The ABCs of 340B: A 101 Webinar on the 340B Drug Discount Program

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NCSD
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Agenda

- 340B 101: Eligibility and Compliance
  - 340B Glossary of Terms attached in materials
- STD 340B FAQs
- Questions and Opportunities for TA

Webinar will be recorded, can be shared with colleagues

PROGRAM ELIGIBILITY AND COMPLIANCE

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.

Administration, Purpose of 340B

- Administered by the Health Resources and Services Administration (HRSA)'s Office of Pharmacy Affairs.
- Purpose: **"to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services"**

What is the 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 faster than the rate of inflation and/or
  - Officer a lower price to certain other purchasers
- Manufacturers voluntarily provide additional discounts

STD Drugs

Medication	Wholesale Cost (Amerisource Bergen)	340B Price	340B Cost Savings
Azithromycin 500 MG Tab 30	$144.75	$9.56	93%
Ceftriaxone 250 MG	$7.50	$6.03	20%
Penicillin Benzathine IM	$1,200.56	$.20	99.9%
Gentamicin Sulfate 40 MG	$80.75	$26.50	67%
Isoniazid Oral Tablet 300 MG	$24.75	$5.28	73%
Isoniazid Oral Tablet 100 MG	$11.78	$.61	95%
Rifampin Oral Capsule 300 MG	$125.73	$30.66	76%
Ethambutol HCL Oral Tablet 100 MG	$45.90	$7.48	84%
Pyridoxine HCL Oral Tablet	$2.18	$1.22	44%
Tuberculin PPD	$261.30	$.05	99.9%
Amikacin Sulfate Injection	$160.00	$82.35	49%
Metformin HCL 1000 MG	$822.46	$.60	99.9%
Moxifloxacin HCL 400 MG	$300.00	$10.37	97%
Rifapentine Oral Tab 150 MG	$91.19	$24.00	74%

Who Pays What? A $100 Drug

Medicaid and 340B

Insurance Reimbursement - $105
WAC plus dispensing fee, typically $5

Wholesale Acquisition Cost (WAC) - $100
List price available from wholesaler

Average Manufacturer Price (AMP) - $92
Calculated as part of the Medicaid program; typically 4-8% lower than WAC.

340B Ceiling Price - $71
AMP minus the Unit Rebate Amount (URA), 23.1%

Copayment - $20
For insured clients; determined by the insurance company

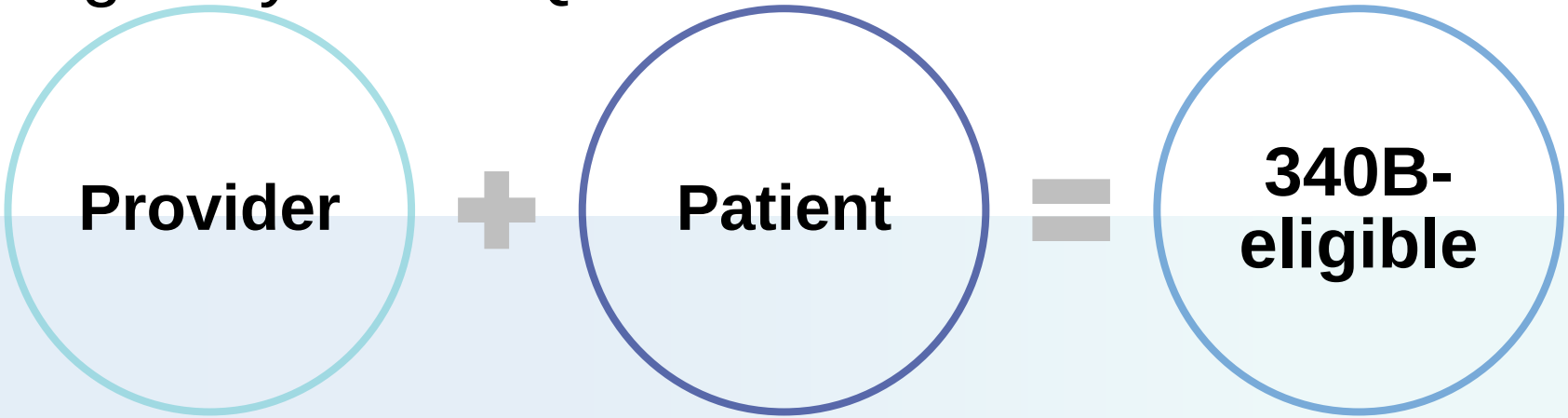
Medicare

Part D Reimbursement - $105
Negotiated by private insurance plans

Part B Reimbursement - $97
Average Sales Price (ASP) + 6%; ASP generally mirrors AMP

**Source/ design: NASTAD*

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

National Family Planning & Reproductive Health Association

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)

Provider Eligibility

- Be an eligible provider
- Register in the 340B database
- Complete annual recertification
- Comply with 340B program requirements

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

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

- Entities must recertify annually during the designated period to remain in the program
- Authorizing official receives email with all necessary info in advance of recertification period
- Failure to recertify will result in termination from the 340B program

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 (i.e., STD PCHD)

Diversion

- BIG 340B compliance no-no!
- 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.

