which data were available for virtually all states.) CBO constructed those estimates for three eligibility categories: children; aged and disabled beneficiaries not enrolled in Medicare; and nonelderly, nondisabled adults. The agency then applied those percentages to the average monthly enrollment figures for each eligibility category for 2010 and 2015 to estimate the number of enrollees in each year who were eligible for partial benefits only. In 2015, the enrollment numbers include adults who were eligible for the program as the result of the Affordable Care Act's expansion of Medicaid: All beneficiaries in that eligibility category had prescription drug coverage.

Comparison With Medicare Part D. Net per capita spending on brand-name specialty drugs was much lower in Medicaid than in Medicare Part D for each year examined in this paper. In 2015, net per capita spending on brand-name specialty drugs was $170 in Medicaid and $800 in Medicare Part D. The estimate for Medicaid is less precise than the estimate for Medicare Part D for the reasons discussed above. However, the difference between the two estimates is far greater than can be accounted for by limitations in the Medicaid data. The difference in per capita spending on specialty drugs between Medicare Part D and Medicaid is the result of several factors. First, the average net price per prescription for brand-name specialty drugs in 2015 was much lower in Medicaid than in Medicare Part D ($1,220 versus $3,590). That difference largely reflects the higher rebates for such drugs in Medicaid than in Medicare Part D, but it also reflects the lower average retail price per prescription for brand-name specialty drugs in Medicaid than in Medicare Part D ($2,360 versus $4,170). The latter difference reflects differences in the mix of drugs used by the two populations. Moreover, in 2015, Medicaid enrollees had about half as many prescriptions for brand-name specialty drugs per person compared with Medicare Part D enrollees. That difference largely reflects differences in the two populations' health status. In 2015, about 85 percent of Medicaid enrollees were children or nonelderly, nondisabled adults; those enrollees use prescription drugs (and health care services more generally) at a much lower rate than the Medicare population. Medicaid's drug benefit primarily serves those beneficiaries. That is because Medicaid beneficiaries who are over age 65 or disabled are usually eligible for Medicare and receive their drug benefits through Medicare Part D. That latter group of beneficiaries tends to have much higher per capita drug spending.

What Is the Outlook for Future Spending on Specialty Drugs in Medicare Part D and Medicaid?

On the basis of recent growth in the share of new drugs that are specialty drugs, information on drugs being developed, and the expected effects in the near term of competition following patent expirations, CBO expects that the share of net spending in Medicare Part D and Medicaid devoted to specialty drugs will continue to grow in the coming years. The share of net spending in Medicare Part D devoted to specialty drugs increased more sharply in 2014 and 2015 than in earlier years, which was partly attributable to the introduction of drugs that treat hepatitis C (see Figure 1).

In 2015, spending for those hepatitis C drugs in Medicare Part D was $8.8 billion at retail prices, or about a quarter of total Part D spending on specialty drugs. Within Medicaid, spending on such drugs amounted to $3.1 billion at retail prices or 17 percent of total Medicaid spending on specialty drugs. Eventually, the utilization of those hepatitis C drugs could decline following an initial surge in which many patients were cured, which would cause spending for those drugs to grow at a slower pace in the future. However, CBO expects that specialty drugs will continue to account for a growing share of total spending in Medicare Part D and Medicaid because of spending on other specialty drugs on the market and those under development.

In recent years, specialty drugs have accounted for a large share of spending on novel drugs introduced to the market within both Medicare Part D and Medicaid. Only brand-name drugs that are a new molecular entity or biologic product that was never previously approved by the Food and Drug Administration (FDA) are considered "novel drug approvals." By 2015, most spending on the novel brand-name drugs introduced to the market between 2011 and 2015 could be attributed to specialty drugs. Within Medicare Part D and Medicaid, among the sales of those novel brand-name drugs in 2015, the share devoted to specialty drugs was about three-quarters (at retail prices). The dominance of specialty drugs in the sales generated by novel drug approvals began with the cohort of drugs approved in 2012 and continued throughout the period. Information on drugs recently approved and under development also suggests that specialty drugs will account for a growing share of total net spending in Medicare Part D and Medicaid in the coming years. For example, over 80 percent of the drugs approved by the FDA in 2017 could be classified as specialty drugs under most definitions.[73]

Since 2010, the entry of new generic versions of brand-name drugs following loss of patent protection has slowed the growth of spending for nonspecialty drugs much more than spending for specialty drugs. Partly because a larger share of sales of nonspecialty brand-name drugs is for older drugs, which are more likely to lose patent protection, CBO expects that, in the near future, competition following the loss of patent protection will continue to play a larger role in slowing growth in spending for nonspecialty drugs compared with spending for specialty drugs in Medicare Part D. Almost 40 percent of brand-name nonspecialty drug sales in 2010 in Medicare Part D (valued at retail prices) were for drugs that experienced new generic competition following a loss of patent protection by 2015. For specialty brand-name drugs, the figure was much lower—just 13 percent of spending for brand-name specialty drugs in 2010. In the next few years, brand-name drugs that have been on the market for 10 years or more are more likely to face new generic competition. In 2015, 38 percent of brand-name nonspecialty drug sales (valued at retail prices) in Medicare Part D were for drugs that had been on the market for 10 years or more (and were still benefiting from patent protection), whereas that was true for only 27 percent of brand-name specialty drug sales.[74]

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[73] Vizient, *Drug Price Forecast: Executive Summary, January 2018* (2018), https://tinyurl.com/yyxqwyba. Also, in 2017, net sales of brand-name drugs introduced within the past two years amounted to $12 billion, 80 percent of which was for specialty drugs. See IQVIA Institute for Human Data and Science, *Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022* (April 2018), https://tinyurl.com/ydatt7bx.

