

The 340B Drug Pricing Program

Benefits and Challenges for Title X

The 340B Drug Pricing Program, administered by the Health Resources and Services Administration's (HRSA) Office of Pharmacy Affairs, makes it possible for Title X-funded health centers and other qualifying entities to access significant discounts on prescription drugs and offer those drugs to patients at a reduced price. The 340B program is designed to help Title X-funded health centers "stretch scarce federal resources as far as possible, reach more eligible patients, and provide more comprehensive services."

How 340B Works

- All pharmaceutical manufacturers selling their drugs in Medicaid are required to participate in the 340B program as part of the Pharmaceutical Pricing Agreement, which mandates that manufacturers provide up-front discounts on covered outpatient drugs purchased by eligible providers.
- Providers participating in the 340B program (referred to as "covered entities") can purchase discounted drugs through the Prime Vendor Program (run by Apexus), wholesalers, state purchasing programs, and group purchasing programs. They can also purchase drugs directly from the manufacturer.
- 340B covered entities can only provide drugs that they purchase at the discounted rate to patients that meet the established definition. The current patient definition requires that the individual: 1) have an established relationship (i.e. a medical record) with the covered entity; 2) receive health care services from a health care professional employed by the covered entity (or who provides care under contractual or other arrangements); and, 3) receive a health care service consistent with the services supported by the grant which makes a covered entity eligible for 340B.ⁱⁱ
- Providing 340B drugs to patients who do not meet the definition above is considered diversion and is illegal.

Providers Eligible for 340B

- By statute, Title X-funded health centers are designated as covered entities under the 340B program. Safety-net family planning health centers that do not receive Title X funds may also be eligible for 340B if they receive Section 318 sexually transmitted disease funds from the Centers for Disease Control and Prevention. Other eligible providers are:
 - Federally qualified health centers (FQHC) and FQHC "look alike" centers
 - Native Hawaiian and Tribal/Urban Indian Health Centers
 - Ryan White HIV/AIDS program grantees
 - Certain types of hospitals, including children's hospitals, critical access hospitals, disproportionate share (DSH) hospitals, free-standing cancer hospitals, rural referral centers, and sole community hospitals
 - Other types of specialized clinics, including: black lung clinics; hemophilia treatment centers, and, tuberculosis clinicsⁱⁱⁱ

340B under Increased Scrutiny

- The 340B program has grown considerably since its establishment in 1992. In 2011, the Government Accountability Office (GAO) reported that there were 16,500 covered entities participating in the program^{iv}, up from 12,000 in 2005.^v The Affordable Care Act (ACA) also expanded provider eligibility to include critical access hospitals, rural referral centers, and other hospital types.^{vi}
- This rapid growth has led to increasing levels of opposition from pharmaceutical manufacturers, which formed the Alliance for Integrity and Reform of 340B (AIR 340B), a coalition formed in 2013 of manufacturers, pharmaceutical trade groups and some patient groups.
- AIR 340B has called for increased accountability and transparency in the program and has advocated for a narrowing of the definition of the patient definition to limit access to 340B drugs to patients who are low-income or uninsured.^{vii}
- AIR 340B and other groups calling for narrowing the 340B patient definition have supporters on Capitol Hill. In 2012, Representative Joseph Pitts (R-PA), Chairman of the House Energy and Commerce Committee Subcommittee on Health, and then-Rep. Bill Cassidy (R-LA) wrote a letter to HRSA calling on it to release an updated patient definition limiting 340B drugs to patients who are "medically uninsured, on marginal incomes, and with no other source to turn to for preventive and primary care services."^{viii}

340B Challenges for Title X

- Many state Medicaid agencies have moved toward only reimbursing 340B providers for their actual acquisition cost plus a small dispensing fee. This policy takes the savings intended for providers and moves them to the state, defeating the purpose of the program as it was conceived.
- Efforts to restrain growth in the program, particularly in the form of narrowing the patient definition, could result in lower savings for Title X providers, which could limit the value of participating in the 340B program.

Looking Ahead

- HRSA proposed omnibus guidance covering most facets of the 340B program in August 2015, and NFPRHA submitted comments on that proposal. It is unclear when, or even whether, the guidance will be finalized.
- NFPRHA continues to advocate on Capitol Hill and with the Obama administration to emphasize the importance of the 340B program to Title X and other safety-net family planning health centers.

ⁱ "The 340B Drug Pricing Program," The Health Resources and Services Administration, Office of Pharmacy Affairs, accessed March 11, 2015 <http://www.hrsa.gov/opa>.

ⁱⁱ "340B Eligibility and Registration," The Health Resources and Services Administration, Office of Pharmacy Affairs, accessed March 11, 2015 <http://www.hrsa.gov/opa/eligibilityandregistration/index.html>.

ⁱⁱⁱ Ibid.

^{iv} U.S. Government Accountability Office. *Drug Pricing: Manufacturer Discounts in the 340B Program Offers Benefits, but Federal Oversight Needs Improvement (GAO-11-836)*, accessed March 11, 2015, <http://www.gao.gov/assets/330/323702.pdf>.

^v "Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of "Patient." *Federal Register* 72:8 (January 12, 2007) pp. 1543-66.

^{vi} Patient Protection and Affordable Care Act of 2010, Pub. L. No. 11-148, 124 Stat. 119 (2010).

^{vii} "AIR 340B Core Principles," Alliance for Integrity and Reform of 340B website, accessed March 11, 2015, <http://www.340breform.org/page.asp?id=76>.

^{viii} Rep. Joseph Pitts and Rep. Bill Cassidy to HRSA Administrator Mary Wakefield, July 18, 2010, <http://pitts.house.gov/sites/pitts.house.gov/files/documents/071812%20Mary%20K%20%20Wakefield%20340b%20Drug%20Pricing%20Program%20Ltr.pdf>.