

The Bridge to 340B Comprehensive Pharmacy Services Solutions in Underserved Populations



Information and Tools for Decision Makers

Prepared for Medpin by
Katheryne Richardson, PharmD

April 2004

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This manual was prepared by Medicine for People in Need (Medpin) with support from the Health Resources and Services Administration's Pharmacy Services Support Center (PSSC).

Medicine for People in Need (Medpin) works with safety net providers to improve access to medicine and pharmaceutical care for people in need. Medpin provides training and education, direct technical assistance services, policy analysis, and research.

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Health Resources and Services Administration (HRSA) / Pharmacy Services Support Center (PSSC)

is a unique collaboration between the federal government and the American Pharmacists Association (APhA) to bring comprehensive pharmacy services to patients who receive care at 340B-eligible health care delivery sites. The PSSC provides information, education, and policy analysis to help eligible health care entities optimize use of the 340B program to provide affordable comprehensive pharmacy services that improve medication use and advance patient care.

A key resource available through the PSSC is "PSSC PharmTA," the government-supported pharmacy technical assistance program available to covered entities participating in the 340B Drug Pricing Program. The program assigns expert consultants to work with entities based on need in areas such as basic 340B program and contract pharmacy arrangements, providing clinical pharmacy services, writing business plans, and using the 340B Prime Vendor Program to optimize savings.

PSSC PharmTA services are provided through phone consultations, materials or sample forms and documents, and limited site visits, depending on need.

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This manual is intended for informational purposes only and should not be construed as legal advice. Consult a licensed attorney before undertaking any new business arrangement.

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Katheryne Richardson is a pharmacist who focuses on delivering pharmacy services to underserved populations. Her practice includes doing volunteer work at free clinics and providing technical assistance to health centers on all aspects of pharmacy. She has worked extensively to increase participation in the 340B Drug Pricing Program, a federal discount program operated by the Office of Pharmacy Affairs. Dr. Richardson has worked with numerous federal grantees to develop and evaluate outcomes from the Comprehensive Pharmacy Services Implementation Projects, a grant opportunity intended to promote innovative pharmacy practice offered by the Bureau of Primary Health Care of the Health Resource and Services Administration. In addition to her work in the United States, she has developed educational material, technical drug references, and standard operating procedure to prepare sites in Kenya for the introduction of antiretroviral medications. Dr. Richardson received her Bachelor's of Science in pharmacy and her Doctor of Pharmacy from the University of Kentucky College of Pharmacy in Lexington, Kentucky. She has prior experience as a pharmacist for the Bureau of Prisons and the Department of Defense, and as an intern at the National Institutes of Health and the Food and Drug Administration. She lives and works in Charleston, South Carolina.

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Information and Tools for Decision Makers

Do these statements by health center administrators sound familiar?¹

- “The administrative hassles [of pharmacy] are like getting through a maze!”
- “All rules in the pharmacy environment are foreign to us.”
- “The business of pharmacy is out of the center’s realm.”
- “If only there were a how-to book [on] the complicated and scary process [of pharmacy implementation]!”

Rising prescription costs present clinic administrators with a difficult challenge: providing pharmacy services that are cost-effective for the clinic yet affordable for patients. Fortunately, the PHS 340B Drug Discount Program² provides significant discounts on drugs for eligible entities.³ As the quotes above reveal, administrators report hesitancy to even investigate 340B pharmacy options due to seemingly insurmountable implementation barriers. Such tentativeness typically results from inadequate information, and barriers may be overcome with the proper tools. The purpose of this manual is to equip administrators with the **information** and **tools** to build a bridge connecting pharmacy needs with 340B comprehensive pharmacy services solutions.

Due to the variety of clinic needs and capabilities, there is not a “one size fits all” system for pharmacy services. Using this manual in conjunction with an experienced pharmacy consultant⁴ will simplify the process of arriving at an individualized approach. A consultant can lend the critical expertise needed to ensure the delivery model contains all four cornerstones of comprehensive pharmacy services: affordable access to medications using the 340B and prime vendor programs, outcomes-driven pharmaceutical care, efficient business practices, and quality assurance. The first step in building a bridge toward a 340B comprehensive pharmacy services solution is to understand basic information about the 340B program.

SECTION I. INFORMATION



A. The PHS 340B Discount Drug Pricing Program

Current Issues

Despite the fact that the 340B program affords an average of 20% savings⁵ on clinic prescription purchases, not all entities participate: estimated participation varies between 39%⁶ and 73%⁷ of eligible clinics.⁸ Although the benefits of the 340B program are significant, clinic administrators are hesitant to participate in the program due to a variety of perceived barriers. Fortunately, the most commonly reported barriers to participation can be overcome.

Most Common Barriers to Implementing 340B Pharmacy Services ⁹	Solutions to Overcoming Barriers
The start-up costs are too high.	Proven, successful models allow 340B access with minimal or no clinic start-up costs.
The record keeping is overwhelming and too complex.	Record keeping is much less complicated than often envisioned, and technical assistance is available to ensure that the process is correctly established.
The 340B program is too confusing, and there is not sufficient information about it.	Handbooks, brochures, and the Internet offer information that simplifies the 340B program and describes successful models. ¹⁰

History

Alarmed by the escalating costs of drugs in the early 1990s, a consortium of safety net providers began to strategize around the best way to provide pharmacy services for patients. Their efforts resulted in the federal legislation¹¹ that created the Public Health Service 340B Discount Drug Pricing Program. This program required drug manufacturers to provide outpatient drugs to specific entities at a reduced price. A branch of the federal government, now called the Office of Pharmacy Affairs (OPA), was developed to administer the program. A key function of the branch is to maintain the official website database that lists the eligible and participating entities.¹² Wholesalers and manufacturers check this website before selling at 340B prices to a buyer.

Although state laws govern most pharmacy activities via a state board of pharmacy, it is important to note that the 340B program resulted from federal law. Despite the fact that the 340B legislation is federal, some states have chosen to pass additional laws regarding 340B. This section provides an overview of the federal legislation, but it is wise to investigate state policies regarding 340B before participating in the program.

The Office of Pharmacy Affairs

The Office of Pharmacy Affairs (OPA) is located within HRSA's Health Care Systems Bureau.

Office of Pharmacy Affairs
U.S. Department of Health and Human Services
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Rockville, MD 20857
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(800) 628-6297

The 340B Price

The 340B price is a ceiling price, meaning it is the highest price a participating entity could be charged, and it is determined by the Centers for Medicare and Medicaid Services (CMS) using a complex formula. The 340B price is at least as low as the price the state Medicaid agency pays. Some 340B purchasers are able to pay less than the Medicaid price because they are able to negotiate sub-ceiling prices, and some entities save further by not paying drug mark-ups and dispensing fees to a retail pharmacy.¹³ 340B prices have been reported as:

1. About half (49%) of Average Wholesale Price (AWP)¹⁴
2. An average savings of 19–22% of clinic purchases¹⁵
3. About 20–50% below true wholesale price¹⁶

The 340B savings belongs to the entity. There is no mandate in the law that requires the entity to pass the 340B savings to patients, although many choose to do so. Entities most commonly report¹⁷ using 340B savings to:

- increase the number of patients served
- offset losses from providing pharmacy services for less than full compensation
- reduce prescription prices to patients
- increase services offered at clinics

The 340B price is a confidential price, so there is no standard price list available to entities to verify that the 340B price they receive is accurate.¹⁸ If an entity questions the accuracy of a given 340B price, OPA is able to investigate and confirm it. Entities may also check with the manufacturer directly through quarterly price lists that are compiled by most major companies. These are available in both printed and electronic formats.

Eligibility

The eligibility¹⁹ to purchase at the 340B price belongs to the entities outlined in the legislation, which include:

- Federally qualified health centers (FQHC)
 - FQHC look-alikes²⁰
 - Migrant health centers
 - Health Care for the Homeless programs
 - Healthy Schools, Healthy Communities (school-based programs)
 - Health Centers for Residents of Public Housing
 - Office of Tribal Programs or urban Indian organizations
- Family planning projects
- Ryan White Care Act subpart II of part C or Early HIV Intervention Services Grantees
- Certified AIDS Drug Assistance Programs (ADAP)
- Black lung clinics
- Comprehensive hemophilia diagnostic treatment centers
- Native Hawaiian health centers
- Urban Indian organizations
- Certified tuberculosis clinics
- Disproportionate share hospitals
- Certified sexually transmitted disease clinics

Because 340B eligibility belongs to the entities but the ultimate recipients of the drugs are patients, a guideline was issued to clarify under what conditions patients of the entity were eligible for 340B. This guideline is referred to as the “definition of a patient”:²¹

In summary, an individual is a “patient” of a covered entity (with the exception of state-operated or -funded AIDS drug purchasing assistance programs) *only if*:

1. the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual’s health care; and
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.e., 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 or federally qualified health center look-alike status

has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

An individual will not be considered a “patient” of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

An individual registered in a state-operated AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHS Act will be considered a “patient” of the covered entity for purposes of this definition if so registered as eligible by the state program.

Enrollment and Participation

Eligible entities are not automatically enrolled in 340B. They must submit an enrollment form²² by fax or mail to OPA notifying the agency of their intent to participate. After OPA receives the form, the entities will be added to the official website listing participating entities at the next quarterly update. OPA must receive the form prior to each quarterly update in order for the entity to appear on the website as of that update. The deadlines for receipt of the form follow.

Submit the Form by:	To Be Added to the Database as of:
December 1	January 1
March 1	April 1
June 1	July 1
September 1	October 1

What Does the 340B Program Look Like Today?	
Number of 340B-eligible entities ²³	≈ 15,000
Number of 340B participating entities ²⁴	≈ 11,442
Dollar volume of purchases ²⁵	≈ \$3–3.5 billion
Total percent of entities offering some pharmacy services ²⁶	70%
Total percent of entities offering no pharmacy services ²⁷	30%
Total number of contracted pharmacies ²⁸	699

Purchasing

It is the covered entity's responsibility to notify drug manufacturers and wholesalers of its participation in the 340B program. Once the entity's name appears on the OPA website, the wholesalers or manufacturers must then recognize the entity by selling drugs at the 340B price.

Most wholesalers are familiar with the 340B program, but the original legislation mandated the establishment of a prime vendor program. The prime vendor is a single preferred agent that specializes in serving covered entities that participate in the 340B program. The 340B prime vendor is meant to provide high-quality services and low drug prices for the benefit of the covered entities and their patients.

Benefits of the prime vendor program include:

- familiarity with subtleties of the section 340b program
- value-added services
- sub-340b prices, due to negotiations with drug manufacturers using the collective purchasing volume and market share potential of covered entities

The current exclusive agreement for HRSA's official 340B prime vendor program is with HealthCare Purchasing Partners International (HPPI). A major goal for HPPI is to focus on securing sub-340B discounts through contract negotiations and competitive bidding processes.²⁹ Because the program is funded through nominal fees charged to distributors and suppliers, there are no costs or risks for the covered entity. To participate in the program, the entity must:

1. Enroll in the 340b program by meeting the qualifications above and submitting the application documents online to the HRSA Office of Pharmacy Affairs through its website, <http://bphc.hrsa.gov/opa>. Verification of enrollment on the website can take up to 90 days.
2. Complete the prime vendor participation agreement and submit two originals to the 340b prime vendor program at HPPI at www.340bpvp.com. Once the covered entity is registered through the HRSA website, the appropriate distributor will be notified to extend the prime vendor program contracting pricing. The covered entity should monitor this process to ensure that the appropriate prices are being charged.

Additional Requirements and Prohibitions

The additional requirements and prohibitions associated with the 340B program are listed briefly below. Detailed information may be found by reading the pertinent guidelines cited in Appendix VI of this manual (340B Forms, Eligibility Information, and Guidelines).

Definition of a Patient³⁰

Double-Discounts

Medicaid programs typically receive rebates on drugs purchased for patients. The rebates are dollar amounts paid by the manufacturers to Medicaid after the sale of the drug, thereby resulting in a lower drug price for the Medicaid agency. The 340B legislation specifically prohibits *double-discounts* – that is, charging the manufacturer twice via a rebate and a 340B discount on the same drug. To ensure that there is no overlap of 340B drug discounts and Medicaid rebates, OPA requests the Medicaid billing status and number of the entity and maintains this information on OPA's website. The Medicaid agencies receive an exclusion list each quarter from OPA to ensure that the Medicaid agencies do not request a rebate on drugs purchased for 340B patients.

Resale / Transfer / Diversion

Resale or transfer of a 340B drug to a person who is not a patient of the entity is called *diversion* and is specifically prohibited. The definition of a patient³¹ is helpful in determining appropriate recipients of 340B drugs.

Audit

Covered entities must maintain accurate records documenting that no double-dipping, or diversions by reselling/transferring of drugs to ineligible patients, is occurring. Entities are subject to audit by the manufacturer or the federal government, and any entity that fails to comply with these requirements will be liable to the manufacturer for refunds of the discounts obtained illegally.

GPO Exclusion

Outpatient pharmacies of disproportionate share hospitals are not permitted to purchase through a 340B contract *and* a group purchasing organization concurrently unless they purchase through the prime vendor program.

B. 340B Implementation Options

The 340B legislation mandates certain requirements and prohibitions, but it does not otherwise specify how the delivery of drugs to patients should occur. In other words, there are many possible options for setting up a 340B delivery system, as long as they follow the legislation and guidelines. The most common ways of structuring a 340B pharmacy program can be classified into three broad categories: in-house pharmacy, contract pharmacy, and in-house dispensing. In addition to these categories, OPA has established a mechanism to test alternative methods of 340B participation.

This section provides:

- a chart describing the three most common 340B options
- a narrative summary of alternative methods to 340B participation
- a chart of implementation criteria for 340B options
- a brief narrative section describing each 340B option

Comprehensive information about each option, including helpful hints, case studies and timelines, appears in Appendix V.

Overview of the Three Most Common 340B Implementation Options

	In-House Pharmacy	Contracted Pharmacy	Provider / In-House Dispensing
General Description	<p>Health Center:</p> <ul style="list-style-type: none"> Owns drugs, pharmacy, and pharmacy license Purchases drugs Assumes fiscal responsibility for pharmacy Pays pharmacy staff <p>Additional: Special guidances^{32,33} may be helpful for issues regarding in-house pharmacies operated by management companies</p>	<p>Health Center:</p> <ul style="list-style-type: none"> Owns drugs Purchases drugs³⁴ Pays dispensing fees to contracted pharmacy or arranges for patients to pay dispensing fees to contracted pharmacy Signs contract with pharmacy to provide pharmacy services <p>Contracted Pharmacy:</p> <ul style="list-style-type: none"> Owns pharmacy and pharmacy license Manages and is fiscally responsible for pharmacy operation Pays pharmacy staff <p>Additional:</p> <ul style="list-style-type: none"> Drugs are usually sent from drug wholesaler directly to pharmacy for dispensing under a ship-to/bill-to arrangement Special guidelines³⁵ apply to contracted pharmacy arrangements 	<p>Health Center:</p> <ul style="list-style-type: none"> Owns drugs Employs providers licensed to dispense in the state Holds a license for dispensing for the health center³⁶ Assumes fiscal responsibility for operating and/or dispensing costs <p>Additional:</p> <ul style="list-style-type: none"> Hiring a full-time pharmacist is usually not required for provider dispensing If a pharmacist is employed by the clinic, some states will not permit that pharmacist to dispense medications if the clinic does not also hold a pharmacy license (however, these pharmacists usually may provide patient care services)
Subtypes	<ul style="list-style-type: none"> Traditional Telepharmacy³⁷ Management company–operated 	<ul style="list-style-type: none"> Retail contract Mail order contract 	<ul style="list-style-type: none"> Provider dispensing Provider dispensing in a licensed dispensary³⁸

Alternative Methods³⁹

Soon after the 340B Program was initiated in 1992, entities began expressing interest in the possibilities of exploring new ways to increase access to 340B priced medications. Advances in computers and changes in pharmacy practice have since produced pharmacy options that make sense for entities and patients, but were not conceivable at the time the legislation was written. To deal with unique situations in light of the advances in pharmacy practice, the Office of Pharmacy Affairs (OPA) began allowing entities to submit proposals in June 2001 to increase access to

the 340B program through alternative means that were outside of standard 340B guidelines.

Approved, time-limited demonstration projects are carefully evaluated based on benefits provided and compliance with requirements of the 340B law. These demonstrations are still under evaluation, but if found to be successful, the new methods of accessing discounted drugs may be incorporated into the 340B program's published guidelines. The OPA website contains details regarding the approval process and criteria. It is important to note that demonstration projects are **not funded** grant activities, and there is **no deadline** for submission of proposals. Proposals may be submitted at any time.

The following types of alternative methods are considered, alone or in combination with one another:

Alternative Method Type	Rationale
The development of a network of covered entities	340B eligibility is conferred to entities and patients of the entities. However, patients of one entity have not been permitted to visit another entity's pharmacy for 340B drugs, unless a contracted relationship was in place. This method allows eligible entities to purchase as a network of entities and/or share patients among the network pharmacies without instituting a traditional contracted pharmacy relationship.
The use of multiple contracted pharmacy services sites for a single clinic	The guidelines for contracted pharmacy specifically state that one pharmacy per covered entity is permitted in a contracted situation, but that "alternative methods" will be investigated to explore other options.
The utilization of a contracted pharmacy to <i>supplement</i> in-house pharmacy services	Traditionally, a clinic has been permitted to either operate an in-house pharmacy <i>or</i> participate in a contracted arrangement. This method would permit simultaneous operation of both types of pharmacy services for a single clinic.

	Full In-House Pharmacy	Operated by Management Company	Telepharmacy	Provider Dispensing/ Licensed Dispensary	Contract with Community Pharmacy	Contract with Mail Order Pharmacy
Start-up dollars	High, usually > \$200,000	Medium, will vary depending on program structure	Variable, depending on program structure	Low, usually <\$50,000	\$0+	\$0+
Ongoing dollars⁴⁰	High	High	High	Low	Low	Low
Expertise	Pharmacist	Company would likely supply	Pharmacist, technical / computer	Consultant pharmacist recommended or required	Consultant pharmacist or pharmacist at pharmacy	Consultant pharmacist or pharmacist at pharmacy
Time to start up	9+ months	6–9+ months	9+ months	3 months	3–6 months	3–6 months
Level of financial risk to health center⁴¹	High	Medium	Medium	Low	Low	Low
Control of day-to-day pharmacy operations	Health center	Management company ⁴²	Health center	Health center	Contracted pharmacy	Contracted pharmacy
Pharmacy space necessary for health center to provide	Most	Most	Most	Least	None	None
Health center's pharmacy-related record-keeping requirements	High	Low	High	Low	Moderate	Moderate
Staff supplied/ required by health center	Pharmacist ± technicians	None, or Pharmacist ± technicians	Pharmacist ± technicians	Dispensing providers (licensed)	None ⁴³	None

Narrative Summaries of 340B Options

1. In-House Pharmacies

In-house pharmacies are licensed to and owned by the health center. Most are located on-site within the health center.⁴⁴

Strengths	Challenges
<ul style="list-style-type: none"> ■ A pharmacist is an asset to clinicians (by providing drug information) and to patients (by providing pharmaceutical care) ■ A pharmacist may help establish a comprehensive, cost-effective, indigent drug program, complete with samples, PAPs, and Pfizer's Sharing the Care⁴⁵ ■ There may be potential for added revenue from the pharmacy, depending on the payer mix and fee structure ■ In-house pharmacies are highly convenient for the patient and the provider ■ Significant discounts/savings may be able to be passed on to patients, if desired, where per unit overhead cost allocation is less than fees to another pharmacy to provide service ■ Can tap revenue sources that are unavailable in other models ■ If successful, can be a revenue (instead of cost) center for the organization 	<ul style="list-style-type: none"> ■ In-house pharmacies carry the potential for significant financial risk to the health center (with a high start-up cost and a potentially high ongoing cost) if they are not self-sustaining ■ The ability to hire a pharmacist may be compromised due to a national shortage of pharmacists, the inability to offer a competitive compensation package, or geography ■ The health center may not have enough space available to accommodate an in-house pharmacy

The Three Subtypes of In-House Pharmacies

Traditional

The pharmacy is owned and operated by the health center, the pharmacy license is in the health center's name, and a pharmacist is employed (as an employee or an independent contractor) by the health center. This option works well if the health center is able to hire a pharmacist, has confidence in the pharmacist or the administration to operate the pharmacy, and has a payer mix and collection capability that will enable the pharmacy to break even. Health centers that want complete control over the day-to-day operation of the pharmacy find a traditional model appealing.

Management Company–Operated

The pharmacy is owned by the health center but operated by a management company, the pharmacy license is in the health center's name, the overall responsibility for the pharmacy remains with the health center, and the pharmacist is often employed (as an employee or an independent contractor) by the management company. This option works well if the health center is not able to hire a pharmacist or does not have confidence in the administration to operate the pharmacy. Health centers that do not want to manage the day-to-day operation of the pharmacy find this option appealing. However, keep in mind that all funds paid to the management company could potentially belong to the health center instead, and that the management option results in increased cost to either the center or its patients.

Telepharmacy

The pharmacy utilizes technology (high-speed Internet, video equipment, remote dispensing machines, and pharmacy computer software) to enable a pharmacist at a central site to dispense drugs in real-time to a remote site(s) that typically does not have a pharmacist. This option may be a traditional in-house pharmacy, or a contracted pharmacy may supply the dispensing machines to the clinic. In the case of a contracted pharmacy arrangement, the pharmacy may buy or lease the equipment, place the unit in the clinic, and dispense remotely. Telepharmacy is appealing to health centers with multiple sites (especially if the remote sites do not have access to local pharmacies, i.e. rural locations), if there is difficulty hiring and retaining pharmacists for the different sites, if the health center is comfortable with a high level of technology, and if the health center has considerable start-up funding to purchase or lease the technology. This option requires consent from and cooperation with the state board of pharmacy.

2. Contracted Pharmacies

Contracted pharmacies are licensed, owned, or operated by chain or independent drug stores rather than by the health center. The pharmacy signs a contract with the health center to provide all of the pharmacy services for the health center. The health center purchases and maintains overall responsibility for the 340B drugs but contracts with the pharmacy for the services related to ordering, dispensing, and pharmaceutical care.

Strengths	Challenges
<ul style="list-style-type: none"> ■ The health center may be able to provide the pharmacy service with little to no start-up or ongoing financial risk ■ The pharmacy's economy of scale negates the need for attaining a "break even" point to offset overhead costs ■ The health center does not have to worry about the day-to-day operation of the pharmacy ■ The health center gains access to existing expertise in pharmacy operations (e.g., third-party billing) ■ The pharmacy "usual and customary" charge becomes the retail billing basis for third-party transactions⁴⁶ ■ The health center gains access to capabilities inherent in pharmacy management software for recording, report generation, and convenience for audit functions ■ The pharmacy hours and location may be more convenient for patients ■ The health center does not have to hire a pharmacist yet gains access to a pharmacist, whose ability to provide drug information and/or other professional services is an asset to clinicians at the center ■ Patients have access to pharmacist consulting services, drug interaction guidance, and other services 	<ul style="list-style-type: none"> ■ Finding a willing pharmacy may be a challenge, due to (a) a lack of pharmacies whose location or business model position them as potential partners and (b) those whose existing misconceptions about the program present a barrier ■ The health center will not have access to Pfizer's Sharing the Care⁴⁷ unless a grandfathered arrangement through the potential pharmacy partner is in place ■ Initially setting up the terms of the contract (reporting systems, fees, etc.) may take considerable upfront time ■ Special state requirements may unnecessarily complicate the program (e.g., Board of Pharmacy regulations requiring dual physical inventories or restricting certain efficient practice models) ■ Under current guidelines, a health center may only contract with one pharmacy, which could create tension in a community with multiple qualified and interested potential pharmacy partners⁴⁸ ■ There may be less opportunity to offer low prices to patients due to the fact that the pharmacy will likely require a fee that covers its costs and possibly adds profit for the pharmacy and/or the center ■ Designated clinic staff must be responsible for oversight and auditing functions reconciling pharmacy billing and the medications dispensed

The Two Subtypes of Contracted Pharmacies

Community/Retail Contracts

The local pharmacy holds the pharmacy license, employs the pharmacist, and manages the day-to-day operation of the pharmacy. The health center or patients send the prescriptions to the pharmacy via fax, email, or in person; and the patients visit the pharmacy to pick up their medications and access face-to-face pharmaceutical care services. This option works well if the health center cannot or does not want to take responsibility for the day-to-day operation of a pharmacy, if the health center is unable to hire a pharmacist, or if the health center does not have space for a pharmacy. Opportunity exists for collaborative patient care services where the local pharmacy currently offers comprehensive pharmacy services and participates as a care team member, or has interest in developing such services. A local pharmacy is appealing to health centers that wish to support local businesses.

Mail Order Contracts

The mail order pharmacy holds the pharmacy license, likely employs the pharmacist, and manages the day-to-day operation of the pharmacy. The health center or patients send the prescriptions to the pharmacy via fax, telephone, email, or mail; and patients receive the prescriptions through the mail. This option works well if the health center cannot or does not want to take responsibility for the day-to-day operation of the pharmacy, if the health center is unable to hire a pharmacist, if the health center does not have space for a pharmacy, if there are no interested or convenient local pharmacies, if the patients deem mail order as an acceptable way to receive prescriptions, if the health center does not have a high percentage of transient patients, if the patients use predominately maintenance medications (as opposed to acute care medications), and/or if the health center is not worried that using mail order pharmacy will create friction with local businesses.

3. Provider Dispensing

Provider dispensing utilizes health center providers to dispense drugs to patients on-site. Typically the state boards of medicine or pharmacy⁴⁹ regulate this practice, so guidelines⁵⁰ are slightly different in each state. *The 340B legislation does not directly address provider dispensing.* Provider dispensing options usually incorporate drugs purchased from a wholesaler, samples, and patient assistance programs (PAPs). Most states require the providers to follow the same prescription labeling and record-keeping requirements that fully licensed pharmacies follow.

Strengths	Challenges
<ul style="list-style-type: none">■ There is little financial risk to the health center■ Additional staff is not always required■ Most states do not require the health center to hire a pharmacist as staff, which is helpful for sites in rural areas or sites severely impacted by the pharmacist shortage■ This may be the only option if the health center is unable to have an in-house or contracted pharmacy	<ul style="list-style-type: none">■ Providers may find dispensing time-consuming and burdensome, viewing time committed to dispensing as a lost opportunity for providing primary care services■ No pharmacist⁵¹ is intimately involved in the dispensing and medication use process, which may increase the risk of medication errors, drug interactions, and therapeutic duplications■ There is not a great potential for revenue from provider dispensing, particularly in states that restrict provider dispensing activities■ No access to Pfizer's Sharing the Care■ Limited access to medications due to inventory capabilities, possible space restrictions, and difficulty obtaining reimbursement from third-party payers■ Using physicians as dispensers increases the true cost of dispensing due to their associated salary costs and the lost revenue from fewer encounters

The Two Subtypes of Provider Dispensing⁵²

Traditional Provider Dispensing

Traditional provider dispensing uses providers that volunteer or are employed by the health center to dispense drugs to their patients. Most providers are licensed to dispense by their respective state board, as opposed to the entity receiving a license to dispense (although some states do require both). The providers assume full responsibility for dispensing to their patients. This model is appealing to sites that have patients with transportation barriers to pharmacies, no nearby pharmacies or no pharmacists willing to work for the entity, little or no start-up funding for a pharmacy, small patient populations with limited medication needs, and providers that are willing to take on extra administrative work.

Licensed Dispensaries⁵³

Licensed dispensaries afford certain health centers the ability to obtain a state-issued dispensary license in the entity's name, which allows the clinic to purchase drugs for administration or dispensing to clinic patients under a physician's direction. The advantage of this model compared to traditional provider dispensing is that a licensed dispensary allows the entity to hold a dispensary license instead of having every provider licensed to dispense. In other words, in a licensed dispensary, one provider may assume responsibility for the entire dispensing operation. However, this one provider must be licensed by the state to dispense medications. To obtain the entity's dispensary license, the entity must develop written policy and procedures that are pharmacist-approved. A consultant pharmacist is typically required to supervise the dispensary by approving policies and procedures and making regular visits to the clinic. Individual providers that are not specifically licensed to dispense (without a dispensing permit) would need to own the medications.

C. The Four Cornerstones of Comprehensive Pharmacy Services

The 340B program is a powerful tool for entities, but merely participating in the program is not enough to ensure a successful pharmacy service. Successful pharmacies ensure that a *comprehensive pharmacy service*⁵⁴ is delivered to patients. A comprehensive pharmacy service consists of four critical cornerstones:

- I. Access to affordable medications using 340B and prime vendor programs
- II. Outcomes-driven pharmaceutical care
- III. Efficient business practices
- IV. Quality assurance⁵⁵

All pharmacy models considered by clinics should be evaluated on the model's ability to deliver each aspect of comprehensive pharmacy services.

This section will provide:

- a description of each remaining cornerstone
- suggested actions for maximizing value
- suggested areas for evaluation

Cornerstone I: Access to Affordable Medications

This manual has already addressed on pages 2–16 the first cornerstone of comprehensive pharmacy services: access to affordable medications using the 340B and prime vendor programs.⁵⁶ The remaining three cornerstones are explained in this section of the manual.

Cornerstone II: Outcomes-Driven Pharmaceutical Care

Description

Pharmaceutical care is a patient-centered, outcomes-oriented pharmacy practice that requires the pharmacist to work in concert with the patient and the patient's other health care providers to promote health, to prevent disease, and to assess, monitor, initiate, and modify medication use to assure that drug therapy regimens are safe and effective. The goal of pharmaceutical care is to optimize the patient's health-related quality of life and achieve positive clinical outcomes, within realistic economic expenditures.⁵⁷

Suggested Actions for Maximizing the Value of Pharmaceutical Care

- Seek reimbursement for pharmaceutical care services
- Manage drug formulary
- Provide immunization services
- Utilize pharmacist-directed disease management clinics, or utilize pharmacist as a member of the interdisciplinary disease management team directed by a physician, nurse, or PA
- Provide patient counseling
- Offer health promotion seminars for patients
- Ensure unbiased medication education to providers
- Undertake drug utilization review
- Establish collaborative practice agreements between pharmacists and providers

Suggested Areas for Evaluation of Pharmaceutical Care

- Financial impact
- Patient or provider satisfaction
- Drug utilization
- Clinical interventions
- Patient compliance
- Formulary adherence
- Patient outcomes
 - Health measurements
 - Hospitalization rates
 - Quality of life assessments

Administrators commonly make this plea at the onset of investigating ways to implement pharmacy services: “I need to figure out how to get affordable drugs for patients.” Although it is tempting to focus on the provision of “affordable drugs,” it is essential to grasp the fact that pharmacy provides value in terms of the drug product and the associated service, called *pharmaceutical care*. The American Pharmacists Association has defined pharmaceutical care as a patient-centered, outcomes-oriented pharmacy practice that requires the pharmacist to work in concert with the patient and the patient’s other health care providers to promote health, to prevent disease, and to assess, monitor, initiate, and modify medication use to assure that drug therapy regimens are safe and effective. The goal of pharmaceutical care is to optimize the patient’s health-related quality of life and achieve positive clinical outcomes, within realistic economic expenditures.⁵⁸

One practical example of pharmaceutical care is manifested in a pharmacist-directed disease management clinic. This involves a pharmacist monitoring patients' health and drug regimens through private, scheduled appointments; making recommendations to physicians for changes in drug therapy; prescribing under protocol through collaborative practice agreements;⁵⁹ receiving reimbursement for such services through third-party or cash payers; and monitoring and affecting patient outcomes. Considering that costs associated with the adverse effects of pharmaceuticals in the United States exceed \$177 billion each year – more than the cost of drugs themselves⁶⁰ – inclusion of pharmaceutical care is a vital component of a safe and cost-effective overall pharmacy system.

Imagine pharmacy services as a seesaw, with one side representing the delivery of drugs and the other side representing delivery of pharmaceutical care. If the pharmacy system simply provides drugs and no pharmaceutical care, what is the outcome? The system is lopsided. The ultimate goal should be balanced provision for the delivery of affordable drug product and pharmaceutical care.

