THE 340B DRUG PRICING PROGRAM

A SMALL PART OF THE PRESCRIPTION DRUG MARKET, DELIVERING LARGE BENEFITS TO PATIENTS AND COMMUNITIES

Report prepared for the American Hospital Association by Healthsperien

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Executive Summary

The 340B Drug Pricing Program allows hospitals caring for large numbers of underserved patients to stretch scarce federal resources and provide more comprehensive care by requiring drug companies to offer discounted prices on certain outpatient drugs. As the program has grown to cover more eligible providers, some policymakers and industry experts have raised questions about the ongoing benefit to patients and the impact on drug companies and taxpayers. This report offers new insights into this issue with an analysis of the impact of the evolving program on drug company revenues and benefits to patients.

The report's key findings include:

- **The estimated amount of 340B discounts to eligible hospitals is a small share of drug company revenues.**
    - Drug companies provided an estimated $46.5 billion in discounts to 340B hospitals in 2022—roughly 3.1 percent of global revenues and 7 percent of U.S. revenues that year.
    - Revenue growth for drug companies was an estimated $347 billion and the U.S. drug market grew by $331 billion between 2017 and 2022, while the discounts provided to 340B hospitals grew by $30 billion. Therefore, the scale at which the discounts drug companies are providing to 340B hospitals pales in comparison to their revenue growth and the growth of the U.S. drug market.
- **Forces shaping the 340B program and its scope include a mix of factors.**
    - Direct impacts on the scope of the 340B program include legislation that expanded program eligibility to additional types of hospitals, including critical access hospitals and other rural providers.
    - Indirect impacts on the program include policy decisions that shift care delivery from inpatient to outpatient settings and changes to patent and extended exclusivity policies for drug companies.
    - Other forces shaping the program include increasing the use of drugs, including both specialty drugs and medical advances that rely on drugs over other interventions, and sharply rising drug prices.
- **Expansions of the 340B program increased access to care for underserved patients and their communities.** Estimated increases in the amount of 340B hospitals' community benefits have outpaced the growth in 340B discounts, consistent with the Congressional intent of the program. This outsized impact with direct benefits to patients comes at no additional cost to taxpayers and accounts for a small share of drug company revenues.

Introduction

For more than 30 years, the 340B program has played an essential role in ensuring health care providers caring for underserved communities have the necessary resources to provide vital programs and services for their communities at no additional cost to taxpayers.

The 340B Program ensures access to care for patients most in need. A bipartisan effort by Congress in 1992 designed the program to protect hospitals from rising drug costs—a dynamic that continues to present challenges today. Under the program, eligible hospitals may purchase certain outpatient drugs at a discounted price, dispense these drugs to patients through either an in-house pharmacy or a community or specialty pharmacy, and then use the price savings to maintain and expand access to programs and services targeted to the unique needs of the patients and communities they serve (*see The 340B Program: How it Delivers Value to Patients and Providers for more information).*

Current law defines the 340B discounted price as 23.1 percent off the drug price that wholesalers pay drug companies to acquire a drug. When drug companies decide to offer a lower price in the market than the 340B price or if they decide to raise the price of a drug faster than the rate of inflation, the 340B discount percentage increases and results in a lower 340B price for the drug. By lowering the net costs of drugs needed for patient care (as opposed to raising taxpayer funds), the program provides significant value to hospitals and patients. For this reason, Congress expanded the program to more hospitals in 2010, even as other external factors contributed to program growth.[1]

However, gaps exist in the economics and policy literature about how the program operates and the scope of its impact. Based on public data and expert insights, this report describes the scope of the 340B program, the many factors that contribute to its growth as a program, and the way the program's growth supports care for a greater number of patients.[2]

Defining 340B Program Scope

Unlike other government programs, the 340B program operates based on "savings" from discounted prices that drug companies offer participating entities. Those savings provide program participants with more resources to support the needs of patients in their communities. An estimate of the total amount of discounts offered by drug companies provides insights into the scope of the program. In this report, we estimate the total dollar amount of discounts drug companies provide to 340B hospitals (this is also how much drug companies forego in revenues from entities participating in the program).

