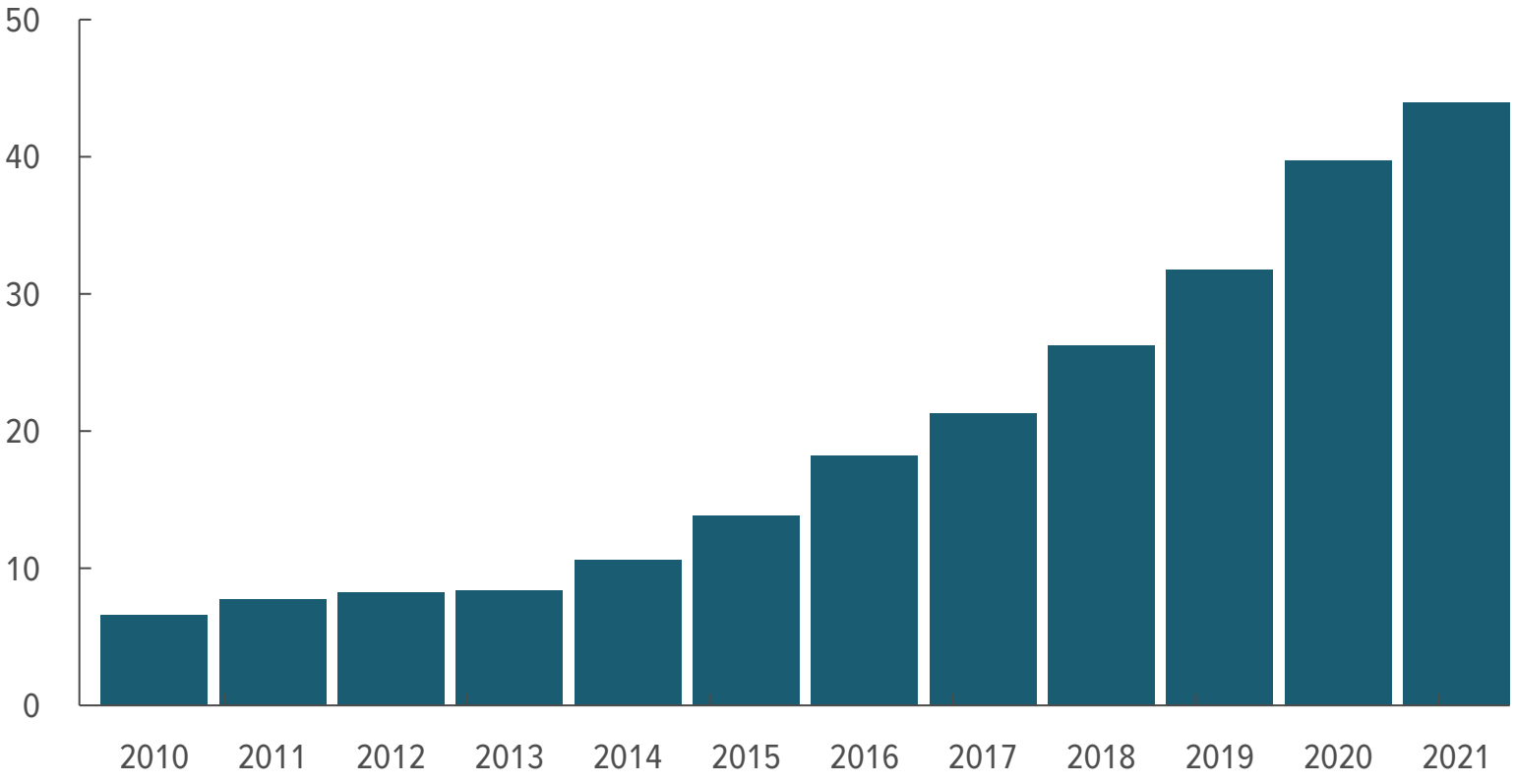
Congressional Budget Office
Nonpartisan Analysis for the U.S. Congress

Growth in the 340B Drug Pricing Program

Spending on Drugs Purchased Through the 340B Program, 2010 to 2021
Billions of dollars



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At a Glance

The 340B Drug Pricing Program requires pharmaceutical manufacturers to sell outpatient prescription drugs to participating health care facilities at discounted prices. Facilities that participate in the 340B program are hospitals, clinics, and other providers of health care services as well as other organizations that purchase drugs, such as those affiliated with state and local governments. In this report, the Congressional Budget Office examines trends in drug purchases through the 340B program (known as 340B drugs) over the 2010–2021 period.

- **Drugs Purchased Through the Prime Vendor Program.** About 90 percent of health care facilities that participate in the 340B program also participate in the Prime Vendor Program (PVP). Through that program, the Health Resources and Services Administration contracts with an external organization, known as the prime vendor, to support 340B operations. Health care facilities participating in the PVP spent $43.9 billion on 340B drugs in 2021, up from $6.6 billion in 2010. Most spending on drugs purchased through the PVP in 2021—87 percent—was on drugs that were administered or distributed in outpatient departments of hospitals and their off-site outpatient clinics. Spending on cancer drugs was 41 percent of purchases through the program, almost three times the amount spent on any other drug class.
- **Factors Contributing to Growth in the 340B Program.** CBO estimates that one-third of the increase in spending in the program from 2010 to 2021 can be attributed to trends in marketwide growth in drug spending and disproportionate growth among drug classes that account for more spending in the 340B program than in the overall market. CBO examined three additional factors that contributed to growth in spending under the 340B program: the integration of hospitals and off-site clinics, increased facility participation after the implementation of the Affordable Care Act, and expanded use of off-site pharmacies. CBO does not have sufficient data to quantify those factors' effects, but in the agency's assessment, the largest of those three factors was the integration of hospitals and clinics.
- **Effects of the 340B Program on the Federal Budget.** In CBO's assessment, the 340B program encourages behaviors—including the prescription of more and higher-priced drugs, the expansion of services, and the integration of hospitals and off-site clinics—that tend to increase federal spending. In many cases, the evidence about the behaviors is limited, and the magnitude of each is unknown. CBO has not estimated how legislation affecting those behaviors would alter federal spending.

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Notes About This Report

In this report, 340B spending is the total dollar value of drugs acquired at the discounted 340B price at all facilities participating in the 340B Prime Vendor Program; 340B facilities are hospitals, clinics, and other providers of health care services as well as other organizations that purchase drugs, such as those affiliated with state and local governments. The Health Resources and Services Administration contracts with an external company, known as the prime vendor, to set up drug distribution networks, negotiate discounts in addition to those provided by the drug manufacturer on behalf of health care facilities that participate in the 340B program, and provide those organizations with education and technical support. Apexus has served as the prime vendor since 2004. The data reflect transactions by the prime vendor at a given point in time and do not include all 340B program sales, because the prime vendor does not have data from 340B facilities that do not participate in the Prime Vendor Program. Approximately 10 percent of 340B facilities do not participate in the Prime Vendor Program.

Marketwide spending refers to the dollar amount (net of discounts and rebates) that public and private (commercial) payers and patients paid for prescription drugs. Only brand-name drugs sold by publicly traded companies are included in marketwide spending calculations. Unless otherwise stated, in this report, CBO adjusted raw spending on drug purchases and marketwide spending to 2021 dollars using the gross domestic product price index to remove the effects of general inflation. For more details about the terminology used in this report, see Appendix A. For details about CBO's methods, see Appendix B.

Unless this report indicates otherwise, all years referred to are calendar years.

Numbers in the text and figures may not add up to totals because of rounding.

Growth in the 340B Drug Pricing Program

Summary

The 340B Drug Pricing Program requires pharmaceutical manufacturers to sell prescription drugs at discounted prices to health care facilities that meet statutorily defined eligibility criteria. In this report, 340B facilities are hospitals, clinics, and other providers of health care services as well as other organizations that purchase drugs, such as those affiliated with state and local governments. About 50,000 such facilities participated in the 340B program in 2021.[1] The Health Resources and Services Administration (HRSA) administers the program and contracts with a prime vendor through the Prime Vendor Program (PVP) to negotiate discounts and provide participants with education and technical support. Most facilities that participate in the 340B program—about 90 percent—also participate in the PVP.

In 2021, health care facilities that participated in the PVP spent $43.9 billion on drugs purchased through the 340B program, up from $6.6 billion in 2010 (adjusted to 2021 dollars). Annual purchases represent the total dollar value of drugs acquired at discounted 340B prices and do not reflect spending by insurers to reimburse participating facilities. For explanations of the terminology used in this report, see Appendix A; for details about the data and the Congressional Budget Office's methods, see Appendix B.

In this report, CBO examines drug purchases made through the PVP in 2021, growth in such purchases from 2010 to 2021, and factors that contributed to that growth. CBO also assesses how the 340B program affects the federal budget.

What Is the 340B Drug Pricing Program?

The 340B program requires drug manufacturers to sell outpatient drugs at discounted prices to participating health care facilities. The maximum price that manufacturers may charge those facilities, referred to as the 340B ceiling price, is set by statute, but the prime vendor may negotiate further discounts with drug manufacturers.

Participating facilities fall into one of two categories: hospital-based facilities and federal grantees. Most hospital-based facilities (that is, hospitals and their off-site outpatient clinics) are eligible to participate on the basis of the share of their patients who have low income as measured by their disproportionate patient percentage. That percentage is based on two factors: the share of the hospital's Medicare patients who are also eligible for Supplemental Security Income and the share of patients eligible for Medicaid. To qualify, most hospitals must have a disproportionate patient percentage of more than 11.75 percent. Some hospitals qualify by meeting other criteria, such as serving a primarily rural population. Nearly half of the community hospitals in the United States participated in the 340B program in 2021. The category of participating facilities referred to as federal grantees consists mostly of clinics designated as eligible in section 340B of the Public Health Service Act because they receive federal funding, including certain grants through HRSA.

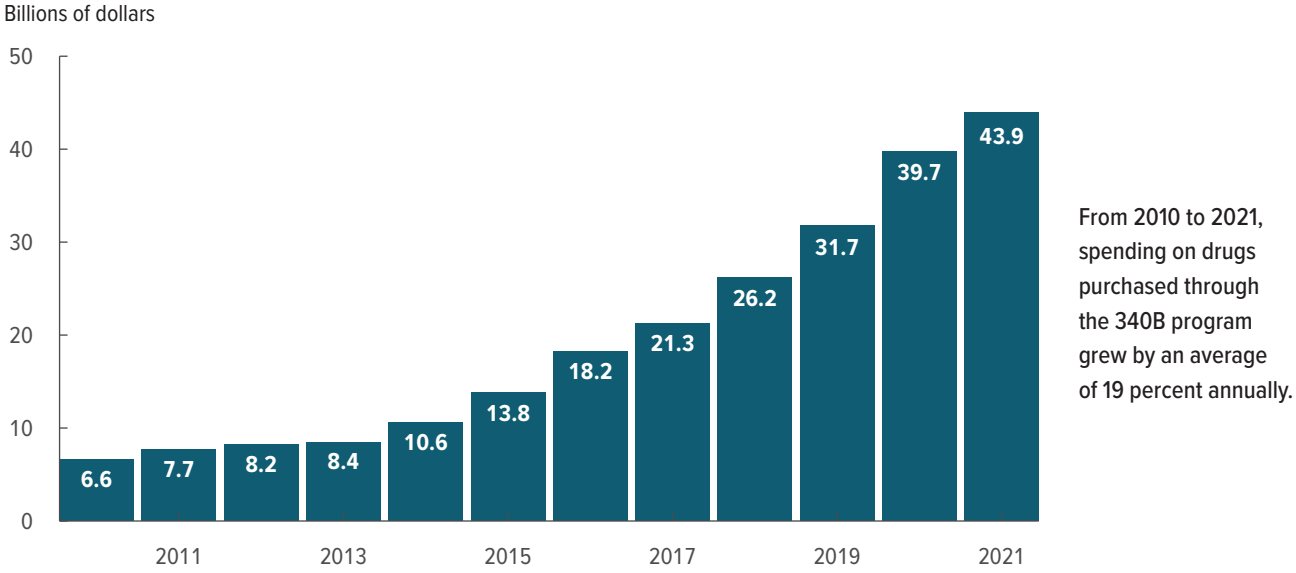
In 2021, 61 percent of participating facilities were hospital-based; drugs purchased by those facilities and their affiliated pharmacies accounted for 87 percent of purchases through the PVP. That year, 39 percent of participating organizations were federal grantees. Their purchases accounted for 13 percent of purchases made through the PVP.

Participating facilities pay discounted rates for drugs for all patients who receive a clinical service from a health professional at that facility, regardless of the patient's income or insurance status. The 340B program generates net revenues for organizations that serve low-income or otherwise vulnerable populations among their overall mix of patients. That is because the discounted price for purchasing drugs through the 340B program is lower than the price the organizations would pay without the program,

1. The number of 340B facilities in CBO's total may differ from HRSA's total because CBO counts hospitals and their affiliated clinics as well as federal grantees and their service delivery sites as separate facilities if both participate in the program. In contrast, HRSA and others may only count the parent hospitals and grantee sites.

Figure 1.

Spending on Drugs Purchased Through the 340B Program, 2010 to 2021



Data source: Congressional Budget Office, using data from the Health Resources and Services Administration. See www.cbo.gov/publication/60661#data.

Amounts are adjusted for inflation using the gross domestic product price index and are expressed in 2021 dollars.

Spending refers to the dollar amount that participating facilities spent on discounted drugs purchased through the 340B program, as reported by the Prime Vendor Program. Approximately 10 percent of 340B facilities do not participate in the Prime Vendor Program.

Average annual growth in spending reflects the compound annual growth rate.

and payments from insurers are typically higher than the discounted price that participating organizations pay.[2]

Those revenues enable participating facilities to expand services. However, the program statute does not set requirements for how participating facilities use 340B net revenues (for example, by limiting their use to services for patients with low income), nor does the statute require that 340B participants report how they use those net revenues. Therefore, CBO cannot assess how participants in the 340B program use net revenues or which patients benefit from those revenues.

2. Medicaid fee-for-service (FFS) is an exception. States pay the 340B acquisition cost for drugs dispensed to Medicaid FFS enrollees through the 340B program. The acquisition cost is generally considered to be the 340B ceiling price. (Payments for drugs not traditionally dispensed through retail pharmacies are not required to follow that regulation.) In certain cases, a 340B facility may not receive insurer reimbursement for drugs purchased under 340B. For example, when HRSA's AIDS Drug Assistance Program provides drugs purchased with 340B discounts to low-income individuals with no or limited insurance, they may not be reimbursed by insurance. See Health Resources and Services Administration, "Part B: AIDS Drug Assistance Program" (August 2024; archived February 10, 2025), https://tinyurl.com/msn95dwu.

What Types of Drugs Were Purchased Through the 340B Program in 2021?

Drugs purchased through the 340B program in 2021 included injected and infused drugs that were administered by physicians as well as self-administered drugs and oral medications used in connection with a service provided in a hospital or clinic.

Of the drugs purchased by organizations participating in the PVP, 41 percent were cancer drugs, 15 percent were anti-infective drugs, and 14 percent were immunosuppressants. Nearly all spending on cancer drugs purchased through the program was by outpatient departments of hospitals and their off-site outpatient clinics. In contrast, most spending on anti-infective drugs purchased through the 340B PVP was by federal grantees.

What Factors Contributed to Growth in 340B Purchases From 2010 to 2021?

The total amount that participating organizations spent on drugs purchased through the PVP increased from $6.6 billion in 2010 to $43.9 billion in 2021 (see Figure 1). That $37.3 billion increase reflects average annual growth of 19 percent. CBO estimates that over

the same period, total spending on brand-name drugs sold by publicly traded companies grew, on average, by 4 percent per year.[3] (Growth in total brand-name spending reflects increases in the overall market for a drug; growth in spending under the 340B program reflects increases in purchases of brand-name and generic drugs at discounted prices and increases in those prices, including increased purchases caused by expansions of the 340B program during the 2010–2021 period.)

In CBO's estimation, about one-third of the program growth from 2010 to 2021 is attributable to two factors:

- Trends in marketwide drug spending, and
- Disproportionate growth among drug classes that have greater representation in the program than in the overall market, such as cancer drugs and anti-infective drugs.

