



# Establishing On-Site Pharmacy Services in a Community Health Center: A Case Study

**MARCH 2012**

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# Acknowledgements

Callen-Lorde Community Health Center would like to acknowledge the support and assistance of two people critical to the success of this effort: Sarah Sheffield, Executive Director, NYC Rx, in the development of this report and our pharmacy program, and Angela Serio Harney, Executive Vice President of Operations, Maxor National Pharmacy Services Corporation, in the design, implementation, and ongoing operation of our on-site pharmacy.

Support for this work was provided by the New York State Health Foundation (NYSHealth). The mission of NYSHealth is to expand health insurance coverage, increase access to high-quality health care services, and improve public and community health. The views presented here are those of the authors and not necessarily those of the New York State Health Foundation or its directors, officers, and staff.



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# Executive Summary

**T**his report provides a case study of how one Federally Qualified Health Center (FQHC) in New York—the Callen-Lorde Community Health Center—established an on-site pharmacy to enhance its offering of comprehensive services. It discusses the opportunities contained in a Federal program, known as the 340B Drug Pricing Program, which allows health centers to offer deeply discounted medications to their patients. It describes the factors that other health centers should consider in deciding whether to establish an on-site pharmacy. Finally, the report provides an example of the sort of planning and financial projections that are required to succeed in bringing a concept to reality.

Each health center, including Callen-Lorde, has some unique attributes that will affect its pharmacy program choices. FQHCs considering this case study should carefully consider aspects of their own patient populations and payer mixes that will affect pharmacy programming decisions. With that caveat, Callen-Lorde's experience offers practical guidance for other entities considering establishing pharmacy programs.

# About Callen-Lorde

Callen-Lorde Community Health Center is a Federally Qualified Health Center (FQHC) in New York City. It is New York's only primary health care center dedicated to meeting the health care needs of the lesbian, gay, bisexual, and transgender (LGBT) communities and people living with HIV/AIDS—regardless of any patient's ability to pay. It serves all patients, especially local residents of its community, regardless of sexual orientation or insurance coverage

Callen-Lorde was founded in 1983. Then known as the Community Health Project (CHP), it was established as a result of the merger of the St. Mark's Community Clinic and The Gay Men's Health Project—two clinics from the late 1960s and early 1970s. Begun as a mostly volunteer-staffed program, Callen-Lorde remains the New York metropolitan area's only health center geared primarily to the LGBT community and those living with HIV/AIDS. Its services are vital to LGBT persons, who often face discrimination in the mainstream medical community and, as a result, do not receive adequate medical care.

Callen-Lorde is housed in a facility on the lower west side of Manhattan, an area which is a federally designated medically underserved area. The facility is a 27,000 square foot, Americans with Disabilities Act (ADA) compliant, fully licensed New York State Department of Health Article 28 Diagnostic and Treatment Center. Callen-Lorde achieved FQHC status in 2002 as a sub-recipient of the Lutheran Family Health Centers.

As an FQHC, it provides more than \$4.4 million of uncompensated care to uninsured patients each year. The patient profile and payer mix at Callen-Lorde differ from the average FQHC in New York State. More than 40% of its patients are uninsured, a proportion that is substantially higher than average. More than 25% of Callen-Lorde's patients are privately insured, which is also greater than average among FQHCs in New York. Simultaneously, Callen-Lorde serves fewer percentages of patients with Medicaid and other public insurance than many health centers, and it has a large number of patients (approximately 3,200 at the time of this report, or 21% of its total patient population) living with HIV. These statistics have significant bearing on the finances of a pharmacy program, as the medications used with HIV disease are expensive and are almost exclusively brand as opposed to generic, greatly impacting cost as well as reimbursement from third-party payers.

# Providing Low-Cost Pharmaceuticals: Basics of the Federal 340B Program

This section provides a basic overview of the Federal 340B Drug Pricing Program and key elements that will impact the decision-making of eligible providers in implementing a 340B pharmacy program. Additional information and resources about the 340B program can be found in Appendix C of this report.

The Federal 340B Drug Pricing Program provides a powerful resource in aiding safety net providers to expand uninsured, low-income, and other vulnerable populations' access to deeply discounted medications. The 340B program has cut drug costs for participants by as much as 50% in some instances. The amount of savings per health center depends on the volume and type of drugs that are purchased. The program also provides an opportunity for these providers to generate revenue to further discount medications or support other essential parts of their mission to the community.

The 340B program was created in 1992 to provide access to reduced price prescription drugs to health care facilities certified by the U.S. Department of Health and Human Services (HHS) as "covered entities." Such entities include health care providers such as FQHCs and safety net hospitals. The program's started purpose is "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." The program is administered by the Office of Pharmacy Affairs (OPA) of the Health Resources and Services Administration (HRSA) within HHS.

In practice, 340B-eligible entities purchase discounted medications from drug wholesalers and manufacturers that participate in the Medicaid Drug Rebate program. The 340B discount is roughly equivalent to the discount that manufacturers are required to provide to state Medicaid agencies.

HRSA has also established the Prime Vendor Program (PVP), which is able to negotiate even deeper discounts off of the 340B prices. The PVP, through its national group purchasing strength, can negotiate deeper discounts off of the ceiling price and also negotiates discounts for medical supplies and other non-340B eligible medications (e.g., vaccines).

340B designation is restricted to the scope of the Federal program in which the covered entity has funding or licensure. As an example, an outpatient medical facility may provide services to a broad array of patients but only qualify for 340B status for its family planning program. In such a case, the eligible entity may only purchase discounted medications related to family planning and dispense them only to eligible patients of that program. Some entities like FQHCs and

## Providing Low-Cost Pharmaceuticals: Basics of the Federal 340B Program *(continued)*

disproportionate share hospitals have such a broad federally mandated scope that essentially all registered patients are eligible for 340B medications.