According to Health Resources and Services Administration (HRSA) data, total 340B drug sales in 2022—or the amount of money spent by all 340B covered entities purchasing drugs at the discounted 340B price—was $53.7 billion.[3] Of this amount, HRSA data show that 340B hospitals accounted for approximately $46.5 billion. Generally, the discounts offered to 340B hospitals are statutorily set at 23.1 percent for brand-name drugs, which account for most drugs purchased through the program.[4] The discount percentage, however, can be higher—50 percent *or more* in cases where drug companies increase their drug prices faster than inflation or provide a lower price elsewhere on the market. HRSA, which oversees the 340B program, estimates that the average 340B discount for a drug can range between 25 percent and 50 percent.[5]

Given those estimates of drug spending by 340B hospitals, an important question is how to calculate the discounts drug companies provide those hospitals. As those figures are not publicly available, we estimated the amount of those discounts under a scenario in which there was a 50 percent discount on the average 340B covered drug—the higher end of the average, according to HRSA, but consistent with industry estimates of the gross cost of those drugs.[6] **Under that scenario, sales for drugs purchased by 340B hospitals would have been approximately $93 billion absent the 340B program, meaning drug companies provided an estimated $46.5 billion ($93 billion - $46.5 billion) in discounts to 340B hospitals in 2022.**

By increasing prices beyond inflation and offering steeper discounts elsewhere in the market, drug companies had to pay higher discounts to 340B participants than statutorily required. Congress designed the 340B policy to incentivize drug companies to keep price increases low and avoid steep discounts to other parties, but drug companies have pursued those approaches to some extent, even given the trade-off of offering higher discounts to 340B providers.

Scope of the 340B Program in Context

Understanding the impact of the 340B discounts on drug companies offers insights into ongoing policy questions related to the program. The $46.5 billion in 340B discounts provided by drug companies to hospitals in 2022 accounted for approximately 7 percent of the U.S. drug market (**Figure 1**).[7] Compared to the full scale of drug company revenues, 340B discounts to hospitals accounted for 3.1 percent of their global revenues, estimated at $1.48 trillion (**Figure 2**).[8]

Figure 1: 2022 340B Hospital Benefit Compared to U.S. Drug Company Revenues ($ Billions)

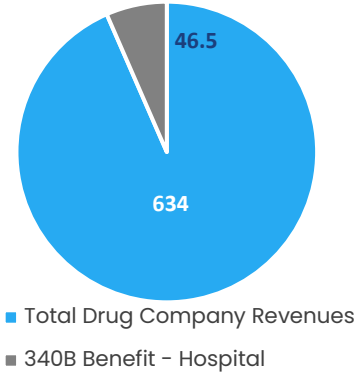
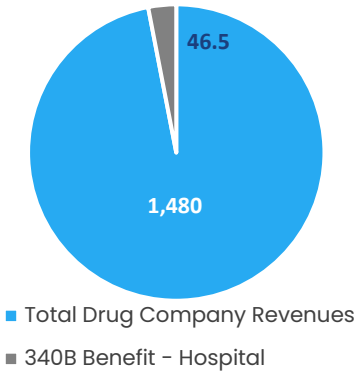
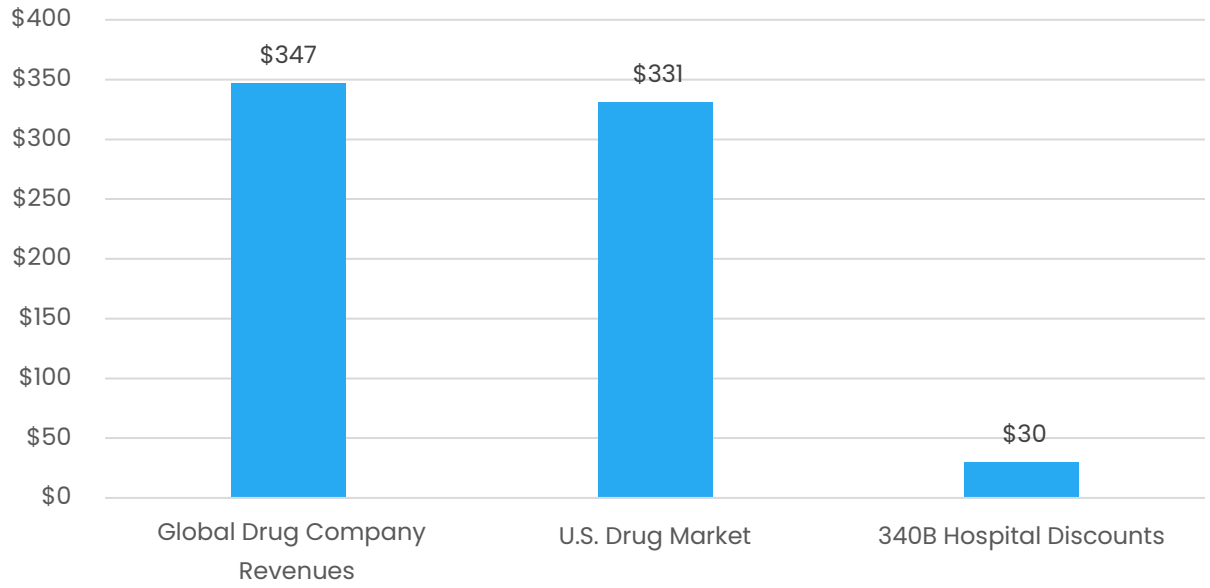