A pharmacist is the best-prepared professional to achieve this critical balance. Pharmacists' extensive training consists of undergraduate work, a four-year professional program, optional residency, fellowship, and/or postdoctoral work. This focused study results in licensed professionals with the documented ability to improve financial and health outcomes. Literature affirms the following:

- Pharmacists providing pharmaceutical care services generate a return-on-investment (ROI) of \$17 per patient for every dollar invested.⁶¹
- As hospitals increase the number of pharmacists providing pharmaceutical care, medication errors decrease by more than 65%.⁶²
- Pharmacists providing asthma management services and pharmaceutical care to employers decreased cost, improved care, and improved work absence rates.⁶³
- As a result of comprehensive pharmacist counseling, ambulatory patients used significantly fewer health services, saving over \$640 a year in health costs per individual (\$280,000/year per pharmacist).⁶⁴

The expertise of a pharmacist is critical to a successful pharmacy operation. Although all 340B pharmacy options discussed in this manual do not require hiring a staff pharmacist, each option involves some pharmacist oversight.

What Services Can a Pharmacist Provide?

- Help control drug costs for clinics and patients
- Design and manage a drug formulary and sliding fee scale
- Provide patient-specific education
- Provide unbiased medication education to providers
- Present seminars for patients on health promotion

- Actively manage chronic disease states by working in collaborative arrangements with physicians and other providers
- Check for drug interactions and medication concerns/medication appropriateness
- Reduce medication errors
- Bolster clinic Joint Commission on Accreditation of Healthcare Organizations (JCAHO) / Accreditation Association for Ambulatory Health Care (AAAHC) visits by improving quality of care, reducing medication errors, and enhancing medication safety
- Support clinic-based quality assurance activities

One primary care physician from an underserved health care setting reports:

“I can eagerly vouch for the value to patients, physicians, and other health care staff of including a pharmacist on the primary care team. I have seen lifesaving clinical interventions, improvements in patient compliance, and effective management of pharmacotherapy all initiated by alert pharmacists directly involved in patient care. I have enjoyed the benefits of tapping the clinical pharmacists’ unique body of knowledge concerning drug therapy, pharmacoeconomics, drug interactions and kinetics, and their application to patient treatment. The pharmacist is a powerful resource to improve the therapeutic milieu that impacts patient outcomes.”

– P.B. AMADIO, MD⁶⁵

Suggested Actions for Maximizing the Value of Pharmaceutical Care

Seek reimbursement for pharmaceutical care services.

In addition to cash payers, some third-party payers, Medicare,⁶⁶ and state Medicaid agencies currently reimburse for pharmaceutical care services. State Medicaid agencies permitting reimbursement of pharmaceutical care services generally utilize a HCFA-1500 claim form in conjunction with the Professional Pharmacy Service (PPS) codes.⁶⁷

If health center payers do not reimburse for pharmaceutical care, establishing a systematic approach to the service and proving its value results in the greatest likelihood of obtaining reimbursement. Suggested steps include:⁶⁸

1. Applying for a provider number from the third-party program, or utilizing the physicians’ group practice provider number for billing
2. Procuring and submitting appropriate claim forms with proper documentation of services
3. Developing data collection and documentation systems
4. Establishing professional fees, possibly using the American Medical Association’s current procedural terminology (CPT) codes
5. Creating a marketing plan

6. Developing an accounting and billing system
7. Obtaining a statement of medical necessity from the patient's physician

The Medicare Modernization Act (to be implemented in 2006) contains a special provision for a medication therapy management program for beneficiaries.⁶⁹ It establishes provider status for pharmacists, and allows pharmacists to be paid to counsel targeted beneficiaries with the goal of lowering the plan's and the consumer's out-of-pocket costs as well as improving health outcomes. Expect the details to be released via regulation in 2005.

Manage a drug formulary.⁷⁰

Pharmacists interpret drug information to make recommendations and decisions regarding the safest, most appropriate and cost-effective drugs for patients. This can help lower the drug inventory the pharmacy maintains (resulting in lower costs for the clinic) and help patients receive only the most cost-effective therapies (resulting in lower costs and better medication outcomes).

Utilize pharmacist-directed disease management clinics, provide patient counseling, and offer health promotion seminars.

Education that the pharmacist provides to patients includes counseling at the time of medication pick-up, but it can be supplemented through written information, scheduled appointments with the pharmacist,⁷¹ group training and consultations, or a health promotion initiative.

Ensure unbiased medication education to providers.

The pharmacist provides updates to providers in the form of a periodic newsletter or provider meetings. This communication is essential to encourage rational prescribing and formulary adherence, especially if the clinic has frequent visits from drug representatives. Rational prescribing and formulary adherence should result in improved patient health, as well as reduced clinic and patient costs.

Undertake drug utilization review.

A pharmacy and therapeutics (P&T) committee provides oversight and guidance on various pharmacy matters, most notably the drug formulary. The P&T committee reviews such reports as drug utilization, quality assurance, error rate, and performance improvement. This information is used to set or change policy, which often results in controlling pharmacy or patient costs. Performance-improvement activities can help minimize medication errors to improve patient outcomes and potentially decrease the cost to the clinic from prevented lawsuits/malpractice.

Establish collaborative practice agreements between pharmacists and providers.⁷²

Such agreements typically allow physicians (or in some states, nurse practitioners) to authorize pharmacists to engage in adjusting and/or initiating drug therapy. This will allow the pharmacist and provider to work as a team to maximize the benefits

of their unique skill sets. Health centers can incorporate such services in ongoing or anticipated Health Disparity Collaborative activities. Each state generally governs collaborative practice via the state pharmacy practice act, although some boards of pharmacy have created regulations based on broad authorizing language. For additional information, visit www.healthdisparities.net/index.html.

Suggested Areas for Evaluation of Pharmaceutical Care

The rationale for measuring the impact of pharmaceutical care is to ensure the pharmacy is providing a safe, effective, outcomes-driven service. The primary methods for assessment include documenting the financial impact, assessing the patient and provider satisfaction, evaluating drug utilization, tracking clinical interventions, patient compliance, formulary adherence, and patient outcomes. Specific patient outcomes might include health measurements, hospitalization rates, or quality of life assessments. The information learned from clinical evaluation can be used to gauge the effectiveness of pharmaceutical care, or to trigger related improvements or changes.

Cornerstone III: Efficient Business Practices

Description

Efficient business practices in pharmacy can be addressed from the administrator's perspective and categorized into two major components:

1. **Operational** (location, space, equipment, hardware/software, competition, marketing, staff allocation, integration with the clinic, pharmacy management structure, design/layout, work flow)
2. **Financial** (acquiring the drug, setting the price, collecting compensation)

Suggested Actions for Maximizing the Value of Efficient Business Practices

Operational

- Ensure that the physical layout and space of the pharmacy facilitates smooth work flow and private patient counseling
- Develop a manual of policies and procedures
- Use technology appropriately
- Establish immediate, intermediate, and long-term goals for the pharmacy service
- Think “location, location, location” when allocating space for pharmacy
- Position the pharmacy as an integral part of the clinic operation
- Establish an accountable pharmacy manager/director
- Always clarify perspective when discussing pharmacy issues (e.g., medication costs for the patient vs. costs to the pharmacy)
- Consider using the 340B program for purchasing medications administered in the clinic

Financial

- Negotiate effectively with a supplier
- Ensure that drug purchasing is cost-effective by participating in the 340B program and evaluating various wholesalers, including the prime vendor
- Keep an eye out for low prices, but do not overbuy to save money
- Carefully scrutinize the overall impact of samples and PAPs before incorporating them into the pharmacy service
- Use payer sources and inventory needs in addition to cost and clinical factors when designing a formulary
- Tightly control inventory
- Strive for reimbursements to cover overall pharmacy costs
- Structure the sliding fee scale to suit the health center’s philosophy and meet the pharmacy’s operational/financial goals
- Evaluate the Medicaid carve out option
- Consider the new Medicare Drug Benefit
- Assess the effect of accepting all-inclusive rates on the pharmacy
- Analyze capitated pharmacy reimbursement before accepting it
- Consider conflict of interest and rebates when working with PBMs
- Market the pharmacy service
- Target and measure the pharmacy’s capture rate for prescriptions
- Analyze refilled prescriptions

Suggested Areas for Evaluation of Efficient Business Practices

Operational

- Average wait time for patients
- Appropriate use of staff
- Breaking down the dispensing process to look for inefficient practices
- Appropriateness of the pharmacy space, location, equipment, and physical layout

Financial

- Total pharmacy expense and revenue
- Average cost and margin per prescription
- Number of prescriptions filled per unit time
- Payer mix of pharmacy patients
- Inventory turnover rate
- Pharmacy prescription capture rate
- Sliding fee scale (number of prescriptions and clinic cost)
- Brand vs. generic mix (this measure is less relevant than accurate evaluation of margins, because 340B and Pfizer Share the Care programs frequently make brand usage less costly than generics)

Administrators have described the operational and financial aspects of pharmacy as “an unknown quantity and a black hole of unknown costs.”⁷³ With that impression, it’s no wonder that administrators are deterred from implementing a pharmacy service!

Fortunately, efficient business practices in pharmacy can be addressed from the administrator’s perspective and categorized into two major components:

1. Operational
2. Financial

This section describes the major players, transactions, and concepts associated with each component of efficient business practices.

Operational

The key aspects of pharmacy operations include the location, space, equipment, hardware/software, competition, marketing, staff allocation, integration with the clinic, pharmacy management structure, design/layout, and work flow. The associated costs to the pharmacy represent fixed costs.

Financial

Acquiring the Drug

Drug manufacturers set prices for drugs and sell to buyers – most commonly drug wholesalers, but also pharmacies or other buying groups. Drug wholesalers tack on a very small margin and sell the drugs to pharmacies. The variable costs to the pharmacy associated with purchasing are attributed to the drugs and the fees charged by the wholesaler. Drug products that the pharmacy or health center owns represent inventory.

Setting the Price

Drug pricing is incredibly elusive, and prices for drugs are adjusted by drug manufacturers. The standard reference point used in drug pricing is AWP (average wholesale price), which is similar to a sticker price for a car. Buyers do not pay AWP, sellers do not sell at AWP – and hence AWP represents a superficial number. CMS administrator Mark McClellan recently said of AWP, “Nobody knows what it means!”⁷⁴ Nevertheless, the standard for drug pricing currently remains AWP, despite widespread criticism about its usefulness.⁷⁵ CMS drug reimbursement changes for Medicare Part B-covered drugs are likely to lead to the abandonment of AWP as a benchmark in the future. However, drug prices are currently often determined using a formula derived from discounts on AWP. Other methods to establish drug prices are based on pricing terms such as MAC, WAC, AMP, and AAC.⁷⁶ Because AWP is the most frequently used standard in drug pricing, this manual will use AWP-based formulae for simplicity.

Collecting Compensation

Pharmacies collect money from payers such as patients paying cash or third parties paying on behalf of patients. The purpose of collecting compensation is to allow the pharmacy to profit or at least cover its costs, which consist of variable costs (purchasing drugs) and fixed costs (performing services). The amount collected compared with the cost determine whether the pharmacy operates at a profit or a loss, or if it breaks even.

Traditional Fee-for-Service

Compensation collected from payers varies in terms of the amount of compensation and the formula used to derive the compensation. Because the most common way to derive pricing is based on AWP, the following example uses AWP. Although it seems logical that reimbursements for drug and fees for service would be balanced with costs for drug and service, the formula tends to overcompensate the drug reimbursement and undercompensate the fee for pharmacy service. Magically, the overall compensation usually covers total costs.

For example:



Third party payers typically state the drug reimbursement formula in a contract, and the health center chooses to accept the payer source and terms. Prices for cash-pay patients are set by the pharmacy using the same basic formula, and these prices are called “retail” prices.

Pricing Example for Brand Drugs^{77,78}			
Drug Manufacturer	Wholesaler	Clinic/Pharmacy	Payer
Sets drug prices	Charges distribution fees to clinics / pharmacies	Sets patient prices or agrees to reimbursement terms	Pays for drug
	Pays manufacturer: AWP–23%	Pays wholesaler: AWP–20%	Cash patient pays: AWP+4% Third party pays: ⁷⁹ AWP–13% + \$2.50 Medicaid pays: ⁸⁰ AWP–10% + \$2.50
AWP=\$100.00	Pays \$77.00	Pays \$80.00	Cash patient pays: \$104.00 Third party pays: \$89.50 Medicaid pays: \$92.50

Capitation Managed care contracts are sometimes signed between pharmacies and insurers. In these situations, the pharmacy is paid a fee, usually per member, per month, to provide pharmacy services to covered patients. This fee can vary widely depending upon the patient population, its utilization patterns, the part of the country, and other factors. Capitation is typically used by HMOs and other managed care providers.

All-Inclusive Rates Payers, notably Medicaid in some states, may contract with clinics to reimburse at an “all-inclusive rate” for patient visits. This rate includes all or most services the patients receive from the clinic. For example, the rate might include the provider’s time, lab, radiology, and pharmacy.

Pharmacy Benefit Managers (PBMs): The Middle Men Because managing a pharmacy benefit requires considerable expertise and constant attention, many insurance companies, private companies, or other groups contract with pharmacy

benefit managers to perform services on their behalf. PBMs usually have contracts with wholesalers/manufacturers for drug rebates based on formulary placement, companies for the management of their pharmacy benefit, and pharmacy networks for dispensing and reimbursement management. The PBMs often charge a fee for their services to clinics or pharmacy on a per-prescription basis, and fees range from \$0.25 to \$1.00 per prescription. They also charge pharmacies on a per claim basis.

Entities Contracting with PBMs	
Wholesalers/ Drug Manufacturers	<ul style="list-style-type: none"> ■ PBMs negotiate prices with wholesalers / manufacturers⁸¹ ■ PBMs get rebates from wholesalers for timely payment and from manufacturers for moving market share
Clinic	<ul style="list-style-type: none"> ■ Under contract, the PBM provides services for the clinic including: data collection, formulary design, co-pay management, on-line reimbursement /billing/payment, and disease management arrangement ■ Clinic pays PBMs a per prescription fee
Pharmacy	<ul style="list-style-type: none"> ■ Pharmacy serves as a provider for the PBM and pharmacy accepts reimbursement terms ■ PBM's computer systems communicate critical information to the pharmacy's computer, including: patient co-pays, pharmacy's reimbursement (this is passed from company to pharmacy via PBM), covered drugs, and patient eligibility ■ Pharmacy may also pay PBMs a per prescription fee

Data collection and claims adjudication (price negotiation, bouncing claims against plan parameters, checking eligibility, paying claims) are some of the most critical services that a PBM provides. Without data, it would be difficult for payers to know what drugs patients take, where patients visit pharmacies, and how much the pharmacy benefit costs.

Suggested Actions for Maximizing the Value of Efficient Business Practices

The relevant models – in-house, contract, provider dispensing – are listed in parentheses at the end of each suggested action.

Operational

Ensure that the physical layout and space of the pharmacy facilitate smooth work flow and private patient counseling.

If the pharmacy will be the result of new construction, there are fixture companies that can help design the pharmacy space. Pharmacy wholesalers will likely have contact information for fixture companies in the local area. Usually this design is given as a free estimate. Patient privacy is extremely important, and ideally a space should be devoted to providing patient counseling that is sheltered from the waiting area. The

pharmacy space should be big enough to store inventory and allow adequate work flow, but not so large that rental costs are excessive. (ALL MODELS)

Develop a manual of policies and procedures.

Not only will this help the overall organization of the service, many states will require this in order to obtain a pharmacy license. (ALL MODELS)

Use technology appropriately.

The appropriate use of technology can increase productivity, especially if prescription volume is high and staff supply is low. Examples of technology commonly used in pharmacies include automatic pill counters, electronic signature capture, electronic formulary management, IVR systems, workflow management systems, robotics, automated refill systems, and user-friendly computer systems. (ALL MODELS)

Establish immediate, intermediate, and long-term goals for the pharmacy service.⁸²

It is preferable to start small and grow the service over time. (ALL MODELS)

Think “location, location, location.”

Whether the pharmacy is located in-house or off-site, a convenient location will encourage patients to use the pharmacy. Before constructing a new pharmacy, evaluate the impact of local competing pharmacies on the new pharmacy. (ALL MODELS)

Position the pharmacy as an integral part of the clinic operation.

The success of the pharmacy will in part depend on patients' use of the pharmacy, providers' adherence to the formulary, and budget considerations. The pharmacy should have a representative (such as a director) that attends provider meetings and has a voice for pharmacy in the overall clinic management structure. Seamless communication between the pharmacy and the rest of the clinic will serve all parties well. (IN-HOUSE, PROVIDER DISPENSING)

Establish an accountable pharmacy manager/director.⁸³

Given direct accountability for the pharmacy operation, the pharmacy director will be empowered to make decisions and take responsibility. Consider having the pharmacy director report to the CEO as opposed to the CMO. Although many pharmacy issues are clinical in nature, the CEO is usually more familiar with the financial issues that impact pharmacy services. (IN-HOUSE, PROVIDER DISPENSING)

Always clarify perspective when discussing pharmacy issues.

For example, terms such as *cost* and *price* mean different things to different people: a pharmacist might think of *cost* as meaning the pharmacist's cost to purchase a drug, whereas a patient will think of it as the patient's cost to buy the drug. The price of a

drug will mean a very different number to the manufacturer and to the final payer for the drug. Paying careful attention to perspective will simplify communication.
(ALL MODELS)

Consider using the 340B program for purchasing medications administered in the clinic.

An example would include injectables, such as Depo-Provera.

Financial

Negotiate effectively with a supplier.

The pharmaceutical supply sector operates within a highly competitive marketplace. Astute purchasers may take advantage of this competitive environment to lower acquisition costs. Some strategies for effective negotiation include:

- **Group Purchasing Organizations (GPOs):**⁸⁴ The power to direct a compliant membership to purchase drugs from a particular vendor gives the GPO leverage to negotiate for a better price. In the case of wholesalers, the GPO negotiates the percentage-based service charge or WAC discount. GPOs similarly negotiate with generic distributors and multi-source drug manufacturers, and pharmacy-related product suppliers. The use of preferred product lists prompts the supplier to offer incentives to the GPO to be included on these lists. The national prime vendor program is intended to serve as a GPO for 340b-eligible entities.
- **Volume purchasing:** Large purchasers, such as hospitals or large clinics with multiple sites, are similarly positioned to negotiate better pricing. Their negotiated arrangements can include the GPO, where they may be entitled to larger discounts based on contract participation (volume).
- **Payment terms:** Suppliers carry huge inventories, and the cost of maintaining those inventories is substantial. They rely on manufacturer credit arrangements (usually 30 days, or 10 days from the end of the month) to “float” those inventories. When the float is exhausted (i.e., payment is due before the inventory is sold and/or payment from the retail customer is forthcoming), the supplier depends on costly bank loans to satisfy the manufacturer. To offset the cost of money, the supplier usually creates incentives for early payment. Traditionally, retail pharmacies pay on the 10th and 25th of the month for purchases from the 15th to the 31st of the preceding month, or the 1st through the 15th of the current month, respectively. Improving the promptness of payment will improve the terms from the supplier. For example, if the pharmacy pays the wholesaler weekly, the pharmacy might receive an additional 0.125% discount, whereas prepayment of a whole month’s anticipated purchases might bring an additional 0.5% discount off of the price. Likewise, the supplier will always assess a late payment penalty for payment beyond contract terms. (All models)

Ensure that drug purchasing is cost-effective by participating in the 340B program and evaluating various wholesalers, including the prime vendor.

All entities receiving funding from HRSA receive the following statement in the Notice of Grant Awards (NGA) that addresses purchasing using 340B and the prime vendor:

If your organization purchases or reimburses for outpatient drugs, an assessment must be made to determine whether the organization's drug acquisition practices meet Federal requirements regarding cost-effectiveness and reasonableness (see 42 CFR Part 50, Subpart E, and OMB Circulars A-122 and A-87 regarding cost principles). If your organization is eligible to be a covered entity under Section 340B of the Public Health Service Act and the assessment shows that participating in the 340B Drug Pricing Program and its Prime Vendor Program is the most economical and reasonable manner of purchasing or reimbursing for covered outpatient drugs (as defined in section 340B), failure to participate may result in a negative audit finding, cost disallowance or grant funding offset.⁸⁵

(ALL MODELS)

Keep an eye out for low prices – but do not always overbuy to save money.

Occasionally, prices for specific drugs will drop to \$0.01/per bottle⁸⁶ due to wholesaler overstock or short expiration dates. Buying such drugs in bulk might save the clinic on purchasing costs, but it is wise to ensure before purchasing the drug that the supply will be prescribed by the provider, dispensed by the pharmacy, and used by the patient prior to the expiration date. (ALL MODELS)

Carefully scrutinize the overall impact of samples and PAPs before incorporating them into the pharmacy service.

Federal regulations⁸⁷ set forth in 2000 addressed the management of samples by free clinics and other safety net providers. A guide available through Volunteers in Health Care explains these requirements, as well as strategies for operating a sample program.⁸⁸ In addition to federal regulations, states often have regulations regarding the management of samples,⁸⁹ and it is best to investigate state requirements before incorporating samples into a pharmacy program.

Samples are a seemingly “free” source of medication for some patients, but in reality, sample supplies are limited and only given for brand-name (i.e., the most expensive) medications. Patients are started on an expensive drug that they likely cannot afford, which may result in discontinuity of care or patient noncompliance once the stock of supplies is exhausted. Although samples do have a place in therapy, the overall impact on the patient and the clinic should be considered before they are dispensed.

Furthermore, disposing of unused samples properly according to state law may require clinics pay a fee for sample destruction – sometimes as high as \$3/pound. This negates the idea that samples are “free.” Because of such costs, clinics often place limits on accepting samples for non-formulary drugs or for samples that are close to expiring (within 1–2 months).

In addition to samples, patient assistance programs (PAPs) – another seemingly “free” source of medications – are available to needy patients that meet specific criteria such as income, asset, and lack of insurance. The application process typically involves completing a form; submitting the form by mail, fax, or email; having the application approved by the manufacturer; and eventually shipping the drug to the patient or clinic. Because each drug manufacturer has a different process and eligibility criteria, the entire PAP system has been characterized as tedious and difficult to navigate. Clinics that assist patients in obtaining PAP medications invest considerable staff time in PAP administration and must assume significant costs in managing the PAP program.⁹⁰ Structuring an effective PAP system takes considerable time and effort, and is extensively explained in documents provided by Volunteers in Health Care.^{91,92} (ALL MODELS)

Balance payer sources and inventory needs with cost and clinical factors when designing a formulary.

A formulary ensures that patients are given the most cost-effective and safe medications, and it helps the pharmacist maintain appropriate inventory. It is a constant challenge in most pharmacies to stock the right amount of drugs for the right amount of time. Drugs are expensive and expire, and maintaining a high dollar amount of inventory could end up costing the pharmacy money. A formulary will enable the pharmacist to limit the variety of drugs that the pharmacy will stock, thereby resulting in a manageable inventory. Payer sources should also be a consideration in formulary design. For example, if most patients are cash payers, a generic-only or tightly monitored formulary might best suit the patients’ needs. However, if third-party payers comprise a significant portion of pharmacy income, limiting the formulary too much might drive patients and thus potential revenue sources away from the pharmacy. (ALL MODELS)

Control inventory tightly.

Pharmacies usually have limited funds to invest in inventory. In order to generate the cash necessary to pay bills and cover costs or return a profit, drugs must be sold before they expire. The inventory “turnover rate” measures how quickly inventory moves through a pharmacy. The goal of controlling inventory is to keep the minimal amount of drug on the shelf to serve the needs of the patients. Pharmacies often have weekly or even daily deliveries of drugs, because buying less product more often will improve inventory turns.

The turnover rate is calculated by taking the pharmacy’s annual cost of goods sold and dividing it by an actual annual inventory. Turnover rates are typically expected to be at least six times a year for pharmacies that have gross margins above about 15%. Lower-margin pharmacies will likely require a higher turnover rate. Higher-turn rates benefit all pharmacy models.

Strive for reimbursements to cover overall pharmacy costs.

If an in-house pharmacy is established, it should be financially self-sustaining. This means that either each payer covers the costs of service, or the pharmacy will allow profit from some payers (e.g., a third party) and loss from others (sliding fee cash), resulting in a net break-even or profit for the pharmacy. Pharmacies might decide only to accept contracts from third-party payers that adequately cover costs. It is important to note that since third-party contracts are based on AWP – % + fee, it is only the spread between AWP and 340B that makes most contracts financially acceptable to CHCs. The temptation to negotiate with third parties using tactics to give away portions of that spread must be approached with caution and understanding of the consequences. (ALL MODELS)

Structure the sliding fee scale to suit the health center’s philosophy and meet the pharmacy’s operational/financial goals.

Health centers that receive grants from HRSA are expected to offer “a method of discounting or adjusting fees based upon the patient’s income and family size from current Federal Poverty Guidelines” *for all services offered to patients*.⁹³ As long as the pharmacy’s costs are covered, the pharmacy can be creative in the design of the fee scale. (ALL MODELS)

Evaluate the Medicaid Carve-Out option. The 340B law requires Medicaid agencies to reimburse covered entities for 340B purchases according to a cost + fee formula, as opposed to a typical AWP – X% + fee formula. Medicaid dispensing fees typically range between \$2.50–\$5 per prescription and vary considerably by geographic region.⁹⁴ A non-340B pharmacy is able to make a margin on the drug cost, so the fact that the dispensing fee is low and doesn’t reflect actual costs is compensated for by the fact that the pharmacy will make a margin on the drug cost. However, since 340B pharmacies only receive their actual cost plus an often inadequate dispensing fee, many 340B pharmacies will not break even on Medicaid prescriptions. If the covered entity has a significant Medicaid population, a strategy for allowing the covered entity to cover costs is called the Medicaid Carve-Out. It means that the covered entity would have two contracts with its wholesaler for drug purchasing:

- one contract would allow the entity to purchase at the 340b price
- one contract would allow the entity to purchase at another (non-340b) price

The entity would maintain separate physical or electronic inventories for each contract, and then use the non-340B priced drugs for Medicaid patients, thereby allowing the entity to receive reimbursement from Medicaid at a rate that would likely at least cover the pharmacy’s cost. At least one company⁹⁵ has developed a software program specifically designed to manage a Medicaid Carve-Out option. Also purchasing off 340B means that the clinic has to routinely purchase below the Medicaid discount rate to reap any benefit from this option. This is often difficult for a small-volume operation. However, the emergence of HPPI as the designated prime vendor may

offer significant advantages to entities in this arena. Entities should ensure that when carving out 340B, the pharmacy service is auditable, there is no duplicate discounting, the group purchasing organization exclusion is not violated, and the definition of a patient is followed.⁹⁶ When using the carve-out, you can use non-340B drugs for both Medicaid and *non*-eligible patients if your pharmacy is properly licensed. (IN-HOUSE)

Consider the new Medicare Drug Benefit.

In the short term (June 2004–January 2006), consider if the pharmacy will be able to participate as a network pharmacy in a Medicare-approved drug discount card program. This would allow the pharmacy to keep Medicare patients and receive payments (through the \$600 per year/per eligible low-income patient transitional assistance subsidy). In the long term, consider that although currently Medicare patients pay cash for prescriptions, after January 2006, they may elect to have third-party coverage. Pharmacies may want to participate in approved Medicare networks for the full 2006 benefit, due to the fact that patients must receive drugs at approved pharmacies to have their benefits tracked by Medicare (e.g., to qualify as meeting their deductibles and out-of-pocket spending limits). (ALL MODELS)

Assess the effect of accepting all-inclusive rates on the pharmacy.

The pharmacy will want to scrutinize agreements (typically Medicaid) that pay at all-inclusive rates. The cost of pharmacy has been rising at a greater rate than other components of health care, so the all-inclusive rate may not adequately cover pharmacy costs or be adjusted at a high enough rate over time to keep up with pharmacy cost inflation. It is advisable to calculate the pharmacy cost from the all-inclusive rate to ensure that costs are covered. Health centers that have determined that the all-inclusive rate does not adequately cover pharmacy costs may have several strategies for negotiating with the payer to do so.⁹⁷ (ALL MODELS)

Analyze capitated pharmacy reimbursement before accepting it.

Capitated rates for pharmacy reimbursement should be carefully examined to ensure that pharmacy costs are covered. For a start-up pharmacy, it is difficult to predict patient utilization and therefore to make projections as to whether the capitated rate is adequate. For new programs that have little data upon which to rely, it may be advisable for the pharmacy to assess the operating costs and general population utilization before accepting capitated reimbursement. Managing patients' pharmacy utilization (how many drugs they take, what kind, how often they take them) is key to making capitated reimbursement work for the pharmacy. (IN-HOUSE)

Consider conflict of interest and rebates when working with PBMs.

Some PBMs are owned by or affiliated with drug manufacturers, mail order pharmacies, or wholesalers. There has been concern voiced in the industry over the potential for conflict of interest in such situations.^{98,99} For example, if a drug

manufacturer owns a PBM, and the PBM determines the formulary, it might be possible for the PBM to choose only the manufacturer's drugs for the formulary. Administrators should be aware of such affiliations and potential for conflict of interest. PBMs often receive rebates for drugs that they process. If a PBM is managing a group of health center patients, consider asking the PBM for transparency in reporting all rebates and to share a portion of the rebate savings with the health center. (IN-HOUSE, CONTRACT)

Market the pharmacy service.

Clinics emphasize attributes of their pharmacy service – such as low-cost drugs, extended pharmacy hours, and convenient on-site location – to encourage patients to use their pharmacy service. Common ways to inform patients of these attributes include making brochures available, posting signs in the clinic, and telling patients at the point of prescribing. Regardless of how the pharmacy service is marketed, be sure to maintain patient choice, as the 340B program prohibits requiring patients to go to a particular pharmacy. (ALL MODELS)

Target and measure the pharmacy's capture rate for prescriptions.

Patients who have prescriptions written by a clinic's providers will not necessarily choose to fill the prescriptions at that clinic's pharmacy. Capturing target patients and their prescriptions in the pharmacy can be a challenge for many clinics, and calculating the pharmacy "capture rate" for prescriptions is a useful tool to assess how adequately the pharmacy is meeting its goals for prescription volume.

The capture rate for the pharmacy can be calculated by dividing the number of prescriptions filled at the pharmacy by the total number of prescriptions written in the clinics. Finding the total number of prescriptions written is difficult for many clinics. The average number of prescriptions written per visit has been estimated to be from 0.65–2.4 per patient visit.^{100,101,102} An accepted industry standard is 2.2 prescriptions per visit.¹⁰³

Multiply the number of clinic visits by 2.2 to arrive at a ballpark figure for the total number of prescriptions written. This will only provide a rough estimate, as different populations may generate more or less prescriptions than the 2.2 used in the approximation. Other ways to arrive at the total number of prescriptions written in a clinic would be to ask providers to keep track of or estimate this number. Although it may seem that a higher capture rate is better, not all clinics will strive to have a high rate. For example, some clinics have pharmacy services that only serve the uninsured, so it would be more meaningful for such a clinic to measure the capture rate of its uninsured patients only.

Measuring the capture rate is useful when planning a pharmacy or when a pharmacy is not filling an adequate numbers of prescriptions. Due to built-in inaccuracies and the difficulty of obtaining data for the calculation, busy pharmacies rarely use this measure. (ALL MODELS)

Analyze refilled prescriptions.

Depending on the duration of therapy and the quantity of medication dispensed at the initial filling, prescriptions are generally written with additional refills authorized. From an operational perspective, the capture rate for those refills is also important. Reasons for loss of refills to other pharmacy providers should be evaluated. (ALL MODELS)

Suggested Areas for Evaluation of Efficient Business Practices

Operational

The rationale for measuring operational function is to ensure that the pharmacy is operating efficiently. Suggestions for methods to assess operational outcomes include:

- evaluating average wait time for patients
- determining appropriate use of staff (pharmacists spend time doing tasks only pharmacists are allowed to do, or number of prescriptions filled per staff per day)
- breaking down the dispensing process to look for inefficient practices
- evaluating the appropriateness of the pharmacy space, location, equipment, or physical layout

The information gleaned can be used to make changes in processes, deal with complaints, consider recommendations for policy improvements, and increase operational efficiency.

Financial

The rationale for measuring financial health is to ensure that the pharmacy is financially sound and able to sustain operation. The methods for measuring financial indicators usually take the form of reports generated by a computer system, but small pharmacy operations might collect and analyze data by hand. The table on the following page describes methods for assessing financial health.

Suggestions for Pharmacy Financial Evaluation

The shaded indicators are suggestions for all pharmacy operations to measure, regardless of model or size.

