COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS

Explanatory Statement: 340B Drug Discount Program

Background

In 1992, Congress created Section 340B of the Public Health Service Act, known as the 340B drug discount program. The program was intended to provide discounted outpatient medications for qualifying hospitals and clinics that treat low-income and uninsured patients. As a condition of their participation in Medicaid and Medicare Part B, all pharmaceutical manufacturers are required to offer discounted drugs to 340B participating facilities, known as covered entities. Drug manufacturers are responsible for absorbing the difference in cost for the discounted drugs.

In 2010, the Health Resources and Services Administration (HRSA), which oversees the 340B program, issued final guidance[i] allowing covered entities to have arrangements with an unlimited number of contract pharmacies that can access discounted drugs through the program. Both the original law and the 2010 rule were vaguely written and left room for interpretation, which has created much debate over the intended execution of the 340B program.

The volume of drugs purchased through the program has grown significantly over the past three decades. HRSA reported a 23% increase in medications purchased through the 340B drug discount program between 2017-2018 and again from 2018-2019.[ii] Due to the program's growth, stakeholders have introduced a variety of legislative proposals that would clarify the scope of 340B responsibilities for hospitals, clinics and manufacturers. Manufacturers have also filed several lawsuits challenging the scope of their responsibility to the program.

Legislative Activity

In addition to the legal action taking place in the district courts, Congress and state legislatures have been forced to address the issue as well. By 2024, six states (AR, KS, LA, MN, MO, MS, WV) passed legislation that prohibits pharmaceutical manufacturers from restricting the contract pharmacy's ability to acquire 340B discounted drugs through their relationship with a covered entity. The model language also prohibits restrictions on the "number, location, ownership or type of 340B contract pharmacy."

At the federal level, six bipartisan Senators, known as the Group of 6[iii], are working to modernize the 340B program, which has not been addressed by Congress since the original law was enacted in 1992. In 2024, Congress introduced legislation that would reform various aspects of the 340B drug discount program – including transparency, contract pharmacy requirements, and federal agency oversight.

Stakeholders

Covered Entities

340B covered entities include disproportionate share hospitals, Federally Qualified Health Centers, Native Hawaiian or Tribal Indian health centers, Ryan White HIV/AIDS facilities, among others. Covered entities may access 340B pricing on outpatient drugs for all patients, regardless of their insurance status. 340B covered entities may dispense 340B purchased drugs through in-house pharmacies or through agreements with contract pharmacies. Contract pharmacies are not owned by these entities; instead, their 340B eligibility is tied to their relationship with the covered entity. According to a 2018 US Government Accountability Office (GOA) report, these covered entities can save 20-50% of the cost of the drug through their 340B discount. They can also generate additional revenue by purchasing drugs at the 340B price for patients whose insurance reimbursement exceeds the 340B price paid by the entity.[iv]

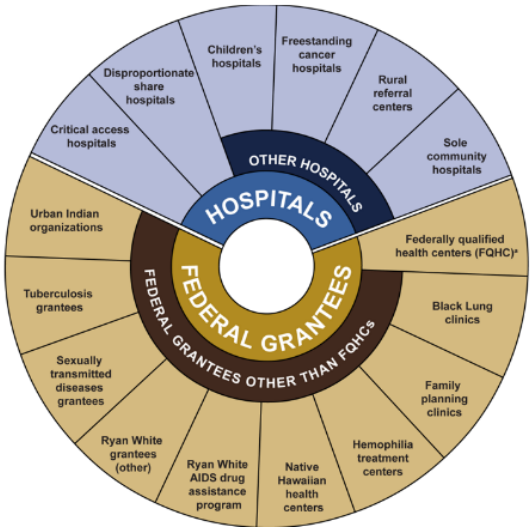

Figure 1. Types of Entities Eligible to Participate in the 340B Program

Contract Pharmacies

According to GOA, the number of pharmacies that contract with 340B entities, also known as contract pharmacies, has increased "more than fifteen-fold" since the 2010 final rule guidance that allows for an unlimited number of contracts. Initially these contract pharmacies were primarily located in the same communities as the covered entity. However, today GOA reported that contract pharmacies are located between 0-5,000 miles away from their associated covered entity.[v] More than half of all U.S. pharmacy locations act as a contract pharmacy for a covered entity participating in the 340B program.[vi] CVS Health, Walgreens, Cigna (via Express Scripts), UnitedHealth Group (via OptumRx), and Walmart, all publicly traded vertically integrated pharmacy-PBMs, account for 75% of all contract pharmacy relationships with 340B covered entities.[vii]

