



Case Study: How the 340B Drug Pricing Program Helped a Local Sexual Health Clinic Expand HIV Prevention Services

Opportunity

Since 2011, a community-based organization located in a large urban city in the Southern US has provided sexual health services, including community-based outreach and linkage to HIV-medical care, to more than 1,500 individuals each year. The organization's sexual health clinic offers HIV and STD screening, diagnosis, treatment, and referrals to clients who otherwise have limited access to healthcare. Despite high interest among clients, staffing and clinic capacity prevented the organization from offering direct PrEP services.

Through its strategic planning process, the Sexual Health Clinic (SHC) concluded it would expand its current clinical services to include screening and provision of HIV prevention medications including pre-exposure prophylaxis (PrEP) and non-occupational post-exposure prophylaxis (nPEP), thereby providing a more comprehensive continuum of care in HIV prevention and treatment. To proceed with this endeavor, the organization would seek to participate in the 340B Drug Pricing Program--which increases access for low-income and uninsured/underinsured populations by making prescription drugs more affordable--enabling the sexual health clinic to expand its resources to improve public health outcomes.

Approach

Steering Committee: To implement the 340B Program, the SHC formed a steering committee that would conduct an assessment to examine current pharmacy operation practices and identify costs and resources required for 340B Program implementation. The 340B Steering Committee consisted of the Sexual Health Clinic Manager, Director of Operations, Director of Finance and Compliance, and Legal Counsel.

340B Steering Committee Objectives:

1. Determine **strategy** and assess related **policies and procedures**
2. Establish an **audit structure** for internal and external audits
3. Develop standards for **best practices**
4. Maintain 340B **standards** per HRSA, OPA, and Apexus
5. Ensure **compliance** and provide related oversight
6. Ensure needed **resources** for program administration
7. Assess **expansion or optimization** of the 340B program
8. Correct and/or report **deficiencies** within expected timeframes
9. Verify **maintenance of records** and transactions

Implementation Plan and 340B Pharmacy Model: The 340B Steering Committee concluded the SHC's current experience in pharmacy operations was somewhat limited. Since 2014 the sexual health clinic had received 340B STD medications through the State Health Department's Pharmacy Division. Medications were shipped to the clinic to be administered on-site from a Class D Pharmacy. The SHC maintained a license for the Class D Pharmacy and complied with the state's policies and procedures, maintained drug inventory, and participated in program audits led by the State Health Department's Pharmacy Division and State Pharmacy Board.

After completion of the organizational assessment, the 340B Steering Committee set forth a plan to operationalize the 340B Program and create a Pharmacy Access Program for SHC patients seeking PrEP and/or nPEP services. With technical assistance from the Apexus, HRSA's 340B Prime Vendor Program, the SHC created its policies and procedures to establish the scope of STD 340B services, define patient eligibility, and establish prescribing practices for PrEP and nPEP. The 340B Steering Committee's decision was to "carve-out" for Medicaid, which meant it would not use 340B discounted drugs for Medicaid patients. The SHC coordinated its eligibility status for the 340B Program with the State Health Department and would complete registration in the Office of Pharmacy Affairs Information System (OPAIS) as a Covered Entity (CE) receiving in-kind support (i.e. STD medications) paid for by Section 318 funds. The SHC's Executive Director was designated as the Authorizing Official and the Sexual Health Clinic Manager as Primary Contact.

In selecting its pharmacy services for the new Pharmacy Access Program, the 340B Steering Committee established criteria to assess which model would best fit the needs of the patients and the organization. Essential elements of pharmacy operations and oversight included the pharmacy entity's ability to comply with HRSA requirements, provide convenient hours and services to patients, and minimize financial risk.

Table 1: Comparison of In-House and Contract Pharmacy Services

| | In-House Pharmacy | Contracted Pharmacy |
|---------------------------------------|--|--|
| General Description/ Overview: | Covered Entity owns drugs, pharmacy, and pharmacy license | Covered Entity owns drugs and maintains Pharmacy Services Agreement (PSA) with contracted pharmacy entities |
| Drug Inventory and Dispensing: | Covered Entity purchases and receives drugs directly through wholesaler and maintains a physical inventory | Drugs are purchased on behalf of the CE and are usually sent from drug wholesaler directly to pharmacy for dispensing under ship-to/bill-to arrangements Many require the use of a replenishment model or “virtual” inventory and a third-party administrator (TPA) to manage the inventory |
| Staff Resources: | Pays pharmacy staff Pharmacist can manage medication use in the entity and provide education and resources for patients and providers | Signs a contract with pharmacy to provide pharmacy services Entity does not hire pharmacy staff, but still has access to their clinical knowledge |
| Billing and associated fees: | Assumes fiscal responsibility for pharmacy Covered Entity directly bills third-party insurances | Third-party billing/contracts already in place Covered Entity pays dispensing fees to contracted pharmacy or arranges for patients to pay dispensing fees |
| 340B Revenue: | Covered Entity retains full 340B revenue or “spread” (the difference between third-party reimbursement and the discounted 340B purchase price) | Contract pharmacy takes a percentage (e.g., 15 - 30%) of the gross 340B revenue or “spread” (the difference between third party reimbursement and the discounted 340B purchase price) |

