

# Establishing an On-site Pharmacy in a Community Health Center to Help Indigent Patients Access Medications and to Improve Care

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**Objectives:** To describe the establishment of an on-site pharmacy in a community health center (CHC) to improve access to medications for indigent patients, the implementation of pharmaceutical care programs and clinical pharmacy services to improve patient care and therapeutic outcomes, and the development of an ambulatory care site for training pharmacy students. **Setting:** Partnership Health Center (PHC), a federally funded CHC in Missoula, Mont. **Practice Description:** Establishment of an on-site pharmacy and strategies for accessing medications for indigent patients, including participation in the U.S. Public Health Service pricing program, pharmaceutical manufacturers' assistance programs, and drug sampling, are described. The clinical pharmacy, disease management, and pharmaceutical care programs developed at the site to improve medication use and therapeutic outcomes are discussed. Development of an ambulatory care clerkship site at the CHC for training University of Montana pharmacy students is reviewed. **Practice Innovation:** Partnership between PHC and the University of Montana School of Pharmacy and Allied Health Sciences (SPAHS) to establish an on-site pharmacy to help medically indigent patients access medications and to improve care. **Interventions:** Programs to help indigent patients access, adhere, and appropriately use needed medications while decreasing clinic expenditures for medications. **Main Outcome Measures:** Number of prescriptions dispensed per month, clinic expenditures on medications per month, and number of clinical services and pharmaceutical care programs developed. **Results:** Between November 1, 1999, and April 30, 2000, the average number of prescriptions filled for PHC clients increased from 219/month to 838/month and the average expenditure per prescription decreased from \$16.55/month to \$0.51/month. A pharmacist-assisted refill program was implemented. Programs in diabetes, hypertension, dyslipidemia, asthma, anticoagulation, and peptic ulcer disease were developed. **Conclusion:** Establishing an on-site pharmacy in a CHC in collaboration with a school of pharmacy significantly improved indigent patients' access to medications while decreasing clinic expenditures. Pharmaceutical care programs improved therapeutic outcomes, and clinical pharmacy services complemented the clinical activities of other health care providers in managing chronic diseases and resolving drug-related problems. The CHC provided an excellent setting for training pharmacy students in ambulatory care.

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Opportunities for pharmacists in community health centers (CHCs) are increasing,<sup>1</sup> yet the literature describing pharmacy practice experiences in the CHC setting is sparse. Oke<sup>2</sup> described the establishment of clinical pharmacy services at the St. Thomas Health Care Services Outpatient Clinic in a low-income housing

area in New Orleans. These services improved the delivery of health care in the neighborhood. Lamsam et al.<sup>3</sup> described the participation of pharmacist volunteers in a medication program for homeless persons in Ramsey County, Minn. Pharmacists' duties included establishing and monitoring the program formulary; reviewing patients' records and prescriptions for allergies, potential drug interactions, and appropriate dosages; counseling patients on medication use; and consulting with other members of the health care team. The pharmacists' efforts led to improvements in monitoring and stocking of medications. The cost of the pharmacy program decreased from \$1,800 a month to as little as \$300 a month. The value of donated supplies and medications increased from \$8,600 in 1991 to more than \$122,000 in 1994. This program improved the cost-effectiveness and quality of medications in a homeless population. Tiggelaar et al.<sup>4</sup> described the implementation of a pharmacy clinic in a city-county health department by a

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pharmacy resident. This program provided health care to patients with chronic illnesses, expanded the revenue base of the health department pharmacy, and provided a training site for pharmacy students.

In this article we describe the establishment of an on-site pharmacy in a CHC in Missoula, Mont., by a University of Montana School of Pharmacy and Allied Health Sciences (SPAHS) faculty member. We also discuss the implementation of clinical pharmacy and pharmaceutical care programs to prevent and resolve drug-related problems and to improve therapeutic outcomes. The development of an ambulatory care site for training of pharmacy students is reviewed.

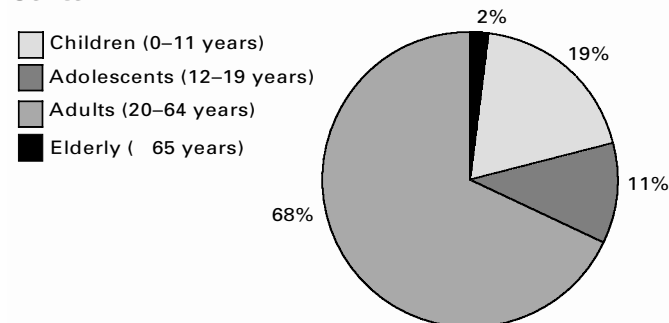
## Community Health Centers

CHCs were first introduced in 1965, when the federal government supported the creation of Neighborhood Health Centers to provide health care to underserved populations, including low-income, inner-city residents and migrant farm workers.<sup>5</sup> CHCs were included as one category of Federally Qualified Health Centers in 1996 with the revision of Section 330 of the Public Health Service Act, which consolidated earlier programs for CHCs, Migrant Health Centers, Health Care for the Homeless Programs, and Public Housing Primary Care Programs.<sup>1,5</sup>

The mission of CHCs is to provide family-oriented primary and preventive health care services for people living in medically underserved communities. While Medicaid assists many needy patients, other medically indigent patients have no such safety net. These patients include the working poor who earn too much to qualify for Medicaid but cannot afford health insurance for themselves or their families.

