

“Starting a Pharmaceutical Program”

Crisis Control Ministry

Field Report

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volunteers
in health care

A report written by organizers of volunteer-based health care programs serving the uninsured.

PHARMACEUTICAL

“Starting a Pharmaceutical Program”

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Volunteers in Health Care Note: Please be advised that regulations exist in every state regarding the dispensing of pharmaceuticals. In addition, the U.S. Food & Drug Administration has its own regulations regarding drug samples and in December, 2000 issued new regulations for their handling, management and distribution. Before starting a program, be sure to look into the regulations in your state as well as those of the FDA. For more information on the new FDA regulations specific to drug samples please visit the VIH web site at www.volunteersinhealthcare.org or call toll-free at 1-877-844-8442.

Who we are

Crisis Control Ministry (CCM) is a nonprofit organization established in 1973 to provide emergency assistance to residents of Forsyth County, North Carolina who find themselves in serious financial crisis. Crisis Control Ministry provides assistance with rent, utilities, fuel, food and clothing and operates a pharmacy to provide free medication to eligible clients. The pharmacy is a program of CCM.

Crisis Control Ministry's Pharmacy operates 5 1/2 days per week, serving qualifying indigent and chronically ill individuals in Forsyth County. The patient population is 40% elderly, 30% working poor, 15% chronically poor and/or disabled, and 15% the "medically underinsured." By "medically underinsured," we mean those clients who have health insurance that covers some of the costs of prescription medications but who cannot afford whatever co-payments may exist under their health plan. Medications are dispensed for both acute and chronic conditions, with a majority of prescriptions dedicated to on-going chronic conditions, such as diabetes, renal disease, high blood pressure, and so forth. CCM partners with the local free medical clinic, referring clients to them and, in many cases, providing the prescriptions needed for those patients. We do not charge for prescriptions and there is no limit on the number of medications we provide for a client.

How we got started

The impetus behind CCM's creation of a free pharmacy was to provide life-saving and life-enhancing medications, as a matter of both moral imperative and cost-effectiveness, to those who could not otherwise afford them. Before our pharmacy was created in 1987, CCM's practice was to pay pharmacies for client medication needs. When our pharmacy was formed in the 1980s, drug price inflation was extensive, and our direct spending on prescriptions was very high. The Executive Director at that time, along with several physician volunteers, realized that if CCM could procure medication samples that were being discarded by the county's two major hospitals and local physicians' offices, CCM could realize both cost-savings and greater client services. Initially, we created a pharmacy committee comprising local physicians, pharmacists, and other community members. This committee solicited local hospitals, physician practices, and nursing homes for excess inventory and drug samples donated by pharmaceutical companies. The committee approached individual physicians throughout the county and asked the local medical society for their assistance and support. They also held a meeting of drug representatives from various pharmaceutical companies. Positive reinforcement from these key

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Crisis Control Ministry (CCM), located in Winston-Salem, NC, is a nonprofit organization established in 1973 to provide emergency assistance to residents of Forsyth County who find themselves in serious financial crisis. Crisis Control Ministry provides assistance with rent, utilities, fuel, food and clothing and operates a pharmacy to provide free medication to eligible clients. The pharmacy is a program of CCM.

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groups paved the way in 1987 for the opening of the first free, state-licensed, limited-service pharmacy in North Carolina at Crisis Control Ministry. "Limited service" means that our pharmacy dispenses medications limited to:

1. Persons who have life-threatening conditions and cannot otherwise procure their medications; or
2. Certain kinds of medical conditions.

For instance, we do not offer certain prescriptions for people with HIV or cancer. We will dispense other medications in the cases of non-life threatening conditions provided that we have ample supplies of donated drugs on hand. We do not purchase drugs for conditions that are not life threatening.

Recommendations/observations

When considering creating a pharmaceutical access program, ask these questions:

Whom will the program serve?

The client population profile will affect much of the operation and design of the program. Not all persons needing medications can be served; therefore, beginning programs might want to establish criteria for service. For instance, perhaps the program decides to serve only the indigent elderly. These criteria will in part drive the decision of which model to use.

Which model will be utilized?