Figure 2: 2022 340B Hospital Benefit Compared to Global Drug Company Revenues ($ Billions)



Additionally, the growth of the 340B program over the last five years was approximately $30 billion, while global drug company revenues grew by approximately $347 billion, and the U.S. drug market grew by $330 billion (**Figure 3**).[9] This suggests that growth in the 340B program is minuscule in scale compared to the growth of revenues that drug companies have experienced. Further, despite this modest growth, the data show that the 340B program is a small share of the drug market.

Figure 3: Growth of Drug Company Revenues vs. Growth of 340B Program 2017-2022 ($Billions)

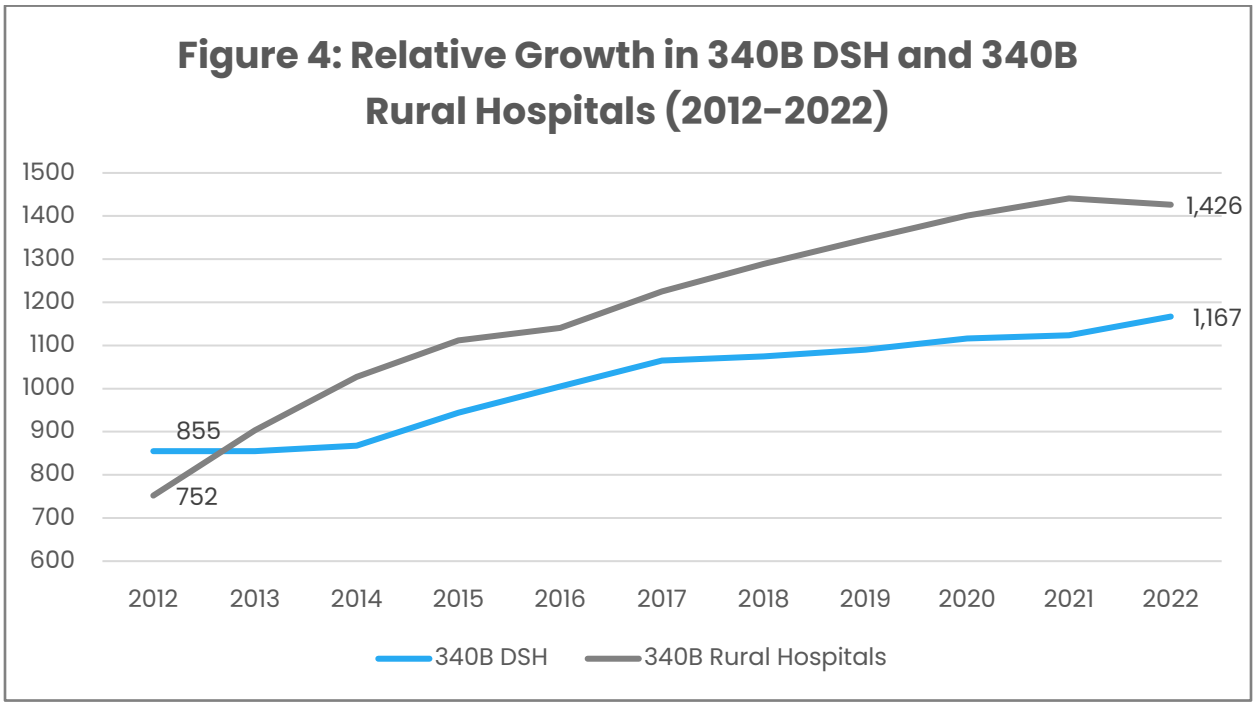


Drivers of 340B Program Growth

The scope of the 340B program has grown since 1992, especially in its expansion to rural communities. Several factors have helped drive the growth of the 340B program. Most notably, all these factors are due primarily to changes in regulatory policies or larger health care trends that have had a downstream impact on the program.

Direct Legislative and Regulatory Impacts on the 340B Program

Congressional action expanded the number of 340B hospitals. In 2010, Congress expanded 340B eligibility to additional categories of hospitals, including children's hospitals, freestanding cancer hospitals, sole community hospitals, rural referral centers, and critical access hospitals. Because of that legislation, the number of rural hospitals in the program has almost doubled over the last decade, demonstrating the importance of the 340B program to rural areas (**Figure 4**). Currently, there are 2,600 340B hospitals, of which about 60 percent serve rural areas and include over 1,200 critical access hospitals.[10,11] In comparison, the growth of 340B disproportionate share (DSH) hospitals—hospitals that qualify for the 340B program not based on their rural status but due to the high numbers of low-income Medicare and Medicaid patients they care for—increased by about a third over the same period.



