

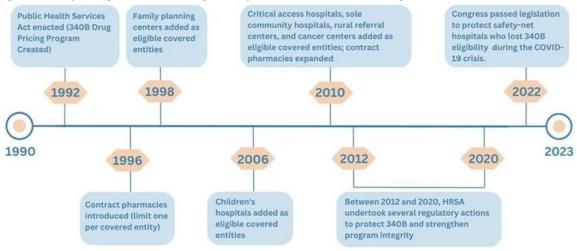
# The 340B Program: How it Delivers Value to Patients and Providers

Over the past 30 years, the 340B Drug Pricing Program has played an essential role in ensuring health care providers have the necessary resources to provide vital programs and services for underserved patients and communities. Ongoing bipartisan support of the program is critical to ensuring continued access to needed care for patients. As drug prices continue to rise rapidly with advances in specialty pharmacy and biologics, 340B will become even more important to addressing access, affordability, health outcomes and disparities.

### History of the 340B Program

In 1992, Congress created the 340B Drug Pricing Program as part of a strong bipartisan effort to protect hospitals and patients from the growing problem of rising drug costs. Lawmakers modeled the program after the Medicaid Drug Rebate Program, which protects state Medicaid programs from the high costs of drugs with limits on the amount those programs must pay. The 340B program adopted a similar approach to help certain hospitals stretch scarce resources to reach as many patients as possible and provide more comprehensive services at **no additional cost to taxpayers**. With the emergence of specialty drugs to treat chronic and acute conditions — and extensive patents protecting drug companies' abilities to price these drugs with limited to no competition — the 340B program has become an even greater resource for hospitals and their patients as they struggle to pay the high prices for many of these lifesaving drugs and treatments.

Serving as a crucial lifeline for 340B hospitals, the program mitigates health disparities and reduces health care costs while improving patient outcomes.<sup>1</sup> To ensure participation by pharmaceutical manufacturers, current law requires them to participate in the 340B program to receive Medicaid reimbursement. The Health Resources and Services Administration (HRSA) administers the 340B program and has developed strict rules and regulations to ensure program integrity consistent with the intent of Congress. Following the program's implementation and demonstrated success, Congress expanded it several times to allow more types of providers and their patients to access the benefit (Figure 1). HRSA has also repeatedly recognized the need to support facilities' access to drugs, especially those without in-house pharmacies, by allowing 340B providers to contract with external pharmacies to dispense drugs to patients on their behalf (see section below: "The More You Know: Contract Pharmacies").



#### Figure 1: Major Legislative and Regulatory Actions of the 340B Program

## How the 340B Program Works

The 340B program permits eligible providers, including hospitals and certain federal grantees, to enroll in the program and purchase certain outpatient drugs at a discounted price. Six types of hospitals are eligible for 340B: disproportionate share hospitals, rural referral centers, sole community hospitals, critical access hospitals, freestanding cancer hospitals, and freestanding children's hospitals. **Under current law, the 340B discounted price is 23.1% less than the price drug wholesalers pay to drug companies. However, the discount percentage can increase when drug companies decide to offer a lower price in the market than the 340B price or if they raise the price of a drug faster than the rate of inflation.** As a result, HRSA estimates the average discount is between 25% and 50%.<sup>ii</sup>

Due to this access to discounted drug prices, 340B eligible hospitals can achieve savings when purchasing drugs and use those savings to support care for underserved patients (see Figure 2):

**Step 1:** The drug manufacturer sets the outpatient drug's list price and then decides the price to sell to the wholesaler for hospital distribution. In the example below, the drug's list price is \$120, and it is sold to the wholesaler for \$100.

