

Demystifying 340B: What Providers Need to Know

Stephanie S. Arnold Pang

Senior Director,

Policy and Government Relations



NCS D

National Coalition
of STD Directors

Disclosure

Disclosure: Stephanie Arnold Pang has no financial interest to disclose.

This continuing education activity is managed by The St. Louis STI/HIV Prevention Training Center and accredited by Missouri State Medical Association (MSMA) in cooperation with the Chicago Department of Public Health.

Agenda

- What 340B is and is not
- Program Overview and Eligibility
- 340B Compliance Basics
- Resources

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.
- Stretch scarce federal resources and extend discounts directly to patients

What 340B is NOT

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



PROGRAM OVERVIEW AND ELIGIBILITY

Eligibility: Two Step Process

PROVIDER



COVERED ENTITIES
Tied to certain federal grants
and hospital types



PATIENT



PATIENT DEFINITION
Must be met at a visit for
eligibility



340B-
ELIGIBLE



Eligibility Requirements

- Receive funds from a designated grant (STD 318, Title X, Ryan White, FQHC*)
- Register in 340B OPAIS
- Recertify Annually
- Ongoing commitment to compliance

**Among other federal grants. Some hospital types also qualify.*

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

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

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



Annual Recertification

- Once registered, entities must recertify annually during the designated period to remain in the program (May 3- June 5, 2023!)
- 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



PATIENT ELIGIBILITY

Eligibility: Two Step Process

PROVIDER



COVERED ENTITIES
Tied to certain federal grants
and hospital types

PATIENT



PATIENT DEFINITION
Must be met at a visit for
eligibility

340B-
ELIGIBLE



340B 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

318 STD Patient Eligibility

- Patients should, at a minimum, have a sexual health history and a discussion of STD risk factors
- Receive any STD testing and treatment warranted, per CDC STD guidelines

340B COMPLIANCE BASICS

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

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

340B Key Concepts- Review

- 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)

340B RESOURCES

NCSD 340B Resources

STD RESOURCE

340B AND ENDING THE EPIDEMICS

NCSD 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.



www.ncsddc.org/resource/340b-and-ending-the-epidemics/

340B Resources for the Field

Memorandum of Understanding for STD 340B Covered Entities

The 340B Drug Pricing Program: FAQs

Contract Pharmacy Guide for 318 Grantees & Subgrantees

Sample 340B Policies and Procedures for CDC Section 318 Recipients

340B HRSA Audit Overview and Checklist

Case Study: How the 340B Drug Pricing Program Helped a Local Sexual Health Clinic Expand HIV Prevention Services

Additional 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](#)

Thank you! Contact info



sarnold@ncsddc.org