Growth due to changes in 340B registration requirements. Requirements for hospitals to register outpatient sites of care that administer 340B drugs as a separate 340B entity have raised the number of entities included in public data on the program (including as a separate reimbursable line in hospital Medicare cost reports).[12] As a result of this guidance, the number of 340B hospital sites registered in the program appeared to grow significantly. However, the actual number of 340B hospitals grew much more modestly. In fact, the number of disproportionate share hospitals participating in the 340B program, which accounts for a significant share of drug purchases in the program, has experienced relatively modest growth over the past decade.

Value of 340B for Rural Hospitals

The expansion of 340B has had a significant and positive effect on rural hospitals and their communities and has helped to address affordability and access issues in rural health care. Many rural hospitals are struggling with solvency issues and are at risk of closing due to rising expenses, labor shortages, and a lack of available resources. From 2013 through 2020, over 100 rural hospitals closed.[30] A report from the Center for Healthcare Quality and Payment Reform (CHQPR) found that over 600 rural hospitals are at risk of closing in 2023.[31]

While the 340B program has grown, this growth has been particularly important for access to care in rural communities by providing resources to rural hospitals to address the unique social and clinical challenges that these communities face. The program supports the availability of specialty care at rural health facilities, meaning patients who live in remote areas do not have to travel as far to access the care they need.