The verification of patient eligibility for 340B prescriptions both in terms of the designation of the provider (as in the above example regarding family planning-related drugs and family planning-eligible patients) and insurance coverage status of the patient (Medicaid and related programs) is a critical requirement. Uninsured patients are the primary intended recipients of 340B discounted drugs. However, the Federal government does permit dispensing to patients covered under private insurance and Medicare Part D.

States differ in their approaches to allowing covered entities to use 340B discounted medications for Medicaid beneficiaries and other patients with government-sponsored prescription drug coverage. New York State has historically not encouraged most covered entities to use 340B drugs under its Medicaid program, choosing instead to use the Medicaid Rebate Program to take advantage of Federal discounts. States may not use duplicate discounts, such as combining a 340B discount and a Medicaid rebate.

In October 2011, however, New York Medicaid “carved in” pharmaceuticals for its managed care beneficiaries and now permits health plans to purchase 340B medications on behalf of Medicaid beneficiaries. Notably, 340B entities must still identify to Medicaid which dispenses are made from 340B inventory so that the State does not claim a rebate for those prescriptions.

# Getting Started with 340B: Using an Off-Site Retail Pharmacy

**E**ligible entities, after they have been approved by OPA and have entered into a purchasing arrangement with a wholesaler/manufacturer, may purchase discounted drugs and other covered pharmacy related products and supplies. However, a pharmacy license is required to dispense medications. Many 340B eligible entities, with the exception of disproportionate share hospitals, are not licensed pharmacies. In recognition of this licensing and capacity limitation, OPA has allowed entities to enter into contractual arrangements with retail pharmacies. Until March 2010, OPA required 340B eligible entities to have a single contractual relationship with a single retail pharmacy. However, in recognition of the limitations on patient access caused by the single pharmacy requirement, OPA now broadly approves multiple pharmacy arrangements.

Callen-Lorde implemented its 340B program with the local branch of a retail pharmacy chain in 2004. Initially, an arrangement with an off-site retail pharmacy made the most sense for numerous reasons. At that time, Callen-Lorde had little organizational capacity to secure a pharmacy license and manage an on-site pharmacy, which includes establishing purchasing arrangements; managing inventory; and contracting with pharmacy benefit managers, Medicaid, and other public payers. Moreover, the 340B program has significant requirements, including contracting with the Prime Vendor Program, managing relationships with wholesalers, and especially ensuring that 340B medications are not diverted to ineligible patients. Accordingly, a decision was made to seek out a contracted pharmacy arrangement, which would allow for appropriate program management as well as dispensing.

Callen-Lorde selected a local pharmacy that is part of a national pharmacy chain and was knowledgeable about 340B requirements. While many FQHCs use a third-party administrator to manage 340B programs with a contracted retail pharmacy, this pharmacy offered to provide program administration as well as dispensing and inventory maintenance to Callen-Lorde for a per-prescription fee. Activities associated with program management included:

- contracting with the PVP,
- ensuring appropriate access to medications through drug wholesalers,
- managing inventory,
- contracting with Pharmacy Benefit Managers for reimbursement from commercial and Medicare Part D carriers,
- billing third parties,



## Getting Started with 340B: Using an Off-Site Retail Pharmacy *(continued)*

- providing financial reporting, and
- ensuring that 340B medication stock was not diverted to ineligible patients.

While Callen-Lorde did not opt to use a third-party 340B program administrator, these entities can provide a valuable interface between the eligible entity and a local retail pharmacy. There are a number of important factors in selecting a community retail pharmacy, including close proximity, favorable associations by a center's patient community, and accessible hours. However, local retail entities may not have the internal knowledge and capabilities to manage a 340B program. Third-party administrators offer a technology solution to partner retail pharmacies, enabling appropriate 340B inventory management, pricing, and compliance. In general, these entities provide their services on a fee-per-prescription basis charged to the 340B entity. One such entity in New York City is NYCRx, a not-for-profit organization with a mission to increase pharmacy access to medically underserved populations. One of the ways NYCRx fulfills its mission is by providing 340B program management services at low cost to covered entities. NYCRx works with covered entities to identify retail pharmacies that will partner in this model; its RFP for a contract pharmacy and related documents can be found in Appendix A.

In addition to needing technical expertise to implement and manage the program, Callen-Lorde had very limited financial resources to establish an initial inventory of medications and continue stocking inventory until the program had achieved fiscal self-reliance. By using a retail pharmacy with an existing inventory that could be dispensed until 340B replenishment inventory was purchased, Callen-Lorde was able to avoid initial cash outlays totaling hundreds of thousands of dollars. Dispensing from an existing wholesale-purchased medication stock is called a 340B virtual inventory, and is a model approved by OPA given the sizable expense of establishing and maintaining a medication inventory.

In the virtual inventory scenario, a contracted retail pharmacy may dispense from its inventory purchased at retail prices to 340B eligible patients and then replenish that stock with 340B discounted medications, thereby alleviating the need to purchase and maintain a dual inventory. This arrangement also allows for a quicker turnover of inventory for drugs purchased at high fixed quantities. For example, the most discounted 340B price for a medication may only be available for a large fixed volume (e.g., 1,000 10-miligram tablets of Simvastatin). It might take several months for this amount of stock to be dispensed to 340B eligible patients, requiring an extended cash outlay by the 340B provider. By using a high-volume retail pharmacy with a virtual 340B inventory, the period between purchase and reimbursement can be reduced significantly.

Another critical issue in the selection of an external pharmacy for the implementation of the program was quality assurance and risk management. As a growing health center, Callen-Lorde was devoting much of its clinical infrastructure to developing its primary care practice and expanding its scope of medical services. Pharmacy licensure, oversight of the clinicians in

## Getting Started with 340B: Using an Off-Site Retail Pharmacy *(continued)*

the pharmacy, and careful monitoring of each dispensed medication represented a considerable undertaking that could have delayed the development of other patient service programs.

