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340B DRUG PRICING PROGRAM

An Overview

Introduction

The 340B Drug Pricing Program allows certain healthcare organizations, called covered entities, to buy drugs from manufacturers at heavily reduced prices. The federal program, established by Section 340(B) of the Public Health Service Act and administered by the Health Resources and Services Administration (HRSA), an agency within the U.S. Department of Health and Human Services, is intended to enable safety net providers to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[1]

History

Since its inception in 1992, the 340B program has undergone various changes, including expanded eligibility for new covered entities and relaxed eligibility criteria for some existing covered entities. Acts of Congress that have modified the program include the Medicare Modernization Act of 2003, which made it easier for rural hospitals to participate; the Deficit Reduction Act of 2005, which expanded eligibility to children's hospitals; and the Patient Protection and Affordable Care Act of 2010, which opened new categories of covered entities: critical access hospitals, sole community hospitals, rural referral centers, and cancer hospitals.

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How 340B Works

The program requires drug manufacturers that participate in the Medicaid Drug Rebate Program to sell certain drugs to 340B covered entities at a discount. Covered entities must register to participate before they can purchase drugs at 340B prices. Each type of entity has its own requirements to become eligible. For example, hospitals (except critical access hospitals) must serve a disproportionate number of low-income patients. Once registered, covered entities must recertify annually to continue participation.

Covered entities may purchase outpatient drugs directly from drug manufacturers or distributors. Covered outpatient drugs are dispensed through a prescription and are not provided during inpatient stays or most outpatient hospital services. Orphan drugs — those used to treat rare diseases or disorders — are not covered 340B drugs. A covered entity may deliver drugs to eligible patients at various locations such as retail pharmacies owned by the covered entity, pharmacies that contract with the covered entity, or clinical settings.[2]

Covered Entities

Below is the list of eligible organizations.

HOSPITALS

- Hospitals serving a disproportionate number of low-income patients
- Children's hospitals
- Critical access hospitals
- Free-standing cancer hospitals
- Rural referral centers
- Sole community hospitals

HEALTH CENTERS

- Federally qualified health centers and look-alikes
- Native Hawaiian health centers
- Tribal/Urban Indian health centers

PROGRAM GRANTEES

- Ryan White HIV/AIDS Program grantees

SPECIALIZED CLINICS

- Black lung clinics
- Comprehensive hemophilia diagnostic treatment centers
- Title X family planning clinics
- Sexually transmitted disease clinics
- Tuberculosis clinics

340B Statistics

- 340B drug sales account for approximately 5% of the total U.S. drug market.[3]
- Covered entities save 25–50% on covered outpatient drugs.
- About a fourth of covered entities contract with pharmacies to provide 340B drugs.
- 49 hospitals in Arkansas are covered entities (see the pie chart below for a categorical breakdown).
- In Arkansas, 86% of covered entities dispense and/or administer 340B drugs to Medicaid patients.[4]

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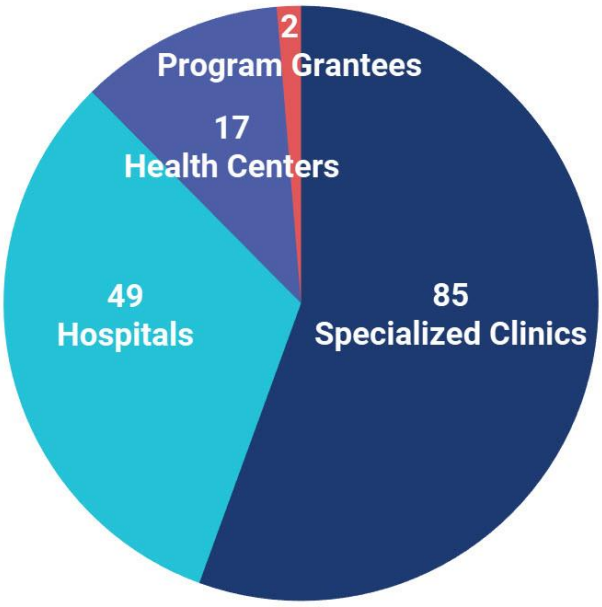
Not every patient receiving care at a covered entity may receive drugs purchased through the program. An eligible patient is one who has established a relationship with the covered entity; receives healthcare services from a professional who is either employed by the covered entity or provides care under contractual or other arrangements (e.g., referral for consultation); and receives care consistent with the service for which grant funding[a] or federally qualified health center look-alike[b] status has been provided.[5] Patient eligibility is not based on financial need.

BREAKDOWN OF COVERED ENTITIES IN ARKANSAS



Source: Office of Pharmacy Affairs, HRSA. Only the primary entity is included in the count for each category.

Covered entities are prohibited from reselling or transferring drugs to individuals who are not eligible patients. In addition, 340B entities are prohibited from receiving duplicate discounts (e.g., receiving a 340B discount and a Medicaid rebate on the same drug). To avoid this, a covered entity chooses whether to include ("carve in") or exclude ("carve out") Medicaid patients.