[74] Including brand-name drugs that have been on the market for 8 years or more (and that faced no generic competitors in 2015) would account for another 17 percent of nonspecialty drug sales and another 10 percent of specialty drug sales in 2015. Some studies have shown that brand-name drugs have an average of 12 years of patent protection on the market. That period of protection could be longer on average for many brand-name specialty drugs that are biologic products or other complex molecules because they can have multiple patents protecting the manufacturing process. Some of the brand-name drugs might also be protected from generic or biosimilar competition by an exclusivity period and not a patent.

Within Medicaid, patent expirations also played a bigger role in lowering spending on nonspecialty drugs, compared with specialty drugs over the 2010–2015 period. Fifty-four percent of brand-name nonspecialty drug sales in 2010 faced generic competition for the first time by 2015. For brand-name specialty drugs, just 10 percent of 2010 sales had a generic competitor for the first time by 2015.

Looking ahead, a similar share of spending on brand-name specialty and nonspecialty drugs in Medicaid are older drugs that could face generic or biosimilar competition for the first time. Thirty-seven percent of Medicaid spending on brand-name specialty drugs in 2015 was for drugs that had been on the market for 10 years or more without facing any generic or biosimilar competition, compared with 34 percent of spending on nonspecialty brand-name drugs (valued at retail prices).

Biologic drugs make up a large share of the sales of brand-name specialty drugs that have been on the market for 10 years or more. Although biologics make up 20 percent of total spending for specialty drugs in Medicare Part D, they constitute 44 percent of spending on brand-name specialty drugs that have been on the market for 10 years or more and are still benefiting from patent protection (valued at retail prices).[75] Within Medicaid, biologics make up 37 percent of overall spending for specialty drugs and 62 percent of spending on brand-name specialty drugs that have been on the market for 10 years and still benefit from patent protection (valued at retail prices). Thus, in the coming years, the success of the pathway established in 2009 to approve biosimilar products (which have the same therapeutic effect as their brand-name counterparts) will be key to helping to hold down specialty drug spending.[76] Although biosimilar products are now available in the United States, those drugs are primarily covered by Medicare Part B.[77] Biosimilar versions of Humira and Enbrel, two top-selling specialty drugs in Medicare Part D and Medicaid, have been approved but are not yet available because patents on those drugs are preventing entry to the market.

Biosimilar competition following the loss of patent protection of a top-selling brand-name biologic product is expected to create more modest savings compared with what has been observed in the markets for most top-selling nonspecialty drugs (which are usually small-

[75] Those figures include spending on drugs approved under a Biologics License Application established by the Public Health Service Act and a very small amount of spending ($160 million) on biologics approved under a New Drug Application that the FDA has indicated will transition to a regulation under the Public Health Service Act in 2020. Insulins are biologic products that are not considered specialty drugs in this paper.

[76] The Biologics Price Competition and Innovation Act of 2009 established an abbreviated pathway for biosimilar products to enter the market when a brand-name biological product is no longer protected by a patent. Under this approval process, manufacturers of the biosimilar product must demonstrate that it is highly similar to the brand-name product but does not need to undertake large clinical trials to prove its efficacy.

[77] Those products include Zarxio (a substitute for Neupogen) and Inflectra (a substitute for Remicade).

molecule drugs).[78] The share of the market that biosimilars will capture is expected to be smaller partly because those drugs are similar to but not interchangeable with their brand-name counterparts.[79] Also, because of higher production and development costs, there are likely to be fewer biosimilar manufacturers entering the market for a top-selling brand-name drug compared with a small-molecule brand-name drug market of similar size in sales. Because prices fall as the number of competitors increases, that also contributes to higher average prices of biosimilar products relative to the brand-name product and to smaller savings.[80] In addition, generic versions of top-selling specialty drugs that consist of other types of complex molecules may also offer more modest savings when the number of generic manufacturers that enter such markets is small. The number of generic entrants may be limited in such cases because the cost of demonstrating bioequivalence and obtaining FDA approval can be more costly for complex generic drugs. Nonetheless, competition following patent expiration for such drugs has the potential to bring significant savings to the Medicare Part D and Medicaid programs as well as to other purchasers.[81]

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[78] See for example Henry G. Grabowski, Rahul Guha, and Maria Salgado, "Regulatory and Cost Barriers Are Likely to Limit Biosimilar Development and Expected Savings in the Near Future," *Health Affairs*, vol. 33, no. 6 (June 2014), www.healthaffairs.org/doi/full/10.1377/hlthaff.2013.0862; and Fiona Scott Morton and Lysle Boller, *Enabling Competition in Pharmaceutical Markets*, Hutchins Center Working Paper 30 (Brookings, May 2017), http://tinyurl.com/yxhc5ebm.

