



Office of Public Health (OPH)

STD/HIV/Hepatitis Program (SHHP)

# **340B Partner Manual**

for HIV/STI Testing and Treatment Contracts  
in Health Care Settings

Version 1.0

March 2026

*This manual is intended to be used as both an onboarding and reference guide as your clinic or agency moves forward with providing HIV/STI testing and treatment services and participating in the 340B program as a Section 318 of the Public Health Services Act covered entity through a contractual partnership with the Louisiana Department of Health (LDH), Office of Public Health (OPH), STI/HIV/Hepatitis Program (SHHP).*

## **Section 1. Partners Seeking to Become 340B Covered Entities Through Their Contract with SHHP**

### **I. Definitions**

340B Pharmaceutical Program – A federal program operated by HRSA and OPA that allows covered entities to purchase prescription medications at significantly discounted costs.

Covered Entity – A health care provider or organization (partner) that's eligible for the 340B Program per the 340B statute.

340B Covered Entity – A facility or program that is listed in the 340B statute as eligible to purchase drugs through the 340B Program.

HRSA – Health Resources and Services Administration

OPA – Office of Pharmacy Affairs

Program Income – Revenue generated when a covered entity purchases a discount medication through the 340B Program and then bills the patient’s public or private insurance the market, customary, or negotiated network price for that medication.

Priority Populations – Groups of people that represent a significantly greater proportion of new STI, HIV, and/or HCV diagnoses than their proportion of the total population. Priority populations can be defined singularly or by a combination of factors, such as socioeconomic status, living in high-incidence or prevalence geographic areas, engaging in high-transmission risk behaviors, and belonging to disproportionately impacted sex/gender, racial, or ethnic groups. Priority populations for STI, HIV, and HCV prevention and linkage to treatment services are groups with historically high incidence or prevalence, including Louisiana Medicaid participants, Black and Latino people, and gay and bisexual men, transgender individuals, and people who use injection drugs of all races/ethnicities.

## **II. Entering into a STI/HIV/Hepatitis Screening and Treatment Contract with LDH OPH SHHP:**

The LDH OPH SHHP partners with medical providers/clinics that have access to priority populations in Louisiana who are living with diagnosed HIV, STIs, or HCV and those at increased risk of acquiring HIV, STIs, or HCV. The following procedures are followed to establish such partnerships:

- Potential covered entities (partners) contact SHHP’s 340B Program ([SHHP340B@la.gov](mailto:SHHP340B@la.gov)) to discuss their interest and ability to enter into a testing Contract to advance the state and federal STI, HIV, and Hepatitis goals.
- Within one week following a new partner expressing interest in becoming a SHHP 340B Contractor, the SHHP Testing Supervisor emails information regarding the minimum eligibility, contract requirements, and expected deliverables. If requested, the Testing Supervisor schedules a meeting with the prospective partner to review

the requirements and answer any questions.

- Potential Contractors will provide services consistent with the purpose of Section 318 grants as described in the relevant CDC Notice of Award to LDH OPH SHHP and the statement of work (SOW) of their contract, and will receive contributions paid for by Section 318 funds in the form of fee-for-service reimbursement for patients screened for HIV, HCV, *and* syphilis. Contracts may facilitate the Contractor's participation in the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) 340B Pharmaceutical Discount Program (340B Program). **All potential contractors must meet the following minimum eligibility criteria to be considered for a SHHP 340B Contract:**
  - Must demonstrate knowledge of and ability to comply with all HRSA 340B Program policies and regulations. The potential Contractor shall designate a 340B Compliance Manager who has authority and oversight over all services and 340B-related functions/requirements associated with the potential 340B Contract. The potential Contractor's designated 340B Compliance Manager must complete the four-hour 340B University Core Curriculum training (at minimum) provided by the Prime Vendor Program and attach copies of their completion statements with the completed 340B Contract Interest Form. Additional information about the 340B University Training can be found here: <https://www.340bpvp.com/340b-university/online-learning#ondemand> .
  - Must be willing to provide routine opt-out HIV, Syphilis, *and* HCV screening to all patients served (a minimum of 85% of all patients seen at the clinic every 6 months should receive the HIV, Syphilis, *and* HCV screening panel).
  - Must be willing to provide laboratory-based confirmatory testing for all patients with positive/reactive HIV, Syphilis, and/or HCV screening results.
  - Must be willing to provide Syphilis treatment to all patients with positive/reactive syphilis results on the same day of the positive screening results whenever possible, and within no more than 7 days when same-day