CBO examined three additional factors that, in the agency's assessment, contributed to the remaining two-thirds of the growth in the amount of money that participating facilities spent on 340B drugs from 2010 to 2021. Those factors are the following:

- The integration of hospitals and off-site clinics from 2010 to 2021 led to more facilities becoming eligible;
- The enactment of the Affordable Care Act (ACA) expanded facility participation; and
- A 2010 change in program guidance allowed hospitals to contract with multiple off-site (or contract) pharmacies, enabling participating facilities to increase the share of prescriptions for which they receive a 340B discount.

CBO does not have sufficient data to quantify the effects of those factors, but in the agency's assessment, the integration of hospitals with off-site outpatient clinics is the largest of the three factors in terms of contribution to the growth in drug purchases under the program.

How Does the 340B Program Affect the Federal Budget?

In CBO's assessment, the 340B program encourages behaviors that tend to increase federal spending. Those behaviors include the prescription of more drugs and drugs that cost more, reductions in negotiated rebates for insurers, the expansion of services, and increased vertical integration among facilities. In many cases, the evidence about the behaviors is limited, and the magnitude of their effects is unknown. CBO has not estimated how legislation affecting those behaviors would alter federal spending.

In addition, the 340B program affects the federal budget through funds that the Congress appropriates to HRSA for program administration and oversight. In fiscal year 2024, that appropriation was $12.2 million.[4]

In some cases, insurers may reduce their reimbursement rates for drugs purchased through the program. That reduces federal spending, but the effects of any such reductions are probably small and only partially offset the effects that increase federal spending.

The 340B Drug Pricing Program

The 340B Drug Pricing Program was created by the Veterans Health Care Act of 1992 and codified in section 340B of the Public Health Service Act. The 340B program allows participating health care facilities to purchase outpatient drugs at statutorily discounted prices. Those facilities are certain hospitals that generally serve a specified share of patients with low income and nonhospital facilities, which mostly qualify by receiving federal funding and are referred to collectively as federal grantees.[5]

340B Discounted Drug Purchases

The 340B program requires drug manufacturers that participate in Medicaid and Medicare Part B to sell outpatient drugs at discounted prices to facilities that participate in the 340B program. For the most part, those organizations pay discounted prices for outpatient drugs distributed or

3. Average annual growth in spending through the 340B PVP and growth in total spending are calculated as compound annual growth rates.

4. Health Resources and Services Administration, "FY 2024 Operating Plan" (May 2024; archived March 9, 2025), https://tinyurl.com/7cr84jv7.

5. Some hospitals have to meet additional criteria to participate in the 340B program. For example, hospitals that qualify on the basis of their disproportionate patient percentage (which reflects their share of patients who have low income), children's hospitals, and freestanding cancer hospitals must also certify that they will not purchase outpatient drugs covered by the 340B program through a group purchasing organization. For details, see 340B Health, "Criteria for Hospital Participation in the 340B Drug Discount Program" (accessed January 22, 2025), https://tinyurl.com/53ctaj85. "Look-alike" health centers make up a small share of organizations that participate in the 340B program and are classified as federal grantees. Those clinics do not receive federal funding under section 330 of the Public Health Service Act but meet all requirements of that statute.

administered to any patient who receives a clinical service from a health professional at the facility. Some facilities that qualify on the basis of providing a specific type of care may only purchase drugs at discounted prices for those services. For example, Ryan White HIV/AIDS clinics (a subcategory of federal grantees) must use 340B drugs to provide HIV/AIDS-related care.

The program generally does not dictate how much insurers pay for drugs distributed by facilities that participate in the 340B program (or their off-site pharmacies).[6] Participating facilities retain the difference between the amount they pay for a drug and the amount insurers reimburse for the drug (see Figure 2). The intention of the program is for facilities to use that net revenue to reach more patients and provide more comprehensive services; however, the program statute does not include specific requirements about how participants use any savings generated by the program.

Pricing. CBO refers to the amount that a 340B organization pays for a drug purchased through the 340B program as the 340B price. That price is equal to the 340B ceiling price set by statute, less any additional discounts, which are not set by statute and are negotiated outside of the HRSA-administered program (see Figure 3). The 340B ceiling price is the difference between a drug's average manufacturer price (AMP) and the unit rebate amount, which is based on a formula set in statute.[7] A drug's AMP is the average price paid to a manufacturer for a drug distributed to retail pharmacies, either through wholesalers or directly from manufacturers. (It does not account for rebates or other price concessions that manufacturers provide to pharmacy benefit managers or health insurers.) Manufacturers report the AMP for each drug to the Centers for Medicare & Medicaid Services (CMS).

The Medicaid unit rebate amount used to determine the 340B ceiling price is divided into two components: the basic rebate and inflation rebate. The basic rebate is the larger of a flat rebate amount or, for a brand-name drug, the difference between the AMP and the "best price" (the lowest net price extended to any private buyer, excluding Medicare Part D plans). The flat rebate equals 23.1 percent of the AMP for a brand-name drug and 13.0 percent for a generic drug.[8] The inflation rebate is equal to the growth in the AMP that exceeds the rate of overall inflation as measured by the consumer price index for all urban consumers (CPI-U).[9]

The discounted 340B purchase price also includes any subceiling discounts negotiated by the 340B prime vendor on behalf of participating facilities and any additional discounts that those facilities negotiate directly with manufacturers.[10] As a result, different 340B facilities may pay different prices for the same drug.

Eligible Drugs. Facilities participating in the program purchase drugs used or administered in an outpatient setting and those distributed by an in-house or contract pharmacy at the 340B price. Facilities cannot purchase vaccines or drugs administered in an inpatient setting through the program. Some 340B participants face additional restrictions in the drugs they can distribute.

6. Medicaid FFS payment regulations require that the state pay the 340B acquisition cost for drugs dispensed through the 340B program. However, FFS payment rules apply to the minority of Medicaid payments because the majority of Medicaid enrollees are in managed care plans; for example, in 2022, 75 percent of enrollees were in managed care plans. See Elizabeth Hinton and Jada Raphael, "10 Things to Know About Medicaid Managed Care" (KFF, February 27, 2025), https://tinyurl.com/49ba8ae6.

7. If the ceiling price is less than $0.01 (for instance, if the rebate under Medicaid is larger than the AMP), the 340B price is set at $0.01, a policy referred to as the penny-pricing rule. For more information, see 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210 (January 5, 2017), https://tinyurl.com/4myyh6td; and Health Resources and Services Administration, "What Is HRSA's Penny-Pricing Policy Regarding 340B Ceiling Prices?" (July 2020), https://tinyurl.com/ycybrf6u.

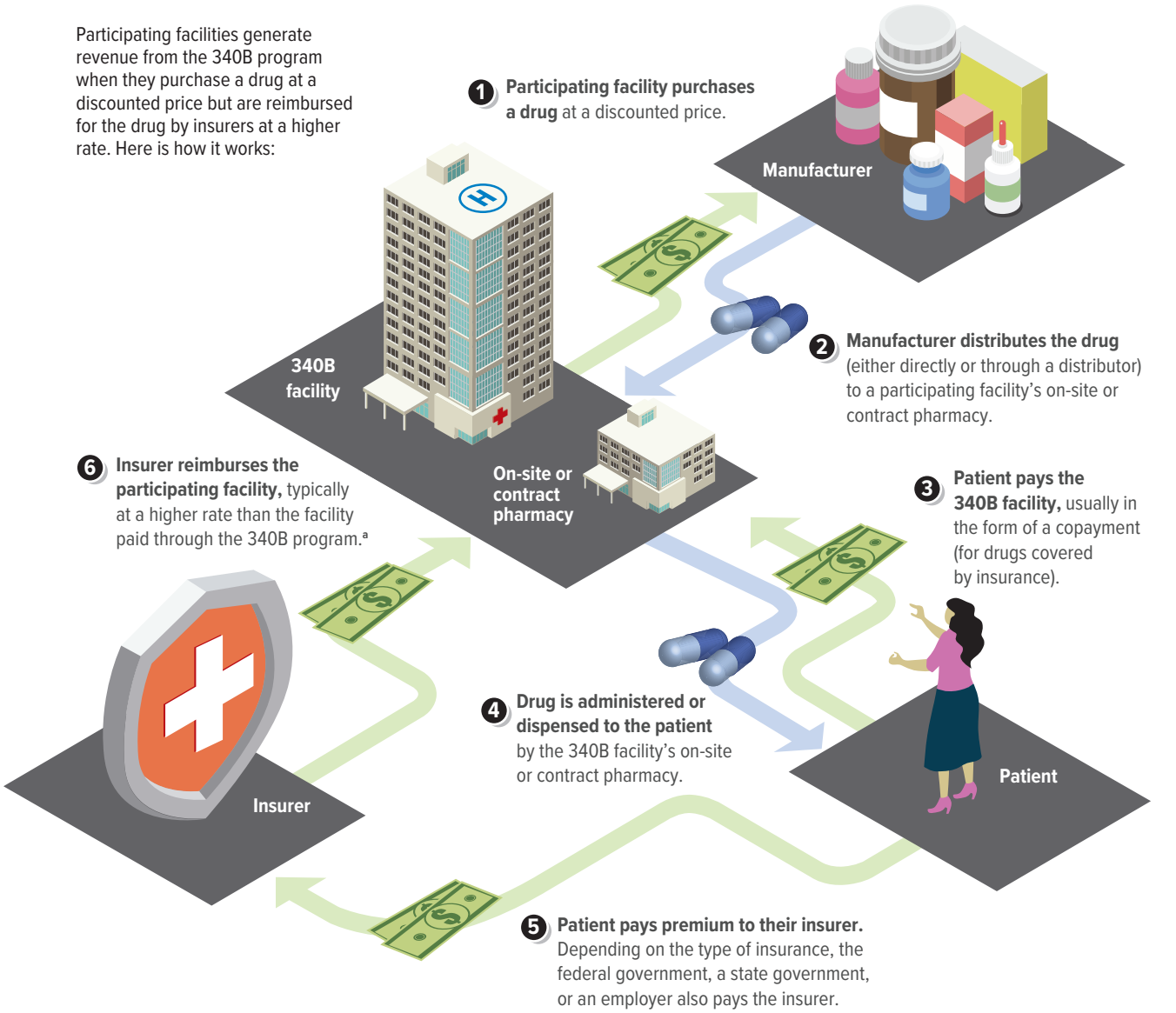
8. For blood clotting factor drugs and drugs approved by the Food and Drug Administration exclusively for pediatric uses, the flat rebate is 17.1 percent of the AMP. See Medicaid, "List of Pediatric Drugs and Blood Clotting Factors" (accessed April 16, 2025), https://tinyurl.com/y7kf7bz7.

9. The inflation rebate is calculated differently depending on whether a drug is a brand-name or a generic drug. For brand-name drugs, it is computed on the basis of the growth of the AMP relative to the CPI-U from a base period, which for each drug is either the quarter in which the drug entered the market or the quarter before the federal drug rebate program began, whichever is later. For generic drugs, the inflation rebate is based on AMP growth relative to 2014 or the year after the drug was marketed as a generic, whichever is later. See Medicaid and CHIP Payment and Access Commission, *Medicaid Payment for Outpatient Prescription Drugs*, MACPAC Issue Brief (May 2018), https://tinyurl.com/ywespm9r.

10. For more information about the prime vendor's role in negotiating subceiling discounts, see 340B Prime Vendor Program, "The PVP Supports the 340B Drug Pricing Program" (accessed September 13, 2024), www.340bpvp.com/about-340b-and-pvp.

Figure 2.

How Drugs and Payments Move Through the 340B System



Data source: Congressional Budget Office.

a. Medicaid fee-for-service is an exception. See Box 1 for more information about insurers' reimbursement for drugs purchased through the 340B program.

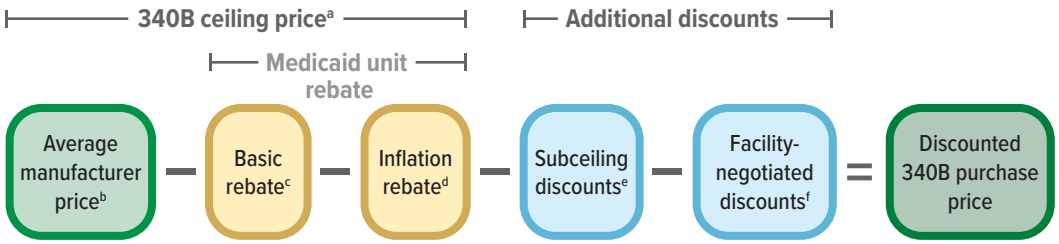
For example, certain 340B participants are prohibited from purchasing drugs that are classified as orphan drugs (those used to treat a rare disease or condition).[11]

Benefits to Participating Facilities. Participating facilities generate net revenue when a drug purchased at the 340B discounted price is sold to a patient who has commercial insurance, Medicare, or a Medicaid managed care plan that reimburses the facility at a higher rate. (For more information about how health insurers reimburse facilities and pharmacies for drugs purchased through the 340B program, see Box 1.) For 340B facilities that provide drugs for free or on the basis of a patient's income, purchasing drugs at a discount extends their capacity to

11. Health Resources and Services Administration, "340B Drug Pricing Program: Orphan Drugs" (June 2024), https://tinyurl.com/28dx95z4.

Figure 3.

How Discounted 340B Purchase Prices Are Calculated



The discounted 340B purchase price is determined by subtracting Medicaid unit rebates and additional discounts from the average manufacturer price. Different participating facilities may pay different prices for the same drug purchased through the 340B program because additional discounts may vary among facilities.

Data source: Congressional Budget Office.

a. The 340B ceiling price is the maximum price a manufacturer can charge a participating facility to purchase a drug.

b. The average manufacturer price (AMP) is the average price paid to a manufacturer by wholesalers and pharmacies that purchase directly from the manufacturer. It does not account for rebates or other price concessions that manufacturers provide to pharmacy benefit managers or health insurers.

c. The basic rebate is used to compute rebates in the Medicaid program. The basic rebate for most brand-name drugs is equal to the greater of two calculations: 23.1 percent of the AMP or the difference between the AMP and the best price. (The best price is the lowest net price at which a drug is offered to any private buyer.)

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

e. Subceiling discounts consist of further discounts negotiated by the 340B prime vendor on behalf of a participating facility.

f. Facility-negotiated discounts are those negotiated directly between a facility and a manufacturer.

offer subsidized or free care and to expand the range of services they offer.

Participating federal grantees are subject to statutory requirements that govern the use of revenue generated by discounted purchases through the 340B program. Those requirements vary by specific program or grant. For example, the Ryan White HIV/AIDS Program publishes guidance on how grantees under that program may use "program income," which includes any income generated through the 340B program.[12] That guidance specifies that program income must be used only for allowable costs under the original grant.

The net revenue that accrues to a 340B facility from discounted drug purchases depends on the discounted prices, the amount of insurance reimbursement, the volume and type of drugs the facility distributes, the facility's patient pool, and the administrative costs associated with implementing the 340B program. Those characteristics vary substantially among organizations. Data from Minnesota show that in that state, in 2023, participating facilities made 42 cents in net revenue for every dollar they received in payment for retail (non-physician-administered) drugs purchased through the 340B program.[13] CBO does not have national data pertaining to the discounted prices organizations pay to purchase drugs through the 340B program or about how

12. Health Resources and Services Administration, "Clarifications Regarding the Ryan White HIV/AIDS Program and Program Income," Policy Notice 15-03 (accessed June 6, 2025), https://tinyurl.com/5y9rmpua.

13. Minnesota Department of Health, *340B Covered Entity Report: Report to the Minnesota Legislature* (November 25, 2024), https://tinyurl.com/5b7j5naa. HRSA estimates that nationally, facilities may realize cost savings of 25 percent to 50 percent on prescription drugs purchased through the 340B program. See Government Accountability Office, *340B Drug Discount Program: Oversight of the Intersection With the Medicaid Drug Rebate Program Needs Improvement*, GAO-20-212 (January 2020), www.gao.gov/products/gao-20-212.