More than 1,000 CHCs exist today in areas where economic, geographic, or cultural barriers limit access to primary health care for a substantial portion of the population.<sup>1</sup> CHCs tailor their services to the needs of the community. These clinics provide health care to 11 million Americans, 4.4 million of whom are uninsured, at an annual cost of less than \$350 per patient.<sup>6</sup> An estimated 207 CHC clinics operate an on-site pharmacy.<sup>6</sup>

**Figure 1. Age of Patients at Partnership Health Center**



In the original legislation creating CHCs, pharmacy services were considered optional.<sup>5</sup> The 1978 amendments to Sections 329 and 330 of the Public Health Service Act, however, designated the provision of pharmaceuticals as a “primary service” that CHCs had to offer patients, either on-site or externally.<sup>5</sup>

While the U.S. Bureau of Primary Health Care (BPHC) has effectively controlled prescription drug prices affecting CHCs, the nature and quality of pharmacy services from one center to the next are unknown.

Pharmacists, as key members of the health care team, can play a significant role in decreasing the disparity in care for medically indigent patients. To identify opportunities for pharmacists in CHCs, the University of Texas was awarded a grant in March 2000 to conduct a survey of CHCs to assess the extent to which traditional pharmacy services and pharmaceutical care services are provided by these centers and to describe any relationships that might exist between CHCs and colleges and schools of pharmacy. In addition, the grant will enable a set of guidelines for delivery of pharmaceutical care services and recommendations for effective collaborations with colleges and schools of pharmacy to be developed. This project was funded by BPHC in collaboration with the American Association of Colleges of Pharmacy (AACP). For further information, visit the Web site [www.utexas.edu/pharmacy/focus/backissues/summer2000/migrant.html](http://www.utexas.edu/pharmacy/focus/backissues/summer2000/migrant.html).

## Partnership Health Center

In Missoula County, Mont., approximately 26% of the population lacks either the economic means or the insurance coverage necessary to access health care. As a result of this high percentage of low-income, medically indigent residents, the county is federally recognized as having a medically underserved population.<sup>7</sup>

In response to this need, Partnership Health Center (PHC) was established in Missoula in 1992 as a federally funded CHC. In 1998 SPAHS partnered with PHC to establish pharmacy services at the clinic. PHC provided space in the clinic, and SPAHS funded a position for a clinical pharmacy faculty member to provide pharmacy services to clinic patients.

The PHC clinic provides medical care to patients on a sliding fee scale according to income. Currently, 84% of PHC’s patients live on incomes at or below 150% of the federally defined poverty level, and 75% have no public or private health insurance.<sup>8</sup> The federal poverty level varies yearly and according to the number of family members; for example, the poverty level in 2000 for a family of four was \$17,050.<sup>9</sup> The average age of patients seen in the clinic is 35 years (see Figure 1), and women constitute 56% of the patient population. The most common diagnoses made at PHC are hypertension, depression, diabetes, otitis media, and acute sinusitis.

Clinical programs provided at PHC include general medicine, dentistry, breast and cervical health screenings, social services, human immunodeficiency virus (HIV) testing and counseling, mental health counseling, and pharmacy services. The medical staff

consists of a medical director, two mid-level practitioners, one registered nurse, one licensed practical nurse, four certified medical assistants, a social worker, a breast and cervical health educator, and a pharmacy technician. Part-time medical staff include a second physician, a dietitian, a nurse administrator for the Ryan White Program, and a dental coordinator. Other clinic staff include the executive director, project coordinator, finance director, accounting clerk, medical transcriptionist, three receptionists, and two secretaries. Volunteers include local physicians, dentists, dental hygienists, pharmacists, clinical psychology students, and pharmacy students. Recently, in addition to the SPAHS-funded clinical pharmacist, PHC hired a part-time pharmacist-manager and a second part-time pharmacist to cover the pharmacy hours.

### Public Health Service Pricing Program

PHC's initial approach to providing for the pharmaceutical needs of its non-Medicaid and uninsured patients consisted primarily of subsidizing the costs of prescriptions filled by local pharmacies for these patients. Affected by national trends in the costs for prescription drugs, PHC's strategy proved to be financially draining to the organization and limited its ability to help those in need. Nationally, wholesale prices for many commonly used drugs have soared. Over the 6 years from January 1994 to January 2000, the prices of the prescription drugs most frequently used by older Americans rose on average 30.5%. This was twice the rate of inflation, which was 15.4% over that period.<sup>10</sup> Despite strict formulary restrictions, PHC showed an increase in average prescription price of 14.4% for the first 4 months of 1999, compared with the same period in 1998.

As a Federally Qualified Health Center, PHC is eligible to participate in the drug pricing program established under Section 340B of the Public Health Service Act. Enacted into law as part of the Veterans Health Care Act of 1992, this program allows Federally Qualified Health Centers to access medications, including injectable drugs for clinic use, at greatly reduced prices if a pharmacy is established on-site. These prices are at least as low as the prices paid by state Medicaid agencies. CHCs participating in the 340B Drug Pricing Program report substantial savings over what they were paying for outpatient drugs before the legislation was enacted; savings average between 25% and 50% for covered outpatient drugs.<sup>11</sup>

CHCs and other covered entities are eligible to participate in the U.S. Public Health Service (USPHS) prescription drug program by virtue of the federal operating grants they have received. CHCs must inform the BPHC Office of Pharmacy Affairs (OPA) of their intent to purchase drugs at USPHS prices by completing and submitting an Entity Participation Form. This form helps to identify and prevent "duplicate discounts" being paid by manufacturers for the same drugs to the CHC and the state Medicaid agency.<sup>12</sup> An application or confirmation of eligibility for USPHS pricing can be obtained by contacting OPA (formerly the Office of Drug Pricing) at 301-594-4353.

