

340B DRUG PRICING PROGRAM

In 1992, with the support of the biopharmaceutical industry, Congress created the 340B Drug Pricing Program to help uninsured and vulnerable patients. As part of the law, drug manufacturers provide significant discounts on outpatient medicines and treatments to select eligible health care “covered entities” — often referred to as safety-net providers.

It is expected that these covered entities use the discounts they receive to provide access to outpatient prescription drugs and other services to uninsured and vulnerable patients. However, there are growing concerns that this program expanded well past the intent of Congress, and patients are not seeing the benefits they deserve.

Eligible Covered Entities

- Certain public and non-profit Disproportionate Share Hospitals (DSH)
- Federally qualified health centers (FQHCs) and FQHC-like entities
- Certain community health centers
- Certain federal grantees such as Health Care for the Homeless, Migrant Health and Public Housing Primary Care Programs
- Certain entities receiving grants under the Ryan White CARE Act
- Certain-operated AIDS Drug Assistance Programs (ADAPs)
- Urban Indian Health Centers
- Family Planning Clinics
- Certain qualifying children’s hospitals*
- Free-standing cancer hospitals
- Critical access hospitals**
- Rural referral centers
- Sole community hospitals
- Certain clinics receiving grants to treat STDs.

How does it work?

- 1 The 340B statute requires manufacturers provide a discount **averaging between 25% and 50%,¹ sometimes much higher near 100%**, for outpatient drugs and biologics to covered entities who then dispense them to their patients, regardless of a patient’s insurance status, excluding Medicaid.²
- 2 A patient’s insurer or payer pays the safety-net provider its full negotiated amount for that drug.
- 3 The covered entity retains the difference between the 340B discounted drug’s acquisition cost and the amount of the insurer or payer’s reimbursement.



There is no requirement that the discounts be passed along to an uninsured patient. In most cases, the uninsured patient (or the patient’s insurance) must pay full retail price for the drug and the covered entity receives the discounted price.

¹ Health Resources and Services Administration

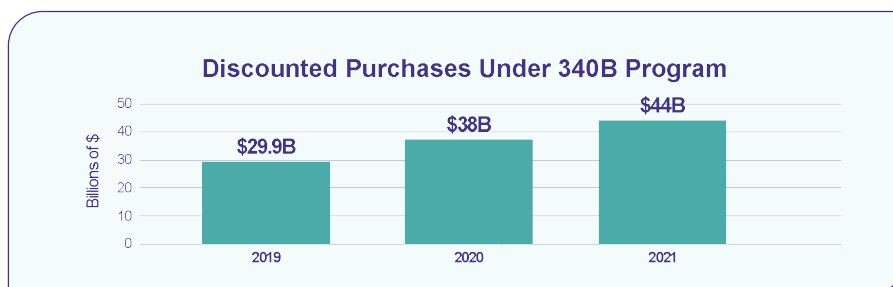
² Section 256(a)(5)(A) prohibits covered entities from requesting a discount under the 340B Drug Pricing Program if the drug is subject to a rebate under the Medicaid program. This would result in a “duplicate discount” in which a manufacturer would provide both the 340B discount and a Medicaid rebate for the same drug dispensed to a Medicaid patient. Hence, duplicate discounts are prohibited under the statute.

Program Growth

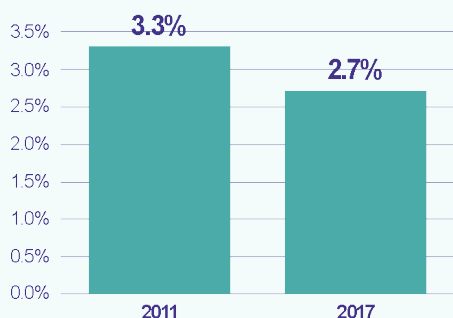
The program has grown exponentially in recent years, from a few hundred entities in 1992 to more than 50,000 today. Discounted

purchases made under the program totaled at

least \$38 billion in 2020 — an increase of 27% over the \$29.9 billion for 2019. In 2021, discounted purchases now total \$44 billion, representing \$93.6 billion in sales at list prices.³ By the end of 2021, 340B Program sales made up 14% of total U.S. brand-name pharmaceutical sales and grew four times faster than the overall pharmaceutical market. The program is now the second largest pharmaceutical program in the nation behind Medicare Part D.