[79] In the future, manufacturers of biosimilars may be able to demonstrate that those drugs are interchangeable with the original brand-name products, in which case the drugs' market share would probably be much greater. However to date, no biosimilar product has obtained that type of approval from the FDA.

[80] By contrast, a top-selling brand-name nonspecialty drug usually has many generic competitors within the first year of losing patent protection. When top-selling brand-name nonspecialty drugs lose patent protection, the generic manufacturers generally quickly gain over 90 percent of the market; as a result, those drugs are usually sold at a small fraction of the brand-name price after multiple generic manufacturers have entered the market.

[81] Manufacturers of biosimilar products are now required to pay the brand manufacturer discount of 70 percent in the coverage gap for purchases by beneficiaries who do not receive low-income subsidies. That change is likely to help biosimilar products to be less expensive alternatives for both the Part D plan and the beneficiary. However, manufacturers of high-priced generic versions of specialty drugs are not required to pay this rebate, which actually can cause the generic version to be more costly to the beneficiary (who does not receive a low-income subsidy) and to the Part D plan as well, in some cases. Within Medicaid, manufacturers of biosimilar products pay the same types of statutory rebates as their brand-name counterparts, but makers of complex generic drugs do not.

Appendix

How Excluding Physician-Administered Drugs From the Analysis Affects the Results

Physician-administered drugs are usually covered under the medical benefits of Medicaid and Medicare. However, in some instances, physician-administered drugs can be covered under a prescription drug benefit. The Centers for Medicare & Medicaid Services specifies the types of drugs covered under Medicare Part D and Medicare Part B, which helps keep most spending for physician-administered drugs out of the Part D benefit. [82] However, state Medicaid agencies have wide latitude in many cases in determining whether drugs are paid for under the prescription drug benefit or the medical benefit. In 2015, just over 20 percent of specialty drug spending in Medicaid's prescription drug benefit was for physician-administered drugs, whereas such drugs accounted for less than 5 percent of specialty drug spending under Medicare Part D.

It is unclear why some state Medicaid agencies choose to cover physician-administered drugs under the program's prescription drug benefit. Medicaid's statutory rebates apply to drugs covered under both the medical benefit and the prescription drug benefit. However, some states may find it easier to track spending on particular drugs and perhaps negotiate for supplemental rebates when the spending on such drugs is tracked through the prescription drug benefit. Another possibility is that a specialty pharmacy could deliver the drug to the physician and then submit a claim to Medicaid's prescription drug benefit. Since payment policies vary by state, it is difficult to determine the primary reasons why physician-administered drugs accounted for just over 20 percent of specialty drug spending in Medicaid's prescription drug benefit in 2015.

The Congressional Budget Office conducted a sensitivity analysis to investigate how the results of this paper are affected if physician-administered drugs are excluded from the analysis. Overall, in CBO's estimation, the main findings of this paper still hold—namely, the average rebate for specialty drugs is much higher in Medicaid than in Medicare Part D, the average price of a prescription for brand-name specialty drugs grew much faster in Medicare Part D than in Medicaid over the 2010–2015 period, and net spending on specialty drugs also grew much faster in Medicare Part D than in Medicaid during that period.

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[82] For a description of the drugs covered under Medicare Part D and Medicare Part B, see https://www.cms.gov/outreach-and-education/outreach/partnerships/downloads/11315-p.pdf (268 KB).

CBO's Method for Identifying Physician-Administered Drugs

Identifying physician-administered drugs that are paid for under a prescription drug benefit is challenging. In some cases, a specialty drug can be either administered by a health professional or self-administered at home. After speaking with a few physicians and other experts, CBO developed the following method to identify drugs primarily administered by a physician or health professional:

- If the drug is administered orally, it is considered to be a self-administered drug;
- If the drug is administered intravenously, infused, or if it is an intramuscular injection, it is regarded as a physician-administered drug; and
- If a drug is injected subcutaneously, it is considered self-administered if the patient can be trained to inject the drug at home.[83] Otherwise, it is considered to be a physician-administered drug.

Examples of drugs that cannot be easily categorized include those that treat hemophilia (which are usually infused or taken intravenously). Patients frequently go to clinics for the administration of such drugs. However, many people also learn to take those drugs at home. Hemophilia drugs account for about 7 percent of Medicaid specialty drug spending at retail prices in 2015. Since drugs that treat hemophilia are given intravenously or infused, they are considered to be a physician-administered drug in this sensitivity analysis.

In order to exclude physician-administered drugs from the analysis of specialty drug pricing and spending, CBO took the following steps:

- First, all drugs administered intravenously or as an intramuscular injection were excluded from the analysis using the "route of administration" data field available at the National Drug Code level in the Red Book data.[84]
- Second, CBO checked the 100 top-selling brand-name specialty drugs in Medicare Part D and Medicaid in 2010 and 2015, which accounted for over 85 percent of specialty drug spending in those years in both programs. Among those drugs that required subcutaneous

[83] To determine whether patients could choose to be trained to take a drug at home, CBO referred to the Mayo Clinic website (www.mayoclinic.org/).