Once accepted into the USPHS program, the CHC is listed on the Electronic Data Retrieval System located at [www.hrsa.gov/odpp/drugquery.cfm](http://www.hrsa.gov/odpp/drugquery.cfm). To help understand the intricacies of USPHS pricing, a publication titled *Handbook of PHS Drug Pricing Program Policy Guidances and Technical Assistance Information* can be obtained from the National Association of Community Health Centers by calling 202-659-8008.

Health centers without their own in-house pharmacy may participate in the USPHS 340B Drug Pricing Program if an agreement with a community pharmacy can be negotiated to dispense the medications. The CHC must be responsible for purchasing the drugs and, as with an in-house pharmacy, must ensure that Medicaid is not billed for prescriptions under this contracted arrangement to prevent problems with duplicate discounts. The contracted pharmacy must keep separate inventory and prescription records to prevent diversion of drugs to non-CHC patients.<sup>11</sup> The CHC is able to obtain USPHS pricing but must pay a fee to the contracted pharmacy for each prescription dispensed.

### Establishment of the On-site Pharmacy

To take full advantage of the USPHS pricing program and to realize the benefits of an on-site pharmacy, PHC established a small, closed-shop, in-house pharmacy on June 15, 1999. Measuring only 121 ft<sup>2</sup>, the space used for the pharmacy is located in an area of the clinic originally designated as an exam room. PHC purchased PDX pharmacy software (PDX-NHIN, Fort Wayne, Tex.) to process prescriptions because the University of Montana uses this system to train pharmacy students. Figure 2 shows the timeline for the opening of the pharmacy.

Initially, the pharmacy opened for 20 hours per week, with the SPAHS-funded clinical pharmacist working during these hours. Community pharmacists occasionally volunteered, depending on availability. A second SPAHS-funded pharmacist was soon enlisted to help cover the hours. If a pharmacist was unavailable to work, the pharmacy closed, but this was rare. As business demands increased, PHC hired a part-time pharmacist-manager and a second part-time pharmacist, allowing for expansion of pharmacy hours to 40 per week. The SPAHS-funded clinical pharmacist is currently working about 10 hours per week in the pharmacy in addition to time spent on clinical activities and teaching.

PHC entered into a purchasing agreement with the Texas Association of Community Health Centers (TACHC), a large purchasing group that contracts with a prime vendor, Cardinal Health, for distribution of USPHS-discounted drugs. TACHC also negotiates contracts with drug companies, such as Bristol-Myers Squibb, Lilly, Merck, Novartis, and Pfizer, for pricing even lower than USPHS prices.

Recently, OPA selected AmerisourceBergen as the prime vendor to serve CHCs participating in the 340B Drug Pricing Program. This is a voluntary program and does not preclude CHCs from joining TACHC or other groups and purchasing drugs through these other groups' contracted prime vendors.<sup>12</sup>

**Figure 2. Timeline for Establishing a Pharmacy at Partnership Health Center**

Activity	Month 6	Month 5	Month 4	Month 3	Month 2	Month 1	Week 4	Week 3	Week 2	Week 1	Opening
Renovation plans											
Board approval of design											
Renovations											
OPA notification											
Computer procurement											
Purchase agreements											
Computer training											
License procurement											
Sharing the Care application											
Equipment procurement											
Inventory procurement											

OPA = Office of Pharmacy Affairs, U.S. Bureau of Primary Health Care.

**Formulary**

A drug formulary was developed for the on-site pharmacy at PHC. Medications were selected for inclusion based on the most frequently encountered diagnoses among clinic patients; most therapeutic drug categories are represented on the formulary. Within each therapeutic category, the most commonly used drugs are included. The choice of a drug for formulary inclusion is also based on the availability of a generic formulation and the cost of the generically equivalent product. A selection of over-the-counter (OTC) items is also included on the formulary, excluding vitamins or herbal products. The pharmacist periodically reviews the formulary to evaluate the addition of new agents or the deletion of seldom-used or unused items. Only orders for formulary medications can be dispensed at the pharmacy. Prescriptions written for nonformulary medications must be changed to orders for therapeutically equivalent drugs on the formulary, filled with samples of prescribed nonformulary drugs if available, or filled at an outside pharmacy at the patient's expense. Table 1 lists PHC's most frequently prescribed drugs and supplies ranked by number of prescription orders.

Patients are limited to a 30-day supply of medication per copay on most formulary medications. However, certain designated

inexpensive generic medications can be dispensed in 100-day quantities per co-pay. A balance must be struck between providing adequate supplies of medications, receiving appropriate amounts of co-pays, limiting patients' inconvenience, and managing staff workload as the number of prescriptions processed monthly increases.

Expensive formulary medications that are also available through the Indigent Drug Program (IDP), discussed below, are limited to a 1-month supply with a maximum of one refill to ensure that the medication is well tolerated and effective. Using a limited quantity of PHC's stock of the medication also allows the patient to start the medication as soon as possible without having to wait for the drug to arrive through IDP, which may take several weeks.

