

Welcome to  
Part 4

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, Jasmine & 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:
  - **Final session: May 5**
  - Every other Wednesday at noon ET



# 340B Implementation

*for Viral Hepatitis Programs*

## Hepatitis TA Center (HepTAC)

Erin Fratto, MS, CHES  
Public Health Consultant



# TODAY'S AGENDA

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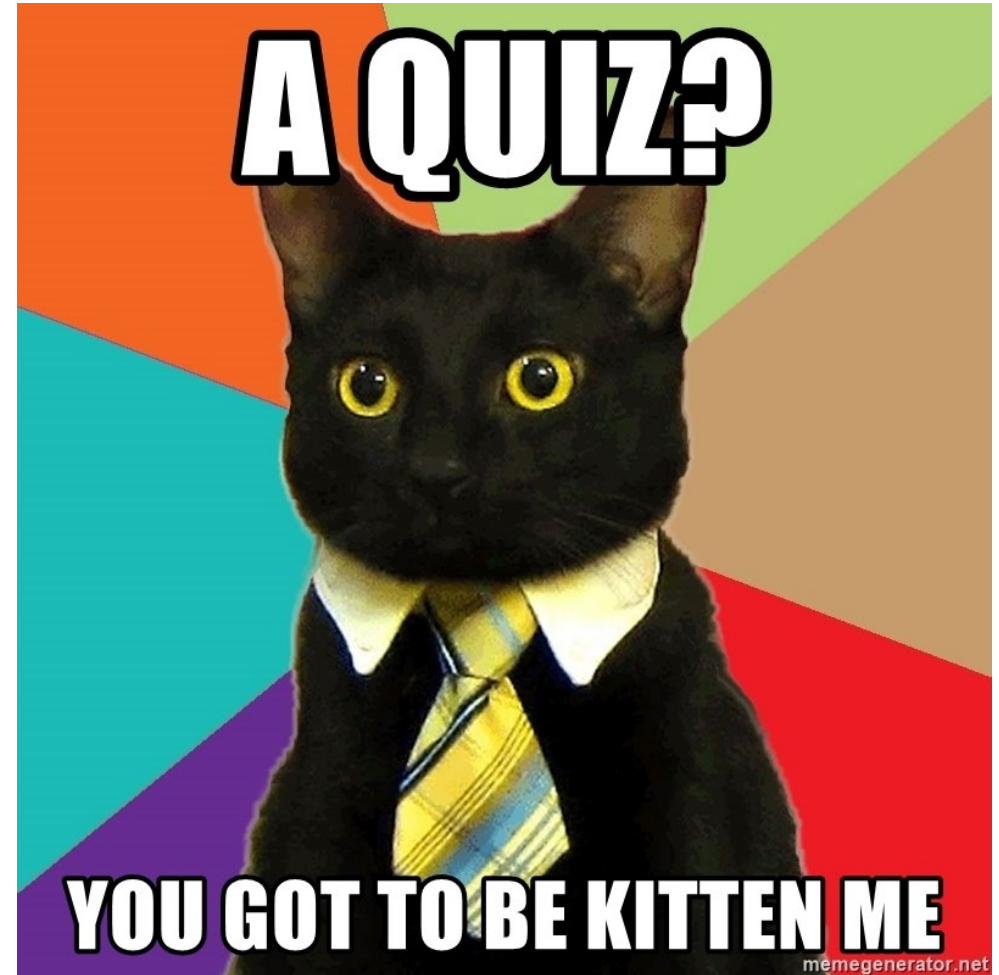
- Review:
  - ✓ 340B basics
  - ✓ Role(s) of the health department
  - ✓ Registration process
  - ✓ Contract pharmacies
  - ✓ Compliance
- Discuss how local programs are leveraging the 340B program for viral hepatitis activities



# 340B BASICS POP QUIZ

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1. Covered entities aren't responsible for the operations of their contract pharmacies.
2. A covered entity can have multiple contract pharmacies.
3. What makes an organization 340B eligible?



# 340B REVIEW

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- Part 1: 340B Basics for Viral Hepatitis Programs available [here](#)
- Part 2: 340B Roles and Registration available [here](#)
- Part 3: 340B Contract Pharmacies and Medication Management [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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- Not Health Department Roles:
  - Enroll subgrantees into the 340B program
  - Serve as a subgrantee's authorizing official or primary contact
  - Attest to another agency's compliance
  - Create policies or procedures for subgrantees
  - Audit their 340B compliance
  - Take all their 340B revenue



# 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



# 340B Review

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- Medications are acquired through wholesalers or contract pharmacies
  - Covered entities are **responsible for ensuring compliance** of their contract pharmacy arrangement(s) with all 340B Program requirements

*The covered entity retains responsibility to prevent diversion and duplicate discounts, maintain auditable records, and meet all other 340B Program requirements*

- Compliance elements include:
  - Comprehensive, Written 340B Program Policies and Procedures
  - Contract Pharmacy Agreement and 340B OPAIS Record
  - Prevention of Diversion
  - Prevention of Duplicate Discounts



# 340B Implementation Panel

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Introductions: Name, organization, Role in the 340B program

1. California
2. Iowa
3. Utah



# 340B Implementation Panel

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1. What grant authorizes your 340B designation?
2. What does your qualifying grant support look like? Actual funding, in-kind contributions or both?
  - a) If it's in-kind support, what is that in-kind support?
3. What does your 340B grant/agreement/contract look like with the health department/covered entity?
  - a) What components do you feel are most beneficial?
4. How do you leverage the 340B program for viral hepatitis activities?
  - a) How have you operationalized the 340B patient definition?
  - b) How do you monitor your 340B program and ensure compliance?

# RESOURCES

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- [HRSA 340B Drug Pricing Program](#)
- [Apexus: 340B Prime Vendor Program](#)
- [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](#)
- [340B Health](#)
- [Contract Pharmacy FAQs](#)
- [340B Tools \(Policy, Procedures, Auditing/Compliance\)](#)



# SUMMARY

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- Public health partnerships are crucial in reaching vulnerable populations
- Patient definition implementation can look different for Section 318/STD covered entities
- 340B medications stretch limited resources and improve medication access for patient populations

# QUESTIONS AND DISCUSSION

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## Final Webinar:

The Role of 340B in Health Equity

Wednesday, May 5, 2021

12:00 pm ET