Indicator	Calculation	What to Look For
Total pharmacy expense	Add all pharmacy expenses including staff costs, rent, equipment, liability insurance, computer services, design and build-out, etc.	Total expense should ideally be less than total revenue Individual expenses should be monitored for changes or excessive values
Total pharmacy revenue	Add all pharmacy revenue, including patient payments and third-party reimbursements	Total revenue ideally should be greater than total expense
Average cost to dispense one Rx ¹⁰⁴	Total fixed pharmacy cost/total #Rxs	Average cost to dispense one Rx should be ≤ average margin/Rx Cost to dispense one Rx should ideally be recouped from payer
Average margin per Rx	Total revenue–total cost/#Rxs	Analyze by payer, by drug, by pharmacy site, and by brand/generic Average margin/Rx should be ≥ to average cost to dispense one Rx
Number of Rxs filled per unit time	#Rxs/day, month, week, or year	Changes in the #Rxs may indicate growth or problems with pharmacy Evaluate adequacy of staffing when there are changes in Rx volume
Payer mix of pharmacy patients	Count #Rxs dispensed by categories such as: cash non-sliding fee, cash sliding fee, third party, Medicaid, etc.	These data are useful when evaluating capture rate and average margin/Rx
Inventory turnover rate	Annual pharmacy cost of goods sold/annual average inventory investment	Look for a high turnover rate to minimize cash tied up in inventory
Pharmacy Rx capture rate	Total #Rxs dispensed/Total #Rxs written ¹⁰⁵	Set goals and check to see if pharmacy is meeting goals Evaluate by payer or in aggregate
Number and clinic cost of sliding fee prescriptions dispensed	Count # of sliding fee Rxs Calculate clinic's subsidy by fee category or in aggregate	Evaluate clinic's cost to maintain sliding-fee scale in conjunction with pharmacy revenue; revenue should be adequate to support sliding fee scale; if not, scale should be adjusted
Brand vs. generic mix ¹⁰⁶	Count #Rxs and average margins for brand and generics Calculate cash/sliding fee patients' costs for brand and generic	Adjust formulary, if clinically appropriate, to reflect drugs with lowest patient cost and optimal pharmacy margins

Cornerstone IV: Quality Assurance

Description

A high-quality pharmacy service is likely to promote safe practices, and be valued and used more by patients, providers, and other consumers. Pharmacy quality is typically assessed internally and externally.

Suggested Actions for Maximizing Quality Assurance

- Regularly assess pharmacy quality within the organization
- Focus on the purpose of pharmacy quality assessment
- Develop standards that clearly define pharmacy quality
- Take action to correct processes and outcomes when quality standards are not met
- Investigate serious problems or drug errors by using root cause analysis
- Evaluate pharmacy processes and outcomes periodically to monitor for quality, even if no problems are apparent
- Document all quality improvement activities
- Follow up on actions taken as a result of quality assessment, and document ongoing results
- Regularly measure patient and provider satisfaction with the pharmacy service
- Engage in Drug Utilization Evaluation (DUE)

Suggested Areas for Quality Assurance Evaluation

- Satisfaction surveys for providers, patients, and pharmacy staff (by phone, by mail, collecting written comments from suggestion cards at the clinics, or conducting focus groups)
- Medication error rate
- QRE (Quality Related Events) "near misses"
- Dispensing process
- Refill request process (from provider and patient perspective)
- Compliance rates for patients on a particular drug
- Medication outcomes for patients on a particular drug, having a particular disease state, or meeting other criteria
- Formulary adherence by providers
- Drug Utilization Evaluation (DUE)

Patients make decisions about utilizing pharmacy services based on the perceived quality and cost of the program. Pharmacy managers document the worth and continually improve the merit of the service by utilizing quality measurements. In other words, a high-quality pharmacy service is likely to promote safe practices and be valued and used more by patients, providers, and other consumers. Pharmacy quality is typically assessed internally and externally.

Internal assessment is usually determined by an overall-clinic quality committee or a pharmacy-specific quality committee. Other ways to internally evaluate quality include appointing a quality manager or assigning pharmacy quality responsibility to a member of the Pharmacy and Therapeutics Committee.

External quality assessment is usually determined through regulation or accreditation. State boards of pharmacy have traditionally focused on regulating the **structure of activities** provided by pharmacists (such as licensing and continuing education) and pharmacies (including space, permits, equipment, hours of operation) as opposed to **pharmacy outcomes**. However, it has been indicated that state boards may begin to monitor pharmacy outcomes as well. The National Association of Boards of Pharmacy recently recommended incorporating pharmacy-specific standards for a Continuous Quality Improvement (CQI) program. A CQI program represents a system of standards and procedures to identify and evaluate quality-related events. The program should be designed to constantly enhance the efficiency and effectiveness of the pharmacy system processes that determine the outcomes of medication use. In addition, NABP also recommended that state boards encourage their licensed pharmacies to develop and conduct an annual survey of patients as part of the pharmacy evaluation process.¹⁰⁷

Accreditation, which results from a survey or inspection of the pharmacy by an independent organization, certifies that the pharmacy meets certain criteria.¹⁰⁸ Organizations such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the National Committee for Quality Assurance (NCQA) use the accreditation process to focus on assessing the **structure of activities** and **the outcomes** associated with quality in pharmacy services. Federally supported health centers satisfy on-site quality review requirements via a Primary Care Effectiveness Review (PCER)¹⁰⁹ or a combination PCER/JCAHO review.

Suggested Actions for Maximizing Pharmacy Quality Assurance

Regularly assess pharmacy quality within the organization.

This could be accomplished through a committee or a quality manager.

Focus on the purpose of pharmacy quality assessment.

It is easy to become overwhelmed gathering details or following formats simply with the intention of satisfying survey requirements. It may be helpful to ask, “What is the point of the quality assessment?” If there is not a distinct answer, reevaluate the feature being targeted.

Develop standards that clearly define pharmacy quality.

The pharmacy policy and procedures manual should have a section devoted to assessing, measuring, and acting upon quality-related issues. Specific goals and objectives should be listed and periodically reviewed for relevance. The following section (“Suggested Areas for Evaluation of Pharmacy Quality,” page 40) gives specific examples.

Take action to correct processes and outcomes when quality standards are not met.

Following a stepwise approach to analyzing performance improvement may simplify the process.¹¹⁰ For example:

1. Consider institutional context
2. Obtain and maintain stakeholder agreement
3. Define desired performance
4. Describe actual performance
5. Describe performance gaps
6. Find root causes
7. Select and design interventions
8. Implement interventions
9. Evaluate outcomes

Investigate serious problems or drug errors by using root cause analysis.

Root cause analysis is a systematic format used to investigate problematic situations for outcomes. Extensive information and sample worksheets may be downloaded for free from the JCAHO website.¹¹¹

Evaluate pharmacy processes and outcomes periodically to monitor for quality, even if no problems are apparent.

An ounce of prevention is worth a pound of cure! This might include targeting a process, such as that for refill requests; breaking down the steps of the process; collecting data by interviewing patients, providers, and pharmacy staff; synthesizing recommendations for improvements; and taking action to improve the process.

Document all quality-improvement activities.

This documentation is usually in the form of meeting minutes and reports that detail the processes used and actions resulting from quality evaluation. Such documentation is useful during JCAHO and PCER visits, and would be critical in the unfortunate event of a malpractice claim or medical error.

Follow up on actions taken as a result of quality assessment, and document ongoing results.¹¹²

Determine the long-term outcomes from quality-related changes; short-term assessment may not be enough to depict the true impact of the change.

Regularly measure patient and provider satisfaction with the pharmacy service.

Conduct written or telephone surveys of patients. At physician/provider staff meetings, include opportunities for providing feedback on pharmacy services.

Engage in Drug Utilization Evaluation (DUE).

The most common way to conduct DUE is for pharmacists and physicians to retrospectively analyze whether drugs are used appropriately, safely, and effectively.¹¹³ Often a random selection of charts or prescriptions is reviewed according to a set of established program criteria (e.g., long-term use of short-term sedative/hypnotics, etc.).

Suggested Areas for Quality Assurance Evaluation

The information learned from quality evaluation can be used to make changes in practices that improve the safety and efficiency of the pharmacy service. In addition, independent organizations conducting routine quality inspections expect entities to participate in and document quality assessment and performance improvement activities.

Suggestions for measuring quality include:

- satisfaction surveys for providers
- patients and pharmacy staff (verbally, by phone, mail, collecting written comments from suggestion cards at the clinics, or conducting focus groups)
- medication error rate
- the dispensing or refill request process (from the perspective of the provider, patient, and pharmacy staff)
- compliance rates for patients on a particular drug
- medication outcomes for patients taking a particular drug, having a particular disease state, or meeting other criteria
- formulary adherence by providers
- drug utilization evaluation

Section I Summary

Incorporating the 340B program with the four cornerstones of comprehensive pharmacy services offers the greatest likelihood of constructing a thriving pharmacy operation. The INFORMATION section of this manual has supported the following take-home messages:

1. The 340B program provides *significant savings* to clinics on prescription purchases, but perceived barriers to implementation have stunted participation.
2. The three most common categories for 340B pharmacy implementation are:
 - in-house
 - contracted pharmacy
 - provider dispensing
3. The ideal pharmacy system relies on *balanced provision of drug product and outcomes-driven pharmaceutical care*. In other words, a health center's pharmacy system should encompass all areas of medication use in the center, rather than solely the drug distribution system.
4. Efficient business practices in pharmacy can be addressed from the administrator's perspective and categorized into two major components: *operational* and *financial*.
5. A high-quality pharmacy service is likely to *promote safe practices* and *be valued and used more* by patients, providers, and other consumers.

The next step will be to draw on this information throughout a pharmacy needs assessment, decision analysis, and action plan.

SECTION II. TOOLS



A. Pharmacy Needs Assessment

Prepare for idealism to confront reality. To avoid the pitfall of implementing a pharmacy service that is not practical or sustainable, the pharmacy needs assessment will force the separation and confrontation of pharmacy “idealism” and pharmacy “reality.”

Pressure from outside authorities (such as governing boards and patients) to implement a particular model of pharmacy system based solely on individuals’ preferences is a fact of life. For example, patients may demand access to medications beyond clinic hours or at outside pharmacies, or object to formulary or sliding fee scales. This pressure may result in the choice of a pharmacy system based solely on the needs of the population, despite the fact that the decision may not be practical or financially sound for the health center.

This needs assessment will result in a customized list that compares perceived ideal pharmacy options with sustainable and practical pharmacy options. If the clinic has multiple sites that need pharmacy services and the sites vary considerably, consider completing a separate needs assessment for each site.

Needs Assessment: Pharmacy Idealism

Option and Criteria Preferences

Instructions

Complete the following, in order:

1. Circle the number of all options/criteria you would consider.
2. Draw a line through the number for the options/criteria you would eliminate.
3. Place a “+” to the left of the options/criteria you would prefer.
4. Write the major goals and criteria for success for your pharmacy service in the box on the next page.

+	Option/Criteria
	1. In-house pharmacy staffed with a pharmacist
	2. In-house dispensary staffed with clinic providers (not necessarily a pharmacist)
	3. Automated dispensing equipment, including remote dispensing machines (similar to vending machines), for multi-site use
	4. Pharmacy owned and operated by health center
	5. Pharmacy owned by health center but operated by a management company
	6. Contract with a retail pharmacy
	7. Contract with a mail order pharmacy
	8. Combination of the above methods or other
	9. Formulary
	10. Sliding fee scale
	11. Samples
	12. Patient assistance programs
	13. Expanded access for patients beyond normal clinic hours

Write the major goals and criteria for success for your pharmacy service.
(Remember to include immediate, intermediate, and long-term goals.)

Immediate Goals:

Intermediate Goals:

Long-Term Goals:

Criteria for Pharmacy Success:

Needs Assessment: Pharmacy Reality

This portion of the assessment will help you characterize your pharmacy reality. It has two parts: Numerical Inputs (Part I) and Capabilities (Part II).

Part I. Numerical Inputs

Fill in all of the numbers you can under the Response column. If you are unsure of a response, the right-hand column gives tips on how to find or calculate numbers.

Data Element	Response	Tips
Start-up funding available		Consider grant funding, one-time allocation from the clinic's budget, private donations, etc.
Annual ongoing pharmacy budget available		The amount that the clinic will be able to allocate to the pharmacy budget annually
# encounters/month		Should be available from clinic data
# prescriptions/month generated		If unknown, multiply the # encounters per month by a standard of 2.2 Rxs/encounter. If there are only a few local pharmacies nearby, consider asking them for a report that would tally the number of Rxs filled for clinic patients (simplest way would be based on the provider's last name).
# prescriptions/month captured		This will likely be an estimate. Consider competition from other pharmacies, and any factors that might deter patients from filling prescriptions (barriers such as cost, language, transportation).
# sites needing access to pharmacy		Consider all clinic sites.
Projected staff needs for pharmacy: FTE Pharmacists FTE Technicians FTE Other (describe)		Estimate 1–1.25 FTE RPh and 1–2 FTE technicians for every 100 Rxs/8-hour day filled. The more technology the service uses (automated pill counters, etc.), the lower the staff requirements.
Projected inventory needs for pharmacy		Estimate \$40,000–60,000 for 100–200 Rxs/day. ¹¹⁴ Dispensaries likely will have lower-cost inventory requirements if samples/PAPs/pre-packs are used. Contracted pharmacies could have arrangements with clinics for \$0 start-up inventory.

Data Element	Response	Tips
Payer mix: % Medicaid % Medicare % Third party % Cash (sliding fee only) % Cash (non sliding fee) % Other		Estimate based on clinic figures. Although Medicare patients currently pay cash for prescriptions, consider that reimbursement may be possible in 2006.
Maximum time from today until pharmacy services are needed		What is the longest amount of time the clinic can wait for pharmacy services to be up and running?

Part II. Capabilities

Respond by checking YES (indicating the clinic has the capability or can arrange to have the capability), NO (indicating the clinic does not have the capability or will not be able to arrange for the capability), or UNSURE.

Capability	Yes	No	Unsure
To capture majority of clinic prescriptions			
To bill third parties online for prescriptions			
To collect a significant portion of cash pay (sliding fee and non-sliding fee)			
To market the pharmacy service			
To locate and hire consultant pharmacist			
To hire and retain pharmacist			
To hire and retain other staff (technicians, nurses, etc.)			
To enforce formulary			
To compete with nearby pharmacies			
To assume financial risk for the pharmacy			
To ensure patients have transportation to pharmacy location			
To reconstruct an existing space			
To ensure patients have translation services at pharmacy			

Needs Assessment Results

Complete as instructed:

1. Under the columns labeled “A: Pharmacy Idealism,” write the options/criteria marked with a “+” on page 45 under the “I would prefer” column, and write the options/criteria circled but not receiving a “+” under the “I would consider” column.
2. Under the columns labeled “B: Pharmacy Reality,” work with a consultant pharmacist to arrive at the sustainable and potentially sustainable options.
3. Write the major goals and criteria for success for your pharmacy service in the box at the bottom.
4. Work with a consultant pharmacist to complete this summary page in its entirety.

A: Pharmacy Idealism	B: Pharmacy Reality
I would prefer...	Sustainable Options
I would consider...	Potentially Sustainable Options

Write the major goals and criteria for success for your pharmacy service.
(Remember to include immediate, intermediate, and long-term goals.)

Immediate Goals:

Intermediate Goals:

Long-Term Goals:

Criteria for Pharmacy Success:

B. Decision Analysis

The needs assessment helps present potentially sustainable pharmacy options based on individual input, but there are additional factors to consider before arriving at a final decision regarding the most appropriate type of pharmacy service. To assist you in this process, this manual provides several decision analysis tools:

Spreadsheet Tools and Narrative Summaries allow the user to input different financial scenarios to produce snapshots of budgets, co-pays, fee scales, and expenses/revenues for in-house and contracted pharmacy. The program permits individualized data input or will calculate estimations based on data collected from other health center models around the country. Working in conjunction with a pharmacist consultant on these spreadsheets is highly recommended.

Critical Considerations in Pharmacy Option Selection: a narrative explanation and checklist

Action Plan Format: a template

Resource Organizations provides detailed contact information for organizations offering pharmacy technical assistance, found in Appendix IV

Overview of the Three Most Common 340B Implementation Options: chart found in Section I B (340B Implementation Options)

Implementation Criteria for 340B Options: chart found in Section I B (340B Implementation Options)

Additional Detailed Option Information, Helpful Hints, Case Studies, and Timelines: found in Appendix V

In-House Pharmacy Financial Model

Definitions of Terms and Variables

Financial Model Overview

The user will input values on two worksheets in the model: “Revenue” and “Expenses.” Information about many of the variables on these worksheets is described below. As data is entered, the user will observe the net effect on the “Profit/Loss Summary” section of the Revenue worksheet. The “Calculations” worksheet serves as an organizing page for background calculations and should be ignored by the user.

Revenue Worksheet

Pharmacy Payer Type

This represents the types of programs from which a patient's medications can be paid. "State Medicaid" represents the percent of patients who are on a state-based Medicaid program, not managed by an HMO. In other words, the pharmacy benefit is paid by submitting a claim for the medication to the state Medicaid program. Also, because this model predicts the volume of prescriptions to be filled based on the number of clinic visits each year, samples and prescriptions filled through pharmaceutical manufacturer assistance programs (MAPs) must be accounted for in this section even though they usually do not serve as a source of revenue for the health center.

Utilization Rate

The utilization rate is an assumption of the number of prescriptions a patient will have filled during a year for each clinic visit. A commonly used utilization rate is 2.2 medications per medical visit.

Capture Rate

The capture rate is the percent of total prescriptions from each payer type that you feel will be filled via the in-house pharmacy. The capture rate is often highest for sliding fee scale/cash-paying patients, as these individuals have a financial incentive to use the in-house pharmacy. It may be lower for patients who have medication coverage, because their co-pay will likely be the same at any pharmacy. Factors such as geography, transportation, convenience, and services offered by the in-house pharmacy will affect the capture rate for individuals with medication coverage.

Generic Medication Utilization

This represents the percentage of all medications prescribed for which a generic product will be used. The composition of a health center's formulary will greatly influence this variable. The generic utilization rate may be higher for sliding fee scale patients as the ability to pay cash for a brand medication may be challenging, thus emphasizing the prescribing of medications available generically. A typical percentage used in the third-party environment is approximately 40%, but this may be higher for cash-paying patients with active formulary management within the health center.

Brand and Generic Margin

The margin represents the difference between the amount reimbursed for a medication by a payer and the actual cost of the medication. The margin does not include any dispensing fees applied. If a health center is "carving out" its state Medicaid patients from the pharmacy program (i.e., 340B medications will not be used for this group of patients), it is not necessary to estimate a margin for this group. However, some health centers have negotiated special arrangements with their state

Medicaid program and, as a result, do not “carve out” this business. In these cases, margins will not be as high as that seen with private insurance; however, the program will generate some revenue for the health center.

Sliding Fee Scale Structure

Dispensing Fee: This is a fee added to the cost of the drug, which is charged to the patient.

% Mark-up on Medications: A health center may apply a “mark-up” on the cost of a medication in order to generate revenue and thus offset some of the expenses of offering the pharmacy program. This may be in lieu of or in addition to a dispensing fee. This model allows the user to apply either or both.

NOTE: A clinic may apply one or both of the above fees on to the cost of a medication within its pharmacy program. If a clinic does not intend to apply one or the other, simply leave the corresponding cells blank.

Maximum Charge: To help ensure the affordability of medications for low-income patients, health centers may establish a “maximum charge” that represents the most a patient would be charged for a prescription. For instance, a health center could establish a maximum fee of \$25, whereby this is the amount a patient would pay even if the cost of the medication to the health center was \$50. Creating this type of sliding fee scale component requires the health center to assume the risk of creating revenue from insured sources or from administrative fees and mark-up on less costly medications, or from sliding fee scale/cash-paying patients exempt from the maximum charge (e.g., over 200% of poverty) while limiting losses on sliding fee scale patients.

Manufacturer Assistance Program (MAP) Fee

Health centers that help patients apply for and receive medications from assistance programs offered by various pharmaceutical manufacturers may choose to charge patients an administrative fee for processing necessary forms. This revenue can be accounted for in this model.

Pharmacy Services in Medicaid “All-Inclusive” Rates

In many states, when a health center owns and operates a pharmacy, medication costs for those Medicaid patients who are enrolled in an HMO managed program cannot be billed on a per prescription basis. Rather, the cost of pharmacy services is included in the health center’s “all inclusive” rate. If the health center will receive payment for pharmacy services via an all-inclusive rate, indicate “Y” in the appropriate box and then indicate an estimate of the amount received within the all inclusive rate for pharmacy services, as well as the number of clinic visits anticipated for this patient group. If pharmacy services are not included in the all-inclusive rate, put an “N” in the box, and the model will calculate revenue based on a fee-for-service model.

Revenue from Clinical Services

Revenue for patient care activities delivered by pharmacists (unrelated to medication dispensing) can be estimated, and the corresponding revenue will be added to overall program revenue.

Expenses Worksheet

This worksheet allows input of data related to recurring and start-up expenses. For each item listed, note whether the cost is to be entered as a monthly or annual expense.

Personnel

Enter the number of FTEs associated with the pharmacy program for each type of staff person.

Average Drug Cost

Often referred to as the “ingredient cost,” this represents the average cost of brand and generic medications to the health center, per prescription, using 340B prices. This amount does not include any mark-up on the medication or fees that may be charged to a patient. This average cost will be significantly influenced by prescribing practices and the clinic’s formulary.

Profit/Loss Summary (Revenue Worksheet)

The data in this box is calculated from each of the values input by the user and represents an estimate of the profitability of the in-house pharmacy program. The model calculates an estimate of the pharmacy profitability based on projected recurring revenue and expenses, and also provides an estimate of the profitability during the first year of pharmacy operation.

The assumptions used to calculate this first year profitability:

- Staffing costs listed in the “start-up costs” portion of the expenses worksheet will, on average, begin service three months prior to opening the pharmacy.
- Revenue from pharmacy services during the first six months that the pharmacy is open will be half of the projected recurring revenue. Revenue will reach 100% of projections six months after opening.
- Recurring costs during the first year of operation will be 75% of projections, as it is likely that the pharmacy will not be staffed at full projections before the end of the first year.

Contracted Pharmacy Financial Model

Definitions of Terms and Variables

Pharmacy Payer Type

This represents the types of programs from which a patient's medications can be paid. "State Medicaid" represents the percent of patients who are on a state-based Medicaid program, not managed by an HMO. In other words, the pharmacy benefit is paid by submitting a claim for the medication to the state Medicaid program. In a contract pharmacy environment, Medicaid patients managed by an HMO are treated the same as privately insured patients.

Because this model predicts the volume of prescriptions to be filled based on the number of clinic visits each year, samples and prescriptions filled through pharmaceutical manufacturer assistance programs (MAPs) or patient assistance programs (PAPs) must be accounted for in this section, even though these are not traditionally filled via the contracted pharmacy.

Utilization Rate

The utilization rate is an assumption of the number of prescriptions a patient will have filled during a year for each clinic visit. A commonly used utilization rate is 2.2 medications per medical visit. If you know your clinic's actual utilization rate, insert that number. If you don't know, you can use 2.2 per visit, or adjust this number as you deem appropriate.

Capture Rate

The capture rate is the percent of total prescriptions from each payer type that you feel will be filled via the contract pharmacy. The capture rate is often highest for sliding fee scale/cash paying patients, as these individuals have a financial incentive to use the contracted pharmacy. It may be lower for patients who have medication coverage, as their co-pay will likely be the same at any pharmacy. Factors such as geography, transportation, convenience, and services offered by the contracted pharmacy will affect the capture rate for individuals with medication coverage.

Generic Medication Utilization

This represents the percentage of all medications prescribed for which a generic product will be used. The composition of a health center's formulary will greatly influence this variable. The generic utilization rate may be higher for sliding fee scale patients, as the ability to pay cash for a brand medication may be challenging, thus emphasizing the prescribing of medications available generically. A typical percentage used in the third-party environment is approximately 40%, but this may be higher for cash-paying patients with active formulary management within the health center.

NOTE: Because of lower retail pricing of some generics, a percentage of generic medication prescriptions may fall outside of the program, since the contracted pharmacy's usual and customary price may be lower than the product cost plus negotiated dispensing fee.

Average Drug Cost

Often referred to as the “ingredient cost,” this represents the average cost of brand and generic medications to the health center, per prescription, using 340B prices. This amount does not include any mark-up on the medication or fees that may be charged to a patient. This average cost will be significantly influenced by prescribing practices and the clinic's formulary.

Brand and Generic Margin

The margin represents the difference between the amount reimbursed for a medication by a payer and the actual cost of the medication. The margin does not include any dispensing fees applied. If a health center is “carving out” its state Medicaid patients from the pharmacy program (i.e., 340B medications will not be used for this group of patients), it is not necessary to estimate a margin for this group. However, some health centers have negotiated special arrangements with their state Medicaid program and, as a result, do not “carve out” this business. In these cases, margins will not be as high as that seen with private insurance; however, the program will generate some revenue for the health center.

NOTE: Because of lower retail pricing of some generics, a percentage of generic medication prescriptions may fall outside of the program, since the amount reimbursed may be lower than the product cost plus negotiated dispensing fee.

Sliding Fee Scale Structure

Dispensing Fee: This is a dispensing fee charged to the patient. It is not necessarily the same as the fee charged to the health center by the contracted pharmacy.

Clinic Administration Fee: Some health centers add a flat fee to the cost of a medication for program administration. This may be represented by a dispensing fee charged to the patient, or it may be a separate fee; thus this financial model allows both to be included.

% Mark-up on Medications: A health center may apply a “mark-up” on the cost of a medication in order to generate revenue and thus offset some of the expenses of offering the pharmacy program. This may be in lieu of or in addition to a dispensing or clinic administration fee. This model allows the user to apply either or both.

NOTE: A clinic may apply only one, two, or all three of the above fees on to the cost of a medication within its pharmacy program. If a clinic does not intend to use all three, simply leave the corresponding cells blank.

Maximum Charge: In order to help ensure the affordability of medications for low-income patients, health centers may establish a “maximum charge” that represents the most a patient would be charged for a prescription. For instance, a health center could establish a maximum fee of \$25, whereby this is the amount a patient would pay even if the cost of the medication to the health center was \$50. Creating this type of sliding fee scale component requires the health center to assume the risk of creating revenue from insured sources or from administrative fees and mark-up on less costly medications, or from sliding fee scale/cash paying patients exempt from the maximum charge (e.g., over 200% of poverty) while limiting losses on sliding fee scale patients.

Manufacturer/Patient Assistance Program (MAP/PAP) Fee

Health centers that help patients apply for and receive medications from assistance programs offered by various pharmaceutical manufacturers may choose to charge patients an administrative fee for processing necessary forms. This revenue can be accounted for in this model.

Expenses

Pharmacy Dispensing Fee: This is the amount that is paid to the contracted pharmacy for each medication dispensed on the health center’s behalf. This financial model is constructed with the assumption that the pharmacy will provide all program-related revenue collected by the pharmacy (cash, co-pays, third-party reimbursement, etc.) to the health center, and the health center will in turn provide payment to the pharmacy at its contracted rate for the number of prescriptions dispensed over a defined period of time.

In-Clinic Program Support Staff: Offering a pharmacy program, even through a contract pharmacy arrangement, will likely require dedicating a limited amount of health center staff time to implement, promote, manage, and maintain the program. An estimate of the cost of this staff time can be included here.

Inventory Start-up/Carrying Expenses: Depending on how a health center establishes its contracted pharmacy program, it may incur start-up costs for a medication inventory and/or incur expenses associated with maintaining the inventory. An estimate of these expenses can be included in this model, if desired.

Medicaid Carve Out

If a health center will “carve out” its state-based Medicaid patients (i.e. the health center will not use 340B medications for this group), place a “Y” in this cell. This will zero out the revenue generated from this patient population, regardless of data entered for the size of this population or a margin for medications dispensed. Place an “N” in this cell if your health center has an agreement with your state Medicaid office to use 340B medications for these patients. In this case, the anticipated margin for medications dispensed for these patients should be entered into the Brand Margin and Generic Margin sections of the spreadsheet.

Contact Medpin
 (info@medpin.org or
 510-302-3300) for an
 electronic version of this
 spreadsheet

	A	B	C	D	E	F	G	H	I
1	Pharmacy Payer Type	Mix					Expenses		
2	3rd Party and/or HMO Medicaid			SFS Structure			Pharmacy Dispensing Fee per Rx		
3	State Medicaid			Level 1			In-Clinic Program Support Staff (Total \$)		
4	Sliding Fee Scale - Level 1			Dispensing Fee	\$0.00		Inventory Start-up/Carrying Expenses		
5	Sliding Fee Scale - Level 2			Clinic Admin Fee	\$0.00		Other recurring expenses		
6	Sliding Fee Scale - Level 3			% Mark-up on Meds	0.0%				
7	Sliding Fee Scale - Level 4			Maximum Charge? (Y/N)	N				
8	Sliding Fee Scale - Level 5			Maximum Charge					
9	Manf. Assistance Programs			Level 2					
10	Samples			Dispensing Fee	\$0.00				
11	Total (must be 100%)	0.0%		Clinic Admin Fee	\$0.00				
12				% Mark-up on Meds	0.0%				
13	Clinic Prescription Volume			Maximum Charge? (Y/N)	N				
14	Utilization Rate (Rxs/visit/year)			Maximum Charge					
15	Clinic Visits/year			Level 3					
16				Dispensing Fee	\$0.00				
17	Capture Rate (%)			Clinic Admin Fee	\$0.00				
18	3rd Party/HMO Medicaid			% Mark-up on Meds	0.0%				
19	State Medicaid			Maximum Charge? (Y/N)	N				
20	SFS			Maximum Charge					
21				Level 4					
22	Generic Medication Utilization			Dispensing Fee	\$0.00				
23	% Generic, SFS			Clinic Admin Fee	\$0.00				
24	% Generic, Non-SFS			% Mark-up on Meds	0.0%				
25				Maximum Charge? (Y/N)	N				
26	Avg. Drug Cost/Ingredient Cost (\$)			Maximum Charge					
27	per Brand Rx			Level 5 (Cash U&C)					
28	per Generic Rx			Dispensing Fee	\$0.00				
29				Clinic Admin Fee	\$0.00				
30	3rd Party/HMO Margin (%)			% Mark-up on Meds	0.0%				
31	Brand			Maximum Charge? (Y/N)	N				
32	Generic			Maximum Charge					
33				MAP Fee per Rx	\$0.00				
34									
35									
							Revenue Summary		
							3rd Party/HMO Medicaid	\$0	
							State Medicaid	\$0	
							SFS Level 1	\$0	
							SFS Level 2	\$0	
							SFS Level 3	\$0	
							SFS Level 4	\$0	
							SFS Level 5	\$0	
							MAP Administration	\$0.00	
							Projected Income	0.00	
							Projected Pharmacy Dispensing Fees Paid	0.00	
							Total Projected Expenses	\$0	
							Projected Profit/Loss	\$0.00	
<p>Copyright ©2004 Medpin - A Program of the Public Health Institute Worksheet developed via support provided by the Pharmacy Services Support Center of the American Pharmacists Association (http://pscc.aphanet.com) and HRSA. Author: Todd D. Soemmer, Pharm.D., University of Minnesota</p>									

Critical Considerations in Pharmacy Option Selection

Political Climate

Consider the preferences of governing boards, patients, clinicians, and other administrators. Although it will be impossible to please everyone, soliciting input from these groups may still uncover facts that might be important in decision-making. For example, some groups may be opposed to the idea of a particular model such as mail-order pharmacy. Despite the fact that this model might suit the clinic best on paper, if the opposition to the model is strong enough, the pharmacy service may not be utilized.

Competition

Determine whether there are other retail pharmacies in the area, and whether the clinic's pharmacy will have trouble competing or will cause tension in the community.

Provision of the Four Cornerstones of Comprehensive Pharmacy Services

Evaluate the degree to which the model has the ability to encompass each of the four cornerstones of comprehensive pharmacy services: access to affordable medications using the 340B and prime vendor programs, outcomes-driven pharmaceutical care, efficient business practices, and quality assurance.

Patient Demographics

Certain population characteristics may influence costs, revenue, and utilization. Consider these statistics:¹¹⁵

- Females have more prescriptions ordered per visit than males.
- Whites and blacks have more prescriptions ordered per visit than other racial categories.
- Americans over age 65 have about 10 percent more prescriptions ordered per visit than those ages 45–64 in 1997.
- Individuals who have Medicare as an expected source of payment have about 28 percent more prescriptions ordered per visit than those with private insurance.

