

Welcome to  
Part 2

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
  - Operationalize the 340B Drug Pricing Program in viral hepatitis elimination efforts
- Multi-part series:
  - **March 24, April 7, April 21, May 5**
  - Every other Wednesday at noon ET



# 340B Roles and Registration

*for Viral Hepatitis Programs*

## Hepatitis TA Center (HepTAC)

Erin Fratto, MS, CHES  
Public Health Consultant



# TODAY'S AGENDA

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1. Review 340B basics
2. Discuss the role(s) of the health department
3. Review the registration process and discuss special considerations
4. Workshop and answer questions

340B

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# 340B BASICS REVIEW

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- Part 1: 340B Basics for Viral Hepatitis Programs available here
- Summary:
  - 340B is a federal program administered by HRSA Office of Pharmacy Affairs (OPA)
  - Eligibility is dependent on the grant or funding a provider receives, and patients must meet a 3-part definition
  - All grant authorized by Section 318 of the Public Health Service Act are eligible
    - Integrated Viral Hepatitis Surveillance and Prevention Funding for Health Departments
    - Integrated HIV Surveillance and Prevention Programs for Health Departments
    - Strengthening STD Prevention and Control for Health Departments
  - 340B allows revenue to be generated or significant savings to be had

# HEALTH DEPARTMENT ROLES

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- Health Departments may be the covered entity
- Health Departments may be the administrators of funding that covered entities receive
- Health Departments may be a covered entity *and also* provide funding and support to other covered entities





# 340B REGISTRATION

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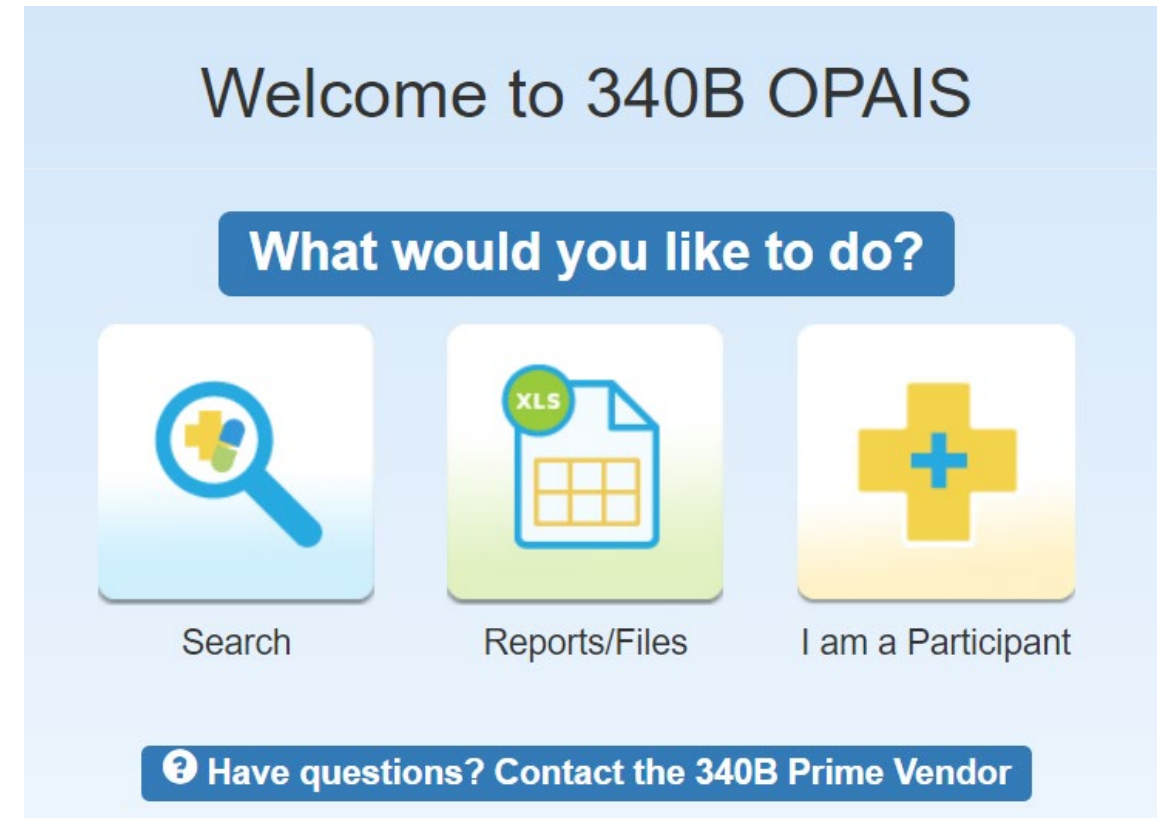
- Remember: *eligible* entities serving *eligible* patients
- 4 annual registration periods
  - The first 15 days of every quarter
- Registration is done at the service level site
  - A state-level administrator should not register their contractor or partner



# 340B REGISTRATION CHECKLIST

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- ✓ Determine who your authorizing official is
- ✓ Determine who your primary contact will be
- ✓ Create an account in the [HRSA Office of Pharmacy Affairs 340B Information System](#)
- ✓ 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



