



340B Drug Pricing Program Guidance for Viral Hepatitis Programs

*Addressing health equity by expanding
treatment access and improving services*

NOVEMBER 2021

Introduction

The 340B Drug Pricing Program (340B Program) is a federal program authorized by Section 340B(a) (8) of the Public Health Service Act that enables covered entities to stretch scarce federal resources as far as possible, providing outpatient medications to covered entities at significantly reduced prices. The 340B Program is administered through the Office of Pharmacy Affairs (OPA) within the Health Resources and Services Administration (HRSA).

Section 340B(a)(4) of the Public Health Service Act specifies which covered entities are eligible to participate in the 340B Program. These include qualifying hospitals and various recipients of federal grants from HRSA, the Centers for Disease Control and Prevention (CDC), the Department of Health and Human Services' Office of Population Affairs, and the Indian Health Service. Early in 2019, HRSA revised the STD 340B covered entity type to include any program receiving federal funding authorized by Section 318 of the Public Health Service Act, granting 340B eligibility to over two dozen CDC cooperative agreements. State health department viral hepatitis programs receive federal funding authorized by Section 318 of the Public Health Service Act, in turn granting them 340B eligibility under the federal grantee STD covered entity category.

The 340B Program is an instrumental tool in ending the viral hepatitis epidemic, enabling viral hepatitis programs to expand and improve services, address health equity, and reduce health disparities. The 340B Program provides viral hepatitis programs with up-front cost 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 is reinvested in services and expands programmatic reach.

As NASTAD supports public health officials who administer HIV and hepatitis programs, 340B guidance is essential in the implementation of impactful, innovative, and compliant 340B programming. This guidance is designed to provide an outline of the 340B Drug Pricing Program for viral hepatitis programs and build capacity of local viral hepatitis programs by offering 340B Drug Pricing Program best practices.

NASTAD strongly encourages 340B program administrators to incorporate [health equity](#) into their programs. Health equity means that everyone has a fair and just opportunity to be as healthy as possible and this requires removing obstacles to health such as structural racism and the intentional lack of social safety nets and investments that lead to poverty, unstable housing, food deserts, inadequate infrastructure and environmental injustices. Reducing health disparities – worse health in excluded or marginalized groups- is an important step toward achieving health equity. Addressing the [social determinants of health](#) with 340B Program savings and insurance payments is one way to address health disparities and work towards health equity.

The purpose of this document is to provide an overview of the 340B Drug Pricing Program, offer implementation guidance and provide best practice recommendations as it pertains to the 340B designations authorized by Section 318 of the Public Health Service Act. This guidance is written based upon the best understanding of NASTAD and its contractors. Covered entities should refer to the 340B statute, HRSA published guidance, and HRSA policy releases for additional guidance. Covered entities 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.

340B Program Eligibility

Providers

A 340B Program eligible viral hepatitis program receives qualifying funding awarded from a federal funding source authorized by Section 318 of the Public Health Service Act (PHSA). If a viral hepatitis program is unsure of the statutory authority of their grant funding, administrators should reference grants, cooperative agreements, or notice of funding opportunity (NOFO) documents. Grants and cooperative agreements are also tracked by a five-digit number assigned by the federal government called Assistance Listings, or catalog for domestic assistance (CFDA) numbers. NOFO numbers and statutory authority may be found through this mechanism as well. Please see Appendix A for images directly from a CDC funding opportunity announcement for NOFO, CFDA, and Statutory Authority examples.

Additionally, most viral hepatitis programs subcontract Section 318 grant funds to local health departments, community-based organizations, as well as clinics and healthcare providers. As these organizations form a financial relationship with viral hepatitis programs and receive Section 318 funds through government grants and subcontracts, they also become 340B Program eligible. It is important to note that HRSA also considers in-kind contributions provided through Section 318 programs as qualifying support. These in-kind contributions must be paid for by qualifying Section 318 grant funds and may be in the form of real property, equipment, supplies, other expendable property, and goods and services directly benefitting, and specifically identifiable, to the project or program.