[84] In 2015, such drugs accounted for 80 percent of the sales of all physician-administered specialty drugs that were excluded from the analysis (valued at retail prices). The Food and Drug Administration assigns National Drug Code (NDC) codes to drugs that can be used to identify the manufacturer, product name, dosage form, strength, and package size. Red Book provides pricing data as well as certain characteristics of the drug by NDC code including its route of administration.

injection, CBO removed them from the analysis if the patient could not be trained to take them at home. In addition, CBO reviewed the top 50 Medicare Part B drugs based on total spending, and also the top 50 based on spending per beneficiary.[85]

How Excluding Physician-Administered Drugs Affects Key Results

The average net price of a prescription for a brand-name specialty drug was not affected very much in either Medicaid or Medicare Part D by limiting the analysis to self-administered drugs (see Table A-1). Furthermore, the rate of growth in the average net price of a brand-name prescription was still much higher in Medicare Part D than in Medicaid when the analysis was restricted to self-administered specialty drugs (25 percent compared with 13 percent). Finally, the rebates and discounts as a share of drug spending did not change much in either Medicaid or Medicare Part D when the analysis was limited to self-administered drugs (see Table A-2).

Overall, after excluding physician-administered drugs from specialty drug spending in both Medicare Part D and Medicaid, specialty drug spending still grew much faster in the Medicare Part D program over the 2010–2015 period. Spending on self-administered specialty drugs in Medicaid more than doubled, growing from $3.5 billion in 2010 to $7.7 billion in 2015 (see Table A-3). The rate of growth in spending on self-administered specialty drugs in Medicaid over the period was only slightly faster than the rate of growth in spending on all specialty drugs (17 percent compared with 16 percent). Within Medicare Part D, only a small fraction of net specialty drug spending was for physician-administered drugs—less than 5 percent in both 2010 and 2015. Therefore, it is not surprising that the rate of growth of spending on specialty drugs in Medicare Part D was not affected much when limited to self-administered drugs: Over the 2010-2015 period, such spending still grew at an average annual rate of 31 percent (Table A-3).

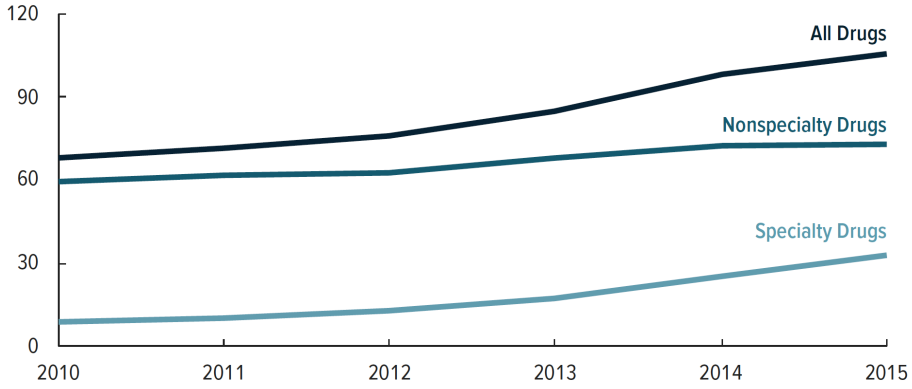
Within Medicaid, after excluding physician-administered drugs from the analysis, specialty drug spending as a share of total prescription drug spending fell from 25 percent to 19 percent in 2010 (see Table A-4). That share is close to that in Medicare Part D in 2010, which was 12 percent for self-administered specialty drugs (and 13 percent for all specialty drugs). Over the 2010–2015 period, the share of self-administered specialty drug spending in total prescription drug spending grew by 10 percentage points in Medicaid to 29 percent. Within Medicare Part D that share grew by 18 percentage points to 30 percent for self-administered specialty drugs. The share of self-administered specialty drug spending in total drug spending grew faster in Medicare Part D than in Medicaid, which is consistent with the finding that even when the analysis is limited to self-

[85] A list of those drugs was obtained from the following report: Government Accountability Office, *Medicare Part B: Medicare Represented at Least Half of the Market for 22 of the 84 Most Expensive Drugs in 2015* (December 2017), https://www.gao.gov/products/GAO-18-83. Through this latter process of proofing the top-selling brand-name specialty drugs in Medicare Part D, Medicaid, and Medicare Part B, 13 products that are injected subcutaneously were identified as physician-administered specialty drugs. Examples include Epogen and Xolair.

administered specialty drugs, specialty drug spending grew much faster in Medicare Part D than in Medicaid over the 2010–2015 period.

