

FACT SHEET

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 health centers "stretch scarce federal resources as far as possible, reach more eligible patients, and provide more comprehensive services."¹

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 organizations. 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.²

PROVIDERS ELIGIBLE FOR 340B

- By statute, Title X-funded health centers are designated as covered entities under the 340B program. Other eligible providers are:

- Recipients of Centers for Disease Control and Prevention section 318 sexually transmitted disease treatment and prevention funds or in-kind donations
- 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 clinics³

340B UNDER INCREASED SCRUTINY

- Growth in the number of covered entities participating in the 340B program has led to increasing levels of opposition to the current requirements of the program from pharmaceutical manufacturers and some members of Congress. Many of these stakeholders have called for increased accountability and transparency in the program, particularly for hospitals. Some have also advocated for a narrowing of the patient definition to limit access to 340B drugs to patients who are low-income or uninsured.⁷
- In the 115th Congress, the House Energy and Commerce committee and the Senate HELP committee held hearings evaluating various aspects of the 340B program. Several members of Congress have also introduced legislation reforming the program, but none of this legislation has progressed past the committee level thus far.

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 original purpose of the program.
- 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.

¹ "The 340B Drug Pricing Program," The Health Resources and Services Administration, Office of Pharmacy Affairs, accessed March 11, 2015 <http://www.hrsa.gov/opa>.

³ Ibid.

² "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>.

⁴ "AIR 340B Mission," Alliance for Integrity and Reform of 340B website, accessed December 7, 2018, <http://340breform.org/our-mission>