Provider Types/Specialties

Different types of providers and provider specialties tend to generate different volumes of prescriptions per visit. Data collected from physicians' assistants by specialty include (see next page):

Estimated Number of Patient Visits and Medications Prescribed or Recommended by Physician Assistants in 2002:¹¹⁶

	Mean Prescriptions per Visit
Family Practice	1.41
General Internal Medicine	1.5
Internal Medicine: Cardiology	1.08
Other IM Subspecialty	1.17
Obstetrics/gynecology	0.86
Emergency Medicine	1.19
General Pediatrics	0.86
Pediatric Subspecialty	1.12
General Surgery	0.69
Cardiovascular Surgery	1.06
Orthopedic Surgery	0.73
Other Surgical Subspecialty	0.87
Occupational Medicine	0.65
Other	1.23
Total	1.22

Other data sources cite:

- Physician assistants and nurse-practitioners write between 0.8-1.1 prescriptions per patient visit.¹¹⁷
- The average number of prescriptions written per patient visit is 2.4.¹¹⁸
- The average number of prescriptions per patient visit is 2.2.¹¹⁹

Alternative Methods

If none of the models seems to meet your pharmacy service needs completely, you may wish to explore an alternative method of accessing 340B.¹²⁰

Funding

Consider if and how the health center wishes to subsidize patients' prescriptions. Will the subsidy be covered by profits from the pharmacy, by a clinic budget allocation, or by grant funding? Will it be written off as bad debt? The spreadsheet tools will help forecast possible profit and loss scenarios.

Language/Cultural Issues

If the patient population has considerable linguistic or cultural diversity, ensure the pharmacy service is able to appropriately handle this diversity.

Critical Considerations in Pharmacy Option Selection

Consideration	Notes
Political climate	
Competition	
Provision of the four cornerstones of comprehensive pharmacy services: <ol style="list-style-type: none"> 1. Access to affordable medications using 340B and prime vendor programs 2. Outcomes-driven pharmaceutical care 3. Efficient business practices 4. Quality assurance 	
Patient demographics	
Provider types/specialties	
Alternative methods	
Funding	
Language/culture	

Conclusion

This manual's purpose is to equip administrators with information and tools to build a bridge connecting pharmacy needs with a 340B comprehensive pharmacy services solution. By providing information, a needs assessment, and a decision analysis, it should minimize the ambiguity surrounding 340B and pharmacy services.

It is time to cross the bridge connecting pharmacy needs with a 340B comprehensive pharmacy services solution.

APPENDICES



APPENDIX I: Glossary¹²¹

340B-eligible entity An entity specifically listed in the original 340B legislation as eligible to purchase at 340B prices.¹²²

340B-eligible patient Any established patient of a covered entity.

Actual acquisition cost (AAC) The net cost of a drug paid by a pharmacy; it includes discounts, rebates, and charge-backs, but not dispensing fees.

Average manufacturer price (AMP) The average price manufacturers receive from wholesalers for drugs distributed to retail pharmacies. AMP was created as a benchmark by Congress in 1990 for use in calculating Medicaid rebates. AMP is a confidential number but has been estimated to be equal to about AWP – 20% for a survey of drugs purchased by Medicaid recipients.

Average wholesale price (AWP) A publicly available, national average of list prices charged by wholesalers to pharmacies.

Comprehensive Pharmacy Services A term consisting of four cornerstones that encompass a complete, ideal pharmacy service:

- I. ACCESS TO AFFORDABLE MEDICATIONS USING 340B AND PRIME VENDOR PROGRAMS
- II. OUTCOMES-DRIVEN PHARMACEUTICAL CARE
- III. EFFICIENT BUSINESS PRACTICES
- IV. Quality assurance

Formulary A list of preferred drugs that often sets limits to the variety of drugs available. Drug formularies may be open (have little or no restrictions), closed (have clear limits on the types of drugs allowed), and may be tiered (may classify drugs into levels according to co-pay amount). Most tiered formularies have three levels: non-preferred brand only drugs (highest co-pay), preferred brand only drugs (medium co-pay), and generic drugs (lowest co-pay).

Maximum allowable cost (MAC) A ceiling price commonly used as the basis for reimbursement for selected generic drugs.

Office of Pharmacy Affairs (OPA) The branch of the federal government responsible for 340B program administration. The Office of Pharmacy Affairs is located within the Department of Health and Human Services, Health Resources and Services Administration, Bureau of Primary Health Care, Division of Health Center Development.

Pharmacy benefit manager (PBM) An organization providing administrative services related to prescription claims processing. Services provided by PBMs include formulary design, co-pay structure management, rebate negotiation, disease management facilitation, drug-interaction protection, online adjudication (price

negotiation, bouncing claims against plan parameters, checking eligibility, paying claims), data collection, and drug utilization review.

Pharmacy Services Support Center (PSSC) A collaboration between the Office of Pharmacy Affairs and the American Pharmacists Association (APhA) to bring comprehensive pharmacy services to patients who receive care at 340B-eligible health care delivery sites. The PSSC provides information and assistance to help eligible sites optimize the value of the 340B Program.

Prime Vendor Program A program mandated by the 340B legislation that specializes in serving covered entities that participate in the 340B program by offering GPO services and negotiates sub-ceiling prices on 340B drugs.

Repackager A business that takes drugs out of their original manufacturer stock bottles and puts them into new packaging. Some repackagers specialize in “prepacked” drugs; these are small quantities of drugs that are ready to dispense, either in bottles or unit-of-use packaging, with preprinted labels.

Wholesale acquisition cost (WAC) The price a wholesaler pays for drugs purchased from the drug manufacturer, but this number may not reflect all available discounts.

Wholesaler An organization that buys drugs from drug manufacturers and resells drugs to retailers and other purchasers.

APPENDIX II: Budget Items

These charts list sample items to consider in a pharmacy budget. Refer to the decision analysis spreadsheet tool¹²³ for specific numerical estimations regarding in-house and contracted pharmacies.

Costs	
Pharmacists' Salaries + Fringe	
Technicians' Salaries + Fringe	
Other Salaries + Fringe	
Rent	
Utilities	
Taxes	
License Fee	
Insurance	
Accounting and Legal	
Advertising and Promotion	
Maintenance	
Education and Training	
Additional Information/Reference Resources	
Supplies and Equipment	
Inventory Costs	
Dispensing Fees for Contracted Pharmacy, Fees to a Management Company, or Repackaging Fees for Provider Dispensing or Telepharmacy	
Other	
TOTAL	

Revenues

Drug Product

Cash Payer

Third Party Payer

Medicaid

Medicare

Grants

In-kind

Samples

PAPs

Donations

Volunteer labor

Clinical Services

Cash Payer

Third Party Payer

Medicaid

Medicare

Grants

TOTAL

APPENDIX III: Sliding Fee Scales

A sliding fee scale is a way to structure patients' payment for services according to income or ability to pay. Most health centers already have a sliding fee scale in place that reflects the overall philosophy of the center. For example, some clinics are “free” clinics that charge no fees to patients, and other centers always attempt to cover costs. Health centers that receive grants from HRSA have a *grant expectation* to offer “a method of discounting or adjusting fees based upon the patient’s income and family size from current Federal Poverty Guidelines” for all services offered to patients.¹²⁴

The most critical aspect of the sliding fee design is that the clinic is able to *cover the overall pharmacy costs*. Both fixed costs (associated with providing the service) and variable costs (attributed to drug product) should be covered. Arbitrarily setting fees for patients might result in a financial pitfall for the pharmacy service; setting an appropriate fee scale is critical to the pharmacy service’s sustainability and survival.

Free clinics usually rely on donations or grants to cover costs, while other types of clinics rely on the payer mix to find a financial balance, using profits from some payers to offset losses from other payers.¹²⁵ Sliding fee scales are not required to be structured so that medications are provided for free; providing *affordable* medications will help patients and give the pharmacy service a greater likelihood of financial success.¹²⁶

As long as the clinic’s overall costs are covered, creativity can be used in the construction of the sliding fee scale. For example, the pharmacy service fee scale might:

- Mirror the clinic’s scale for other services
- Have a completely different structure than the clinic’s scale for other services
- Slide any portion of the drug pricing formula
- Set minimum or maximum payments
- Charge a flat fee for prescriptions

An example of a sliding fee scale that always minimally covers costs and slides only the clinic profit is presented below:¹²⁷

Category	Formula
I (<149% Federal Poverty Limit)	340B Cost + Dispensing Fee + \$0 = Total Price
II (150–199% Federal Poverty Limit)	340B Cost + Dispensing Fee + \$1.50 = Total Price
III (>200% Federal Poverty Limit)	340B Cost + Dispensing Fee + \$3.00 = Total Price

After the scale has been established, updating and monitoring it on a continuing basis is crucial. Neglecting to monitor the scale or postponing changes may be detrimental for the pharmacy service. Suggestions for data to monitor include:

- Average drug acquisition costs
- Average margin per prescription¹²⁸
- Average fixed (or non-drug) cost per prescription

Regardless of the design of the pharmacy service fee scale, it should cover overall costs *and* reflect the philosophy of the organization.

APPENDIX IV: Resource Organizations

Source/Contact Information	Assistance
<p>HRSA Pharmacy Services Support Center (PSSC) 2215 Constitution Avenue, NW Washington, DC 20037 PSSC Call Center: (202) 429-7518 & 1(800) 628-6297 Fax: (202) 223-7193 Email: pssc@aphanet.org http://pssc.aphanet.org/askpssc/contactpssc.htm</p>	<p>Manages the PharmTA Program to provide technical assistance to 340B-eligible entities via a cadre of experienced consultants. Assistance varies from phone consultations, provision of materials, sample forms, documents, as well as limited site visits. Also maintains a website with useful information regarding 340B and related pharmacy issues.</p>
<p>Medicine for People in Need (Medpin) 180 Grand Ave., Suite 750 Oakland, CA 94612 Phone: (510) 302-3300 Fax: (510) 444-8253 Email: info@medpin.org www.medpin.org</p>	<p>Works with safety net providers to improve access to medicine and pharmaceutical care for people in need. Provides training and education, direct technical assistance services, policy analysis and research. Conducts teleconference training, regional and statewide meetings. Provides instruction to pharmacists on consulting or contracting with safety net providers.</p>
<p>Volunteers in Health Care (VIH) 111 Brewster Street Pawtucket, RI 02860 Phone: (877) 844-8442 www.volunteersinhealthcare.org</p>	<p>Moderates free listserv regarding pharmacy issues in underserved settings. Gives periodic teleconferences on pharmacy-related issues (samples, PAPs, Medicare Drug Benefit) and other topics (charitable immunity, dental issues, grant writing, mental health). Provides limited amount of pharmacy-specific technical assistance through experienced pharmacy consultants. Maintains a website that is a resource of detailed information regarding patient assistance programs.</p>
<p>National Association of Community Health Centers (NACHC) National Association of Community Health Centers, Inc. 7200 Wisconsin Ave., Suite 210 Bethesda, MD 20814 Phone: (301) 347-0400 Fax: (301) 347-0459 Email: contact@nachc.com www.nachc.org</p>	<p>Serves and represents the interests of America's community health centers.</p>
<p>340B Prime Vendor Program/HPPI 125 E. John Carpenter Freeway Irving, TX 75062-2324 Phone: (888) 340-BPVP (2787) www.340bpvp.com</p>	<p>Enables hospitals, community health centers, and other safety net providers to purchase outpatient pharmaceuticals at discounted pricing, thereby expanding access to care to low-income and vulnerable segments of the population. As the sub-contractor to the 340B Prime Vendor, HPPI is responsible for the negotiation of pharmaceutical pricing below the 340B price as well improving access to affordable medications by establishing a distribution network for pharmaceuticals to covered entities.</p>

APPENDIX V: Additional Detailed Option Information, Helpful Hints, Case Studies, and Timelines

In-House Pharmacy: Additional Detailed Information

Management Company–Operated In-House Pharmacy¹²⁹

Contracting with a management company to operate an in-house pharmacy presents several complex legal situations. It is advisable to obtain legal counsel during the contract writing and establishment process. Some major points to keep in mind are:

- This model is *not* the same as contracting with a retail pharmacy
- The health center retains the pharmacy license and overall legal responsibility for the pharmacy
- The health center (never the management company) remains the 340b covered entity and should be the purchaser for 340b drugs
- Specific state laws may influence specific contract terms¹³⁰
- The health center may wish to approve all contract staff
- There is no access to Pfizer’s Sharing the Care PAP
- The health center may wish to avoid contractor fees based on a percentage of pharmacy revenue¹³¹

Names of local or regional management companies may be obtained from wholesalers or resource organizations providing pharmacy technical assistance.¹³²

Telepharmacy

Companies that Provide Telepharmacy	
Company	Contact Information
Rx e-source SM / Cardinal Health	www.cardinal.com
Telepharmacy Solutions	Carl W. Geberbauer, RPh, MBA Vice President, Sales and Marketing 875 Woodlands Parkway Vernon Hills, IL 60061 Direct: (847) 808-7304 / Cell: (847) 340-1227 Fax: (847) 808-3322 / E-Fax: (646) 304-1315 carlg@automedrx.com www.addsinc.com
PickPoint Corporation	4234 Hacienda Drive, Suite 101 Pleasanton, CA 94588 Phone: (925) 924-1700 Fax: (925) 924-1900 www.pickpoint.com

Definition

The National Association of the Boards of Pharmacy (NABP) defines telepharmacy as the “provision of pharmaceutical care through the use of telecommunications and information technologies to patients at a distance.”¹³³

Legality

Many states have regulations regarding the use of telepharmacy. The regulations generally pertain to exactly who may remove the drugs from the remote cabinets, and how a pharmacist is required to supervise the process.

Software Compatibility

In most cases, the telepharmacy software is or may be made compatible with existing clinic software. Specific determinations will depend on the telepharmacy company and the existing software.

Safety

Most systems allow for multiple checks using bar code technology. The loading of the machines is usually under the pharmacist’s control, and the dispensing is always under a pharmacist’s control. The label will not be printed until the proper medication is scanned using the bar code technology.

Purchasing Equipment

Options may vary depending on the company, from purchase, lease-to-purchase, and long-term lease options. There may be discounts based on the Federal Supply Schedule or other types of discounts.

Controlled Substances

Individual sites may be approved to dispense controlled substances, depending on state law. The cabinets are DEA-compliant for the dispensing and storage of controlled substances in most situations.

Break-even Estimation

According to one telepharmacy provider,¹³⁴ an average margin of \$10/per prescription on 20 to 25 prescriptions a day would be the minimum to enable a site to successfully use telepharmacy.

Repackaging

Because the remote dispensing machines can only fit a certain size bottle, sites have the option to repackage medicines at an in-house pharmacy or to send drugs to a repackager. Repackagers typically charge between \$1–2 per unit of use repackaged. The telepharmacy company usually has a business relationship with a “recommended” repackager and will refer clients to that repackager. However, new technology¹³⁵ is soon expected that will enable remote dispensing machines to accept all package types and sizes by the user easily changing to a different size internal component. This will allow the entity to purchase the items in the correct quantity directly from a wholesaler or manufacturer, and it will eliminate extra work and cost associated with repackaging.

In-House Pharmacy: Helpful Hints¹³⁶

Hire the pharmacist as early as possible.

The pharmacist can then take on the responsibility for implementing the pharmacy.

Contact the state board of pharmacy early in the process.

In order for in-house pharmacies to be licensed, they must pass an inspection by the state board of pharmacy. This step (preparing for the license and scheduling the inspection) often takes a long time, so the earlier a contact is made with the board, the earlier the inspection is likely to occur.

If construction is necessary for an in-house pharmacy, companies that sell fixtures (counter tops, shelving, etc.) will usually provide a plan for the layout of the pharmacy free of charge.

A good starting place is the drug wholesaler, who will either operate a fixture company or be able to refer you to several companies for estimates.

Decide early on what third-party (if any) reimbursements the pharmacy will accept, and begin the process of completing the paperwork.

This step can hold up the reimbursements if the contracts with the third parties are not in place when the pharmacy opens.

Immediately enroll the pharmacy as a participant in the 340B program with OPA.

Because the updates are only made quarterly, waiting to enroll could cost the health center money if the health center is forced to buy inventory at a non-340B price (if the center is forced to buy the inventory before the center appears as a 340B participating entity on the OPA database).

Contact the DEA early on in the process.

The DEA will issue a controlled substance permit to the pharmacy that allows the pharmacy to handle controlled substances. Receiving the permit may take several weeks to months.

Create a formulary.

Establishing a formulary is especially important to assist in inventory control and cost-effective management of sliding fee patients' medications.

Work with a wholesaler in conjunction with using the health center's formulary to plan an opening inventory order.

The wholesaler will often suggest an opening order, but the entity's formulary will also be helpful.

Establish a sliding fee scale.

Health centers that receive grants from HRSA are expected to offer "a method of discounting or adjusting fees based upon the patient's income and family size from current Federal Poverty Guidelines" for all services offered to patients.¹³⁷

Market the pharmacy service.

It is critical to establish a plan for marketing the service to patients. This will include deciding when and how to inform patients that the pharmacy will provide the service. Emphasis should be placed upon the fact that the pharmacy is a low-cost provider of drugs and has a convenient location.

Incorporate the four cornerstones of comprehensive pharmacy services.

This includes affordable access to medications, outcomes-driven pharmaceutical care, efficient business practices, and quality assurance.

Understand alternative methods.¹³⁸

Currently the guidelines permit a health center to dispense only to patients of the health center. This means that even though other 340B-eligible entities may be nearby, the pharmacy of one entity only may serve patients of that entity. An alternative method is required for networks purchasing or sharing of entities' patients.

Communicate with other health centers that have successful in-house pharmacies.

The secrets to success are not always obvious to newcomers to the pharmacy arena, but they may be easily shared between sites. Good opportunities for networking include annual meetings (such as the APhA annual meeting, the 340B Coalition annual conference, and the NACHC annual meeting).

Compare several different pharmacy computer systems.¹³⁹

Consider if the system will interface with the clinic's software, the user support, and the overall needs of the pharmacy. The cost of the programs will vary, but expect to spend at least \$15,000¹⁴⁰ for hardware, software, and technical support services for the first year.

Build in additional start-up time for any unforeseen delays.¹⁴¹

CASE STUDY #1: Traditional In-House

Snapshot ¹⁴²	
# Pharmacy Sites	4
Total Annual # Encounters	98,822 (varies by site from as low as 11,808 to 20,703)
Total Annual # Rxs	85,567 (varies by site from as low as 14,233 to 43,822)
Hours of Operation	8–5 M–F
RPH FTE	4 FTE
Part-Time RPH FTE	0.6 FTE
Technician FTE	7 FTE
Avg. Sq Feet	Varies by site from 382–600 sq feet

History

A few years ago a new pharmacy director was hired in this clinic to manage a struggling, dual site, in-house pharmacy. The challenge was to make the pharmacy operation self-sustaining or face closure. Since that time, the pharmacy has become financially successful and grown from two in-house sites to four.

Development

The pharmacist hired to revive the pharmacy had prior experience in retail pharmacy, and relied largely on this experience to develop, restructure, and expand the pharmacy service. The pharmacist spent extensive time networking with other health center pharmacists, visiting in-house pharmacies, and observing operations. The pharmacist continues to maintain these contacts and relies on shared ideas even today. During the revamping of the existing pharmacy and the opening of the new sites, the pharmacist also relied on the fixture company to assist in drawing the plans for the physical layout of the pharmacies.

The initial decision to have an in-house pharmacy was made before the current pharmacist arrived. After turning the pharmacy around from a struggling operation to a successful one, the current pharmacist added in-house pharmacies at two other sites as soon as there was adequate prescription volume to cover the operating costs at each site. The largest operating cost for the pharmacy was the pharmacist's salary (approximately \$100,000 in salary and benefits in this area), so the revenue generated from the prescription volume needed to reach a level to at least support this salary. The pharmacist reported that a volume of greater or equal to 1,200 prescriptions filled per month (60/day) would be the absolute minimum to support the costs of operating an in-house pharmacy. Dispensing fewer prescriptions than this threshold would cause the pharmacy to operate at a loss and eventually be forced to close. (This number is based on the fee structure, sliding fee scale, and payer mix of this organization. As these variables change, the volume necessary for success also changes.)

The time that elapses between conception and opening the doors of the new pharmacy sites can vary from nine months to more than 18 months. Based on this pharmacist's experience, this implementation time has lengthened over the years, mostly due to the increase in regulatory requirements, fees, and the various organizations and people that now have input into decision-making. The biggest time-determinants are construction issues, zoning, permits, and licenses.

Management Responsibilities

The pharmacy director visits each site once a month and participates in training and quality assurance for each site. A typical week for this director consists of three dispensing days, one administrative day, and one clinical day. The clinical day involves the pharmacist as a provider of drug and disease information to patients participating in a diabetic clinic.

Finances

The level of financial risk to the health center is low for these pharmacies, and this is by design. Balancing the fixed operation costs of the pharmacy with the revenue generated is the biggest key to determining the financial success of the pharmacy. In other words, the pharmacist ensures that the pharmacy costs to the clinic are always covered by adequate revenue. The health center serves patients that have various sources of payment (cash, Medicaid, uninsured-sliding fee, private insurance, etc.), but the main focus of the health center is to be able to serve uninsured patients. Despite the large number of uninsured patients, the pharmacist has structured the pricing formula for drugs and the patients' fee scale to ensure that each patient contributes something financially to the prescription cost. This system is designed to spread risk among all of the patients.

The sliding fee scale is structured into four categories that align with the scale of the clinic:

- Category 1: less than or equal to 100% poverty ≈ 50% off of the retail cost of drug
- Categories 2 & 3: less than or equal to 200% poverty ≈ 25% off of the retail cost of drug
- Category 4: greater than 200% poverty ≈ retail cost of drug

Retail cost of each drug is calculated as approximately $AWP - 9\% + \$5$; however, this formula may vary greatly by drug. The health center periodically checks the competition's prices and balances this with what the patients can afford. Some drugs have a formula that may be as low as $AWP - 80\% + \$5$. Setting the prices for drugs is a key aspect to ensuring optimal financial performance of the pharmacy. The pharmacist has developed reports that capture and calculate the average dollar margin per drug, and the pharmacist or designee reviews these reports daily to catch price errors or price changes, or to flag drugs for possible price modification.

Estimations of financial figures that the pharmacy tracks (reflective of the averages of all four sites) include:

- ≈ \$6.25 average cost to the clinic to buy one prescription
- ≈ \$9.20 average net margin per prescription
- ≈ \$15.45 average billing to patient or payer per prescription
- ≈ \$8.60 average fixed cost to dispense one prescription (this number can vary from \$6 to \$20, depending on the site)

Typical retail pharmacies (non-340B pharmacies) are likely to have a higher acquisition cost and a lower net margin per prescription than 340B pharmacies. Typical retail pharmacies usually have to share profits with stockholders and may accept insurance payments that barely or may not cover operating costs to try and lure patients into stores or to bolster prescription volume.

Administrative Oversight

The administrative involvement (chief executive officer/chief financial officer) in the pharmacy is minimal. There is little time commitment, as the pharmacist completely manages and operates the pharmacy. The pharmacist is part of the executive team, comprised of the chief executive officer, chief financial officer, chief medical officer, chief nursing officer, human resources director, and chief operating officer, and meets with this team biweekly.

Despite the pharmacist shortage, this pharmacy does not have trouble hiring and retaining pharmacists. This is due to factors such as:

- the operating hours of the pharmacy are 8–5 M–F with an hour off for lunch, which is more desirable than many retail hours (which may be open 24+ hours)
- a competitive salary and benefits package is provided
- the pharmacists have input into the operation and improvement of the pharmacy and are part of the clinic management team

The director reports some difficulty with retaining part-time pharmacists. Scheduling is difficult because part-time pharmacists often have other jobs, and the health center does not offer benefits for these pharmacists.

The pharmacy director has developed extensive and detailed reports, and these are critical to portraying the financial health of the pharmacy operation. Reports are generated and reviewed at intervals ranging from daily to annually. Types of reports include:

- Financial (daily margin/prescription, cost to clinic to dispense each prescription, average billing to patients)
- PAP (AWP value, number of PAPs)
- Monthly provider meeting and P&T committee meeting
- Vaccine
- Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
- Total Quality Improvement (TQI)

Keys to Success

The keys to the pharmacy's success lie in the management of the pharmacy service and the integration into the clinic structure. The assimilation of pharmacy is achieved by having the pharmacy director participate in the provider meetings, P&T meetings,

etc. Such integration is essential to assuring that the pharmacy services are relevant and flexible enough to the needs of the providers, administrators, and patients.

The formulary is an example of how integration of the pharmacy service into the clinic is critical. The formulary must be a “living” document that is responsive to prescribing patterns in order to increase the prescription capture rate for the pharmacy. The pharmacist feels that the pharmacies and the clinics work as a team, resulting in a successful formulary for the clinic (financially) and patients (therapeutically). Some other health centers design formularies to focus on the insured population (by selecting formulary drugs that are covered by the major insurers in hopes of capturing these patients and their revenue). The pharmacist in this clinic warns that it might be tempting to cater to the insured population in this manner to enhance clinic profits, but that this may result in a formulary driven by the rebates received by the PBMs and not the therapeutic drugs of choice.

Challenges

The biggest challenges for the pharmacist are staying on top of the many daily challenges. These will vary and might be from patients, administrators, payers, or other factors – just discovering the sources of the problems and finding solutions is a constant challenge!

Samples and PAPs

Although providers distribute samples, the patients are not charged, and the pharmacy doesn't maintain records. This clinic (through its four pharmacy sites) annually helps patients receive at least 14,140 PAP prescriptions valued at over \$1.65M (AWP value). There are actually more PAPs dispensed, but an increasing number of patients receive PAPs at their home (instead of from the pharmacy or clinic), and it is virtually impossible to track these medications.

CASE STUDY #2: In-House Management Company–Operated Clinic

Snapshot	
# Pharmacy Sites	1
Total Annual # Encounters	50,000
Total Annual # Rxs	100,000
Hours of Operation	8–5 M–F
RPH FTE	1 FTE
Part-Time RPH FTE	0.5 FTE
Technician FTE	3 FTE
Approximate Sq Ft	250 sq ft

History

This community health center provides medical and dental services at two delivery sites (a main site and a smaller site about five miles away) using 13 physicians, two dentists, one physician assistant, one nurse-practitioner, and one dental hygienist. The patient population is ethnically diverse, and payer types consist primarily of undocumented aliens/indigent patients (70%) and Medicaid patients (25%). The insured population is about 5%.

There is an on-site pharmacy at the main site that was originally owned and operated by the clinic. After a few years, the pharmacy began to have trouble retaining a pharmacist and eventually became such a large cost-center for the clinic that a management company was hired for the day-to-day management of the pharmacy. The management company that was originally hired was unable to manage the pharmacy in a cost-effective manner, broke the contract, and rapidly left the clinic with no pharmacy service. This rapid departure forced the clinic to sign a new contract for management services quickly to avoid closing the pharmacy and leaving patients without access to affordable pharmacy services. The clinic CEO reports that the day-to-day operations of the pharmacy are now managed adequately, although the fee to the management company is expensive.

Development

The clinic has always had existing pharmacy space and equipment. The development of the management services contract consisted primarily of writing the contract and approving of the management company's hired staff. The clinic's board has advocated an in-house pharmacy service for patient convenience for a long time, despite the expense and inability of the clinic to manage an in-house pharmacy. Because the clinic does not have the ability to retain a pharmacist or expertise to manage a traditional in-house pharmacy, the CEO feels that the only pharmacy option that will please the board is contracting with the management company. The CEO would like to locate a willing, local retail pharmacy and attempt to institute a traditional, off-site 340B contract for pharmacy services and try to convince the board of the financial benefits to the clinic. However, the CEO has not yet been able to locate a willing contract pharmacy. The CEO continues to talk with pharmacies in the area in hopes that a pharmacy might someday be willing to participate in a contract for pharmacy services.

Management Responsibilities

The clinic administrative staff has little day-to-day management responsibilities for the pharmacy, although the clinic retains overall legal “oversight” for the pharmacy operation. According to the CEO, the administrative staff of the clinic relies heavily on the pharmacy management company to “follow all of the pharmacy laws!”

Finances

The pharmacy dispenses approximately 375 prescriptions per day and utilizes the 340B program. The clinic pays fees to the management company for “management” (approximately \$156,000/year or \$13,000/month) and “other pharmacy expenses,”¹⁴³ such as staff salaries and supplies (approximately \$232,000/year or \$19,333/month). Thus the annual cost to the clinic for using the management company is \$388,000.

The pharmacy is able to collect a small amount of money from insured patients and Medicaid patients (the clinic carves out the Medicaid program from 340B and purchases instead from a non-340B contract to help generate revenue). However, the pharmacy did not provide exact revenue numbers and reports operating at an overall loss, estimated between \$50,000 and \$100,000 a year. The current CEO did not have figures from the prior pharmacy service options (the first contract for management services or the in-house pharmacy) to be able to compare how the current contract for management services fared to past options.

However, ballpark financial estimations for a traditional pharmacy service would be: 1.5 FTE pharmacists at approximately \$150,000 salary + benefits and 3 FTE technicians at approximately \$80,000 per year, total annual staff cost \$230,000, and no “management fee.” Since the inventory costs are not included in the management company’s fees or clinic’s pharmacy budget, the inventory costs would likely remain unchanged in either option. Based on these major expenses, an in-house pharmacy could potentially cost at least \$156,000 per year less than hiring a management company. In other words, the clinic would likely have similar equipment and supply costs, but would forego the management fee.

Keys to Success

The CEO reports that a major key to success is being able to afford the management company’s service fee. Currently the clinic is able to use collections from patients and other payers, coupled with allocations from the clinic’s budget to pay for this fee. The CEO does not know how long the clinic will be able to sustain the pharmacy service in this manner by allocating a portion of the overall operating budget to the pharmacy service.

Challenges

The pharmacy has outgrown its existing space of approximately 250 square feet, but there is no available space in the clinic for pharmacy expansion. Despite the extra expense associated with having a pharmacy management company, the CEO feels pressure from the board to operate an in-house pharmacy for patient convenience. The CEO feels that past experience with a traditional in-house pharmacy “scared” the board and clinic from attempting this option again. Although the CEO would like to convince the board to change to a traditional contracted pharmacy services relationship with a local pharmacy, the CEO has yet to find a willing pharmacy.

Samples and PAPs

The clinic participates in a limited number of PAPs, but does not quantify the number of prescriptions, estimated value, or number of patients served. The pharmacy does not dispense samples.

CASE STUDY #3: In-House Telepharmacy¹⁴⁴

Snapshot	
# Pharmacy Sites	1 base site, 5 remote sites
Total Annual # Patients Served	20,000
Total Annual # Rxs	≈ 40,000
RPH FTE	2 FTE
Part-Time RPH FTE	0.5–1 FTE
Technician FTE	≈ 5 FTE

History

This health center had an empty existing space for a pharmacy in its main site, but decided that telepharmacy would best fulfill the needs of all its sites. Telepharmacy allows the patients to receive medications and a one-on-one consultation with the pharmacist at the time of their visit, and minimizes medication errors due to the numerous checks in the dispensing process.

Development & Finances

Telepharmacy is appropriate in this system because it expands the availability of 340B pharmacy services to a wide geographic area, including dispensing services, the direct provision of patient education, and responses to providers' questions. The health center purchased its remote dispensing machines a few years ago, and at that time the retail price per machine was \$60,000. However, as a nonprofit health center, there was a discount applied to this price. It also would have been possible to lease the machines rather than purchase them. The main site does all billing on behalf of the remote sites, but the majority of the population is uninsured, so the billing is minimal.

Patients pay co-payments at the time the medication is dispensed, on an income-based sliding fee scale. Medications are not withheld if patients are unable to pay, but the rate of nonpayment is low.

The five remote sites are located between a few miles and more than 80 miles away from the base site. The remote sites store medications in a machine called an Automatic Drug Delivery System (ADDS).

Communication between the remote sites and the base pharmacy occurs via an electronic network and a videoconferencing system. The entire process (receipt of the prescription by fax, processing and dispensing of the medication, and counseling of the patient via teleconferencing) generally takes 10 to 15 minutes. When a prescription is submitted by phone, fax, or Internet from a remote site to the base pharmacy, the following sequence of events occurs:

1. A pharmacist at the base site processes the prescription and verifies the label for accuracy through the computerized drug dispensing system. The label is then transmitted to the remote site to be dispensed with the medication. Authorized dispensing personnel (providers, pharmacists, and pharmacy technicians) need a user ID and a password to access the computer system.
2. After the prescription information appearing on the computer screen has been re-verified, the pharmacist at the base pharmacy authorizes the order. At the remote site, a pharmacy technician presses the Dispense button on the computer and a bottle of the prescribed medication drops from the ADDS machine.