Figures

Figure 1.
Net Drug Spending in Medicare Part D
Billions of Dollars

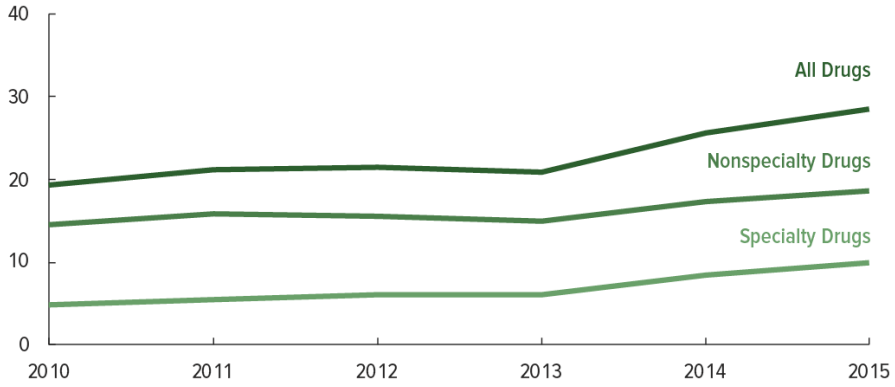


In Medicare Part D, net spending on specialty drugs rose from $8.7 billion in 2010 to $32.8 billion in 2015, an average annual increase of 31 percent. That increase accounted for much of the growth in Part D spending.

Source: Congressional Budget Office.

Estimates have not been adjusted to remove the effects of general inflation.

Figure 2.
Net Drug Spending in Medicaid
Billions of Dollars



In Medicaid, net spending on specialty drugs rose from $4.8 billion in 2010 to $9.9 billion in 2015, an average annual increase of 16 percent.

Source: Congressional Budget Office.

Estimates have not been adjusted to remove the effects of general inflation.

Tables

Table 1.
Calculating Net Plan Costs in the Catastrophic Phase of the Medicare Part D Benefit at Different Drug Rebate Levels

	Base Case: Manufacturer Rebates Are 12 Percent (Dollars)	Alternative Scenario: Manufacturer Rebates Increase to 30 Percent (Dollars)
Retail price per prescription	1,000	1,000
Rebates negotiated with manufacturer	120	300
Net cost of drug	880	700
Beneficiary out-of-pocket costs (5 percent of retail price)	50	50
Reinsurance (before accounting for rebates)	800	800
Amount deducted from reinsurance payment to account for rebates (based on average rebates collected by the plan across all drugs)[a]	144	144
Total reinsurance payment to the plan for the prescription	656	656
Net plan cost		
Base case equal to $880 - $656 - $50	174	
Alternative scenario equal to ($700 - $656 - $50)		(6)

Source: Congressional Budget Office.

This illustrative example reflects the assumption that the prescription is adjudicated entirely in the catastrophic phase of the benefit.

In this table, "rebates" are all forms of price concessions referred to by the Centers for Medicare & Medicaid Services as direct and indirect remuneration received by the plan sponsor from both drug manufacturers and pharmacies.

a. Assumes that the plans' average rebate collected across all drug spending was 18 percent (18% of $800 = $144).

Table 2.
Average Retail Prices and Spending for the 10 Top-Selling Specialty Drugs in Medicare Part D, 2015

Drug Name	Average Retail Price per Prescription (Dollars)	Annual Part D Spending per User of Each Drug (Dollars)	Medicare Part D Spending (Millions of dollars)	Condition(s) Treated
Harvoni	31,050	92,850	7,030	Hepatitis C
Revlimid	10,130	68,220	2,080	Anemia, Multiple Myeloma, Lymphoma
Humira	3,700	29,280	1,660	Rheumatoid Arthritis, Crohn's Disease, Plaque Psoriasis
Enbrel	3,330	27,120	1,380	Rheumatoid Arthritis, Plaque Psoriasis
Copaxone	5,380	54,050	1,380	Multiple Sclerosis
Sovaldi	27,890	89,300	1,320	Hepatitis C
Gleevec	9,070	81,150	1,230	Leukemia and Other Types of Cancer
Tecfidera	5,580	46,580	850	Multiple Sclerosis
Xtandi	8,630	46,750	790	Prostate Cancer
Zytiga	7,720	46,570	790	Prostate Cancer
Total			18,500	
All Brand-Name Specialty Drugs	4,170	n.a.	36,700	
All Brand-Name Nonspecialty Drugs	260	n.a.	65,600	

Source: Congressional Budget Office, using data from the Centers for Medicare & Medicaid Services, IBM Micromedex (formerly Truven Health Analytics), and IQVIA (formerly IMS Health).

In its analysis, CBO combined Medicare Part D claims data from 2015 for all enrollees (obtained from the Centers for Medicare & Medicaid Services) with Red Book data on drug characteristics (obtained from IBM Micromedex) and a list of specialty drugs on the market in 2015 (obtained from IQVIA).

The table presents average prices per standardized prescription. When a medication is prescribed for a number of days that equals 30 or less, the number of standardized prescriptions is equal to one. In cases in which the number of days supplied by a prescription exceeds 30, then the number of standardized prescriptions is equal to the number of days a medication is supplied divided by 30. For example, a 90-day supply of medication would be equal to three standardized prescriptions.

All spending is reported at retail prices.

n.a. = not applicable.