**Prescription Pricing**

The PHC pharmacy's prescription pricing formula is based on a usual and customary (U&C) fee calculated by using the following formula:

$$\{ \text{Average Wholesale Price (AWP)} - 12\% \} + \$4.25$$

This pricing approach was chosen to correspond with the formula most commonly used for calculating prescription fees paid by Montana Medicaid. This method of calculating the fee allows the

**Table 1. Most Frequently Prescribed Drugs and Supplies at Partnership Health Center**

Category (Brand)	Strength or Quantity	Ranking (No. Units)	Ranking (Sales Volume)
Accu-Check Comfort Curve	50 count	1	1
Albuterol inhaler (Proventil, Ventolin)	90 mcg/spray	2	4
Naproxen (Naprosyn)	500 mg	3	3
Insulin (Humulin-N)	100 units/mL	4	5
Amoxicillin (Amoxil)	500 mg	5	11
Ranitidine (Zantac)	150 mg	6	2
Cyclobenzaprine (Flexeril)	10 mg	7	7
Cephalexin (Keflex)	500 mg	8	6
Conjugated estrogens (Premarin)	0.625 mg	9	13
Trazodone (Desyrel)	50 mg	10	22

PDX prescription software to generate a report of the savings patients receive by having prescriptions dispensed through the PHC pharmacy instead of through a community pharmacy.

The co-pay is assessed on a sliding scale based on patients' incomes (see Table 2). If patients cannot verify their income, they are required to obtain their prescriptions in the community. Receptionists at the clinic are responsible for verifying income and collecting pharmacy co-pays. If a patient is unable to pay, the co-pay can be billed to the patient's PHC account.

OTC medications used for symptomatic treatment are priced at cost plus 30%, with patients bearing the entire cost. The co-pay for diabetic strips, syringes, and lancets is half of the net cost of the product for A through D patients, then 60% for E, 80% for F, and 100% of cost for G patients.

**Eligibility**

To participate in the federal drug pricing program, a CHC pharmacy must have a system in place to ensure patient eligibility. At PHC, a patient is eligible if he or she has an established medical chart and a PHC provider orders the prescriptions. If a patient has third party insurance coverage on prescriptions, including Medicaid, he or she is referred to a pharmacy in the community. The pharmacy is closed to non-PHC patients.

The goal of the in-house CHC pharmacy is to help people in need who have no other means of obtaining medications. Because CHCs can purchase drugs at some of the lowest prices available, every effort must be made to foster a noncompetitive relationship with area pharmacies. It is important to establish a

working relationship with the pharmacists in the community because prescriptions for nonformulary items are referred to area community pharmacies.

**Analysis of the USPHS Pricing Program**

Before PHC's in-house pharmacy was established, prescriptions for formulary medications were dispensed by contracted pharmacies in the community, and the co-pays were collected in the clinic. In an arrangement similar to Montana Medicaid's, PHC would pay the contracted pharmacy AWP less 12% plus a contracted fee per prescription. From November 1998 through April 1999, PHC's expenditures on medication averaged \$3,625 per month for 219 outsourced prescriptions, or \$16.55 per prescription. Once the on-site pharmacy was established, all PHC formulary medications were required to be dispensed in-house. Patients pay full price for prescriptions dispensed in the community.

The average number of prescriptions dispensed at the on-site pharmacy from November 1999 through April 2000 increased from 219 to 838 per month. However, the average net expenditure per prescription for PHC decreased from \$16.55 to \$0.51 with the in-house pharmacy. This was calculated by subtracting the average co-pay of \$5.78 per prescription from \$6.29, which is the average ingredient cost per prescription. This does not account for any overhead expenses. Tracking and reporting the prescription dollars saved is important for when the clinic seeks renewal of its federal grant.

The in-house pharmacy has been able to increase the number of prescriptions filled for medically indigent patients while substantially decreasing the overall medication expenditures for the clinic. However, to more completely offset the cost of the drugs, the average co-pay of \$5.78 needs to be adjusted periodically to approximate the average cost per prescription, currently \$6.29. Adjusting the minimum co-pay of the sliding fee scale A to 10% of U&C or a minimum of \$4.00 per prescription, instead of the \$4.00 minimum co-pay, should account for the dynamic nature of prescription drug prices, allowing for the co-pays to more effectively offset the cost of drugs.

**Table 2. Co-pay Schedule for Partnership Health Center Patients**

Income Category (% Poverty Level)	Co-pay/Coinsurance
A (100)	\$4.00 per prescription
B (120)	20% usual & customary <sup>a</sup> price
C (140)	40% usual & customary price
D (150)	50% usual & customary price
E (160)	60% usual & customary price
F (180)	80% usual & customary price
G (200)	100% usual & customary price

<sup>a</sup>{AWP - 12%} + \$4.25.

## Indigent Drug Programs

The research-based pharmaceutical industry has a long-standing tradition of providing prescription medications free of charge to physicians whose patients might not otherwise have access to necessary medications. There are few reports on the impact of these IDPs. Decane and Chapman<sup>13</sup> reported on a program for procuring free medications for indigent patients from pharmaceutical manufacturers at a cancer research center in Duarte, Calif. The center provides free care to indigent patients and was looking for a way to offset drug costs. A full-time pharmacist was hired to identify patients likely to qualify for such assistance, help patients apply for assistance, and coordinate the receipt and distribution of medication supplies. The acquisition cost of the medications received was \$448,851 in 1992 and \$504,211 in 1993.

