

340B Drug Pricing Program: Fundamentals and its Changing Landscape

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About Us

NASTAD is a leading non-partisan non-profit association that represents public health officials who administer HIV and hepatitis programs in the U.S. We work to advance the health and dignity of people living with and impacted by HIV/AIDS, viral hepatitis, and intersecting epidemics by strengthening governmental public health through advocacy, capacity building, and social justice.

NASTAD represents public health officials in all 50 U.S. states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, seven local jurisdictions receiving direct funding from the Centers for Disease Control and Prevention (CDC), and the U.S. Pacific Island jurisdictions.

Presentation Roadmap

1. 340B Drug Pricing Program Basics
2. Leveraging 340B Savings and Revenue
3. Changing Landscape of 340B
4. Questions and Discussion

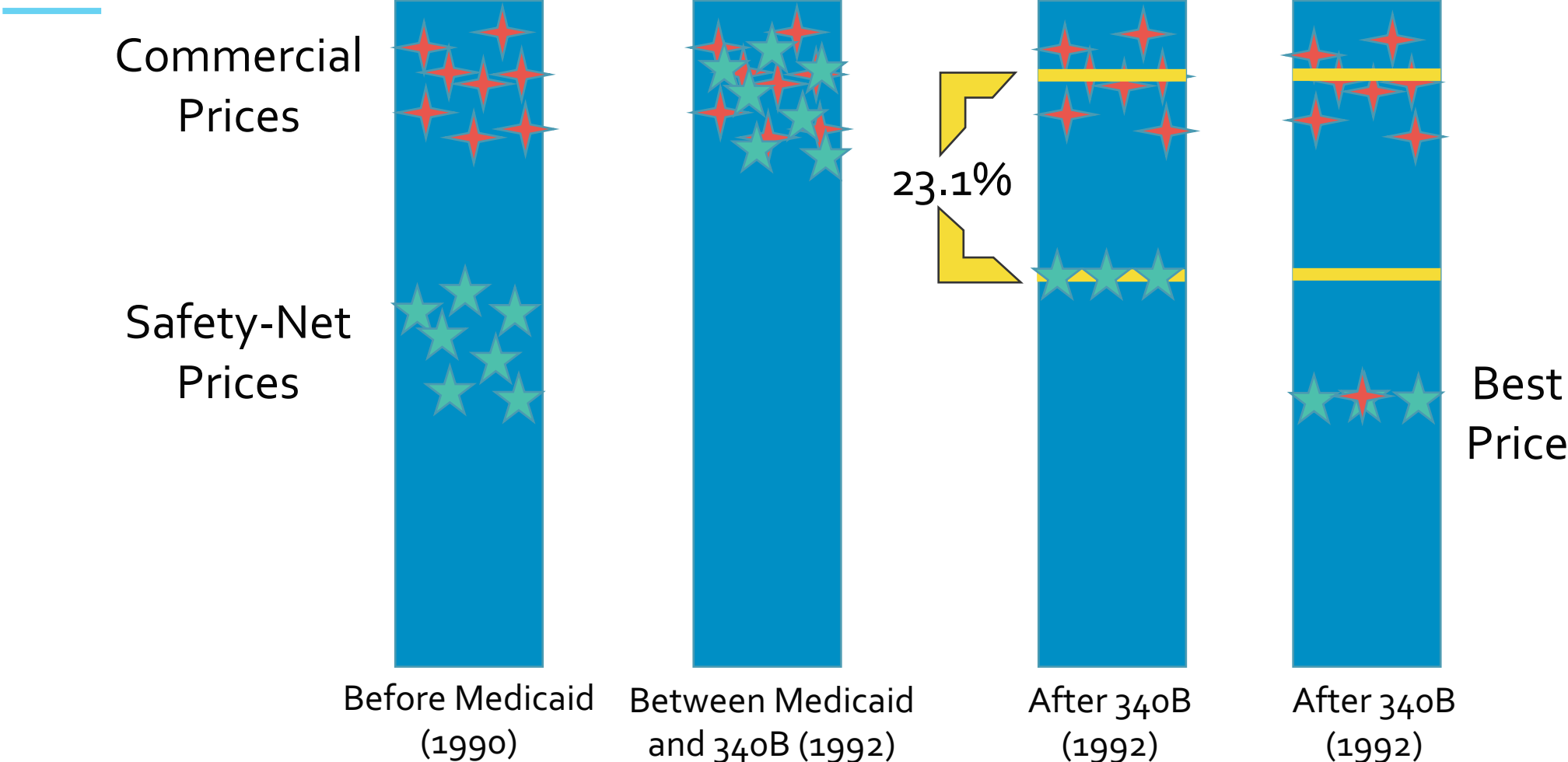
340B Drug Pricing Program Basics

340B Background

- The 340B Drug Pricing Program was created by Congress in 1992 following adoption of the Medicaid Drug Rebate Program
- Allows certain federal grantees and hospitals (“covered entities”) to obtain discounted prices on outpatient drugs from manufacturers
- Resulting cost-containment and revenue helps to “stretch scarce Federal resources as far as possible, with the intent of reaching more eligible patients and providing more comprehensive services.”¹

¹ Language from a House Energy and Commerce Committee report on legislation that eventually became section 340B of the Public Health Service Act (U.S. House of Representatives 1992).

340B Background - Graphically



Manufacturers and 340B

- Manufacturers are not required to participate; strong incentives to do so
 - Participation is the only way to receive Medicare Part B and Medicaid reimbursement
- Manufacturer may not condition the offer of 340B discounts upon a covered entity's assurance of compliance with 340B¹

¹Clarification on nondiscrimination policy. 340B Drug Pricing Program notice. Release no. 2011–1.1. HRSA. 2012

340B Covered Drugs & Biologics

- Prescription drugs and biologics other than vaccines
- FDA-approved insulin
- Over-the-counter drugs with prescription
- Excludes inpatient drugs
- Hospitals added under ACA (e.g., critical access hospitals) excluded from purchasing orphan drugs at 340B discount price

340B Eligibility



Covered Entity Eligibility.

Federal grantees/subgrantees and certain hospitals



Patient Eligibility.

Three requirements; all must be met

340B Covered Entities

Health Centers

- Federally Qualified Health Centers
- Federally Qualified Health Center Look-Alikes
- Native Hawaiian Health Centers
- Tribal / Urban Indian Health Centers

Hospitals

- Children's Hospitals
- Critical Access Hospitals
- Disproportionate Share Hospitals