Pharmaceutical Manufacturers

All pharmaceutical manufacturers are required to offer 340B drug discounts to covered entities as a condition of their participation in Medicaid and Medicare Part B. Manufacturers have attempted to limit the breadth of their responsibility to the program by challenging HRSA regulations and by placing contractual limitations on contract pharmacies and covered entities that purchase their medications. In recent years, manufacturers have placed restrictions on contract pharmacies to reign in broad reaching arrangements between covered entities and contract pharmacies. In 2021, following a legal challenge on these restrictions, a U.S. Circuit Court confirmed that manufacturers may impose conditions on how they distribute medications through the program. In 2024, manufacturers filed at least four lawsuits challenging state laws that prohibit manufacturers from restricting contract pharmacy use by covered entities in the state. A previous lawsuit in Arkansas (*PhRMA v. McClain*) was dismissed as the district court determined that the 340B statute did not preempt the state law.

Patients

The 340B drug discount program was created with a noble mission – to ensure that underserved, low-income and uninsured patients receive the medications they need at little to no cost. This was to ensure that vulnerable patients can better adhere to their prescribed medications and improve the healthcare of patients who may otherwise be unable to afford their medications.

However, the focus of the original law was on the facility, not on the patient. Therefore, HRSA does not define a 340B eligible patient beyond the patient's relationship with the covered entity. The patient must:

- have an established relationship with the covered entity through documented health records
- receive services from a health care professional who is employed or contracted by the covered entity
- receive care from the covered entity for services for which grant funding or FQHC look-alike status has been provided (Disproportionate share hospitals are exempt from this requirement)

Patients are not permitted to engage with the covered entity for the sole purpose of receiving medication.

The most specific criterium for 340B patient eligibility is that patients registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHS Act are covered under the program as long as they receive care from a covered entity.

The 340B program does not dictate how covered entities must use the 340B savings or require discounts on the drugs to be passed along to patients. That said, FQHCs, Ryan White AIDS clinics and other covered entities serve some of this country's most vulnerable patients, often time at little to no charge to the patient. Many of these organizations have historically reinvested their 340B savings back into patient care, including subsidized uncompensated care, dispensing free or low-cost medications, offering patients transportation, and providing patient educational services.

Areas of Concern

Healthcare Consolidation

According to a 2022 Congressional Budget Office report, the 340B program could encourage large healthcare systems that prescribe expensive 340B eligible medications to acquire physician practices, such as rheumatology and oncology. These acquisitions threaten the viability of rheumatology practices across the United States. HRSA allows 340B covered entities to register their off-campus outpatient facilities, or child sites, under their 340B designation. Covered entities, such as hospitals and their off-campus facilities, have a competitive advantage as they can purchase drugs at a 20-50% discount through their 340B status.

According to a study in the New England Journal of Medicine, after accounting for drug, patient, and geographic factors, price markups at 340B eligible hospitals were 6.59 times as high as those in independent physician practices. Covered entities can acquire drugs at the 340B price, while imposing markups on the reimbursement they submit to private insurance. In this study, 340B eligible hospitals earned $650.24 more per drug unit than independent physician practices. This may also have the unintended consequence of exacerbating federal healthcare spending.

Figure 2. Median Ratio of Drug Reimbursement Price to Drug Acquisition Price for Hospitals and Physician Practices.

Drug Type	Hospitals Eligible for 340B Discounts	Hospitals Not Eligible for 340B Discounts	Independent Physician Practices
		median ratio (interquartile range)	
All drugs	3.08 (1.87–6.38)	2.44 (1.40–4.95)	1.12 (1.02–1.63)
Drugs for oncologic conditions	3.19 (1.94–7.07)	2.48 (1.42–5.23)	1.13 (1.02–1.81)
Drugs for inflammatory conditions	2.26 (1.63–3.98)	1.54 (1.08–2.99)	1.07 (1.00–1.23)
Drugs for blood-cell deficiency disorders	2.95 (1.88–4.73)	2.57 (1.58–4.44)	1.20 (1.04–1.76)

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. Between 2016-2022, large 340B hospitals were responsible for

approximately 80% of hospital acquisitions.[viii]

Transparency and Oversight

Many advocates for reform have highlighted the lack of transparency and oversight over the program. Covered entities claim that the program's growth is an essential tool in providing uncompensated care to millions of uninsured Americans. Advocates have called for confirmation that the intended patient populations are actually receiving the discounted drugs that are intended for them.

