

November 21, 2025

Unintended Consequences: How the 340B Program Impacts Patients Across the Healthcare System

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Key 340B Terms

| Term | Definition |
|-------------------------------|---|
| Covered Entity (CE) | Healthcare organization that qualifies for 340B discounts, including hospitals that serve patients that are low income and/or uninsured (e.g., Disproportionate Share Hospital [DSH], children's hospitals) or are federal grantees (e.g., Federally Qualified Health Centers [FQHC], Ryan White Human Immunodeficiency Virus [HIV]/Acquired Immunodeficiency Syndrome [AIDS] clinics). |
| Child Site | An off-site clinic that is owned and operated by a CE and is eligible to participate in the 340B program. |
| Contract Pharmacy (CP) | Pharmacies that agree to dispense 340B drugs on behalf of a CE to eligible patients. |

Executive Summary

The 340B Drug Pricing Program requires drug manufacturers to provide discounted outpatient drugs to eligible sites of care (SOCs) in an effort to stretch federal resources to better serve patients. The evolution of the 340B Drug Pricing Program has had unintended consequences for patients, including those who do not directly benefit from the program. Stakeholders, including employers, taxpayers, and providers, are affected by the changes the 340B program has created within the healthcare ecosystem, with downstream impacts on patients.

Employer-sponsored plans may be affected by the 340B program as they often reimburse CEs at a higher amount than the drug acquisition cost, increasing drug spending for the plan. The growth in employer drug costs driven by 340B program dynamics may be passed on to employees through changes to plan design that increase premiums, deductibles, and cost-sharing.

The 340B program also affects public payer programs by reducing the rebates state Medicaid agencies can collect, driving down program budgets for patient services. Low-income enrollees

may be impacted directly by decreased funding for critical patient care programs, while taxpayers may bear the burden of state budget pressures that require policymakers to consider changes to Medicaid benefits.

Finally, insufficient transparency regarding the allocation of 340B savings creates uncertainty about whether these savings directly benefit patients. The growth of the program through hospital consolidation has resulted in more SOCs becoming eligible for the 340B program and a significant increase in the volume of 340B drugs administered or dispensed. As a result, there has been an increase in healthcare costs for payers and patients may face higher prices through increased out of pocket (OOP) costs or premiums and reduced access to charity care. Because hospital consolidation and expansion of CEs is largely focused in more affluent areas, resources may be diverted away from low-income communities. The confluence of factors that negatively impact patients require policymakers to assess opportunities to reform the 340B program in a manner that prioritizes patients.

Background and Program Evolution

The 340B program was established in 1992 under the Public Health Service Act and requires drug manufacturers to provide outpatient drugs to eligible CEs at a reduced price. The program allows hospitals and other SOC authorized as CEs that treat Medicaid and other low-income patients to purchase drugs at or below a ceiling price, with average estimated discounts of 25% to 50% off the list price of a product.¹

The Congressional Budget Office (CBO) reports that dramatic growth in 340B drug purchases is driven by a combination of factors including the allowance for expanded site participation post-ACA enactment, higher CP use, and hospital-clinic integration.² While the program was initially limited in scope, several policy changes resulted in significant growth over the last 15 years. Between 2000 and 2020, the number of covered entity sites (including child sites) participating in the 340B program increased from 8,100 to 50,000, a 517% increase.³ One of the growth drivers has been the integration of hospital and off-site clinics (i.e., new child sites) which increased the number of facilities eligible for the 340B program and therefore the number of products administered in those sites or prescribed by affiliated providers.⁴ Additionally, regulatory guidance issued in 2010 allowed CEs to contract with an unlimited number of CPs, which are pharmacies that partner with CEs to be able to dispense 340B drugs to patients of the

¹ The Commonwealth Fund. (2022). "The Federal 340B Drug Pricing Program: What It Is, and Why It's Facing Legal Challenges." [Available here](#).

² CBO. (2025). "Growth in the 340B Drug Pricing Program." [Available here](#).

³ Mulligan, K. (2021). "The 340B Drug Pricing Program: Background, Ongoing Challenges, and Recent Developments." [Available here](#).

⁴ CBO. (2025). "Growth in the 340B Drug Pricing Program." [Available here](#).