3. The technician uses a handheld scanner to scan the bar code on the medication bottle. If the medication is the correct one, a label is automatically printed out.
4. After the label has been printed, the technician scans the bar code on the label, completing the transaction.
5. The pharmacy technician at the remote site dials up the pharmacist at the base clinic. The pharmacist re-verifies the prescription information and counsels the patient about the use of the medication. The pharmacist also verifies that the prescription label printed out at the remote site is accurate, that the label is being placed on the correct bottle, and that the medication bottle is sealed.
6. To preserve confidentiality, both patient and pharmacist use telephone handsets to speak to each other. No one else is present in the videoconferencing room during the consultation. The labeled medication bottle is given to the patient.

Challenges

The telepharmacy system began using the base site and one remote site a few years ago. Providers dispensed medications from the ADDS machines initially, but began to resist this responsibility. The health center then contacted the state board of pharmacy and requested that certain qualified technicians be permitted to dispense medications from the remote unit. The board granted approval with a stipulation that the base clinic pharmacist must reverify both the label and medication bottle before the technician can dispense the medication.

In order for the clinic to receive 340B prices on the medications, the clinic has to purchase the drugs, receive the drugs, verify that the order was correct, send the drugs to a repackager that works in conjunction with the telepharmacy company (this is due to the fact that the ADDS machines only accept certain bottle sizes), and then wait for the repackager to send the medications back to the clinic. The cost to repackage each unit of use bottle is approximately \$1.25.

A pharmacy and therapeutics (P&T) committee was set up to review the health center formulary monthly. Due to the limited capacity of the ADDS machines (87 medications), they must be stocked with medications that are the most effective and most frequently used by the patient population. The health center initially had 87 medications on the formulary but now has about 200 medications. Medications that are not stocked in the ADDS machines are stored at the base site and mailed to patients.

All remote sites, except for one, were already connected by a computer network with high-speed internet access at the start of the project. The final remote site was connected after the project began, and it took time to figure out how to get high-speed access at that site. Two remote sites have not been able to hire technicians, and physicians reluctantly operate the ADDS machines with no assistance.

The ADDS machines occasionally require maintenance, but the manufacturer generally provides on-site service within 24 hours when a machine breaks down. The cost of machine maintenance needs to be taken into account when initial estimates of the costs of a telepharmacy system are prepared.

Keys to Success

Establishing a strong working relationship between sites, mastering the technology, and setting up efficient policies and procedures are keys to a successful operation.

Pharmacy: In-House Timeline¹⁴⁵

Note that these are suggested steps for action to open a traditional in-house pharmacy. Steps particular to in-house management company–operated or telepharmacy are denoted by an asterisk (*). These steps may be inserted as appropriate on the entity’s action plan.¹⁴⁶

Month 1

1. Hold initial meetings with clinic’s board and directors to determine need and available funding for pharmacy services.
2. Perform market analysis or feasibility study.
 - Fixed and variable costs
 - Projected sales
 - Pricing of pharmacy benefit
 - Break-even analysis
3. Initiate relationship with wholesalers and begin to compare contract terms.
4. Contact an organization for technical assistance or for help in locating a consultant pharmacist.¹⁴⁷
5. Develop staffing plan. (The results from the decision analysis and feasibility study will help you with this.)
6. Contact state board of pharmacy to request material. It should have a procedure for opening a new pharmacy. Also, be sure to ask for rules and procedures relating to operating a pharmacy (e.g., requirements such as a separate counseling area, sink, reference books, and prescription balance). Determine what type of license you need, as some states license according to site. It will most likely be a retail/ community license. Ask if there are any state requirements that apply to the 340b program.
7. Initiate communication with other pharmacies in the area. You may want to do this to ensure a good relationship with the other pharmacies. This may also provide you with contacts of pharmacists who may be looking for another job. Sometimes existing pharmacies will see a new pharmacy as a threat to their

business. You may be able to explain that the pharmacy is opening for the primary benefit of serving clinic patients, most of whom need access to a special discount program to help them afford pharmaceuticals.

8. Begin the pharmacist recruitment process. The earlier you hire a pharmacist, the better. It will be very helpful to have a pharmacist perform functions such as ordering the starting drug inventory and dealing with the board of pharmacy.
9. *Contact pharmacy management companies and compare and determine fees. Arrive at a decision as soon as possible. The management company may be able to complete the start-up process on behalf of the clinic.
10. *Contact telepharmacy companies, obtain prices, and make a selection as to the equipment needed.
11. *Contact repackagers, if desired, obtain prices, and make a selection.
12. Enroll in 340b drug pricing program by completing and submitting the enrollment form.¹⁴⁸

Month 2

13. Determine plan for pharmacy layout and fixtures. This may involve construction or renovation to your existing site, as well as purchasing fixtures. A good place to start would be with drug wholesalers for estimates; they may provide this service or will connect you with companies who will.
14. Purchase pharmacy fixtures and have existing space remodeled to suit your needs. If construction is involved, allow an extra two to three months, depending on the amount of construction needed.
15. Negotiate wholesaler contract.
16. Conduct pharmacist interviews and hire pharmacist ASAP. This may actually take months until the process is completed.
17. Consider and prepare for JCAHO reporting requirements (if desired).

Month 3

18. Review and select pharmacy computer system.
19. Review and select a system to handle indigent drug programs.
20. Conduct pharmacist assistant interviews.
21. Select multidisciplinary team of clinicians to form P&T committee and begin formulary development process.
 - Review clinical guidelines and standards of care related to drug therapy, and combine this with existing knowledge of provider drug selection and cost in developing the formulary.
 - Develop policies & procedures for the medication use process and for approval of non-formulary medications.

- Streamline the pharmacy product line to decrease the inventory and improve cash flow.
- Promote quality, cost-effective prescribing using evidence-based medicine.

Month 4

22. Develop third-party / Medicaid contracts.
23. Determine and purchase necessary equipment & supplies (this will include items such as prescription labels, bottles, counting trays, spatulas, automated counting equipment, cash register, tape/dispenser, prescription pads, receipt pads, pens, pencils, highlighters, paper clips, fax, telephones, prescription balance and weights, pharmacy reference books, distilled water, water dispensing equipment, mortar and pestle, ointment slab). The state board of pharmacy will have a complete list of the required equipment and supplies.
24. Complete pharmacy licensure forms with state.
25. Schedule Board of Pharmacy inspection to occur in month 6 or within close proximity to opening the pharmacy.
26. Complete DEA licensure / HIN.
27. File for Federal tax ID # / local tax / state tax.
28. Research and select liability insurance / pharmacy insurance.
29. Research pharmacy security systems.

Months 5–7

30. Establish clinic formulary.
31. Select pharmacy security system.
32. Ensure pharmacy staff is trained on pharmacy software system.
33. Hold meetings with CFO to discuss pharmacy revenue/expenses.
34. All staff should be hired at this point. Select pharmacist to be pharmacy manager.
35. Purchase pharmacy opening inventory and stock. Most drug wholesalers have suggested initial orders if you need help deciding what to order.

Month 8+

36. Open pharmacy.
37. Consider adding clinical pharmacy services and pursuing reimbursement for cognitive services.

Contracted Pharmacy Services: Additional Detailed Information¹⁴⁹

Background

Because there was no provision or guidance in the legislation for pharmacy services furnished by an outside pharmacy, initially all entities wishing to access 340B prices had to implement pharmacy services through an in-house pharmacy or provider dispensing. The entities that participated in the program quickly learned that offering pharmacy services was very different from the provision of other aspects of health care. These safety net providers were faced with issues that made maintaining a 340B pharmacy service a challenge, including: a high percentage of uninsured patients, often a small prescription volume, a lack of pharmacy expertise, confusion regarding the 340B program, and difficulty finding and retaining pharmacists due to a growing pharmacist shortage.

As a result of these issues, 340B contracted pharmacy services were introduced by a notice published in the *Federal Register*.¹⁵⁰ The design was to ensure that eligible entities would access 340B prices without having to maintain their own pharmacy. As a replacement for the entity's in-house pharmacy, it could instead choose to contract for pharmacy services with one pharmacy in the community. This contracted pharmacy would function to provide *all* of the pharmacy services (hence the term *contracted pharmacy services*) in lieu of an in-house pharmacy. For the first time, entities had a choice as to how to deliver pharmacy services to patients: through an in-house pharmacy, provider dispensing, or a contracted pharmacy.

How 340B Contracted Pharmacy Usually Works

The contracted pharmacy services guideline sets general boundaries on procedures, but the details of exactly how to operate and manage the service are purposely omitted. As a consequence, there is a certain degree of flexibility in the design of the service, as long as the integrity of the 340B legislation is protected.

Guideline Requirements

The following list is a brief summary of the guidelines published in the *Federal Register*. A thorough review of the entire guideline text is recommended.¹⁵¹

1. The eligible **entity will purchase the drug** and assume responsibility for establishing its price.
2. A “**ship to/bill to**” procedure may be used in which the drug is shipped to the pharmacy but billed to the entity. The pharmacy will compare all shipments received against the orders and inform the covered entity of any discrepancy within five business days of receipt.

3. The pharmacy will provide **all pharmacy services**,¹⁵² and may provide the eligible entity services **other than pharmacy services** (e.g., reimbursement services). Currently the guidelines permit only **one** contracted pharmacy per eligible entity.¹⁵³
4. The clinician at the eligible entity will inform the patient of the **freedom to choose** any pharmacy provider.
5. The contractor and entity will adhere to **all federal, state, and local laws** and requirements. PHS grantees will adhere to all rules and regulations established by the grant funding office.
6. The contractor will provide the covered entity with **reports** consistent with customary business practices.
7. **Both parties agree that they will not resell or transfer a drug purchased at 340b to an individual who is not a patient of the entity.** The contractor, with the assistance of the covered entity, will establish and maintain a **tracking system suitable to prevent diversion of 340b drugs to individuals who are not patients**¹⁵⁴ of the eligible entity.
8. Both parties will **not use drugs purchased under 340b to dispense Medicaid** prescriptions, unless the contracted pharmacy and the State Medicaid agency have established an arrangement to prevent duplicate discounting.
9. Both parties understand that they are subject to **audits** (by the Department of Health and Human Services and drug manufacturers) of records that directly pertain to the entity's compliance with the following prohibitions: a) drug resale, b) drug transfer, c) duplicate discounts with Medicaid.
10. The contractor's 340b **records will be separate** from the contractor's own operations.¹⁵⁵
11. Upon request, a **copy of the contract** will be provided to a drug manufacturer that sells drugs to the entity.
12. A **Self-Certification** form¹⁵⁶ should be submitted to the Office of Pharmacy Affairs.
13. Contractor and entities must not violate any provision of the **Medicare and Medicaid anti-kickback statute**, 42 U.S.C. 1320a-7b.

Practical Implementation of the Guidelines

There are virtually endless ways to structure a contracted pharmacy services agreement, as long as the basic guidelines presented in the previous section are followed. The table on the next page summarizes the flow of money and drugs in contracted pharmacy services. It is followed by a narrative description of one way to implement contracted pharmacy services.

How Contracted Pharmacy Often Works

	340B Covered Entity	Wholesaler	Contracted Pharmacy	Patient
Money Flow¹⁵⁷	Collects Payments collected by pharmacy	Collects Money from entity	Collects¹⁵⁸ A per prescription dispensing fee from entity Co-pays from patients Third-party reimbursement on behalf of entity	
	Pays Wholesaler for drugs Contracted pharmacy a per prescription dispensing fee		Pays Collections due to the entity	Pays¹⁵⁹ Pharmacy amount determined by entity in accordance with contract terms; this is usually a set fee, determined by a formula such as $AWP - X\% + \text{Fee}$, or $340B \text{ Cost} + \text{Fee}$
Drug Flow	Opens account with wholesaler under a ship-to/bill-to arrangement; drugs are shipped to pharmacy, but owned by and billed to the entity	Delivers drugs to contracted pharmacy	Dispenses drugs to patients Manages and stores drug inventory owned by entity Often orders drugs on behalf of health center	Receives drugs from contracted pharmacy

The following is an example of *one* way to make this work:

1. A health center decides to initiate contact with a pharmacy to explore providing 340b contracted pharmacy services for its patients. Alternatively, a community pharmacy could decide to explore a contracted pharmacy relationship by contacting the entity. The health center¹⁶⁰ contacts the Pharmacy Technical Assistance Hotline provided by the PSSC¹⁶¹ (1-866-PharmTA); a consultant provides information to the health center and, by its request, to the potential contracted pharmacy, such as:

Assistance to Health Center	Assistance to Potential Contracted Pharmacy
<ul style="list-style-type: none"> ■ Decision analysis to determine the most appropriate means for implementing a comprehensive pharmacy program ■ The effect of introducing contracted pharmacy services on the community, especially local pharmacy competition ■ An estimate of the annual number of patient visits, prescriptions, and capture rate for the contracted pharmacy ■ The effect of the payer mix (cash, Medicaid, Medicare, other third party, sliding fee) on the program ■ Potentially sustainable subsidies for sliding fee¹⁶² patients ■ Appropriate dispensing fees to the pharmacist and mark-up (if any) on the drug ■ Sample contracts 	<ul style="list-style-type: none"> ■ Information resources concerning the 340B program ■ Locations of nearby FQHCs and other eligible entities ■ Sample reports (including data and timeframe for reporting) ■ Methods for determination of the pharmacy's cost basis prior to the negotiation of dispensing fees ■ Steps to implementation ■ Advice regarding inventory handling, space allocation, and monetary exchanges ■ Formulary assistance ■ Computer system structure ■ Final check of program to ensure compliance with federal guidelines ■ Assistance determining any special state requirements

2. Using this information, the following decisions are agreed upon by the community pharmacy and the health center (these will vary from site to site, are not specifically required by the guidelines, and are listed for example purposes only):
 - The pricing formula for each cash-paying patient will be determined based on AWP. However, there are many options, and two of the most common are:¹⁶³

$$\text{Total Cost} = (\text{340B Drug Cost}) (\% \text{ Mark-Up}) + \text{Pharmacist's Dispensing Fee}$$

or

$$\text{Total Cost} = (\text{AWP} - X\%) (\% \text{ Mark-Up}) + \text{Pharmacist's Dispensing Fee}$$
 - The pharmacist's dispensing fee, for example, is \$8 per prescription, and the percent mark-up to the patient is 20% (a percent mark-up is not required, but it may be helpful to the clinic to help cover the cost of sliding fee patients' medications).
 - The cash and sliding fee patients pay the dispensing fee of \$8, or the health center will subsidize a portion of the fee. The insured patients pay their co-pay to the pharmacy, and the pharmacy submits claims on behalf of the health center at the pharmacy's usual and customary price. The pharmacy gives all allowable reimbursement and collections to the health center, and the health center pays the pharmacy the dispensing fees owed at \$8 per prescription.
 - The clinic will use the revenue it generates on insured patients and cash payers to subsidize sliding fee patient's prescription costs and/or expansion of primary care services.
 - The clinic will set up a formulary of mostly generic medications, where available in the therapeutic class, that it will subsidize for the sliding fee clinic patients.

- The sliding fee scale¹⁶⁴ will mirror the scale of the clinic, although there are many possibilities. Some clinics prefer to slide the *cost (mark-up)* portion of the formula by a percent; other clinics prefer to have every patient pay the cost portion of the formula, and slide only the mark-up to ensure that the clinic does not lose money on this program. Some clinics slide the dispensing fee, and some clinics slide the entire cost formula. The structure of the sliding fee scale will be determined by the payer mix and unique circumstances at different clinics.
 - Where permitted by state law or pharmacy board regulation, a single physical inventory will be used, with separation of 340b and non-340b drugs electronically.
 - A replenishment system for the 340b drugs will be used, with trigger points for reordering set at 75%. This means that as soon as 75% of any 340b drug's total bottle quantity is used (for example, as soon as 75 tablets from a bottle of 100 tablets are used), a new bottle is ordered at the 340b price.
 - A tracking system to ensure that only eligible patients receive medications is established.
 - Payment terms and reporting requirements are set, including data to be reported and frequency of reports. The pharmacist meets with the health center's chief financial officer (CFO) once a month to reconcile reports. At this meeting, the pharmacist writes a check to the health center for the money that it has collected from payers and keeps the dispensing fees. The health center writes a check to the drug wholesaler for the amount of the drugs purchased.
 - At the request of the health center, the pharmacy does the ordering and collects payment from payers, if the payer contracts allow the pharmacy to collect on behalf of the health center.
 - The pharmacy manages the inventory and supplier accounts, reporting shortages, processing salable and outdated returns, etc.
 - Periodic audits are scheduled and will be performed by the health center staff to ensure only patients of the center receive medication, Medicaid patients are not receiving medications purchased at 340b prices if the Medicaid agency is being billed, and the process is running smoothly.
 - The clinic will purchase approximately \$5,000 worth of inventory that will represent the projected most commonly used formulary drugs. The pharmacy will commingle this inventory with its existing inventory. It would have been possible for the pharmacy to dispense out of its existing inventory and order at 340b (under the clinic's account) to replenish the inventory retrospectively.¹⁶⁵ This would allow the clinic to have no initial inventory cost.
3. After a review of the contract by the both parties' legal counsel, the contracted pharmacy agreement is signed.

4. The clinic submits a 340b enrollment form and Contract Self-Certification Form to OPA. This 340b enrollment form should be completed early in the process so that the clinic may begin purchasing medications for in-clinic administration immediately, if desired. The “ship to/bill to” arrangement can be added when the contract is established. The pharmacy’s Medicaid provider number is submitted to OPA for reporting to the state Medicaid agency use in rebate determination. The clinic signs a contract with a drug wholesaler using a “ship to/bill to” arrangement. The drugs are shipped to the pharmacy, but are paid for by the clinic. The pharmacy DEA license is used, since the DEA issues such licenses only to licensed persons and entities based on the location of the drug inventory.¹⁶⁶

Contracted Pharmacy Services: Helpful Hints¹⁶⁷

Be aware that both state law and federal law can impact the 340B program.

Although pharmacists are used to dealing with state laws regarding pharmacy activities, it is important to note that 340B contracted pharmacy services resulted from federal law. Despite the fact that the 340B legislation is federal, some states have chosen to pass additional laws regarding 340B. Examples of such state requirements include a mandatory physically separate inventory for 340B drugs or a special license (such as a wholesaler’s license) for the health center.¹⁶⁸ It is critical to investigate state policies regarding 340B before participating in the program.

Be informed of special reimbursement issues.

Medicaid: The 340B contracted pharmacy regulations require that *drugs purchased under 340B are not to be dispensed to Medicaid patients unless the contracted pharmacy and the state Medicaid agency have established an arrangement to prevent duplicate discounting.* Typically, Medicaid¹⁶⁹ patients of the clinic take their prescriptions to the pharmacy, the pharmacy dispenses drugs purchased at non-340B prices, and the pharmacy bills Medicaid at the usual rate.

Third Party: Many contracted pharmacy services arrangements include provisions for the pharmacy to act as a billing agent for the health center. This means that the pharmacy will bill the third party/PBM on behalf of the health center owned drugs. It is important for the pharmacy to check state law and the PBM/third party contracts to make sure that this practice is not prohibited.

Create a formulary.

Establishing a formulary is especially important to assist in inventory control and cost-effective management of sliding fee patients’ medications.

Establish a sliding fee scale.

Health centers that receive grants from HRSA are expected to offer “a method of discounting or adjusting fees based upon the patient’s income and family size from current Federal Poverty Guidelines” for all services offered to patients.¹⁷⁰

Market the contracted pharmacy service.

It is critical to establish a plan for marketing the service to patients. This will include deciding when and how to inform patients that the contracted pharmacy will provide the service. Emphasis should be placed upon the fact that the pharmacy is a low-cost provider of drugs, offers hours that are likely even more convenient than the health center's hours, and has a convenient location.

Incorporate the four cornerstones of comprehensive pharmacy services.

This includes affordable access to medications, outcomes-driven pharmaceutical care, efficient business practices, and quality assurance. Additional services (such as pharmaceutical care) may be provided by the contract pharmacy and included in the contract.

Establish an accountable pharmacy liaison at the clinic.

This person may be the CEO, CFO, chief medical officer (CMO), or an administrative assistant. It is important to keep the lines of communication open, and that there is a responsible person at the clinic who is knowledgeable about issues that affect patients and the pharmacy.

Understand alternative methods.¹⁷¹

Currently the guidelines permit a health center to contract with one pharmacy for all of its 340B pharmacy services. An alternative method is required in order for a health center to have a contracted pharmacy and an in-house pharmacy, or in order for a health center to contract with multiple pharmacies.

Set up inventory procedures carefully.

Federal law permits the 340B drug inventory to be commingled or physically separated, but state law may require physically separate inventories. When using physically separate inventories, space requirements must be carefully considered by the contracted pharmacy. If separate physical inventories are not required, the computer system used by the pharmacy should be able to virtually separate 340B inventory from non-340B inventory.¹⁷²

Ensure that the contracted pharmacy has an appropriate computer tracking system.

Share the following information with the contracted pharmacy, as these tips refer to the computer system that the contracted pharmacy will maintain:

1. The computer system must be able to accept duplicate NDC numbers so that the pharmacy can differentiate 340B stock from non-340B stock. Many systems do not allow an NDC to be put into their system twice. Some pharmacists have requested that their existing software provider provide a customized enhancement to allow this capability. Other pharmacists have installed another side-by-side computer system dedicated to the 340B program. Although a separate computer

system seems like an acceptable idea, it may pose problems if a 340b-eligible patient needs a non-formulary 340b medication (the patient's record would be split between two computer systems), or if the pharmacy has an automated computer refill system (this feature wouldn't likely work with two separate computer systems).

2. The computer system must have a drug inventory record keeping and reporting capability. This is necessary for a good audit trail and to minimize diversion.
3. The computer system must have a formulary group identifier field within its drug record screen. This allows for easy report generation for the eligible entity's drugs: by putting an identifier on 340b drugs, they are able to be easily sorted for reports. This identifier needs to be within the drug record screen of each of the formulary drugs; in some systems this is called a "group" field, and in others, this field is called a "formulary" field. If the software doesn't have a labeled field, it may be necessary to contact the provider of the software to identify some unused field that can be used for this purpose.
4. The computer system must have a contract price field and pricing formula capability for accessing the 340b contract price. Ensure that contract pricing fields can be blocked from automatic drug price updates, or the system's pricing capability may be compromised. The prescription pricing should not be attached to the particular formulary drug, but should be set up as a separate price formula. (This should be just as a cash or third-party price code is setup within the system, directing the computer to use the price of the 340b price field instead of AWP or ACQ, etc.)

Contracted Pharmacy Services: Sample Reports

The following sample reports provide a guide as to the type of information that a contracted pharmacy would want to gather. The reports may follow any structure, and most pharmacies simply use reports that are already inherent in their software programs that capture this information. In other words, the contracted pharmacies do not have to use these exact reports presented as samples; they are merely provided as guidance.

The information in these sample reports was compiled based upon the *Federal Register* (August 23, 1996, vol. 61, no. 165, pp. 43549-56). The relevant text appears below:

(g) The contractor, with the assistance of the covered entity, will establish and maintain a tracking system suitable to prevent diversion of section 340b discounted drugs to individuals who are not patients of the covered entity. *Customary business records* may be used for this purpose. The covered entity will establish a process for a periodic random (sample) comparison of its prescribing records with the contractor's dispensing records to detect potential irregularities.

(2) The covered entity will verify, using the contractor's (readily retrievable) customary business records, that a tracking system exists which will ensure

that drugs purchased under the Act are not diverted to individuals who are not patients of the covered entity. Such records can include: *prescription files, velocity reports, and records of ordering and receipt*. These records will be maintained for the period of time required by State law and regulations.(3) Prior to the pharmacy providing pharmacy services pursuant to this agreement, the covered entity will have the opportunity, upon reasonable notice and during business hours, to examine the tracking system. For example, such a tracking system may include *quarterly sample comparisons of eligible patient prescriptions to the dispensing records and a six (6) month comparison of 340B drug purchasing and dispensing records as is routinely done in other reconciliation procedures*.

Monthly 340b Prescription Cover Sheet

Complete and return to clinic no later than the 5th business day¹⁷³ of each month.

Pharmacy Name: _____

Report Period: From _____ To _____

Category	CHC	Pharmacy
Total \$ Collected from Clinic Patients	(+) Prescription Amount: \$	Dispensing Fees Due (#Rx x Fee): \$
Total Offset Paid by Clinic	(-) \$	
Total Insurance Reimbursements	(+) \$	
Totals		

Category	
Total Amount Ordered from Wholesaler	\$
Total Number of Prescriptions filled for Clinic Patients	#

I certify that the above information is accurate.

Pharmacist's Signature: _____ Date: _____

Monthly 340B Prescription Summary by Patient¹⁷⁴

Complete and return to clinic no later than the 5th business day¹⁷⁵ of each month. Attach report for all out-dates with record of destruction.¹⁷⁶
 Attach report of all prescriptions filled. Attach report of all return to stocks from previous period. Attach report for all out-dates with record of destruction.¹⁷⁶
 Please contact _____ with questions.

Pharmacy Name: _____
 Report Period: From _____ To _____

Cash and Sliding Fee Patients									
Patient Name	Rx#	SF Indicator	Drug Name, Strength (NDC)	QTY	Date	Acquisition Cost (at Time of Dispensing)	Mark-Up Amount	Amount Collected from Patient	Amount Clinic Subsidized
Totals									

Insured Patients									
Patient Name	Rx#	Insurance Identifier	Drug Name, Strength (NDC)	QTY	Date	Acquisition Cost (at Time of Dispensing)	Amount Collected from Insurance	Amount Collected from Patient	Total to Clinic
Totals									

Monthly 340B Prescription Summary by Product					
Product Name	NDC	Strength	Manufacturer	QTY (Monthly Usage)	QTY (Projected Next Month's Order)

Medpin Model Contract

For a 340B Participant Community Clinic Contracting with a Retail Pharmacy to Dispense Drugs Owned by that Clinic to the Clinic's Patients

MEDPIN™ – Medicine for People in Need

This Model Contract is provided for general information only, and is not offered or intended as legal or financial advice. When a clinic is confronted with a specific legal or financial question regarding its organization, it should seek the advice of an attorney or other appropriate professional for an independent evaluation of the issues and their application to that organization. Visit Medpin's website at www.medpin.org for an electronic copy.

PREScription DRUG SERVICES AGREEMENT

THIS PRESCRIPTION DRUG SERVICES AGREEMENT (“**AGREEMENT**”) is made and entered into by and between [Legal Name of Clinic] (“**CLINIC**”) and [Legal Name of Retail Pharmacy] (“**PHARMACY**”), as of [Date] (“**EFFECTIVE DATE**”)

RECITALS

- A. The 1992 Veteran’s Health Care Act created Section 340B of the Public Health Services Act, which classifies certain health care clinics, including CLINIC, as “**Covered Entities**” eligible to purchase outpatient prescription drugs for their patients at favorable discounts from drug manufacturers who enter into drug purchasing agreements with the United States Department of Health and Human Services (“**DHHS**”).
- B. California Business & Professions Code §4126, effective January 1, 2002, authorizes Covered Entities, including CLINIC, to contract with pharmacies licensed under California state law, such as PHARMACY, to dispense Covered 340B Drugs for the Covered Entity, provided certain requirements are met, including adequate inventory control and limitation of dispensing to eligible outpatients of the Covered Entity.
- C. CLINIC and PHARMACY mutually desire to enter into a “ship to/bill to” arrangement under which PHARMACY will order Covered 340B Drugs and receive shipment, maintain inventory and controls, dispense such drugs on behalf of CLINIC only to eligible CLINIC outpatients, and charge and collect for such drugs, all on CLINIC’s behalf, and CLINIC will be billed and will pay for such drugs, in compliance with applicable laws and regulations.
- D. CLINIC and PHARMACY mutually acknowledge that their intent in entering into this Agreement is solely to facilitate CLINIC’s participation in the 340B drug purchasing program, without having to establish and operate its own pharmacy. The services provided each to the other are only those necessary in order to fulfill this intent, and all financial arrangements established herein are mutually determined to represent either cost or fair market value for the items and services received. The parties expressly do not intend to take any action that would violate state or federal anti-kickback prohibitions, such as those appearing in Section 1128B of the Social Security Act, 42 USC Section 1320a-7b. Instead, it is the intention of the parties that this Agreement and all actions taken in connection herewith shall fully comply with the regulatory requirements of the safe harbor for personal services and management contracts appearing in 42 CFR Section 1001.952(d), and this Agreement shall in all respects be construed consistent therewith.

NOW, THEREFORE, in consideration of the promises, covenants and agreements hereinafter set forth, CLINIC and PHARMACY hereby agree to the following terms and conditions:

1. Covered 340B Drugs. The prescription outpatient drugs covered by this Agreement (hereinafter “**Covered 340B Drugs**”) include “Legend” drugs, that is those drugs which by federal law can be dispensed only pursuant to a prescription and which are required to bear the legend “Caution – Federal Law prohibits dispensing without prescription.” Other qualified prescriptions include insulin (on prescription only) and over the counter medications as long as prescribed by an authorized medical provider. All Covered 340B Drugs purchased under this Agreement are the property of CLINIC. All Covered 340B Drugs subject to this Agreement are also subject to the Limiting Definition of “covered outpatient drug” set forth in Section 1927(k) of the Social Security Act, 42 USC 1396r-8(k)(2) & (3), which is incorporated as the applicable definition for the section of the 1992 Veterans Affairs Act that created Section 340B of the Public Health Services Act.
2. Eligible Patients. Only outpatients of CLINIC, excluding CLINIC’s patients who are Medicaid beneficiaries and for whom claims for pharmaceuticals will be submitted to a state Medicaid program (see paragraph 11 below), are eligible to purchase or receive Covered 340B Drugs from PHARMACY (“**Eligible Patients**”). Under no circumstances will PHARMACY dispense Covered 340B Drugs to anyone other than Eligible Patients of CLINIC. Pharmacy shall dispense Covered 340B Drugs to Eligible Patients only in the following circumstances:
 - 2.1 Upon presentation of a prescription form bearing CLINIC’s name, the Eligible Patient’s name, a designation that the patient is an Eligible Patient, a designation of the dispensing fee, if any, to be charged by the PHARMACY to the Eligible Patient, and the signature of a legally qualified health care provider affiliated with CLINIC; or,
 - 2.2 Upon receipt of a prescription ordered by telephone or electronically on behalf of an Eligible Patient by a legally qualified health care provider affiliated with CLINIC who states that the prescription is for an Eligible Patient, and designating the dispensing fee to be charged by the PHARMACY. CLINIC will furnish a list to Pharmacy of all such qualified health care providers and will update the list of providers to reflect any changes. PROVIDED, however, that no electronic transmission of patient specific information hereunder shall occur on or after the compliance date for healthcare providers of final HIPAA regulations, currently scheduled for October 16, 2002, unless and until the Parties have provided for strict compliance with applicable HIPAA rules, as described in paragraph 19 hereof.
3. Restocking and Inventory Maintenance.
 - 3.1 Restocking. PHARMACY agrees to place orders as necessary with one or more pharmaceutical supplier (“**SUPPLIER**”) to maintain and replenish the drugs consumed pursuant to this Agreement. CLINIC and PHARMACY shall arrange with SUPPLIER to ship directly

to PHARMACY. PHARMACY shall provide CLINIC a copy of each and every order so placed, as well as shipping orders and invoices showing prices.

3.2 Inventory Maintenance. PHARMACY and CLINIC agree that PHARMACY shall dispense no controlled substances that might be purchased by CLINIC.

3.3 Inventory Maintenance. PHARMACY agrees to maintain

OPTION 1: an electronic inventory of Covered 340B Drugs accurately and in sufficient detail **OR**

OPTION 2: a stock of Covered 340B Drugs physically separate from its other drug inventory, and] to protect its inventory of Covered 340B Drugs against diversion to anyone other than Eligible Patients. PHARMACY shall maintain such records as are adequate to permit it to prepare the reports required under paragraph 6 hereof, and to permit CLINIC, DHHS, or any eligible drug manufacturer to determine upon audit to whom such Covered 340B Drugs have been dispensed. Upon termination of this Agreement, PHARMACY shall deliver all unused items of inventory purchased by or on behalf of CLINIC hereunder to CLINIC, if CLINIC has a valid permit, or, in the absence of such a permit, return them to SUPPLIER for CLINIC's credit, if possible, or destroy them, if they cannot be returned or transferred within thirty days following termination.