Table 3.
Average Retail Prices and Spending for the 10 Top-Selling Specialty Drugs in Medicaid, 2015

Drug Name	Average Retail Price per Prescription (Dollars)	Medicaid Spending (Millions of dollars)	Condition(s) Treated
Harvoni	27,350	2,200	Hepatitis C
Humira	3,640	810	Rheumatoid Arthritis, Crohn's Disease Plaque Psoriasis
Truvada	1,390	740	HIV
Sovaldi	22,560	620	Hepatitis C
Atripla	2,270	610	HIV
Stribild	2,570	460	HIV
Enbrel	3,170	450	Rheumatoid Arthritis, Plaque Psoriasis
Advate	20,630	350	Hemophilia
Prezista	1,260	340	HIV
Complera	2,240	320	HIV
Total		6,800	
All Brand-Name Specialty Drugs	2,360	17,700	
All Brand-Name Nonspecialty Drugs	280	25,200	

Source: Congressional Budget Office, using data from the Centers for Medicare & Medicaid Services, IBM Micromedex (formerly Truven Health Analytics), and IQVIA (formerly IMS Health).

In its analysis, CBO combined Medicaid prescription drug data from 2015 for all enrollees (obtained from the Centers for Medicare & Medicaid Services) with Red Book data on drug characteristics (obtained from IBM Micromedex) and a list of specialty drugs on the market in 2015 (obtained from IQVIA).

All spending is reported at retail prices.

Table 4.
Weighted Average Prescription Prices in Medicare Part D and Medicaid for 50 Top-Selling Brand-Name Specialty Drugs and Nonspecialty Drugs, 2015

Federal Program	Average Retail Pharmacy Price[a] (Dollars per prescription)	Average Price Net of Rebates and Discounts (Dollars per prescription)	Average Rebates as a Share of the Retail Price (Percent)	Price Ratios: Medicaid Retail Price to Medicare Part D Retail Price (Percent)	Price Ratios: Medicaid Net Price to Medicare Part D Net Price (Percent)
			Specialty Drugs		
Medicare Part D (Excluding 50 Percent Discount in Coverage Gap)[b]	4,380	3,800	13	99	51
Medicare Part D (Including 50 Percent Discount in Coverage Gap)[b]	4,380	3,600	18	99	53
Medicaid[c]	4,330	1,920	56	n.a.	n.a.
			Nonspecialty Drugs		
Medicare Part D (Excluding 50 Percent Discount in Coverage Gap)[b]	300	200	35	102	27
Medicare Part D (Including 50 Percent Discount in Coverage Gap)[b]	300	150	50	102	36
Medicaid[c]	310	55	83	n.a.	n.a.

Source: Congressional Budget Office, using data from the Centers for Medicare & Medicaid Services, IBM Micromedex (formerly Truven Health Analytics), and IQVIA (formerly IMS Health).

In its analysis, CBO combined data from the following sources: Medicare Part D claims data from 2015 for all enrollees, as well as data on Part D rebates, and data on Medicaid prescription drug spending, pricing, and rebates from 2015 (obtained from the Centers for Medicare & Medicaid Services); Red Book data on drug characteristics (obtained from IBM Micromedex); and a list of specialty drugs on the market in 2015 (obtained from IQVIA). The 50 drugs were selected using data on retail sales in the Medicare Part D program.

n.a. = not applicable.

a. These average prices reflect what Medicare Part D actually paid in 2015 and what it would have paid, on average, had the Medicaid pricing structure been applied to Part D purchases. For the 50 drugs considered in the analysis, the number of prescriptions purchased under the Medicare Part D program was used to estimate the weighted average price within both Medicare Part D and Medicaid. Each drug's contribution to the weighted average price was proportional to the total number of prescriptions dispensed for the drug under Medicare Part D. The prices are for a standardized prescription, which roughly corresponds to a 30-day supply of medication

b. The price paid by Medicare Part D, net of rebates, reflects the 50 percent discount paid by manufacturers on spending between the initial coverage limit and the catastrophic threshold for beneficiaries who did not receive cost-sharing subsidies based on their income. (In 2015, beneficiaries entered the catastrophic phase of the Part D benefit after incurring out-of-pocket costs of $4,700.)

c. The Medicaid net prices do not account for supplemental rebates negotiated by the states or any rebates negotiated by Medicaid managed care organizations beyond the statutory rebates.

Table 5.
Change in the Average Net Price of Brand-Name Specialty Drugs and Nonspecialty Drugs in Medicare Part D and Medicaid, 2010 and 2015

In 2015 Dollars

Federal Program	Average Net Price per Prescription in 2010[a] (Dollars per prescription)	Average Net Price per Prescription in 2015 (Dollars per prescription)	Average Annual Percentage Change From 2010 to 2015 (Percent)
Medicare Part D			
Brand-Name Specialty Drugs			
All Drugs	1,310	3,590	22.3
Older Drugs (On the market by 2010)	1,310	2,570	14.4
New Drugs (Introduced after 2010)[b]	n.a.	8,680	n.a.
Brand-Name Nonspecialty Drugs			
All Drugs	130	165	4.5
Older Drugs (On the market by 2010)	130	160	4.0
New Drugs (Introduced after 2010)[b]	n.a.	210	
Medicaid			
Brand-Name Specialty Drugs			
All Drugs	700	1,220	11.7
Older Drugs (On the market by 2010)	700	900	5.1
New Drugs (Introduced after 2010)[b]	n.a.	4,660	n.a.
Brand Name Nonspecialty Drugs			
All Drugs	80	70	-2.8
Older Drugs (On the market by 2010)	80	70	-3.9
New Drugs (Introduced after 2010)[b]	n.a.	190	

Source: Congressional Budget Office.