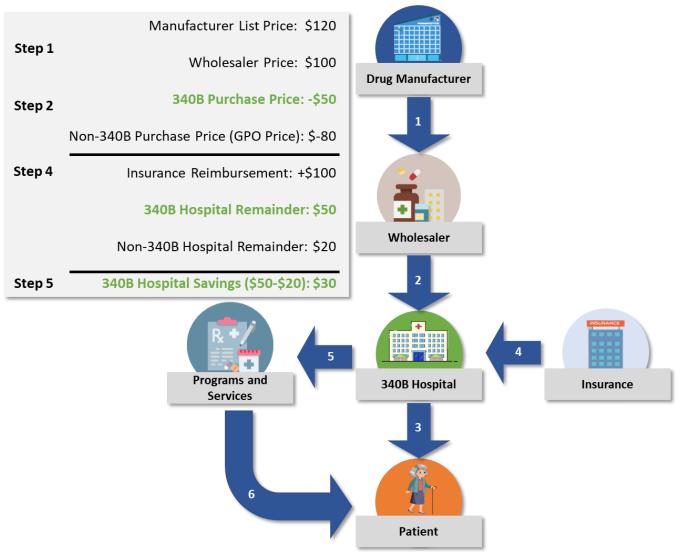
**Step 2:** The 340B hospital purchases the drug from the drug wholesaler at a lower price than that paid by non-340B hospitals. In the example below, the 340B hospital can purchase the drug at a 50% discount for a price of \$50. However, had they not participated in 340B, the same hospital would have purchased the drug at a higher price, such as through a group purchasing organization (GPO) arrangement. In this example, the hospital not participating in 340B would pay the "GPO price" of \$80.

**Step 3:** Eligible patients receive the drug treatment through either the hospital's in-house pharmacy or a contracted community or specialty pharmacy.<sup>iii</sup>

**Step 4:** The hospital generates a claim for the drug provided to the patient and bills the patient's insurance — either a public or private payer — for reimbursement. **The reimbursement amount from either public or private payer is the same for both the 340B hospital and the non-340B hospital. In the case of public payers, these are fixed reimbursements for all hospital providers.** In the example below, payers reimburse the hospital \$100 for the drug regardless of whether the hospital participates in 340B or not.

**Step 5:** The 340B hospital achieves savings because it purchased the drug at a lower price than it would have had it not been in the 340B program. In the example below, the savings are \$30, or the difference between the 340B discounted price of \$50 and the non-340B price of \$80. These savings are then used to support critical programs and services.

**Step 6:** These programs and services supported by 340B savings directly benefit patients by improving their health outcomes, improving access to care, and reducing disparities in care. Examples of these services and programs include the provision of free or discounted drugs, behavioral health therapy services, and diabetes treatment clinics.



## Value of the 340B Program to Hospitals

Hospitals increasingly face significant inflationary cost pressures from areas such as staffing and medical supplies; with drug price inflation adding to that burden.<sup>iv</sup> In fact, drug companies increased the price of their drugs faster than inflation for over 1,200 drugs between July 2021 and July 2022, with an average price increase of 31.6% and several drugs experiencing over 500% price growth.<sup>v</sup> In particular, specialty drugs — injectables and biologics — and oncology drugs continue to drive costs that outpace the rest of the health care services market.<sup>vi</sup> Additionally, price increases for nearly half of all Medicare outpatient drugs — 48% of 568 drugs — exceeded inflation in 2019 and 2020.<sup>vii</sup> Hospitals also face growing cost pressures amid chronic underpayments by Medicare and Medicaid for services more broadly, threatening their ability to provide access to needed care. As a result, many hospitals are at risk of closure or reduced service offerings due to their location and patient population — 340B is a critical lifeline.

Hospitals can use their program savings to maintain and, in many cases, expand access to care. The program allows each 340B hospital to best support the unique needs of the patients and communities they serve. For example, a small, rural hospital in West Virginia may use its 340B savings to support mobile treatment services for rural patients who cannot travel long distances for care. At the same time, an urban hospital in California may use its 340B savings to support a program that offers drug treatments free of cost for the local homeless population. Because different hospitals and populations have different needs, Congress decided not to restrict how hospitals should use their savings.