340B Pricing

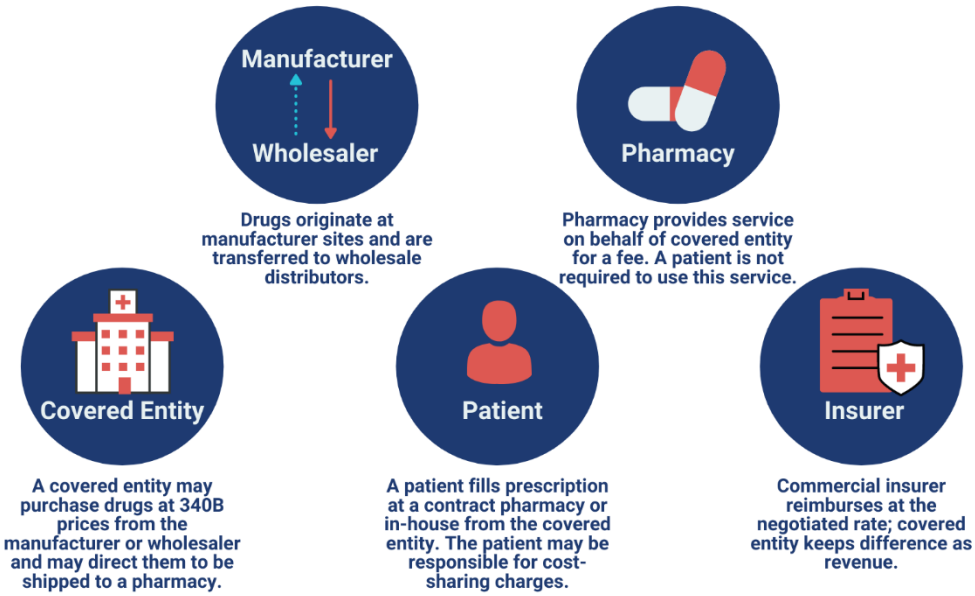
Drug manufacturers may not charge more than a "ceiling price" when selling drugs to 340B covered entities.[6] The 340B ceiling price is set by a statutory formula using confidential information.[c] Distributor fees and package size may affect the selling price. HRSA publishes

[a] Eligible grantees include clinics that offer primary and preventive care services, such as federally qualified health centers, clinics that target specific conditions or diseases, and AIDS drug assistance programs.
[b] Federally qualified health center look-alikes are community-based healthcare programs that provide primary care services in underserved areas on a sliding fee scale based on ability to pay.
[c] The ceiling price equals the average manufacturer price (AMP) minus unit rebate amount (URA). The AMP is the average price paid to the manufacturer for a drug by wholesalers and retail pharmacies. The URA is a computed Medicaid rebate based on the manufacturer's reported pricing; percentage varies by drug classification.

both the ceiling price and the package adjusted price[d] to help covered entities understand maximum allowable prices for 340B covered drugs.

While the 340B program regulates the ceiling price paid by covered entities, it does not control the price charged to patients. Patients may be required to pay out-of-pocket costs for the drug. Covered entities may also bill insurers for payment if the patient is insured. Covered entities may generate revenue if reimbursement from insurers exceed the 340B selling price. The 340B statute does not restrict how covered entities can use revenue from the 340B program.[7]

340B STAKEHOLDERS AND THEIR ROLE IN DRUG DISTRIBUTION



340B Pricing Program Policy Issues

The 340B program is contentious; issues arising from it have prompted both state and federal policy actions. The program offers substantial benefits to rural hospitals by allowing them to provide medication to low-income patients while generating revenue to keep providing services in vulnerable communities. Recognizing that the 340B program had resulted in some hospitals profiting more than intended, the Centers for Medicare and Medicaid Services cut Medicare Part

[d] The package adjusted price equals the ceiling price multiplied by the package size multiplied by the case package size.

B reimbursement for drugs purchased at 340B discounts. Advocacy groups like the American Hospital Association oppose the cut and stress that the rebates are essential for safety net hospitals.[8] Other concerns focus on the program's effects on hospitals serving a disproportionate number of low-income patients and whether certain populations — i.e., low-income patients who would be eligible for Medicaid expansion but live in the states that did not expand Medicaid — should be included for purposes of eligibility.[9] Another concern is that many 340B-eligible entities lack reporting requirements to ensure the revenue generated flows back to vulnerable patients. On the supply side, two recently enacted Arkansas laws support pharmacies by requiring pharmacy benefit managers to reimburse pharmacies at or above acquisition cost[10] and prohibiting a drug manufacturer from excluding a pharmacy from a network based on its participation in the 340B drug program.[11]

Conclusion

The 340B program is a complex federal program that is intended to provide protection from drug price increases for clinics and hospitals. Several changes have impacted the program since its inception, and it has been met with criticism, particularly around transparency, that will likely result in congressional changes. However, the program has been critical in expanding access to prescription drugs for the most vulnerable populations.

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[10] Arkansas Act 900 of 2015.

[11] The Arkansas Drug Pricing Nondiscrimination Act of 2021.