APPLIED POLICY®

Congressional Budget Office Report on 340B Program Growth, 2010-2021

EXECUTIVE SUMMARY

On September 9, 2025, the Congressional Budget Office (CBO) published a report, Growth in the 340B Drug Pricing Program, analyzing trends in drug purchases made through the 340B Drug Pricing Program between 2010 and 2021. The report provides background on the program and examines drug purchases through the program, factors driving program spending growth, and the program's impacts on federal spending.

Overall, CBO's assessment found the 340B Program "encourages behaviors that tend to increase federal spending", citing incentives for vertical integration through acquisition or establishment of off-site clinics by existing 340B facilities, expanded options for facility participation through provisions in the Affordable Care Act (ACA), and 2010 Health Resources and Services Administration (HRSA) guidance that allows 340B facilities to contract with an unlimited number of pharmacies.

BACKGROUND

Overview: The 340B Drug Pricing Program requires drug manufacturers participating in Medicaid to sell outpatient drugs at statutorily discounted prices to 340B participating entities, including hospitals, clinics, and other organizations affiliated with state and local governments. Participating facilities are then (generally) reimbursed for these drugs by Medicare, Medicaid, or commercial insurance at higher rates than their acquisition cost, creating net revenues for participating entities. According to HRSA, these additional funds are intended to "enable covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1]

Almost 90 percent of participating facilities are in the Prime Vendor Program (PVP), which is administered by Apexus on behalf of HRSA, and helps establish drug distribution networks, negotiate discounts, and provide technical support. All 340B

[1] https://www.hrsa.gov/opa

Program data from this report was sourced from Apexus, therefore it does not include the 10 percent of facilities which purchase 340B drugs under separate arrangements.

Participants: Participating facilities fall into two groups: hospital-based facilities and federal grantees. Hospital-based facilities must be non-profit or public and typically qualify because more than 11.75 percent of their Medicare patients are eligible for Social Security Income (SSI) or Medicaid, a metric called the disproportionate patient percentage.[2] Federal grantees are nonhospital facilities that qualify for 340B due to their status as a Federally Qualified Health Centers (FQHCs), Ryan White HIV/AIDS Program grantees, or are other specialized clinics.[3] In 2021, hospital-based facilities represented 61 percent of participants but accounted for 87 percent of drugs purchased through the PVP, while federal grantees accounted for 39 percent of participants and 13 percent of purchases.

Pricing: Participating organizations receive discounted drug rates regardless of patient income or insurance status. The 340B ceiling price, or the maximum price manufacturers can charge, is set by statute as a drug's Average Manufacturer Price (AMP) minus the Medicaid unit rebate amount.[4] The AMP price is the average price a manufacturer receives for a drug set to be distributed in retail pharmacies, irrespective of whether the drug is purchased by the retail pharmacy or a wholesaler.

The 340B Program generates revenue because the discounted purchasing price is lower than market prices and insurance payments are often higher than this amount. Net revenues can be used to support expanded services, but participants are not required to report or restrict how they use net revenues, which limits CBO's ability to assess how funds are spent, or which patients benefit. Federal grantees, by contrast, must follow statutory requirements that limit how program revenue may be utilized. Overall, net revenue depends on discounted prices, insurance reimbursement, drugs distributed, patient population, and program administration costs.

See Figure 2 on page 5 of the report for a graphic of how drugs and payments move through the 340B system.

---

[2] Different conditions apply for certain types of hospitals including Critical Access Hospitals and Rural Referral Centers. For more information about 340B eligibility, see: https://www.hrsa.gov/opa/eligibility-and-registration

[3] For more information, see https://www.hrsa.gov/opa/eligibility-and-registration

[4] For drugs where the ceiling price is below $0.01 (e.g. because the Medicaid rebate is larger than the AMP), the drug price is set at $0.01, a policy called penny pricing. For more information, see: https://www.hrsa.gov/about/faqs/what-hrsas-penny-pricing-policy-regarding-340b-ceiling-prices

DRUGS PURCHASED THROUGH THE 340B PROGRAM IN 2021

Healthcare facilities participating in the PVP spent $43.9 billion on 340B drugs in 2021, up from $6.6 billion in 2010 and accounting for 10.8 percent of total net United States drug spending (see Appendix B on page 29 for spending measurement methodology).