- Free Standing Cancer Hospitals
- Rural Referral Centers
- Sole Community Hospitals

HRSA RWHAP Recipients/Subrecipients

- RWHAP Providers
- AIDS Drug Assistance Programs

Specialized Clinics

- Black Lung Clinics
- Comprehensive Hemophilia Treatment Centers
- Title X Family Planning Clinics
- STD Clinics (Section 318)
- Tuberculosis Clinics (Section 317)

CDC Section 318 Grantees/Sub-grantees

- CDC Division of STD Prevention (DSTDP)
- CDC Division of HIV/AIDS Prevention (DHP)
- Division of Viral Hepatitis (DVH)

340B Patient Definition

1. The covered entity (CE) established a relationship with the individual, such that the CE maintains records of the individual's health care; **and**
2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements such that responsibility for the care provided remains with the CE; **and**
3. The individual receives a health care service or range of services from the CE which is consistent with the service or range of services for which grant funding ... has been provided to the entity

340B Patient Definition – ADAPs

1. The covered entity (CE) established a relationship with the individual, and
2. *An individual registered in a State operated or funded AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHS Act will be considered a "patient" of the covered entity for purposes of this definition if so registered as eligible by the State program.*
3. The individual receives a healthcare service or range of services from the CE which is consistent with the service or range of services for which grant funding ... has been provided to the entity

Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility. HRSA. 1996.

340B Discount and Rebate Basics

- 340B ceiling price for outpatient medicines is based on unit rebate amount (URA) formula established for Medicaid Drug Rebate Program:
 - 340B CEs are subject to a minimum discount/rebate of 23.1% off AMP for branded drugs (13% generics)
 - When a manufacturer takes a price increase that exceeds the Consumer Price Index for All Urban Consumers (CPI-U), an additional rebate – or “inflation penalty” – is added to base discount

340B Discounts and Rebates (continued)

- Most covered entities taking up-front 340B discounts via wholesalers
- ADAPs are only 340B covered entities that may claim back-end 340B rebates from manufacturers
 - ADAPs may leverage up-front discounts and/or rebates for their full-pay medication program and insurance program

Voluntary Supplemental Discounting

- Manufacturers are free to provide voluntary supplemental (sub-ceiling) discounting to 340B covered entities
- Sub-ceiling prices are available via:
 - Negotiations between Apexus Prime Vendor Program and manufacturers
 - Negotiations between ADAP Crisis Task Force and manufacturers (available only to AIDS Drug Assistance Programs)
 - Voluntary provision by manufacturers to covered entities