Increased transparency and oversight of the 340B program could improve the program's integrity, ensuring patients in need receive these discounted medications, while curbing hospital systems' unfair advantage over non-340B physician practices. According to GOA, as of 2018, HRSA only audited 200 entities per year, or approximately 1.6% of all covered entities.[ix] A 2017 HRSA report confirmed noncompliance for covered entities was between 63-82%. Noncompliance includes flawed recordkeeping on 340B program eligibility, duplicate discounting and diversion of 340B product. Shockingly, HRSA generally relies on covered entities to self-attest that all violations have been addressed and does not require evidence that corrective action has been taken.[x]

Currently, covered entities are not required to report their 340B revenue, how 340B revenue is used, or confirmation of the volume of uncompensated care offered by the covered entity. The New York Times, the Washington Post, the Wall Street Journal and STAT News have recently documented how 340B hospitals are not reinvesting savings in underserved communities, but instead diverting those funds to more lucrative healthcare markets in affluent suburbs. Reporting on these areas would promote trust and accountability within the 340B program, ensuring patients are the beneficiaries of 340B instead of covered entities.

Realigning the Program's Mission

According to HRSA, the goal of the 340B program is to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[xi] While this mission strives to serve the patient, it has been executed in a manner that puts the covered entity before the patient. There are no clear requirements that covered entities must pass 340B drug discounts on to underserved, low-income and uninsured patients. Instead, there is an expectation that covered entities will reinvest those funds judiciously to serve those patients. It's clear that the directive must be more explicit to best serve vulnerable patient populations.

Conclusion

The 340B drug discount program was created with a noble mission – to ensure that underserved, low-income and uninsured patients receive the medications they need at little to no cost. This ensures that vulnerable patients can better adhere to their prescribed medications and improves the healthcare of patients who may otherwise be unable to afford their medications. However, over the past three decades, the program has grown greatly, demonstrating weaknesses in its implementation and execution. These weaknesses fail to consistently serve patients in need and compromise the ability of providers outside the 340B program to continue offering essential care in the community. The 340B drug discount program would benefit from realigning the program's mission by placing the patient first and by establishing greater transparency and accountability to ensure the program's success.

Updated: 9/20/2024

Sources

Figure 1: U.S. Government Accountability Office. Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement. June 2018.
Figure 2: New England Journal of Medicine. Hospital Prices for Physician-Administered Drugs for Patients with Private Insurance. January 2024.

[i] Notice Regarding 340B Drug Pricing Program—Contract Pharmacy Services, 75 Fed. Reg. 10272 (Mar. 5, 2010).
[ii] Drug Channels. New HRSA Data: 340B Program Reached $29.9 Billion in 2019; Now Over 8% of Drug Sales. June 2020.
[iii] As of Sept 2024, the 340B Group of 6 includes Senators John Thune (R-SD), Tammy Baldwin (D-WI), Jerry Moran (R-KS), Shelley Capito (R-WV), Ben Cardin (D-MD), and Debbie Stabenow (D-MI)
[iv] Congressional Budget Office. Policy Approaches to Reduce What Commercial Insurers Pay for Hospitals' and Physicians' Services. September 2022.
[v] U.S. Government Accountability Office. Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement. June 2018.
[vi] Drug Channels. EXCLUSIVE: For 2023, Five For-Profit Retailers and PBMs Dominate an Evolving 340B Contract Pharmacy Market. July 2023.
[vii] ibid
[viii] Avalere. Characteristics of Hospitals Undergoing Mergers and Acquisitions. February 2023.
[ix] U.S. Government Accountability Office. Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement. June 2018.
[x] ibid
[xi] HRSA. 340B Drug Pricing Program.