- treatment is not possible.
- Must be willing to provide in-house treatment for all patients who have confirmed HIV or HCV diagnoses or provide a detailed plan (including referral MOUs, etc., as applicable) for how those patients will be linked to and initiate treatment within 7 days of their HIV or HCV diagnosis.
  - Must be able to accurately collect and timely report on all data metrics as specified in the Contract and the SHHP 340B Partner Manual.
  - Must be enrolled as a network provider with all Medicaid MCOs.
  - Must ensure at least 45% of total patients served annually are uninsured and Medicaid-covered patients.
  - Must meet at least one of the following location-related criteria:
    - The clinic(s) must be located in a zip code within the applicable LDH public health region where the top 60% of new HIV, syphilis, and/or HCV diagnoses occurred during the last calendar year for which complete data are available. SHHP maintains and distributes the priority zip code list on an annual basis (go to <https://louisianahealthhub.org/340b-partners> for the most current priority zip code list).
    - The clinic(s) must provide primary or specialty medical services for which there is a shortage of these services for Medicaid participants in the service area. Medicaid will provide an annual list of primary and specialty medical service shortage areas.
  - **SHHP maintains quarterly 340B contract partner application periods each year as follows (see Appendix I – 340B Partner Calendar<sup>i</sup>):**
    - March 1 – 30, for contracts that will begin January 1<sup>st</sup>
    - June 1-30, for contract that will begin April 1<sup>st</sup>
    - September 1 – 30, for contracts that will begin July 1<sup>st</sup>
    - December 1 – 30, for contracts that will begin October 1<sup>st</sup>

- Potential partner submits a completed **340B Contract Interest Form (Appendix II<sup>ii</sup>)** during one of the application periods stated above.
- SHHP will also request a brief proposal that includes the types of HIV, STI, and Hepatitis services the potential partner intends to provide, to include a linkage to care plan, and a detailed description of their existing patient demographics.
- The SHHP Statewide Testing Supervisor responds with confirmation to the submitter that their completed form has been received, along with details of anticipated processing times (up to four weeks).
- The Testing Supervisor evaluates all potential Contractors for meeting the prerequisites and requirements described herein within four weeks of receipt of the completed Contract Interest Form. The primary goals that these partnerships should advance include, but are not limited to, the following:
  - Increase STI screening, treatment, management, and care among all people, particularly priority populations; and
  - Expand Medicaid participants' access to primary and specialty medical services.
- When advancing a partnership is appropriate, SHHP prepares a testing Contract, to be reviewed and signed by all parties (**see Appendix III – 340B FFS Contract SOW Template<sup>iii</sup>**).
- Once all parties sign the agreement, SHHP instructs the partner on how to register to become a covered entity to participate in the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) 340B program.

### **III. HRSA OPA Registration Process for New Covered Entities:**

- HRSA requires registration (by providers) and approval (by state grantees/authorizing officials) for covered entities to participate in the 340B Program.

- HRSA limits the registration period for 340B Program registration of new covered entities and the addition of outpatient facilities to the following:
  - **January 1-January 15 for an effective start date of April 1**
  - **April 1-April 15 for an effective start date of July 1**
  - **July 1-July 15 for an effective start date of October 1**
  - **October 1-October 15 for an effective start date of January 1**

If the 15th falls on a Saturday, Sunday, or federal holiday, the deadline will be the next business day. Covered entities cannot submit registrations outside the dates above except when the HHS Secretary (federal level) declares a Public Health Emergency.