Additionally, the contract pharmacy model offered considerable savings associated with general and business liability coverage for insuring the medication inventory from disaster or theft. For non-FQHCs, this business relationship would also mean considerable savings on professional liability coverage.

Finally, the retail pharmacy offered strong patient access because it had evening hours during the week and was open on weekends. Filling a high volume of prescriptions from insured patients would make the program more financially successful, and filling the prescriptions of privately insured patients—of which Callen-Lorde had a sizable population—was highly important. Privately insured patients are usually employed full time and are more likely to fill prescriptions on evenings and weekends; providing expanded pharmacy hours was considered important to the program's success.

# Considering an On-Site Pharmacy: Why Callen-Lorde Did It

**F**or several years, the retail pharmacy arrangement met Callen-Lorde's patient service and financial needs. It provided a low administrative burden along with financial benefits. Because the pharmacy provided its own inventory at the start of the program, Callen-Lorde saw net profits from the program within the first few months.

With the passage of time, Callen-Lorde began to sense that bringing this program in-house, despite the greater administrative burdens, would provide additional clinical benefits for patients and potentially increase revenues. One of the clinical benefits desired, but not achieved with the contracted pharmacy arrangement, was the ability to track adherence to prescribed medications. The contracted pharmacy did not offer a mechanism for real-time tracking of prescription fills, which can be used as a proxy for medication adherence. With a large number of chronically ill patients, especially those with HIV, the ability to track adherence offered significant opportunities for quality of care enhancements.

In addition to monitoring medication adherence, an in-house pharmacy offered many opportunities to improve quality of care and outcomes. It could strengthen Callen-Lorde's capacity to educate and counsel its patients about the medications they were being prescribed. While retail pharmacists are required to offer counseling, an in-house pharmacy offered the ability to target certain conditions and patients for counseling in order to promote treatment adherence. Moreover, in-house pharmacists can be given access to the electronic health record in order to integrate pharmacy services into primary care and avoid negative consequences from erroneously prescribed medications. It is well established that an integrated, multi-disciplinary care team that includes a pharmacist can improve coordination of care for a patient, increase the patient's ability to adhere to a prescribed treatment course, and improve health outcomes.

The contracted pharmacy model also did not at that time provide the ability to include Medicaid and AIDS Drug Assistance Program (ADAP) prescriptions, which in New York State were then ineligible for 340B purchased medications. Callen-Lorde believed that these patients, among the center's most medically complex and socially fragile, were not receiving optimal care in terms of counseling and adherence support that may have been provided through an in-house pharmacy model.

Finally, Callen-Lorde also believed that an in-house pharmacy would increase the rate of filled prescriptions, which would provide both clinical and financial benefits. Anecdotally, the center's staff knew that many patients were failing to fill their prescriptions once they left the premises. Patient feedback suggested that there was a lack of cultural sensitivity and support,

## Considering an On-Site Pharmacy: Why Callen-Lorde Did It *(continued)*

as well as confidentiality concerns, at some local retail pharmacies. Callen-Lorde overcomes these barriers by providing culturally competent primary health care services in a setting that is user friendly and conducive to patient care. Because patients had a trusting and loyal relationship with the health center, Callen-Lorde believed that patients would be more likely to fill prescriptions on-site than if they had to rely on external providers. Finally, the proposed location for the pharmacy—in the facility’s lobby, immediately across from the elevators—provides an exceptional level of convenience that the center staff were confident would also facilitate higher rates of adherence.

# The Planning Process

**W**hile there are considerable potential benefits to implementing an on-site pharmacy, there are also considerable financial risks. The implementation of any 340B program, with either a contracted pharmacy or an on-site pharmacy, carries some financial risk because of the subsidies that are embedded in the sliding fee scale for uninsured patients. The contracted pharmacy model mitigates some of this risk through the virtual inventory scenario and by avoiding the start-up costs of staffing and pharmacy management systems that would be needed for an on-site pharmacy. In a self-owned, on-site pharmacy model, the full expenses for the program are borne by the covered entity. Business planning that projects a break-even point and plans for start-up capital is therefore a critical exercise for any health center considering an on-site pharmacy.

## Business Planning

Callen-Lorde sought external expertise to assist with the strategic decision about on-site pharmacy implementation. It received technical and planning assistance from NYCRx in developing pro-forma business plans and operational viability assessments.

To successfully develop a pro-forma profit and loss projection for a 340B program or on-site pharmacy, health centers must begin by assessing their payer mix. Health centers with high percentages of uninsured patients, particularly indigent uninsured, must carefully consider the risks associated with subsidizing drug costs for these patients. If a health center is already providing medication to patients, 340B purchasing can substantially lower expenses.

Health centers with commercially insured patients should look at historic prescribing patterns for these patients and perform an analysis to determine the difference between 340B pricing and usual and customary commercial reimbursements to assess potential net revenues that can support program operations and low-income uninsured patient subsidies. However, because 340B pricing is not visible to non-covered entities, FQHCs without a history of purchases and third-party reimbursements may not have access to these data, and should look for a local community partner or a 340B manager to assist with this analysis.

With assistance from NYCRx, Callen-Lorde also undertook extensive financial modeling in its consideration of the viability of an owned on-site pharmacy. Projections suggested that the on-site pharmacy would achieve break-even results after 12 months and thereafter be self-sustaining through reimbursement revenues. Beginning in year two of operations, an on-site pharmacy was anticipated to generate net profits that would improve the financial stability of the center and provide needed revenues to cross-subsidize care for uninsured and underinsured patients.

