Abuse of the Safety-Net 340B Drug Pricing Program: Why Should Physicians Care?

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Madelaine (Mattie) A. Feldman, MD

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The 340B Drug Pricing Program began as a noble endeavor, a lifeline designed to help safety-net providers deliver affordable care to America's most vulnerable populations. However, over the years, this well-intentioned program has strayed from its original purpose, becoming a lucrative space where profits often outweigh patients. Loopholes, lax oversight, and unchecked expansion have allowed some powerful players, such as certain disproportionate share hospitals and their "child sites" as well as for-profit pharmacies, to exploit the system. What was once a program to uplift underserved communities now risks becoming a case study in how good intentions can go astray without accountability.

What exactly is this "340B program" that has captured headlines and the interest of legislatures around the country? What ensures that pharmaceutical manufacturers continue to participate in this program? How lucrative is it? How have underserved populations benefited and how is that measured?

The 340B Drug Pricing Program was established in 1992 under the Public Health Service Act. Its primary goal is to enable covered entities (such as hospitals and clinics serving low-income and uninsured patients) to purchase

outpatient drugs from pharmaceutical manufacturers at significantly reduced prices in order to support their care of the low-income and underserved populations. Drug makers are required to participate in this program as a condition of their participation in Medicaid and Medicare Part B and offer these steep discounts to covered entities if they want their medications to be available to 38% of patients nationwide.

The hospitals that make up 78% of the program's spending are known as disproportionate share hospitals (DSHs). These hospitals must be nonprofit and have at least an 11.75% "disproportionate" share of low-income Medicare or Medicaid inpatients. The other types of non-hospital entities qualifying for 340B pricing are known as initial "federal grantees." Some examples include federally qualified health centers (FQHC), Ryan White HIV/AIDS program grantees, and other types of specialized clinics, such as hemophilia treatment centers. It needs to be noted up front that it is not these initial non-hospital federal grantees that need more oversight or reform, since according to the Health Resources and Services Administration (HRSA) 2023 report they make up only 22% of all program spending. It is the large, predominantly DSH health systems that are profiting immensely through exponential growth of their clinics and contract pharmacies. However, these health systems have not been able to show exactly who are their eligible patients and how they have been benefiting them.

When the 340B program was established to offer financial relief to hospitals and clinics taking care of the uninsured, it allowed them to save 20%-50% on drug purchases, which could be reinvested in patient care services. It was hoped that savings from the program could be used to provide free or low-cost medications, free vaccines, and other essential health services, essentially allowing safety-net providers to serve their communities despite financial constraints. The initial grantees are fulfilling that mission, but there are concerns regarding DSHs. (See the Coalition of State Rheumatology Organization's 340B explanatory statement and policy position for more.)

Why Should Independent Practice Physicians Care About This?

Independent doctors should care about the lack of oversight in the 340B program because it affects healthcare costs, patient assistance, market

competition, and access to affordable care for underserved and uninsured patients.

It also plays a strong hand in the healthcare consolidation that continues to threaten private physician practices. These acquisitions threaten the viability of independent practices in a variety of specialties across the United States, including rheumatology. HRSA allows 340B-covered entities to register their off-campus outpatient facilities, or child sites, under their 340B designation. Covered entities can acquire drugs at the 340B price, while imposing markups on the reimbursement they submit to private insurance. The additional revenue these covered entities can pocket provides them with a cash flow advantage that physician practices and outpatient clinics will never be able to actualize. This uneven playing field may make rheumatology practices more susceptible to hospital acquisitions. In fact, between 2016 and 2022, large 340B hospitals were responsible for approximately 80% of hospital acquisitions.

Perhaps the most important reason that we should all be concerned about the trajectory of this well-meaning program is that we have seen patients with hospital debt being sued by DSHs who receive 340B discounts so that they can take care of the low-income patients they are suing. We have seen Medicaid patients be turned away from a DSH clinic after being discharged from that hospital, because the hospital had reached its disproportionate share (11.75%) of inpatient Medicare and Medicaid patients. While not illegal, that type of behavior by covered entities is WRONG! Oversight and reform are needed if the 340B program is going to live up to its purpose and not be just another well-intentioned program not fulfilling its mission.

Areas of Concern

There has been controversy regarding the limited oversight of the 340B program by HRSA, leading to abuse of the program. There are deep concerns regarding a lack of transparency in how savings from the program are being used, and there are concerns about the challenges associated with accurate tracking and reporting of 340B discounts, possibly leading to the duplication of discounts for both Medicaid and 340B. For example, a “duplicate discount” occurs if a manufacturer sells medications to a DSH at the 340B price and

later pays a Medicaid rebate on the same drug. The extent of duplicate discounts in the 340B program is unknown. However, an audit of 1,536 cases conducted by HRSA between 2012 and 2019 found 429 instances of noncompliance related to duplicate discounts, which is nearly 30% of cases.

