

The ABCs of 340B

National Coalition of STD Directors, DPHHS STD Program,
Montana Family Planning, and Board of Pharmacy

April 2, 2024



DEPARTMENT OF
**PUBLIC HEALTH &
HUMAN SERVICES**

Welcome &
Introductions

Why does
340B matter
to you?



Agenda

- Importance of the 340B program
- 340B Program Overview and Eligibility
- Eligibility in Montana
- Registering for 340B
- Compliance Basics
- Resources

Disclosures

- Today's presenters have no financial interests to disclose

NCSD Mission & Values



MISSION

To advance equitable, effective STI prevention programs and services in all communities across the country.

We do this as the voice of our membership.

VISION

A nation where all people are empowered to live sexually healthy lives.

VALUES

Integrity. Transparency. Collaboration.
Equity. Innovation.

What We Do



Capacity Building



Policy & Advocacy



National Leadership & Strategic Communications

Promoting Health Equity



Organizational Strengthening



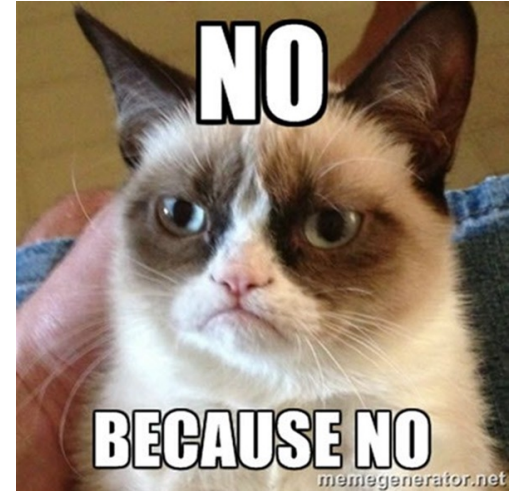
340B PROGRAM OVERVIEW AND ELIGIBILITY

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 funding source
- ❌ Free medications
- ❌ Testing or laboratory support
- ❌ For vaccines



Dramatic Discounts

| Medication | Wholesale Acquisition Cost (for 10) | 340B Package Price | 340B Cost Savings |
|------------------------------------|--|--------------------|-------------------|
| Penicillin Benzathine (4 ml) IM | \$5,681.56 | \$.40 | 99.9% |

\$5,681.16

340B Key Concepts

Only certain
providers are
eligible

Only certain
patients are
eligible

Tracking and
keeping records
are key

Need to choose
between 340B
drugs and
Medicaid drugs

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



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)

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.*

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

340B ELIGIBILITY IN MONTANA

340B Access in Montana

- Public Health Section 318
 - Receive funding or in-kind contributions from STD Program, HIV Prevention Program, or Viral Hepatitis Program
- Memorandum of Agreement with STD, HIV, Viral Hepatitis Section





montanafamilyplanning.org/find-a-clinic

Board of Pharmacy Licensing

GENINE PITTS, PHARMD

MONTANA BOARD OF PHARMACY INSPECTOR



Montana Department of
LABOR & INDUSTRY

Limited Service Pharmacy License

Administrative Rules of Montana 24.174.830

A family planning clinic:

- a. operating under contract with the Department of Public Health and Human Services (DPHHS)
 - b. providing pharmaceutical care under the review of a consulting pharmacist and dispensing legend drugs, but which is not under contract with DPHHS.
- Dispense factory prepackaged contraceptives and prepackaged antibiotics used to treat chlamydia
- \$45 application fee and \$45 renewal fee
- Application requires a floor plan and description of secure storage for prescription drugs

Medical Practitioner Dispenser Registration

Statute authority MCA 37-2-104

Administrative Rules of Montana 24.174.1801 through 24.174.1803

Registers a medical practitioner to dispense legend drugs directly to their patients

- Register with the Board of Pharmacy
 - \$240 application and \$150 annual renewal
- Must dispense directly to their patients
 - Cannot delegate dispensing or mail out
- Must be a condition for which they are treating and within their scope of practice
- Cannot dispense controlled substances

Statute and Rule References

Administrative Rules of Montana Chapter 24.174: Board of Pharmacy

<https://rules.mt.gov/gateway/ChapterHome.asp?Chapter=24%2E174>

Montana Code Annotated Title 37 Chapter 2 Part 1. Prescribing and Dispensing of Drugs

https://leg.mt.gov/bills/mca/title_0370/chapter_0020/part_0010/sections_index.html



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
- 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.”