CE.⁵ Finally, in 2010, the Affordable Care Act (ACA) expanded the type and number of organizations eligible for the program (e.g., critical access hospitals, rural referral centers), boosting the number of CEs along with affiliated child sites and CPs.⁶

These factors taken together have contributed to a substantial increase in the volume of 340B drugs being purchased by CEs. In 2023, \$66.3 billion worth of discounted drugs were purchased at 340B prices, a 444% increase since 2015, demonstrating the vast growth of the program in the last decade.⁷

Stakeholder Impacts on Patients

The 340B program applies across patients with all types of health insurance coverage for outpatient prescription drugs provided by CEs, including prescriptions filled at pharmacies and physician-administered drugs provided in an outpatient setting. Given the expansion of the program since its inception, the impacts of the 340B program grows across stakeholders including employers, taxpayers, and providers, which can result in significant direct and indirect impacts on patients.

Employers

The 340B program was designed to provide discounted drugs to CEs regardless of a patient's source of coverage. In 2023, approximately 60% of individuals under the age of 65 (~165.7M people) had employer-sponsored coverage, making it the nation's largest payer segment.⁸ The 340B program introduces financial dynamics that directly impacts employer costs to provide insurance coverage for their employees. As a result, any shift to employer-sponsored insurance design and premiums caused by the 340B program will have an impact on a large portion of the U.S. population.

Typically, plans negotiate with manufacturers to establish rebates that are based on the volume of drugs purchased and distributed to beneficiaries. However, these agreements typically prohibit a plan from receiving rebates on a drug that has been sold at a discounted price, including a 340B discount. Under the 340B program, CEs purchase drugs at a discounted price, while billing employer health plans at a standard negotiated rate. As a result of the 340B program, an employer's pharmacy benefit manager (PBM) may not receive rebates from the

⁵ HRSA. (2010). "Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services. 75 Fed. Reg. 10272." [Available here.](#)

⁶ Barlas S. (2010). "Health Care Reform Bill Expands Access to Section 340B Discounted Drugs for Hospitals." [Available here.](#)

⁷ Avalere Health. (2024). "340B Purchase Data Highlights Continued Program Growth." [Available here.](#)

⁸ Claxton, G. et al. (2024). "Employer-Sponsored Health Insurance 101." [Available here.](#)

manufacturer that they would typically collect, effectively increasing costs to the health plan which may be passed on to the employer.⁹ Given the increase in 340B drug volume, employer-sponsored health plans may forgo manufacturer rebates, resulting a smaller discount and higher drug spending.¹⁰

A recent analysis from the National Pharmaceutical Council highlights that the expansion of the 340B program has had a direct impact on employer healthcare costs.¹¹ An additional study shows that self-insured employers face drug costs approximately 4.2% higher due to the loss of rebates on 340B-acquired products.¹² An increase in drug spending for employer-sponsored plans can directly impact employer costs for providing insurance coverage for its employees. Consequently, employees may absorb these costs through higher insurance premiums, more restrictive benefit designs, and higher OOP costs from copayments or coinsurance.¹³ In 2023, 340B program growth accounted for approximately \$23B in costs for employer-based plans, of which, about \$4.5 billion per year is absorbed by patients in the form of higher premiums.¹⁴

Taxpayers

The 340B program operates based on discounts provided by drug manufacturers with no direct contribution from taxpayers. Despite this structure, it is important to consider the indirect effects the program can have on taxpayers. Several 340B dynamics contribute to higher overall costs across federal and state systems which can place increased pressure on taxpayers.

Medicare is federally funded, while Medicaid is jointly funded by the federal government and states; as such, increased drug spending can result in downstream impacts on taxpayers. A recent CBO report notes that the 340B program increases federal spending by increasing the prescription of high-cost drugs, decreasing drug manufacturer rebates to insurers, and consolidation of CEs.¹⁵ 340B CEs are able to purchase more expensive drugs at a 340B discount and be reimbursed at their usual Medicare rate. At the same time, Medicare Part D must forgo its usual manufacturer rebates for non-340B drugs, which ultimately increases Medicare drug spending. These factors lead to increased federal spending via the Medicare

⁹ Sun, C. (2025). "The Cost of the 340B Program Part 1: Self Insured Employers." [Available here.](#)