2021 Drug Purchases, by Drug Class

70 percent of spending was concentrated in three drug classes:

- **Cancer drugs ($18.1 billion, 41 percent),** including molecularly targeted therapies (87 percent of spending), chemotherapies (8 percent), and hormone therapies (3 percent).
- **Anti-infectives ($6.6 billion, 15 percent),** including HIV/AIDS drugs (85 percent of anti-infective spending) and Hepatitis C drugs (9 percent). Federal Grantees were responsible for $4.4 billion of this total spending, with hospital-based facilities accounting for the remaining $2.2 billion.
- **Immunosuppressants ($6.2 billion, 14 percent)**

Six other drug classes each accounted for at least $0.5 billion of PVP drug spending, totaling $8.5 billion (19 percent). These included blood formulation and coagulation drugs; serums, toxoids, and vaccines; respiratory drugs; hormones and synthetic substances; central nervous system drugs; and cardiovascular drugs. The remaining 24 classes comprised $4.4 billion (10 percent) of 340B purchases.

Approximately half of PVP drug spending ($21.3 billion) was on physician-administered drugs, or drugs injected or infused in a physician's office or out-patient setting. These included 72 percent of facilities' purchases of cancer drug purchases, 57 percent of immunosuppressants, and 3 percent of anti-infectives.

2021 Drug Purchases, by Type of Facility

In 2021, about 87 percent ($38.2 billion) of PVP drug spending was on drugs administered or distributed through hospital outpatient departments or off-site outpatient clinics. These facilities represented only 61 percent of all 340B-participating facilities, suggesting that they purchased higher-cost drugs, filled more 340B prescriptions per facility, or both, compared with federal grantees. Federal grantees accounted for 13 percent ($5.7 billion) of total spending, including through FQHCs ($2.4 billion, 6 percent), Ryan White clinics ($2.2 billion, 5 percent), and specialized clinics ($1.1 billion, 3 percent).

2021 Drug Purchases, by Drug Class and Type of Facility

Drug spending and the type of drugs purchased differed between facilities and federal grantees. For example:

- Almost all spending (99 percent) on cancer drugs came from hospital-based facilities. Hospital-based facilities spent 47 percent of their total spending on cancer drugs, while federal grantees spent less than 1 percent on cancer drugs.
- Immunosuppressants accounted for 16 percent of hospital-based facility spending, compared with just 1 percent for federal grantees.
- Federal grantees devoted 77 percent of their spending to anti-infective drugs: 59 percent at FQHCs, 98 percent at Ryan White clinics, and 75 percent at specialized clinics.

CBO ANALYSIS: FACTORS CONTRIBUTING TO GROWTH IN 340B SPENDING

340B spending increased by $37.3 billion between 2010 ($6.6 billion) and 2021 ($43.9 billion), reflecting an average annual growth rate of 19 percent. In contrast, overall United States prescription drug spending, measured by all payers' spending on brand-name drugs sold by publicly traded companies, increased by about 4 percent per year. CBO argues this growth can be divided into two buckets: factors related to trends in marketwide spending on prescription drugs and other factors.

Factors Related to Trends in Marketwide Spending on Prescription Drugs

CBO attributes one-third ($13.6 billion) of this growth to two factors:

1) **Marketwide growth in spending on prescription drugs:** Overall prescription drug spending grew at an average annual rate of 4 percent between 2010 and 2021.

2) **Disproportionate spending on high-growth drug classes:** $10.4 billion of this growth resulted from 340B facilities' spending concentrated in drug classes that grew faster than the overall market.
    a. The share of spending on cancer drugs was 20 percent higher than the overall market, and 8 percentage points higher for anti-infective drugs. This reflects differences in participating providers, patient populations served by those providers, and the specific drugs prescribed at 340B facilities.
    b. Marketwide spending on cancer drugs and anti-infective drugs grew more quickly than other drugs, at 11 percent and 5 percent per year, respectively, compared with 2 percent per year for other drugs. Growth was driven in part by the introduction of novel treatments, such as cancer immunotherapies and new antiviral therapies for HIV and hepatitis C.

CBO found that actual growth in spending exceeded marketwide spending growth for many drug classes. For example, at the marketwide growth rate, spending on cancer drugs would have increased 3.1 times from 2010 to 2021, but actual 340B spending grew 8.6 times over the same period ($18.1 billion vs. $2.1 billion). See Figure 10 on page 17 of the report for the projected actual growth in spending on drugs purchased

through the 340B Program compared with the projected growth for cancer drugs, anti-infective drugs, immunosuppressants, and other drugs.

Other Factors

After accounting for these marketwide trends, CBO ascribes the remaining two-thirds ($23.7 billion) of spending growth to three other factors:

- **Vertical integration of hospitals and off-site clinics:** Providers have many incentives to consolidate, including higher payment rates, greater bargaining power with insurers, increased scale and scope of practices, access to more and better technology, and eligibility to purchase drugs at 340B prices. From 2013 to 2021, the number of 340B off-site outpatient clinics increased dramatically, growing from 6,100 to 27,700. The share of hospitals with at least one off-site outpatient clinic also grew from 50 to 76 percent.