4. Payment to SUPPLIER by CLINIC. CLINIC agrees to timely pay SUPPLIER amounts owing to SUPPLIER for Covered 340B Drugs purchased hereunder. In the event that SUPPLIER is not paid and does not ship Covered 340B Drugs in sufficient quantity to PHARMACY, PHARMACY shall notify CLINIC in writing of its lack of 340B Drugs, and, if CLINIC continues to write prescriptions for PHARMACY to fill, may thereafter, in its sole discretion, fill prescriptions from its non-340B inventory, and charge for its own account Eligible Patients or CLINIC according to its own, non-340B prices, or PHARMACY may refuse to fill prescriptions of CLINIC, until satisfactory arrangement is made by CLINIC.
5. PHARMACY Dispensing Fee. PHARMACY and CLINIC agree that PHARMACY shall receive a Dispensing Fee, as specified in Exhibit A, for each prescription of Covered 340B Drugs filled for Eligible Patients and that such Dispensing Fee covers PHARMACY's costs and constitutes the sole and exclusive payment PHARMACY is entitled to receive hereunder. With respect to each prescription, CLINIC shall designate whether such Dispensing Fee is to be collected from the Eligible Patient, from CLINIC, or in part from the Eligible Patient and in part from the CLINIC. If CLINIC is to pay all or part of the Dispensing Fee, or if PHARMACY fills prescriptions out of its non-340B stock after notifying CLINIC of a lack of 340B Drugs due to CLINIC nonpayment to SUPPLIER, pursuant to paragraph 4, PHARMACY shall bill CLINIC not more frequently than monthly for the amounts owing. CLINIC agrees to make payment within fifteen (15) days of receipt of PHARMACY's invoice for such Dispensing Fees. In the event that payment is late, CLINIC agrees to pay interest at the rate of seven percent (7%) per annum on the late balance. In the event that the amount owed under paragraphs 4 or 5 by CLINIC to PHARMACY exceeds _____ dollars, PHARMACY shall have the right to refuse to fill further prescriptions of CLINIC, unless satisfactory arrangement is made by CLINIC.
6. Reports. By the tenth (10th) day of each month, PHARMACY shall transmit to CLINIC a detailed report showing each Eligible Patient served, the prescription filled, with specific details about each claim, including the drug name, strength, unit dose, appropriate identification codes, manufacturer, quantity dispensed, amount charged and collected, for the previous month.
7. Maintenance of Records. PHARMACY will preserve all records of shipment, receipts, and dispensing of 340B drugs for audit at any reasonable time for a period of three years following date of provision of services. It is understood by both parties under this Agreement that, under Section 340B(a)(5)(C) of the PHS Act, they are subject to audit by the drug manufacturers and the U.S. Public Health Service of DHHS of records that directly pertain to compliance with the Act.
8. Pharmacy Compliance Responsibility. PHARMACY shall be solely responsible for all professional advice and services rendered by it for the Eligible Patients. PHARMACY is responsible for and agrees to render services as herein provided in accordance with the rules and regulations of the California State Board of Pharmacy [or other applicable state, if PHARMACY is located in such state], all laws of the State of California, and all applicable laws and regulations resulting from the Veteran's Health Care Act of 1992 (P.L. 102-585, sec 602). It is expressly understood that relations between the Eligible Patients and PHARMACY shall be subject to the rules, limitations, and privileges incident to the pharmacy-patient relationship. PHARMACY shall be solely responsible, without interference from the CLINIC or its agents to said Eligible Patient for pharmaceutical advice and service, including the right to refuse to serve any individual where such service would violate pharmacy ethics or any pharmacy laws or regulations.
9. Insurance. Pharmacy shall at its own expense maintain a policy of insurance covering professional acts and omissions with a licensed insurance carrier to be in an amount not less than one million dollars (\$1,000,000) per incident and three million dollars (\$3,000,000) in the aggregate, and said policy shall be maintained during the term of this agreement. PHARMACY shall cause its insurer to name CLINIC as an additional named insured on such policy, and shall provide CLINIC with a certificate to such effect.
10. Medicaid Prescriptions. Notwithstanding anything herein to the contrary, PHARMACY will not use Covered 340B Drugs to dispense prescriptions paid for by a state Medicaid agency, but will use its non-340B inventory, and bill and collect Medicaid on its own account. When a Medicaid agency pays for drugs for its beneficiaries, it is generally entitled to claim a rebate from the drug manufacturer, to reduce its effective cost to a statutorily established price. Section 340B extends a similar price to Covered Entities, and requires that there be a mechanism to protect drug manufacturers from Medicaid rebate claims for Covered 340B Drugs purchased pursuant to Section 340B. To avoid any chance that a State Medicaid agency will pay for 340B Drugs purchased hereunder and then submit

prohibited rebate claims to the drug manufacturers, PHARMACY agrees to dispense non-340B drugs from its own inventory in filling Medicaid prescriptions for CLINIC patients who are Medicaid beneficiaries, and all charges collected in connection therewith shall be for PHARMACY's account. PHARMACY further agrees that, for CLINIC patients who are Medicaid beneficiaries, PHARMACY will take all reasonable steps necessary to obtain coverage from Medicaid for the costs associated with drugs prescribed for those patients, including activities necessary for requesting a Treatment Authorization Request from Medicaid. CLINIC shall not be liable to PHARMACY for dispensing fees or other costs in connection with prescriptions filled for Medicaid beneficiaries receiving a prescription whose cost will be covered by Medicaid.

11. Patient Choice. PHARMACY understands and agrees that Eligible Patients of CLINIC may elect not to use PHARMACY for pharmacy services. In the event that an Eligible Patient elects not to use PHARMACY for such services, the patient may obtain the prescription from the pharmacy provider of his or her choice. Subject to a patient's freedom to choose a provider of pharmacy services, CLINIC will inform Eligible Patients that they may be eligible for a discount on prescription drugs ordered by CLINIC, other than Medicaid prescriptions, and advise them that such discount has been arranged for only at PHARMACY.
12. Pharmacy Site. Pharmacy agrees it will provide pharmacy services contracted for under this Agreement at one site only, as specified in Exhibit B.
13. Inspection by Manufacturer. PHARMACY and CLINIC understand and agree that a copy of this Pharmacy Services Agreement will be provided, upon request, to a drug manufacturer who has signed a purchasing agreement with DHHS. In the event either party receives such a request, it shall immediately inform the other party.
14. Non-Assignment. This Agreement may not be assigned by either party without the prior written agreement of the other party.
15. Term and Termination. This Agreement shall commence on the EFFECTIVE DATE, and shall continue for a period of one year until the first anniversary of the EFFECTIVE DATE, and thereafter shall automatically renew for consecutive one year renewal terms, unless either party provides prior written notice to the other of such party's intention not to renew, at least thirty (30) days prior to such anniversary date, or until terminated by:
 - 15.1 Mutual agreement of the parties;
 - 15.2 Sixty (60) days prior written notice by either party;
 - 15.3 CLINIC, immediately and without prior notice, upon a material breach of this Agreement by PHARMACY. Without limiting CLINIC's right to assert any other act or failure to act as constituting a material breach by PHARMACY, PHARMACY's dispensing of a Covered Drug to an individual who is not an Eligible Patient or any other diversion of a Covered Drug shall be deemed to be a material breach. CLINIC's failure to take action with respect to PHARMACY's failure to comply with any term or provision of this Agreement shall not be deemed to be a waiver of CLINIC's right to insist on future compliance with such term or provision.
 - 15.4 Either party, immediately upon written notice to the other, for material breach of patient confidentiality requirements under HIPAA, as specified in paragraph 18.
16. Choice of Law. This Agreement shall be interpreted according to the laws of the State of California.
17. Dispute Resolution.
 - 17.1 Any controversy or claim arising out of or relating to this Agreement or breach of the Agreement that cannot be resolved by the parties meeting and conferring shall first be referred to mediation at a mediation service agreed to by the parties, or, in the absence of agreement, at JAMS in San Francisco, pursuant to JAMS rules for commercial mediation. The parties covenant that they will engage in mediation in good faith, and will share equally in the cost of mediation. In the event that mediation is unsuccessful, or the parties are unable to agree upon a mediator, the dispute shall be settled by one arbitrator in accordance with the commercial rules of the JAMS. The venue for any arbitration proceedings under this Agreement shall be in _____ County, California. Judgment on the award rendered by the arbitrator shall be binding on the parties and may be entered in any court having jurisdiction over the dispute. The cost of the arbitration shall be paid by the losing party.
 - 17.2 The arbitrator's authority to grant remedies shall be limited to those remedies that could be granted or awarded by a judge of the Superior Court of the State of California applying California law to the claims asserted. The arbitrator shall prepare and provide to the parties a written decision on all matters subject to the arbitration, including factual findings and the reasons that form the basis of the arbitrator's decision. The arbitrator shall not have the power to commit errors of law, and the award of the arbitrator shall be vacated or corrected for any such error or any other grounds specified in Code of Civil Procedure Section 1286.2 or Section 1286.6. The award of the arbitrator shall be mailed to the parties no later than thirty (30) days after the close of the arbitration hearing. The arbitration proceedings shall be reported by a certified shorthand court reporter. Written transcripts of the proceedings shall be prepared and made available to the parties. In any arbitration proceedings, the parties shall have the right to discovery in accordance with California Code of Civil Procedure Section 1283.05.
 - 17.3 The parties shall each have the right to file with a court of competent jurisdiction an application for temporary or preliminary injunctive relief, writ of attachment, writ of possession, temporary protective order, or appointment of a receiver if the arbitration

award to which the applicant may be entitled may be rendered ineffectual in the absence of such relief or if there is no other adequate remedy. This application shall not waive a party's mediation and arbitration rights under this Agreement.

18. **Confidentiality of Records.** The parties agree to protect the confidentiality of each other's records and business information disclosed to it and not to use such information other than as necessary and appropriate in connection with performance of this Agreement. Each party acknowledges that disclosure of confidential information of the other would cause the other party irreparable harm and may, without limiting the remedies available for such breach, be enjoined at the instance of the harmed party. Upon termination of the Agreement, each party agrees to cease use of the other's information and to return it, or destroy it, as appropriate.
19. **Patient Privacy and HIPAA Compliance.** The parties recognize that each may be a health care provider and a covered entity within the meaning of the federal Health Insurance Portability and Accountability Act ("HIPAA"), and therefore responsible for compliance with HIPAA standards for electronic transactions by not later than October 16, 2002, and for HIPAA privacy standards by not later than April 26, 2003. The Parties agree to protect and respect the rights of the patients of CLINIC and PHARMACY to privacy and confidentiality concerning their medical and pharmaceutical records, and to protect all individually identifiable health information as protected health information from misuse or disclosure, in compliance with all applicable state and federal law. Without limiting the generality of the foregoing, the parties agree to use patient-specific information only for permitted treatment, billing and related record-keeping purposes, and to protect patient-specific information from unnecessary disclosure to persons not employed or contracted for by the parties, and from their own employees and contractors unless they have a need to know and agree to maintain the confidentiality of patient specific information. In the event that any patient information created, maintained or transmitted in connection with this agreement is to be transmitted electronically, the Parties agree that they shall comply in all respects with the requirements of HIPAA governing electronic transmission of individually identifiable patient information. See 42 CFR Section 160 et seq. Failure by either party to abide by these requirements shall be a basis for immediate termination of this agreement.
20. **Entire Agreement.** This Agreement represents the entire understanding of the parties. There are no other agreements or understandings between the parties, either oral or written, relating to Covered 340B Drugs. Any amendments to this Agreement shall be in writing and signed by both parties.
21. **Notice.** Any notice required or given under this Agreement shall be provided in writing by one of the following methods: hand delivery, placing in the U.S. Postal Service, first class postage prepaid, facsimile transmission or email transmission, to the addresses and to the attention of the person specified below, or as modified at any time by either party by written notice hereunder.

CLINIC:

PHARMACY:

[Company Name]

[Company Name]

By: _____

By: _____

Title: _____

Title: _____

Date: _____

Date: _____

Address: _____

Address: _____

Provide notice at this address to:

Provide notice at this address to:

Attention: _____

Attention: _____

Telephone: _____

Telephone: _____

Facsimile: _____

Facsimile: _____

Email: _____

Email: _____

EXHIBIT A**PRICING.**

1. *Dispensing Fee.* The Parties agree that the Dispensing Fee to be paid for each 340B prescription filled hereunder shall be _____ & _____/100 Dollars (\$ _____). CLINIC will determine in each case whether CLINIC will pay the Dispensing Fee, or the patient. If CLINIC will pay the Dispensing Fee, the prescription written by the CLINIC shall specify that there shall be no Dispensing Fee charged to the patient. Otherwise, PHARMACY shall collect the Dispensing Fee for each prescription filled. CLINIC will pay PHARMACY for Dispensing Fees in each case where it specifies that no Dispensing Fee shall be collected by PHARMACY, pursuant to paragraph 5 of the Agreement. CLINIC is also free to charge the patient all or a portion of the cost of the drug, but CLINIC will make clear upon collecting any such charge from the patient that such charge is not inclusive of the Dispensing Fee which PHARMACY will collect.
2. *Medicaid Patients.* If CLINIC determines that patient is an eligible beneficiary under a state Medicaid program, and that Medicaid coverage for the cost of the drug is available, the CLINIC shall identify the patient as a Medicaid patient, and PHARMACY shall charge and collect the amount permitted by Medicaid on PHARMACY's own account, dispensing non-340B drugs from its own inventory. For all of CLINIC's Medicaid-eligible patients, PHARMACY will take all reasonable steps necessary to obtain coverage from Medicaid for the costs associated with drugs prescribed for those patients, including activities necessary for requesting a Treatment Authorization Request from Medicaid.

EXHIBIT B

PHARMACY LOCATION. The sole location at which PHARMACY will provide prescription drug services hereunder is:

[Insert name and address of PHARMACY location]

Pharmacy Services Agreement

This sample contract was based on a contract initially developed by the National Association of Community Health Centers (NACHC).¹⁷⁷

PHARMACY SERVICES AGREEMENT

This Contract Agreement made this ____ day of _____, 20____, is entered into by and between _____ (hereinafter health center), whose principle place of business is _____ and _____ (hereinafter Pharmacy), whose principle place of business is _____.

WHEREAS, the Health Center is a "Covered Entity" as defined in Section 340B of the Public Health Services Act (hereinafter "Section 340B") and is eligible to purchase certain outpatient drugs at reduced prices for use by the Health Center patients (hereinafter "Eligible Patients") from drug manufacturers who have signed a drug purchasing agreement with the United States Department of Health and Human Services (hereinafter "DHHS"); and,

WHEREAS, the Pharmacy is duly licensed as a pharmacy in the State of _____; and,

WHEREAS, the Health Center desires to engage the Pharmacy to provide Pharmacy Services, as specified in this Agreement, to Eligible Patients and to legally qualified health care providers affiliated with the Health Center on behalf of Eligible Patients with respect to outpatient drugs purchased pursuant to Section 340B;

NOW, THEREFORE, the parties agree as follows:

1. **Covered Drugs:** The prescription outpatient drugs covered by this Agreement (hereinafter "Covered Drugs") are listed on Attachment A of this Agreement. The parties agree that the Health Center may add or remove Covered Drugs from Appendix A at its sole discretion during the life of this Agreement.
2. **Purchase and Shipment of Drugs:** The Pharmacy shall monitor its inventory of Covered Drugs and maintain sufficient supplies of such drugs to meet the day-to-day needs of Eligible patients. No later than the fifth business day of each month, the Pharmacy will provide the Health Center with a dispensing report which lists all prescriptions filled for Eligible Patients under this Agreement, including the Eligible Patient, drug name, strength, quantity of the drug dispensed. Such report shall also include a summary of the usage of Covered Drugs by product (including drug name, strength, manufacturer, and quantity) for the preceding calendar month and a drug order for projected usage for the next month.

The Health Center will order Covered Drugs directly from the manufacturer/Wholesaler or a designated sales representative of the manufacturer/wholesaler within three (3) business days of receipt of the Pharmacy's dispensing report and arrange to be billed directly for such drugs. The Health Center will arrange for shipment of such drugs to the Pharmacy. The Health Center shall advise Pharmacy of Covered Drugs ordered and the Pharmacy shall compare all shipments received to the orders and inform the Health Center of any discrepancy within five (5) business days of receipt.

The pharmacy will maintain records of receipt and disposition of 340B drugs and reimbursement account records separate from its own operation. Records of disposition of 340B drugs include dispensing, loss, theft, return to supplier, etc. Should there be reasonable cause to believe that theft occurred, the law enforcement agency having jurisdiction should be promptly notified, and a copy of the resulting police report be maintained in the records of the health center and the pharmacy for a period of at least two (2) years.

3. **Tracking System:** The parties to this Agreement understand that pursuant to Section 340B, the Health Center is liable to the manufacturer of the Covered Drug in an amount equal to the reduction in the price of the Covered Drug in the event that a discounted Covered Drug is sold or otherwise transferred to a person who is not an Eligible patient. The Pharmacy shall establish and maintain a tracking system suitable to prevent the diversion of Covered Drugs to Individuals who are not Eligible Patients (e.g. a periodic printout of eligible patient's prescriptions with the dispensing records and a six-month comparison of purchasing and dispensing records). The Pharmacy will provide a monthly listing of all drugs dispensed, to include the name of the patient, Center Identification Number, name of the drug(s) dispensed. A copy of the Prescription Receipt will also be attached to the monthly listing.

Prior to the Pharmacy providing pharmacy services pursuant to this agreement, the Health Center shall have the opportunity, upon reasonable notice and during business hours, to examine the tracking system and may require the Pharmacy to make any modifications to such system as the Health Center may, in its sole discretion, require. The Pharmacy shall permit the Health Center or its duly authorized representatives to have reasonable access to the Pharmacy's facilities and records during the term of this Agreement in order to make quarterly checks regarding the efficacy of such tracking system. The Pharmacy agrees to make any and all adjustments to the tracking system, that the Health Center advises are reasonably necessary to prevent diversion of Covered Drugs to individuals who are not Eligible Patients.

The health center will order triplicate prescriptions. The health center will keep the bottom copy as a record of prescriptions that were written at that facility. This will allow record keeping of the number of prescriptions filled at the contractor pharmacy, as well as provide a double check of eligibility.

The health center and pharmacy will communicate on a monthly basis to discuss payment and program function.

4. **Prescriptions:** The Pharmacy shall dispense Covered Drugs only in the following circumstances:
 - (a) Upon presentation of a prescription form bearing the Health Center's name, the Eligible Patient's name, a designation that the patient is an Eligible Patient, and the signature of a legally qualified health care provider affiliated with the Health Center, or,
 - (b) Receipt of a prescription ordered by telephone or fax on behalf of an Eligible Patient by a legally qualified health care provider affiliated with the Health Center, stating that the prescription is for an Eligible Patient. The Health Center will furnish a list to the Pharmacy of all such qualified health care providers and will update the list of providers to reflect any changes.
5. **Pharmacy Services:** The Pharmacy shall provide the following services:
 - (a) Dispensing Covered Drugs to Eligible Patients in accordance with all applicable State and Federal statutes and regulations;
 - (b) Maintaining all records and reports required under this Agreement, Section 340B, and by any applicable Federal and State law and regulations. Such records shall be retained for not less than three (3) years after the expiration of this Agreement and shall be available for inspection or audit by Health Center and as otherwise permitted by law and this Agreement;
 - (c) Eligible Patient drug utilization review;
 - (d) Formulary maintenance, including providing drug-related information services to the Health Center on the purchase of Covered Drugs, and identifying and disposing of Covered Drugs in its inventory which are out of date;
 - (e) Maintaining Eligible Patient drug profiles;
 - (f) Counseling and advising Eligible Patients consistent with the rules, limitations, and privileges incident to the pharmacy-patient relationship.

The Pharmacy is an independent contractor and shall be solely responsible for its acts and omissions regarding advice and services it is required to provide to Eligible Patients and Health Center. The Pharmacy agrees to render all services provided under this Agreement in accordance with professional standards applicable to pharmacy services and in accordance with rules and regulations of _____ Drugs. The Pharmacy shall have the right to refuse to serve any Eligible Patient where such service would violate any statute, regulation, or professional standard applicable to pharmacy services. The Pharmacy shall notify the Health Center of any refusal of service within twenty-four (24) hours of such refusal.

6. **Pharmacy Site:** The Pharmacy agrees it will provide pharmacy services contracted for under this Agreement at one site only, namely: _____ site.
7. **Payment for Services:** The Health Center agrees to pay Pharmacy for Pharmacy Services in accordance with terms provided on Attachment B to this Agreement. The Health Center and the Pharmacy have freely negotiated the payment terms provided herein and neither has offered or received any inducement or other consideration from the other party for entering into this Agreement. The compensation to be paid to Pharmacy is consistent with fair market value in arms-length transactions for Pharmacy Services and is not determined in a manner that takes into account the volume or value of any referral or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.
8. **Patient Choice:** The Pharmacy understands and agrees that Eligible Patients of the Health Center may elect not to use the Pharmacy for pharmacy services. In the event that an Eligible Patient elects not to use the Pharmacy for such service, the patient may obtain the prescription from the pharmacy provider of his or her choice. Subject to a patient's freedom to choose a provider of pharmacy services, the Health Center will inform Eligible patient that they are eligible for a discount on covered Drugs and advise them that such discount may be obtained only at _____ Drugs.
9. **Quarterly Reports:** The Pharmacy shall provide the Health Center with quarterly financial statements, a detailed status report of collections, and a summary of receiving and dispensing records in a form satisfactory to the Health Center.
10. **Prohibition on Resale or Transfer:** The Pharmacy agrees that it will not resale or transfer a Covered Drug to an individual who is not an Eligible Patient of the Health Center. The Pharmacy further agrees that, in the event of transfer, diversion, or resale of a covered Drug in violation of this Agreement, it will pay the Health Center an amount equal to the price discount the Health Center received from the manufacturer. For purposes of this provision, the Health Center's determination of the amount of the discount on a covered Drug payable to the manufacturer shall be conclusive.

The Health Center agrees that it will not resale or transfer a covered Drug to an individual who is not an Eligible Patient.

11. **Medicaid Prescriptions:** The Health Center will not use Covered Drugs to dispense prescriptions paid for by Medicaid unless Pharmacy and the State Medicaid Agency have established an arrangements which will prevent duplicate discounts and/or rebates.

12. **Audits:** The Pharmacy understands and agrees that both the Pharmacy and the Health Center are subject to audit by the Public Health service and by drug manufacturers who have signed a drug purchasing agreement with DHHS. These audits may pertain to the Health Center’s compliance with the prohibition on drug resale or transfer and the prohibition on duplicate Medicaid rebates and discounts. The Pharmacy further understands that the Public Health Service has published proposed guidelines for such audits. The Pharmacy agrees to cooperate with such audits and to comply with applicable provisions of the audit guidelines and amendments thereto that may be published from time to time.
13. **Inspection by Manufacturer:** The Pharmacy and the Health Center understand and agree that a copy of this Pharmacy Services Agreement will be provided, upon request, to a drug manufacturer who has signed a purchasing agreement with DHHS. In the event either party receives such a request, it shall immediately inform the other party and each party shall then have the opportunity to delete any information in this Agreement and attachments which it considers to be proprietary and confidential prior to submitting the Agreement to the requesting manufacturer.
14. **Insurance:** The Pharmacy shall maintain during the term of this agreement a policy of insurance with a responsible insurance carrier in an amount not less than \$_____ per incident.
15. **Non-Assignment:** This Agreement may not be assigned by either party without the prior written agreement of the other party.
16. **Term and Termination:** This Agreement shall commence on _____, 2000 and shall continue thereafter until terminated by:
 - (a) Mutual agreement of the parties;
 - (b) Sixty (60) days prior written notice of either party;
 - (c) The Health center, immediately and without prior notice, upon a material breach of this agreement by the Pharmacy. Without limiting the Health Center’s right to assert any other act or failure to act as constituting a material breach by the Pharmacy, Pharmacy’s dispensing of a covered Drug to an individual who is not an Eligible Patient or any other diversion of a Covered Drug shall be deemed to be a material breach. The Health center’s waiver or failure to comply with any term or provision of this Agreement shall not be deemed to be a waiver of the Health Center’s right to insist on future compliance with such term or provision.
17. **Choice of Law:** The contractor(s) and health center will adhere to all Federal, State, and local laws and requirements. This Agreement shall be interpreted according to the laws of the State of _____.
18. **Entire Agreement:** This Agreement represents the entire understanding of the parties. There are no other agreements or understandings between the parties, either oral or written, relating to covered Drugs. Any amendments to this agreement shall be in writing and signed by both parties.

 WITNESS

BY: _____
 PHARMACIST

 DATE

 WITNESS

BY: _____
 EXECUTIVE DIRECTOR

 DATE

CASE STUDY #4: Contracted Pharmacy Services¹⁷⁸

Snapshot	
Prescription Department Pharmacy Size (Sq Ft)	500 sq ft
Total Size of Pharmacy	1,000 sq ft
Total # (340B and Non-340B) Prescriptions Filled per Day	225
# 340B Prescription Filled per Day	45
# 340B Clinics Served	3
Total Annual # Clinic Encounters (Primary Site)	14,000
Total Annual # Rxs Filled for Clinic Account	13,200 (annualized monthly)
Daily Time Devoted to 340B Patients by Pharmacy Staff	1.8 hours
Pharmacy Hours of Operation	51 hours/week
Pharmacist FTE ¹⁷⁹	3 FTE
Technician FTE	2 FTE

Background

Pharmacy

Community Drugs¹⁸⁰ is an apothecary-type pharmacy, long established in its rural community of 17,000 people. The decision to become active within the HRSA 340B program was in part driven by OPA's support and acceptance of comprehensive patient care services through its grants activities.

Community Drugs has served as the safety-net provider for the residents of the county since the senior pharmacist assumed the practice. Early in the 1980s, staff volunteered to assist the administrator of the Community Health Center with updating its indigent patient prescription program to a formulary-based system. Because of attrition of other participating pharmacies due to lack of interest or inability to provide formulary and contract adherence and its level of pharmacy services, Community Drugs became the primary provider of these services among the network of provider pharmacies.¹⁸¹ Concurrently, staff worked with the county health department in the development of its safety-net pharmacy program. Community Drugs also maintains a provider relationship with the local AIDS alliance, volunteer cancer organization, and the county-administered Ryan White-funded HIV

emergency prescription program (for which it recently developed a program-wide formulary), and is an adjunct provider for the local hospice.

Health Center

The clinic is a federally qualified community health center with its main office located in the same town as Community Drugs. The clinic has been in operation since 1974 and started receiving U.S. Public Health funds in 1978. The health center receives both community – CHC (330E) – and migrant – MHC (330G) – funds through the U.S. Public Health Service. These funds represent approximately 20% of the center's total resources.

The clinic is the only comprehensive community health center in the service area, providing primary health care to approximately 10,000 medically underserved individuals including migrant workers. It provides a broad range of primary care services to the community in the most accessible and cost-effective manner. These services include: primary medical care provided by board-certified or board-eligible physicians at three sites and nurse-practitioners, comprehensive dental care provided by general dentists and dental hygienists at two of the primary medical care sites, a migrant program with extensive outreach activities, an on-site school-based program at four sites, and comprehensive pharmacy services through its sole contract pharmacy. In addition, the health center provides health education, transportation, translation, and social services to its patients.

In 2000 a new clinic CEO was appointed, bringing knowledge and experience in the operation of an in-house pharmacy utilizing the 340B program. After a decision analysis process contrasted establishing an in-house pharmacy at the clinic's primary site with establishing a Contracted Pharmacy Agreement with a community pharmacy, the Contracted Pharmacy option was selected. The CEO established the criteria for pharmacy participation and critically evaluated the pharmacies then participating under the existing non-340B indigent program. Community Drugs was selected as the pharmacy that most fully met the participation criteria. Community Drugs was approached to gauge its interest. After careful consideration, the senior pharmacist agreed to the tasks of accumulating knowledge about the 340B program, developing policies and procedures, and moving to implement 340B-contracted pharmacy services with the clinic.

Description of Service Area/Community and Target Population

The target population is the low-income population of the county. The county is rural, comprised of largely agricultural communities. According to the most recent data, the county has the highest unemployment rate and the lowest per capita income in the state. According to the HRSA Community Health Status Indicators Project, 14.5% of the County or 20,314 individuals fall below 100% of the federal poverty level, and more than 40,000 individuals fall below 200% of the federal poverty level. Most migrant workers fall below 100% of the federal poverty level.

The county lags behind the rest of the state in several health indicators. Low immunization rates, high teen pregnancy, poor dental health, and a growing number of HIV+ individuals are just a few of the major health issues confronting the community. Other health status indicators that document unmet need of the target population include:

- 30% of the infants born in 1998 were to mothers who lacked adequate prenatal care and nutritional support.
- Age-related rates of coronary and cancer deaths suggest unmet needs for prevention care, including access to medication and early detection and treatment of illness.

340b Program Planning by Pharmacy

The Process

After selection of the pharmacy, on October 1, 2000, a conference call with the Office of Pharmacy Affairs, PharmTA Consultant, and the CEO of the clinic set the stage for program development. The timeline was tight, since the clinic requested service delivery beginning by early 2001. With the consultant's assistance, the clinic filed an application with OPA for listing as a covered entity.

The senior pharmacist initially performed an internal decision analysis, assessing Community Drugs' goals and capabilities to determine if 340b program participation was desirable and achievable with available resources. Members of the pharmacy staff were polled for their opinions concerning implementation and task assumption. The staff concurred with the senior pharmacist's opinion that program implementation would take a significant amount of administrative resources, but that such resources were available. An analysis of the percentage of business the clinic generated (approximately 10% vs. an estimated 40% of the clinic's primary site-generated prescriptions) was one major factor considered. Additionally, the clinic was interested in the comprehensive nature of Community Drugs' clinical services, which indicated an opportunity for expansion of such services, a long-term goal of the pharmacy.

Financial forecasting took into account the probable need to increase pharmacy staff by 1.0 FTE technician to accommodate an estimated 20% increase in business with the doubling of the current volume of clinic prescriptions. One barrier was that the pharmacy had no Spanish-speaking staff, a temporary situation but also an opportunity, since the community was experiencing an influx of Mexican immigrants. Thus administrative, labor, and supply costs were the significant costs considered when negotiating the dispensing fee (revenue). Program implementation was viewed as incremental business, since minimal third-party billing was involved. Fee-for-service Medicaid and related state programs accounted for the majority of insurance for those clinic patients with insurance coverage.

The clinic/community drugs inventory “flow” model

- Inventory is acquired under a “ship to/bill to” arrangement. Title of physical inventory does not pass to the pharmacy. Community Drugs was appointed as agent to purchase on behalf of the clinic.
- Inventory is based on a replenishment model. Adequate records are kept and available for inspection.
- Nearly all inventory is dispensed from pharmacy stock, title passes to the clinic at the time of dispensing, and it is replenished by the clinic through its “ship to/bill to” arrangement with its wholesaler.
- The clinic agreement allows Community Drugs to order one-month anticipatory supply, though in practice the pharmacy usually waits until a full unit is used before reordering.
- When the generic drug available from the wholesaler at reasonable cost is not the usual brand stocked by Community Drugs, that drug is specially ordered in anticipation of use based on past experience and placed in separate inventory. Community Drugs does try its best to match generics to avoid this situation. Unique generics represent a very small percentage of the actual dollar volume of 340b drugs, and separate inventory is likewise small. Such inventory is regularly audited and adjusted at the time of each wholesaler order. Returns are handled directly by the pharmacy with the 340b wholesaler.
- 340b drugs are differentiated in the Community Drugs proprietary Pharmacy Management System by the addition of an “8” prefix. This tag allows the system to generate drug usage and patient usage reports. Within each such drug, the inventory system control has been activated with the wholesale order number entry for order generation. Additionally, the drug has been given a clinic drug category designation that allows third-party liability (TPL) reconciliation and audit by payer, thus providing a tool to limit the possibility of billing a Medicaid-related program, which is prohibited under Section 340b.
- Although guidelines suggest quarterly reporting, Community Drugs submits monthly reports to the clinic. This provides the opportunity for the pharmacy to do a monthly internal audit; thus the pharmacist manager keeps on top of an otherwise large, accumulating data file.
- Guidelines for discontinued medication or disposal of inventory in the event of the termination of the contract pharmacy agreement are addressed in the contract.

Baseline Service Delivery

The clinic currently has contract pharmacy agreements with Community Drugs to supply 340B medication to eligible patients who are clients at each of its sites.

In April 2002, an addendum to the contract provided access to 340B drugs to eligible patients who are clients at the clinic’s site in the neighbor community. Access, however, is less than universal. The neighbor community site is approximately 12 miles away from Community Drugs. Many, if not most, clients of the site in the

neighbor community are challenged to obtain timely transportation services. No interested pharmacy has been identified in the neighbor community.