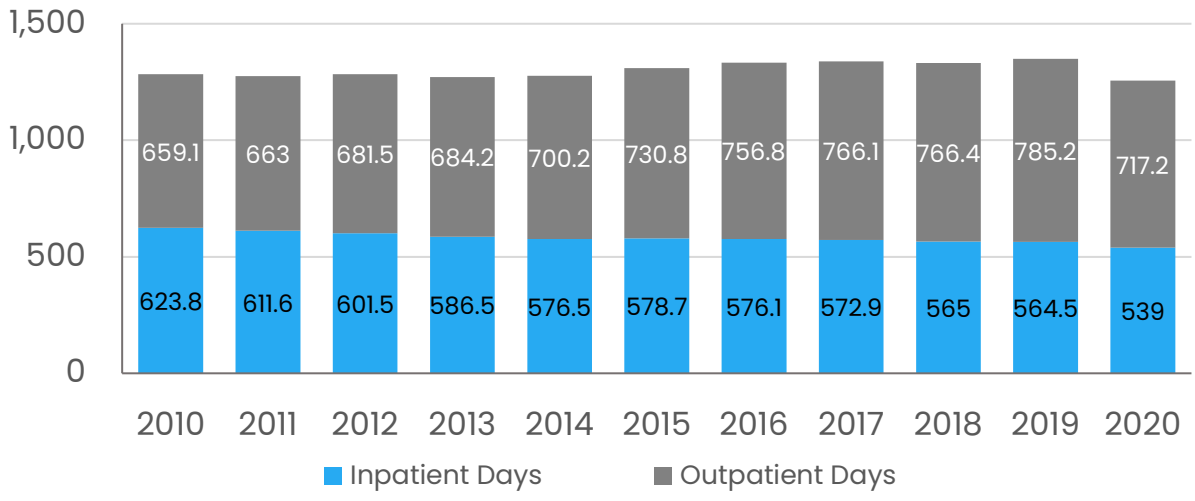
Rural residents are, on average, older and experience worse health outcomes than urban residents.[32] Shorter life expectancy, higher all-cause mortality, and higher rates of poverty are challenges for rural residents, who are also less likely than urban residents to have health care coverage through their employers, resulting in more uncompensated care for hospitals that 340B savings help offset. The 340B program allows health care facilities to care for those who are uninsured or those for whom cost is a burden, all without any financial implication on the taxpayer.

Indirect Impacts of Public Policies on the 340B Program

Pharmaceutical patents and extended exclusivity. Current law affords companies 20 years of patent exclusivity for newly filed pharmaceutical patents to offer financial incentives for investment and innovation in pharmaceutical research and development. During this period, drug companies made sizeable profits from their products; one of the impacts of this market exclusivity was to keep high-cost drugs on the market without competition from generic drug manufacturers. For 340B hospitals, the resulting high drug prices due to exclusivity contribute to the higher discounts that drug companies provide to 340B hospitals.[13,14]

Shifts in care delivery from inpatient to outpatient settings. With advances in medicine and technology, there has been a growing shift in care delivery from inpatient care to outpatient settings, a trend likely to continue as the population ages. The Centers for Medicare & Medicaid Services (CMS) has taken regulatory action to move services to less expensive hospital outpatient settings (**Figure 5**). For example, procedures like knee replacements and shoulder replacements, as well as many chemotherapy services (formerly provided in inpatient settings), are now almost exclusively outpatient procedures. Hospital outpatient departments and ambulatory surgery centers are also projected to experience patient growth, with estimated increases of 19 percent and 25 percent, respectively, by 2029.[15] One of the results of the industry-wide shift in the site of care from inpatient to outpatient is the growth in 340B discounts exclusively for certain drugs used in the outpatient setting.

Figure 5: Total Inpatient Vs Outpatient Visits to Community Hospitals*



*Data provided by the American Hospital Association

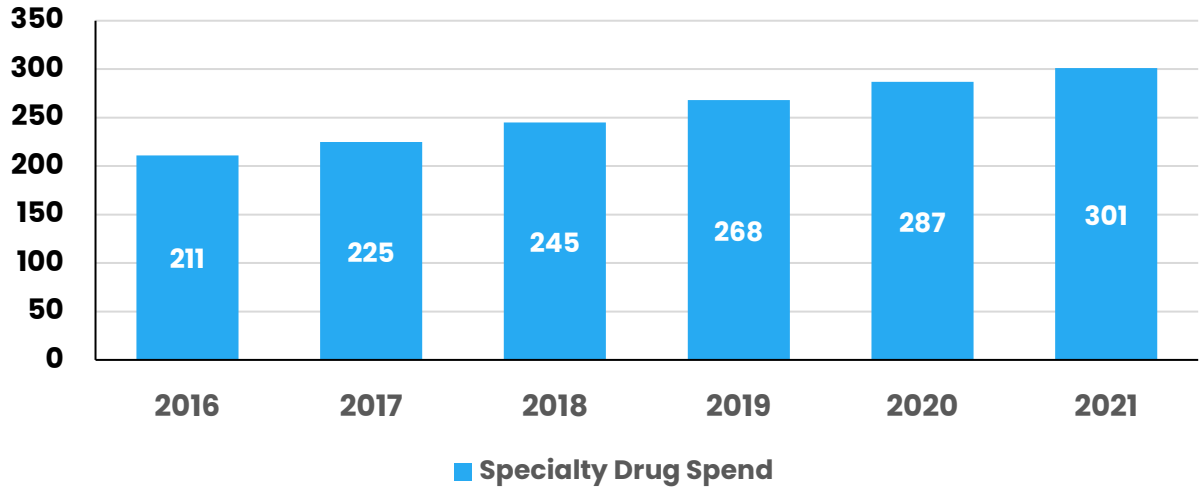
External Forces Shaping the 340B Program

