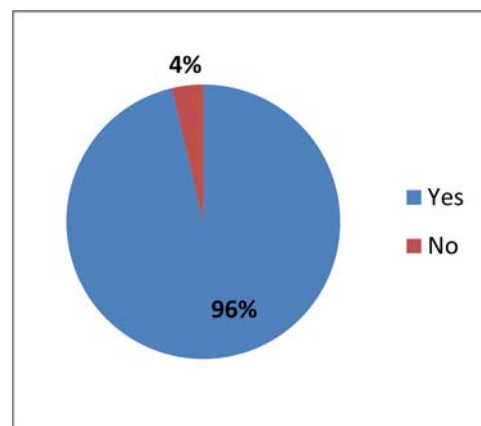


The 340B Drug Discount Program: Benefits and Challenges for Title X

The Role of 340B in Title X

The 340B Drug Pricing Program makes it possible for Title X health centers and other qualifying entities to provide drugs to low-income patients at a significant discount. 340B-priced drugs often have a lower cost than those provided through the Medicaid program.

In addition to benefitting patients, the 340B program results in significant savings for Title X-funded health centers. According to a 2004 study by Mathematica Policy Research, Inc., family planning health centers saved an estimated \$97.5 million annually by utilizing the 340B program.ⁱ More than 90% of all Title X family planning providers are enrolled in 340B.ⁱⁱ



96% of NFPRHA members are enrolled in the 340B program.

How 340B Works

The 340B program is administered by the Health Resources and Services Administration's (HRSA) Office of Pharmacy Affairs. All pharmaceutical manufacturers participating in Medicaid are required to participate in the 340B program as part of the Pharmaceutical Pricing Agreement (PPA), which mandates that manufacturers provide up-front discounts on covered outpatient drugs purchased by covered entities. The list of covered entities includes, but is not limited to, Title X health centers, STD clinics (entities receiving funds under Section 318 of the Public Health Service Act), hospitals serving a high percentage of uninsured patients, and federally qualified health centers. Covered entities participating in the 340B program may purchase discounted drugs through wholesalers, state purchasing programs, and group purchasing programs. They can also purchase drugs directly from the manufacturer.

Drugs are discounted at the set rate of 23.1% for brand-name drugs and 13% for generic and over-the-counter (OTC) drugs from the average manufacturer price.ⁱⁱⁱ The ceiling price of a drug is the lower of either the 340B-discounted price or the lowest available price. Additional discounts are available if the price of the drug has increased faster than the rate of inflation.^{iv}

Covered entities can only provide drugs that they receive under the 340B program to patients, legally defined as those individuals with whom a covered entity has an established relationship and who receive services consistent with the scope of the covered entity's grant funding or status. Providing 340B drugs to anyone other than a patient is considered drug diversion and is illegal.^v

Once a Title X-funded health center is registered as a covered entity in the 340B program, it can receive 340B price lists. These prices must be honored by manufacturers and can even be negotiated downward by the

covered entity. Some health centers also choose to participate in the federally contracted group-purchasing Prime Vendor Program, currently run by Apexus. Apexus is responsible for negotiating lower drug prices for covered entities.^{vi}

340B Challenges for Title X

Title X health centers have raised concerns that the 340B program's pricing methods are unclear and change often. Fluctuations in prices make it difficult for health centers to stock and budget accurately. The frequent price changes also challenge health centers' ability to make timely adjustments to their sliding-fee scales. This may cause patients to switch to medications other than their preferred methods, and those alternatives may be less effective for them.

Participation in the 340B program also comes with several logistical challenges. Title X health centers often use multiple purchasing systems because some methods are only available directly from the manufacturer. Health centers have reported some difficulties organizing the stock needed to meet patient needs because of differing drug purchasing rules. Safeguarding against drug diversion is also an ongoing concern that results in health centers having to maintain separate inventories to monitor which patients access 340B drugs. Some health centers have decided to write prescriptions to be used at an outside pharmacy instead of dispensing on-site medications to prevent diversion. While this reduces time-consuming inventorying within a health center, the practice can be a barrier to care for patients.

340B in Congress

The 340B program has recently come under heightened scrutiny from several members of Congress who allege the program has deviated from its original intent. The program's integrity was questioned in a 2011 Government Accountability Office study commissioned by Senators Orrin Hatch (R-UT) and Mike Enzi (R-WY) who followed up the study with a March 2012 request of the Pharmaceutical Manufacturers Association of America, Biotechnology Industry Organization, Apexus, Inc. and the Safety Net Hospitals for Pharmaceutical Access, for a detailed accounting of the program.^{vii} Other attacks have been based on the false premise that the 340B program and its growth contribute to drug shortages. In 2012, Representatives Joe Pitts (R-PA) and Bill Cassidy (R-LA) asked HRSA to issue a revised 340B patient definition that would limit the program to uninsured patients only. However, limiting 340B coverage based on insurance status would force covered entities to abandon established relationships with many underinsured and low-income patients in need of affordable drugs. Such a change would be detrimental to the patients and the providers that benefit from the 340B program. NFPRHA and its coalition partners will continue to fight to protect the 340B program, which greatly benefits Title X health centers and their patients.

ⁱ The Lewin Group and the Guttmacher Institute, *Analysis of the Effectiveness of Title X Family Planning Providers' Use of the 340B Drug Pricing Program*, October 2009, <http://www.hhs.gov/opa/pdfs/304b-analysis-of-effectiveness.pdf>.

ⁱⁱ *Ibid.*

ⁱⁱⁱ "Pharmacy Affairs & 340B Drug Pricing Program: Glossary of Pharmacy-Related Terms," US Health Resources and Services Administration website, accessed July 13, 2012.

^{iv} The Lewin Group and the Guttmacher Institute.

^v "Pharmacy Affairs."

^{vi} "An Overview of The Section 340B Drug Discount Program," Safety Net Hospitals for Pharmaceutical Access website, accessed July 13, 2012, http://www.snhpa.org/public/340b_overview.cfm.

^{vii} Office of Senator Chuck Grassley, "Grassley, Enzi, Hatch, Pitts Seek Details of Discount Drug Program," news release, March 5, 2012, http://www.grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=39441.