Box 1.

Insurers' Reimbursement for Drugs Purchased Through the 340B Program

Hospitals and other facilities generate net revenue when the amount an insurer reimburses for a drug exceeds the price that the facility paid to purchase that drug. When reimbursement rates are held constant, 340B facilities generate more revenue from drug purchases than non-340B facilities that dispense a similar volume and mix of drugs do. Whether health insurers reimburse 340B and non-340B facilities at the same rate varies by payer and by state.

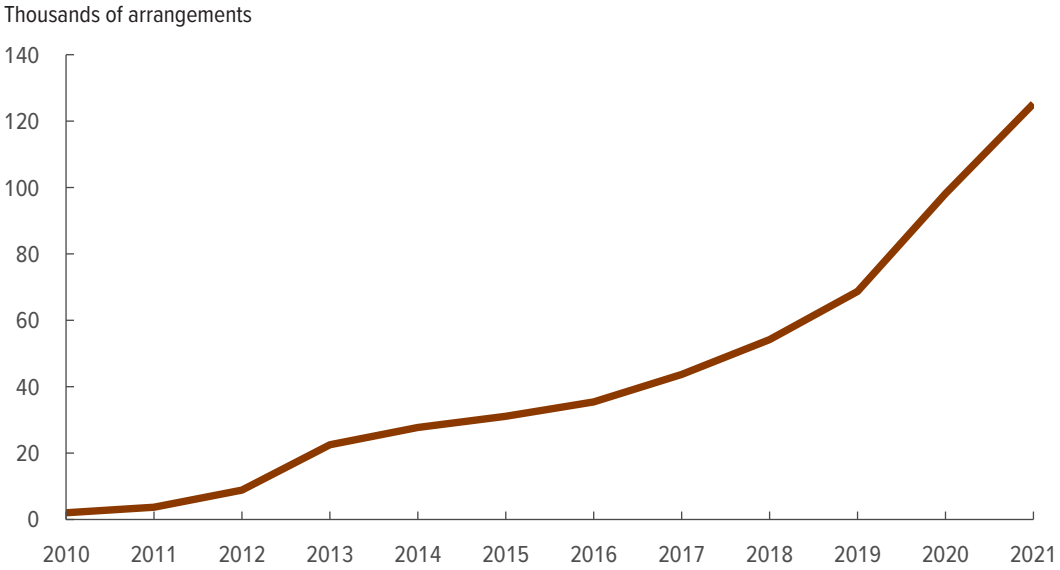
- Medicare Part B reimburses participating and nonparticipating facilities at the same rate.[1] Most of the drugs it reimburses for are physician-administered drugs that patients receive in hospital outpatient departments or off-site clinics.
- Insurers who offer Medicare Part D and Medicare Advantage plans negotiate with facilities and pharmacies to determine reimbursement rates. Those negotiations may result in different facilities' and pharmacies' receiving different reimbursement rates for the same drugs. However, limited information exists about payment differences.
- Commercial insurers also negotiate with facilities and pharmacies to determine reimbursement rates. As in Medicare Part D and Medicare Advantage plans, negotiations may result in different facilities' and pharmacies' receiving different reimbursement rates for the same drugs. Information about differences in drug payment rates in commercial plans is also limited.
- Reimbursement rates from Medicaid depend on whether the payment is made through the Medicaid fee-for-service (FFS) program or through a managed care plan.[2] In Medicaid FFS, payments are set at the cost to the facility to acquire the drug and thus account for 340B discounts.[3] Medicaid managed care plans are not required to differentiate payments on the basis of whether whether a facility participates in the 340B program. Rather, insurers offering Medicaid managed care plans typically negotiate with facilities to determine payment rates.[4]

State laws affect negotiations between insurers and health care facilities to determine payment rates. As of May 2024, more than half of all states prohibited insurers from paying lower rates for drugs distributed through the 340B program in a variety of ways.[5] Some states' laws regulate the payment rates for all drugs acquired by 340B facilities, and others regulate rates for drugs acquired at discounted 340B prices. The types of insurers subject to those laws also vary by state.

1. Medicare Part B previously paid a lower rate for drugs purchased through the 340B program. Starting in 2018, the Centers for Medicare & Medicaid Services reduced Part B drug reimbursement for separately payable drugs or biologics acquired through the 340B program and furnished by a hospital paid under the Outpatient Prospective Payment System. The calculation for reimbursement was changed from the average sales price (ASP) plus 6.0 percent to ASP minus 22.5 percent. However, that payment policy was reversed by the Supreme Court in 2022. See Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022, 88 Fed. Reg. 44078 (July 11, 2023, corrected July 14, 2023), https://tinyurl.com/tmy6fy4n.
2. State Medicaid agencies receive rebates for drugs from manufacturers to ensure that they pay the lowest price. Federal law prohibits Medicaid agencies from billing manufacturers for rebates on drugs dispensed to Medicaid patients that have already been discounted through the 340B program under a prohibition on "duplicate discounts." To avoid issues with duplicate discounts, some 340B facilities choose not to dispense drugs purchased through the 340B program to Medicaid patients (in a process known as carving out Medicaid patients). Rules surrounding facilities' ability to carve out Medicaid FFS or managed care plans vary among states. See Medicaid and CHIP Payment and Access Commission, *The 340B Drug Pricing Program and Medicaid Drug Rebate Program: How They Interact*, MACPAC Issue Brief (May 2018), https://tinyurl.com/yc529crh.
3. That requirement only applies to non-physician-administered drugs in Medicaid FFS. See Medicaid Program; Covered Outpatient Drugs, 81 Fed. Reg. 5170 (February 1, 2016), https://tinyurl.com/mr43msy2.
4. There are exceptions in which certain Medicaid managed care payments are subject to requirements. For instance, in Minnesota, all Medicaid payments to federally qualified health centers for dispensing drugs must equal the 340B price. See Minnesota Department of Health, *340B Covered Entity Report: Report to the Minnesota Legislature* (November 25, 2024), https://tinyurl.com/5b7j5naa.
5. National Association of Community Health Centers, "32 State-Level Laws to Protect CHCs' 340B Savings" (May 2024; archived February 27, 2025), https://tinyurl.com/yctey6ry.

Figure 4.

Contract Pharmacy Arrangements in the 340B Program, 2010 to 2021



The use of contract pharmacies in the 340B program grew substantially from 2010 to 2021, driven largely by changes in program guidance that allowed facilities to enter into contract pharmacy arrangements with an unlimited number of off-site pharmacies.

Data source: Congressional Budget Office, using data from Health Resources and Services Administration, Office of Pharmacy Affairs Information System, https://340bopais.hrsa.gov/. See www.cbo.gov/publication/60661#data.

much net revenue organizations accrue by purchasing discounted drugs.

Dispensing 340B Drugs. By statute, organizations that participate in the 340B program can dispense drugs purchased through the program at their facility, their facility's in-house pharmacy, or a contract pharmacy.[14] A contract pharmacy is an off-site retail or specialty pharmacy that has an agreement with a 340B facility to dispense drugs purchased through the program on the organization's behalf. Without a contract pharmacy arrangement, a 340B facility cannot dispense drugs purchased through the 340B program at an off-site pharmacy location. Facilities use contract pharmacies because they offer an additional route through which the facility may dispense drugs purchased through the program, allowing the organization to collect 340B discounts on a greater share of its prescriptions. Organizations may also use contract pharmacies to meet requirements from manufacturers (such as requiring their drug be dispensed at a specialty pharmacy) or to improve patients' access.

The use of contract pharmacies to dispense drugs purchased through the 340B program increased significantly over the 2010–2021 period (see Figure 4). That growth is attributable in part to changes made to program guidance in 2010 that allowed 340B facilities to enter into an unlimited number of contract pharmacy arrangements. (Before 2010, 340B facilities without an on-site pharmacy could enter into an arrangement with a single off-site pharmacy; facilities with an on-site pharmacy could not enter into any contract pharmacy arrangements.) The number of contract pharmacy arrangements grew from about 2,000 in 2010 to nearly 130,000 in 2021. (Facilities may have arrangements with multiple pharmacies and pharmacies may have arrangements with multiple facilities. In those cases, each arrangement was counted individually.)

Facilities' Eligibility and Participation

Two categories of facilities are eligible to participate in the 340B program: certain types of nonprofit or public hospital-based facilities and federal grantees. Eligibility criteria are designed to lower drug costs for organizations that typically serve uninsured patients, patients with low income, or otherwise vulnerable populations. Nearly 50,000 facilities participated in 2021. (For more details about how CBO calculated the number of participating facilities, see Appendix B.)

14. Participating facilities may only distribute drugs purchased at 340B prices to people who qualify as patients of the facility. For details about who qualifies as a patient, see Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55156 (October 24, 1996), https://tinyurl.com/2s9whw3h.

Hospital-Based Facilities. Six types of nonprofit or public (state or local government–operated) hospitals can participate in the 340B program: hospitals that qualify on the basis of their disproportionate patient percentage, referred to as disproportionate share hospitals (DSHs), children's hospitals, critical access hospitals, freestanding cancer hospitals, rural referral centers, and sole community hospitals.[15] Except for critical access hospitals, they must serve a certain share of patients with low income to be eligible for the 340B program. Most hospitals qualify for the 340B program on the basis of their DSH status; those hospitals must have a disproportionate patient percentage greater than 11.75 percent. Other hospitals have different requirements for eligibility; for example, rural referral centers must have a disproportionate patient percentage greater than or equal to 8 percent to participate in the 340B program.[16]

Some qualifying hospitals have outpatient clinics that are part of the hospital but are not on the same campus as the hospital. (HRSA refers to those clinics as child sites.) Those clinics may participate in the 340B program as long as they are listed as reimbursable on the hospital's most recently filed Medicare cost report and are registered with HRSA.[17]

In 2021, hospital-based facilities (that is, hospitals and their off-site outpatient clinics) accounted for 61 percent of the nearly 50,000 health care facilities that participated in the 340B program (see Figure 5). In that year, 2,530 hospitals participated in the program, which is slightly less than one-half of all community hospitals—including investor-owned, for-profit hospitals, which are not eligible to participate in the 340B program—in the United States.[18] About 75 percent of participating hospitals had at least 1 off-site outpatient clinic that participated in the program, and on average, participating hospitals had 11 off-site outpatient clinics.[19] Those off-site clinics accounted for more than 90 percent of all participating hospital-based facilities and over 50 percent of all 340B facilities in 2021.

Disproportionate share hospitals and their off-site outpatient clinics account for the largest share of participating hospital-based facilities.[20] In 2021, 1,081 DSH locations and 20,793 off-site outpatient clinics of disproportionate share hospitals participated in the 340B program. Disproportionate share hospitals and their off-site outpatient clinics made up 72 percent of all hospital-based facilities in the program and 44 percent of all 340B facilities that year.

Federal Grantees. Three types of nonhospital facilities qualify for the 340B program: federally qualified health

15. Nonprofit hospitals qualify for the program partly on the basis of having contracts with state or local governments to provide health care services to individuals not eligible for Medicaid or Medicare. See Health Resources and Services Administration, "How Hospitals Register for the 340B Program" (September 2022), https://tinyurl.com/hntz5x68. Some hospitals have to meet additional criteria to participate in the program. For example, DSHs, children's hospitals, and freestanding cancer hospitals must also certify that they will not purchase outpatient drugs covered by the 340B program through a group purchasing organization. For details, see 340B Health, "Criteria for Hospital Participation in the 340B Drug Discount Program" (accessed January 22, 2025), https://tinyurl.com/53ctaj85.

16. The disproportionate patient percentage is determined, in part, by the share of the hospital's Medicare patients who are also eligible for Supplemental Security Income and the share of patients eligible for Medicaid. For more information, see Sec. 1886(d)(5)(F) of the Social Security Act (codified at 42 U.S.C. § 1395ww (2018 & Supp.)); and Centers for Medicare & Medicaid Services, "Medicare Disproportionate Share Hospital" (fact sheet, September 2024), https://tinyurl.com/58ktdu2w. For more details about the criteria for hospitals' eligibility for the 340B program, see Health Resources and Services Administration, "340B Drug Pricing Program: Hospitals" (April 2022), https://tinyurl.com/58ktdu2w.

17. Health Resources and Services Administration, "FAQs" (accessed September 13, 2024), www.hrsa.gov/opa/faqs.

18. Community hospitals are defined as nonfederal, short-term general, or other speciality hospitals (including long-term acute care and rehabilitation and orthopedic hospitals). Academic medical centers are considered community hospitals if they are nonfederal and short-term hospitals. In 2021, there were 5,157 community hospitals in the United States; 2,978 of those operated as nongovernment nonprofit hospitals, 1,235 operated as investor-owned for-profit hospitals, and 944 operated as state or local government hospitals. See American Hospital Association, "Fast Facts on U.S. Hospitals, 2023" (AHA Data & Insights, May 2023), https://tinyurl.com/yhmvwyxy.

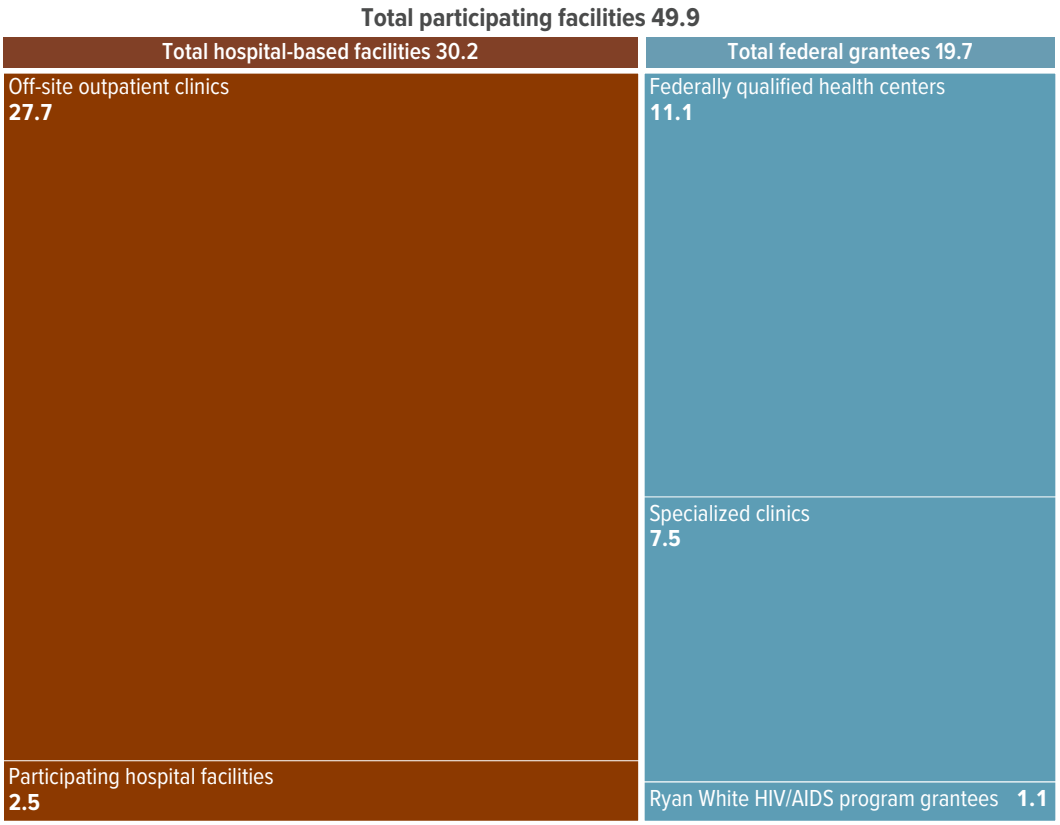
19. That average was largely influenced by 48 qualifying hospital locations that each had more than 100 off-site outpatient clinics participating in the program. If those facilities were removed, the average number of off-site outpatient clinics per hospital would be 7.9.

20. Disproportionate share hospitals serve patients with low income and receive payments from CMS to cover the costs of providing care to uninsured patients. Eligibility is not based on a hospital's participation in the Medicaid Disproportionate Share Hospital Program, which is run by states and reimburses hospitals for uncompensated care for Medicaid patients and uninsured patients. See Centers for Medicare & Medicaid Services, "Disproportionate Share Hospital (DSH)" (accessed September 13, 2024), https://tinyurl.com/u7xfk8dp.