## The Planning Process *(continued)*

The categories of assumptions used to develop the profit and loss projections include the following:

- 1) Estimated number of prescriptions filled at pharmacy:** First, an estimate of the total number of prescriptions written for Callen-Lorde patients by payer type in one year was gleaned from Callen-Lorde's electronic health record. A conservative prescription capture rate of 18% was used for Year 1 projections, based on data from the center's contracted pharmacy program, which captured approximately 15% of current 340B eligible prescriptions plus another 20% of the non-340B eligible (Medicaid and ADAP-reimbursed) prescriptions. Year 2 capture rates were estimated at 35%, which include full capture of current pharmacy partner users. Year 3 capture rates were estimated at 50% based on increasing penetration through internal marketing as well as development of operational incentives for on-site pharmacy use.
- 2) Estimated revenue by payer:** Callen-Lorde projected per-prescription revenues by payer based on Callen-Lorde's current 340B program data as well as known Medicaid and ADAP reimbursement formulas.
- 3) Estimated expenses:** Callen-Lorde received external assistance in developing staffing plans and expense estimates based on other urban pharmacies.
- 4) Other funding:** Callen-Lorde created targets for grant support of its start-up pharmacy costs.

### Space Planning

Given the potential clinical and financial benefits of an on-site pharmacy, Callen-Lorde then considered the viability of the plan in terms of space. In New York City, physical plant considerations are often paramount, and this project was no exception. New York State requires that licensed pharmacies are no less than 300 square feet of contiguous space and meet other specific requirements, including the amount of dispensing and compounding space and the location of restrooms, refrigerators, and signage. Inability to meet these requirements would have created an insurmountable barrier to the implementation of an on-site pharmacy.

# Beginning Implementation

**A**fter thorough consideration and planning, Callen-Lorde decided in 2008 to implement an on-site pharmacy. In assessing the administrative resources necessary to open, operate, and staff a pharmacy, Callen-Lorde decided to outsource program management and staffing to a pharmacy operations entity. Although Callen-Lorde had increased its overall administrative and clinical capacity, pharmacy licensure and operations are a specialized venture that could be delivered more cost effectively by a management services entity. Of particular concern were the staffing resources and backup necessary for a relatively small pharmacy.

The initial development tasks and ongoing operational responsibilities for which Callen-Lorde sought a contractor were as follows:

- Assistance in obtaining pharmacy licensure, which included the development of policies and procedures for the purchase, dispensing, and reconciliation of medication stock; emergency procedures; and the credentialing of pharmacy staff.
- Completing provider applications to bill Medicaid and ADAP for covered pharmaceuticals.
- Entering into billing agreements with pharmaceutical benefit managers (PBMs) for commercially insured and Medicare Part D covered patients;
- Implementation of technology (i.e., software) for the management of inventory, online adjudication of prescriptions dispensed to third-party-covered patients, charges for self-pay patients, financial reconciliation, and reports that provide information to ensure appropriate management of the pharmacy.
- Revised PVP and wholesaler purchasing agreements.
- Medication procurement systems.
- Staffing for all hours of operation.
- Telephone, fax, and electronic prescription receiving capability and telephone and online prescription refill request capability.
- Clinical consultations for medical staff.

Callen-Lorde sought an entity that could provide comprehensive management of the program. The health center released an RFP that defined the scope of the work requested and issued it to several potential partners, including the existing contracted pharmacy, additional local pharmacies that had previously expressed interest in working with Callen-Lorde, and a national pharmacy services firm that specialized in management of pharmacies within safety net medical institutions. Two proposals were received.

## Beginning Implementation *(continued)*

Based on responses to the RFP, Callen-Lorde selected the firm that specialized in safety net pharmacy management. The firm, Maxor National Pharmacy Services Corporation, is a highly qualified vendor with significant 340B program management and community health center pharmacy management experience. The firm completed most of the administrative start-up activities, including applying for licensure, contracting with third party payers, enrolling in Medicaid and ADAP, assisting with the construction of a self-pay pricing model, interfacing its own IT systems with Callen-Lorde's existing electronic health record, and hiring a supervising pharmacist, which is required for licensure.

The health center was also successful in securing financial support from the New York State Health Foundation, HRSA, and the Heinz Foundation to partially fund the resources needed for pharmacy planning, the physical build-out of the pharmacy space, and support for initial operating expenses, including medication inventory.



# Early Experiences

Opening the pharmacy took much longer than anticipated, primarily because of reimbursement and licensure issues. The pharmacy opened in November 2010.

Pharmacy start-up saw strong patient volume and required additional inventory purchases before third-party reimbursements began to be received. Additionally, Callen-Lorde provided non-340B medications to Medicaid and ADAP patients, which required the maintenance of a dual (340B and retail) inventory. The combination of increasing growth and near-cost reimbursement for Medicaid prescriptions resulted in an ongoing inventory expense that quickly exceeded \$1 million per month. As the demand for the pharmacy continues to increase, so does the need to purchase more inventory, resulting in a considerable cash outlay.

Despite these challenges, the on-site pharmacy has been a significant success. Actual cash profits are not expected to be realized until approximately month 18 of the project, given start-up costs and constantly growing inventory needs. However, in its first full year of operation, the on-site pharmacy filled more than 43,000 prescriptions and yielded a net profit per prescription of approximately \$22.

# Conclusion

The 340B Drug Pricing Program offers a tremendous opportunity for FQHCs and other eligible entities to improve patient access to prescribed medications and to generate revenues that support the provision of indigent care services. However, health centers must carefully consider the costs and risks of 340B program implementation and the method of program implementation in the context of the particular needs of their patient populations, technological capabilities, administrative capacity and competency, and access to working capital. Callen-Lorde's particular case may or may not prove similar to other health centers' situations.

The use of a contracted retail pharmacy or pharmacies can enable relatively quick program implementation and reduce start-up costs and the need for capital investments. An on-site pharmacy can potentially add the benefits of service integration, higher prescription fill rates, and higher revenues, but carries more financial and operational risk and liability.

