

Advancing 340B Within Health Department Leadership for Viral Hepatitis Programs

Supporting viral hepatitis program administrators in educating and preparing leadership to support 340B program implementation and partnerships

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Introduction

The 340B Drug Pricing Program (340B Program) is instrumental to ending the viral hepatitis epidemic, enabling viral hepatitis programs to expand and improve services, contain costs, address health equity, and reduce health disparities. The 340B Program provides viral hepatitis programs with up-front savings on medications, as well as the potential to generate revenue in the form of insurance payments. Up-front cost savings as well as additional revenue provide viral hepatitis programs with valuable resources, which are reinvested in services and expands programmatic reach.

340B Program administration is often delegated to program-level managers, grant administrators, and program specialists. As NASTAD supports viral hepatitis

staff in understanding and utilizing the 340B Program, it may be necessary and beneficial to educate and inform health department leadership and other stakeholders of the purpose and intent of the 340B Program, as well as planned activities and partnerships that involve the 340B Program. This information may be shared with bureau and division directors, those who serve as the principal investigator for the qualifying funding, as well as health department executive leadership including the legal department and the executive director.

The support of the viral hepatitis program's chain of command is crucial in implementing policies, conferring eligibility, maintaining compliance, and is needed when executing formal partnerships including contracts and/or memorandums of understanding and agreement.

Goals of Informing Leadership

The goals of informing health department leadership of the 340B Program will vary from jurisdiction to jurisdiction and may often be nuanced. Viral hepatitis programs may need to inform and prepare leadership to:

- Ensure appropriate 340B Program administration. This may include ensuring the 340B authorizing official and primary contact duties are aligned with the appropriate health department staff person.
- Implement a 340B program within their own organization or clinic.
- Confer eligibility to partners including local health departments, health care providers, correctional facilities, and/or community-based organizations.
- Remove eligibility from partners including local health departments, health care providers, correctional facilities, and/or community-based organizations.
- Build 340B capacities among viral hepatitis subgrantees and partners.
- Coordinate with different health department divisions (e.g., STD, HIV prevention, and HIV care/treatment) with grantees and/or subgrantees leveraging the 340B Program.

****Additional Considerations:** This resource does not cover communicating more complex 340B concepts to health department leadership including considerations around 340B Medicaid billing, duplicate discounts, and modifying existing 340B operations. This resource is written based upon the best understanding of NASTAD and its contractors. Health departments should refer to the 340B statute, HRSA published guidance, and HRSA policy releases for additional guidance. Health departments should also use their own judgement and legal counsel to assist in ensuring compliance with 340B Program requirements. The materials herein do not constitute, and should not be treated as, professional advice regarding compliance with laws or regulations. This is not a legal document and should not be used to substitute the 340B statute, 340B program regulations, HRSA published guidance, HRSA policy releases, and other relevant resources. Liability for compliance with 340B Program requirements resides solely with the covered entity.*

Recommendations When Approaching Leadership

The 340B Program is a complex federal program and it is recommended that viral hepatitis administrators understand the 340B Program and how it relates to their program and subgrantees. This foundational understanding helps viral hepatitis program administrators then synthesize key information and action items for leadership. To assist viral hepatitis programs in building this foundational knowledge, NASTAD has created a [340B Drug Pricing Program Guidance & Webinar Series](#) resource.

When communicating to health department leadership about the 340B Program it is best to try and make the information you share about this complex federal program as clear, concise, and action oriented as possible. Include the 340B concepts that are necessary to understand the action items that are included in the memo or communication. Keeping the end goal in mind will help communications stay focused. Clearly state any timelines, deadlines,

deliverables, or expectations. Make sure health department leadership knows that you are an STD 340B resource by offering to share more information if needed and upon request. Also be aware that this may just be the starting point of a more in-depth STD 340B dialogue among leadership.

When communicating with health department leadership, make sure it is clear what the viral hepatitis program as well as the health department is responsible for, and not responsible for. Remember 340B compliance and liability always rests with the covered entity so make sure it is clear if your program is the covered entity, or if you are supporting a subgrantee's enrollment or 340B eligibility – this makes a difference to leadership! It's important to accurately describe any administrative considerations when communicating with leadership so they can understand how this may affect program operations and staff capacity.

Simplifying Complex 340B Program Principles

The following 340B principles may be useful to share with leadership:

The 340B Program is a federal program administered by HRSA, and programs authorized by Section 318 of the Public Health Service Act are eligible to participate. This includes health department viral hepatitis programs, along with our HIV and STD prevention programs [list eligible NOFOs for clarity].

The purpose of the 340B Program is to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services and it is how many health care providers purchase deeply discounted medications.

The 340B Program provides viral hepatitis programs and subrecipients with access to up-front cost savings on medications as well as the potential to generate revenue in the form of insurance payments.