Figure 5.

Facilities Participating in the 340B Program in 2021

Thousands of facilities



Participating hospitals and their off-site outpatient clinics made up the largest share of 340B facilities in 2021.

Data source: Congressional Budget Office, using data from Health Resources and Services Administration, Office of Pharmacy Affairs Information System, https://340bopais.hrsa.gov/. See www.cbo.gov/publication/60661#data.

Multiple off-site outpatient clinics or grantees may operate at the same address. CBO treats off-site outpatient clinics and grantees' service delivery sites that register separately with the Health Resources and Services Administration's Office of Pharmacy Affairs as unique facilities.

centers (FQHCs), Ryan White HIV/AIDS Program grantees, and specialized clinics.[21] To participate in the program, those facilities must meet certain requirements defined by statute, and they must apply through HRSA.

The majority of FQHCs receive funding through HRSA's Health Center Program to provide comprehensive primary care services to individuals in medically underserved areas, regardless of the individual's ability to pay.[22] FQHCs also include health center look-alikes and tribal and urban Indian health centers.[23] All told, the 11,144 FQHCs accounted for 22 percent of the almost 50,000 facilities that participated in the 340B program in 2021.[24]

Ryan White HIV/AIDS Program grantees receive federal funding authorized under title XXVI of the Public

21. For more information about eligible federal grantees, see 42 U.S.C. § 256(b); and Health Resources and Services Administration, "340B Eligibility" (June 2024), www.hrsa.gov/opa/eligibility-and-registration.

22. Health Resources and Services Administration, "Health Center Program Award Recipients" (June 2024), https://tinyurl.com/e96a8m8z.

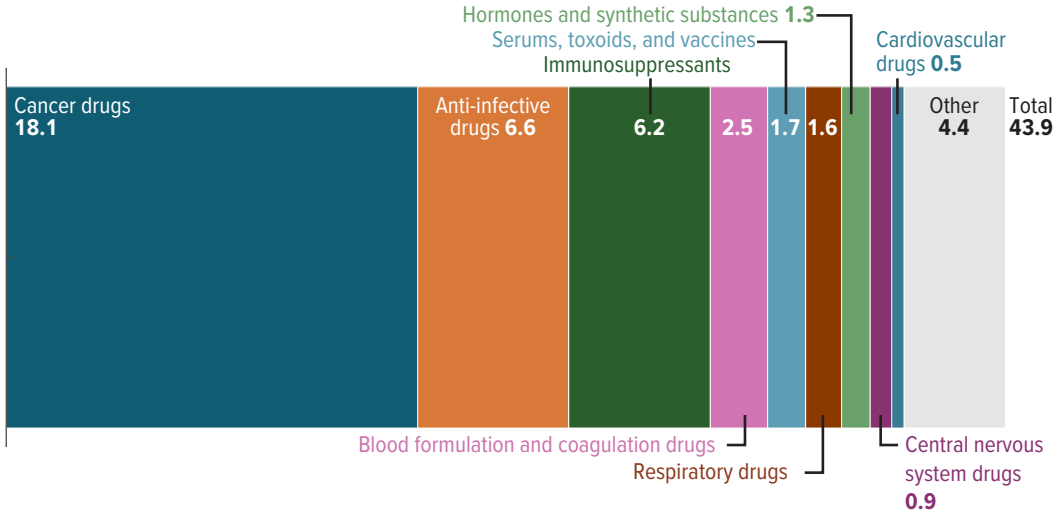
23. In this report, CBO groups all Native Hawaiian health centers with FQHCs regardless of whether they receive health center program funding from HRSA.

24. The FQHC category includes both qualifying grant sites and service delivery sites. A service delivery site is a facility where a qualifying grant site delivers care that is in a different location from the qualifying grant site. Each qualifying grant site may have multiple service delivery sites. In 2021, there were 1,528 qualifying locations and 9,616 service sites. When calculating the total number of participating facilities, CBO considered each qualifying grant site and service delivery site to be its own facility.

Figure 6.

Spending on Drugs Purchased Through the 340B Program in 2021, by Drug Class

Billions of dollars



Spending on cancer drugs, anti-infective drugs, and immunosuppressants accounted for 70 percent of total 340B spending in 2021.

Data source: Congressional Budget Office, using data from the Health Resources and Services Administration and Micromedex Red Book Expanded database (produced by Merative). See www.cbo.gov/publication/60661#data.

For additional information about drug classes, see Appendix B.

Spending refers to the dollar amount that participating facilities spent on discounted drugs purchased through the 340B program, as reported by the Prime Vendor Program. Approximately 10 percent of 340B facilities do not participate in the Prime Vendor Program.

Health Service Act to provide HIV/AIDS treatment and related services to people living with HIV/AIDS who are uninsured or underinsured. They made up 2 percent of the participating facilities in 2021.

Specialized clinics are authorized under various statutes and receive federal funding from various sources, such as HRSA and the Centers for Disease Control and Prevention. They include black lung clinics, comprehensive hemophilia diagnostic treatment centers, title X family planning clinics, sexually transmitted disease clinics, and tuberculosis clinics. In 2021, specialized clinics accounted for 15 percent of facilities in the 340B program.

Drug Purchases Through the 340B Program in 2021

In 2021, health care facilities that participated in the PVP spent $43.9 billion on drugs purchased through the 340B program. (For details about how CBO measured spending, see Appendix B.) CBO estimates that spending on drugs purchased by facilities participating in the PVP made up 10.8 percent of total net spending on drugs in 2021.[25] Cancer drugs accounted for 41 percent of spending through the PVP that year, the largest share of spending among all drug classes. By far, purchases by hospital-based facilities accounted for the greatest proportion of 340B spending.

Drug Purchases, by Drug Class

In 2021, 70 percent of facility spending on drugs purchased through the PVP was attributable to three classes of drugs: cancer drugs, anti-infective drugs, and immunosuppressants (see Figure 6). For more details about each drug class, see Appendix B. Spending on cancer drugs was $18.1 billion, or 41 percent of total drug purchases through the program, which is almost three times the amount spent on any other drug class. Within that class, molecularly targeted therapies accounted for

25. To determine this share, CBO calculated total spending on drugs through the PVP ($43.9 billion in 2021) as a share of total net spending on medicines ($407 billion in 2021). Total net spending on medicines is reported by IQVIA and includes spending on all types of products (generics, brands, small-molecule drugs, and biologics) dispensed in pharmacies and health care settings. Net spending reflects revenues received by manufacturers after discounts and spending. See IQVIA Institute, *The Use of Medicines in the U.S. 2022* (April 2022), https://tinyurl.com/ytrwdd5m.

87 percent of spending on drugs purchased through the PVP, chemotherapies accounted for 8 percent, and hormone therapies accounted for 3 percent.[26]

Anti-infective drugs made up the second-largest share (15 percent, or $6.6 billion) of facility spending on drugs purchased through the PVP in 2021. Anti-infective drugs are used to treat many different infectious diseases and vary in terms of cost. For example, azithromycin, a relatively low-cost antibiotic, is used to treat a range of bacterial infections such as strep throat. Other drugs in the class treat diseases that require more expensive drugs, such as emtricitabine, which is used to treat HIV/AIDS, and velpatasvir, which is used to treat hepatitis C. Drugs that treat HIV/AIDS made up 85 percent of facilities' spending on anti-infective drugs purchased through the program; drugs that treat hepatitis C accounted for 9 percent.[27]

Immunosuppressants made up the third-largest proportion of spending on 340B purchases (14 percent, or $6.2 billion) in 2021 by facilities that participated in the PVP. Immunosuppressants inhibit the activity of the immune system and include treatments for rheumatoid arthritis, multiple sclerosis, and Crohn's disease.

Six other drug classes each accounted for purchases of at least $0.5 billion in 2021, collectively making up $8.5 billion (or 19 percent) of spending on drugs purchased through the PVP: blood formulation and coagulation drugs; serums, toxoids, and vaccines; respiratory drugs; hormones and synthetic substances; central nervous system drugs; and cardiovascular drugs.[28] The remaining 24 drug classes made up $4.4 billion (or 10 percent) of spending on 340B purchases in 2021.

Approximately half of spending on drugs purchased through the PVP—$21.3 billion—was on physician-administered drugs, which include injected or infused drugs typically administered in physicians' offices or outpatient clinics.[29] Physician-administered drugs accounted for 72 percent of facilities' purchases of cancer drugs under the program, 3 percent of their purchases of anti-infective drugs, and 57 percent of their purchases of immunosuppressants.

Drug Purchases, by Type of Facility

The largest proportion of spending by participating facilities on drugs through the 340B program occurred at hospitals and their off-site outpatient clinics. In 2021, hospital-based facilities participating in the PVP spent $38.2 billion on drugs through the 340B program, accounting for 87 percent of total spending on drug purchases through the program (see Figure 7). Given that those facilities made up only 61 percent of all facilities participating in the 340B program, they purchased drugs with higher prices than federal grantees did, filled more 340B prescriptions per facility, or both.

Drug purchases by federal grantees accounted for $5.7 billion in 2021, or 13 percent of total purchases through the PVP. Among grantees, FQHCs spent the most on purchases through the program, at $2.4 billion, or 6 percent of total 340B purchases. Ryan White HIV/AIDS clinics spent $2.2 billion, or 5 percent of total purchases. Specialized clinics spent $1.1 billion on 340B purchases, or 3 percent of total purchases.

Drug Purchases, by Drug Class and Type of Facility

Hospital-based facilities differ from federal grantees in the types of drugs they dispense. Among hospital-based facilities, 47 percent of total spending on drugs purchased through the PVP in 2021 was on cancer drugs, whereas it was less than 1 percent among federal grantees. Nearly all spending through the PVP on cancer drugs (99 percent) was by hospital-based facilities. The same relationship holds true for immunosuppressant drugs—16 percent of total spending through the 340B program at hospital-based facilities was on immunosuppressants, compared with just 1 percent at federal grantees.

26. Molecularly targeted therapies consist of treatments that target cancer cells, such as immunotherapies and monoclonal antibodies. Hormone therapies encompass treatments that alter hormones associated with certain types of cancer.

27. The proportion of anti-infective spending accounted for by hepatitis C drugs increased from 2 percent in 2012 to 40 percent in 2015 before declining to 9 percent in 2021. The spike coincided with the entrance to the market of direct-acting antiviral treatments for hepatitis C. Direct-acting antiviral treatments have higher cure rates than other treatments for hepatitis C but are also more expensive. See Congressional Budget Office, *Budgetary Effects of Policies That Would Increase Hepatitis C Treatment* (June 2024), www.cbo.gov/publication/60237.

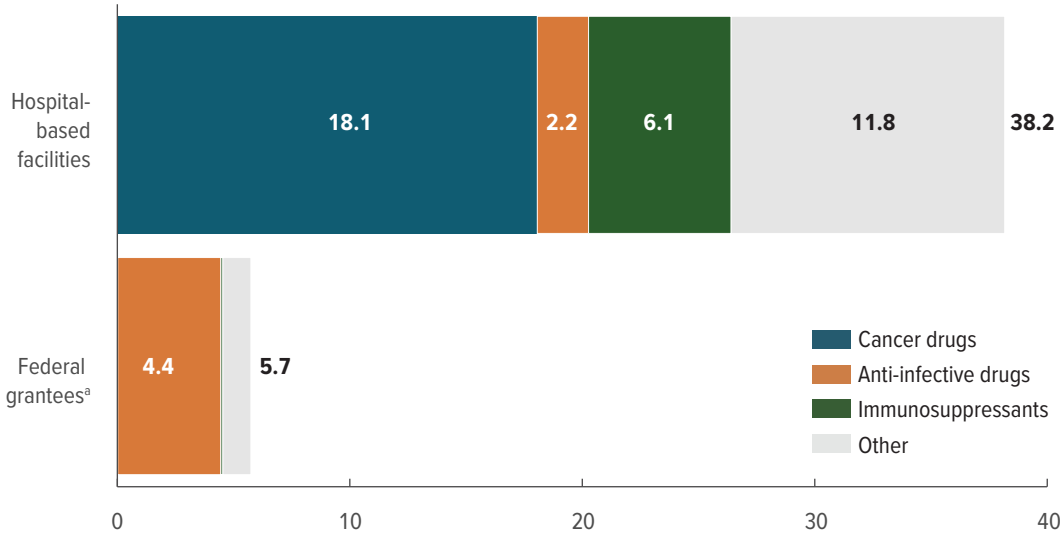
28. Serums, toxoids, and vaccines is the name of the therapeutic class in Micromedex Red Book (see Appendix B). CBO's measures of spending through the 340B program do not include any spending on vaccines because facilities are not allowed to purchase vaccines through the program.

29. CBO estimated the share of spending on physician-administered drugs on the basis of each drug's route of administration in Micromedex Red Book. Drugs with administration routes that are only sometimes physician-administered, such as subcutaneous injections, were not included in the count of physician-administered drugs.

Figure 7.

Spending on Drugs Purchased Through the 340B Program in 2021, by Type of Facility and Drug Class

Billions of dollars



In 2021, spending on cancer drugs accounted for the largest share of purchases through the 340B program at hospital-based facilities, at 47 percent. By contrast, spending on anti-infective drugs accounted for the largest share of purchases at facilities designated as federal grantees, at 77 percent.

Data source: Congressional Budget Office, using data from the Health Resources and Services Administration and Micromedex Red Book Expanded database (produced by Merative). See www.cbo.gov/publication/60661#data.

For additional information about drug classes, see Appendix B.

Spending refers to the dollar amount that participating facilities spent on discounted drugs purchased through the 340B program, as reported by the Prime Vendor Program. Approximately 10 percent of 340B facilities do not participate in the Prime Vendor Program.

a. Clinics designated as eligible because they receive certain federal grants, are identified as look-alike health centers, or meet some other qualification.

Among federal grantees, 77 percent of spending on drugs purchased through the PVP in 2021 was on anti-infective drugs. At FQHCs, spending on that class of drugs made up 59 percent of total purchases under the program; at Ryan White HIV/AIDS clinics, such spending made up 98 percent of their 340B purchases; and at specialized clinics, spending on anti-infective drugs made up 75 percent.

Factors Contributing to Growth in 340B Spending

Annual spending on drugs purchased by health care facilities participating in the PVP increased from $6.6 billion in 2010 to $43.9 billion in 2021. That $37.3 billion increase represents an average annual growth rate of 19 percent over the 2010–2021 period. SSR Health data indicate that over that same period, spending by all payers on brand-name drugs sold by publicly traded companies grew by an average of 4 percent per year, reflecting smaller growth in the overall prescription drug market.

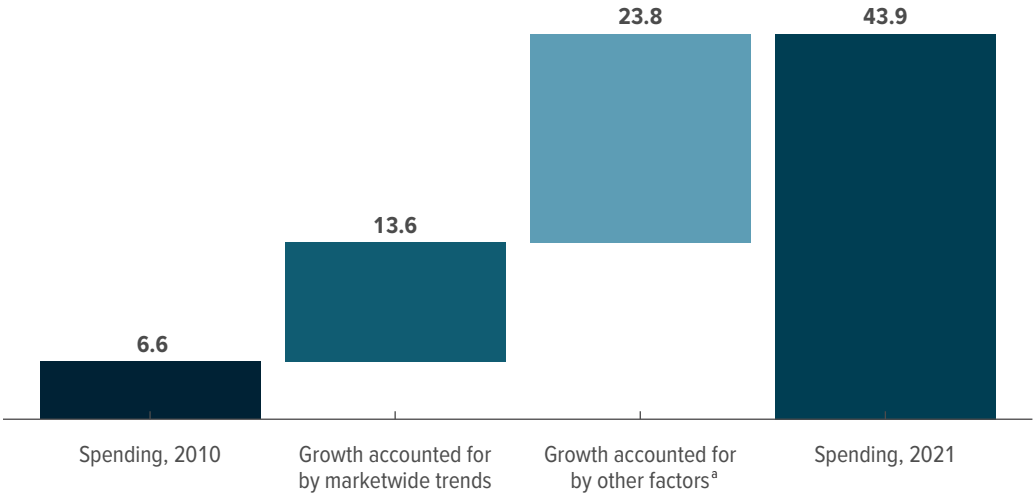
Several factors contributed to the increase in annual spending on drugs purchased through the 340B program from 2010 to 2021. In CBO's assessment, about one-third of the increase is attributable to two factors: marketwide growth in spending on prescription drugs and disproportionate growth in drug classes that account for a greater share of spending through the 340B program than in the overall market (see Figure 8).

