

Welcome to  
Part 3

340B

FOR  
Viral  
Hepatitis



# Glad you could join us today, friends

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- Please use the chat box to introduce yourselves and to ask your questions
  - This webinar is being recorded, will be distributed at a later time
  - Everyone's mics will be placed on mute for optimal audio
- Your questions guide our TA so please ask here or email them to us  
[hepatitis@nastad.org](mailto:hepatitis@nastad.org)

Special thank you to Alex, Boatemaa,  
Edwin, Emily & Tim

# WEBINAR OVERVIEW

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- Series Learning Objectives:
  - Increase functional knowledge of HRSA's 340B Drug Pricing Program
  - Identify the role for the 340B Drug Pricing Program in viral hepatitis programs
  - Understand the roles of health departments and registration processes
  - Operationalize the 340B Drug Pricing Program in viral hepatitis elimination efforts
- Multi-part series:
  - **April 21, May 5**
  - Every other Wednesday at noon ET



# Contract Pharmacies and Management

*for Viral Hepatitis Programs*

## Hepatitis TA Center (HepTAC)

Erin Fratto, MS, CHES  
Public Health Consultant



# TODAY'S AGENDA

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- Review:
  - ✓ 340B basics
  - ✓ Role(s) of the health department
  - ✓ Registration process
- Contract Pharmacies
- Audit Pitfalls
- Workshop and answer questions

340B

FOR  
Viral   
Hepatitis

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# 340B REVIEW

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- Part 1: 340B Basics for Viral Hepatitis Programs available [here](#)
- Part 2: 340B Roles and Registration available here
- Summary:
  - 340B is a federal program administered by HRSA Office of Pharmacy Affairs (OPA)
  - Authorized by the Public Health Service Act
    - STD Clinics (Section 318 grantees)
      - **Viral Hepatitis, HIV Prevention, and STD programs all fall under Section 318**
  - Covered entities must have a *financial relationship* with a qualifying section 318 program that is eligible for 340B and must receive either *direct financial support* or receive *in-kind contributions* supported by the qualifying section 318 funding

# 340B REVIEW

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- Eligibility is dependent on the grant or funding a provider receives, and patients must meet a 3-part definition
  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
- All grants authorized by Section 318 of the Public Health Service Act are eligible

This NOFO builds on CDC-RFA PS17-1703 which funded 14 states to build registries of hepatitis B and hepatitis C cases and improve completeness of case reports; and CDC-RFA-PS17-1702 which funded 50 jurisdictions to identify high burden areas for hepatitis B and/or hepatitis C and improve prevention and treatment in those areas. Both awards have been in place since fiscal year 2017.

**b. Statutory Authorities**

This program is authorized under **Section 318** of the Public Health Service Act (42 U.S.C Section 247(c), as amended.

**c. Healthy People 2030**



# 340B REVIEW

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- Health Department Roles:
  - Ensure subgrantees know about the 340B Drug Pricing Program
  - Provide guidance what is considered a service within the scope of each CDC NOFO
  - Understand how your subgrantees are meeting the patient definition
  - Review their policies and procedures
  - Set clear expectations regarding oversight and compliance
  - Be familiar with how the subgrantee will be purchasing medications
  - Update your contracts and agreements to account for 340B considerations and revenue
  - Be aware of registration and recertification periods and ensure subgrantees have the grant number and NOFO number they need
  - Verify to HRSA OPA that they are a subgrantee when asked
  - Notify HRSA OPA if a subgrantee is no longer receiving funding or in-kind support

# 340B REVIEW

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- 4 annual registration periods
  - The first 15 days of every quarter
- Must attest annually
- Registration is done at the service level site
  - A state-level administrator should not register their contractor or partner
- Authorizing officials represent the covered entity and must be fully authorized to legally bind the covered entity
- Must have an account in the Office of Pharmacy Affairs Information System



# PROCURING MEDICATIONS

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## 1. Pharmaceutical Wholesaler

- AmerisourceBergen
- McKesson
- Cardinal Health

## 2. Contract Pharmacy

- Walgreens
- CVS
- Walmart
- Accredo



# WHOLESALE

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- May take up to 8 weeks to set up new accounts
- You can purchase from more than one wholesaler
- 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

# CONTRACT PHARMACIES

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- 340B covered entities may elect to dispense 340B drugs to patients through contract pharmacy services
- 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 3<sup>rd</sup> party administrator involved (i.e. pharmacy benefits manager)

# CONTRACT PHARMACIES

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- In a contract pharmacy arrangement, the covered entity retains responsibility to prevent diversion and duplicate discounts, maintain auditable records, and meet all other 340B Program requirements
- Must register in OPIAS
- Contract with a Contract Pharmacy Considerations:
  - Establish inventory model
    - Replenishment, physical inventory, hybrid
  - Procedures for patient eligibility determination
  - Ensure tracking system is suitable for reconciliation of dispensing, purchasing, and billing records to ensure that diversion and duplicate discounts do not occur
  - Outline fees and that savings/revenue from the 340B program belongs to the covered entity, not the contract pharmacy

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

# VIRAL HEPATITIS CONTRACT PHARMACY EXAMPLE

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- Townsville Hepatitis Alliance receives qualifying grant funding from their state health department and has a HepC clinic twice a month. They've signed a written contract with a contract pharmacy for the dispensing of 340B drugs. They've negotiated a \$25 dispensing fee per prescription and have opted to stock a physical inventory at the contract pharmacy since they treat most of their patients with one medication. The contract pharmacy has their own specialized software for tracking and provides the covered entity with monthly dispensing reports.

# COMPLIANCE ELEMENTS

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- Comprehensive, Written 340B Program Policies and Procedures
  - Program requirements, methodologies for routine self-auditing and internal corrective action.
- Contract Pharmacy Agreement and 340B OPAIS Record
- Prevention of Diversion
  - 340B medications going to non-340B eligible patients
  - Reselling or transferring 340B medications
- Prevention of Duplicate Discounts
  - When a discount is provided to the covered entity and a rebate is also paid to the state under the Medicaid drug rebate program



# COMPLIANCE ELEMENTS

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- Quarterly internal audits and annual independent audits of all contract pharmacies
- Maintain written policies and procedures to describe contract pharmacy oversight activities
  - Patient eligibility determination used at contract pharmacy
  - Reconciliation of dispensing, purchasing and billing
  - Use self disclosure tool to disclose any violations found while self-using

# RESOURCES

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- [Contract Pharmacy FAQs](#)
- NACHC 340B Manual for Health Centers, [Chapter 11 Contract Pharmacies](#)
- [340B Tools \(Policy, Procedures, Auditing/Compliance\)](#)
- [HRSA Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services](#)
- [Apexus: 340B Prime Vendor Program](#)
- [340B FAQs](#)

# SUMMARY

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- Covered entities are free to choose how they provide 340B pharmacy services to patients subject to federal and state laws
  - Contracting with a retail pharmacy
  - Providing in-house pharmacy services
  - Administering medications to patients
- Covered entities are responsible for compliance even when using a contract pharmacy
- There are many contract-pharmacy related resources available through the 340B Prime Vendor Program

# QUESTIONS AND DISCUSSION

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## Next Webinar:

Wednesday, April 21, 2021

12:00 pm ET

## Agenda: 340B Implementation Among Viral Hepatitis Programs

- What Section 318 grant support looks like for viral hepatitis programs
- How the 340B program has expanded viral hepatitis programs
- How viral hepatitis programs are operationalizing the patient definition
- How viral hepatitis programs ensure compliance