- Covered Entities must register for a 340B Office of Pharmacy Affairs (340B OPAIS) user account here: [340B OPAIS site](#).
  - The new covered entity must register all contract pharmacies at initial registration. The entity may register contract pharmacies only after having a written contract with a contract pharmacy before the registration period. (NOTE: The written contract pharmacy contract must match precisely the contract pharmacy name and address registered in OPAIS.)
  - The covered entity must provide a qualifying federal grant number and a copy of the Notice of Award when registering for the 340B Program. SHHP will provide this to new covered entities in time for registration.
  - After the covered entity completes its registration, HRSA verifies its eligibility by sending an email to the appropriate OPH Project Director (PD) or Program Manager (PM) to confirm the entity receives eligible grant funding for the applicable grantee types (e.g., Ryan White, STD/318, Hepatitis, etc.)
  - The PD/PM has five business days to confirm the entity receives eligible grant funding or in-kind resources supported by the eligible award. If they don't respond to the email by the deadline, HRSA rejects the registration(s).
  - Once approved, the designated contacts receive an email confirming successful

enrollment in the 340B Program. This email includes the date on which the covered entity may begin purchasing 340B drugs and the covered entity's 340B identification number.

- The 340B identification number is the covered entity's unique number that manufacturers, wholesalers, and others use to verify their legitimate participation in the 340B Program.

#### IV. **Implementing New 340B Testing Contracts**

- Within one month of a new 340B contract being fully executed (signed by all parties), the Statewide Testing Coordinator initiates the next steps for getting a new Partner established, including:
  - Facilitating warm handoffs to the SHHP Regional Coordinators to schedule site visits and get all Contractor testing locations registered within the state data systems.
  - Connecting with the SHHP Capacity Building Team for training on routine screening procedures, treating or linkage to treatment for positive test results, and data reporting and monitoring procedures (**see Appendix IV – Quality Assurance Protocol for Routine HIV, Syphilis, and HCV Screening and Linkage to Care for Health care Settings<sup>iv</sup>**).
  - Establishing access to secure electronic data reporting systems (for those reporting electronically).

#### V. **Annual Recertification for Existing Partners/Covered Entities:**

- 340B covered entities must annually recertify their eligibility to remain in the 340B Drug Pricing Program and continue purchasing covered outpatient drugs at discounted 340B prices (February 1-15th).
- HRSA sends advance email notifications with preliminary information about the recertification process before the recertification period.

- Once the recertification period begins, the Authorizing Official and Primary Contact must log into the 340B OPAIS and update all information. The Authorizing Official must attest to the covered entity's compliance with all 340B Program requirements and submit the attestation to the Office of Pharmacy Affairs.
- SHHP, in concert with HRSA OPA, may terminate a testing Contract and not recertify a covered entity unwilling or unable to achieve and maintain compliance with applicable agreements and regulations.

SHHP's partnerships with covered entities across the State maximize the reach and impact of the federal STI, HIV, and Hepatitis grants it manages. Covered entities benefit from the cost savings and program income generated from participating in the 340B program, which enables them to support outreach and patient navigation programs that are not well supported by other mechanisms. SHHP currently has the capacity to work with additional providers/clinics that can provide STI, HIV, and/or Hepatitis C-related prevention and treatment services to priority populations in Louisiana.

## **Section 2. Partnership Maintenance Requirements (to remain in compliance as a SHHP 340B Partner) - A Checklist**

- Maintain an active testing Contract as an Official SHHP Partner
  - If testing Contract has expired and SHHP staff has not yet reached out about renewing the agreement:
    - Contact Statewide Testing Coordinator to initiate renewal process
  - Review drafted testing Contract received from Statewide Testing Coordinator
- Ensure that a Linkage to Care and Treatment Plan is maintained, as relevant, and provided to Regional Prevention Coordinator (RC) as it is updated. This plan should mention external agencies being partnered with, that will provide these services.
- Site Registration(s) and **Site ID** assignments received and maintained for *every*

site/location where rapid testing is provided. This number, along with your **Agency ID** is very important and needs to be easily accessible by staff involved with testing.