A more recent report by Weiner et al.<sup>14</sup> describes a medication assistance program for indigent patients at a university medical center. A full-time pharmacist and a full-time social worker run the program with support from technicians and a student extern. The program helped 231 patients between July and December 1999. Program costs totaled \$110,537, but \$237,985 in drug costs were saved. This program has improved indigent patients' access to medications and is cost-effective.

Provision of prescription drugs to patients who otherwise could not afford them significantly improves patient outcomes. Nykamp and Ruggles<sup>15</sup> described a study to determine whether provision of both medical care and prescription drugs at no cost would be associated with a change in overall health care charges secondary to a change in therapy adherence for 36 indigent patients enrolled in an assistance program for 6 months. Inpatient admissions decreased by 39.5% and outpatient visits decreased by 64.4%, amounting to a cost avoidance to the hospital of \$378,183. The cost of drugs supplied during the study was \$27,588. This study revealed that maintaining adherence to needed medications improves care for indigent patients and leads to decreased health care expenditures.

To make it easier for physicians to identify the growing number of programs available to medically indigent patients, member companies of the Pharmaceutical Research and Manufacturers of America publish a directory of prescription drug patient assistance programs.<sup>16</sup> The description for each program includes information about how to request assistance, which prescription medications are covered, and basic eligibility criteria. Several Internet-based programs are also available that can be used to streamline IDPs. Those programs include *IndiCare* ([www.indicare.com](http://www.indicare.com)), The Medicine Program ([www.themedicineprogram.com](http://www.themedicineprogram.com)), NeedyMeds ([www.needymeds.com](http://www.needymeds.com)), and RxAssist ([www.rxassist.org](http://www.rxassist.org)).

At PHC, the pharmacy technician serves as the medication clerk responsible for ordering medications from pharmaceutical companies' patient assistance programs. The technician meets with patients to complete the paperwork required for accessing medications, works with providers to complete paperwork, and charts and tracks orders. Most companies will allow the patient to receive a 90-day supply of medications.

Once the IDP application is submitted, delivery of the drugs takes approximately 2 to 6 weeks. Some medications, such as Pharmacia's products, are available through pharmaceutical company certificates only, which must be redeemed at a community pharmacy. Although most drug companies allow pharmacists to collect a fee from patients to offset administrative expenses, PHC patients are not currently charged a co-pay or administrative fee for accessing these medications.

Tracking IDP medications involves maintaining individual patient records to determine when patients need to be notified to make appointments to reorder medications on a timely basis. The technician provides PHC with a quarterly report of medications accessed, the value of medications donated, and the number of patients served by this program.

CHCs do not need to have an on-site pharmacy to provide patients access to IDPs. At PHC, the IDP is currently a physician-driven program that is partially separate from the pharmacy since this program was in place at the clinic before the on-site pharmacy was established.

### Analysis of the Indigent Drug Program

At PHC, the IDP has obtained as many as 60 different drugs from 31 different pharmaceutical manufacturers and serves between 89 and 141 patients per fiscal quarter. Quarterly, the average retail value of the drugs accessed is over \$34,000. This program provides many patients with expensive medications that would otherwise be unavailable to them. Sustaining this program is time- and labor-intensive, however. It is also inconvenient for patients, who risk an interruption of medication therapy if any important steps are missed in the application renewal process. To offset the clinic expenses involved in administering this program, a co-pay may need to be charged in the future.

### Pfizer's Sharing the Care Program

Sharing the Care is a special IDP that provides most of Pfizer's medications to eligible, uninsured low-income patients free of charge. Once a CHC is registered in Sharing the Care, it receives an initial 2-month supply of all branded Pfizer products, and the stock is replenished on an ongoing basis.

To be eligible to participate in Sharing the Care, a CHC must be funded under Section 330 of the Public Health Service Act. Sharing the Care operates only in CHCs with in-house pharmacies owned and operated by the health center and governed by a pharmacy license that requires a pharmacist to dispense prescription medications to patients.<sup>17</sup>

The CHC must ensure patients' eligibility for the Sharing the Care program. Only patients whose annual family income is at or below the federal poverty level—in PHC's case, sliding fee A patients (Table 2)—qualify to receive Sharing the Care drugs. Pfizer products on the formulary for noneligible patients are purchased from the wholesaler and stocked separately from the Shar-

ing the Care inventory. Patients are allowed a 90-day supply of Sharing the Care medications, for which PHC requires a \$2.00 co-pay per prescription to administer the program.

Centers must complete and submit vouchers to Pfizer on a weekly basis. Sharing the Care vouchers are entered into the database at Pfizer's processing center, and, if the pharmacy's inventory falls below 75% of the optimal 2-month level, a shipment is made. Health centers interested in participating in Sharing the Care can call the general information line at 800-984-1500 to receive program information and registration materials. Once a pharmacy procures its license, it can submit an application to participate in Sharing the Care. Approximately 9 months elapsed from the time that PHC signed up for Sharing the Care and the arrival of the first shipment of drugs.

#### Analysis of Sharing the Care

PHC started participating in the Sharing the Care program on November 1, 1999. For the first full quarter of usage, January–March 2000, 95 patients received 138 prescriptions with a value of just over \$8,900, or an average of about \$64.00 per prescription. To offset administrative expenses, a higher co-pay may need to be charged in the future.