# NEW REQUIREMENT

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- [As of August 1, 2020](#) STD/TB/RW entities are required to enter the following in 340B OP AIS at the time of registration:
  - The notice of funding opportunity number
  - The date range of their NOFO funding
  - The type of in-kind support they are receiving (if applicable)

*\*Active STD/TB/RW entities will be required to update this information during their next recertification submission*



Centers for Disease Control and Prevention

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

Integrated Viral Hepatitis Surveillance and Prevention Funding for Health Departments

**CDC-RFA-PS21-2103**

Application Due Date: 12/01/2020

# AUTHORIZING OFFICIAL

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- Authorizing Official:
  - The authorizing official **represents the covered entity** and must be fully authorized to **legally bind the covered entity**. The authorizing official must annually recertify covered entity eligibility, **attest to compliance** with all program requirements, verify contract pharmacy arrangements, and receive all communications from HRSA regarding the 340B program, including **audit reports**. For many non-hospital covered entities, the authorizing official is the grantee of record based upon federal funding streams. For hospital covered entities, the authorizing official is usually the **CEO, CFO, COO/President/Vice President** or equivalent.
- Primary Contact:
  - A secondary contact for the covered entity. Receives information and reminders from HRSA. They do not have authority to update or change any items within OPAIS

# 340 STD COVERED ENTITIES

<input type="checkbox"/>	<a href="#">STD043337</a>	STD	MAINE DEPT OF HEALTH & HUMAN SERVICES	MAINE CDC, HIV,STD AND VIRAL HEPATITIS PROGRAM	286 WATER STREET, 6TH FLOOR	AUGUSTA	ME	01/01/1999		10/22/2020
<input type="checkbox"/>	<a href="#">STD075052</a>	STD	Paterson Counseling Center, Inc.	Hepatitis Program	319-321 Main Street	Paterson	NJ	04/01/2019		06/02/2020
<input type="checkbox"/>	<a href="#">STD200249</a>	STD	DEPARTMENT OF HEALTH	HIV, AIDS, STD, TB, HEPATITIS, ADMINISTRATION (HAHSTA)	77 P St NE	WASHINGTON	DC	01/01/2000		05/15/2020
<input type="checkbox"/>	<a href="#">STD46202</a>	STD	INDIANA STATE DEPARTMENT OF HEALTH	HIV, STD, VIRAL HEPATITIS DIVISION	2 NORTH MERIDIAN ST., 6-C	INDIANAPOLIS	IN	04/01/2000		05/06/2020

<input type="checkbox"/>	<a href="#">STD191364</a>	STD	Philadelphia Department of Prisons	Philadelphia Industrial Corrections Center	8301 State Road	Philadelphia	PA	10/01/2020		08/19/2020
<input type="checkbox"/>	<a href="#">STD50169</a>	STD	Department of Corrections	Iowa Correctional Institution for Women	420 Mill St SW	Mitchellville	IA	04/01/2019		05/04/2020
<input type="checkbox"/>	<a href="#">STD52241</a>	STD	Department of Corrections	Iowa Medical and Classification Center	2700 Coral Ridge Avenue	Coralville	IA	04/01/2019		05/04/2020
<input type="checkbox"/>	<a href="#">STD53023</a>	STD	Wisconsin Department of Corrections	Kettle Moraine Correctional Institution	W9071 Forest Dr	Glenbeulah	WI	01/01/2021		11/06/2020
<input type="checkbox"/>	<a href="#">STD531431</a>	STD	Wisconsin Department of Corrections	Kenosha Correctional Center	6353 14th Ave	Kenosha	WI	01/01/2021		11/06/2020

# ANNUAL RECERTIFICATION

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- 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



# VIRAL HEPATITIS PROGRAM EXAMPLE

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- The Rainbow Brite Center:

- An eligible provider serving eligible patients
  - They receive funding from a section 318 grant (PS21-2103)
  - They employ medical providers, have established relationships with their patients, maintain records, and provide services that are consistent with their qualifying funding
- Contracts with the State Health Department
  - Has gotten the NOFO number and grant number
- Has a contract pharmacy
- Ready to Register!
- Enrolls on July 1, can access 340B priced medications on October 1
  - Generates revenue and can now pay their bill from the Public Health Laboratory and also hire another navigator



# RESOURCES

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- [Office of Pharmacy Affairs 340B OPAIS](#)
- [HRSA 340B Drug Pricing Program](#)
- [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](#)
- [340B Health](#)



# SUMMARY

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- Ensure eligibility is met
- Understand roles of authorizing official and primary contact
- Make sure contracts and agreements are in place ahead of registration
- Register and be familiar with OPAIS
- Be aware of the four registration periods
- Be ready for the annual recertification period

# QUESTIONS AND DISCUSSION

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## Next Webinar:

Wednesday, April 7, 2021

12:00 pm ET

## Agenda: Leveraging the 340B Program for Viral Hepatitis Programs

- In-kind partnerships and contractual agreements
- 340B saving and revenue impacts across communities