¹⁰ Magnolia Market Access. (2025). "How the 340B Program Impacts Federal & State Tax Liability." [Available here.](#)

¹¹ Health Capital Group. (2025). "The 340B Drug Purchasing Program and Commercial Insurance Premiums." [Available here.](#)

¹² Sun, C. (2025). "The Cost of the 340B Program Part 1: Self Insured Employers." [Available here.](#)

¹³ Robinson, J. et al. (2024). "Hospital Prices for Physician-Administered Drugs for Patients with Private Insurance." [Available here.](#)

¹⁴ Health Capital Group. (2025). "The 340B Drug Purchasing Program and Commercial Insurance Premiums." [Available here.](#)

¹⁵ CBO. (2025). "Growth in the 340B Drug Pricing Program." [Available here.](#)

program, which could result in changes to Medicare benefits, such as increased Part B premiums.

In addition to its effects on Medicare, the 340B program also presents challenges for Medicaid. Notably, a key dynamic impacting Medicaid programs is the intersection between 340B discounts and Medicaid rebates. To participate in the 340B program, drug manufacturers must agree to participate in the Medicaid Drug Rebate Program (MDRP) and provide rebates to the state Medicaid program. This is to ensure that the Medicaid program receives drugs at the lowest price available on the market, also known as Medicaid “best price.” Federal law prohibits manufacturers from providing both a 340B discount and a Medicaid rebate on the same unit of a drug (otherwise known as “duplicate discounts”).¹⁶ When 340B drugs are dispensed to Medicaid patients, states can either “carve-in” or “carve-out” 340B drugs. When states allow for “carve in” of 340B products, CEs may use their 340B-acquired products for Medicaid enrollees. However, this means a state cannot claim a Medicaid rebate for that drug. Meanwhile, when 340B drugs are “carved-out,” 340B-purchased drugs are not used for Medicaid patients and states retain their Medicaid rebate.

Several states have passed mandatory carve-out policies to reduce the risk of duplicate discounts, while other states have passed mandatory carve-in legislation to explicitly shift rebate revenue toward hospitals to retain 340B discounts.¹⁷ In states that require 340B drugs be carved in, there can be an increase in drug spending given the loss of the Medicaid rebates for a given drug.^{18,19} This dynamic resulted in a loss of about \$2B in Medicaid rebates for hospital outpatient department drugs in 2023 alone.²⁰ This loss of Medicaid rebates could increase Medicaid drug spend and place increased pressure on Medicaid budgets, potentially limiting Medicaid benefits for patients.

Additionally, the passage of the One Big Beautiful Bill Act has added financial pressure on state Medicaid programs by decreasing federal Medicaid spending.²¹ A decrease in federal Medicaid spending and the loss of MDRP rebates places increased financial strain on state budgets. This financial burden may reduce the benefits available to Medicaid enrollees and create additional pressures for additional taxpayer revenue.

¹⁶ DiGiorgio, A. et al. (2024). “Increasing Transparency in the 340B And Medicaid Drug Rebate Programs.” [Available here.](#)

¹⁷ Berkeley Research Group (2024). “The Financial Impact to Medicaid from the 340B Drug Pricing Program.” [Available here.](#)

¹⁸ AIR 340B. (2024). “340B Impact on the Federal Budget.” [Available here.](#)

¹⁹ Berkeley Research Group (2024). “The Financial Impact to Medicaid from the 340B Drug Pricing Program.” [Available here.](#)

²⁰ Avalere Health. (2025). Impacts of 340B on State Medicaid Programs and Patient OOP Costs.” [Available here.](#)

²¹ One Big Beautiful Bill Act, H.R. 1, 119th Cong. § 71112 (2025). [Available here.](#)