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|------------------------|--|--|
| <p>Summary:</p> | <ul style="list-style-type: none"> - Enables the greatest degree of control, but is the most expensive start-up option - Lengthy startup time to acquire pharmacy license and hire/train staff - Requires physical space of pharmacy and drug inventory - May offer convenience for patients to directly fill on-site, but “In-house” capture rate is critical | <ul style="list-style-type: none"> - No startup costs - Organization's pharmacy expertise is not required - Expanded formulary - May offer convenient access points and extended hours for patients - Positive selection and higher third-party capture - Use of specialty or retail pharmacies may be restricted by some commercial insurance plans |
|------------------------|--|--|

Taking into consideration the start-up costs and staffing requirements, the 340B Steering Committee concluded that a contract pharmacy model would best fit the needs of the SHC and began the procurement process to solicit bids from contract pharmacy entities.

Compliance and Oversight: To ensure the integrity of 340B Program participation, the 340B Steering Committee worked closely with Apexus tools to develop an audit structure for compliance and related oversight. Roles and responsibilities of 340B Program staff were identified to ensure needed resources for program administration and the 340B Steering Committee would continue to meet regularly after the program launch to maintain 340B Program standards per HRSA, OPA, and Apexus.



Table 2: 340B Compliance Roles and Responsibilities

| 340B Activity Review Tool/Program Requirement | Impacted Program(s) or Person(s) | Operations Responsibility | Compliance Monitoring |
|--|--|--|--|
| <p>OPAIS Website Enrollment review</p> | <p>Primary Contact and Authorizing Official</p> <p>State Health Department 340B official</p> | <p><i>Quarterly</i> - confirm presence of all covered entities and accuracy of information; verify contact information including phone and email, and ship-to/bill-to information</p> | <p><i>Quarterly</i> - request of information for review</p> |
| <p>Patient and Provider Eligibility Review</p> | <p>Sexual Health Clinic Manager</p> <p>Contract Pharmacies</p> | <p><i>Monthly</i> - review 10% of randomized prescriptions. Review will consist of verifying patient eligibility and provider eligibility. Any variance are corrected and documented on 340B Audit Report</p> <p><i>Quarterly</i> - review eligible providers/prescriber, including their name, National Provider Identifier (NPI) numbers, and evidence demonstrating whether the individual is employed by or under contract with the covered entity</p> | <p><i>Monthly</i> - receive applicable report on corrected variances</p> <p><i>Quarterly or Annually</i> - audit/validate sample audit</p> |
| <p>Maintain inventory-- compare replenishment for purchases for contract pharmacies with accumulated dispenses</p> | <p>Sexual Health Clinic Manager</p> <p>Contract Pharmacies/TPA</p> | <p>Monthly - review 10 drug purchases from each contract pharmacy to ensure 340B replenished medications are tracked back to eligible patient dispensaries. Any variance are corrected and documented on 340B Inventory Report</p> | <p><i>Monthly</i> - receive applicable report on corrected variances</p> <p><i>Quarterly or Annually</i> - audit/validate sample audit</p> |

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|-----------------------------------|---|--|---|
| Education and Training | All employees with designated 340B duties | <i>Annually</i> - Develop consistent policies and procedures for training new employees and continuous learning for current employees on 340B Program requirements/changes and maintaining documentation | <i>Annually</i> - validate policy and procedures and monitor training/education |
| Recertification of Covered Entity | Primary Contact and Authorizing Official State Health Department 340B Official | <i>Annually</i> - file required documentation for recertifications and 340B IDs | <i>Annually</i> - monitor recertification filings and approvals |
| Annual Independent Audit | Entire Covered Entity Contract Pharmacies | <i>Annually</i> - (unless HRSA conducts audit that year) - participate in external audit | <i>Annually</i> - request and participate in external audit as recommended by OPA |

Key Steps

October 2015

Formed 340B Steering Committee to conduct an organizational assessment and develop an implementation plan for the 340B Program and PrEP/nPEP clinical services.

January 2015

The SHC solicited proposals for 340B contract pharmacy services.

February 2016

Development of 340B policies and procedures.