The remaining two-thirds of the growth in spending is not fully captured by marketwide trends in prescription drug spending; it is attributable to at least three other factors. First, a growing number of off-site outpatient clinics became eligible for the program through their establishment or acquisition by 340B hospitals (referred to in this report as vertical integration); second, the number of facilities participating in the program increased after the implementation of the Affordable Care Act; and finally, the use of contract pharmacies increased. CBO does not have the data to determine the share of the growth in spending attributable to each of

Figure 8.

Components of the Growth in Spending on Drugs Purchased Through the 340B Program, 2010 to 2021

Billions of dollars



Annual spending on drugs purchased through the 340B program increased from $6.6 billion in 2010 to $43.9 billion in 2021. About one-third of that increase can be explained by trends in marketwide prescription drug spending over that period.

Data source: Congressional Budget Office, using data from the Health Resources and Services Administration, SSR Health, and Micromedex Red Book Expanded database (produced by Merative). See www.cbo.gov/publication/60661#data.

Amounts are adjusted for inflation using the gross domestic product price index and are expressed in 2021 dollars.

Spending refers to the dollar amount that participating facilities spent on discounted drugs purchased through the 340B program, as reported by the Prime Vendor Program. Approximately 10 percent of 340B facilities do not participate in the Prime Vendor Program. Marketwide spending refers to the dollar amount (net of discounts and rebates) that public and private (commercial) payers and patients paid for prescription drugs. Only brand-name drugs sold by publicly traded companies are included in marketwide spending calculations.

a. Other factors include vertical integration of hospitals and off-site outpatient clinics, increased facility participation after the implementation of the Affordable Care Act, and increased use of contract pharmacies.

those factors; however, in the agency's assessment, vertical integration was the largest.

Factors Related to Trends in Marketwide Spending on Prescription Drugs

About one-third, or $13.6 billion, of the increase in annual spending on drugs purchased through the PVP over the 2010–2021 period is associated with overall increases in marketwide spending on prescription drugs and disproportionate spending under the 340B program on drug classes with particularly high spending growth.

Overall Increases in Prescription Drug Spending. From 2010 to 2021, marketwide spending on prescription drugs (adjusted to remove the effects of inflation) grew at an average annual rate of 4 percent, CBO estimates. That overall increase accounts for $3.2 billion of growth in 340B spending over that period.

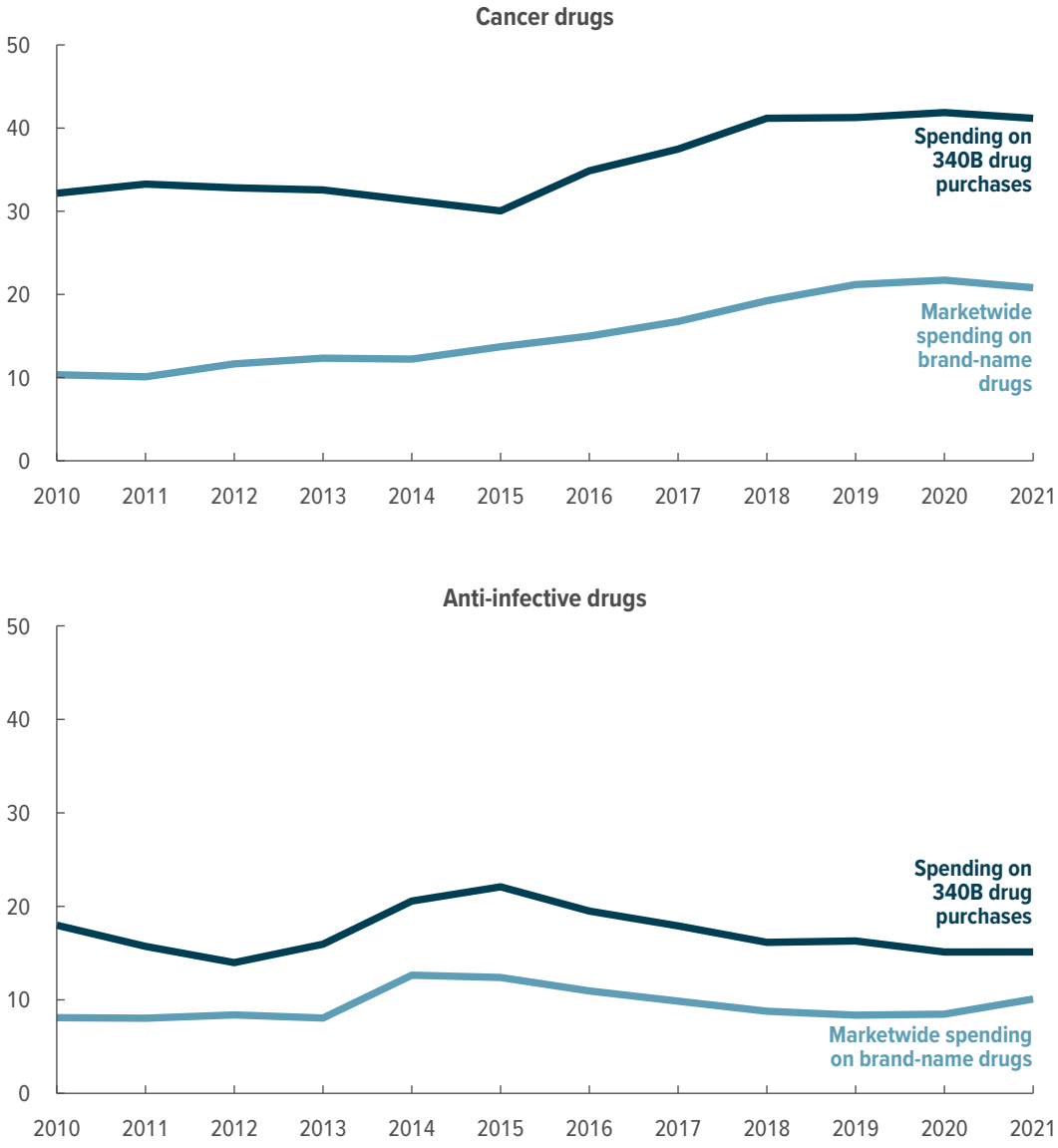
Disproportionate Spending on High-Growth Drug Classes. The remaining $10.4 billion of the $13.6 billion in spending growth attributable to marketwide trends over the period is due to disproportionate spending by 340B facilities on drugs in classes with high spending growth. For example, the share of spending on cancer drugs under the 340B program was 20 percentage points higher, on average, than it was in the overall market over the 2010–2021 period. That share was, on average, 8 percentage points higher for anti-infective drugs (see Figure 9). Those differences are attributable to several factors, including differences in the types of providers that participate in the 340B program, the patient pool served by 340B providers, and the specific drugs prescribed at 340B facilities.

Marketwide spending on cancer drugs and anti-infective drugs grew more quickly than average spending on all drugs. From 2010 to 2021, marketwide spending on cancer drugs increased by an average of 11 percent per

Figure 9.

Share of Spending on Drugs Purchased Through the 340B Program Compared With the Share of Marketwide Spending on Those Drugs, by Drug Type

Percent



Cancer and anti-infective drugs account for a larger share of spending in the 340B program than spending in the overall market.

Data source: Congressional Budget Office, using data from the Health Resources and Services Administration, SSR Health, and Micromedex Red Book Expanded database (produced by Merative). See www.cbo.gov/publication/60661#data.

Spending refers to the dollar amount that participating facilities spent on discounted drugs purchased through the 340B program, as reported by the Prime Vendor Program. Approximately 10 percent of 340B facilities do not participate in the Prime Vendor Program. Marketwide spending refers to the dollar amount (net of discounts and rebates) that public and private (commercial) payers and patients paid for prescription drugs. Only brand-name drugs sold by publicly traded companies are included in marketwide spending calculations.

year and on anti-infective drugs by 5 percent per year. In comparison, spending on other classes of drugs grew by 2 percent per year. Marketwide spending grew more quickly for cancer drugs and anti-infective drugs in part because new forms of treatments entered the market, including novel cancer immunotherapies and novel antiviral treatments for HIV and hepatitis C. For example, anti-infective drugs saw a large increase in spending in 2014, coinciding with the introduction of new treatments for hepatitis C.

To examine the role that spending on drugs in certain high-growth drug classes played in the overall growth in purchases through the 340B program, CBO estimated what spending on drugs purchased through the 340B PVP would have been in 2021 if that spending had grown at the marketwide growth rate for each subclass of drugs over the 2010–2021 period.[30] (A subclass of drugs is made up of specific types of drugs within a larger class; for example, hormone-modifying drugs are a subclass of cancer drugs.) Specifically, CBO multiplied PVP spending on each subclass in 2010 by the marketwide growth rate in spending on that subclass from 2010 to 2021.[31]

CBO found that actual growth in spending on 340B purchases exceeded marketwide spending growth for multiple classes of drugs (see Figure 10).[32] For example, CBO estimated that if spending on cancer drugs through the 340B program had grown at the same rate as it did marketwide, 340B spending on those drugs in 2021 would have been 3.1 times spending in 2010. Actual spending on cancer drugs in the 340B program in 2021 was 8.6 times spending for such drugs in 2010 ($18.1 billion and $2.1 billion, respectively). That estimate does not account for any disproportionate use of drugs with higher spending growth within a subclass.

Growth in spending on 340B purchases in excess of marketwide spending growth probably reflects a number of factors, including an increase in the number of facilities purchasing drugs with 340B discounts, an increase in the number of prescriptions for drugs purchased through the 340B program at those facilities, and faster growth in the prices of drugs that are disproportionately purchased through the program. CBO does not have the data to distinguish among those factors.

Other Factors

CBO examined three factors unrelated to trends in marketwide prescription drug spending: vertical integration of hospitals and off-site outpatient clinics, increased participation in the 340B program after the implementation of the ACA, and increased use of contract pharmacies (see Figure 11).

Vertical Integration of Hospitals and Off-Site Clinics.

In this report, vertical integration refers to the acquisition or establishment of an off-site clinic, such as an infusion center or a specialty medicine practice, by a hospital or hospital system. Such integration increased among health care providers over the 2010–2021 period. For example, one study shows that the percentage of physician practices owned by a hospital or health system increased by more than 20 percentage points from 2007 to 2017, particularly among oncology and cardiology practices. More recent studies show that integration between hospitals and physicians' practices continued through 2021.[33]

Providers face various incentives to consolidate. Hospitals and clinics may choose to integrate so that they can receive higher payment rates—Medicare and many commercial insurers make additional payments to hospital-based

30. CBO measured marketwide prescription drug spending growth using SSR Health data, which include spending net of discounts and rebates for both public payers and private (commercial) payers as well as any cost sharing by enrollees. The data only contain information for brand-name drugs sold by publicly traded companies. CBO estimates that from 2010 to 2021, 89 percent to 97 percent of 340B spending was on brand-name drugs in a given year.

31. CBO's projection uses a marketwide growth rate for prescription drugs across all public and private transactions that includes drugs purchased through the 340B program. Since spending growth in the 340B program was faster than marketwide spending growth over the 2010–2021 period, CBO's estimate may overstate the contribution of marketwide factors to 340B spending growth.

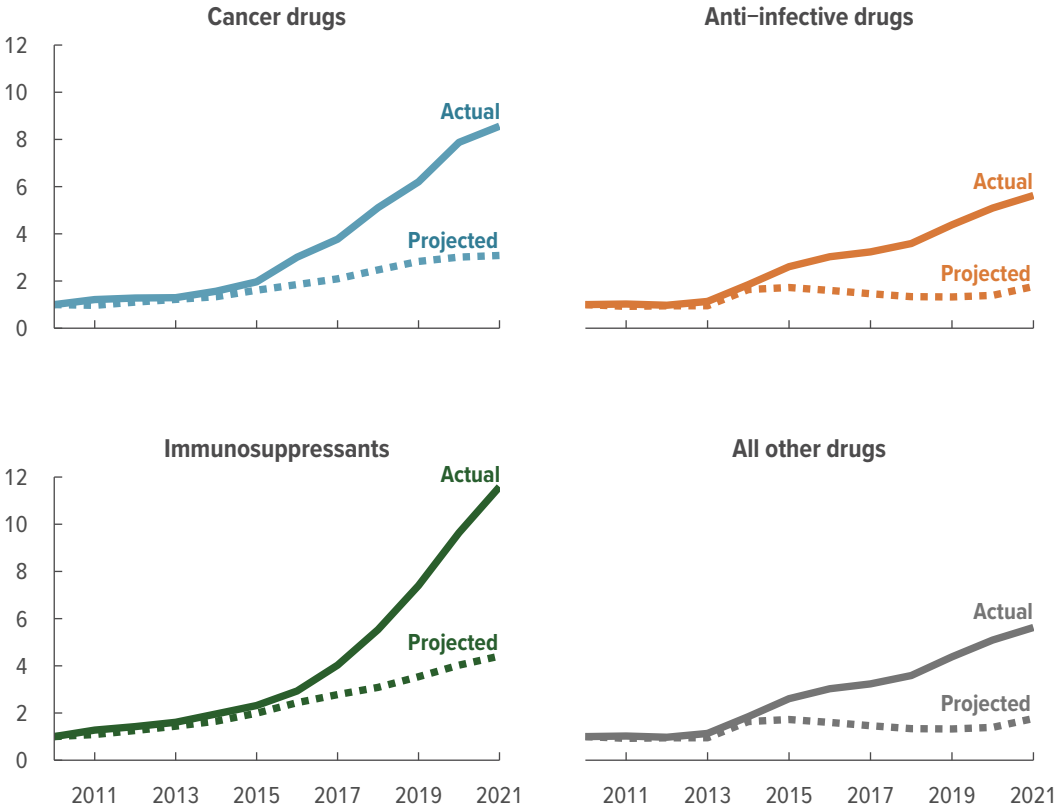
32. CBO indexed spending for each drug class in 2010 to 1 so that spending levels would be comparable across classes.

33. Physicians Advocacy Institute, *COVID-19's Impact on Acquisitions of Physician Practices and Physician Employment 2019–2021* (prepared by Avalere Health, April 2022), https://tinyurl.com/muvc8s2e; Rachel M. Machta and others, "Health System Integration With Physician Specialties Varies Across Markets and System Types," *Health Services Research*, vol. 55, no. S3 (December 2020) pp. 1062–1072, https://doi.org/10.1111/1475-6773.13584; and Sayeh S. Nikpay, Michael R. Richards, and David Penson, "Hospital-Physician Consolidation Accelerated in the Past Decade in Cardiology, Oncology," *Health Affairs*, vol. 37, no. 7 (July 2018), pp. 1123–1127, https://doi.org/10.1377/hlthaff.2017.1520.

Figure 10.

Actual Growth in Spending on Drugs Purchased Through the 340B Program Compared With Projected Growth, by Drug Type

Index, 340B spending in 2010 = 1



Actual growth in spending on 340B purchases exceeded spending growth explained by trends in marketwide prescription drug spending for all drug classes.

Data source: Congressional Budget Office, using data from the Health Resources and Services Administration, SSR Health, and Micromedex Red Book Expanded database (produced by Merative). See www.cbo.gov/publication/60661#data.

Amounts are adjusted for inflation using the gross domestic product price index and are expressed in 2021 dollars.

Spending refers to the dollar amount that participating facilities spent on discounted drugs purchased through the 340B program, as reported by the Prime Vendor Program. Approximately 10 percent of 340B facilities do not participate in the Prime Vendor Program.