Increasing drug prices. Prices for approximately 2,000 drugs increased faster than general inflation, with an average price increase of 15.2 percent in the last year.[16] This follows a year where drug companies increased prices for nearly 1,200 drugs by an average of 32 percent.[17] Many of the drugs with relatively high price increases are new therapies that treat cancer and other chronic conditions. Price increases for drugs exceed the growth in inflation, which was approximately 6.4 percent during the January 2022-2023 timeframe. Hospital spending on drugs has grown at relatively high rates; compared to pre-pandemic levels in 2019, hospitals' drug expenses per patient have risen 20 percent.[18]

New oncology drugs raise specific challenges for hospitals and contribute to growth in the 340B program (both spending and discounts). Median prices for oncology drugs currently average $257,000 per year for treatment and are 3.7 times higher than non-oncology drugs.[19, 20] Growth in the average launch price—adjusted for inflation—for oral cancer drugs increased by more than 25 percent to over $235,000 per year over the 2017-22 period.[21] If these trends continue, the average new self-administered cancer medication could potentially cost over $300,000 per year by 2025.[22] Even with relatively small patient utilization, these costly drugs contribute to cost pressures for the many 340B hospitals that serve cancer patients.

Increasing use of and cost of specialty drugs. Growth in the use of specialty drugs is also contributing to increases in hospital spending and related discounts under the 340B program. Specialty drugs commonly are high-cost therapies and often treat cancer and rare diseases. They often require special handling during transportation and administration, patient monitoring for safety and efficacy, and the use of a limited distribution network. By 2014, the number of FDA-approved specialty drugs rose to 27 (from six in 2006), with many new ones in the drug development pipeline. Meanwhile, specialty drug sales have increased significantly in the United States, accounting for $211 billion in 2016 and growing to $301 billion in 2021, an increase of 43 percent **(Figure 6)**.[23] Specialty drugs represented approximately half of total drug spending in 2021 and 70 percent of non-retail (hospital) drug spending. **The main drivers of spending increases are the number of drugs and their prices; the increase in the number of prescriptions has remained relatively flat, with a 0.5 percent increase.**

Figure 6: U.S. Specialty Drug Spending 2016-2021 ($ Billions)



Expected annual growth in the specialty drug market is about 13.5 percent from 2022 to 2027; that trend will continue to raise cost pressures on hospitals in the 340B program.[24] Many specialty drugs are also the ones experiencing the highest price increases, resulting in steeper 340B discounts, which inflate the size of 340B program discounts that drug companies have to offer.