March 2016

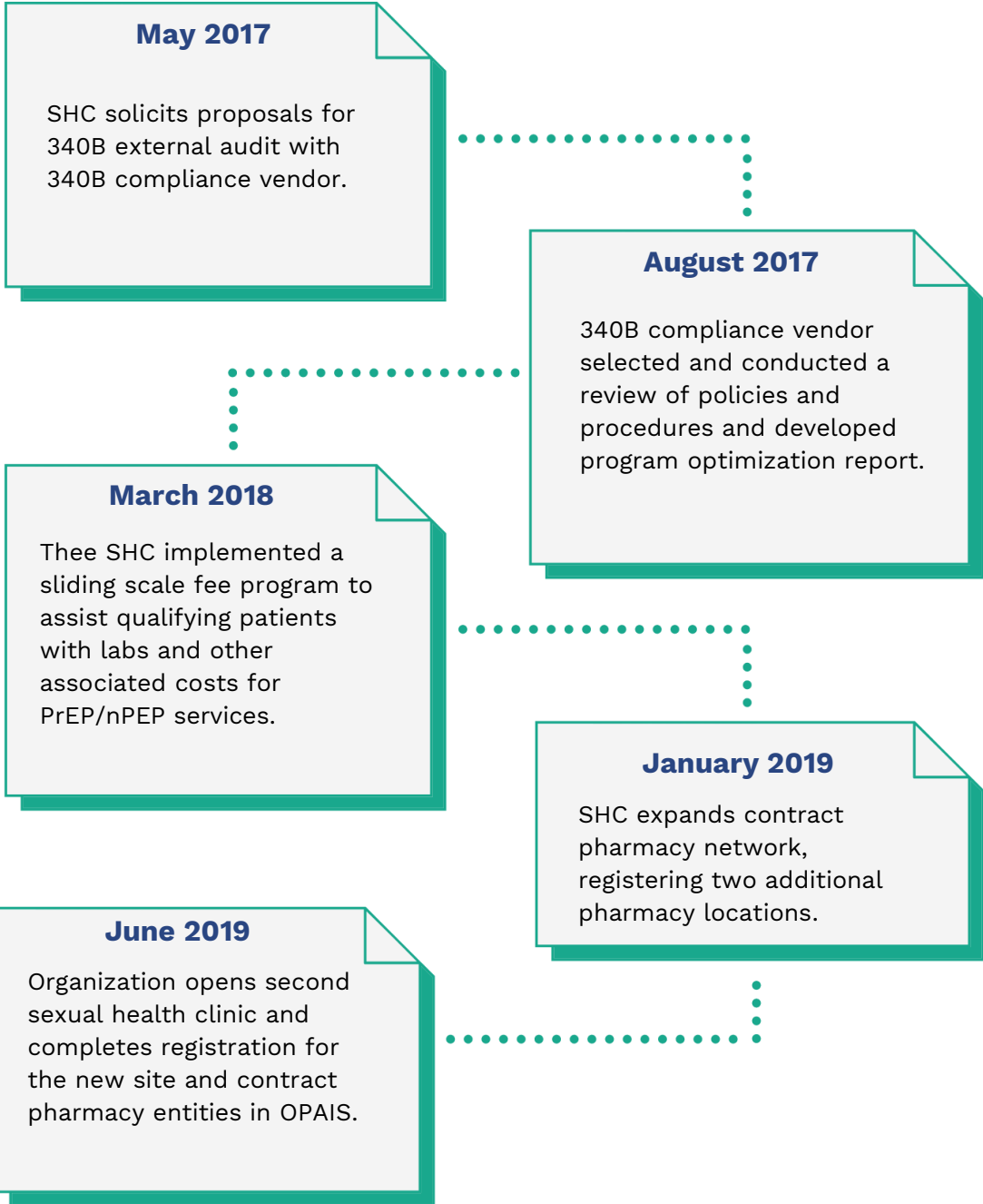
Pharmacy entity was selected from bids and the Pharmacy Services Agreement (PSA) was executed by all parties. Wholesaler Agreement and Third Party Administrator (TPA) contracts (required by contract pharmacy) were also executed.

April 2016

HRSA OPAIS open registration for Covered Entities. AO/PC registers all three contract pharmacy locations for the sexual health clinic.

July 2016

STD registration and contract pharmacies are approved and active. SHC started processing 340B claims.



Results

The contract pharmacy entity began working with the SHC in March of 2016 to assist with development of the Pharmacy Access Program. Program implementation included contract pharmacy services at three dispensing locations which offered mail-order and same-day prescription delivery. The contract pharmacy entity was also able to support the organization’s patient care programs and assisted with navigation services for co-pay and medication assistance programs, prior authorizations, and adherence support for patients.

Starting with 50 patients, the program has grown to include more than 1,250 patients who were prescribed PrEP and/or nPEP. 340B revenue was reinvested into the program to improve clinic infrastructure, expand hours, hire new program staff (e.g. Nurse Practitioners and PrEP Navigators), open a second sexual health clinic location, and initiate a process to begin third party billing for clinical services. Additionally, 340B revenue helped to increase patient engagement in STD prevention and sexual health services with an additional 12,100 people reached through the development of health promotion and marketing campaigns, outreach and mobile testing, and patient support services.