Projected spending growth is based on trends in marketwide spending. Marketwide spending refers to the dollar amount (net of discounts and rebates) that public and private (commercial) payers and patients paid for prescription drugs. Only brand-name drugs sold by publicly traded companies are included in marketwide spending calculations.

clinics delivering physician services but not to off-site clinics unaffiliated with hospitals.[34] Hospitals and clinics may also integrate to gain bargaining power with insurers, to increase the scale and scope of their practices, and to acquire more or better technology.

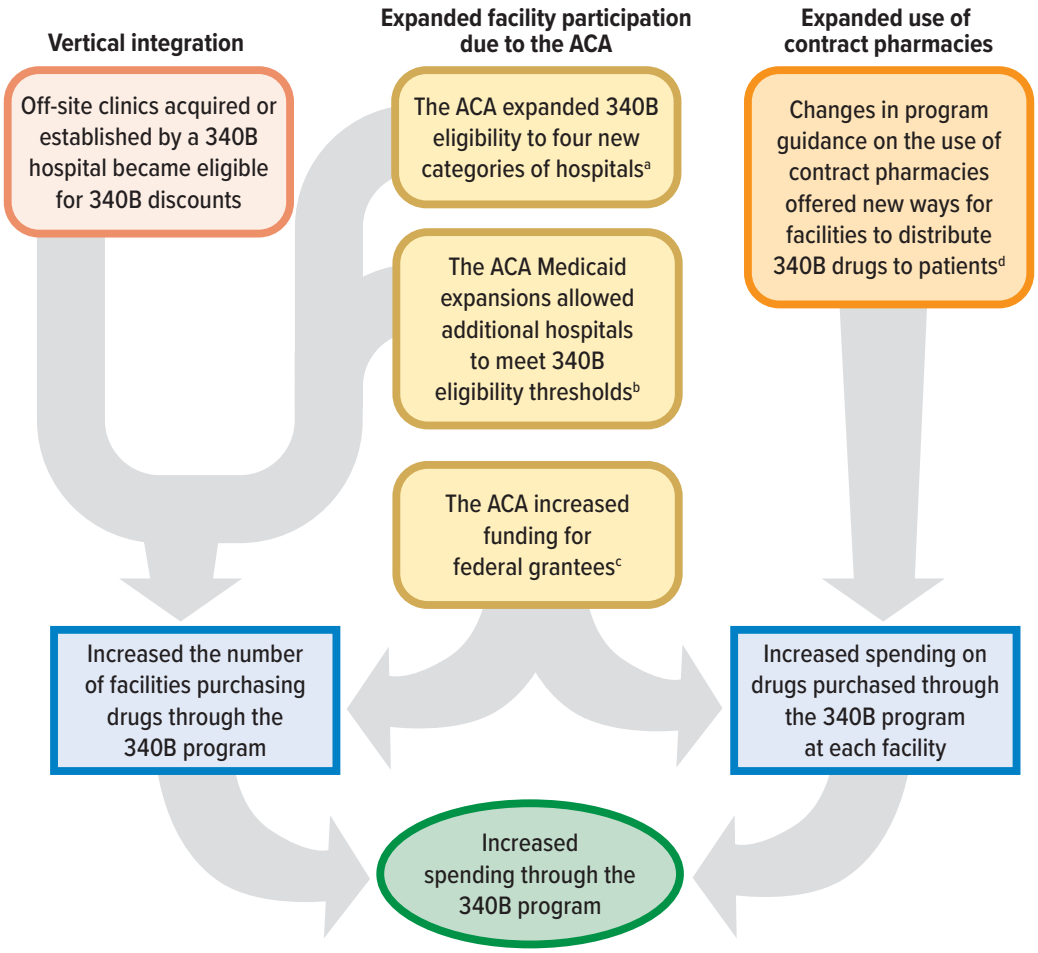
Consolidation with a 340B facility in particular provides additional benefits. When an off-site clinic's services are consolidated with a 340B hospital's services, the practice becomes an off-site outpatient clinic of the 340B hospital. That makes the clinic eligible to purchase drugs at 340B prices. As more off-site clinics are acquired by hospitals and become eligible to purchase drugs at 340B prices, the volume of drugs purchased through 340B increases.

Between 2013 and 2021, the number of off-site outpatient clinics participating in the 340B program increased from about 6,100 to 27,700, and the share of hospitals with at least one off-site outpatient clinic increased from

34. Congressional Budget Office, *Policy Approaches to Reduce What Commercial Insurers Pay for Hospitals' and Physicians' Services* (September 2022), www.cbo.gov/publication/58222.

Figure 11.

Factors Not Related to Trends in Marketwide Spending That Contributed to the Growth in Spending on Drugs Purchased Through the 340B Program, 2010 to 2021



Three factors led to growth in spending on drugs purchased through the 340B program by increasing the number of facilities that participate in the program, by increasing the dollar amount spent at each facility, or both.

Data source: Congressional Budget Office.

ACA = Affordable Care Act.

a. The four types of hospitals are critical access hospitals, freestanding cancer centers, rural referral centers, and sole community hospitals.

b. Medicaid expansion increased hospitals' disproportionate patient percentages by increasing the number of Medicaid patients served by hospitals in states that expanded access to Medicaid.

c. The ACA established the Community Health Center Fund, which provides mandatory funding that the Health Resources and Services Administration (HRSA) allocates to health centers.

d. Beginning in 2010, HRSA guidelines allowed 340B facilities to contract with an unlimited number of off-site pharmacies.

50 percent to 76 percent.[35] Those increases also reflect any improvements in the reporting of off-site outpatient clinics to HRSA and the entry of large health systems (with many off-site outpatient clinics) into the 340B program.

Expanded Participation in the 340B Program Due to the Affordable Care Act. Expanded facility participation resulting from changes in eligibility requirements in the ACA also contributed to growth in spending on drugs purchased through the 340B program from 2010 to 2021. The ACA expanded hospital eligibility for the program in several ways, including allowing four new types of hospitals to qualify for the program: critical access hospitals, freestanding cancer centers, rural referral centers, and sole community hospitals.[36] In 2021, about 6,900 facilities qualified for the 340B program under one of those designations, including 1,400 participating hospitals and 5,500 hospital off-site outpatient clinics. They accounted for about $2.6 billion (or 6 percent) of total spending on drugs through the 340B program in 2021.

The ACA also increased the number of hospitals eligible for the 340B program indirectly through its Medicaid expansions, which permitted states to expand Medicaid coverage to adults with income below a certain threshold. Most hospitals must have a disproportionate patient percentage that exceeds a certain threshold to be eligible for the 340B program. Because the disproportionate patient percentage is determined in part by the proportion of Medicaid patients served by the hospital, as states opted to expand Medicaid beginning in 2014, hospitals in those states began serving more Medicaid patients, thereby increasing the number of eligible hospitals.

From 2014 to 2017, the number of participating hospitals that qualified on the basis of their disproportionate patient percentage grew more quickly in states that expanded Medicaid than it did in states that did not expand Medicaid (see Figure 12). That trend was not observed among critical access hospitals, which qualify for 340B regardless of their disproportionate patient percentage.[37]

The ACA also increased funding for HRSA-funded health centers and expanded access to insurance coverage among patients using those centers.[38] In CBO's assessment, those changes enabled the health centers to expand the services they provide. Because some of those services included providing more drugs purchased at the 340B discounted price, the changes contributed to growth in 340B spending. From 2010 to 2021, the number of HRSA-funded health center sites participating in the 340B program grew from 3,548 to 10,679, and spending by those facilities on drugs purchased through the PVP grew from $292 million to $2.24 billion.

Expanded Use of Contract Pharmacies. The expanded use of contract pharmacies increased the proportion of prescriptions for which 340B facilities received a 340B discount. When an eligible provider at a 340B facility writes a prescription for a self-administered drug, the patient may choose where to fill that prescription. If the facility does not have an agreement with an off-site (contract) pharmacy, that facility only receives the discounted price if the patient fills the prescription through the facility's on-site pharmacy. If the facility has an agreement with an off-site pharmacy, however, the facility may dispense discounted drugs through its on-site pharmacy or at that contract pharmacy.[39]

35. Because of changes in reporting requirements for off-site outpatient clinics, 2013 is the first year for which reliable data exist on the number of such facilities in the program. A coronavirus pandemic–era waiver that removed requirements for hospitals to register off-site locations with HRSA may have led to inaccurate reporting of the number of off-site outpatient clinics in 2020 and 2021. For more information about the waiver, see Registration Requirements in the 340B Drug Pricing Program, 88 Fed. Reg. 73859 (October 27, 2023), https://tinyurl.com/dumrrbyn.

36. The ACA also clarified eligibility rules for freestanding children's hospitals included under the Deficit Reduction Act of 2005.

37. Changes in payer mix during the pandemic temporarily lowered the disproportionate patient percentage for some hospitals. The Consolidated Appropriations Act, 2022, protected hospitals from losing 340B eligibility.

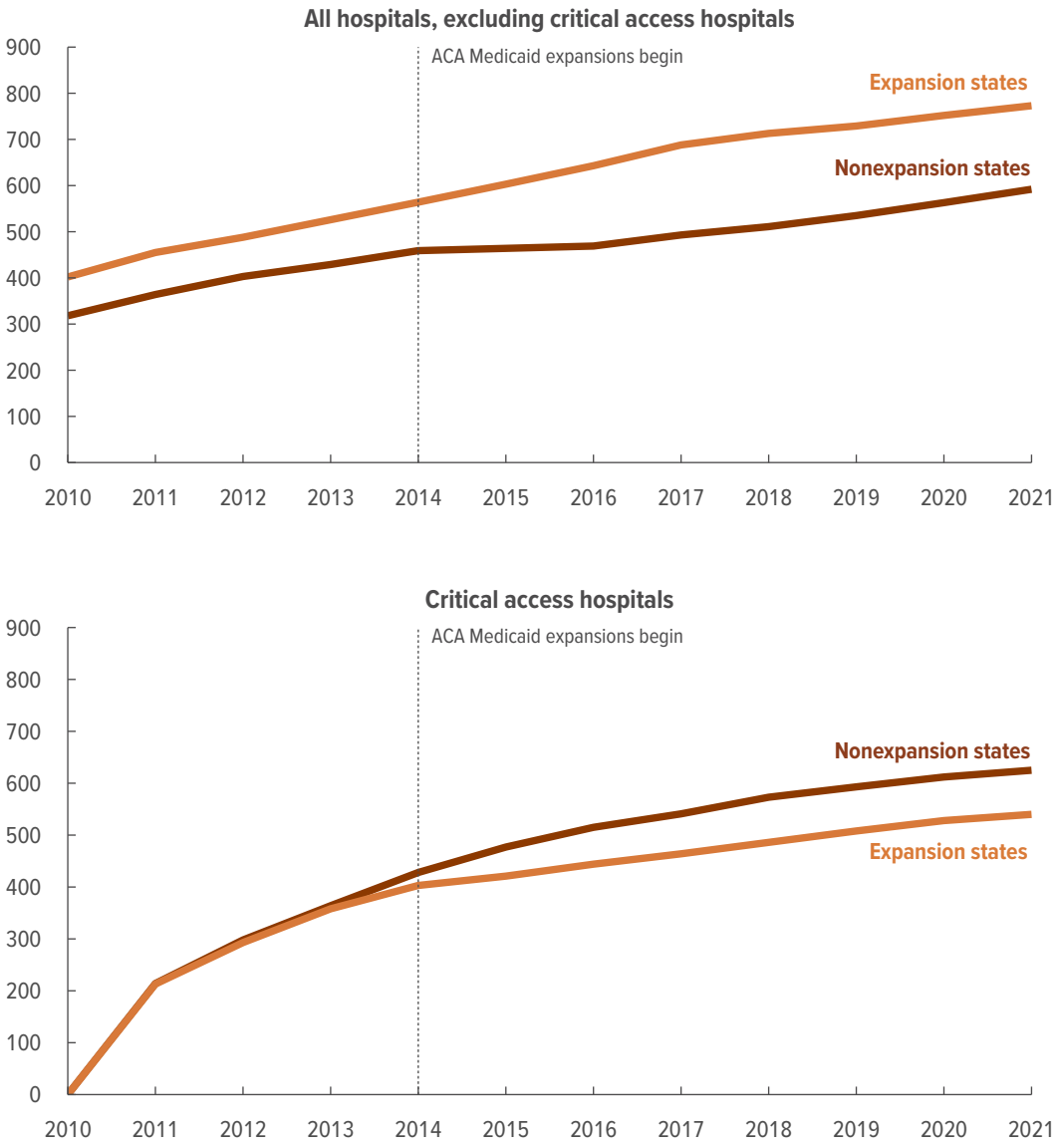
38. In 2010, the ACA established the Community Health Center Fund, which provides funding for HRSA to allocate to health centers through a competitive grant process. As a result, the amount of federal funding for such facilities increased from $2.2 billion in 2010 to $5.6 billion in 2019. Expanded Medicaid access contributed to a 97 percent increase in Medicaid payments to health centers from 2010 to 2017 as more of their patients qualified for Medicaid. See Sara Rosenbaum and others, "Community Health Center Financing: The Role of Medicaid and Section 330 Grant Funding Explained" (KFF, March 26, 2019), https://tinyurl.com/3c5vvksm. Other measures—such as the American Rescue Plan Act—have subsequently increased funding for HRSA-funded health centers.

39. Sayeh Nikpay and others, "Trends in 340B Drug Pricing Program Contract Growth Among Retail Pharmacies From 2009 to 2022," *JAMA Health Forum*, vol. 4, no. 8 (August 2023), e232139, https://doi.org/10.1001/jamahealthforum.2023.2139.

Figure 12.

Hospitals Participating in the 340B Program, by Hospital Type

Number of hospitals



States that expanded Medicaid under the ACA saw faster growth in the number of participating hospitals that qualified for the 340B program on the basis of the share of their patients who have low income (as measured by hospitals' disproportionate patient percentage) than did states that opted not to expand access to Medicaid. Critical access hospitals qualify regardless of the share of their patients who have low income; therefore, the expansion of Medicaid did not affect their rate of participation in the program.

Data source: Congressional Budget Office, using data from the Health Resources and Services Administration, Office of Pharmacy Affairs System, https://340bopais.hrsa.gov/. See www.cbo.gov/publication/60661#data.

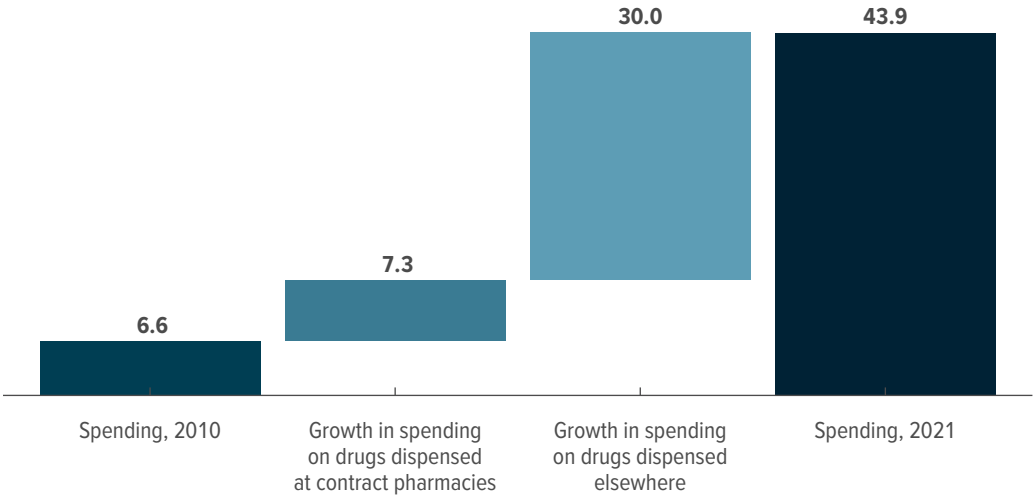
CBO considered a state an expansion state if it expanded Medicaid before January 1, 2015. Critical access hospitals are the only type of hospital that do not need to meet a disproportionate patient percentage to qualify for the 340B program. The disproportionate patient percentage is determined, in part, by the proportion of Medicaid patients served by the hospital.