In-kind contributions often provided by viral hepatitis programs include rapid HCV test kits, HCV confirmatory testing, courier service for specimen transportation, medical supplies, medical supply disposal, educational

**The term BIPOC was developed to prioritize Black and Indigenous people when responding to the harms that all people targeted by structural racism face. It is imperfect in both its description and its politics.*

***Here the acronym LGBTQIA+ stands for lesbian, gay, bisexual, trans, queer/questioning, intersex, and asexual people, and any other identity a person might have that is non-heterosexual and non-cisgender. It is an attempt to refer to the diverse and fluid spectrum of people while also recognizing that even within this umbrella acronym, LGBTQIA+ people face compounding forms of oppression when applying an intersectional lens.*

340B HEALTH EQUITY CONCEPT

- Viral hepatitis disproportionately affects Black, Indigenous, and people of color (BIPOC*) as well as people that identify as LGBTQIA+**, people who use drugs, individuals experiencing incarceration and people living with HIV. Historical oppression of these communities leads to intentional discriminatory institutional policies and practices. Furthermore, this oppression also means that simply providing equal access is not enough to achieve equity and public health programs must actively help remove structural barriers—often referred to as [social determinants of health](#). Viral hepatitis programs are in a unique position to provide funding and/or in-kind support to organizations serving the most impacted and marginalized populations by providing 340B Program eligibility at the organizational level.
- Choose your viral hepatitis program partners using an equity lens and ask equity-minded questions before entering into a partnership. The organization may already have health equity directives, projects, or programs that serve as a blueprint for viral hepatitis programs. Is the proposed 340B Program able to reduce disparities in care and treatment of BIPOC and/or individuals experiencing incarceration? Is health equity addressed in any contracts or agreements? This could mean establishing service delivery goals by population, tracking health outcomes by population and addressing gaps, or revising institutional policies and practices to ensure services are designed to compensate for structural barriers and provide the tools, services, benefits, etc. each person needs to achieve optimal health outcomes.

materials, and technical assistance. It is a best practice to formalize in-kind contributions and public health partnerships through an agreement such as a memorandum of understanding (MOU).

Patients

Patients of qualifying providers (covered entities) must meet a three-part patient definition to qualify for the 340B Program. An individual meets Patient eligibility when:

1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care;
2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (i.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and
3. The individual receives a health care service 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.

Viral hepatitis programs should look to the notice of funding opportunity that is providing 340B Program eligibility to ensure services are in line with the intent of the funding opportunity as Section 318 grants differ in scope and range of services. Viral hepatitis programs operationalize the third part of the patient definition in a variety of ways, the most common being ongoing viral hepatitis risk assessments, screening, and testing. Patients receiving health care remotely via telehealth or during outreach/mobile operations are also eligible, given the three-part patient definition is met.

340B HEALTH EQUITY CONCEPT

- Require 340B Program providers to implement scientific and evidence-based practices within their 340B supported programs and remove discrimination in viral hepatitis screening and treatment practices. For example, eliminate the use of fibrosis scores to drive treatment eligibility; remove drug use prohibitions; cease sobriety requirements. Treatment is recommended for all patients with acute or chronic HCV regardless of comorbid conditions or substance use disorders ([AASLD](#), [IDSA](#)).

Registration and Administration

Once a viral hepatitis program determines they are eligible for the 340B Program and are confident they will be serving eligible patients, they should prepare to register for the 340B Program. There are four annual registration periods, which are the first 15 days of every calendar quarter. It is important to note that OPA may take up three months to verify and activate registration. Viral hepatitis programs should plan at least three months ahead of 340B program implementation to account for OPA's waiting period. 340B Program enrollment and registration is completed at the service level; a state-level viral hepatitis program administrator should not register their contractors or subgrantees.

As of August 1, 2020, STD, TB, and Ryan White HIV/AIDS Program grantees and subgrantees are required to enter the NOFO number, the date range of their NOFO funding, and the type of in-kind support they are receiving (if applicable). Active covered entities will be required to update this information during the next recertification submission.

When viral hepatitis programs are preparing for enrolling and registering for the 340B Program, an authorizing official and primary contact should be identified and designated. A 340B authorizing official is responsible for 340B compliance and program integrity. Additionally, the authorizing official is responsible for certification and termination within the jurisdiction; they also are responsible for the covered entities protocols and records. Authorizing officials range from program managers to the chief operating officer or executive director. The designation depends on organizational authority delegation, legal structure, and familiarity with the 340B Program. The primary contact is usually more of a day-to-day administrator, clinic manager, or assistant.

Some viral hepatitis programs may choose program managers to serve as authorizing officials, while others find the primary contact role more appropriate. It is recommended that viral hepatitis programs support their executive director or health officer in serving as their authorizing official. Viral hepatitis program-level staff should only serve as 340B authorizing officials if they can legally bind their organization to agreements.