In its analysis, CBO combined data from the following sources: Medicare Part D claims data from 2015 for all enrollees, as well as data on Part D rebates, and data on Medicaid prescription drug spending pricing, and rebates from 2015 (obtained from the Centers for Medicare & Medicaid Services); Red Book data on drug characteristics (obtained from IBM Micromedex); and a list of specialty drugs on the market in 2015 (obtained from IQVIA).

In CBO's analysis, Medicare Part D prescriptions were standardized to a 30-day supply in cases in which the prescription exceeded 30 days. However, that adjustment was not possible to make for Medicaid. Average net prices are equal to total payments to pharmacies, less rebates and discounts, divided by the number of prescriptions dispensed within each program. The net prices in Medicaid do not account for any supplemental rebates negotiated by states or any rebates negotiated by Medicaid managed care organizations beyond the statutory rebates.

n.a. = not applicable.

a. Prices for 2010 were converted to 2015 dollars using the price index for personal consumption expenditures.

b. The category “New Drugs (Introduced After 2010)” is limited to new molecular entities and biologic products that appear on the Food and Drug Administration’s list of approved “Novel Drug Products” over the 2011–2015 period.

Table 6.
Discounts and Rebates on Brand-Name Drugs in Medicare Part D and Medicaid, 2010 and 2015

	All Brand-Name Drugs		Brand-Name Specialty Drugs		Brand-Name Nonspecialty Drugs	
Type of Discount or Rebate	**2010**	**2015**	**2010**	**2015**	**2010**	**2015**
	Rebates and Discounts as a Share of Retail Prices (Percent)					
Medicare Part D						
Manufacturer rebates to plans[a]	15.2	22.0	2.6	10.5	17.4	28.4
50 percent discount to beneficiaries[b]	0	5.3	0	2.2	0	7.1
Other discounts[c]	n.a.	1.6	0	1.3	0	1.8
Total Rebates and Discounts	15.2	28.9	2.6	14.0	17.4	37.3
	Statutory Rebates as a Share of the Average Manufacturer Price (Percent)[d]					
Medicaid						
Basic rebate	29.2	35.4	23.5	28.2	31.4	40.6
Inflation rebate	27.1	37.3	18.6	22.3	30.5	48.2
Total rebate[e]	56.3	66.9	42.1	50.0	61.9	79.1

Source: Congressional Budget Office.

In its analysis, CBO combined data from the following sources: Medicare Part D claims data from 2015 for all enrollees, as well as data on Part D rebates, and data on Medicaid prescription drug spending pricing, and rebates from 2015 (obtained from the Centers for Medicare & Medicaid Services); Red Book data on drug characteristics (obtained from IBM Micromedex); and a list of specialty drugs on the market in 2015 (obtained from IQVIA).

n.a. = not available.

a. Reflects rebates paid by brand-name drug manufacturers to Medicare Part D plan sponsors.

b. Reflects discounts provided to Medicare Part D beneficiaries who did not receive cost-sharing subsidies based on income. Those discounts are provided after the beneficiary reaches the initial coverage limit and before reaching the catastrophic threshold. (In 2015, beneficiaries entered the catastrophic phase of the Part D benefit after incurring out-of-pocket costs of $4,700.)

c. Includes certain discounts provided by the pharmacy to the Medicare Part D plan sponsor. Those discounts have expanded since 2010 with the use of preferred pharmacy networks. For 2010, CBO was only able to acquire data on

manufacturer rebates, which accounted for over 99 percent of all discounts and rebates obtained by Medicare Part D plan sponsors.

d. The estimated rebates are weighted by sales. The average manufacturer price, or AMP, is the average price received by manufacturers on sales to pharmacies before accounting for any rebates paid subsequently to insurers or pharmacy benefit managers. For brand-name drugs, the AMP is about 95 percent of the retail price. These are sales-weighted average rebates.

e. The total rebate can be less than the sum of the basic and inflation rebate because those two rebates combined cannot exceed the AMP for a given drug.

