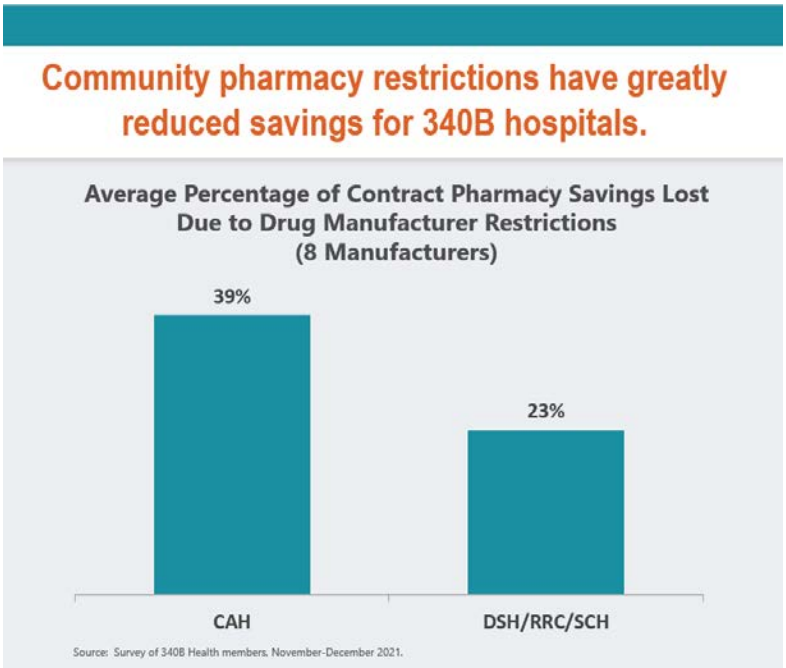
340B HEALTH

MANUFACTURER LIMITS ON COMMUNITY PHARMACY DISCOUNTS HURT FINANCES OF 340B HOSPITALS, HARM PATIENTS

Since July 2020, multiple drug companies have announced that they will limit 340B discounts on outpatient prescription drugs sold to safety-net hospitals and dispensed through community pharmacies, despite government warnings that such actions violate the law. While several of these actions have been in effect for more than a year, others took effect more recently. Today, 12 companies restrict or plan to restrict 340B pricing for such pharmacies: Eli Lilly, AstraZeneca, Sanofi, Novo Nordisk, Novartis, United Therapeutics, Merck, Boehringer Ingelheim, Amgen, UCB, AbbVie, and Bristol Myers Squibb.



BACKGROUND

The 340B drug pricing program, established in 1992, requires drug manufacturers to provide outpatient drugs to eligible health care organizations (covered entities) at reduced prices. In return, these companies are provided access to the Medicare and Medicaid Part B formularies. Covered entities under 340B include providers that are critical to treating low-income and rural populations, such as certain public and non-profit hospitals, federally qualified health centers, and Ryan White HIV/AIDS clinics, among others. 340B was established to allow these providers to purchase outpatient drugs at a reduced cost and to use those savings "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1] 340B provides resources for the safety net at no cost to taxpayers. Drug manufacturers provide the discounts, and the savings from the discounts are invested in patient care.

340B providers receive discounts for drugs dispensed to eligible patients by the covered entity as well as for those dispensed to their patients by community pharmacies with whom they contract. Community pharmacies are an integral part of 340B. These relationships allow better patient access to the medications they need, and the savings provide critical funding for safety-net and rural providers.

THE ISSUE

340B has operated under these rules for nearly 30 years. In July 2020, Eli Lilly became the first drug company to unilaterally impose restrictions on 340B discounts on drugs purchased by covered entities to be dispensed by community pharmacies. Since then, 11 other companies have followed suit. The Health Resources & Services Administration (HRSA), which oversees and administers 340B, determined these restrictions violate the law and has begun the process of notifying drug companies to restore 340B pricing and refund

overcharges. The agency has referred some cases to the Health and Human Services Office of Inspector General (OIG) for potential civil monetary penalties for noncompliance.

Eight of these drug companies have filed lawsuits challenging HRSA's enforcement actions in federal court. To date, two district courts have agreed with HRSA's position that drug companies cannot impose limits on 340B discounts, while a third court said HRSA's reading of the law is not the only possible interpretation. Meanwhile, 340B providers face significant reductions in 340B savings that are creating financial hardship and harming patients. Providers have reported an increasing impact on patients they serve, including being forced to change medications to continue affording their treatments.

KEY FINDINGS

To determine the financial impact to date of the drug companies' actions, 340B Health conducted a survey of its member hospitals. The survey, conducted in November and December 2021, indicates a growing financial burden. The impact is especially severe for small, rural hospitals participating in 340B.

Discounts on drugs dispensed at community pharmacies make up an average of about a quarter of overall 340B savings for hospitals participating in 340B. Among critical access hospitals (CAHs), savings from partnerships with community pharmacies represent an average of 52% of their overall 340B savings. CAHs have 25 or fewer acute care inpatient beds, are located more than 35 miles from another hospital, maintain an average length of stay of 96 hours or less, and provide 24/7 emergency services.

The impact of these policies is growing over time as more manufacturers impose restrictions and as the more recent restrictions have time to take full effect. A survey of 340B hospitals conducted in November and December 2021 by 340B Health found:

- On average, 340B hospitals that are mostly larger and urban already have lost 23% of their community pharmacy savings. These include disproportionate share hospitals (DSH), sole community hospitals (SCHs), and rural referral centers (RRCs).
- For critical access hospitals (CAHs), the percentage loss is significantly greater, averaging 39%.

Annualized dollar losses are substantial. For CAHs, the median reported loss is $220,000, and 10% of these hospitals face losses of $700,000 or more. For DSH/RRCs/SCHs, which often are substantially larger, the median reported loss is $1 million, and 10% of these hospitals reported losses of $9 million or more.

Losses of this magnitude can have a significant impact on safety-net hospitals. Options for hospitals include reducing the scope of services and programs supported by 340B savings, eliminating services, and reducing the number of people employed to provide those services. In the most severe circumstances, a hospital could be forced to close if its losses grow. CAHs consistently have reported that 340B savings are one of the ways they keep their doors open and that a loss of savings could lead to closure. Such options often are the last resort for hospital leaders who are focused on fulfilling their missions as public or private nonprofit hospitals.

METHODOLOGY

Findings are based on a 340B Health survey of members conducted in November and December 2021. A total of 510 hospitals responded to this survey. At the time of the survey, only eight manufacturers had imposed restrictions (Eli Lilly, AstraZeneca, Sanofi, Merck, Novo Nordisk, Novartis, United Therapeutics, and Boehringer Ingelheim). Four more since have joined that group. Thus, the impact presented in this report underestimates the financial impact currently facing 340B providers.

[1] 102nd Congress, Second Session. (1992). H.R. No. 102-384, Part II