There are two additional sites slated for contracted pharmacy services in the next fiscal year. They too have no local access to 340B pharmaceutical services. One of these sites is located in a rural community and currently has no physician or pharmacy to serve its population. The intention is to add remote pharmacy capability to improve pharmacy service access to patients of each site as it becomes operational.

Impact on Pharmacy's Financial Picture

	12 months prior to 340B	Months 24–36 after 340B
340B Rx's	0	10,635
Pre-340B Indigent Rx's Under a Subsidized Voucher Program	820	0
Total Clinic-Generated Rx's	4,442	11,883
Total Rx's	42,497	59,213
Non-340B (Third Party, Non-Form)	3,622 (82% CHC)	1,248 (11%)
Growth Over Period	–	39% (13% avg./yr)
Clinic as % of Growth	–	45%
% Clinic of Total	10%	20%
Gross Sales¹⁸²	2,550,000	3,700,000
Cost of Goods (COG)¹⁸²	2,100,000	2,900,000
Gross Margin¹⁸²	470,000	800,000
Expenses¹⁸²	380,000	580,000
Net Corporate Revenue^{182, 183}	90,000 (4%)	220,000 (6%)

Efficient Pharmacy Management

Overall administration of the pharmacy program is the clinic's responsibility. This includes:

- oversight of the contracted pharmacy
- audit
- order approval
- report processing
- program reporting
- grant reporting
- quality improvement

A sliding scale co-payment program, common to all sites to simplify administration, has been instituted.

The contract pharmacy agreement has been modified to (1) include all entities and sites, (2) to mandate separate patient prescription activity reporting capability for each site, and (3) to mandate separate 340B drug usage per entity. All 340B ordering, inventory system (replenishment), trigger points, reporting frequency, and format are uniform across sites.

A pharmacy & therapeutics (P&T) committee assumes responsibilities as an advisory committee on policy and procedure issues relating to collaborative drug therapy treatment plan and disease management protocol development. The medical director, a standing member of the P&T committee, is responsible for promoting multidisciplinary cooperation.

Keys to Success

- Accommodate an accelerated learning curve concerning the 340b program.
- Access information from OPA's website; download, study, and review.
- Enlist key pharmacy personnel in the process; additional input and analysis is critical.
- Identify key employees within the covered entity and pursue relationship-building.
- Access the PSSC PharmTA program; request access to a consultant.
- Find a good attorney to assist in negotiating the contract; make sure the attorney becomes knowledgeable about 340b statute and regulation.
- Become knowledgeable about the P&T committee and formulary-writing processes.
- Establish solid lines of communication between the health center and the pharmacy.

Contracted Pharmacy Services: Timeline¹⁸⁴

These are suggested steps for action to begin contracted pharmacy services, presented from the health center's perspective. Steps are similar for contracts with mail order and retail/community pharmacies. Reciprocal steps may be inserted as appropriate on the entity's action plan.

Month 1

1. Establish a responsible point of contact at the health center (Project Management and Oversight) and pharmacy.
2. Inform OPA of intent to participate in the 340b program by submitting a 340b enrollment form.¹⁸⁵
3. Establish a relationship with the board of pharmacy and obtain written approval of concepts.
4. Obtain special license from the board of pharmacy, if required, and learn any state regulations regarding contract pharmacy.
5. Become informed about the functioning of a P&T committee and how a formulary process works. Assist the health center in the formation of a P&T committee.
6. Estimate costs to clinic and pharmacy.
7. Establish a sliding fee schedule.
8. Determine if the pharmacy or the clinic will place the drug order.
9. Determine if third-party prescription reimbursement will be pursued, and by whom.
10. Work with the state Medicaid agency to prevent duplicate discounts, if Medicaid patients will be included in the contract. (Most contracts omit Medicaid patients from the service, and the Medicaid patients receive prescriptions at the pharmacy of their choice. Even in 340b contract situations, all patients technically must maintain freedom to choose any pharmacy.)
11. Negotiate the fixed professional fee for pharmacy dispensing.
12. Establish a relationship with a wholesaler.

Month 2

13. Establish formulary for covered drugs.
14. Determine reporting requirements and pharmacy management system reporting capability. Modify as required.
15. Determine any special population needs for pharmacy (interpretation, cultural competency training, etc). Hire or train personnel as required.
16. Place all operational details into the contract.
17. Present contract and discuss requirements.

18. Obtain approval from legal counsel.
19. Sign contract.
20. Notify OPA jointly with health center of intent to participate in 340b contracted pharmacy services by submitting a Self-Certification form.¹⁸⁶

Months 3–4

20. Ensure pharmacy has set up a computer system (sliding-scale plans, third-party tracking, inventory tracking, usage tracking, 340b identification and differentiation).
21. Set up flowcharts and checklists for record keeping. The pharmacy should include items such as program and third-party revenue (to health center), billing (health center to pharmacy), purchase tracking (duplicate invoicing), dispensing (by patient/Rx), return to stocks, and wholesaler/manufacturer returns.
22. Set up process for diversion prevention. Include self-audit process to retroactively identify and adjust unintended errors (e.g. refill of Rx's previously filled on sliding scale for newly active Medicaid patient). Run process at regular intervals. Work with pharmacy in the design and implementation of a process to identify eligible patients and their sliding scale fee placement.
23. Purchase any materials necessary for process (for instance, announcement flyers or brochures).
24. Conduct clinic staff education and ensure pharmacy staff has been trained. Set up a system of communication between pharmacy and clinic staff, e.g., regular provider meetings, updates, or a newsletter.

Months 5–6+

25. Market to the participants at the effective date and repeat as required.
26. Start contracted pharmacy services.
27. Continually evaluate system functionality by interviewing pharmacists, providers, administrators, and patients.

Provider Dispensing: Additional Detailed Information

Licensed Dispensary

In California, a special provision exists for operation of a licensed dispensary. The section of the law that addresses licensed dispensaries appears below.

California Business and Professions Code

Chapter 9, Division 2

Article 13 – Nonprofit or Free Clinics

4180. (a) (1) Notwithstanding any provision of this chapter, any of the following clinics may purchase drugs at wholesale for administration or dispensing, under the direction of a physician, to patients registered for care at the clinic:
- (A) A licensed nonprofit community clinic or free clinic as defined in paragraphs (1) and (2) of subdivision (a) of Section 1204 of the Health and Safety Code.
 - (B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.
 - (C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.
 - (D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than 20 hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.
 - (E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code.
 - (F) A nonprofit multispecialty clinic as referred to in subdivision (l) of Section 1206 of the Health and Safety Code.
- (2) The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of seven years for inspection by all properly authorized personnel.
- (b) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board. Each license shall be issued to a specific clinic and for a specific location.
4181. (a) Prior to the issuance of a clinic license authorized under Section 4180, the clinic shall comply with all applicable laws and regulations of the State Department of Health Services relating to the drug distribution service to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.
- (b) These policies and procedures shall include a written description of the method used in developing and approving them and any revision thereof.
- (c) The dispensing of drugs in a clinic shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.
4182. (a) Each clinic that makes an application for a license under Section 4180 shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.
- (b) The consulting pharmacist shall certify in writing at least twice a year that the clinic is, or is not, operating in compliance with the requirements of this article, and the most recent of those written certifications shall be submitted with the annual application for the renewal of a clinic license.
- (c) For the purposes of this article, "professional director" means a physician acting in his or her capacity as medical director.

4183. No clinic dispensing drugs pursuant to this article shall be eligible for any professional dispensing fee that may be authorized under the Medi-Cal program (Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code).
4184. No Schedule II controlled substance shall be dispensed by the clinic. This limitation shall not be construed to prohibit a physician dispensing a Schedule II drug to the extent permitted by law.
4185. The board shall have the authority to inspect a clinic at any time in order to determine whether a clinic is, or is not, operating in compliance with this article.
4186. (a) Automated drug delivery systems, as defined in subdivision (h), may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.
- (b) Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division.
- (c) The stocking of an automated drug delivery system shall be performed by a pharmacist.
- (d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.
- (e) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.
- (f) The pharmacist operating the automated drug delivery system shall be located in California.
- (g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076.
- (h) For purposes of this section, an "automated drug delivery system" means a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

Provider Dispensing: Helpful Hints¹⁸⁷

Check with the both the state board of pharmacy¹⁸⁸ and board of medicine¹⁸⁹ to determine the exact state requirements before undertaking provider dispensing.

The requirements vary so much by state that it is important to understand local laws before proceeding.

Evaluate prepacking medications as an option to streamline the dispensing process.

Prepacking, sometimes called *repackaging*, is a process intended to save time, whereby a stock bottle of medication is broken down into “ready-to-dispense unit of use” bottles in anticipation of prescriptions that will be dispensed. These bottles are usually pre-labeled, safety sealed, and have childproof caps.

The entity has a choice to either (a) purchase stock bottles of drugs from the wholesaler and have the providers dispense as each prescription arrives, or (b) order medications that arrive at the clinic already prepackaged by a company. Many states will only allow pharmacists or clinics holding special repackaging permits¹⁹⁰ to repack, so having the providers prepack medications is not always a feasible option.

The entity should determine how much overhead is associated with having the providers do all of the dispensing work. This would involve summing all costs to dispense (cost of supplies, space, staff time, etc.) and dividing this cost by the number of prescriptions dispensed. The result would represent how much it costs the clinic to dispense one prescription. The clinic would also want to examine how much staff time is devoted to repackaging the prescription versus how much staff time is devoted to record-keeping and patient counseling. It is important to separate this staff time into these categories, because the record-keeping and patient counseling will occur regardless of who does the medication repackaging. The entity can then obtain prepacking estimates (per prescription) from companies, and compare the costs of having the providers dispense against the cost of using a prepackaging company.

Entities that wish to use prepackaging services will have to appear on the OPA database as a participating 340B entity, meet state requirements for provider dispensing, and open accounts with a wholesaler and/or the repackaging company. There are two ways of receiving prepacked 340B drugs:

1. The entity could purchase the stock bottles of drugs from the wholesaler, receive the drugs from the wholesaler, mail the drugs to a repackager, and have the repackager mail the prepacked drugs back to the clinic, or
2. The entity could open an account with one of two companies¹⁹¹ that work with wholesalers to provide a seamless process whereby the clinic orders the medications and the medications are delivered directly to the clinic already prepackaged.

Both of the two companies that work directly with wholesalers charge per unit of use (i.e. repackaged bottle), bill from the respective wholesaler so that the chargeback is handled appropriately, and ship via UPS. The companies differ in that Allscripts/AmerisourceBergen offers a nationwide program including all brand-name drugs at the 340B contract price plus a program fee of approximately \$5 per unit of use bottle, thousands of generic drugs at a non-340B contract price without a program fee, (shipping charges extra) no selection limitation by a formulary, placement and shipment of the order with Allscripts, and daily placement of orders.¹⁹² Cardinal Health offers brand name drugs at the 340B price, generic drugs from a 340B contract price, a repackaging fee of approximately \$1.35–1.45 per unit of use bottle with a minimum order of 100 repackaged unit of use bottles, an initial formulary of over 50 of the most commonly used drugs, placement and shipment of the order with Cardinal Health, no shipping charges passed along to the entity, and the ability for orders to be placed weekly.¹⁹³

Carefully investigate the ability to collect payment and market these services.

Some states prohibit billing Medicaid agencies for dispensing fees from provider dispensing operations, and other states require that provider dispensing ventures cannot be marketed as “pharmacies” or even “dispensaries.” Most private insurers do not recognize provider dispensing as a reimbursable service.¹⁹⁴

Consider how samples and PAPs will be incorporated into the model.

Samples and PAPs are characteristically not governed by the board of pharmacy but by the board of medicine. Typical state regulations regarding samples and PAPs include that they are dispensed in the original manufacturer’s packaging and no charge is made to the patient. Many manufacturers do not permit patients to be charged a processing fee, but individual programs will differ on this point.

Incorporate the four cornerstones of comprehensive pharmacy services.

This includes affordable access to medications, outcomes-driven pharmaceutical care, efficient business practices, and quality assurance.

Plan for other options, such as the expansion of the provider dispensing space, incorporation of technology, or the eventual implementation of an in-house or contracted pharmacy, that might be necessary in the long term.

The prescription volume may eventually exceed the capabilities of the provider and ancillary staff. Set realistic goals upfront that will appropriately handle program growth.

CASE STUDY #5: Traditional Provider Dispensing

Snapshot	
# Pharmacy Sites	1
Total Annual # Encounters	14,000
Total Annual # Rxs	≈ 25,000
Hours of Operation	7 weekly; 2–3 hour clinics
RPH FTE	0
Part-Time RPH FTE	0
Technician FTE	0
Provider FTE	2 FTE
Dispensing Nurse	1 FTE
Approximate Sq Ft	25 sq ft

History

This health center is part of a large homeless center that opened in the mid-1990s and can sleep nearly 350 people a night. The homeless center opened a largely volunteer-based free health clinic a few years ago. The free clinic started a small drug closet where it stored medication samples, but the closet began to grow over the years as medications were donated and PAPs were pursued. Eventually, the clinic added contracted pharmacy services and worked with a repackager for selected drugs; however, the clinic does not access 340B prices. The clinic currently uses all of these venues to obtain medications and describes it as a “patchwork” attempt to fulfill the patients’ needs.

The clinic has four provider rooms, a waiting area, and a small (25 sq. ft.) drug closet. The clinic is staffed with one medical director (who spends most of the time with patients), one nurse-practitioner, one registered nurse (dispensing nurse), and three technical assistants. Volunteers include physicians, dentists, optometrists, and pharmacists. Pharmacist volunteers are hard to find and usually only spend about two hours at a time, a few days a month, in the clinic. Because the facility is unlicensed as a pharmacy or dispensary, the board of pharmacy has told several past volunteers that their pharmacist license is at risk by providing pharmacy services in an unlicensed facility.

Development

During the development of the provider dispensing operation, the biggest needs were general organization of the drug closet, creation of a policy and procedure manual, obtaining pharmacy references, locating patient-friendly handouts, and developing a formulary. The clinic would like to someday operate a fully licensed in-house pharmacy, but it does not have the funding to support a pharmacist, and the clinic’s philosophy is that the services provided will be free to patients (i.e., no collections).

The clinic is enrolled in 340B but does not purchase at 340B prices. The clinic’s contract with a nearby pharmacy is not using 340B due to the fact that the pharmacy does not want to handle the record-keeping. The clinic was unaware that it could purchase prepacked medications through 340B.

Management Responsibilities/Oversight

The medical director is legally responsible for the dispensing, but the registered nurse actually does most of the dispensing. The nurse works full-time either taking vital signs of patients or preparing medications. The nurse is the only staff member that is familiar with the operation of the dispensing, and the physician in charge of the clinic admits to rarely visiting the drug closet.

Finances

The clinic spends about \$60,000 a year on drug purchases (through the prepacking company and through the local contracted pharmacy), and dispenses the remaining medications through samples, donations, or PAPs. This \$60,000 is allocated from the homeless center's main budget for pharmaceuticals. The clinic does not have easily identifiable records because it does not use dispensing software. There is no way to report the percentage of patients served with the \$60,000 of purchased medications.

Challenges

The clinic has an abundant supply of samples, but it has a hard time keeping track of the samples to ensure they are used before expiration. The clinic recently implemented a policy that it will only accept samples for formulary drugs, and it will not accept samples that will expire within two weeks. The clinic pays a fee to a disposal company (~\$3.00/pound) to destroy samples in a manner that is appropriate according to state law. Although the clinic could follow the state law requirements and dispose of the samples in-house, the director feels the requirements are too tedious to undertake on a regular basis.

The drug closet organization is another challenge. The nurse manager is the primary staff member working in the drug closet, but the volunteer providers change daily, and the organization of the closet is hard to maintain. Some providers misplace drugs on the wrong shelf, and if the nurse is not aware of the misplacement, the drug can expire before it is used. The clinic recently implemented a formulary of drugs with a categorized listing of locations in the drug closet, and volunteers are provided with a list as soon as they show up to volunteer. Keeping the list current is another challenge!

Providing medications that meet the patients' needs and are low-cost to the clinic is another challenge. Because the clinic has a limited amount of money to spend on pharmaceuticals, samples and PAPs are used first, and then prepacked medications and contract pharmacy medications. The clinic often runs out of samples or has a delay in receipt of the PAPs (both usually brand-name medications), which causes patients' continuity of care to be interrupted. The nurse that dispenses the medications describes the dispensing process as "a puzzle to try and meet the patients' needs and save money at the same time."

Keys to Success

The dedicated dispensing nurse is one key that makes this operation a success. Another key to success has been the utilization of a website to locate PAPs, which has streamlined the PAP application process.

Samples and PAPs

The clinic uses samples and PAPs, but it does not keep easily retrievable records as to the value or amounts dispensed.

CASE STUDY #6: Licensed Dispensary A

Snapshot	
# Pharmacy Sites	1
Total Annual # Encounters	36,000
Total Annual # Rxs	72,000
RPH FTE	0
Part-Time RPH FTE	0
Technician FTE	0
Dispensing Clerk FTE	1 FTE (money collection, inventory organization)
Medical Assistant FTE	1 FTE (typing and labels)
Nurse FTE	1 FTE (combination of 2 staff: 0.8 and 0.2 FTE)
Nurse Manager FTE	1 FTE
PAP Staff FTE	2 FTE
Approximate Sq Ft	300, but site is at capacity and expects to expand soon

History

A “drug closet” stocked with samples, PAPs, and donated medications slowly evolved into a licensed in-house dispensary.¹⁹⁵ Initially, the providers did all of the dispensing from a small closet. This worked for about 1–2 years, until the providers didn’t have time to dispense the volume of medications the patients required. The initial provider dispensing system was described as inefficient and time consuming. The clinic tried contracting with a local pharmacy but was unable to get 340B pricing, and terminated the contract because the cost was prohibitive. The dispensary also investigated using pre-packs, but found that it was too expensive to sustain.

Development

The current dispensary manager, a nurse, was solely in charge of taking the “closet” operation to a legal dispensary. The nurse had access to a pharmacist consultant but undertook most of the implementation by relying heavily on a protocol book for dispensaries supplied by the city. The expansion from a closet to a dispensary was made in appearance over a weekend, but the permits/licensing took much longer. The nurse estimates that a dispensary could be started from the ground up within three

months. When the dispensary manager was brought on board, the closet operation was supporting about 100 prescriptions dispensed per day, and the dispensary now fills about 300 prescriptions per day. The dispensary uses a combination of samples, PAPs, and some 340B medications to fill prescriptions.

Management Responsibilities

The nurse manager spends about four hours a week overseeing dispensary administration, but delegates the dispensing and report generation to the other pharmacy staff.

Finances

The level of financial risk to this health center is low. The clinic receives annual money from a local assistance program, and the dispensary spends this money (approximately \$85,000/year) by using a drug wholesaler to access 340B drug prices. In addition, the clinic receives an all-inclusive rate of \$85/visit from a local payer for some patients. This rate includes the patient visit, the doctor's time, the lab, radiology, x-ray, and pharmacy. The dispensary costs about \$100,000 per year in staff salary and benefits. Drugs not purchased through the wholesaler or donated from private sources are obtained using samples and PAPs. The majority of the clinic's prescriptions are dispensed as PAPs and samples.

The dispensary adheres tightly to a drug formulary. Although the dispensary manager has recently investigated prepacks under 340B, the manager feels that the current system in place at the clinic (hiring staff to dispense) is more cost-effective for the clinic than having to pay additional per prescription prepack costs. The manager doesn't calculate the cost to dispense per prescription or brand versus generic mix.

A dispensary model was chosen for this clinic because a pharmacist's salary would be too much for the clinic to afford, the clinic had tried provider dispensing and contract without success, the patients are mostly uninsured, the Medicaid population is small, and the pharmacy has no guarantee of collections. In addition, the patient population requires language support, and the clinic is already positioned to provide this.

The dispensary usually only accepts patients' monetary donations for drugs; there is no sliding fee scale. Occasionally the patient will pay \$5/prescription if possible, but this is rare. Patients receiving PAPs are charged a nominal fee to help cover the cost of the staff the clinic hires (2FTE) solely for PAP paperwork. The PAP staff use the RxAssist website in conjunction with a clinic specific interface that tracks PAPs in Medical Manager (the clinic's software).

Administrative Oversight

The administrative involvement (CEO/CFO) in the dispensary is minimal. There is little time commitment, as the nurse manager oversees the operation and delegates most of the dispensing duties to staff. The manager stated that setting up the systems was the hardest part for the reports, but now that it is established, the dispensary requires very little oversight.

The dispensary has not had any problems hiring and retaining pharmacy staff.

Keys to Success

The keys to the dispensary's success lie in having good policy and procedures written and followed. In other words, the staff has to know exactly what they can and cannot do. Another key is having loyal, dedicated staff.

Challenges

The biggest challenges for the dispensary were the start-up process, choosing pharmacy software, and dispensing medications while keeping a time-efficient operation with few staff and a high volume of prescriptions.

Samples and PAPs

The dispensary does use samples and PAPs. The samples are not tracked, but the annual PAP value is estimated at ≈\$771,000/year using 340B prices.

CASE STUDY #7: Licensed Dispensary B

Snapshot ¹⁹⁶	
# Pharmacy Sites	2
Total Annual # Encounters	95,682
Total Annual # Low-Income Patients	18,000
Total Annual # Rxs	≈ 100,000
RPH FTE	4 FTE
Part-Time RPH FTE	2 FTE
Technician FTE	2 FTE (4 part-time staff)
Average Sq Feet	250, but site is at capacity and will soon need to expand; estimated space need would be 500 sq feet

History

This dispensary¹⁹⁷ began as a small room with volunteer pharmacists and technicians. It has grown to a state-licensed dispensary with two service sites and over seven FTE dispensary staff.

Development

The current dispensary manager was solely in charge of taking the “closet” operation to a legal, licensed dispensary. A dispensary option was chosen because the clinic had tried provider dispensing using a drug room, but the prescription volume of the clinic made this option inefficient. The clinic administrators saw no real advantage of operating a fully-licensed in-house pharmacy over a dispensary, since a pharmacist was already employed by the clinic and the dispensary could not collect adequate reimbursement from payers. Most clinic patients are cash pay, uninsured, and unable to contribute significantly.

Because the pharmacist was licensed in the state, the pharmacist required no other consultant or expertise to start the operation. The evolution from the “small room” to the licensed dispensary was gradual, but the pharmacist estimates that a dispensary could be started in well under four months from conception to doors opening, as long as an experienced individual is in charge of the process. This dispensary does not use a prepackaging company because pharmacists are available on staff to dispense.

The dispensary serves patients through a patchwork of public programs and private philanthropy, including, samples (5%), PAPs (40%), and donations or 340B purchases (55%). The dispensary also provides pharmaceutical care via an anti-coagulation clinic, a chronic disease management clinic, and a smoking cessation clinic. The dispensary has a tiered system for drug product selection, trying first to use samples if available, next to use PAPs, and lastly to purchase inventory. When the dispensary must buy medications, the goal is to minimize inventory on hand and to buy mostly generic through a 340B wholesaler. The pharmacist estimates that 340B prices for the dispensary's purchases average one tenth of suggested retail prices. The pharmacist tries to take advantage of purchase opportunities where the product cost is \$0.01 per bottle and at that time will purchase in large quantities and hold the product.

The patients are mostly uninsured (88%), and the dispensary has no guarantee of collections. If patients have insurance, the clinic usually sends the patient to fill the prescription at an external pharmacy. The clinic does have a few volunteer pharmacists and interns, but relative to overall labor their contributions are minimal.

Management Responsibilities

The pharmacist director oversees the dispensary, and administration (CEO/CFO) spends a very minimal amount of time with the dispensary operation. The CFO does spend about 10 hours a month collecting and paying bills for the dispensary.

Finances

The level of financial risk to this health center is low. The philosophy of the clinic is to not charge patients for services, so the dispensary relies heavily on donations, samples, and PAPS. The donations come from organizations that are local that collect drugs to be sent overseas or elsewhere. The clinic asks patients for financial donations, but they are not expected or required. The dispensary only purchases medications that it can afford (that is within the budget allocation from the clinic).

The inventory is kept manually, despite the fact that the dispensary uses a pharmacy computer system. This computer system is set up for use by a typical community pharmacy, and the inventory component is difficult for the dispensary to use due to the unique record keeping needs for samples and PAPs. (Most retail pharmacies do not routinely deal with samples and PAPs.)

The major annual costs of the dispensary are labor (\approx \$530,000) and drug costs (\approx \$140,000). The dispensaries' average cost of labor/dispensing per prescription was \$5.42 and the average dispensary cost per entire prescription (labor + drugs cost) per patient was \$21.57.

Keys to Success

The keys to the dispensary's success are attributed to the dedicated staff. The staff is creative and works together with the providers to find the lowest cost, most appropriate medications. The clinic also has taken advantage of an automatic substitution law in the state, allowing pharmacists to automatically therapeutically substitute for certain drugs under protocol.

Challenges

The biggest challenges for the dispensary include getting the providers to use cost-appropriate prescribing and juggling the complex bookkeeping mechanisms of the different sources of medications. Although drug company representatives are allowed to detail products to physicians, the representatives know that leaving only a few samples of a high priced drug will not be helpful or useful for the clinic. In a sense, the drug representatives have learned how to best meet the needs of the health center: to deliver consistent amounts of specifically needed samples at regular intervals. The dispensary has had some difficulty hiring and retaining staff due to the fact that the salary is not competitive with other pharmacies in the area.

Samples and PAPs

The dispensary does use samples and PAPs, but did not report the value of the medications dispensed.

Provider Dispensing: Timeline¹⁹⁸

Note: these are suggested steps for action to open a traditional provider dispensing operation. Steps required or particular for a licensed dispensary are denoted by an asterisk (*). These steps may be inserted as appropriate on the entity's action plan.¹⁹⁹

Month 1

1. Hold initial meetings with clinic board and clinic directors to determine need and available funding for pharmacy services.
2. Develop estimated start-up and ongoing budget.
3. Perform market analysis or feasibility study.
 - a. Fixed and variable costs
 - b. Projected sales
 - c. Pricing of pharmacy benefit
 - d. Break-even analysis
4. Enroll in 340b drug pricing program by completing and submitting the form on the OPA website.

5. Contact state boards of pharmacy and medicine to discover state requirements for physician dispensing.
6. *Select consultant pharmacist and “professional director” (medical director).
7. Select multidisciplinary team of clinicians as P&T committee and begin formulary development process.
 - a. Review clinical guidelines and standards of care related to drug therapy and combine this with existing knowledge of provider drug selection and cost in developing the formulary.
 - b. Develop policies & procedures for the medication use process and for approval of non-formulary medications.
 - c. Streamline the pharmacy product line to decrease the inventory and improve cash flow.
 - d. Promote quality, cost-effective prescribing using evidence-based medicine.
8. Decide what types of medications the pharmacy service will stock and what the priority of the dispensing will be (samples, P&Ps, prepackaged medications, stock bottles, or a combination).
9. Review and select pharmacy computer system or other record-keeping system.
10. Initiate relationship with wholesalers and begin to compare contract terms.
11. Determine extra clinic staffing requirements (if any).
12. Conduct new staff interviews (if needed) and hire staff.
13. Arrange for volunteers, if desired.
14. Train all staff.

Month 2

15. Begin to write the policy and procedure manual.
16. Contact prepackaging companies and compare and determine fees. Arrive at a decision as to whether or not pre-packs will be used and the clinic’s financial limit on pre-pack purchases (if any).
17. Determine plan for dispensing area and fixtures.
18. Purchase necessary equipment and supplies. The state board of pharmacy will have a complete list of all of the required equipment.
19. Complete policy and procedure manual.
20. *Have professional director, administrator, and consultant pharmacist approve policy and procedures.
21. Finalize wholesaler and prepackaging company contracts.
22. *Complete pharmacy licensure forms with state (if any), schedule inspection.
23. Consider and prepare for JCAHO reporting requirements (if desired).

Month 3

24. Purchase opening inventory and stock.
25. Begin provider dispensing.

APPENDIX VI: 340B Forms, Eligibility Information, and Guidelines

340B Forms

Entity Type	Location of Form(s)
Enrollment: Disproportionate Share Hospitals	ftp://ftp.hrsa.gov/bphc/pdf/opa/DSHState.pdf ftp://ftp.hrsa.gov/bphc/pdf/opa/DSHGovtCert.pdf ftp://ftp.hrsa.gov/bphc/pdf/opa/DSHNonpartGPO.pdf
Enrollment: STD/TB Entities	http://bphc.hrsa.gov/opa/howto.htm
Enrollment: All Other Entities	ftp://ftp.hrsa.gov/bphc/pdf/opa/PrgmReg.pdf
Contracted Pharmacy Self-Certification	ftp://ftp.hrsa.gov/bphc/pdf/opa/CPSelfCert.pdf

340B Eligibility Information²⁰⁰

NOTE:

PHSA refers to the Public Health Service Act

SSA refers to the Social Security Act

The following entities are eligible for 340B:

- A. Federally qualified health center (as defined in section 1905(l)(2)(B) of the SSA)
This category includes:
 - FQHC Look-Alikes
 - Consolidated Health Centers (Sec.330(e) PHSA)
 - Migrant Health Centers (Sec.330 (g) PHSA)
 - Health Care for the Homeless (Sec.330(h) PHSA)
 - Healthy Schools/Healthy Communities
 - Health Centers for Residents of Public Housing (Sec. 330(i) PHSA)
 - Office of Tribal Programs or urban Indian organizations (PL. 93-638 and 25 USCS §1651)
- B. A family planning project receiving a grant or contract under Sec.1001 PHSA (42 USCS§3001)

- C. An entity receiving a grant under subpart II of part C of Title XXVI of the Ryan White Care Act (RWCA) (relating to categorical grants for outpatient early intervention services for HIV disease) – Early HIV Intervention Services Categorical Grants (Title III of the RWCA)
- D. A State-operated AIDS Drug Assistance Program (ADAP) receiving financial assistance under the RWCA
- E. A black lung clinic receiving funds under Section 427(a) of the Black Lung Benefits Act (30 USC§901)
- F. A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the SSA
- G. A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988 (42 USC§11701)
- H. An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act (25 USC§1601)
- I. Any entity receiving assistance under title XXVI of the SSA (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary
- J. An entity receiving funds under section 318 (42 USC §247c) (relating to treatment of sexually transmitted diseases) or section 317(j)(2) (42 USC§247b(j)(2)) (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary
- K. A disproportionate share hospital (as defined in section 1886(d)(1)(B) of the SSA):
 - (i) is owned or operated by a unit of State or local government, is a public or private nonprofit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this title;
 - (ii) for the most recent cost-reporting period that ended before the calendar quarter involved had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent²⁰¹ or was described in section 1886(d)(5)(F)(i)(II) of such Act; and
 - (iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

340B Guidelines

The following *Federal Register* notices, listed in chronological order, contain guidelines for participation in the 340B program.

They may be accessed at <http://bphc.hrsa.gov/opa/guide1.htm>.

May 7, 1993 (vol. 58, no. 87, pp. 27289-93) Guidance Regarding Section 602 of the Veterans Health Care Act of 1992; Limitation on Prices of Drugs Purchased by Covered Entities (Introduction, Covered Entities, Covered Drugs, Calculation of the Drug Price, Manufacturers' Information, Covered Entities' Information, Confidentiality Provisions).

May 7, 1993 (vol. 58, no. 87, pp. 27293-94) Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Duplicate Discounts and Rebates on Drug Purchases (All-Inclusive Rates Per Encounter or Visit, Drug Purchases Not Reimbursed Under All-Inclusive Rate).

June 23, 1993 (vol. 58, no. 119, pp. 34058-59) Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Duplicate Discounts and Rebates on Drug Purchases.

December 29, 1993 (vol. 58, no. 248, pp. 68922-25) Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Entity Guidelines (Confidential Drug Pricing Information, Duplicate Discount/Rebate Potential, Eligibility for Retroactive Discounts, Entity Guidelines Regarding Drug Diversion, Audit Requirements, Entity Participation, Group Purchasing, Purchasing Agents, Definition of Covered Outpatient Drug, Dealing Direct or Through a Wholesaler, Manufacturer's Contracts Requiring Entity Compliance).

May 13, 1994 (vol. 59, no. 92, pp. 25110-14) Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Entity Guidelines (Confidential Drug Pricing Information, Duplicate Discount/Rebate Potential, Eligibility for Retroactive Discounts, Entity Guidelines Regarding Drug Diversion, Audit Requirement, Entity Participation, Group Purchasing, Purchasing Agents, Definition of Covered Outpatient Drug, Dealing Direct or Through a Wholesaler, Manufacturer's Contracts Requiring Entity Compliance).