340B Program Registration Checklist for Viral Hepatitis Programs

- ✓ Ensure all grants/contracts/agreements are signed and executed before registering
 - Determine how you will procure medications ahead of time; viral hepatitis programs may need to issue an RFP to identify a contract pharmacy or medication wholesaler
- ✓ Determine who your authorizing official is; ensure they are aware and are kept updated on the process and progress
- ✓ Determine who your primary contact will be; ensure they are aware and are kept updated on the process and progress
- ✓ Create accounts in the HRSA OPA 340B Information System (OPAIS)
 - Both the authorizing official and primary contact will need separate accounts
 - OPAIS requires complex passwords and double authentication
 - Your contract pharmacy will need to register as well. If the pharmacy is already an established contract pharmacy for other covered entities, they still must register with your specific contract agreement and be linked to your 340B ID
- ✓ Know your NOFO and grant number
- ✓ Add noreply@hrsa.gov to your email program's spam filter
- ✓ Register during the first 15 days of every calendar quarter
 - Viral hepatitis programs should register using the STD covered entity category

Once registered, entities must recertify annually during the designated period to remain in the 340B Program. Advance email notifications with preliminary information about the recertification process are sent to both the primary contact and authorizing official. Recertification is done through OPAIS and is generally available for a 30-day period. Failure to recertify will result in termination from the 340B Program.

Program Implementation

As the 340B Program provides discounted medications to patients, providing care and treatment to qualifying patients is the main objective of the program. In order to do so, covered entities must establish a mechanism for medication procurement. How a covered entity purchases 340B medications depends on how the organization is structured. Some health departments and viral hepatitis programs have in-house pharmacies or pharmacy licenses, which allows purchasing medications directly from a wholesaler. Other health departments and viral hepatitis programs use contract pharmacies. Regardless of medication procurement method, this step should be accounted for in program planning, as both methods require administrative effort and a significant amount of time. In accordance with 340B statute, the required 340B discount is either 13% (generic) or 23.1% (brand-name) from Average Manufacturer Price (AMP). Additional discounts are also required if the drug manufacturer has chosen to increase the medication's price or offer a lower price to other purchasers.

Wholesaler

A wholesaler provides 340B priced medications to covered entities that have signed a wholesale account agreement and set up an account. Wholesalers require a covered entity's registration to first be approved by HRSA and for a 340B ID to be issued prior to setting up 340B accounts. Wholesalers' 340B price may be higher than the 340B ceiling price because it includes a wholesaler fee. When searching for a 340B wholesaler, it is important to note that many state agencies have approved vendor lists and purchasing rules and regulations that viral hepatitis program administrators should be familiar with. For reference, the main 340B pharmaceutical wholesalers in the United States are AmerisourceBergen, McKesson, and Cardinal Health.

Contract Pharmacy

Contract pharmacies serve as an extension of the 340B Program covered entity and provide patients access to prescription medications. It is important to note that covered entities are responsible for ensuring compliance of their contract pharmacy arrangement(s) with all 340B program requirements. While contract pharmacies eliminate the costs of operating an in-house pharmacy, they do charge dispensing fees. Viral hepatitis programs should discuss and negotiate dispensing fees with contract pharmacies before entering into an agreement. It is important to note that dispensing fees can be quite significant, particularly when the fee is a percentage of the gross payment received or savings generated.

Additionally, there may also be a third-party administrator, or pharmacy benefits manager involved in this medication procurement model. Other items to consider when reviewing contract pharmacies include inventory model, procedures for patient eligibility determination, tracking system, reconciliation and record keeping, as well as diversion and duplicate discount prevention. OPA may request a copy of the contract pharmacy service agreement be provided. For reference, the largest 340B Program contract pharmacies are Walgreens, CVS, Walmart, and Accredo.

340B HEALTH EQUITY CONCEPT

- Contract pharmacy location, care models, and [structural competency](#) need to be considered when identifying and establishing a contract pharmacy relationship. Will patient populations have equity in access to medications? Contract pharmacies need to be aligned with the needs of the viral hepatitis patient population.