Looking forward, 340B programs will be affected by various industry developments, including the advent of new technologies and interfaces between electronic health records and pharmacy management systems; a growing cadre of 340B experts poised to assist health centers in their decision-making and program implementation efforts; the implementation of health insurance exchanges; and the growing numbers of Americans with prescription coverage.

As medical home models continue to develop and spread, we will likely see more examples of pharmacy integration into primary care and behavioral health homes. Additional data about the clinical and fiscal efficacy of integrated pharmacy will help shape best practices. Ideally, health care reimbursements and other health care funding in New York State will continue to incentivize and prioritize service integration, particularly in regions with poor access to pharmacies and for populations with access barriers to comprehensive care. In adding pharmacy to the medical home model, health centers can continue to lead the way toward improving the health of underserved populations and for all New Yorkers.

# Appendix A

## RFP and Related Documents for Contracted Pharmacy: Forms Used by NYCRx on Behalf of Its Partner FQHCs

### REQUEST FOR PROPOSAL FOR 340B PHARMACY PROGRAM SOLICITOR: [FQHC NAME]

#### BACKGROUND

[FQHC name] is a private non-profit federally funded community health center established in \_\_\_\_\_ to provide comprehensive health services to the poor, the medically indigent, and/or medically underserved residents of \_\_\_\_\_ ...

#### MISSION STATEMENT

[FQHC MISSION STATEMENT]

#### 340B PROGRAM

[FQHC name] seeks to establish a relationship with a community pharmacy for its [specific FQHC site] located on \_\_\_\_\_ to implement a 340B pharmacy program. The 340B program was established in 1992 by section 602 of the Veterans Health Care Act, (U.S. Dept of Health and Human Services), Section 340B of the Public Health Service Act rose from the Veteran's Act. The 340B Drug Pricing Program stipulates that drug manufacturers provide outpatient drugs to certain covered entities specified in the statute 42 U.S.C. 340b(a)(4) at a reduced price. The covered entities are Health Resources and Service Administration (HRSA) grantees such as [specific FQHC site], a Federally Qualified Health Centers (FQHCs). Other organizations that qualified as covered entities include: FQHC look alikes, family planning clinics, HIV/Ryan White Clinics, state-operated AIDS drug assistance programs, black lung clinics, hemophilia treatment centers, Native Hawaiian health centers, sexually transmitted disease and tuberculosis clinics, and disproportionate share hospitals. (HRSA Pharmacy Services Support Center, <http://pssc.aphanet.org>)

The 340B Drug Pricing Program is sometimes referred to as PHS pricing or 602 pricing. It is a ceiling price, which means that this is the highest price a covered entity pays for an outpatient drug. On average 340B prices are about 50% of the average wholesale price (Schondelmeyer, Prime Institute, University of Minnesota (2061)). Under the 340B program, the entity owns the medications and contracts with a licensed pharmacy to dispense these medications to the entity's patients. For this and other included services, the pharmacy is paid a dispensing fee. The goal of this program is to increase patient access to affordable prescription medications.

#### BASIC REQUIREMENTS

AT THIS TIME, [SPECIFIC FQHC SITE] SEEKS TO ESTABLISH A CONTRACTUAL RELATIONSHIP WITH A LOCAL PHARMACY IN THE PROXIMITY OF ITS CLINICS TO PROVIDE MEDICATIONS ACQUIRED THROUGH THE 340B MECHANISM TO ITS ELIGIBLE PATIENTS. WE ARE IN NEED OF A PHARMACY TO:

- |   |   |
|---|---|
| 1 | Prepare, dispense and deliver medications prescribed for clinic patients through a replenishment model;                                   |
| 2 | On behalf of entity, order 340B drugs from the designated distributor using the entity's account;   |
| 3 | Provide a system to monitor the inventory and ensure there are sufficient supplies of medications to meet the needs of eligible patients; |
| 4 | Provide monthly financial and statistical reports;  |
| 5 | Provide maintenance of a tracking system to prevent the diversion of covered drugs to individuals who are not eligible patients;          |
| 6 | Provide refill reminder services.   |

*continued on next page*

Appendix A (continued)

**REQUEST FOR PROPOSAL FOR 340B PHARMACY PROGRAM**

QUALIFICATIONS	
•	The pharmacy must be licensed in New York State
•	The pharmacy must be in good financial standing with no known pending federal or state investigations or restrictions to provide pharmacy services in New York State
•	The pharmacy must have the capacity to manage medication inventory and generate timely reports
•	The pharmacy must have a pharmacist on-site during normal business hours that meet the needs of most patients.
•	The pharmacy must be willing to cooperate with NYC Rx, the 340B manager appointed by [specific FQHC site], to ensure compliance with the 340B program, reporting, and auditing procedures.
SCOPE OF SERVICES	
<b>THE ENTITY WILL CONSIDER NUMEROUS FACTORS IN MAKING ITS DECISION. THESE INCLUDE:</b>	
•	pharmacy location
•	hours of operation
•	[specific FQHC site] patient and staff preference
•	services offered including delivery, medication counseling, and medication tracking.
•	participation in medication adherence program administered by health center.
•	assist in the distribution and tracking of medications provided by manufacturer patient assistance program for a fee
•	dispensing fee charged to [specific FQHC site]
•	dispense prescriptions from clinic patients with Medicare Part D, commercial insured, Medicaid Managed Care, and CHP-B with 340B priced drugs.
•	familiarity with 340 B program
•	familiarity and working relationship with [specific FQHC site] and its patient population
•	automated record keeping and report capabilities
•	participation in health insurance plans utilized by [specific FQHC site] patients
•	inventory tracking and control
•	prudent procurement
•	accountability for all entity medications received and dispensed
•	willingness to implement a replenishment inventory system
•	experience with pharmacy and therapeutic committees
•	formulary management
•	ability to communicate with patients with low English Proficiency