ACA = Affordable Care Act.

Figure 13.

Growth in Spending on Drugs Purchased Through the 340B Program at Contract Pharmacies and Other Locations, 2010 to 2021

Billions of dollars



About 20 percent of the growth in 340B spending over the 2010–2021 period is attributable to spending on drugs dispensed at contract pharmacies.

Data source: Congressional Budget Office, using data from the Health Resources and Services Administration. See www.cbo.gov/publication/60661#data.

Amounts are adjusted for inflation using the gross domestic product price index and are expressed in 2021 dollars.

Spending refers to the dollar amount that participating facilities spent on discounted drugs purchased through the 340B program, as reported by the Prime Vendor Program. Approximately 10 percent of 340B facilities do not participate in the Prime Vendor Program.

In 2010, HRSA modified 340B guidance to allow all 340B facilities to contract with an unlimited number of pharmacies, and the number of arrangements between 340B facilities and contract pharmacies increased from about 2,000 in 2010 to nearly 130,000 in 2021.[40] As those arrangements became more prevalent, the proportion of prescriptions written by a 340B facility that were dispensed with a drug purchased through the 340B program increased. According to a recent study, that proportion rose from 18 percent in 2013 to 50 percent in 2020.[41] CBO estimates that spending on drugs purchased through the 340B program and dispensed at contract pharmacies grew by an average of 34 percent per year from 2010 to 2021, whereas drugs purchased through the 340B program but distributed elsewhere grew at a rate of 17 percent per year. As a result, the proportion of 340B spending occurring through contract pharmacies increased from 4 percent in 2010 to 17 percent in 2021.

In CBO's assessment, however, at most about 20 percent of 340B spending growth from 2010 to 2021 can be attributed to drugs dispensed by contract pharmacies (see Figure 13). And some of that spending growth is probably attributable to shifts in dispensing location rather than to new spending. That is, some of the drugs that were sold at a 340B facility's in-house pharmacy shifted to being sold at a contract pharmacy. Those shifts would contribute to growth in 340B spending through contract pharmacies but not to 340B spending growth overall. Some of the spending growth attributed to drugs dispensed at contract pharmacies also reflects overall growth in prescription drug use over the 2010–2021 period rather than growth specific to the program.

The 340B Drug Pricing Program and the Federal Budget

In CBO's assessment, the 340B program mainly affects the federal budget by encouraging behaviors that tend to increase federal spending because they lead to higher prices or an increased use of drugs and other health care services. Those behaviors include the following:

40. Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (March 5, 2010), https://tinyurl.com/bdduywhd.

41. The study is limited to drugs sold through Medicare Part D, but the findings suggest an increase in the proportion of prescriptions for which 340B facilities dispense a 340B drug across the program. See Sean Dickson, Nico Gabriel, and Inmaculada Hernandez, "Trends in Proportion of Medicare Part D Claims Subject to 340B Discounts, 2013–2020," *JAMA Health Forum*, vol. 4, no. 11 (November 2023), e234091, https://doi.org/10.1001/jamahealthforum.2023.4091.

- Clinicians prescribe more drugs and drugs that cost more.
- Pharmaceutical manufacturers reduce rebates for 340B drugs.
- Participating facilities expand the services they provide.
- More hospitals and off-site clinics integrate.

The 340B program increases federal spending in other ways as well, through the effect of the program's penny-pricing policy on Medicaid drug spending (see below) and the funding that the Congress appropriates to HRSA for program administration and oversight. In CBO's assessment, their effects are smaller than those associated with the behaviors that the program encourages.

The existence of the 340B program may encourage insurers to pay lower reimbursement rates. That would reduce federal costs, but any such effects are probably small. If expanded services at 340B facilities improve patients' health and patients need less costly care as a result, those expansions could reduce federal costs, but when and by how much is uncertain.

Prescription of More Drugs and Drugs That Cost More

Because 340B facilities generate net revenue when they dispense drugs purchased through the program, those facilities have an incentive to prescribe more drugs and to shift prescriptions to drugs for which the difference between the insurance rate and the 340B discounted price is large. Increasing prescription volume results in higher spending on drugs by federal insurers and in larger federal subsidies for insurance premiums. To the extent to which drugs that generate greater net revenue are also more expensive, shifting prescription volume to those drugs also results in higher federal spending. Evidence shows that 340B facilities spend more on prescription drugs than non-340B facilities do.[42] CBO does not have the data to determine whether higher spending is caused by 340B facilities' prescribing more drugs, more expensive drugs, or both.

Reductions in Negotiated Rebates for Insurers

Manufacturers often negotiate rebates with Medicare Part D, Medicare Advantage, and commercial insurance plans and their pharmacy benefit managers in exchange for a greater volume of sales (achieved through, for example, favorable formulary placement). The interaction of those rebates and the 340B program may increase insurers' drug costs for two reasons. First, the agreements between manufacturers and plans may explicitly prohibit plans from receiving rebates for drugs purchased through the 340B program to ensure that manufacturers do not have to pay additional rebates for drugs already sold at a discounted price.[43] When insurers' payment rates are unaffected by the 340B discounts that providers receive, agreements prohibiting additional rebates increase drug costs for insurers.[44]

Second, manufacturers of drugs frequently purchased through the 340B program face incentives to limit the largest rebates offered to commercial insurers because of

42. Sean Dickson and Katelyn James, "Trends in HIV Preexposure Prophylaxis Utilization and Spending Among Individuals With Commercial Insurance," *AIDS*, vol. 38, no. 4 (March 2024), pp. 610–612, https://doi.org/10.1097/qad.0000000000003809; Amelia M. Bond, Emma B. Dean, and Sunita M. Desai, "The Role of Financial Incentives in Biosimilar Uptake in Medicare: Evidence From the 340B Program," *Health Affairs*, vol. 42, no. 5 (May 2023), pp. 632–641, https://doi.org/10.1377/hlthaff.2022.00812; Jessica Chang and others, "Association Between New 340B Program Participation and Commercial Insurance Spending on Outpatient Biologic Oncology Drugs" *JAMA Health Forum*, vol. 4, no. 6 (June 2023), e231485, https://doi.org/10.1001/jamahealthforum.2023.1485; Michael T. Hunter, Katie Holcomb, and Carol Kim, *Analysis of 2020 Commercial Outpatient Drug Spend at 340B Participating Hospitals,* Milliman White Paper (Milliman, September 2022), https://tinyurl.com/2wps8kw6; Medicare Payment Advisory Commission, "Congressional Request on Health Care Provider Consolidation," in *Report to the Congress: Medicare Payment Policy* (March 2020), https://tinyurl.com/mu29w2a9; and Government Accountability Office, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442 (June 2015), www.gao.gov/assets/d15442.pdf.

43. A 2014 government audit of rebate contracts between drug manufacturers and Medicare Part D insurers found that about half of all contracts included language stating that Part D rebates would not be applied to drugs filled at 340B contract pharmacies. See Department of Health and Human Services, Office of the Inspector General, *Medicare Part D Rebates for Prescriptions Filled at 340B Contract Pharmacies*, A-03-16-00002 (July 2019), https://tinyurl.com/5adezc73. For more information about the prohibition on "duplicate discounts" that prevents manufacturers from paying rebates under the Medicaid Drug Rebate Program to the state for drugs purchased through the 340B program, see Government Accountability Office, *340B Drug Discount Program: Oversight of the Intersection With the Medicaid Drug Rebate Program Needs Improvement*, GAO-20-212 (January 2020), www.gao.gov/products/gao-20-212.

44. The IQVIA Institute estimates that the 340B program increased drug costs for self-insured employers by 4.2 percent in 2021 because plans lost manufacturer rebates when drugs were purchased at the 340B discounted price. See Chuan Sun, Shanyue Zeng, and Rory Martin, *The Cost of the 340B Program Part I: Self-Insured Employers* (IQVIA Institute, March 2024), https://tinyurl.com/hrpwbsy2.

the way various prescription drug rebates are calculated. (That is, the biggest discount provided to commercial payers has to be provided on every unit covered by Medicaid or sold under the 340B program.) Smaller discounts to commercial insurers allow manufacturers to secure higher 340B ceiling prices and increase the price of affected drugs in the commercial market.[45]

Higher drug costs raise the federal deficit in two ways: Higher spending for drugs covered by Medicare plans and Medicaid managed care plans increases outlays for those programs, and higher spending for drugs reimbursed by employment-based and nongroup plans increases federal tax subsidies.

Expanded Services

Participating facilities may use net revenue generated through the 340B program to offer new types of services, some of which require prescribing drugs. Surveys and self-reported data from 340B facilities indicate that such facilities use 340B net revenues to open specialty clinics, subsidize uncompensated care, and offer additional patient services, such as transportation to and from appointments.[46]

If some of the new services are covered by federal or commercial insurance plans, the federal deficit increases for the same reasons that it does when manufacturers negotiate higher reimbursement rates: Higher spending for services covered by Medicare and Medicaid increases outlays for those programs, and higher spending for services reimbursed by commercial insurers increases federal tax subsidies for insurance.

Providing additional services may also improve patients' health, which may result in savings if people need less costly care as a result. But the timing and magnitude of any such savings would vary depending on the services offered and the population affected.

Increased Vertical Integration

Vertical integration of hospitals and off-site clinics generally increases the prices that commercial insurers and Medicare pay.[47] Consolidation gives providers more leverage in negotiations with insurers. In addition, consolidated providers can charge additional fees (such as facility fees) because their services are affiliated with a hospital, and Medicare rates at hospital-affiliated settings are higher than the rates at independent clinics or doctors' offices.[48] When the prices that federal programs and commercial insurers pay for health care goods and services increase, outlays for federal programs and federal subsidies for commercial insurance premiums also increase.[49]

In CBO's assessment, the 340B program is one of several factors that incentivize the integration of hospitals and off-site clinics. To the extent that the program amplifies those incentives, it increases the federal deficit. However, evidence that the 340B program intensifies broader market-based incentives is mixed.[50]

45. The best price component of the Medicaid basic rebate discourages manufacturers from agreeing to pay higher rebates to commercial payers by making it more costly for manufacturers to increase the largest rebate to those payers. The best price provisions can therefore lead to higher average prices for brand-name drugs, particularly those for which Medicaid or the 340B program accounts for a large share of sales. For more information about the effect of the Medicaid basic rebate on commercial prices, see Mark Duggan and Fiona M. Scott Morton, "The Distortionary Effects of Government Procurement: Evidence From Medicaid Prescription Drug Purchasing," *Quarterly Journal of Economics*, vol. 121, no. 1 (February 2006), pp. 1–30, https://academic.oup.com/qje/article/121/1/1/1849004.

46. See Ryan P. Knox and others, "Outcomes of the 340B Drug Pricing Program: A Scoping Review," *JAMA Health Forum*, vol. 4, no. 11 (November 2023), e233716, https://doi.org/10.1001/jamahealthforum.2023.3716.

47. Congressional Budget Office, *The Prices That Commercial Health Insurers and Medicare Pay for Hospitals' and Physicians' Services* (January 2022), www.cbo.gov/publication/57422.

48. Jessica Chang and Aditi Sen, *Rising Share of Chemotherapy Services Provided in Outpatient Departments Is Associated With Higher Costs for Patients and Payers* (Health Care Cost Institute, March 2023), https://tinyurl.com/ysmk8vp9; Jessica Chang, Aditi Sen, and Cristina Boccuti, *Price Markups for Clinical Labs: Employer-Based Insurance Pays Hospital Outpatient Departments 3X More Than Physician Offices and Independent Labs for Identical Tests* (Health Care Cost Institute, July 2022), https://tinyurl.com/he9nehsc; Jessica Chang and others, "Site of Care Potentially Limits Cost Savings From Biosimilars," *American Journal of Managed Care*, vol. 27, no. 8 (August 2021), https://tinyurl.com/4vbhjayj; and Aaron N. Winn and others, "Spending by Commercial Insurers on Chemotherapy Based on Site of Care, 2004–2014," *JAMA Oncology*, vol. 4, no. 4 (April 2018), pp. 580–581, https://doi.org/10.1001/jamaoncol.2017.5544.

49. Congressional Budget Office, *Policy Approaches to Reduce What Commercial Insurers Pay for Hospitals' and Physicians' Services* (September 2022), www.cbo.gov/publication/58222.

50. Some evidence suggests that the program leads to additional integration, and other evidence shows similar trends in integration between 340B and non-340B hospitals and physician practices. See Sunita Desai and J. Michael McWilliams, "Consequences of the 340B Drug Pricing Program," *New England Journal of Medicine*, vol. 378, no. 6 (February 2018), pp. 539–548, https://doi.org/10.1056/NEJMsa1706475; and Abby Alpert, Helen Hsi, and Mireille Jacobson, "Evaluating the Role of Payment Policy in Driving Vertical Integration in the Oncology Market," *Health Affairs*, vol. 36, no. 4 (April 2017), pp. 680–688, https://doi.org/10.1377/hlthaff.2016.0830.

Other Factors That Increase Federal Spending

The 340B program increases Medicaid fee-for-service (FFS) spending when Medicaid FFS beneficiaries receive drugs purchased through the program because of a policy known as penny pricing. Consider a drug for which the Medicaid rebate is larger than or equal to the average manufacturing price. If that drug is purchased outside the 340B program, the Medicaid program receives a rebate, making the net cost to Medicaid either zero or negative. By contrast, if that drug is purchased through the 340B program, the 340B price is set at $0.01, and Medicaid FFS reimburses 340B facilities at that price.[51] Therefore, as 340B facilities dispense more of those drugs to Medicaid beneficiaries, state Medicaid FFS programs must reimburse for those drugs, and they lose the rebates that they would otherwise have received if the drugs were not distributed through the 340B program.

Additionally, the 340B program affects the federal budget through funding that the Congress appropriates to HRSA for program administration and oversight. In fiscal year 2024, the Congress appropriated $12.2 million to HRSA to audit 340B facilities and contract pharmacies and to establish a contract with the 340B prime vendor, among other operations.[52]

51. For more information about penny pricing, see 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation, 82 Fed. Reg. 1210 (January 5, 2017), https://tinyurl.com/3tv5ujtu.

52. Health Resources and Services Administration, "FY 2024 Operating Plan" (May 2024; archived March 9, 2025), https://tinyurl.com/2t22tccz.

Lower Reimbursement Rates for 340B Drugs

Since 340B facilities generate net revenues when they purchase discounted drugs through the program, they might agree to a lower negotiated price than a non-340B facility would in order to attract a greater market share of patients, particularly in competitive markets or for drugs for which the insurer is not eligible to receive a rebate from the manufacturer. If Medicare or Medicaid managed care plans pay lower reimbursement rates to facilities and contract pharmacies participating in the 340B program, outlays for federal insurance programs decrease as a result.[53] If commercial insurers pay less, federal subsidies for commercial insurance premiums decrease.[54] However, no evidence exists about the extent to which insurers treat 340B providers differently in negotiations.

53. Medicare Part B previously paid a lower rate for drugs purchased through the 340B program. Starting in 2018, CMS reduced Part B drug reimbursement for separately payable drugs or biologics acquired through the 340B program and furnished by a hospital paid under the Outpatient Prospective Payment System. The calculation for reimbursement was changed from the average sales price (ASP) plus 6.0 percent to ASP minus 22.5 percent. However, that payment policy was reversed by the Supreme Court in 2022. See Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022, 88 Fed. Reg. 44078 (July 11, 2023), https://tinyurl.com/97da9hhk. For additional information about the change in outlays associated with reducing Medicare Part B payment rates, see Congressional Budget Office, *Options for Reducing the Deficit, 2025 to 2034* (December 2024), p. 24, www.cbo.gov/publication/60557.

54. Congressional Budget Office, *Policy Approaches to Reduce What Commercial Insurers Pay for Hospitals' and Physicians' Services* (September 2022), www.cbo.gov/publication/58222.

Appendix A: Glossary

340B ceiling price: The maximum price a manufacturer can charge 340B facilities for a drug. The 340B ceiling price is equal to the difference between the drug's average manufacturer price and its Medicaid unit rebate.