While the 340B program's impact on taxpayers is most directly reflected in Medicare and Medicaid spending, it also has indirect effects via commercial health insurance. Similar to Medicaid, drug manufacturer contracts with commercial plans often prohibit rebates on drugs purchased at a discount, resulting in a loss of manufacturer rebates for 340B-purchased drugs. Fewer rebates from manufacturers can increase the net cost of prescription drugs for employer-sponsored health plans, a type of commercial health plan, which may translate into higher premiums for employees. Because premiums are often paid with pre-tax dollars, any increase to premiums would reduce the amount of income subject to state and federal income and payroll taxes. A recent analysis found that in the commercial market in 2021, healthcare costs increased by an estimated \$7.8B for self-insured and fully insured employers as a result of lost manufacturer rebates because of the 340B program.²² This increase in healthcare costs for plans, which decreased the amount of taxable income for employees, ultimately resulted in a \$1.8B loss in federal and state tax revenue.²³

Providers

CEs, such as hospital clinics and FQHCs, are the primary beneficiaries of the 340B program. In 2022, an estimated \$46.5 billion in 340B discounts were given to 340B hospitals.²⁴ Despite the program's original intent to help CEs access discounted drugs, there are no federal requirements for DSH hospitals, which the largest purchaser of 340B drugs,²⁵ to pass these 340B discounts on to patients nor report how 340B savings are used.

The lack of reporting requirements for CEs has prompted repeated efforts by both state and federal officials to pass legislation that promotes transparency within the 340B program. In September 2025, Representatives Carter (R-GA) and Harshbarger (R-TN) reintroduced the 340B ACCESS Act, which establishes oversight and transparency of the 340B program among other changes.²⁶ Prior federal proposals including the SUSTAIN 340B Act also included transparency provisions but did not advance. Additionally, several states have pursued transparency legislation to address gaps in the 340B data.²⁷ For example, IN passed SB 118 in May 2025, which requires 340B participants to report annual data to the IN Department of Health that will be used to develop a report highlighting the use of 340B funds by CEs.²⁸

²² Magnolia Market Access. (2025). "How the 340B Program Impacts Federal & State Tax Liability." [Available here](#).

²³ Magnolia Market Access. (2025). "How the 340B Program Impacts Federal & State Tax Liability." [Available here](#).

²⁴ Healthsperien. "The 340B Drug Pricing Program: A Small Part of the Prescription Drug Market, Delivering Large Benefits to Patients and Communities." [Available here](#).

²⁵ HRSA. (2024). "2023 340B Covered Entity Purchases." [Available here](#).

²⁶ H.R. 5256, 119th Cong. (2025–2026), *340B ACCESS Act*. [Available here](#).

²⁷ Carter, Buddy, et al. (2025). "Carter, Harshbarger Introduce Legislation to Ensure Access and Transparency in 340B Drug Pricing Program." [Available here](#).

²⁸ Ind. Sen. Enrolled Act No. 118, 2025 Ind. [Available here](#).

In contrast to the lack of transparency required of other types of covered entities, FQHCs must submit annual information on 340B drug costs, revenue from 340B savings, and must offer a sliding fee scale for all services. Although some 340B hospitals may tout the use of 340B revenue on “capital improvement projects” and “community benefit programs,” they are not required to report how these funds are specifically spent or which communities ultimately receive these investments.²⁹ Furthermore, while certain federally funded grantees must provide care on a sliding fee scale including cost sharing for drugs, their contract pharmacies are not required to do the same.

Consolidation of 340B hospitals has further contributed to growth of the 340B program given the increasing number of SOCs that are eligible for 340B discounts. The acquisition of physician practices allows for more clinics to be eligible to purchase drugs at 340B prices, incentivizing consolidation. Research has shown that hospitals undergoing ownership changes are likely to participate in the 340B program and have higher drug margins in more consolidated markets.³⁰ More 340B-eligible CEs increases the volume of 340B drug purchases, which can exacerbate the savings from the 340B program for those SOCs. In fact, from 2016 to 2022, hospitals involved in mergers and acquisitions were more likely to be large facilities with 500+ beds and to be 340B CEs.³¹ Because there is a lack of transparency of how 340B savings are used, it remains unclear whether those savings are used to directly benefit patients. Furthermore, mergers and acquisitions can increase a hospital’s market power with payers, allowing hospitals to negotiate higher reimbursement rates with plans, which increases overall healthcare spending.³²

Synthesis of Cross-Cutting Themes and Patient Impacts

Across stakeholders, there is evidence demonstrating direct and indirect negative impacts of the 340B program on patients. Several key themes emerged:

- **Lack of transparency:** Across the 340B program, there is limited visibility into how 340B savings are used and whether those savings are being used to facilitate patient access and care. Without mandatory reporting for 340B CEs on how program savings

²⁹ Senate Committee on Health Education Labor and Pensions. (2025). “Congress Must Act to Bring Needed Reforms to the 340B Drug Pricing Program.” [Available here.](#)

³⁰ Masia, Neal, et al. (2025). “HPR56 Does the 340B Program Encourage and Reward Non-Profit Hospital Consolidation?” [Available here.](#)

³¹ Avalere Health. (2023). “Characteristics of Hospitals Undergoing Mergers and Acquisitions.” [Available here.](#)

³² Conti, RM, et al. (2016). “The Impact of Provider Consolidation on Outpatient Prescription Drug-Based Cancer Care Spending.” [Available here.](#)

are used, it is difficult to determine direct patient benefits from the program's financial gains.³³

- **Misaligned incentives:** Because 340B drugs are acquired at a discount but reimbursed at a pre-negotiated rate between the plan and provider, 340B CEs can generate significant savings. This can incentivize 340B hospitals to expand their 340B footprint through consolidation to increase 340B savings.³⁴
- **Weak accountability mechanisms:** There are no consistent standards for 340B hospitals focused on community benefit, charity care, or reinvestment of savings as a result of 340B drug purchases, making it difficult to ensure that 340B margins support patient-centered outcomes.³⁵
- **Program complexity and lack of patient awareness:** Many patients are unaware of the program's existence or how it affects their costs and access, limiting their ability to advocate for reform.
- **Inconsistent benefit across patient populations:** Evidence suggests that CE expansion to areas with higher shares of commercially insured and more affluent patients may be prioritized to increase 340B revenues, while underserved populations that are more likely to visit the CE parent site may not see proportional benefit.³⁶
- **Limited oversight and enforcement:** HRSA's limited authority to enforce program standards contributes to inconsistent implementation and accountability.³⁷

Conclusion

Over the last 15 years, the 340B Drug Pricing Program has grown exponentially, particularly as a result of the guidance issued in 2010 by HRSA which permitted CEs to be affiliated with an unlimited number of contract pharmacies. The expansion of the 340B program has resulted in direct and indirect impacts to patients through the dynamics that effect employers, public payer benefits, and misaligned incentives for providers that encourage profit growth over patient care.

The program creates unintended consequences for these individuals through higher premiums, reduced coverage, or constrained state budgets. 340B discounts may not benefit patients as

³³ DiGiorgio, A. et al. (2024). "Increasing Transparency in the 340B And Medicaid Drug Rebate Programs." [Available here.](#)

³⁴ Health Capital Group. (2025). "The 340B Drug Purchasing Program and Commercial Insurance Premiums." [Available here.](#)

³⁵ HRSA. (2024). "340B Eligibility." [Available here.](#)

³⁶ Robinson, J., et al. (2024). "Hospital Prices for Physician-Administered Drugs for Patients with Private Insurance." [Available here.](#)

³⁷ Knox, R., et al. (2023). "Outcomes of the 340B Drug Pricing Program: A Scoping Review." [Available here.](#)

they were intended to with the creation of the program and reforms are needed to better align incentives and ensure patient benefits.³⁸

Several policy solutions can be implemented to strengthen and modernize the 340B program. These policies aim to ensure patients benefit from the 340B savings, increase transparency on how 340B savings are used, and ensure that the 340B program savings are passed onto patients:

- **340B Discount Passthrough:** 340B discounts should be passed directly to patients through lower OOP costs for prescription drugs and sliding fee scales, similar to those used by FQHCs, for patients who are uninsured or earn less than 200% of the federal poverty level.
- **Increased Transparency:** A neutral, 340B claims data clearinghouse should be established to facilitate public reporting on 340B program data. As part of this, CEs should be required to report how much of the total 340B savings are used to lower patient OOP costs.
- **Protect 340B Program Integrity:** Safeguards should be implemented to prevent for-profit entities and PBMs from exploiting the 340B program and to ensure that its savings are reinvested in patient care, supporting the program's safety net mission.

³⁸ Third Way. (2024). "Fixing a Critical Safety Net Program: 340B". [Available here](#).