*continued on next page*

Appendix A (continued)

**REQUEST FOR PROPOSAL FOR 340B PHARMACY PROGRAM**

SCOPE OF SERVICES (continued)			
•	any license restrictions on the pharmacy staff		
•	depth and scope of pharmacist’s consultation		
•	ability to implement the 340B program fully before _____.		
APPLICATION PROCESS			
<b>INTERESTED PHARMACIES ARE ASKED TO SUBMIT THE FOLLOWING ITEMS:</b>			
•	A Letter of Intent indicating desire to enter into a contractual agreement with [FQHC name]. Sample Letter of Intent provided.		
•	The completed pharmacy questionnaire (see next page) along with all requested documentations.		
•	The proposed dispensing fee for patients with no prescription benefits and for patients with prescription benefits who are eligible to receive 340B priced pharmaceuticals.		
SUBMISSION/DEADLINE			
Proposals should be submitted via by _____ 5:00 PM to:			
Sarah Sheffield Executive Director, NYCrx, Inc. 2090 Adam Clayton Powell Blvd., 5th Floor New York, NY 10027			
<b>EMAIL:</b> sarah.sheffield@nycrx.org			
PHARMACY QUESTIONNAIRE			
Health Center Partner: _____			
Legal Name of Pharmacy: _____			
D/B/A: _____			
Address: _____			
Telephone: _____			
NAME OF OWNER(S):	TITLE	IF OWNER IS A HEALTH PROFESSIONAL, PLEASE PROVIDE CURRENT LICENSE AND PROFESSION.	INDICATE WHICH OWNER WILL SIGN DOCUMENTS AND SERVE AS CONTACT
<b>CONTACT INFORMATION OF POINT OF CONTACT:</b>			
Telephone: _____			
Fax: _____			
Email: _____			

*continued on next page*

Appendix A (continued)

REQUEST FOR PROPOSAL FOR 340B PHARMACY PROGRAM

PHARMACY QUESTIONNAIRE (continued)

SUPERVISING PHARMACIST INFORMATION (if different than previous page):

Name: \_\_\_\_\_

License #: \_\_\_\_\_

Registration #: \_\_\_\_\_

Will Supervising Pharmacist be placing orders:

YES  NO

If "Yes," provide email address:

\_\_\_\_\_

PHARMACY OPERATION:

Hours of Operation: \_\_\_\_\_

Is delivery available?:

YES  NO

If "Yes," what are your geographic boundaries for delivery?:

\_\_\_\_\_

Do you accept E-prescribing?

YES  NO

Refill Reminder Services:

YES  NO

Staffing on any one day:

Registered Pharmacist \_\_\_\_\_; Pharmacy Technicians \_\_\_\_\_;

Pharmacy Interns \_\_\_\_\_ (total # of hrs/wk \_\_\_\_\_)

Are there any **third party prescription plans** that pharmacy declines to participate in?

YES  NO

If "Yes," please list: \_\_\_\_\_

Which **pharmaceutical distributor** do you use for the majority of your purchases:

\_\_\_\_\_

Which **software vendor** do you use for your electronic dispensing system?

Software Vendor: \_\_\_\_\_

Name of Account Representative: \_\_\_\_\_

Contact information: \_\_\_\_\_

continued on next page

Appendix A (continued)

**REQUEST FOR PROPOSAL FOR 340B PHARMACY PROGRAM**

<b>PHARMACY QUESTIONNAIRE (continued)</b>	
1.	Have you been found guilty after trial, or pleaded guilty, no contest, to a crime (felony or misdemeanor) in any court? <input type="checkbox"/> <b>YES</b> <input type="checkbox"/> <b>NO</b>
2.	Has any licensing or disciplinary authority revoked, annulled, cancelled, accepted surrender of, suspended, place on probation, or refused to issue or renew a professional license or certificate held by you now or previously, or fined, censured, reprimanded or otherwise disciplined you? <input type="checkbox"/> <b>YES</b> <input type="checkbox"/> <b>NO</b>
3.	Are criminal charges pending against you in any court? <input type="checkbox"/> <b>YES</b> <input type="checkbox"/> <b>NO</b>
4.	Are charges pending against you in any jurisdiction for any sort of professional misconduct? <input type="checkbox"/> <b>YES</b> <input type="checkbox"/> <b>NO</b>
5.	Has any hospital or licensed facility restricted or terminated your professional training, employment, or privileges, or have you voluntarily or involuntarily resigned or withdrawn from such association to avoid the imposition of such action due to professional misconduct, unprofessional conduct, incompetency, or negligence? <input type="checkbox"/> <b>YES</b> <input type="checkbox"/> <b>NO</b>

\*\*If the response for any of the above questions is YES, please provide a brief explanation in a separate document.

Thank you for completing the questionnaire. If you have any questions in completing the questionnaire, please contact Sarah Sheffield at (212) 676-2152. Kindly submit completed questionnaire and accompanying documents to NYCrx via email or priority mail:

**Sarah Sheffield**  
Executive Director, NYCrx, Inc.  
2090 Adam Clayton Powell Blvd., 5th Floor  
New York, NY 10027

Appendix A (continued)



**NYCRx 340B PHARMACY RECOMMENDATION REPORT FOR  
[FQHC NAME]**

NYCRx contacted five pharmacies that are geographically convenient to [FQHC name]. A Request for Proposal was sent to each soliciting a contract retail pharmacy arrangement for [FQHC name]’s proposed 340B program. Below you will find basic organizational information for each pharmacy based on the RFPs submitted to NYCRx which included a pharmacy questionnaire and a letter of intent.