340B Drug Pricing Program: A federal program in which participating health care facilities purchase outpatient drugs at statutorily discounted prices. The program was created by the Veterans Health Care Act of 1992 and codified in section 340B of the Public Health Service Act.

340B facilities: Health care organizations that participate in the 340B Drug Pricing Program. Those include hospital-based facilities and federal grantees. HRSA refers to providers that are eligible to participate in section 340B of the Public Health Service Act as covered entities. The Congressional Budget Office's count of 340B facilities may differ from HRSA's count of covered entities because CBO treats hospitals and their off-site clinics as well as federal grantees and their service delivery sites as separate facilities.

340B price: The dollar amount that a 340B facility pays for a drug purchased through the 340B program. That price is equal to the 340B ceiling price minus any additional discounts. Additional discounts consist of discounts negotiated by the prime vendor on behalf of a facility as well as any discounts the facility negotiates directly with the manufacturer.

Average manufacturer price (AMP): The average price paid to a manufacturer by wholesalers and pharmacies that purchase directly from the manufacturer. The AMP does not account for rebates or other price concessions that manufacturers provide to pharmacy benefit managers or health insurers. Manufacturers report the AMP for each drug to the Centers for Medicare & Medicaid Services (CMS).

Best price: The lowest net price for a drug available to any private-sector purchaser (not including Medicare Part D plans). The best price reflects discounts, rebates, and other pricing adjustments. Manufacturers report the best price for each drug to CMS. Data on the best price are not publicly available and are used to calculate the Medicaid basic rebate.

Centers for Medicare & Medicaid Services (CMS)

Community hospitals: Nonfederal, short-term general, or other speciality hospitals (including long-term acute care and rehabilitation and orthopedic hospitals). Academic medical centers are considered community hospitals if they are nonfederal and short-term hospitals. In 2021, there were 5,157 community hospitals in the United States; 2,978 of those operated as nongovernment nonprofit hospitals, 1,235 operated as investor-owned for-profit hospitals, and 944 operated as state or local government hospitals.

Contract pharmacy: An off-site retail or specialty pharmacy that has an agreement with a 340B facility to dispense drugs purchased through the 340B program on the facility's behalf. Without a contract pharmacy arrangement, a 340B facility cannot dispense drugs purchased through the program at an off-site pharmacy location.

Critical access hospitals: A category of hospitals eligible to participate in the 340B program. CMS certifies hospitals as critical access hospitals on the basis of a variety of measures, including hospital size and location. Critical access hospitals do not need to serve a set share of patients with low income.

Disproportionate share hospitals (DSHs): A category of hospitals eligible to participate in the 340B program. Disproportionate share hospitals serve patients with low income and receive payments from CMS to cover the costs of providing care to uninsured patients. To be eligible for the 340B program, a hospital must have a disproportionate patient percentage greater than 11.75 percent. The disproportionate patient percentage is based on two factors: the share of the hospital's Medicare patients who are also eligible for Supplemental Security Income and the share of patients eligible for Medicaid. Eligibility is not based on a hospital's participation in the Medicaid Disproportionate Share Hospital Program, which is run by states and reimburses hospitals for uncompensated care for Medicaid and uninsured patients.

Federal grantees: A category of 340B facilities that encompasses clinics designated as eligible because they

receive certain federal grants, are identified as look-alike health centers, or meet some other qualification. They include federally qualified health centers (FQHCs), Ryan White HIV/AIDS clinics, and other specialized clinics.

Federally qualified health centers (FQHCs): A category of federal grantees eligible to participate in the 340B program. Most FQHCs that participate in 340B receive funding through section 330 of the Public Health Service Act (HRSA's Health Center Program) to provide comprehensive primary care services to individuals in medically underserved areas, regardless of an individual's ability to pay. In addition to health centers funded under section 330, this category of federal grantees includes "look-alike" health centers, which do not receive Section 330 funding but meet all the requirements of that statute, and tribal and urban Indian health centers. In this report, CBO includes Native Hawaiian health centers in the same category as FQHCs.

Freestanding cancer hospitals: A category of hospitals eligible to participate in the 340B program. To participate, freestanding cancer hospitals must be independent and nonprofit. They also must have either a disproportionate patient percentage greater than 11.75 percent or meet a separate set of criteria, including being located in an urban area, having 100 or more beds, and having at least 30 percent of their net revenue come from state and local governments or Medicaid.

Health Resources and Services Administration (HRSA)

Hospital-based facilities: A category of 340B facilities that encompasses nonprofit and public hospitals and their off-site outpatient clinics. Six types can apply to the 340B program: disproportionate share hospitals, children's hospitals, critical access hospitals, freestanding cancer hospitals, rural referral centers, and sole community hospitals. Except for critical access hospitals, hospital-based facilities must serve a certain share of patients with low income to be eligible for the 340B program.

Look-alike health centers: Clinics that do not receive HRSA funding but that are eligible to participate in the 340B program because they meet certain HRSA requirements.

Marketwide spending: The dollar amount (net of discounts and rebates) that public and private (commercial) payers and patients pay for prescription drugs. Only brand-name drugs sold by publicly traded companies are included in marketwide spending calculations.

Medicaid unit rebate: The rebate provided by manufacturers to Medicaid programs under the Medicaid Drug Rebate Program. The rebate is divided into two components. The basic rebate is generally 23.1 percent of the AMP for a brand-name drug (13.0 percent of the AMP for a generic drug) or the difference between the AMP and the best price, whichever is higher. The inflation-based rebate is an additional rebate provided for drugs whose AMP grows faster than overall inflation as measured by the consumer price index for all urban consumers. The rebate is equal to the excess amount of that growth.

National Drug Code (NDC): Unique product numbers used to identify drugs for human use in the United States. The NDC is an 11-digit number that indicates the manufacturer, drug product, and package size.

Off-site outpatient clinics: Outpatient clinics that are part of a nonprofit or public hospital that is eligible for the 340B program but are not on the same campus as the hospital. Those clinics may be a standalone clinic or a subcomponent of a provider, such as a department of an off-campus facility. Off-site outpatient clinics may participate in the 340B program as long as they are listed as reimbursable on the hospital's most recently filed Medicare cost report and are registered with HRSA. HRSA refers to such clinics as child sites.

Prime Vendor Program (PVP): A program through which HRSA contracts with an external organization, known as the prime vendor, to set up drug distribution networks, negotiate subceiling discounts on behalf of participating facilities, and provide facilities with education and technical support. Participation in the Prime Vendor Program is optional for 340B facilities.

Rural referral centers: A category of hospitals eligible to participate in the 340B program. Rural referral centers are designated by CMS on the basis of their status as a high-volume acute care hospital that serves rural communities. To participate in the program, rural referral centers must have a disproportionate patient percentage greater than or equal to 8 percent.

Sole community hospitals: A category of hospitals eligible to participate in the 340B program. CMS classifies hospitals as sole community hospitals if they are more than 35 miles from the closest similar hospital. (Less remote hospitals may be designated as sole community hospitals if they meet other criteria.) To participate in the 340B program, these hospitals must have a disproportionate patient percentage greater than or equal to 8 percent and must

be under contract with, owned or operated by, or granted governmental powers by a state or local government.

Spending: The dollar amount that 340B facilities spend on discounted drugs purchased through the 340B Prime Vendor Program.

SSR Health data: A dataset that provides a quarterly measure of spending by all payers on brand-name drugs sold by publicly traded companies. This measure of spending reflects discounts and rebates provided by drug manufacturers.

Vertical integration: The acquisition or establishment of an off-site clinic, such as an infusion center or a specialty medical practice, by a hospital or hospital system.

Appendix B: Data and Methods Used in This Report

The Congressional Budget Office relied on data from the Health Resources and Services Administration (HRSA), SSR Health, and Micromedex Red Book (produced by Merative) for its analyses. This appendix describes those data as well as CBO's methods for classifying drug classes and routes of administration.

340B Discounted Drug Purchases

CBO measured spending on discounted drug purchases in the 340B Drug Pricing Program from 2010 to 2021 using data from HRSA. The data are an aggregation of transaction data as captured by the Prime Vendor Program at a given point in time and are accurate as of April 1, 2023.[1] The data do not capture all 340B program sales, because about 10 percent of 340B facilities do not participate in the Prime Vendor Program.[2]

CBO obtained 340B spending data at the National Drug Code (NDC) level. NDCs are unique product numbers used to identify drugs for human use in the United States. The data measure spending at the NDC level in the program overall, by covered entity type, and by whether the drug was distributed through a contract pharmacy. The available data do not allow CBO to analyze purchases made by individual 340B facilities.

1. The prime vendor includes "value added" products in its annual purchase totals. Those products include items such as vaccines, test strips, and other items not defined as "covered outpatient drugs" and account for approximately 1 percent of sales under the 340B program.

2. Participation in the Prime Vendor Program is voluntary and free. Some 340B facilities do not participate, because they are members of another organization that contracts for them. By law, disproportionate share hospitals, children's hospitals, and free-standing cancer hospitals are prohibited from obtaining covered outpatient drugs through a group purchasing organization or other group purchasing arrangement. For details, see Health Resources and Services Administration, "Statutory Prohibition on Group Purchasing Organization Participation," 340B Drug Pricing Program Notice, Release No. 2013-1 (February 7, 2013), https://tinyurl.com/3d6crpp6.

340B Facilities and Contract Pharmacies

CBO used publicly available data from HRSA's Office of Pharmacy Affairs Information System (OPAIS) to count the number of 340B facilities and contract pharmacies participating in the 340B program in a given year. CBO defined a 340B facility or contract pharmacy as participating in a given year if it was active for a period of at least six months in that year.

CBO also used data from OPAIS to determine the number of active hospital off-site outpatient clinics and qualifying hospitals participating in the 340B program in a given year. To count hospital off-site outpatient clinics, CBO restricted the OPAIS data to participating hospital-based facilities and counted a facility as an off-site outpatient clinic if it had an associated "parent covered entity identifier." If the record did not have an associated parent covered entity identifier in the OPAIS database, CBO defined the facility as a qualifying hospital.

Overall Market

CBO purchased data on spending in the overall market from SSR Health to estimate marketwide prescription drug spending. SSR Health's dataset U.S. Brand Rx Net Pricing Tool estimates marketwide spending by drug product for each quarter for the majority of active U.S. brand-name prescription drugs marketed by publicly traded companies. That measure of spending reflects discounts and rebates provided by drug manufacturers. It includes spending by both public payers and private (that is, commercial) payers as well as any cost sharing by enrollees. Because the data include only brand-name drugs and capture only drugs that are manufactured by publicly traded companies, they do not represent all spending in the prescription drug market.

To calculate annual spending for each drug, CBO first converted the quarterly data by product name to the NDC level using a crosswalk provided by SSR Health.

Table B-1.

Drug Classes

Drug class	Use	Examples
Cancer drugs	To treat cancer	Chemotherapies Immunotherapies Hormone therapies
Anti-infective drugs	To treat infectious diseases	HIV treatments Hepatitis C treatments Antibiotics
Immunosuppressants	To inhibit the activity of the immune system	Rheumatoid arthritis treatments Psoriasis treatments Post–organ transplant treatments Multiple sclerosis treatments
Blood formulation and coagulation drugs	To change the composition of the blood or impact the blood-clotting process	Treatments for anemia Treatments for blood-clotting disorders
Serums, toxoids, and vaccines	To prevent or treat infectious diseases by inducing immunity to those diseases	Vaccinations for infectious diseases and viruses
Respiratory drugs	To treat conditions affecting the respiratory system	Treatments for asthma Treatments for chronic pulmonary obstructive disease Treatments for cystic fibrosis
Hormones and synthetic substances	To increase, decrease, or modify current hormone levels or the production of hormones in the body	Insulins Birth control Cortisone
Central nervous system drugs	To treat medical conditions associated with the functioning of the brain or spinal cord	Antidepressants Treatments for opioid use disorder Nonsteroidal anti-inflammatory drugs
Cardiovascular drugs	To treat medical conditions of the heart and blood vessels	Treatments for hypertension Treatments for hypotension Treatments for high cholesterol
Other (24 drug classes)	Drugs not categorized above, including enzymes, gastrointestinal agents, diagnostic agents, and other miscellaneous agents	n.a.

Data source: Congressional Budget Office, using data from Micromedex Red Book Expanded database (produced by Merative).

n.a. = not applicable.

The agency then summed the quarterly data for each calendar year to calculate annual spending by NDC.

Drug Classes

CBO merged the 340B spending data provided by HRSA and SSR Health with Micromedex Red Book data to determine each drug's class. Micromedex Red Book data contain drug characteristics for nearly all prescription drugs, organized by NDC. CBO purchased the data from IBM Watson Health.

The therapeutic class variable in Micromedex Red Book data is multi-tiered. The first tier contains 35 therapeutic classes. CBO presents spending totals for the 10 classes with the greatest shares of 340B discounted drug purchases in 2021. Most of the remaining classes each account for less than 1 percent of 340B purchases in 2021. For more information about the drug classes CBO examined in this report, see Table B-1.

CBO also used the second-tier therapeutic class grouping (referred to as a drug subclass) in some cases. The second tier breaks down the first-tier therapeutic classes into smaller groups to allow for more granular analysis. There are 236 therapeutic subclasses. CBO used that second-tier grouping to examine spending on cancer

Table B-2.

Routes of Administration

Administration category	Included routes of administration
Physician-administered	Epidural, implantation, intracerebroventric, intracavernosal, intradermal, intrauterine, intraocular, intraperitoneal, intrapleural, intramuscular, intrathecal, intratracheal, intratympanic, intravenous, urethral, and urinary bladder
Self-administered	Buccal mucosa, dental, gingival, ophthalmic, oral, oromucosal, otic, rectal, sublingual, topical application, transdermal, and vaginal
Mixed administration	Inhalation, injection, instillation, irrigation, percutaneous, subcutaneous, and transnasal, and routes classified as multiple routes or not applicable

Data source: Congressional Budget Office.

drugs for specific subclasses (chemotherapies and molecularly targeted therapies), to examine spending on anti-infective drug subclasses (specifically, on HIV and hepatitis C drugs), and to calculate marketwide spending growth by drug class.

Routes of Administration

CBO merged the 340B spending data provided by HRSA with Red Book data to determine each drug's route of administration. The route of administration variable identifies the product's intake or application method. Routes are distinguished by 37 codes. CBO grouped routes of administration into three categories: physician-administered, self-administered, or mixed administration. Mixed administration includes drugs that could be either physician- or self-administered as well as those with multiple routes or no applicable route of administration listed. For the routes of administration included in each category examined in this report, see Table B-2.

List of Tables and Figures

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About This Document

This report was prepared at the request of the Chairman of the Senate Committee on Health, Education, Labor, and Pensions and the Chairman of the House Committee on Energy and Commerce. In keeping with the Congressional Budget Office's mandate to provide objective, impartial analysis, the report makes no recommendations.

Rebecca Sachs and Joshua Varcie (formerly of CBO) prepared the report with guidance from Aditi Sen. David Austin, Colin Baker, Carrie Colla (a consultant to CBO), Ryan Greenfield, Mark Hadley, Tamara Hayford, Daria Pelech, Aaron Pervin, Lara Robillard, Sarah Sajewski, Robert Sunshine (a consultant to CBO), Chapin White, and Kate Young (formerly of CBO) offered comments. Scott Laughery, Grace Lin (a consultant to CBO), John McClelland, and Asha Saavoss provided assistance. Julianna Mack (formerly of CBO), Anthony Montano, Kaylee Nielson, and Joyce Shin fact-checked the report.

Sean Dickson of America's Health Insurance Plans, Robert Nelb of America's Essential Hospitals, Sayeh Nikpay of the University of Minnesota School of Public Health, and Chris Park of the Medicaid and CHIP Payment and Access Commission commented on an earlier draft. The Health Resources and Services Administration provided comments about factual accuracy in the report. The assistance of external reviewers implies no responsibility for the final product; that responsibility rests solely with CBO.

Jeffrey Kling reviewed the report. Caitlin Verboon edited it, and R. L. Rebach created the graphics and prepared the report for publication. The report is available on CBO's website at www.cbo.gov/publication/60661.

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

Phillip L. Swagel
Director
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