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.

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
- 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

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Policies and Procedures



Recommended that 340B covered entities develop a set of stand-alone policies and procedures that address all of the components of 340B Program compliance.



Standardize operations and practices throughout the organization; ensure compliance



Will be requested in event of an audit

SAMPLE 340B POLICIES AND PROCEDURES FOR CDC SECTION 318 GRANTEES AND SUBGRANTEES



ncsddc.org/wp-content/uploads/2021/10/Template-340B-Policies-and-Procedures-for-Section-318-Grantees-10.12.21.pdf

Eligibility: Two Step Process

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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

STD “Definition of Patient”

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.

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.



Covered entities must accurately report how they bill Medicaid fee-for-service drugs on the Medicaid Exclusion File



“Carve-in” vs. “Carve-out”

Billing for 340B Drugs in Montana

Carve In: Purchase supplies with the 340B discount and bill the drugs at acquisition cost. ARM 37.85.905 requires you to:

- Notify Medicaid of 340B status upon approval from HRSA
- Remove NDC code from claims to Medicaid for 340B drugs

Carve Out: Purchase supplies without the 340B discount and bill the drugs at their full-fee. When budgets allow, some organizations chose to carve out in an attempt to make some profit off full-priced supplies.

Procuring Medications

1. Pharmaceutical Wholesaler

- AmerisourceBergen
- McKesson
- Cardinal Health

2. Contract Pharmacy

- Walgreens
- CVS
- Walmart
- Accredo



Wholesaler

- May take up to 8 weeks to set up new accounts
- You can purchase from more than one wholesaler
 - State or organizational restrictions may apply
- The Prime Vendor Program has developed a network of traditional, specialty, and limited drug distributors available here:
<https://www.340bpvp.com/distribution/distribution-network>
- Remember to keep auditable records
 - The covered entity is responsible for the medication purchased from manufacturers
 - Keep records, including NDC numbers from purchase to patient

Contract Pharmacies

- HHS estimates that discounts in the 340B Program can range between 25% and 50%
 - Approximately \$30 billion of drugs are sold to covered entities each year, representing almost 6 percent of prescription drugs sold in the United States
- 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

Contract Pharmacies

- Covered entities are **responsible for ensuring compliance** of their contract pharmacy arrangement(s) with all 340B Program requirements
- Must pay for contract pharmacy services
 - Dispensing fees
 - \$12.40 per prescription
 - \$73.58 per prescription
 - % of revenue or savings
 - 7%-22%
- There may also be a 3rd party administrator involved (i.e. pharmacy benefits manager)

ADDRESSING INFECTIOUS DISEASES

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 definition of patient must be met at *every* visit.
- Vaccines are not a “covered outpatient drug” and not subject to 340B pricing

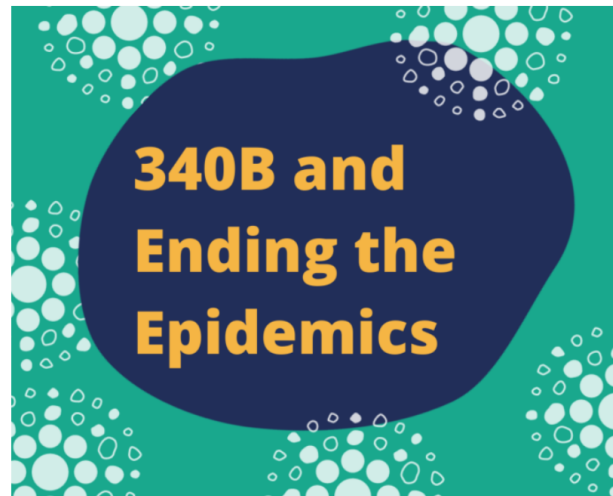
RESOURCES

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

SAMPLE 340B POLICIES AND PROCEDURES FOR CDC SECTION 318 GRANTEES AND SUBGRANTEES



ncsddc.org/wp-content/uploads/2021/10/Template-340B-Policies-and-Procedures-for-Section-318-Grantees-10.12.21.pdf

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](#)

Statute and Rule References

Administrative Rules of Montana Chapter 24.174: Board of Pharmacy

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Questions/ Discussion



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NCSD

National Coalition
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