#### Drug Sampling Program

Samples are obtained from pharmaceutical sales representatives and through donations from area physician offices. Commonly prescribed brand-name drugs from many pharmaceutical companies are provided. In addition, samples of drugs being newly marketed are available. Quantities of samples may vary depending on the availability of the product to the sales representative. Any outdated samples received are discarded.

Due to lack of space at PHC, samples are not currently kept in the pharmacy. The majority of the samples are kept in the clinic's locked medication room, which is accessible to the professional staff with use of a security code. Additional samples are kept in lockable cabinets located in the clinic area. The medical providers distribute the samples. Since the use of samples was established in the clinic before the on-site pharmacy opened, this is currently a physician-controlled program. To comply with FDA regulations, and as part of accreditation by the Joint Commission on Accreditation of Healthcare Organizations, a system to track samples has been instituted.

Pharmacies are encouraged to control samples to the maximum extent possible to document medications on the patient's medical history and to cross-check allergies and drug interactions, to label medications, and to counsel patients. On occasion, samples are used by the pharmacy to fill prescriptions. The patient is not charged a co-pay for samples dispensed through the pharmacy.

#### Analysis of Drug Sampling Program

Due to the limited availability of samples, inappropriate drugs, doses, dosage forms, and quantities may be prescribed at times. Sustained use of samples to treat chronic diseases is difficult, but

they can be used appropriately as a bridge for patients waiting for drugs to arrive from drug companies through the IDP. In addition, use of samples for acute medical problems that require a one-time prescription for an expensive nonformulary medication is helpful.

#### Clinical Pharmacy and Pharmaceutical Care Services

Evidence is beginning to mount that direct pharmacist involvement in patient care can minimize drug-related problems (DRPs). Lazarou et al.<sup>18</sup> conducted a meta-analysis of 39 studies to examine adverse drug reactions in hospitalized patients between 1966 and 1996. Serious drug reactions affected 6.7% of the patients, and 0.32% of these patients died. More than two-thirds of the serious cases reviewed involved reactions that occurred outside hospitals rather than inside them; these patients were subsequently admitted to hospitals for follow-up care. The researchers concluded that approximately half of the reactions reviewed were preventable, especially with the help of a pharmacist.

Pharmacists can also help prevent DRPs in the community setting. Rupp<sup>19</sup> described a study to estimate the economic value created by community pharmacists who routinely screen for and correct prescribing-related problems during the course of their dispensing activities. He found that 28.3% of identified problems could have resulted in patient harm had the pharmacist not intervened to correct the problem. The direct cost of medical care avoided was estimated to be \$122 per problematic prescription.

Providing clinical pharmacy services can help minimize DRPs and control health care costs for ambulatory care patients. Schumock<sup>20</sup> estimated that for every dollar invested in clinical pharmacy services, an average of \$16.70 can be saved in overall health care costs. Many PHC patients present to the pharmacy with DRPs and receive specific services to address the problem.

The on-site pharmacy at PHC has led to many opportunities to improve specific patient outcomes. An anticoagulation clinic was developed in collaboration with the clinic providers to provide management of warfarin therapy. The PHC refill clinic was implemented to provide a systematic approach to target long-term monitoring of patients with chronic diseases with a high prevalence and potential for morbidity, such as hypertension, diabetes, dyslipidemia, and *Helicobacter pylori*-induced peptic ulcer disease. The pharmacy's PDX reporting function is used to identify patients who may benefit from asthma education. A future goal is to do an analysis of costs saved and revenue generated from clinical pharmacy services at PHC.

#### PHC Refill Clinic

To help PHC patients maximize the benefits they obtain from their medications and to prevent DRPs, a pharmacist-assisted refill program was developed and implemented. Upon request for a prescription refill, the patient's medical chart is retrieved and reviewed. Using protocols developed in collaboration with PHC prescribers, medication refills are authorized by the pharmacist

using criteria to determine appropriate use, indication, dose, interactions, duplication, and monitoring parameters. Table 3 lists monitoring criteria for selected drug therapies. This program also provides valuable opportunities for pharmacy students to monitor drug therapy as part of their training in ambulatory care.

**Care for Patients with Diabetes**

Berringer et al.<sup>21</sup> described the implementation of a pharmaceutical care program for diabetes that was integrated with dispensing functions; subjective and objective data related to diabetes care were gathered with each prescription refill. Recommendations were made to patients and their physicians. A significant ( $P < .01$ ) improvement in average morning blood glucose values was noted from initiation to 6 months of the program; a continued decline in values from 6 to 12 months was also noted. Physicians implemented 15 of 20 (75%) recommendations made by the pharmacists. This model provided an effective mechanism for providing pharmaceutical care for patients with diabetes.

Type 2 diabetes mellitus is the third most common diagnosis at PHC. To improve clinical outcomes, patients requiring antidiabetic medications are monitored as part of the pharmacist-assisted refill program. The pharmacist orders a hemoglobin A1c blood test according to protocol, if necessary. PHC patients who have not met the American Diabetic Association treatment guidelines receive counseling on therapeutic goals and are referred to their

primary care provider for further management.

Misuse of diabetes test strips, the most frequently dispensed item from the PHC pharmacy, was confirmed using PDX's reporting function. Although self-monitoring of blood glucose (SMBG) is individualized to each patient, the need for primary care providers and other health care team members to educate patients on the best approach to SMBG became clear. In response, a pharmacy student developed a diabetes test strip protocol and materials to educate patients on the appropriate frequency of testing. Additionally, many PHC patients cannot afford blood glucose test strips, lancets, or other diabetes care supplies, and, therefore, do not test their blood sugar as often as recommended. Since testing of blood glucose is an important factor in determining the outcome of these patients, PHC has established a decreased co-pay program to enable patients to purchase these supplies.

