

340B Basics and Beyond



Agenda

- 340B Basics
- Health Department Eligibility
- Health Department Utilization
- Registration and Compliance
 - [340B Glossary of Terms link in chat](#)
- Addressing Infectious Diseases
- Questions and Opportunities for TA

Setting the Stage

- Many HDs experiencing flat or reduced funding.
 - Examination of spending trends over time shows per capita spending has either held steady or declined after accounting for inflation and population changes. Small LHDs have seen median per capita spending remain essentially unchanged in the last decade, after accounting for inflation, while medium and large LHDs report 14% and 22% declines in median per capita spending, respectively.
- HDs must think about how to stretch their funding.
 - One option is to bill third-party payers such as private insurance companies and Medicaid
 - Another is for HDs to enroll in the 340B Drug Pricing Program which provides a discount on drug prices.
 - If HDs bill and are enrolled in the 340B program, there is additional potential for revenue through the combination of the two programs.

Presenters

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PROGRAM OVERVIEW AND ELIGIBILITY

What is 340B?

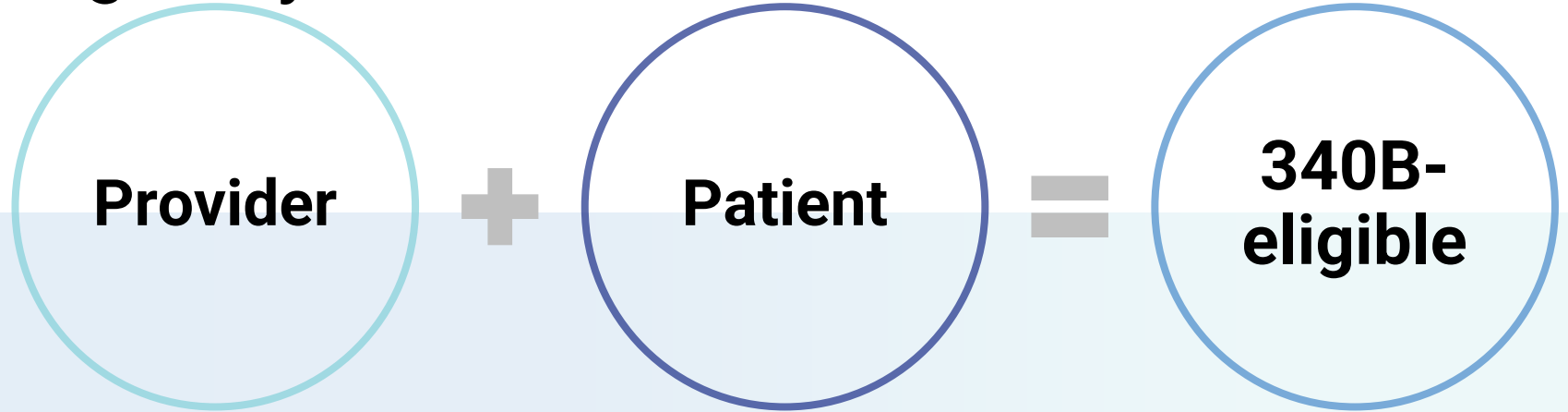
- A federal law that requires drug manufacturers to offer discounts on drugs sold to certain types of safety net providers for outpatient use.
- “340B” refers to the section of the Public Health Service Act where these requirements are found.
- The discounts are not funded by taxpayers.

What 340B is NOT

- ⊘ A grant
- ⊘ Free medications
- ⊘ Testing or laboratory support
- ⊘ For vaccines



Eligibility: Who Qualifies?



COVERED ENTITIES

Tied to certain grants or hospital types

PATIENT DEFINITION

Patients must meet 3-pronged patient definition to qualify for 340B-priced drugs

Which Providers Are Eligible?

- Hospitals (Disproportionate Share Hospitals, Children's, Critical Access, Free-standing Cancer)
- Federal Grantees
 - Federal Qualified Health Centers
 - Ryan White Providers
 - Title X Family Planning Providers
 - Hemophilia clinics
 - STD clinics (Section 318)
 - TB clinics (Section 317)

Section 318 of the PHS

(b) The Secretary may make grants to States, political subdivisions of States, and any other public and nonprofit private entity for—

- (1) research into the prevention and control of sexually transmitted diseases;
- (2) demonstration projects for the prevention and control of sexually transmitted diseases;
- (3) public information and education programs for the prevention and control of such diseases; and
- (4) education, training, and clinical skills improvement activities in the prevention and control of such diseases for health professionals (including allied health personnel).