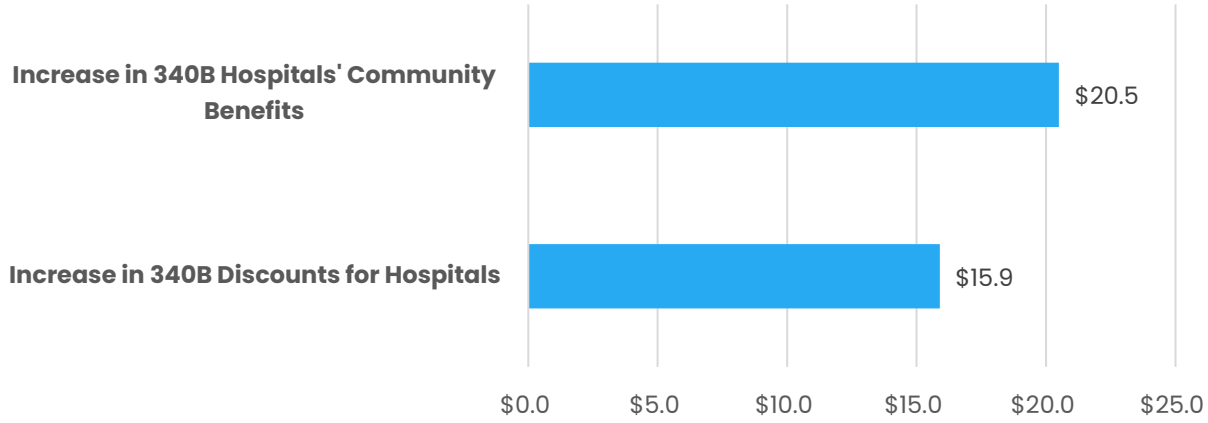
Substitution Effects. Over the past several years, drug therapies have increasingly been able to substitute the need for procedures or surgeries and have contributed to growth in hospital spending on drugs and discounts under the 340B program. One factor amplifying this trend is that there are an increasing number of outpatient drugs subject to 340B discounts for certain conditions. Examples of recent drugs include the use of GLP-1 agonists (e.g., Semaglutide) and repurposed diabetes drugs (e.g., Ozempic and Wegovy) for obesity (to reduce the need for bariatric surgery). CGRP inhibitors (e.g., Aimovig or Nurtec) prevent migraines, which may reduce the need for physician-administered neuromodulation or botulinum toxin administration. Therapeutic advancements in chronic disease management also have resulted in fewer hospitalizations for respiratory, cardiovascular, and inflammatory diseases.

Benefits to Patients Under the 340B Program

The 340B program's discounts on drugs enable participating hospitals and care facilities to stretch resources further to provide high-quality care to more people in need. While the program has grown since 1992 — largely due to the changing treatment landscape for high-cost new therapies — it continues to support affordability and access challenges across the country. The program's growth, especially in rural areas, has helped to reduce disparities in health outcomes by broadening access to treatments and specialty drugs, regardless of insurance, cost, or geographic location.[25,26]

Another important benefit of the 340B program is that savings from the program give hospitals the opportunity to focus on health care disparities in the communities they serve and address challenges in health equity. For example, hospitals have been able to use their additional resources to establish or expand existing programs – such as homeless prevention and nutrition – to address the social determinants of health that are barriers to accessing health care services. One study shows that 340B hospitals were more likely than those not in the program to provide outpatient services for opioid treatment and other medication access services (e.g., discounted medications and prior authorization assistance).[27] Similarly, another study demonstrates that individuals receiving drugs from participating 340B program hospitals for HIV/AIDS maintain higher medication adherence than others due to lower patient costs or improved access to pharmacies.[28]

Figure 7: Increase in Community Benefits vs. 340B Discounts realized by 340B hospitals, 2017-2020 ($Billions)



Estimates of the community benefits—including financial assistance to low-income patients, donations to community programs, and other community-based investments—provided by 340B hospitals show a substantial impact; a review of the most recent IRS 990 data available shows that 340B hospitals provided $84.8 billion in total community benefits.[29] That figure is higher than the estimated discounts from drug purchases under the program and represents a nearly 25 percent increase from the prior year. In fact, looking over time between 2017 and 2020, the increase in community benefits provided by 340B hospitals is considerably greater than the increase in discounts that 340B hospitals have received. (**Figure 7**).

Conclusion

The 340B program plays an important role in ensuring access to essential care for low-income and underserved Americans nationwide. Without the program, fewer patients would be able to access affordable medications and critical health services, jeopardizing their health and well-being. Despite the program's growth, it remains a small share of drug company revenues, illustrating the outsized impact it provides to patients while costing taxpayers no money. Moreover, this growth, largely driven by pricing dynamics and trends in the introduction of new therapies, means more patients can access high-quality care, delivering on its promise to Americans nationwide.

As drug prices continue to rise rapidly with advances in specialty pharmacy and biologics, 340B will become an even more important resource for addressing patient access, affordability, health outcomes and disparities.