Report *all* testing data to SHHP:

- Send in individual-level data on a weekly basis via SHHP's secure electronic data transfer system, along with Linkage into Care and Treatment (LINCT) forms (see **QA Protocol for Forms**)

**OR** Send in data on a weekly basis for those sites that strictly use paper forms\*

**\*Paper Forms include both Part-1 and Linkage into Care and Treatment (LINCT) Forms**

**\*Refer to QA protocol for proper paperwork instructions especially for positive/reactive tests**

- Review quarterly testing, LTC and treatment data reports received from SHHP. Provide feedback and information requested by SHHP to resolve any observed gaps and to help improve SHHP's systems.

Maintain detailed records and report all 340b pharmaceutical purchases and program income data to SHHP:

- Provide a quarterly report listing each patient for which 340B medications were purchased including but not limited to the following elements: the name and date of birth of each patient; the name, NDC, invoice number and invoice date of each medication purchased through the 340B Program for each patient; and the amount of program income generated from each 340B purchased medication for each patient;
- Provide a quarterly accounting report detailing how all 340B-related savings and revenues were spent or planned to be spent by the Contractor during the reporting period specified by LDH OPH SHHP. SHHP may request additional supporting documentation related to this report at any time.

## **SHHP's Partner Monitoring Protocol**

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Contractors' testing, treatment, and 340B data will be reviewed by SHHP on a quarterly basis. In-person site visits or virtual audits may also be completed to provide technical assistance and feedback for quality assurance. More frequent and recurring monitoring practices may be implemented as needed in order to improve performance and uphold partnership obligations as outlined in partner testing Contracts.

A quarterly Partner Performance Monitoring Report will be provided according to the terms of the executed Contract to ensure compliance/alignment with the applicable federal grants and the 340B program and will evaluate progress toward the following performance requirements:

- Whether or not testing is being conducted on a routine opt-out basis (ensuring at least 85% of the total patients served receive the HIV, Syphilis, and HCV screening panel)
- The combined proportion of Medicaid and uninsured patients served (at least 45% of patients served at a minimum)
- Timely submission of testing paperwork/data to SHHP
- Adherence to QA Protocols for HIV, HCV, and Syphilis Testing and Linkage to Care for Health care Settings
- Ability to reach priority populations (sites should achieve and maintain a combined new STI diagnosis rate of at least 2%)
- Successful linkage to care and treatment (at least 90% of patients diagnosed with HIV, HCV, and syphilis should be provided/initiated treatment immediately on site or linked to treatment within 7 days when immediate treatment is not possible)
- Appropriate reporting and utilization of 340B-generated program income as specified in the Contract (**also see Appendix VII – SHHP 340B Reporting Template**).

SHHP to place Contractors on a Corrective Technical Assistance Plan (CTAP) when they are found to be out of compliance with the reporting or performance expectations as outlined in their Contract, the Partner Manual, and/or the Quality Assurance Protocol for STI Screening in Health care Settings. An agency placed on CTAP will receive a written notice of specific areas of programmatic and/or administrative weakness, in addition to technical assistance and support with specific recommendations outlining steps to improve areas cited. Follow-up technical assistance site visits will be conducted in order to assess the agency's ability to resolve deficiencies. Failure to improve on measures as outlined in CTAPs may result in partnerships being terminated.

## **List of Appendices**

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**i - 340B Partner Calendar**

**ii - 340B Partnership Interest Form**

**iii - 340B FFS Contract SOW Template**

**iv - Quality Assurance Protocol for Routine HIV, Syphilis, and HCV Screening and Linkage to Care for Health Care Settings**

**v - SHHP 340B Reporting Template**