In addition to [viral hepatitis program/health department] being eligible, [subrecipients/subgrantees/contractors/partners] who have a financial relationship with the viral hepatitis program, a qualifying section 318 program, are also eligible for 340B Program participation.

HRSA describes a direct financial relationship as either receiving direct financial support or receiving in-kind contributions supported by the qualifying section 318 funding. In-kind contributions maximize the limited Section 318 funding that provides 340B eligibility and allows many community-based health care programs to participate.

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.

STD 340B covered entities are responsible for their own compliance. The viral hepatitis program will not serve as any other organization's 340B authorizing official or primary contact. The viral hepatitis program will support the [subrecipients/subgrantees/contractors/partners] participation in the program but will not be liable for their 340B Program operations.

There are four annual registration periods, which are the first 15 days of every calendar quarter. After enrollment, 340B covered entities recertify on an annual basis attesting to compliance.

A 340B authorizing official represents the covered entity and must be fully authorized to legally bind the covered entity and attest to compliance. A 340B primary contact is a secondary contact for the covered entity and also receives information and reminders from HRSA.

340B covered entities purchase 340B-discounted medications from a pharmaceutical wholesaler and are usually dispensed by an in-house pharmacy or a contract retail pharmacy. For those utilizing a contract pharmacy, the pharmacy must also enroll in the 340B program during the same registration periods as well as attest to compliance.

Instructions

- 1** Understand and follow your chain of command.
- 2** Review policies to ensure you include all the right leaders.
- 3** Communicate in writing for easy documentation and future reference. If you attend a leadership meeting to discuss 340B make sure to include your talking points and save any meeting minutes or notes.
- 4** Keep written communications to a maximum of two pages.
- 5** Provide 340B references and resources, cite sources when applicable.
- 6** Request read receipts on emails and signatures/initials on routing memos.
- 7** Outline deadlines and timeframes that leadership should be aware of.
- 8** Make sure to address follow-up items from leadership in a timely manner.
- 9** Provide leadership with next-steps or an action plan.
- 10** Ask leadership if they would like any additional 340B information or references.

340B Resources

- [340B Drug Pricing Program Guidance & Webinar Series](#), NASTAD
- [HRSA 340B Drug Pricing Program](#), HRSA
- [340B Prime Vendor Program](#), Apexus
- [340B Office of Pharmacy Affairs Information System](#), HRSA
- [Public Health Service Act](#), United States Government

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Sample Memo

A sample memo is provided below and serves as an outline and guide for viral hepatitis programs and will not be applicable for every situation. Viral hepatitis programs should use this example as a starting point for their own communication and memo to leadership and modify based on their own circumstance and need.

[copy onto health department letterhead or memo template]

Memo

To: Health Department Leadership

From: [your name here], Viral Hepatitis Coordinator

CC: Program manager, bureau director, division director, principal investigator, other Section 318 grant administrators (HIV prevention, STD prevention, Ending the Epidemic managers)

Date: xx/xx/xxxx

Re: 340B and Viral Hepatitis

Comments: Please see below regarding STD 340B eligibility, viral hepatitis partnerships, and the role of the Department

- The 340B Drug Pricing Program allows safety-net providers to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services including viral hepatitis screening and treatment.
- The 340B Drug Pricing Program is administered through the Office of Pharmacy Affairs (OPA) within HRSA and is a federal program that provides enrolled covered entities with up-front cost savings on medications as well as the potential to generate revenue in the form of insurance payments.
- STD 340B program eligibility is tied to specific federal funding streams authorized by Section 318 of the Public Health Services Act, which our department of health receives. Those who receive our pass-through support, either in-kind or direct financial assistance, are eligible to participate in the 340B drug pricing program.
- Subgrantees and partners of the viral hepatitis program who are eligible and would like to enroll in the 340B Program with an STD 340B designation will need health department support and approval. HRSA will contact the principal investigator to verify eligibility once a subgrantee or partner enrolls in the 340B Program.
- Once enrolled in the 340B Program, covered entities are responsible for program administration and compliance. The administrative burden on the viral hepatitis program should be/will be minimal and will include supporting the covered entity as needed and monitoring outcomes related to program goals such as viral hepatitis elimination.
- The following subgrantees and partners are interested or may benefit in participating in the 340B Drug Pricing Program:
 - Departments of Corrections
 - Opioid Treatment Programs
 - [Other subgrantees or partners who receive your support that also have clinical capacity]
- The viral hepatitis program will work with our partners to build capacity regarding the 340B Drug Pricing Program, and this may include developing and routing memorandums of understanding, contracts, or other formal agreements.
- Contracts and memorandums of understanding will be routed according to policy.

For questions or concerns about the 340B Program or the viral hepatitis program's planned activities, please send an email to [enter email].