	PHARMACY 1	PHARMACY 2	PHARMACY 3	PHARMACY 4	PHARMACY 5
PROPOSED FEE FOR SELF-PAY PATIENTS					
PROPOSED FEE FOR COMMERCIAL					
HOURS OF OPERATION					
DELIVERY AVAILABLE					
REFILL REMINDER SERVICE					
DISTANCE FROM [FQHC NAME] TO PHARMACY					



# Appendix B

## RFP for Pharmacy Management Firm: Sample Language from Callen-Lorde's RFP

Callen-Lorde Community Health Center (Callen-Lorde) seeks to retain a firm to manage the establishment and ongoing operation of an on-site pharmacy to improve patient access to medications, as well as to increase net revenue by increasing its capture of commercial prescriptions. The on-site Callen-Lorde pharmacy will serve patients from all payers and will thus include 340B and non-340B inventories. The Pharmacy will be branded and marketed wholly as a Callen-Lorde operation, and Callen-Lorde will be the purchaser of record of all drugs.

The results of establishing the on-site pharmacy will be:

- To reduce out of pocket expenses for uninsured patients,
- To improve the quality of patient care by bringing pharmacy services under Callen-Lorde control,
- To improve continuity of care and integration of patient education and adherence initiatives, and,
- To maximize Callen-Lorde's revenue from 340B.

To provide context for proposals, this document briefly outlines Callen-Lorde's history and overview of the first four years of 340B program operation. Following is a response format for proposers to provide information related to their firm, relevant experience, and description of how the requested goals of the strategic business plan will be achieved.

Callen-Lorde is seeking an experienced and highly creative firm to conduct necessary analysis of patient demographic and prescribing data in order to prepare a written proposal for the complete management and operations of the Callen-Lorde on-site pharmacy.

Interested parties should provide a proposal that addresses the following:

- Brief description of agency/individual
- Past relevant experience, specifically including 340B experience in community health centers
- Selected past and current similar clients / engagements
- Brief description of individuals to be involved in this engagement, specifically an identified project leader

## Appendix B *(continued)*

- Description of a proposed process that will include:
  - start-up plan (including all facilities improvements and any capital expenses)
  - start-up timeline
  - draft annual budget including operating expenses and any management fees and administrative overhead expenses
  - staffing plan
  - plan for maintenance of inventory(ies), outlining responsibility for loss, theft, obsolescence
  - plan for establishing 3rd party payer contracts
  - plan for auditing and QA controls
  - outline of possible financing for initial capital improvements, equipment and inventory.

# Appendix C

## The 340B Drug Pricing Program

The Human Resources and Services Administration provides the following overview of the 340B program:

The 340B Drug Pricing Program resulted from enactment of Public Law 102-585, the Veterans Health Care Act of 1992, which is codified as Section 340B of the Public Health Service Act. The 340B Drug Discount Program is managed by the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA). Section 340B limits the cost of covered outpatient drugs to certain federal grantees, federally-qualified health center look-alikes and qualified disproportionate share hospitals. Participation in the program results in significant savings estimated to be 20% to 50% on the cost of pharmaceuticals for safety-net providers. The purpose of the 340B Program is to enable these entities to stretch scarce federal resources, reaching more eligible patients and providing more comprehensive services. ([www.hrsa.gov/opa/introduction.htm](http://www.hrsa.gov/opa/introduction.htm))

Following is a list of the eligible entities that may participate in the 340B program:

- Federally Qualified Health (FQHC) and FQHC Look-alikes
- Federally funded family planning projects
- Ryan White Care funded entities
- State operated AIDS Drug Assistance Programs (ADAP)
- Black Lung Clinics
- Hemophilia Diagnostic Treatment Centers
- Native Hawaiian Health Centers
- Urban Indian Organizations
- Federally funded sexually transmitted disease treatment programs
- Federally funded tuberculosis treatment programs
- Disproportionate Share Hospitals

The Affordable Care Act (ACA) expanded the definition of covered entities that are now eligible to participate. These covered entities include: Critical Access Hospitals, Free Standing Cancer Hospitals, Rural Referral Centers, Children's Hospitals and Sole Community Hospitals.

## Appendix C *(continued)*

All eligible entities must apply to the Office of Pharmacy Affairs (OPA), the Federal oversight agency, for inclusion in the program. This application consists primarily of demonstrating the current Federal funding or licensure that qualifies the entity as eligible for 340B program participation. Once OPA approves the entity, it is listed on the OPA website in the following calendar quarter, at which point the entity may purchase drugs through a wholesaler and enroll in the Prime Vendor Program (PVP).

The verification of patient eligibility for 340B prescriptions both in terms of the designation of the provider and insurance coverage status of the patient is a critical requirement. Both manufacturers and OPA can audit 340B providers for compliance with patient eligibility rules. Entities which violate the rules are subject to repayment to manufacturers and suspension or termination from the program. Audits usually take the form of dispensing reviews to assure that medications are not diverted to ineligible patients. Unlike in the Medicaid rebate program in which manufacturers can receive information that discounted medications have been dispensed to eligible patients, 340B entities purchase discounted stock and then are relied upon to provide these medications only to eligible patients. Given that the 340B discounts may be upwards of 50% off of the average manufacturer's price, there is a great deal of scrutiny placed on this issue by manufacturers. Manufacturers may request an audit of a provider through OPA.

For more complete information about the program the following sites are suggested:

- HRSA Office of Pharmacy Affairs, the Federal agency responsible for the program (<http://www.hrsa.gov/opa/introduction.htm>)
- Pharmacy Services Support Center, HRSA's contracted technical support provider to 340B eligible entities (<http://pssc.aphanet.org/>)
- Apexus, the Prime Vendor Program, HRSA's contracted national group purchasing entity (<https://www.340bpvp.com>)
- NYCRx, a not-for-profit 340B program manager and technical assistance organization (<http://www.nycrx.org/en/>)

Additionally, the websites of the National Association of Community Health Centers ([www.nachc.org](http://www.nachc.org)) and the Safety Net Hospitals for Pharmaceutical Access ([www.snhpa.org](http://www.snhpa.org)) have considerable information and reports on their sites.