Table 7.
Net per Capita Spending in Medicare Part D by Drug Type, 2010 and 2015

In 2015 Dollars

Drug Type	2010[a] (Dollars per beneficiary)	2015 (Dollars per beneficiary)	Average Annual Growth (Percent)
All Drugs	2,620	2,660	0.3
Specialty Drugs			
Total	330	830	20.1
Brand-name	310	800	20.5
Generic	20	30	11.7
Nonspecialty Drugs			
Total	2,290	1,830	-4.3
Brand-name	1,550	1,040	-7.7
Generic	730	790	1.6
Memorandum:			
Percentage of Medicare Part D Enrollees Who Used a Specialty Drug			
Any specialty drug	8.1	7.7	
Brand-name specialty drug	2.8	2.4	
Generic specialty drug	6.1	6.0	

Source: Congressional Budget Office, using data from the Centers for Medicare & Medicaid Services, IBM Micromedex (formerly Truven Health Analytics), and IQVIA (formerly IMS Health).

In its analysis, CBO combined data from the following sources: Medicare Part D claims data from 2010 and 2015 for all enrollees, as well as data on rebates (obtained from the Centers for Medicare & Medicaid Services); Red Book data on drug characteristics (obtained from IBM Micromedex); and a list of specialty drugs on the market in 2015 (obtained from IQVIA).

a. Prices for 2010 were converted to 2015 dollars using the price index for personal consumption expenditures.

Table 8.
Annual Spending on Brand-Name Specialty Drugs Among Medicare Part D Enrollees Who Used Such Drugs, 2010 and 2015

In 2015 Dollars

	Enrollees With No Cost-Sharing Subsidies	Enrollees in Employer-Based Plans	Low-Income Subsidy Enrollees	All Enrollees
		Dollars		
Average Net Spending on Brand-Name Specialty Drugs Among Users of Such Drugs				
2010[a]	8,970	9,140	13,340	11,330
2015	36,730	30,700	32,300	33,460
Average Out-of-Pocket Costs				
2010[a]	1,750	560	60	730
2015	3,540	570	60	1,250
		Percent		
Out-of-Pocket Costs as a Share of Total Net Spending on Brand-Name Specialty Drugs				
2010[a]	19.5	6.1	0.4	6.5
2015	9.6	1.8	0.2	3.7
Share of Total Net Spending on Brand-Name Specialty Drugs in the Catastrophic Region[b]				
2010	66.5	12.6	70.9	65.4
2015	91.3	47.2	87.7	83.5
Share of Enrollees Who Used a Brand-Name Specialty Drug				
2010	1.9	2.8	4.0	2.8
2015	1.4	2.3	4.1	2.4

Source: Congressional Budget Office, using data from the Centers for Medicare & Medicaid Services, IBM Micromedex (formerly Truven Health Analytics), and IQVIA (formerly IMS Health).

In its analysis, CBO combined data from the following sources: Medicare Part D claims data from 2010 and 2015 for all enrollees, as well as data on rebates (obtained from the Centers for Medicare & Medicaid Services); Red Book data on drug characteristics (obtained from IBM Micromedex); and a list of specialty drugs on the market in 2015 (obtained from IQVIA).

a. Prices for 2010 were converted to 2015 dollars using the price index for personal consumption expenditures.

b. The catastrophic phase of the benefit begins after a beneficiary's out-of-pocket costs exceed a certain threshold. In 2015, that threshold was $4,700.

Table A-1.
Average Net Price of a Brand-Name Specialty Drug Prescription

In 2015 Dollars

	2010 (Dollars)[a]	2015 (Dollars)	Average Annual Growth (Percent)
Medicaid			
All specialty brands	700	1,220	12
Self-administered specialty brands	710	1,290	13
Medicare Part D			
All specialty brands	1,310	3,590	22
Self-administered specialty brands	1,270	3,830	25

Source: Congressional Budget Office.

a. Prices for 2010 were converted to 2015 dollars using the price index for personal consumption expenditures.

Table A-2.
Average Rebates and Discounts on Brand-Name Specialty Drugs in Medicare Part D and Medicaid

	Statutory Rebates as a Share of the Average Manufacturer Price (Percent)	
Medicaid		
All brand-name specialty drugs	0.42	0.50
Self-administered brand-name specialty drugs	0.46	0.53
	Rebates and Discounts as a Share of Retail Sales (Percent)	
Medicare Part D		
All brand-name specialty drugs	0.026	0.14
Self-administered brand-name specialty drugs	0.026	0.14

Source: Congressional Budget Office.

Table A-3.
Net Spending on Specialty Drugs in Medicare Part D and Medicaid

	2010 (Billions of dollars)	2015 (Billions of dollars)	Average Annual Growth (Percent)
Medicaid			
All specialty drugs	4.8	9.9	16
Self-administered specialty drugs	3.5	7.7	17
Physician-administered specialty drugs	1.4	2.3	10
Medicare Part D			
All specialty drugs	8.7	32.8	31
Self-administered specialty drugs	8.2	31.6	31
Physician-administered specialty drugs	0.4	1.2	23

Source: Congressional Budget Office.

Table A-4.
Share of Specialty Drug Spending in Total Drug Spending

Percent

	2010	2015
Medicaid		
All specialty drugs	25	35
Self-administered specialty drugs[a]	19	29
Medicare Part D		
All specialty drugs	13	31
Self-administered specialty drugs[a]	12	30

Source: Congressional Budget Office.

a. In calculating this share, physician-administered specialty drugs were excluded from both specialty drug spending and total drug spending in the prescription drug benefit.