

340B Basics

for Health Department Prevention Programs

Hepatitis TA Center (HepTAC)

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WEBINAR OVERVIEW

- Learning Objectives:
 - Increase functional knowledge of HRSA's 340B Drug Pricing Program
 - Identify the role for the 340B Drug Pricing Program in HIV prevention and viral hepatitis programs
 - Operationalize the 340B Drug Pricing Program in viral hepatitis and HIV elimination efforts
- Multi-part series:
 - March 10, March 24, April 7, April 21, May 5
 - Every other Wednesday at noon ET



AGENDA

1. Goal of the 340B Drug Pricing Program
2. Statutory Authority
3. Eligibility
4. Covered Entities and Patient Definition
5. Program Savings and Program Income

WHAT IS 340B?

- Federal law that requires drug manufacturers to offer **discounts** on medications sold to certain types of safety net providers for outpatient use
- Authorized by the Public Health Service Act
- Administered by the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA)
- Purpose is to “stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services”

WHAT IS 340B?

- There are 16 Covered Entity categories, all authorized by different sections of the Public Health Service Act (PHSA)
 - Hospitals
 - Federal Grantees
 - FQHCs
 - Ryan White Providers
 - Title X Family Planning Providers
 - Hemophilia Clinics
 - STD Clinics (section 318 grantees)
 - Viral Hepatitis, HIV Prevention, and STD programs all fall under **Section 318**
 - TB Clinics

WHAT 340B IS NOT



A funding source



Free medications



Testing or laboratory support



For vaccines



340B DISCOUNT

- The required discount is either 13% (generic) or 23.1% (brand-name) from Average Manufacturer Price (AMP)
- Additional discounts are also required if the drug manufacturer has chosen to increase the drug's price or offer a lower price to other purchasers
- Manufacturers also voluntarily provide additional discounts
- Wholesale cost/340B Price

WHO PAYS WHAT? A \$100 DRUG

- Hold for content, waiting on Edwin

WHO QUALIFIES?

Qualifying provider

- Must be an eligible provider
 - Receive qualifying federal funding/support
- Register in the 340B database
- Complete annual recertification
- Comply with 340B program requirements

Qualifying patient

- Meets the 3-part patient definition



PATIENT DEFINITION

To be [eligible](#) to receive 340B medications, patients must receive health care services other than drugs from the 340B covered entity

Patient [eligibility](#) is met when:

1. The covered entity has established a relationship with the individual and maintains records of the individual's health care;
2. The individual receives health care services from an employee or paid contractor of the covered entity – the responsibility of the care provided remains with the covered entity; **and**
3. The individual receives health care services or range of services from the covered entity which is consistent with the service or range of services for which grant funding has been provided to the entity



318 ELIGIBILITY

- Historically “STD Clinics”
- Re-defined in 2019
 - Recipients or subgrantees of an CDC grant that uses Section 318 of the PHSA as its legislative authority
 - Includes HIV Prevention and Viral Hepatitis Surveillance and Prevention Funding for Health Departments

318 Eligible Notice of Funding Opportunity		
NOFO Number	Title	Division
PS11-11120501SU PP16	A National Coalition to Enhance STD/HIV Prevention through Promotion of a Holistic Approach to Health and Wellness	DSTDP
PS13-13020401SU PP16	National HIV Surveillance System (NHSS) Supplemental	DHAP
PS14-140104CONT 17	STD Laboratory-based Surveillance & Gonococcal Isolate Surveillance Project	DSTDP
PS19-1901 Formally PS14-1402	Improving Sexually Transmitted Disease Programs through Assessment, Assurance, Policy Department, and Prevention Strategies (STD AAPPs)	DSTDP
PS14-1403	Building Capacity for HIV Prevention in Non-Healthcare and Healthcare Settings through Training and Technical Assistance	DHAP
PS14-1405	Technical Assistance to Support AIDS Directors and HIV Prevention Program Managers in the 50 States, District of Columbia, the Commonwealth of Puerto Rico, U.S. Virgin Islands, and the Pacific Islands	DHAP
PS14-1406	Community Approaches to Reducing Sexually Transmitted Diseases (CARS)	DSTDP
PS14-1407	STD Clinical Prevention Training Centers	DSTDP
PS14-1408	Disease Intervention Training Centers	DSTDP/DHAP
PS14-1409	Assisting Directly Funded AIDS Directors in Urban Jurisdictions and Other HIV Prevention Partners in Meeting the Changes in the Public Healthcare Systems and HIV Prevention Landscape	DHAP
PS14-1410	Secretary's Minority AIDS Initiative Funding Demonstration Project to Increase HIV Prevention and Care Service Delivery among Health Centers Located in High HIV Prevalence Jurisdiction	DHAP
PS15-1502	Comprehensive High-Impact HIV Prevention Projects for Community-Based Organizations	DHAP
PS15-1505	Enhancing HIV Prevention Communication and Mobilization Efforts through Strategic Partnerships	DHAP/PCB
PS15-1506	Health Department Demonstration Projects to Reduce HIV Infections and Improve Engagement in HIV Medical Care Among MSM and Transgender Persons	DHAP
PS15-1510	Capacity Building Assistance for Grantees Funded through FOA PS15-1509. To strengthen capacity to plan, implement, and sustain comprehensive health prevention and care services to address the needs of MSM of color living with HIV and those at risk of HIV infection	DHAP
PS15-1511	Evaluation of STD Programs Deploying Disease Intervention Specialists (DIS) to Improve HIV Outcomes	DSTDP