Generating Revenue

The 340B Program allows covered entities to generate revenue if they are serving privately insured patients. This is done by dispensing a 340B Program priced medication and billing insurance for the medication. The insurance then pays the retail or negotiated health plan price allowing the covered entity to generate revenue. All savings and revenue generated from the 340B Program belong to the covered entity, not the contract pharmacy. Grantees and subgrantees are required to use all 340B Program revenue and savings for activities that promote the purpose of their qualifying funding/federal grant. For viral hepatitis programs this may include expanding hepatitis screening, improving the quality of services, purchasing a mobile unit to expand services and reach, purchasing equipment and software to participate in Project ECHO, investing in a health communications or outreach campaign, or other activities that support the goals of the viral hepatitis program.

340B HEALTH EQUITY CONCEPT

- Be intentional when allocating 340B revenue and savings to program operations. Extra resources afforded by the 340B Program provide a unique opportunity to think outside of existing structures of racism and other forms of oppression. Require covered entities to implement antiracist frameworks, policies and procedures to advance racial equity and access to viral hepatitis services. Covered entities need to center health equity in their visions and missions and have explicit activities on how they are advancing health equity in their strategic plans. Ensure providers provide evidence-based and non-stigmatizing and non-discriminatory care and treatment and are [structurally competent](#).

Health Department Roles and Responsibilities

Section 318 funds are typically granted to state health departments and several directly funded local health departments (grantees). State health departments and directly funded jurisdictions may be 340B Program covered entities, but they may also contract or grant funds or in-kind contributions to other organizations (subgrantees), resulting in 340B Program eligibility for all organizations that receive Section 318 funds. Health department roles may also vary depending on the public health governance structure across the states with distinct differences in [centralized](#) and [de-centralized systems](#). In general, the following are *appropriate roles* for viral hepatitis programs and health departments:

- Ensure leadership, program staff, and subgrantees know about the 340B Program
- Provide guidance regarding what is considered a service within the scope of each CDC NOFO
- Provide guidance on how subgrantees should meet the patient definition
- Review subgrantee 340B Program policies and procedures
- Set clear expectations regarding 340B Program oversight and compliance
- Be familiar with how the subgrantee will be purchasing medications
- Update contracts and agreements to account for 340B Program considerations and revenue
- Be aware of registration and recertification periods and ensure subgrantees have the grant number and NOFO number they need

- Confirm subgrantee status when requested by HRSA OPA
- Notify HRSA OPA if a subgrantee is no longer receiving funding or in-kind support

Health departments are not required by HRSA or CDC to provide 340B compliance oversight over Section 318 subgrantees' management of the 340B Program, however it is recommended that health departments provide guidance to subgrantees regarding 340B in their contracts with subgrantees, including eligibility considerations, and the use of 340B Program revenue. Ultimately, all covered entities are responsible for their own 340B compliance; every 340B Program must attest to compliance and may be audited by HRSA OPA at any time. Viral hepatitis programs and health departments should not enroll subgrantees into the 340B Program, serve as subgrantee's authorizing officials or primary contacts, attest to another agency's compliance, or create policies or procedures for subgrantees.

340B HEALTH EQUITY CONCEPT

- 340B Program revenue needs to be reinvested back into viral hepatitis programs. As the social determinants of health are linked to viral hepatitis outcomes, programs need to consider designing services and activities that address the social determinants of health and ensure parity of viral hepatitis care across the state or jurisdiction. For many programs this would include utilizing 340B Program savings/income to provide supportive social services including the provision of food support, hygiene items, and transportation assistance.

Compliance Elements

As a covered entity, viral hepatitis program should maintain comprehensive, written 340B policies and procedures. These should contain program requirements, methodologies for routine self-auditing and internal corrective action. They should also maintain contract pharmacy agreements, wholesaler account agreements, and their 340B OPAIS record. The prevention of medication diversion is also a primary compliance element and covered entities are responsible to ensure that 340B Program medications are not dispensed to non-340B Program eligible patients and that 340B Program medications are not resold or transferred. Covered entities also must ensure the prevention of duplicate discounts. A duplicate discount can occur when a discount is provided to the covered entity and a rebate is also paid to the state under the Medicaid drug rebate program. Duplicate discounts may also occur if the 340B covered entity is providing care to a client living with HIV receiving insurance premium and cost-sharing assistance from the state AIDS Drug Assistance Program (ADAP), which may be claiming 340B rebates from manufacturers. Viral hepatitis and Section 318 grantees may want to establish right-of-way policies and procedures with their state's ADAP and ensure that these are communicated with subgrantees). You can review HRSA's program integrity guiding principles to maximize oversight and manage compliance risk here: <https://www.hrsa.gov/opa/program-integrity/index.html>

Additional Considerations for Viral Hepatitis Programs

Once the patient definition is met, the 340B Program can be utilized for any outpatient prescription medication that is warranted by the visit or is clinically indicated. It is important to note that vaccines are not covered, nor are inpatient medications. Additionally, the grant funds that authorized access to the 340B Program do not have to be used. In fact, some grant funds are prohibited from being utilized to purchase medications. Viral hepatitis programs are advised to be aware of limits on the use of grant funding.

