

ADVOCACY

HISTORY OF THE 340B PROGRAM

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A little-known program that establishes pathways of care for underserved communities is under attack by drug manufacturers. Created in 1992, the federal 340B Drug Pricing Program enables covered entities, such as Prism Health North Texas, to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.¹ With parameters established by both covered entities and pharmaceutical manufacturers, the program costs taxpayers nothing. However, 340B has come under great scrutiny in the past few years as program use continues to rise, and manufacturers renege on past agreements. This poses a tremendous threat to Ryan White and STI clinics that serve the uninsured on already limited resources, and creates unnecessary barriers in the fight to end the HIV epidemic.

What Is 340B?

The 340B program is monitored by the federal Health Resources & Services Administration (HRSA), under the Office of Pharmacy

Affairs (OPA) umbrella. Only specific covered entities (CEs) may participate, including Disproportionate Share Hospitals (DSH), children's and free-standing cancer hospitals, Federally Qualified Healthcare Centers (FQHC), Ryan White HIV/AIDS program grantees, sexually transmitted infection (STI) clinics, and Title X family planning clinics. For drug manufacturers to participate in the federal Medicaid program, they must agree to provide outpatient drugs to covered entities at significantly reduced prices. CEs are reimbursed by the manufacturers at the market value and pass those savings along to clients. Savings must go back into programs and care, such as copay assistance, transportation, rapid start medications, and more.

PHNTX: Who We Are

Prism Health North Texas opened services in 1986 during the HIV/AIDS crisis in North Texas. Formed as AIDS Arms Network out of the Communities Foundation of Texas, PHNTX for the past 35 years has served the critical role of connecting people living with HIV to care and services in the area. PHNTX evolved to be

a nationally recognized leader in delivering high-quality HIV and sexual health services, most recently expanding services to address the alarming rise in sexually transmitted infections in Dallas County and North Texas. Roughly 30 percent of people living with HIV in North Texas receive medical care and support at one of our four health centers.

PHNTX is committed to providing health-care for all North Texans in a non-judgmental and affirming environment. The organization strives to remove the barriers that prevent any individual from accessing quality health-care. PHNTX stands for health equity—especially for marginalized populations, including people living with HIV, LGBTQIA+, and ethnic minorities. Every individual has the right to affordable, accessible health care and the opportunity to attain their highest level of health.²

340B Impact

Of the clients we serve, 43 percent have a household income of less than 100 percent of the Federal Poverty Level (FPL), and 54 percent have no health insurance. Texas has



not changed eligibility requirements for Medicaid; therefore only 8 percent of our clients utilize this program. The Ryan White HIV/AIDS Program is a longtime and reliable resource but has remained largely flat-funded over the past 10 years, regardless of growth in participants.³

Without the 340B program, our ability to provide quality healthcare to people living with HIV would be severely compromised. In 2020, PHNTX provided \$3.3 million in specific assistance thanks to the 340B program. With COVID-19 wreaking havoc across North Texas, we were able to accommodate 138 clients with over 1,000 vouchers for emergency housing, in addition to our established 340B funded services. Based on level grant funding since 2010 against the annual medical inflation index, without 340B, we would have the capacity to serve half of our current clients, without accounting for growth. There would be less funding for non-medical wraparound support services, as well as a greater dependence on other safety net programs such as hospital districts. The healthcare system would be more segmented, and health inequities would increase.

Threats to the 340B Program

In the summer of 2020, six pharmaceutical companies began withholding 340B discounts from safety-net providers and federal grantees. The number of companies doing this has grown to include 16. That October, an initial lawsuit was filed by Ryan White Clinics for 340B (RWC 340B) and 340B grantees stating that manufacturers were violating mandated HRSA regulations by refusing to dispense medications through contract pharmacies.⁴ One of the most difficult challenges we face when advocating for the 340B drug pricing program is the failure of HRSA to enforce actions against pharmaceutical companies that refuse to honor 340B discounts on prescription drugs. Without the ability to utilize contract pharmacies, the 340B program will not operate as intended. The Complaint for Declaratory and Injunctive Relief compelled HRSA to enforce rules that are currently in place.⁵ Multiple lawsuits between CEs, manufacturers, and HRSA are ongoing as 340B advocates continue to state their case.

340B Allies

At the 340B Coalition summer conference this past August, speakers such as HRSA Administrator Carole Johnson and the HRSA Director of OPA, Dr. Emeka Egwim, pledged to address the many hurdles that the 340B program currently faces, including enforcing policies already in place.

Two of the strongest legislative allies of the program are Representatives Abigail Spanberger (D-VA) and David McKinley (R-WVA). They have led multiple efforts to gain bipar-

tisan support for the 340B program by asking their colleagues to sign on to letters urging both the past and present HHS secretaries to conclude their investigation and begin enforcement of civil monetary penalties. The most recent letter, sent this past July to HHS Secretary Xavier Becerra, garnered 175 signatures.⁶ Below is an excerpt:

“Specifically, we urge the Department of Health and Human Services (HHS) and its Office of the Inspector General (OIG) to use current statutory authority to impose civil monetary penalties against all drug manufacturers who have unlawfully overcharged safety net health care providers. Manufacturers have received multiple warnings that their overcharges are unlawful, but still refuse to comply. Further delay of enforcement actions emboldens more manufacturers to begin overcharging safety net providers, threatening the integrity of the entire 340B program.”

The Importance of Compliance

Compliance to the original intent of 340B, which is to stretch scarce federal resources to provide optimal care, is key to the success and continuation of the program. Once a CE has completed the rigorous certification process, they must recertify every year. There must be program integrity and compliance related to eligibility, duplicate discounts, and diversion, which is when a 340B medication is dispensed to an ineligible patient. Programs may be audited by HRSA at any time, and many, including PHNTX, participate in multiple self-audits yearly to identify and correct any potential discrepancies. Consequences of non-compliance include repayment of savings to manufacturers, termination of relationships with contract pharmacies, and removal from the 340B program. Smaller CEs rely too heavily on the program to disregard compliance mandates.

How to Support 340B

As a provider, you make your greatest contribution to the 340B program by maintaining compliance with it. This includes:

- Notifying 340B staff if you have prescribing privileges outside of your place of employment, including volunteer commitments
- Providing sufficient documentation for all prescriptions in the patient medical record, including those that are handwritten or prescribed via telephone
- Not steering patients toward specific contract pharmacies—this choice remains with the client
- Prescribing only to eligible patients (must have an established relationship with the CE and provider that maintains responsibility for care)
- Avoiding duplicate discounts and diversion

Traditional advocacy efforts are important as well. Providers are the boots on the ground and can attest to the impact of the 340B program on both their clients and their communities. Consider sharing your stories with federal lawmakers by getting involved with organizations such as Community Voices 340B, which seeks to raise awareness of the important role the program plays in protecting and improving health care access and the quality of care for communities nationwide.⁷ Send your elected officials a tweet asking them to support the 340B program and utilize the hashtags #340Bthankful and #Let340B. Add this issue to your list of talking points when you visit with decision makers.

The Future

Ryan White and STI clinics and the clients and communities we serve have much to lose from drastic changes to the 340B Drug Pricing Program. We strive for transparency and compliance in all that we do. Many years have been spent developing a cohesive plan to end the U.S. HIV epidemic, and 340B plays a crucial role. Without it, we stand to lose momentous gains. **DMJ**

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