June 6, 1994 (vol. 59, no. 107, pp. 29300-01) Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Inclusion of Outpatient Hospital Facilities.

June 10, 1994 (vol. 59, no. 111, pp. 30021-24) Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Manufacturer Audit Guidelines and Informal Dispute Resolution.

September 19, 1994 (vol. 59, no. 180, pp. 47884-86) Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Outpatient Hospital Facilities.

May 26, 1995 (vol. 60, no. 102, pp. 27983-84) Notice Regarding Section 602 of the Veterans Health Care Act of 1992; New Drug Pricing.

August 3, 1995 (vol. 60, no. 149, pp. 39762-39764) Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Patient and Entity Eligibility (Covered Entity Status, Entity Participation Requirements, Definition of Eligible Entity).

October 2, 1995 (vol. 60, no. 190, pp. 51488-51489) Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992; New Drug Pricing.

November 1, 1995 (vol. 60, no. 211, pp. 55586-55587) Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contracted Pharmacy Services.

August 23, 1996 (vol. 61, no. 165, pp. 43549-43556) Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Guidelines Regarding Contract Pharmacy Services (Revised Final Mechanism, Certification, Anti-kickback Statute, Suggested Contract Provisions).

October 24, 1996 (vol. 61, no. 207, pp. 55156-55158) Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Patient and Entity Eligibility (Definition of a Patient).

December 12, 1996 (vol. 61, no. 240, pp. 65406-65413) Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Manufacturer Audit Guidelines and Dispute Resolution Process 0905-ZA-19.

August 29, 1997 (vol. 62, no. 168, pp. 45823-45824) Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Rebate Option (State ADAP Section 340B Rebate Option).

June 29, 1998 (vol. 63, no. 124, pp. 35239-35242) Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Rebate Option (State ADAP Section 340B Rebate Option).

October 22, 1998 (vol. 63, no. 204, pp. 56656-56658) Notice Regarding HRSA Grant Requirement; Participation in the 340B Drug Pricing Program.

February 9, 2000 (vol. 65, no. 27, pg. 6383) Notice Regarding HRSA Grant Requirement; Participation in the 340B Drug Pricing Program.

March 15, 2000 (vol. 65, no. 51, pp. 13983-13984) Notice Regarding the Section 340B Drug Pricing Program; Program Guidance Clarification (Duplicate Discounts).

APPENDIX VII: Formulary Development

Why Have a Formulary and Formulary System?

In the underserved community, a formulary system is especially helpful for:

- determining the safest, most cost-effective drugs for patients (esp. with limited incomes)
- managing inventory
- providing consistency and rationality to prescribing
- minimizing conflict of interest for providers during drug selection for the formulary
- applying outcomes research in addition to results from randomized controlled clinical trials during drug selection for the formulary

Most administrators are likely familiar with the term *formulary*. Its official definition is “a continually updated *list of medications* and related information, representing the clinical judgment of physicians, pharmacists, and other experts in the diagnosis and/or treatment of disease and promotion of health.”²⁰²

Administrators may not be as familiar with an equally important term, a *drug formulary system*. Basically, this is an *ongoing system of policies and procedures* that supports the most medically appropriate, cost-effective drug therapy for a given patient population.²⁰³

The distinction between the two terms is important, because there is a consensus in the medical community that a drug list is more useful when accompanied by a system to support the drug list.

The formulary and formulary system are most commonly overseen at health centers by a *pharmacy and therapeutics (P&T) committee* that is comprised of practicing health care providers and pharmacists. The P&T committee is usually chaired by the chief medical officer or pharmacy director. The primary goals for the P&T committee include developing and maintaining an objective formulary and establishing and implementing policies on the use of drug products.²⁰⁴ P&T committees generally meet at least quarterly. Some additional tasks of P&T committees include:

- Basing formulary drug selection on factors such as safety, cost-effectiveness, outcomes research data, randomized controlled clinical trial data, inventory capacity, and product availability (i.e., whether the drug can be obtained through a sample, PAP, generic, donation, etc.)
- Establishing and executing procedures to inform providers, patients, and pharmacists about drug products and policies
- Reviewing significant adverse drug reactions

- Ensuring clinician buy-in and support of the formulary
- Providing accessible copies of the drug formulary to drug providers and patients
- Overseeing quality improvement programs, especially those involving drug use evaluation
- Instituting procedures for the use of non-formulary drugs
- Ensuring through policies that the P&T committee members have no conflict of interest with pharmaceutical companies

The actual formulary system will vary widely between health centers, depending on the needs of the organization and its patients. The formulary may be “closed” (limited to certain drugs), “open” (not limited to certain drugs), or somewhere in between. The sliding fee scale for the clinic may or may not be tied to the formulary (i.e., drugs with certain formulary designations might cost patients in different fee categories different amounts of money). There is not one correct approach for all health centers, but rather a unique strategy for each health center. There are two particular concepts relating to drug selection for a formulary that warrant special explanation and will likely apply to all clinics:

1. **Consider “cost” associated with a drug from an overall treatment perspective, and not just an “upfront” cost to the clinic or patient.** There is a possibility that drugs with low acquisition costs may have characteristics, such as side effects, multiple daily dosing, drug interactions, etc., that cause reduced patient compliance. Paying less upfront to acquire a seemingly “low-cost” drug may actually end up costing the health system or even the patient more money in the long term due to the need for additional drugs to treat side effects from the original drug, or due to other health complications from non-compliance or drug interactions, etc. When considering various drug options for inclusion on the formulary, long term and overall costs are as important to weigh as acquisition cost to the health center or patient.
2. **Utilize outcomes research in addition to randomized controlled clinical trials to take the subtle and unique needs of each patient population into account during formulary design.** Controlled clinical trials have been the mainstay for formulating decisions about drugs for many years. However, controlled clinical trials are often executed on limited populations (only one gender, specific age groups, certain health status, etc.), with narrow outcomes (examining only one or a limited number of clinical changes in a limited amount of time). The results from such trials may not be generalizable to other populations. Simply put, a drug that looks like it lowers blood pressure well in one study might actually be less effective in a particular health center’s patient population.

For example, if a drug was studied for one month in healthy male patients between the ages of 20–40 with a specific socioeconomic background, that drug may have very different outcomes after six months in a population composed of elderly females with a different socioeconomic background. Instead of making formulary system decisions by solely applying the results of controlled trials, the P&T committee can help design

procedures for data collection that capture the health center's unique population outcomes on given drugs.

A practical example of outcomes research might look like this:

Pharmacists may monitor outcomes such as rate of patient hospitalization, number of additional drugs needed, clinical health indicators (blood pressure reduction, cholesterol reduction, etc.), level of patient satisfaction, or degree of change in patient quality of life. The results from this data may then be examined in conjunction with results from randomized controlled clinical trials, and variations between the data can be considered during formulary drug selection.

These two important considerations can turn a formulary from merely a list of drugs into a practical, powerful, population-specific tool that can help improve patient outcomes.

Regardless of the formulary design, the actual drug list should include relevant drug details for the purposes of informing providers and patients. Such information may include:

- drug category
- drug name (brand and generic)
- drug strength
- dosage form
- relative cost indication²⁰⁵
- quantity limitations (if any)
- drug location²⁰⁶
- drug source²⁰⁷

ENDNOTES & REFERENCES



Endnotes

- ¹ Brandt and Blumenschein 1999 (regarding 340B pharmacy, as reported by entity administrators during focus groups).
- ² Sometimes referred to as “Section 602 Discount” or “PHS Pricing.”
- ³ 340B-eligible entities are listed in Section I A (under Eligibility) and in Appendix VI (340B Forms, Eligibility Information, and Guidelines). Clinics not currently eligible for the 340B program may apply to the Bureau of Primary Health Care to receive Federally Qualified Health Center Look-Alike (FQHCLA) designation. The instructions for application to receive this designation may be found in the Bureau of Primary Health Care Policy Information Notice (PIN) 2003-21: <ftp://ftp.hrsa.gov/bphc/docs/2003pins/2003-21.pdf>.
- ⁴ Organizations providing contacts to pharmacy consultants are listed in Appendix IV (Resource Organizations).
- ⁵ Cook and Dong 1999, p.51.
- ⁶ Cook and Dong 1999, p.23.
- ⁷ Office of Pharmacy Affairs database files, 2004.
- ⁸ The wide variability in reported participation is due to factors such as: a five-year gap between two sources of data; sites’ ability to enroll as participating in the program without actually purchasing drugs (hence the Cook and Dong survey would find less participation than the database); and the fact that sites must update information with OPA but often fail to do so. Legislation was introduced in 2004 that, among other things, would require development of a system to verify the accuracy of information on the database (340B Program Revision and Expansion Act of 2004).
- ⁹ Brandt and Blumenschein 1999 (regarding 340B pharmacy, as reported by entity administrators during focus groups).
- ¹⁰ See Appendix IV (Resource Organizations) for more information.
- ¹¹ Public Law 102-585, The Veterans Health Care Act of 1992, codified as section 340B of the Public Health Service Act.
- ¹² A June 2004 report issued by the Office of the Inspector General (“Deficiencies in the 340B Drug Discount Program’s Database”) found that the database was filled with errors and omissions with respect to the mailing and billing addresses of covered entities. The full report may be found at <http://oig.hhs.gov>.
- ¹³ Von Oehsen 2001, p.ii.
- ¹⁴ Schondelmeyer 2001.
- ¹⁵ Cook and Dong 1999, p.51.
- ¹⁶ Office of Pharmacy Affairs staff 2004.
- ¹⁷ Cook and Dong 1999, pp.55-56.
- ¹⁸ A June 2004 report issued by the Office of the Inspector General (“Appropriateness of 340B Drug Prices”) found that during a single month, 340B providers spent approximately \$41 million above the mandated 340B ceiling price for their pharmaceuticals, and 31 percent of drug prices sampled by OIG exceeded the government mandated ceiling price. The report recommends pursuing legislation that would create penalties for companies that overcharge covered entities for 340B drugs. The full report may be found at <http://oig.hhs.gov>.
- ¹⁹ Detailed definitions for 340B eligible entities appear in Appendix VI (340B Forms, Eligibility Information, and Guidelines). ADAP Title I and II, STD, and TB clinics must be certified annually to be eligible.

- ²⁰ Health centers may apply to receive FQHC look-alike designation from HRSA/BPHC. Information is contained in Program Information Notice 2003-21: <ftp://ftp.hrsa.gov/bphc/docs/2003pins/2003-21.pdf>.
- ²¹ *Federal Register*, October 24, 1996 (vol. 61, no. 207, pp.55156-58).
- ²² Enrollment forms may differ depending on the type of entity. Information regarding the enrollment forms and the actual enrollment forms are located in Appendix VI (340B Forms, Eligibility Information, and Guidelines), or may be found at <http://bphc.hrsa.gov/opa/howto.htm>.
- ²³ Office of Pharmacy Affairs Database files, April 2004.
- ²⁴ Office of Pharmacy Affairs Database files, July 2004.
- ²⁵ Office of Pharmacy Affairs staff, April 2004.
- ²⁶ According to HRSA's 2001 Uniform Data System, collected from entities receiving grant support.
- ²⁷ According to HRSA's 2001 Uniform Data System, collected from entities receiving grant support.
- ²⁸ Office of Pharmacy Affairs Database files, July 2004.
- ²⁹ HealthCare Purchasing Partners International website 2004: www.hppi340bpv.com.
- ³⁰ See definition in this section under "Eligibility."
- ³¹ *Federal Register*, October 24, 1996 (vol. 61, no. 207, pp.55156-58).
- ³² NACHC, "Contracting with a Pharmacy Management Service Company to Operate a Center's Licensed In-House Pharmacy," Issue Brief #16, 1999.
- ³³ Bureau of Primary Health Care Program Assistance, "Health Center Licensed Pharmacies," 2000.
- ³⁴ The contract pharmacy may place order on behalf of the health center, but the health center pays for the drugs.
- ³⁵ *Federal Register*, August 23, 1996 (vol. 61, no. 165, pp.43549-56).
- ³⁶ If a license for the entity is required by the state.
- ³⁷ Although this is listed as an in-house option for simplicity in the chart, a contracted pharmacy may purchase/lease telepharmacy equipment for use at a clinic under a contracted pharmacy services arrangement.
- ³⁸ These models vary by state. States may license the dispensary, license the providers to dispense, require a pharmacist consultant to be on record for the entity, or require a combination of these points. California has a special provision by law for licensing "dispensaries."
- ³⁹ Application guidelines and detailed information may be found on the Pharmacy Services Support Center website: <http://pssc.aphanet.org/about/altmethods.htm>.
- ⁴⁰ Any option has the potential to require high or low ongoing dollars, depending on the overall structure of the program (the payer mix, the collection rate, the subsidy – if any – paid by the health center, etc.). For simplicity in this chart, *ongoing dollars* is a relative term.
- ⁴¹ See above (footnote 40). This term is relative.
- ⁴² Health center still retains overall responsibility for this model.
- ⁴³ Health center will want to have some administrative staff to audit/check program.
- ⁴⁴ Some pharmacies may be located off-site but still owned by the health center.

- ⁴⁵ Pfizer provides its entire line of single source drugs free of charge to health center patients at or below 100% of poverty who are pharmaceutically uninsured and served by centers which own and operate their own pharmacies. (Management company–operated models may not be eligible, depending upon contract terms.) The Sharing the Care program was designed with Pfizer explicitly for health centers using an efficient voucher system that provides immediate product to center patients, unlike many other company patient assistance programs. The Sharing the Care Program has filled 4.6 million prescriptions for over a million health center patients totaling \$240 million at 350 participating health centers.
- ⁴⁶ Office of Pharmacy Affairs staff 2003.
- ⁴⁷ Pfizer provides its entire line of single–source drugs free of charge to health center patients at or below 100% of poverty who are pharmaceutically uninsured and served by centers that own and operate their own pharmacies. The Sharing the Care program was designed with Pfizer explicitly for health centers using an efficient voucher system which provides immediate product to center patients unlike other company patient assistance programs, the Sharing the Care Program has filled 4.6 million prescriptions for over a million health center patients totaling \$240 million at 350 participating health centers.
- ⁴⁸ Guidelines as of May 2004. See Alternative Methods section in this booklet for information on contracting with multiple pharmacies under the 340B Program.
- ⁴⁹ Contact information for boards of pharmacy may be found at www.nabp.net; boards of medicine at www.fsmb.org.
- ⁵⁰ States may govern exactly what types of providers can prepare the medications, what types of providers can hand the medications to patients, the labeling requirements, etc.
- ⁵¹ Some provider–dispensing models employ a consultant pharmacist or even a full–time pharmacist.
- ⁵² These models will vary greatly by state; these two subtypes are listed for simplicity’s sake.
- ⁵³ California Board of Pharmacy, *2004 Pharmacy Law Book*. California is one state that allows certain clinics (nonprofit or free clinics are specifically mentioned) to apply for dispensary licenses.
- ⁵⁴ As defined by the Office of Pharmacy Affairs in 2000 (http://bphc.hrsa.gov/opa/comp pharm _overview.htm). The original comprehensive pharmacy services definition identifies “efficient operations and finances” as “efficient pharmacy management,” and “outcomes–driven pharmaceutical care” as “pharmaceutical care to improve patient outcomes,” but the meanings are the same.
- ⁵⁵ Since the original definition of comprehensive pharmacy services in 2000, the health care system has placed a keen emphasis on the quality of health care delivery. This manual adds quality assurance as the fourth critical component of a comprehensive pharmacy service.
- ⁵⁶ Samples and patient assistance programs (PAPs) are other ways to provide affordable pharmacy services, but they are not appropriate for every model type. For extensive information on samples and PAPs, see References (Richardson K), *Using Pharmaceutical Company Patient Assistance Programs: A Volunteers in Health Care Guide* and *Managing Medication Samples*.
- ⁵⁷ American Pharmacists Association 1995.
- ⁵⁸ American Pharmacists Association 1995.
- ⁵⁹ Find more details on the Pharmacy Access Partnership website: www.go2ec.org/CollabPracticeAgreements.htm.
- ⁶⁰ Ernst FR 2001.
- ⁶¹ Schumock GT 2003.
- ⁶² Bond 2002.
- ⁶³ The Asheville Project 2000.
- ⁶⁴ Borgsdorf LR 1994.

- ⁶⁵ Amadio P 2001.
- ⁶⁶ Reimburses pharmacists for immunization services where permitted by state law.
- ⁶⁷ PPS codes were created by the National Council for Prescription Drug Programs, and classify and operationalize pharmacists' professional services into a coding system. This system serves as the standard communication tool to relay to the payer the pharmaceutical care services a pharmacist provided. PPS codes document eight categories of medication-related problems.
- ⁶⁸ Porier S 1999.
- ⁶⁹ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108-173.
- ⁷⁰ Also called a "preferred drug list." See Appendix VII (Formulary Development) for more information.
- ⁷¹ Or through appointments resulting from a collaborative practice arrangement with a provider.
- ⁷² More detailed information may be found on the Pharmacy Access Partnership website: www.go2ec.org/CollabPracticeAgreements.htm.
- ⁷³ Brandt and Blumenschein 1999 (as reported by entity administrators during focus groups).
- ⁷⁴ BNA Medicare Report 2004.
- ⁷⁵ Prescription Access Litigation website www.prescriptionaccesslitigation.org
- ⁷⁶ Additional drug terminology and definitions appear in Appendix I (Glossary).
- ⁷⁷ Von Oehsen 2001, p.5.
- ⁷⁸ Webb M 2004.
- ⁷⁹ May receive additional rebates to further lower drug cost.
- ⁸⁰ May receive additional rebates to further lower drug cost.
- ⁸¹ Wholesalers also negotiate with in-house PBMs and PBM mail order pharmacies for cost-less discounts based on volume.
- ⁸² Pederson 2001.
- ⁸³ Pederson 2001.
- ⁸⁴ Outpatient pharmacies of disproportionate share hospitals are not allowed, per 340B legislation, to purchase through GPOs and 340B concurrently.
- ⁸⁵ Excerpt from HRSA NGA, official language taken from February 4, 2000, letter from Claude Earl Fox (HRSA Administrator) to all HRSA Senior Staff, "Statement Regarding Participation in the Drug Pricing Program."
- ⁸⁶ Such prices may also be due to a less than or equal to \$0 cost at best price, where the manufacturer lowballs a particular product if the purchaser will put high-profit, highly competitive drugs on the formulary.
- ⁸⁷ Regulations a consequence of the Prescription Drug Marketing Act of 1987, 21CFR 203.39.
- ⁸⁸ Richardson and Walton, *Managing Medication Samples: A Volunteers in Health Care Guide* (2001).
- ⁸⁹ Most states prohibit samples from being stocked in pharmacies or may only be stocked in pharmacies under certain conditions. Many states prohibit selling samples and removing samples from their original packaging.
- ⁹⁰ Richardson and Basskin 2002.

- ⁹¹ Volunteers in Health Care, *Resources for Simplifying Patient Assistance Programs* (2002).
- ⁹² Richardson K and Geller S, *Using Pharmaceutical Company Patient Assistance Programs: A Volunteers in Health Care Guide* (2004).
- ⁹³ BPHC PIN 98-23. For more information, see Appendix III (Sliding-Fee Scales).
- ⁹⁴ NCSL 2003.
- ⁹⁵ Integrated Healthcare Systems 340B Split-Billing Software.
- ⁹⁶ See Appendix VI (340B Forms, Eligibility Information, and Guidelines).
- ⁹⁷ NACHC, "Health Center Reimbursement for Prescription Drugs: Medicaid PPS and Section 340B Drug Pricing Considerations," Issue Brief #20, 12/2001.
- ⁹⁸ Federal Trade Commission, Pharmacy Benefit Manager Conflict of Interest Study, Public Notice.
- ⁹⁹ Zaneski 2004.
- ¹⁰⁰ Wisconsin Hospital Association 2002 reported avg. #Rxs/visit=2.4.
- ¹⁰¹ American Academy of Physician Assistants 2002 reported avg. #Rxs/visit between 0.65-1.4.
- ¹⁰² American Medical News 2000 reported avg. #Rxs/visit between 0.81-1.1.
- ¹⁰³ Webb M 2004 reported avg. #Rxs/visit=2.2.
- ¹⁰⁴ Rx=prescription.
- ¹⁰⁵ See "Target and measure the pharmacy's capture rate for prescriptions," previous section of this document.
- ¹⁰⁶ Not always a useful measure for CHCs, as Share the Care and 340B pricing sometimes make brands less expensive than generics.
- ¹⁰⁷ Press Release: NABP's Task Forces and Committees Present Reports at Annual Meeting, 1999
- ¹⁰⁸ American Pharmaceutical Association, "Quality Improvement in Pharmacy: Report Cards, Continuous Quality Improvement, and Peer Review."
- ¹⁰⁹ HRSA grantees are expected to "have a quality improvement system that includes both clinical services and management" (BPHC Policy Information Notice 98-23).
- ¹¹⁰ Prime II, "Performance Improvement, Stages, Steps and Tools."
- ¹¹¹ Joint Commission on Accreditation of Healthcare Organizations, "A Framework for Conducting a Root Cause Analysis."
- ¹¹² The Florida Pharmacy Association has a Pharmacy TQI manual that is quite useful for identifying and documenting QREs and medication errors.
- ¹¹³ American Society of Hospital Pharmacists 1992-3, "The ASHP guideline on the pharmacist role in drug use evaluation."
- ¹¹⁴ McIntosh 2001.
- ¹¹⁵ EBRI 1999.
- ¹¹⁶ American Academy of Physician Assistants 2002.
- ¹¹⁷ American Medical News 2000.
- ¹¹⁸ Wisconsin Hospital Association 2002.

- ¹¹⁹ Webb M 2004.
- ¹²⁰ Information appears in Section I B of this manual (340B Implementation Options)
- ¹²¹ Some definitions derived from those determined by the Public Hospital Pharmacy Coalition (2004).
- ¹²² Detailed definitions for eligible entities appear in Appendix VI (340B Forms, Eligibility Information, and Guidelines).
- ¹²³ See Section II B (Decision Analysis).
- ¹²⁴ BPHC PIN 98-23.
- ¹²⁵ For a model calculating sliding fee scale payments in in-house and contract options, see the Decision Analysis Spreadsheet Tool described in Section II B (Decision Analysis).
- ¹²⁶ Pederson 2001.
- ¹²⁷ Excerpt from Sliding Fee Scale PowerPoint Presentation, Pederson et al 2004. Fee scales may be based on AWP – X% + fee instead of 340B cost + fee.
- ¹²⁸ Average margin per prescription should always be greater than average non-drug cost per prescription.
- ¹²⁹ This brief list was compiled based on an extensive document which includes a sample contract: “Contracting with a Pharmacy Management Service Company to Operate a Center’s Licensed In-House Pharmacy,” NACHC Issue Brief #16, 1999 (www.nachc.com).
- ¹³⁰ Always confer with the state board of pharmacy; examples might include requiring the management company to obtain a special license.
- ¹³¹ Such fees may diminish the likelihood that the company will reduce pharmacy costs, may violate the Medicare-Medicaid anti-kickback statute, or cause the health center to have adverse tax consequences. See reference in note 119.
- ¹³² See Appendix IV (Resource Organizations).
- ¹³³ National Association Boards of Pharmacy 2003.
- ¹³⁴ Phone conversation with Carl W. Geberbauer, RPh, MBA, Vice President, Sales and Marketing, Telepharmacy Solutions, 4/15/2004.
- ¹³⁵ TSI ADDS System 8.0, expected in 2004.
- ¹³⁶ Applicable to all subtypes of in-house pharmacy.
- ¹³⁷ BPHC PIN 98-23; see Appendix III (Sliding Fee Scales).
- ¹³⁸ See Section I B (340B Implementation Options). Application guidelines and detailed information may be found on the Pharmacy Services Support Center website: <http://pssc.aphanet.org/about/altmethods.htm>.
- ¹³⁹ For available options and comparisons, visit: www.computertalk.com/index.html?=&Profiles_Text=Retail_Pharmacy=best.html.
- ¹⁴⁰ McIntosh 2001.
- ¹⁴¹ McIntosh 2001.
- ¹⁴² All figures are combined for the four sites.
- ¹⁴³ This pharmacy does not include inventory costs in its budget, and the management company and clinic were both unable to provide estimates for this figure or how the costs were covered.

- ¹⁴⁴ Derived from a teleconference presented in 2002. For more detailed information, visit: www.mac1988.com/2010/registration/11_14_02/Summary.pdf.
- ¹⁴⁵ Based on timeline developed by McIntosh 2001, applicable to all subtypes of in-house pharmacy.
- ¹⁴⁶ See Section II C (Action Plan).
- ¹⁴⁷ See Appendix IV (Resource Organizations).
- ¹⁴⁸ See Appendix VI (340B Forms, Eligibility Information, and Guidelines).
- ¹⁴⁹ Applicable to both subtypes of contract pharmacy services.
- ¹⁵⁰ August 23, 1996 (vol. 61, no. 165, pp. 43549-43556), Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Guidelines Regarding Contract Pharmacy Services.
- ¹⁵¹ *Federal Register* October 24, 1996 (vol. 61, no. 207, pp. 55156-58).
- ¹⁵² OPA staff have historically interpreted “all pharmacy services” to mean that an entity has a contract with either a pharmacy *or* an in-house pharmacy, not both. However, OPA is considering “alternative methods” to 340B participation. One such alternative method is allowing an entity to operate an in-house pharmacy *and* a contract pharmacy. For a complete description of alternative methods, see the Alternative Methods description in Section I B (340B Implementation Options).
- ¹⁵³ An “alternative method” to participation in 340B being considered by OPA is multiple contracted pharmacies with a single entity.
- ¹⁵⁴ *Federal Register* October 24, 1996 (vol. 61, no. 207, pp. 55156-58).
- ¹⁵⁵ Two physically separate drug inventories are not required by federal guidelines.
- ¹⁵⁶ See Appendix I (340B Forms, Eligibility Information, and Guidelines).
- ¹⁵⁷ Although it appears that multiple money transactions occur between the pharmacy and the entity, the transactions are usually summed for simplicity. The result is typically one monthly or periodic exchange of money that represents all of the different transactions between the pharmacy and the entity.
- ¹⁵⁸ Depending on the contract, the pharmacy may collect some or all of the items listed.
- ¹⁵⁹ The patient may pay for the drug on a sliding scale, and the entity may absorb the rest of the cost.
- ¹⁶⁰ If the potential contract pharmacy contacts PSSC, it will be given basic program information and advised to have the covered entity – the eligible party – call for technical assistance.
- ¹⁶¹ See Appendix IV (Resource Organizations) for complete contact information.
- ¹⁶² See Appendix III (Sliding Fee Scales).
- ¹⁶³ The contract may stipulate that the pharmacy bills at the regular PBM/third-party negotiated rates for insured patients on behalf of the health center, and passes the reimbursement to the clinic. It is recommended to check the third-party contracts and state law to ensure that the contract pharmacy may bill on behalf of the health center.
- ¹⁶⁴ See Appendix III (Sliding Fee Scales).
- ¹⁶⁵ Some states may not permit this practice. Contact the state board of pharmacy for specific state information.
- ¹⁶⁶ Good, Patricia M. Chief, Liaison and Policy Section, Office of Drug Diversion, DEA, U.S. Department of Justice, Correspondence to James Mitchell, Office of Pharmacy Affairs, December 4, 2001.
- ¹⁶⁷ Applicable to both subtypes of contract pharmacy services.

- ¹⁶⁸ These two examples currently apply to Florida, but other states may have similar or other unique requirements.
- ¹⁶⁹ Applies to non-capitated, non-all-inclusive rate Medicaid Programs.
- ¹⁷⁰ BPHC PIN 98-23, see Appendix III (Sliding Fee Scales).
- ¹⁷¹ See Section I B (340B Implementation Options). Application guidelines and detailed information may be found on the Pharmacy Services Support Center website:
<http://pssc.aphanet.org/about/altmethods.htm>.
- ¹⁷² Cardinal offers a subscription based service called Invantage to assist contract pharmacies with inventory separation and replenishment, and a program called VIN that assists the health center in related areas. Contact Cardinal Health for more information: John Fiacco, Director, HealthSystems Marketing, at (614) 757-5732 or john.fiacco@cardinal.com.
- ¹⁷³ Exact due date can be negotiated. NOTE: Third-party payments generally take up to 30 days for receipt.
- ¹⁷⁴ Pharmacy management system report format should at minimum contain this information.
- ¹⁷⁵ Exact due date can be negotiated. NOTE: Third-party payments generally take up to 30 days for receipt.
- ¹⁷⁶ Purchases and returns to vendor should be reported to pharmacy and health center by arrangement with wholesale vendor or manufacturer.
- ¹⁷⁷ For more information, visit www.nachc.com.
- ¹⁷⁸ A longer, more complete version of this case study, specifically written for the contracted pharmacy's use, is available in a companion manual to this document entitled "Implementing a Comprehensive 340B Contracted Pharmacy Service: Information and Tools for Community Pharmacists." See Section I E of that manual (An Inside Look at a Functioning Contract Pharmacy).
- ¹⁷⁹ FTEs employed by the pharmacy.
- ¹⁸⁰ A fictitious name for a real community pharmacy.
- ¹⁸¹ This was prior to the initiation of a 340B contracted pharmacy services agreement.
- ¹⁸² Based on closest tax year, includes adjustment for pass-through to clinic as COG, revenue from program as income.
- ¹⁸³ Before taxes.
- ¹⁸⁴ Based on timeline developed by McIntosh 2001, applicable to both types of contract pharmacy services.
- ¹⁸⁵ Enrollment forms may differ depending on the type of entity. Information regarding the enrollment forms and the enrollment forms themselves may be found at <http://bphc.hrsa.gov/opa/howto.htm>.
- ¹⁸⁶ See Appendix VI for form. Also downloadable from <ftp://ftp.hrsa.gov/bphc/pdf/opa/CPSelfCert.pdf>.
- ¹⁸⁷ Applicable to both subtypes of provider dispensing.
- ¹⁸⁸ For a listing of boards of pharmacy, visit www.nabp.net.
- ¹⁸⁹ For a listing of boards of medicine, visit www.fsmb.org.
- ¹⁹⁰ Such as an FDA-approved manufacturer's license.
- ¹⁹¹ Allscripts working with AmerisourceBergen on "Allscripts Direct" (contact Allscripts at 1-800-654-0889 x340, Chris Zirzow, RPh) and Cardinal working with Dispensing Solutions Incorporated on "PatientPAK™-340B" (contact John Fiacco, Director, HealthSystems Marketing, at 614-757-5732 or john.fiacco@cardinal.com).
- ¹⁹² As of April 2004, per phone conversation with Chris Zirzow, Allscripts.

- ¹⁹³ As of April 2004, per phone conversation with Scott Summers, Cardinal.
- ¹⁹⁴ McIntosh 2001.
- ¹⁹⁵ Only some states license dispensaries (California is one example).
- ¹⁹⁶ All figures are combined for the two sites.
- ¹⁹⁷ Only some states license dispensaries (California is one example).
- ¹⁹⁸ Based on timeline developed by McIntosh 2001, applicable to both subtypes of provider dispensing.
- ¹⁹⁹ See Section II C.
- ²⁰⁰ Definitions taken from the Office of Pharmacy Affairs website: <http://bphc.hrsa.gov/opa/grantcon1.htm>.
- ²⁰¹ The Medicare Modernization Act of 2003 made it easier for rural hospitals that were otherwise eligible for 340B participation to meet the 11.75 percent threshold.
- ²⁰² United States Pharmacopeia Endorsed Document, “Principles of a Sound Drug Formulary System,” 2000.
- ²⁰³ The official definition of a drug formulary system is “an ongoing process whereby a health care organization, through its physicians, pharmacists, and other health care professionals, establishes policies on the use of drug products and therapies, and identifies drug products and therapies that are the most medically appropriate and cost-effective to best serve the health interest of a given patient population.”
- ²⁰⁴ United States Pharmacopeia Endorsed Document, “Principles of a Sound Drug Formulary System,” 2000.
- ²⁰⁵ Sometimes indicated by a number of asterisks instead of actual dollar cost, due to the frequently changing costs of drugs.
- ²⁰⁶ This is especially helpful in a “drug closet” or pharmacy service such as provider dispensing. The location of the drug refers to its physical location in the pharmacy (i.e. shelf number, row number, etc).
- ²⁰⁷ This is especially helpful if a clinic uses samples, PAPs, or other donations, as this information will assist providers in projecting any potential delays in receipt of drugs or forecasting the likely patient cost.

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