Summary

Every grantee and subgrantee who receives Section 318 funding from CDC is eligible for the 340B Program. This valuable program can be utilized by viral hepatitis programs and their subgrantees to access deeply discounted medications, providing treatment and care to additional patient populations, and improving and expanding services. While initially complex and daunting, the 340B Program can have a significant impact on public health programs due to program savings and revenue potential. Viral hepatitis programs and administrators are uniquely positioned to support and encourage health equity activities among covered entities and the 340B Program should be leveraged to pursue health equity. Viral hepatitis programs should critically and strategically think of uses for 340B savings/revenue and always keep the social determinants of health in mind.

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Resources

Apexus Answers: Provides both phone, email, and live chat support to qualifying programs, partners, and covered entities regarding the 340B Drug Pricing Program or the PVP. <https://www.340bpvp.com/apexus-answers>

HRSA 340B Drug Pricing Program: As the federal administrators of the 340B program, HRSA OPA outlines 340B program requirements, regulations, resources, and provides program updates. <https://www.hrsa.gov/opa/index.html>

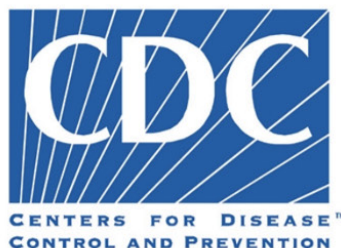
NASTAD/NCSD: Update on 340B Eligibility for Programs Authorized Under Section 318 of the US Public Health Service Act: A memo outlining viral hepatitis and HIV program eligibility as well as provides registration information, meeting the patient definition, avoiding duplicate discounts, and the use of program savings. https://www.nastad.org/sites/default/files/Uploads/2021/nastad_ncsd_memo_sec_318_program_eligibility_for_340b.pdf

Office of Pharmacy Affairs Information System: The 340B registration and pricing database. While covered entity information is viewable by the public, authorized users must have a user account with appropriate roles and permissions granted by HRSA. <https://www.hrsa.gov/opa/340b-opais/index.html>

Public Health Service act links for the Resources Section: All 536 pages of the public health service act, including Section 318: <https://www.govinfo.gov/content/pkg/COMPS-8773/pdf/COMPS-8773.pdf> 340B section of the PHS: <https://www.hrsa.gov/sites/default/files/opa/programrequirements/phsactsection340b.pdf>

The 340B Prime Vendor Program (PVP): Managed by Apexus and responsible for supporting the 340B Program. Contains valuable resources including FAQs, self-auditing and compliance tools, policy and procedures, and other resources. <https://www.340bpvp.com/>

Appendix A: Finding your NOFO and Section 318 Eligibility Image Guide



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

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.

The statutory language under Section 318 of the PHS Act (42 U.S.C. Sections 247c) provides CDC with the opportunity to provide project grants to the States and, in consultation with the State Health Authority, political subdivisions for,

1. Sexually transmitted diseases surveillance activities, including the reporting, screening, and follow-up of diagnostic tests for, and diagnosed cases of, sexually transmitted diseases;
2. Case finding and case follow-up activities regarding sexually transmitted diseases, including contact tracing of infectious case of sexually transmitted diseases and routine testing, including laboratory tests and follow-up systems;
3. Interstate epidemiologic referral and follow-up activities regarding sexually transmitted diseases; and,
4. Special studies or demonstrations to evaluate or test sexually transmitted disease prevention and control strategies and activities as may be prescribed by the Secretary.

As such this statutory language applies to viral hepatitis given the hepatitis B virus is transmitted when blood, semen, or another body fluid from a person infected with the virus enters the body of someone who is not infected. Although infrequent, hepatitis C can also be spread through sex with an HCV infected person.

D. Agency Notice of Funding Opportunity Number:

CDC-RFA-PS21-2103

E. Assistance Listings (CFDA) Number:

93.270