(c) The Secretary is also authorized to make project grants to States and, in consultation with the State health authority, to political subdivisions of States, for—

- (1) sexually transmitted diseases surveillance activities, including the reporting, screening, and followup of diagnostic tests for, and diagnosed cases of, sexually transmitted diseases;
- (2) casefinding and case followup activities respecting sexually transmitted diseases, including contact tracing of infectious cases of sexually transmitted diseases and routine testing, including laboratory tests and followup systems;
- (3) interstate epidemiologic referral and followup activities respecting sexually transmitted diseases; and
- (4) such special studies or demonstrations to evaluate or test sexually transmitted diseases prevention and control strategies and activities as may be prescribed by the Secretary.

(d) The Secretary may make grants to States and political subdivisions of States for the development, implementation, and evaluation of innovative, interdisciplinary approaches to the prevention and control of sexually transmitted diseases.

318 Eligibility

- Historically: STD “clinics”
 - Grantees or “sub-grantees” of DSTPD base STD grant (STD PCHD)
- Recently re-defined
 - Now grantees or “sub-grantees” of any CDC grant that uses 318 as its legislative authority

NOFO and Section 318 Eligibility



Centers for Disease Control

National Center for HIV-AIDS, Viral Hepatitis, STD, and TB Prevention

Strengthening STD Prevention and Control for Health Departments (STD PCHD)

CDC-RFA-PS19-1901

Application Due Date: 07/31/2018

b. Statutory Authorities

Section 318(a) - (c) of the Public Health Service Act [42 U.S.C. Section 247c (a) - (c)], as amended.

Provider Eligibility

- Notice of Funding Opportunities authorized by Section 318 of the Public Health Service Act.
 - PS18-1802: Integrated HIV Surveillance and Prevention Programs for Health Departments
 - PS19-1901: Strengthening STD Prevention and Control for Health Departments
 - PS-20-2010: Ending the HIV Epidemic
 - PS-21-2103: Integrated Viral Hepatitis Surveillance and Prevention Funding for Health Departments

Provider Eligibility

CDC

- Manages and grants federal funding authorized by section 318 of the Public Health Service Act (PHS)

Grantee

- Receives federal funding authorized by section 318 of the PHS directly from HHS
- State health department, local health department, or CBO depending on the NOFO
- Confers eligibility for subgrantees

Subgrantee

- Receives Section 318 pass through federal funding from a grantee
- Can be a local health department, community-based organization, or other provider
- Cannot confer eligibility to other entities

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

Local Health Departments

- Do you receive Section 318 support from your state health department?
 - Contracts
 - MOUs
 - Staffing
- Are you a direct recipient of Section 318 funding?
 - EHE Jurisdictions
- Can you optimize a strategic alliance and partnership?

HEALTH DEPARTMENT UTILIZATION

Local Health Departments

- How can LHDs utilize the 340B program?
 - STD treatment
 - Syphilis elimination
 - Pre-exposure prophylaxis (PrEP)
 - Expedited Partner Therapy (EPT)
 - Any medication clinically indicated for a qualifying patient

Revenue and Savings

- Up-Front Savings:
 - Purchase medications to provide to patients
- Revenue:
 - 340B drugs can be provided to insured patients
 - Covered entities can receive program revenue from the difference between the 340B price and the insurance reimbursement rate

Grantees, including sub-grantees, are required to use all 340B revenue and savings for activities that promote the purpose of their qualifying funding/federal grant

STD Treatment Drugs

Medication	Wholesale Cost (Amerisource Bergen)	340B Price	340B Cost Savings
Azithromycin 500 MG Tab 30	\$144.75	\$9.56	93%
	\$135.19		
Ceftriaxone 250 MG	\$7.50	\$6.03	20%
Penicillin Benzathine IM	\$1,200.56	\$.20	99.9%
	\$1,200.36		
Gentamicin Sulfate 40 MG	\$80.75	\$26.50	67%

REGISTERING FOR 340B

I'm eligible...now what??

340B Registration

- Four annual registration periods (January 1-15, April 1-15, July 1-15, October 1-15)
- Must include grant number in registration
 - Partners will need to contact grantee to get grant numbers
- Registration is effective at the beginning of the next calendar quarter
 - Example: Registration submitted during April registration period becomes effective July 1 of that year
 - May not purchase or dispense 340B drugs until registration becomes effective
- Ideally, registration is done at the service site level, so each location has its own unique 340B database entry

340B Registration Checklist

- ✓ Determine who your authorizing official is
- ✓ Determine who your primary contact will be
- ✓ Create an account in the
- ✓ Know your NOFO and grant number
- ✓ Know if you receive direct financial assistance or in-kind support
- ✓ Your contract pharmacy will need to register too!
- ✓ Add noreply@hrsa.gov to your email program's spam filter



Authorizing Official

- Main contact for the covered entity for the 340B program
- Bares the responsibility for the program's 340B compliance.
- Per HRSA, he/she is “fully authorized to legally bind a 340B covered entity into a relationship with the federal government and has knowledge of the practices and eligible programs at that site.”
- This individual is responsible for registering the site with HRSA and complementing the annual recertification process.