**Care for Patients With Hypertension**

Park et al.<sup>22</sup> described a study documenting the value of providing clinical services to hypertensive patients in a community pharmacy. The researchers found that monitoring drug therapy and educating hypertensive patients contributed to improved blood pressure control. Results showed that blood pressure control was significantly improved in patients receiving pharmacy services, and there was some suggestion that quality of life mea-

**Table 3. Monitoring Criteria for Selected Drug Therapies**

Drug or Drug Class	Monitoring Parameters
Allopurinol	Uric acid, blood urea nitrogen, and serum creatinine every 12 months <sup>30</sup>
Antidyslipidemia agents	Lipid profile on initiation, 6 and 12 weeks after initiation, after dosage changes, then every 6 months; liver function tests initially, at 6 weeks and 12 weeks after initiation of therapy or change of dose, and periodically thereafter <sup>31,32</sup>
Antihypertensive medications	Blood pressure and heart rate every 3 to 6 months <sup>33</sup>
Diabetes medications	Hemoglobin A1c every 3 to 6 months; serum creatinine and complete blood count every 12 months for patients on metformin <sup>34</sup>
Digoxin	Potassium, creatinine, and pulse every 6 to 12 months; serum level as needed or every 12 months <sup>35</sup>
Diuretics	Serum potassium, blood pressure, and weight every 3 to 6 months; other electrolytes, glucose, uric acid, blood urea nitrogen, and creatinine every 12 months <sup>36</sup>
Estrogen and/or progestin agents	Blood pressure, breast, abdomen, pelvic organs, and Pap tests every 12 months; <sup>37</sup> mammogram, ages 50–69 years, every 1–2 years <sup>38</sup>
H <sub>2</sub> -receptor antagonists and proton pump inhibitors	One-time <i>Helicobacter pylori</i> antibody blood test must be documented in the medical record
Lithium	Serum level every 2–3 months until stable, then every 6 months; creatinine, complete blood count, urinalysis, sodium, potassium, fasting glucose, electrocardiogram, and thyroid-stimulating hormone every 12 months <sup>39</sup>
Nonsteroidal anti-inflammatory drugs	Serum creatinine/blood urea nitrogen, blood pressure, and weight every 12 months; occult blood as needed <sup>40</sup>
Oral contraceptives	Blood pressure, breast, abdomen, pelvic organs, and Pap tests every 12 months <sup>41</sup>
Phenytoin, carbamazepine, valproic acid, phenobarbital	Serum level, complete blood count, and liver function tests every 12 months <sup>42</sup>
Theophylline	Serum level every 6–12 months <sup>43</sup>
Thyroid replacement medications	Thyroid-stimulating hormone every 12 months <sup>44</sup>
Warfarin	Prothrombin time/international normalized ratio every 4–6 weeks and complete blood count every 12 months <sup>45,46</sup>

tures were also better in the pharmacist intervention group.

Hypertension is the most common diagnosis prompting pharmacy intervention at PHC. As part of PHC's pharmacist-assisted refill program, patients receiving medications for hypertension are required to have their blood pressure and heart rate checked every 3 to 6 months. The pharmacist or pharmacy student takes the patient to an exam room when checking blood pressure. PHC patients not meeting Joint National Committee (JNC-VI) treatment guidelines for hypertension are provided education on hypertension and referred to their primary care providers for further management.

#### Care for Patients With Dyslipidemia

Shibley and Pugh<sup>23</sup> described a lipid management program in the community pharmacy setting that measured outcomes resulting from provision of pharmaceutical care to patients with hyperlipidemia. Total cholesterol and low-density lipoprotein cholesterol values were significantly decreased at 12 months, compared with baseline and 6-month values ( $P < .02$ ). A study by Bluml et al.<sup>24</sup> demonstrated that pharmacists, working collaboratively with patients and physicians and having immediate access to objective point-of-care patient data, can improve patient persistence and compliance with prescribed dyslipidemic therapy that enables patients to achieve their National Cholesterol Education Program (NCEP) goals. In a population of 397 patients over an average period of 24.6 months, observed rates for persistence and compliance with medication therapy were 93.6% and 90.1%, respectively, and 62.5% of patients had reached and were maintained at their NCEP lipid goal at the end of the project.

To reduce the risk of cardiovascular events associated with dyslipidemia, PHC patients requiring lipid-lowering medications are vigilantly monitored. PHC patients receiving medications for treatment of dyslipidemia are required to have fasting lipid and liver function tests, according to the pharmacist-assisted refill protocol. Patients failing to meet NCEP treatment guidelines are given education to help achieve therapeutic goals and are referred to their primary care provider for further management.

#### Care for Patients With Respiratory Ailments

Rupp et al.<sup>25</sup> described a community pharmacy-based asthma program that was marketed to a health maintenance organization. These patients experienced a 77% decrease in hospitalizations, a 78% decrease in emergency department visits, and a 25% reduction in urgent care visits. They also had improvements in quality of life measurements.

To improve management of patients with asthma and reduce associated complications at PHC, a PDX pharmacy report was used to evaluate possible misuse of albuterol multidose inhalers, identified as the second most prescribed item in the PHC pharmacy. A review of the report made the need for an education program targeting PHC clients with breathing problems apparent.