DSHs and their contracted pharmacies have been accused of exploiting the program by increasing the number of contract pharmacies and expanding the number of offsite outpatient clinics to maximize profits. As of mid-2024, the number of 340B contract pharmacies, counted by Drug Channels Institute (DCI), numbered 32,883 unique locations. According to DCI, the top five pharmacies in the program happen also to be among the top pharmacy revenue generators and are "for-profit." They are CVS, Walgreens, Walmart, Express Scripts, and Optum RX. Additionally, a study in *JAMA Health Forum* showed that, from 2011 to 2019, contract pharmacies in areas with the lowest income decreased by 5.6% while those in the most affluent neighborhoods grew by 5%.

There also has been tremendous growth in the number of covered entities in the 340B program, which grew from just over 8,100 in 2000 to 50,000 in 2020. Before 2004, DSHs made up less than 10% of these entities, but by 2020, they accounted for over 60%. Another study shows that DSHs are expanding their offsite outpatient clinics ("child clinics") into the affluent neighborhoods serving commercially insured patients who are not low income, to capture the high commercial reimbursements for medications they acquired at steeply discounted prices. This clearly is diverting care away from the intended beneficiaries of the 340B program.

Furthermore, DSHs have been acquiring specialty practices that prescribe some of the most expensive drugs, in order to take advantage of commercial reimbursement for medications that were acquired at the 340B discount price. Independent oncology practices have complained specifically about this happening in their area, where in some cases the DSHs have "stolen" their patients to profit off of the 340B pricing margins. This has the unintended consequence of increasing government spending, according to a study in the *New England Journal of Medicine* that showed price markups at 340B

eligible hospitals were 6.59 times as high as those in independent physician practices after accounting for drug, patient, and geographic factors.

Legal Challenges and Legislation

On May 21, 2024, the US Court of Appeals for the DC Circuit issued a unanimous decision in favor of drug manufacturers, finding that certain manufacturer restrictions on the use of contract pharmacies under the 340B drug pricing program are permissible. The court's decision follows a lower court (3rd Circuit) ruling which concluded that the 340B statute does not require manufacturers to deliver 340B drugs to an "unlimited number of contract pharmacies." We're still awaiting a decision from the 7th Circuit Court on a similar issue. If the 7th Circuit agrees with the government, creating a split decision, there is an increase in the likelihood that the Supreme Court would take up the case.

Johnson & Johnson has also sued the federal government for blocking their proposed use of a rebate model for DSHs that purchase through 340B two of its medications, Stelara and Xarelto, whose maximum fair price was negotiated through the Inflation Reduction Act's Medicare Drug Price Negotiation Program. J&J states this would ensure that the claims are actually acquired and dispensed by a covered 340B entity, as well as ensuring there are no duplicate discounts as statutorily required by the IRA. When initially proposed, HRSA threatened to remove J&J's access to Medicare and Medicaid if it pursued this change. J&J's suit challenges that decision.

However, seven states (Arkansas, Kansas, Louisiana, Minnesota, Missouri, Mississippi, and West Virginia) have been active on this issue, passing laws to prevent manufacturers from limiting contract pharmacies' ability to acquire 340B-discounted drugs. The model legislation also bans restrictions on the "number, location, ownership, or type of 340B contract pharmacy."

It should also be noted that there are states that are looking for ways to encourage certain independent private practice specialties (such as gastroenterology and rheumatology) to see Medicaid patients, as well as increase testing for sexually transmitted diseases, by offering the possibility of obtaining 340B pricing in their clinics.

Shifting our focus to Congress, six bipartisan Senators, known as the Group of 6, are working to modernize the 340B program, which hasn't been updated since the original law in 1992. In 2024, legislation was introduced (see here and here) to reform a number of the features of the 340B drug discount program, including transparency, contract pharmacy requirements, and federal agency oversight.

Who's Guarding the Hen House?

The Government Accountability Office and the Office of Inspector General over the last 5-10 years have asked HRSA to better define an "eligible" patient, to have more specifics concerning hospital eligibility criteria, and to have better oversight of the program to avoid duplicate discounts. HRSA has said that it doesn't have the ability or the funding to achieve some of these goals. Consequently, little has been done on any of these fronts, creating frustration among pharmaceutical manufacturers and those calling for more oversight of the program to ensure that eligible patients are receiving the benefit of 340B pricing. Again, these frustrations are not pointed at the initial federally qualified centers or "grantees."

HRSA now audits 200 covered entities a year, which is less than 2% of entities participating in the 340B program. HRSA expects the 340B entities themselves to have an oversight committee in place to ensure compliance with program requirements.

So essentially, the fox is guarding the hen house?

Dr. Feldman is a rheumatologist in private practice with The Rheumatology Group in New Orleans. She is the CSRO's vice president of advocacy and government affairs and its immediate past president, as well as past chair of the Alliance for Safe Biologic Medicines and a past member of the American College of Rheumatology insurance subcommittee. You can reach her at rhnews@mdedge.com.