[1] In 2010, the Affordable Care Act expanded 340B program eligibility to critical access hospitals, sole community hospitals, rural referral centers, freestanding children's hospitals, and freestanding cancer hospitals.
[2] While many types of providers are eligible to participate in the 340B program, including federal grantee programs like federally qualified health centers, our analysis is limited to 340B hospitals, which are the largest purchasers under the program.
[3] "2022 340B Covered Entity Purchases." HRSA. September 2023.
[4] For clotting factors and certain pediatric drugs, the minimum discount percentage is 17.1%, and for generic drugs, it is 13%.
[5] "The 340B Program." *Health Affairs*. 2017.
[6] PhRMA estimates the 340B Drug Pricing Program exceeds $100 Billion in total sales for 2022 at a wholesale acquisition cost (WAC). WAC is an estimate of the manufacturer's list price for a drug to direct purchasers of the drugs (e.g., wholesalers), not including rebates or discounts.

[7] "National trends in prescription drug expenditures and projections for 2023." American Journal of Health System Pharmacies. July 2023.
[8] "Revenue of the worldwide pharmaceutical market from 2001 to 2022." Statista. January 2023.
[9] According to HRSA, total 340B sales in 2020 were $38 billion. Assuming the same 85% ratio for hospitals, 340B sales to hospitals in 2020 were approximately $32.3 billion.
[10] HRSA's Office of Pharmacy Affairs Information System database and Government Accountability Office (GAO).
[11] "Drug Discount Program: Characteristics of Hospitals Participating and Not Participating in the 340B Program." Government Accountability Office. 2018.
[12] "KaufmanHall. *National Hospital Flash Report."* January 2022.
[13] "Emerging Health Care Issues: Follow-on Biologic Drug Competition." U.S. Federal Trade Commission. 2009.
[14] Paradise, Jordan. "REMS as a Competitive Tactic: Is Big Pharma Hijacking Drug Access and Patient Safety." *House. J. Health L. & Policy* 15 (2015): 43.
[15] "Sg2 Releases '2021 Impact of Change' Report." ASC Focus. 2021.
[16] "Changes in the List Prices of Prescription Drugs, 2017-2023." Office of the Assistant Secretary for Planning and Evaluation (ASPE). 2023.
[17] "Price Increases for Prescription Drugs, 2016-2022." Office of the Assistant Secretary for Planning and Evaluation (ASPE). 2022.
[18] "National Hospital Flash Report." Kaufman Hall. 2022.
[19] "How Big Pharma Exploits Launch Prices to Cash in on Cancer." Office of Representative Katie Porter. 2022.
[20] "Focus: Newly Launched U.S. Drugs Head Toward Record-High Prices in 2022." Reuters. 2022.
[21] "Skyrocketing' Launch Prices for New Cancer Drug Need Reform." Medscape. 2022.
[22] "Cancer: Unpronounceable Drugs, Incomprehensible Prices." Forbes. 2014.
[23] "Trends in Prescription Drug Spending, 2016-2021." Assistant Secretary for Planning and Evaluation. 2022.
[24] "Specialty Drug Distribution Market – Forecast (2023 - 2028)." Industry ARC. 2023.
[25] "Key Facts about the Uninsured Population." Kaiser Family Foundation. 2017.
[26] "Evaluation of 340B prescription assistance program on healthcare use in chronic obstructive pulmonary disease." Exploratory Research in Clinical and Social Pharmacy. 2023.
[27] "Budgetary impact analysis of a primary care-based hepatitis C treatment program: Effects of 340B Drug Pricing Program." PLOS One. 2023.
[28] "A comparison of medication access services at 340B and non-340B hospitals." *Research in Social and Administrative Pharmacy* 17, no. 11 (2021): 1887-1892.Rana, Isha, William von Oehsen, Nadia A. Nabulsi, Lisa K. Sharp, Andrew J. Donnelly, Sima Dinesh Shah, JoAnn Stubbings, and Sandra F. Durley.
[29] Internal Revenue Service (IRS) 990 Schedule H forms that all nonprofit 340B hospitals submit to the government.
[30] "Key Facts about the Uninsured Population." Kaiser Family Foundation. 2017.
[31] "Center for Health care Quality & Payment Reform. Rural Hospitals at Risk of Closing." 2023.
[32] "Key Facts about the Uninsured Population." Kaiser Family Foundation. 2017.