Charity Care Level % of Patient Costs



Charity Care at DSH Hospitals is Decreasing

Despite the exponential growth seen in the 340B program, 340B DSH hospitals have been providing less charity care – in 2017, the charity care level was 2.7% of patient costs, down from 3.3% in 2011. Further, the majority of 340B DSH hospitals (63%) provide charity care at a level less than the national average.⁴ In fact, a 2022 study by IQVIA suggests that only 1.4% of patients are receiving discounts on 340B drugs at contract pharmacies.⁵

Child Sites

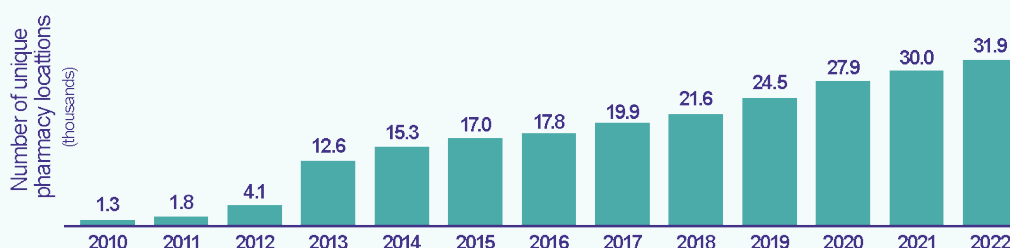
One area in which the 340B Program is experiencing substantial growth relates to the increased participation of hospital child sites (off-site clinics). Specifically, there is evidence to suggest that hospitals are increasingly acquiring community-based practices—often in wealthier or distant locations—motivated, in part, by enabling these acquired facilities to participate in the 340B Program, with substantial financial benefits for the parent hospital. As a result, this is exacerbating previously existing health inequities because facilities in less affluent areas are closing. This practice also often results in greater out-of-pocket costs for patients, as well as disruptions in care, because patient cost-sharing is based on the amount the child site is reimbursed for the drug, not the amount it paid. So patient cost-sharing may be higher for drugs the site prefers, over less-expensive drugs such as generics, to profit from the 340B program.

³ Fein, Adam, "The 340B Program Climbed to \$44 Billion in 2021—With Hospitals Grabbing Most of the Money," Drug Channels, August 15, 2022. Accessed: January 4, 2023. <https://www.drugchannels.net/2022/08/the-340b-program-climbed-to-44-billion.html#:~:text=For%202021%2C%20discounted%20purchases%20under,of%20these%20skyrocketing%20340B%20purchases.>

⁴ "Left Behind: An Analysis of Charity Care Provided by hospitals enrolled in the 340B Discount Program," Air340B, November 2019.

⁵ Martin, Rory, Ph.D., and Illich, Kepler, MA, "Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?", White Paper, IQVIA, September 2022.

340B Contract Pharmacy Locations, 2010 to 2022



Contract Pharmacy

Contract pharmacies are a primary driver of the exponential growth in the program.

Contract pharmacies are a significant source of diversion and duplicate discounts (66%), since they often do not identify patients as 340B-eligible until after the prescription has been dispensed.

Unique pharmacy locations have grown from approximately 1,300 in 2010 to roughly 32,000 in 2022.⁶ This explosive growth has occurred because **arrangements are extremely profitable for for-profit pharmacies**. A contract pharmacy's average gross profit margin on a 340B medicine dispensed at a contract pharmacy is estimated at 72%, compared to just 22% when dispensed as a non-340B drug by an independent pharmacy.⁷

340B-eligible patients receiving their drugs at contract pharmacies are not getting the discount passed on:

- Of the 38,000 claims analyzed, only 1.4% of these patients saw portions of the 340B discounts.
- Of these patients, their out-of-pocket costs were reduced by 92.9%, or roughly \$661.65.⁸

Establishing an effective process to prevent duplicate discounts is even more important now that 340B discounts are also prohibited for drugs subject to inflation rebates and drug price negotiation in Medicare under the Inflation Reduction Act.

Regulatory Oversight

HRSA's authority to oversee the 340B drug pricing program is limited and vague. As a result, HRSA has chosen to interpret this ambiguity in the statute mostly through sub-regulatory guidance that relies heavily on covered entities to police themselves.⁹

Lack of oversight magnifies the harms of the program's rapid expansion, most notably diversion and duplicate discounts.

The lack of oversight exacerbates these problems and calls into question whether the program is still aligned with Congress' original intent: to ensure access to medications and other services for patients who could not otherwise afford them.

⁶ Ibid.

⁷ Vandervelde, 2020.

⁸ Martin, Rory, Ph.D., and Illich, Kepler, MA, "Are Discounts in the 340B Drug Discount Program Being Shared with Patients at Contract Pharmacies?", White Paper, IQVIA, September 2022.

⁹ "Drug Discount Program: Status of Agency Efforts to Improve 340B Program Oversight," US GAO Testimony before the Committee on Health, Education, Labor, and Pensions, US Senate, May 15, 2018.