Leveraging 340B Savings and Revenue

340B Savings and Revenue

- Achieves prescription drug cost savings for no-cost or low-cost access for uninsured or underinsured clients
- Achieves revenue when RWHAP clinics purchase discounted drugs but are reimbursed by third-party payers at a higher usual and customary rate

Prescription Drug Cost Savings

Uninsured/Underinsured Care Program Examples

- **HIV Care:** Comprehensive ADAP formulary coverage (including costly ARVs); drug purchasing by Ryan White clinics
- **HIV Prevention:** Direct purchases of discounted pre- and post-exposure prophylaxis medications (PrEP & PEP) by PrEP-DAP and other public health programs
- **STD Control:** Oral and injectable STD treatment drug purchases by local health department programs
- **Hepatitis C:** Louisiana subscription-based treatment model, notably throughout Department of Corrections system

Uses of 340B Revenue-Based Program Savings

- Grantees, including sub-grantees, are required to use all 340B program savings to expand access to underserved patients
- Specific uses (and oversight) of 340B program income/savings (or rebates) not HRSA OPA requirements, but rather federal funder/grant requirements
- HRSA HAB policies (for RWHAP) are most prescriptive:
 - PCN 15-03: Clarifications Regarding the Ryan White HIV/AIDS Program and Program Income
 - PCN 15-04: Utilization and Reporting of Pharmaceutical Rebates
 - PCN 16-02: Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds

340B Program Savings Benefit HIV and Hepatitis Services



Patient Engagement

- Patient navigation
 - Transportation
 - Telehealth
 - Case management
 - In-home medication delivery
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- No-cost or sliding fees on medications



Community Benefits

- Clinical pharmacy services
- Assistance with insurance or safety net payor enrollment
- Housing and cost-of-living support
- Patient outreach

Financial Assistance

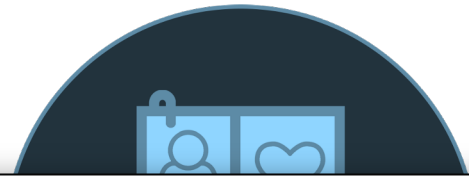
- Copay and Deductible Assistance



Care Programs

- Vaccine programs
 - Drug user health services
 - Transgender care services
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- Premium assistance with eligible healthcare plans

340B Program Savings Benefit HIV and Hepatitis Services



340B and Health Equity

Most Community Health Centers, RWHAP providers, STI clinics, community-based PrEP programs, and viral hepatitis programs in the United States rely at least in part on 340B program savings to provide sliding-scale/free care, including, medical, support, and pharmacy services, to clients with structural barriers

- Patient navigation
- Transportation
- Telemedicine
- Case management
- In-home medication delivery

- Housing and cost of living support
- Patient outreach

Financial Assistance

- No-cost or sliding fees on medications
- Copay and Deductible Assistance
- Premium assistance with eligible healthcare plans

Changing Landscape of 340B

Changing Landscape of 340B

- Manufacturers restricting number of contract pharmacies; sometimes requiring claims data to maintain networks
- Payers/pharmacy benefit managers (PBMs) engaging in discriminatory reimbursement
- Multiple challenges to (limited) HRSA oversight and enforcement
- Potential impact of federal and state drug pricing control legislation
- Increasing program expenditures

Changing Landscape of 340B

- Congressional Attention to 340B
 - PROTECT 340B Act of 2023
 - 340B Accountability Act of 2023
 - 340B Reporting and Accountability Act
 - H.R.3290
 - Drug Pricing Transparency and Accountability Act
 - Lower Drug Costs for Families Act
- State legislation

Louisiana HB 548 (Enacted August 1, 2023)

- ✓ Prohibits actions by a manufacturer or distributor that would deny, restrict, prohibit, or otherwise interfere with the acquisition of a 340B-discounted drug to a pharmacy that is under contract with a 340B entity
- ✓ Prohibits practices by payer/PBM that would limit or impose conditions that would indirectly lower the amount of reimbursement for 340B drug dispensed by a 340B entity or its contract pharmacies

Changing Landscape of 340B



Changing Landscape of 340B

- What's Next?
- What does it mean?

Contacts and Additional Information

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Various 340B Drug Pricing Program resources at:

www.NASTAD.org