Duplicate Discount

- Manufacturers are prohibited from providing a discounted 340B price and a Medicaid drug rebate for the same drug.
- Covered entities must accurately report how they bill Medicaid fee-for-service drugs on the Medicaid Exclusion File
- “Carve-in” vs. “Carve-out”

Contract Pharmacies

- Covered entities may contract with pharmacies to dispense drugs purchased through 340B
- Pharmacies will bill insurance
- Fees for this benefit, portion of the program income
- Covered entities must conduct oversight

STD 340B FAQS

318 Eligibility

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

Centers for Disease Control

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

Strategic Partnerships and Planning to Support Ending the HIV Epidemic in the United States
CDC-RFA-PS19-1906
Application Due Date: 07/12/2019

b. Statutory Authorities

Section 318 of the Public Health Service Act [42 U.S.C. § Section 247c], as amended and the Consolidated Appropriation Act of 2016 (Pub. L. 114-113).

	318 Eligibile Notice of Funding Opportunity	
NOFO Number	**Title**	**Division**
PS11-11120501SUPP16	A National Coalition to Enhance STD/HIV Prevention through Promotion of a Holistic Approach to Health and Wellness	DSTDP
PS13-13020401SUPP16	National HIV Surveillance System (NHSS) Supplemental	DHAP
PS14-140104CONT17	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 Imitative 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

STD “Definition of Patient”

- Goal is good STD prevention—best practices for STD prevention
- Third “prong” of the definition: “service consistent with the scope of the grant”

STD “Definition of Patient,” cont.

- A patient should receive a sexual health history and review of STD risk factors with a provider at every visit.
- Receive any STD testing and treatment warranted, per CDC STD Guidelines, from that sexual health history.

“Sub-grantees”

- Entities that have a financial relationship with an STD program may be eligible for 340B.
- Must receive either direct financial support through the federal STD grant (PCHD grant) or receive in-kind contributions through the STD grant.

In-kind contributions

- Per HRSA: “Qualifying in-kind contributions must be paid for by section 317 or 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 expendable property, and goods and services directly benefiting and specifically identifiable to the project or program.”

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.

What drugs are covered?

- If the 340B patient definition is met, 340B can cover any outpatient prescription that is warranted by the visit.
- But STD definition of patient must be met at *every* visit.
- Vaccines are not a “covered outpatient drug” and not subject to 340B pricing

PrEP, Hepatitis treatment

- Yes!
- If the 340B patient definition is met, 340B can cover any outpatient prescription that is warranted by the visit.
- But STD definition of patient must be met at *every* visit.
- For PrEP, should also include extragential testing (goal: STD prevention)

Bicillin Delivery

- “This funding **can** be used to purchase and dispense Benzathine penicillin G for the treatment of syphilitic infections among uninsured and underinsured patients and their sex partners whose clinical service providers are not able to administer timely treatment with Benzathine penicillin G.”
- “In these critical public health situations, Benzathine penicillin G should be provided under medical orders of the medical director of the STD program or the health department. The health department physician prescribing the Benzathine penicillin G **must** keep a medical record of all patients treated under his or her orders.”
- PCHD grant, p. 15

Program Income/ Savings

- 340B drugs can be provided to insured patients
- Entities can receive program income/ savings from the difference between the 340B price and the insurance reimbursement rate
- Grantees are required to use all 340B savings for activities that “promote the purpose of their Federal grant”
  - Namely, to increase access for their target patient population, ie, those with or at risk for STDs.

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*Program Income: $34

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AMP minus the Unit Rebate Amount (URA), 23.1%

Copayment - $20

For insured clients; determined by the insurance company

Medicare

Part D Reimbursement - $105

Negotiated by private insurance plans

Part B Reimbursement - $97

Average Sales Price (ASP) + 6%; ASP generally mirrors AMP

Source/ Design: NASTAD

Program Income/ Savings

- No regulatory authority to audit
- Left mostly up to the covered entities to determine
- Limited (but growing) use of 340B program income in public health clinics

Additional “Flash points”

- Hospitals vs. Grantees
- Goal/ intent of the program
- Insured or Uninsured/Underinsured?
- Expansion of the program
- Contract Pharmacies
- HRSA’s regulatory authority

QUESTIONS/ DISCUSSION

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Thank you to George Walton (IA), Lynn Sosa (CT), Erin Fratto (UT), NASTAD, Mindy McGrath (NFPRHA)

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