### Value of the 340B Program to Patients

The nation's underserved patient populations rely on the 340B program to address persistent access issues for a variety of critical health care services, including access to behavioral health, telehealth and free or discounted drugs. For example, nearly one-third of Americans report

#### The More You Know: Contract Pharmacies

Some hospitals don't have in-house pharmacies, and if they do, they may serve patients who don't live in the immediate area. To ensure patients have access to medications in the communities in which they live, 340B hospitals contract with community and specialty pharmacies to dispense drugs to these patients on behalf of the hospitals. Contract pharmacies provide an additional access point for patients to receive the drugs they need, including many specialty drugs that are often in limited distribution, without patients having to travel far distances. As a result, the hospital can ensure the patient gets the drug they need, improving adherence to drug treatments while also allowing the hospital to earn 340B savings. Therefore, these arrangements offer another way for 340B hospitals to provide comprehensive patient services and access to care as Congress intended in creating the program.

not taking medications as prescribed due to cost concerns.<sup>viii</sup> Moreover, many of these patients fall in the gap between Medicaid and fully insured, with limited options to assist them in affording needed health care services.<sup>ix</sup> 340B hospitals provide 77% of the nation's care for Medicaid patients.<sup>x</sup> Notably, benefits from the program help address disparities in care and health care outcomes for people living with disabilities and racial and ethnic minorities, particularly those in structurally marginalized communities who face disproportionate illness burdens and barriers to care.<sup>xi</sup> In 2019 alone, 340B hospitals provided nearly \$68 billion in community benefits.<sup>xii</sup> At the same time, total 340B sales were approximately \$30 billion, of which hospitals accounted for approximately 85% or \$26 billion.<sup>xiii</sup> That means for every dollar in 340B sales, 340B hospitals provided over two dollars in benefit to the patients and communities they serve.

The 340B program plays an important public policy role in ensuring access to essential drugs and services for low-income and underserved Americans receiving care at 340B hospitals nationwide. Without the program, many patients could have trouble accessing affordable medications and critical health services, jeopardizing their health and well-being.

<sup>III</sup> Note: In order for the 340B hospital to purchase the drug at a discounted price, the drug must be administered to a patient that had a medical visit with an employed or contracted provider of the 340B hospital. Otherwise, it must purchase the drug at the same price as a non-340B hospital.

<sup>&</sup>lt;sup>1</sup> L&M Policy Research. *Examination of Medicare Patient Demographic Characteristics for 340B and Non-340B Hospitals and Physician Offices*. July 2022. <sup>II</sup> Health Affairs. *The 340B Program*. 2017

<sup>&</sup>lt;sup>iv</sup> Kaufman Hall. National Hospital Flash Report. December 2022.

<sup>&</sup>lt;sup>v</sup> Office of the Assistant Secretary for Planning and Evaluation. Price Increases for Prescription Drugs, 2016-2022. September 2022.

<sup>&</sup>lt;sup>vi</sup> JAMA Network. *Trends in Prescription Drug Launch Prices, 2008-2021*. June 2022.

vii Kaiser Family Foundation. Prices Increased Faster Than Inflation for Half of all Drugs Covered by Medicare in 2020. February 2022.

viii Kaiser Family Foundation. KFF Tracking Poll. February 2019.

<sup>&</sup>lt;sup>ix</sup> Marshall University. *The 340B Program: Benefits and Limitations*. 2018.

<sup>\*</sup> Health Affairs. 30 Years Of 340B: Preserving the Health Care Safety Net. 2022

xi Health Affairs. 30 Years Of 340B: Preserving the Health Care Safety Net. 2022

xii 2022 340B Hospital Community Benefit Analysis. https://www.aha.org/system/files/media/file/2022/06/340b-community-benefits-analysis-6-3-22.pdf

xiii FY2022 HRSA Budget Justification. https://www.hrsa.gov/sites/default/files/hrsa/about/budget/budget-justification-fy20220.pdf