Primary Contact

- A secondary contact for the covered entity listed with HRSA.
- Receive information from HRSA
- Have no authority to change or update with HRSA, nor do they have the responsibility of the Authorizing Official.

Annual Recertification

- Once registered, entities must recertify annually during the designated period to remain in the program
- Advance email notifications with preliminary information about the recertification process are sent to both the Primary Contact Authorizing Official
- Recertification is done through OPAIS
- Failure to recertify will result in termination from the 340B program



340B COMPLIANCE BASICS

Patient Eligibility/Definition of Patient

1. Established relationship between the patient and the 340B covered entity (usually documented in a medical record)
2. Patient receives health care service(s) from a provider employed by the covered entity (or providing services for the covered entity under contractual or other formal arrangement)
3. Patient receives health care service(s) consistent with the grant through which the covered entity gained 340B eligibility

Diversion

- 340B Covered entities must not resell or otherwise transfer 340B drugs to ineligible patients
 - i.e., patients who do not meet the 340B patient definition.
- This would be considered diversion and the entity would be out of compliance with the 340B program

Medicaid and Duplicate Discount

- Manufacturers are prohibited from providing a discounted 340B price and a Medicaid drug rebate for the same drug.
- “Carve-in” vs. “Carve-out”
 - **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

Procuring Medications

1. Pharmaceutical Wholesaler

- AmerisourceBergen
- McKesson
- Cardinal Health

2. Contract Pharmacy

- Walgreens
- CVS
- Walmart
- Accredo



Contract Pharmacies

- HRSA allows 340B covered entities to contract with outside pharmacies to dispense drugs to eligible patients
- Contract pharmacies serve as an extension of the 340B covered entity and provide patients access to prescription drugs
 - The covered entity retains responsibility to prevent diversion and duplicate discounts, maintain auditable records, and meet all other 340B Program requirements
- Must register in OPAIS

OPA may request a copy of the contract pharmacy service agreement be provided

ADDRESSING INFECTIOUS DISEASES

Grantee Combined Purchasing & Distribution

- Taking 340B meds purchased centrally and providing them to other entities/ clinics
- Common in public health, less so in 340B
- The sharing of 340B inventory to other entities is not allowed unless first approved by HRSA
- Otherwise, considered diversion

EPT and 340B

- If a patient meets the 340B patient definition at a visit and tests positive for an STD, you may use 340B drugs for EPT.
- The rationale is that EPT is actually a treatment for your patient because it is preventing reinfection.
- 340B definition of patient + EPT language in PCHD
- Your use of 340B drugs for EPT should be included in your 340B policies and procedures.

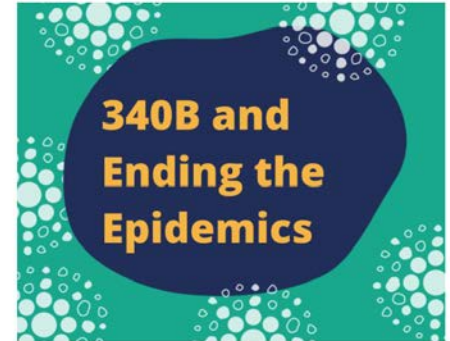
PrEP and HCV Treatment

- If the 340B patient definition is met, 340B can cover any outpatient prescription that is warranted by the visit.
 - PrEP
 - HCV Treatment

STD RESOURCE

340B AND ENDING THE EPIDEMICS

NCSO developed resources and toolkits to guide sexual health clinics through the process of operationalizing the 340B program and supporting STD clinics in expanding their HIV services, including increasing capacity to provide PrEP services.



Public Health Syphilis Response

- Delivers syphilis treatment (Bicillin L-A) directly to where the patient is being seen
- Missed opportunities for treatment
- Congenital syphilis prevention
 - 291% increase in congenital syphilis (2015-2019)
- Reduce loss to follow-up



340B Key Concepts

- Only certain providers are eligible
(eligible providers/ covered entities)
- Only certain patients are eligible
(eligible patients/patient definition/diversion)
- Tracking and keeping records are key
(audible records)
- Need to choose between 340B drugs and Medicaid drugs
(carve-in vs carve-out/duplicate discount)

Resources

- [HRSA 340B Drug Pricing Program](#)
- [Office of Pharmacy Affairs 340B OPAIS](#)
- [Apexus: 340B Prime Vendor](#)
- [340B FAQs](#)
- [NASTAD/NCSD: Update on 340B Eligibility for Programs Authorized Under Section 318 of the US Public Health Service Act](#)
- [The ABCs of 340B, NCSD](#)
- [The Role of 340B in Ending the Epidemics](#)
- [340B Health](#)
- [Contract Pharmacy FAQs](#)

Questions/ Discussion



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