PS15-1512	Connecting Latino and African American Males to Sexual Health Services: An Adaptation of Project Connect	DSTDP
PS16-1601	National HIV Behavioral Surveillance System	DHAP
PS16-1604	Community-based Organization Outcome Monitoring Project PS15-1502 Clients	DHAP
PS17-1702	Improving Hepatitis B and C Care Cascades: Focus on Increased Testing and Diagnosis	DVH
PS17-1703	Enhancing Surveillance in Jurisdictions with High Hepatitis C Virus (HCV) and Hepatitis B Virus (HBV) Incidence	DVH
PS17-1704	Comprehensive High-Impact HIV Prevention Projects for Young Men of Color Who Have Sex with Men and Young Transgender Persons of Color	DHAP
PS17-1707	Community Approaches to Reducing Sexually Transmitted Disease	DSTDP
PS17-1708	Enhancing existing national STD/HIV prevention efforts by promoting more holistic, comprehensive, and evidence-informed health and wellness approaches through key and strategic partnerships	DSTDP
PS17-1711	Use of molecular HIV surveillance to identify networks with active HIV transmission that include Hispanic/Latino men who have sex with men (MSM) to provide targeted HIV interventions including, HIV testing and linkage to care, pre-exposure prophylaxis (PrEP) and other prevention services to reduce onward HIV transmission	DHAP
PS18-1801	Accelerating the Prevention and Control of HIV/AIDS, Viral Hepatitis, STDs and TB in the U.S. Affiliated Pacific Islands	DHAP, DVH, DSTDP, DTBE
PS18-1802	Integrated HIV Surveillance and Prevention Programs for Health Departments	DHAP
PS18-1805	Privacy Data Sharing Tools (Black Box) to Support De-duplication of Cases in the National HIV Surveillance System (NHSS)	DHAP
PS18-1808	National Network to Enhance Capacity of State and Local Sexually Transmitted Disease Prevention Programs (NNECS)	DSTDP
PS18-1812	Sustainable Healthcenter Implementation Pre-Exposure Prophylaxis (PREP) Pilot (SHIPP)	DHAP

*As of May 2019

*Credit: Stephanie Arnold Pang, Director, Policy and Government Relations, NCSD

GRANTEES AND SUBGRANTEES

- Covered entities must have a financial relationship with a qualifying section 318 program that is eligible for 340B
- Must receive either direct financial support or receive in-kind contributions supported by the qualifying section 318 funding

“Qualifying in-kind contributions must be paid for by section 318 grant funds to qualify a site as 340B eligible. In-kind contributions may be in the form of real property, equipment, supplies and other services directly benefiting and specifically identifiable to the project or program”

HRSA

PROGRAM INCOME AND SAVINGS

- Up-Front Savings:
 - Purchase medications to provide to patients (STD program treatment model)
- Income:
 - 340B drugs can be provided to insured patients
 - Covered entities can receive program income from the difference between the 340B price and the insurance reimbursement rate
- Grantees, including sub-grantees, are required to use all 340B income and savings for activities that promote the purpose of their qualifying funding/federal grant
- There is no regulatory authority to audit 340B income/savings



MEDICAID INTERSECTION

- Medicaid Drug Rebate Program
 - Avoid duplicate discounts!!
- Carve-In vs Carve-Out Model
 - Carve-Out: no 340B drugs are used for Medicaid patients
 - Carve-In: includes Medicaid patients in the 340B program, dispensing drugs purchased under 340B to these patients



SUMMARY

- The 340B Program is a drug pricing program that can be utilized by section 318 grantees and sub-grantees to access deeply discounted medications
- There are eligibility requirements as well as a 3-part patient definition that must be met
- The 340B program can have a significant financial impact on public health programs thanks to program savings and program income
- Beware of duplicate discounts if also billing Medicaid

RESOURCES

- [HRSA 340B Drug Pricing Program](#)
- [Apexus: 340B Prime Vendor](#)
- [340B FAQs](#)
- [The ABCs of 340B, NCSD](#)
- [340B Health](#)

QUESTIONS AND DISCUSSION

Next Webinar:

Wednesday, March 24, 2021

12:00 pm ET

Agenda: Discuss the roles of health department viral hepatitis programs and subgrantees in the 340B program, identify oversight approaches, and walk through the registration process and timeline