PHC patients are identified and invited to participate in the Asthma Information Resources (A.I.R.) program developed by

the SPAHS chapter of the American Pharmaceutical Association—Academy of Students of Pharmacy (APhA—ASP). This program was developed a year earlier and was already being implemented in the community.<sup>26</sup> The educational program consists of three 90-minute sessions. With a faculty member as team leader, volunteer pharmacy students and the SPAHS clinical pharmacist conduct each session. Through A.I.R., patients with breathing problems gain a better understanding of their condition and their treatment regimens. The program also enables patients, health care professionals, and students to see the value of forming long-term asthma management partnerships with each other, improving drug therapy outcomes for patients, and providing greater professional satisfaction for health care providers.

#### Care for Patients With Coagulopathies

Knowlton et al.<sup>27</sup> concluded that community pharmacies can effectively implement an anticoagulation education and monitoring program using fingerstick capillary whole blood testing. Of the 235 international normalized ratio (INR) values obtained during the study, 75% were within the individually targeted therapeutic ranges.

To reduce the risk of bleeding and clotting complications, PHC patients on warfarin are referred to the pharmacy for management of anticoagulation. The anticoagulation monitoring service uses point-of-care INR testing with a CoaguCheck monitor (Roche Diagnostics). PHC patients are either scheduled to visit the clinical pharmacist or accepted as walk-in patients. The patient is directed to an exam room and a fingerstick blood test is completed. Under protocol, in collaboration with the clinic providers, the pharmacist adjusts warfarin dosages according to the patient's INR, schedules follow-up visits, counsels and educates the patient, and writes a progress note for the patient's medical records.

#### Care for Patients With *Helicobacter Pylori*

Morreale<sup>28</sup> described a pharmacist-managed *H. pylori* assessment clinic for ambulatory patients receiving long-term acid-suppressive medications. Patients with active peptic ulcer disease and those receiving ulcer prophylaxis are screened for the presence of *H. pylori*. The pharmacist is responsible for treating the disease, adjusting or discontinuing acid-suppressive drugs, ordering laboratory tests, monitoring patients for adverse reactions, collecting data on patient outcomes, and providing patient education. This program enables pharmacists to assume a primary care role and document improvements in patient outcomes.

To optimize the use of histamine H<sub>2</sub>-receptor antagonists and high-cost proton pump inhibitors for treatment of active ulcer disease or ulcer prophylaxis at PHC, patients are screened for the presence of *H. pylori* using an antibody blood test. The pharmacist orders the laboratory test according to the pharmacist-assisted refill protocol. Those who test positive are treated with a quadruple therapy of amoxicillin, metronidazole, ranitidine, and bismuth subsalicylate.<sup>29</sup> Because of the increased chance of noncompliance due to

the complexity of the regimen, each patient receives detailed counseling and written information on the prescribed therapy. This regimen was devised to provide the greatest chance for *H. pylori* eradication at the lowest possible cost.

### Student Clerkship Activities

In addition to participating in the care of the patient populations identified above, pharmacy clerkship students participate in providing patient education and counseling, comprehensive medication consultations for selected patients receiving multiple medications, and consultations for walk-in patients or patients who call the clinic about DRPs. Responding to drug information requests, conducting medication use reviews, giving in-service presentations, producing newsletter articles, and developing patient educational materials are also common clinic activities of pharmacy students.

Opportunities to participate in clinical research projects are available at PHC. While research funds have yet to be obtained, several research proposals have been submitted, including a student proposal to study and improve medication compliance among hypertensive patients and a faculty proposal to improve medication compliance among patients with depression.

### Future Enhancements to Clinical Pharmacy Services

In collaboration with SPAHS, PHC recently obtained a grant from BPHC to improve pharmacy services at six CHCs in Montana. This multiyear demonstration project will help improve clinical services at one center, establish on-site pharmacies at three centers, and complete pharmacy services needs assessments at two other centers. Clinical pharmacy services will be established at each site for patients with hypertension, diabetes, asthma, and hyperlipidemia and for patients on anticoagulant therapy. This project is expected not only to improve health outcomes for clients, but will also increase the number of clinical sites where pharmacy students can be trained.

## Conclusion

Pharmacy services have reduced CHC medication acquisition expenses. CHCs not utilizing a pharmacy are ineligible to participate in the USPHS pricing program or Pfizer's Sharing the Care program and, therefore, are not taking full advantage of all available programs for expanding indigent patients' access to needed medications. CHCs with an in-house pharmacy can provide medications for indigent patients using all available drug acquisition programs, thus improving patient care.

CHC managers can benefit from the expertise of a pharmacist to set up the pharmacy, access medications, dispense prescriptions, manage the formulary, counsel and educate patients, provide clinical pharmacy services, decrease risks of adverse effects, and decrease clinic expenditures for medications and health care. Government policy makers can help indigent patients by requiring CHCs to utilize a pharmacy to be eligible for federal funding

and renewal of grants.

CHCs can provide excellent ambulatory care clerkship sites for training pharmacy students. Students obtaining their clerkship experiences at PHC are exposed to both traditional and clinical pharmacy experiences, and they will have increased patient care opportunities as pharmacy services at PHC expand to more fully meet the needs of the clinic's clientele. The success of PHC's collaboration with SPAHS suggests that other colleges and schools of pharmacy would benefit from training students in CHCs. PHC might serve as a model for other established CHCs interested in developing pharmacy services.

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