# Appendix D

## Summary of Considerations and Additional Factors

### Key Considerations

As highlighted by Callen-Lorde’s experiences, there are essentially two options for implementing a 340B program: a self-owned in-house pharmacy or a contracted retail pharmacy agreement, either off-site or on-site. Each of the options has advantages and limitations. Entities seeking to implement a 340B program should consider each of the major areas outlined below before deciding on an implementation strategy.

ISSUE	RETAIL PHARMACY ARRANGEMENT	SELF-OWNED IN-HOUSE PHARMACY ARRANGEMENT
Patient access	Retail pharmacies usually have convenient evening and weekend hours. As 340B covered entities are now able to contract with multiple retail entities, this can present opportunities for greater access.	Health centers may have limited hours on evenings and weekends, potentially impeding access. The convenience of an on-site pharmacy, however, improves patient access.
Drug purchasing	Drug purchasing is conducted through the PVP. Retail pharmacies that are part of national chain may be able to achieve additional savings through volume purchasing.	Drug purchasing is conducted through the PVP. Group purchasing arrangements may be available through the PVP or other entities that can obtain additional discounts.
Third-party contracts and billing	Existing contracts with PBMs and the capabilities in the implementation of third-party billing allows for the ability to readily implement these functions for the 340B entity.	Contracting with PBMs is likely to require consultative support. Billing these carriers would require the implementation of a pharmacy billing system and online adjudication software.
Inventory management	The implementation of the virtual inventory and the potentially relatively large volume in a retail setting reduces the outlay of funds for initial pharmacy and improves cash flow during ongoing operation.	Initial inventory purchases are financially substantial and purchases of large quantities of medicines may present a cash drain.
Technology services for pharmacy management	Retail entities will likely already have the technology solutions that will allow for inventory management, third-party billing and report writing functions.	Numerous pharmacy software systems exist that meet inventory management, dispensing, and billing needs. However, the licensing of these systems may be costly and require extensive training.
Staffing	Retail pharmacies have existing staff that can usually accommodate the additional volume resulting from a dispensing arrangement.	Staffing will need to be recruited and supervised by the 340B entity or an outsourced management company. Small and mid-sized health centers may be significantly challenged by the need to provide staffing coverage at all hours of operation and for vacation/sick time.

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## Appendix D (continued)

ISSUE	RETAIL PHARMACY ARRANGEMENT	SELF-OWNED IN-HOUSE PHARMACY ARRANGEMENT
Quality assurance and risk management	Retail pharmacies have existing mechanisms to ensure clinically appropriate dispensing of medications and tracking of inventory to avoid theft. Retail entities will carry their own professional, general, and business liability insurance. The 340B eligible entity will need to indemnify these entities but this additional coverage will be less than the outright purchase of coverage.	Eligible entities will need to develop quality assurance and risk management mechanisms as well as physical security systems.
Physical space	Existing retail pharmacies have their locations. Most can provide confidential counseling space, but depending on the 340B entity patient base, some patients may feel intimidated or unwelcomed in a retail setting (e.g., family planning or mental health consumers).	Safety net providers may not have the excess or available physical space to dedicate to a pharmacy, which by New York State regulation must be at least 300 square feet of contiguous space plus potential for additional storage, space for confidential counseling, and waiting room space.
Capture rate	Retail pharmacies have advantages in expanded hours of operation, and multi-site programs provide particular ease of access for a geographically diverse patient base.	In-house pharmacies have the convenience of capturing patients after provider visits and the advantage of patient loyalty.
Direct costs	Retail pharmacies generally charge a per-prescription dispensing fee as well as a management fee or work with a third-party administrator that charges management fees.	Self-owned in-house pharmacy costs include staffing, insurance, supplies other than pharmaceuticals, and information technology. On a per-prescription basis, these costs are likely to be higher than a retail pharmacy's dispensing fees during start-up and then eventually lower. This analysis should be considered in profit and loss projections.
Value-added patient services	Retail pharmacies often have extensive patient educational materials and programs for the most prevalent chronic diseases.	In-house pharmacies can access the patient health record or communicate directly with prescribing providers to assist in tailoring educational messages to specific patient needs. The staff of in-house pharmacies is likely to be in tune with the social and cultural values of the patients served and thereby improve the patient experience.

## Appendix D (continued)

### Additional Factors to Consider for On-Site Pharmacies

There are two mechanisms by which health centers may open on-site pharmacies:

- 1) **Renting to a retail pharmacy.** This model has the same issues described above in contracting with an external pharmacy. However, by bringing a pharmacy on-site, both the health center and the pharmacy are more likely to capture a greater market share of the medications prescribed within the health center, and to enhance the coordination of care by the close proximity of the pharmacy. There is also the advantage to the health center of generating revenue from the rental of the pharmacy.
- 2) **Applying for a pharmacy license (self-owned pharmacy).** Under this model, the health center gains full control over the pharmacy program—clinically, financially and from a patient relations perspective—but then also absorbs all the risks associated with the program, including malpractice liability, general liability insurance expense for the high cost medication inventory at the health center, and maintenance of the physical setting of the pharmacy. Operating a pharmacy may also pose a considerable draw on the clinical and administrative resources of a primary care-focused health center. Entities may therefore decide to apply to add these programs to their operating certificate but then seek a management services entity to run the program for the health center, as Callen-Lorde did. These arrangements can include the full scope of administrative services as well as clinical oversight and quality assurance. Appendix B contains sample language for an RFP for a pharmacy manager.

One considerable advantage to obtaining a pharmacy license is that patient adherence to prescribed regimens can be clearly seen and documented. Treatment adherence is vitally important in chronic disease management and can be leveraged with third-party payers and government entities for increased reimbursement.



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