Figure 1: PrEP Program Enrollment

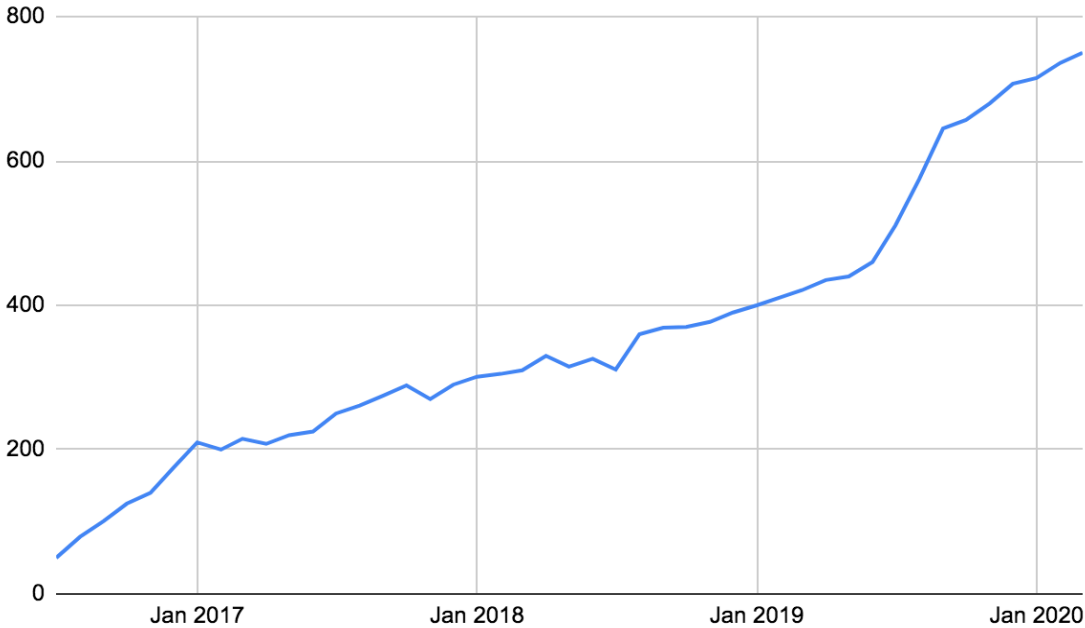
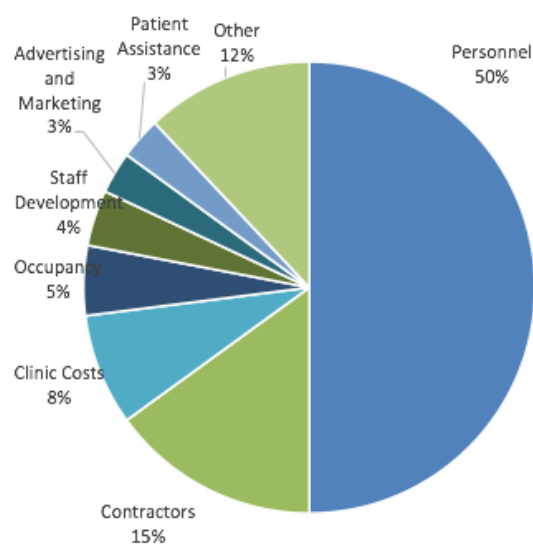


Figure 2: Use of 340B Program Revenue



Highlights and Lessons Learned

Audit Preparedness: One year after implementation of the Pharmacy Access Program, the organization solicited bids for a 340B compliance vendor to assess program compliance and conduct an external audit. The compliance vendor was able to identify areas of inaccuracy with self-auditing practices and assisted the organization with establishing a material breach threshold and process for responding to non-compliance and repayments to the manufacturer.

Pharmacy Expansion and Optimization: Ongoing support from the 340B pharmacy partners and Apexus provided the organization with the means to optimize their 340B Program. This included offering solutions for integrating EHR and electronic prescription data with pharmacy operations software which led to improving reporting and visualization of 340B program data. Additionally, the 340B compliance vendor helped the organization examine where prescriptions were filled and assisted with contract negotiations to expand the network of pharmacy services and increase 340B claims capture.

Flexible Use of Savings: To address barriers associated with PrEP and nPEP services, such as out-of-pocket costs for laboratory services and other medical needs, the organization used 340B revenue to establish a patient support program and sliding scale fees for qualifying patients. This patient support program helped to provide wrap-around services, such as substance use counseling and mental health support, that helped to improve patient engagement and retention in HIV prevention services.