- **Increased facility participation after ACA implementation:** The ACA extended 340B eligibility to critical access hospitals, freestanding cancer centers, rural referral centers, and sole community hospitals. These facilities now comprise 6 percent of total spending ($2.6 billion) in 2021 across 6,900 locations. Medicaid expansion also indirectly increased facility eligibility by helping facilities reach the qualifying disproportionate patient percentage threshold. The legislation also provided additional resources for HRSA-funded health centers and increased patients' level of insurance coverage for those facilities, enabling these centers to broaden their services and increase 340B drug purchases. Between 2010 and 2021, the number of HRSA-funded health centers more than doubled from 3,548 to 10,679, with spending ballooning from $292 million to $2.24 billion.

- **Expanded use of contract pharmacies:** Expanded contract pharmacy arrangements have increased the proportion of prescriptions where 340B discounts apply. In 2010, HRSA published new guidance that allowed 340B facilities to contract with an unlimited number of contract pharmacies, in stark comparison to the previous maximum of zero or one – depending on whether the facility had an on-site pharmacy.[5] This led to a dramatic rise in the number of contract pharmacy arrangements, growing from 2,000 in 2010 to nearly 130,000 in 2021. Correspondingly, the proportion of 340B spending through contract pharmacies grew from 4 percent to 27 percent over the same period. In CBO's view, a

[5] Previous regulations did not allow 340B facilities with an on-site pharmacy to enter into any contract pharmacy arrangements, while facilities without an on-site pharmacy were permitted to contract with a single pharmacy. To read the Federal Register notice regarding these changes, see: https://www.federalregister.gov/documents/2010/03/05/2010-4755/notice-regarding-340b-drug-pricing-program-contract-pharmacy-services

maximum of 20 percent of 340B spending growth can be attributed to drugs dispensed through contract pharmacies, with some of this growth reflecting overall increases in prescription drug use and shifts in dispensing locations rather than program-specific factors.

THE 340B DRUG PRICING PROGRAM AND THE FEDERAL BUDGET

CBO also expands on how the 340B Program affects the federal budget, including:

- ***Prescription of More Drugs and Drugs That Cost More*:** Facilities are incentivized to prescribe more drugs and to favor those with a large gap between insurance reimbursement and the 340B discount to maximize net revenue. This can increase federal insurers' spending and result in higher federal subsidies for insurance premiums. The report cites several studies showing 340B facilities spend more on prescription drugs than non-340B facilities, but CBO does not have the data determine whether this is caused by higher volume, higher-cost drugs, or both.[6]

- ***Reductions in Negotiated Rebates for Insurers:*** The 340B Program can increase insurer drug costs because 1) some agreements explicitly prohibit rebates for 340B purchases so that manufacturers do not pay additional rebates for already discounted drugs, and 2) manufacturers of frequently purchased 340B drugs may limit the largest rebates offered to commercial insurers to maintain higher 340B ceiling prices and raise commercial drug prices. Higher drug costs increase the federal deficit because 1) higher spending for drugs covered by Medicare and Medicaid managed care programs raises federal outlays, and 2) higher spending for drugs reimbursed by commercial plans increases federal tax subsidies.

- ***Expanded Services**:* 340B facilities can use net revenue to fund services like opening specialty clinics, subsidizing uncompensated care, and offering patient assistance services. If covered by insurance, these services increase the federal deficit by raising program outlays and tax subsidies. Expanded services at 340B facilities could improve patient health which may reduce the need for more costly care, but the timing and magnitude of such savings are uncertain.

- ***Increased Vertical Integration:*** Greater vertical integration offers providers greater bargaining power and the ability to charge hospital-associated fees (including facility fees). These both increase the prices federal programs pay for goods and services, as well as increasing outlays for federal subsidies.

---

[6] For more information, see footnote 42 in the CBO report.

- ***Lower Reimbursement Rates for 340B Drugs****:* 340B facilities may agree to lower negotiated prices for drugs than non-340B facilities to attract a greater market share of patients, especially in competitive markets or for drugs where the insurer is ineligible to receive a manufacturer rebate. If Medicare or Medicaid managed care plans pay lower reimbursement rates to 340B-participating facilities and associated contract pharmacies, federal program outlays decrease. If commercial payers pay less, federal subsidies for premiums decrease. However, CBO does not have detailed evidence regarding the extent to which insurers treat 340B providers differently in negotiations.
- ***Other:*** CBO also briefly discusses increasing Medicaid fee-for-service penny-pricing[7] and additional funding requirements for HRSA oversight.

[7] For drugs where the ceiling price is below $0.01 (e.g. because the Medicaid rebate is larger than the AMP), the drug price is set at $0.01, a policy called penny pricing. For more information, see: https://www.hrsa.gov/about/faqs/what-hrsas-penny-pricing-policy-regarding-340b-ceiling-prices