We see three basic models:

1. *The "on-site pharmacy" model.* This model is labor intensive and requires access to a great number of volunteers who are willing to go get donated pharmaceuticals and repackage them. It also requires access to volunteer or paid pharmacists willing to oversee the program. CCM eventually hired a licensed pharmacist to direct our program, while still utilizing lay volunteers for much of the labor (i.e., drug pick-up, client screening, etc.). It also requires a devoted cadre of physicians, nurses, and other health care professionals who are willing to maintain and expand relationships with hospitals, physician practices, and nursing homes in order to keep our donated drugs coming in regularly. The principal benefits of this design are the ability to serve a large number of clients and the low start-up costs (assuming access to large quantities of sample medications). The principal drawbacks to this model are that it is labor-intensive, most likely requires a license by the State Board of Pharmacy, and requires access to professional pharmacists under whose license the program operates. CCM hired a licensed pharmacist but initially used the license of a volunteer pharmacist who was retired and could devote many hours weekly to the program.
2. *The "voucher or prescription card" model.* In this model, the program makes arrangements with local pharmacies to fill prescriptions that are paid by the program. The program does client screening and patient education, usually with a pharmacist's oversight. Benefits of this model are low labor needs, low start-up costs, and quick set-up profile. Drawbacks include high continuing costs of purchasing medications, even with negotiated discounts with retail pharmacies, which limits the type and kind of prescriptions (and therefore clients) that the program can serve, unless there is a ready source of funds available.
3. *The "medication assistance program" model.* This model helps clients access the indigent care programs of pharmaceutical companies. With this model, the program screens clients for eligibility and specific drug needs, does the paperwork with the pharmaceutical company, and gets the client's prescription sent to the client's physician. This model is inexpensive and efficient provided that staff/volunteers know how to access the pharmaceutical companies' indigent care programs and can fill out the paperwork properly and quickly.

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What are your organizational and community resources?

Conduct an organizational assessment and environmental scan, examining:

1. Local sources of free medications
 - i. How many and what kind?
 - ii. How difficult to access?
 - iii. How difficult to maintain relationships or grow relationships?
 - iv. How labor intensive (recruiting, picking-up drugs, etc)?
2. Local sources of funding
 - i. Churches
 - ii. Foundations
 - iii. Individuals
 - iv. Groups
 - v. Civic clubs
3. Other organizations conducting similar or complementary activities
 - i. Pharmaceutical access as add-on?
 - ii. Use another organization as fiscal sponsor?
4. Health care professionals and organizations
 - i. Use as advisory panel?
 - ii. Enough in the area?
 - iii. How to access as volunteers or advisors?
5. The resources you can currently exploit (volunteers, donated samples, grant funds, knowledge of or access to pharmaceutical indigent care programs, etc.).
6. Your organization's current functioning and how to fit the program into it.

Choosing a model

CCM's program combines all models. Initially, we purchased medications directly for clients through dispensing arrangements with independent local pharmacies. Over time, the prohibitive costs of direct drug purchase and our wish to serve more clients necessitated our move toward procuring and dispensing donated pharmaceuticals and becoming a freestanding pharmacy. Recently, we have begun using the Internet to access information about pharmaceutical companies' patient assistance programs.

Factors that influenced our decisions included:

1. Our desire to spend less on drugs but help more clients with their drug needs;
2. Our ready access to a large pool of volunteer labor (including pharmacists and pharmacists-in-training) and a potentially large source of donated pharmaceuticals (health care is one of Winston-Salem's primary industries, with many physician practices and hospitals);
3. Our organizational stability and resources to hire professional staff to oversee the program; and
4. Our knowledge of patient assistance programs and our technological capacity to access information on them over the Internet.

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The growth of our program over time also compelled operational changes. For instance, after our initial tightening of eligibility restrictions due to spiraling drug costs, we have relaxed eligibility guidelines as we were able to serve more clients. Our screening process itself, however, has become more sophisticated, and we are more thorough than in the past. For instance, we attempt to make sure that a client has exhausted all other venues of drug assistance, such as Medicaid, before we assist them. Minor changes in our formulary have occurred respective to current patient demographics and with changing drug availability and pricing.

A majority of our medications are dispensed on-site with 100% of the legend (non-scheduled) medications dispensed in-house. We have arrangements with an outside independent pharmacy to provide Schedule II medications, such as Duragesic patches, Oxycontin, and Tylox. For patients with non-life-threatening conditions, we provide sample medications when available, such as Flonase for nasal allergy; however, we typically do not purchase medications for conditions that are not life threatening. For clients that need “life-sustaining” medications, we purchase medications if samples are not available. Factors affecting this decision are: the seriousness of the patient’s condition, the patient’s ability to pay, the cost of the medication(s), and whether other agencies might be more specialized in a particular condition and able to provide the medication(s). For instance, Cancer Services of North Carolina would be a better drug supplier to a client with cancer.

CCM’s pharmacy is licensed by the state of North Carolina. The time from application to approval and opening of the pharmacy was approximately one year. Reporting requirements in North Carolina are minimal.

Procuring medications

Drug samples

Physicians’ offices advise us of sample availability and our couriers pick them up. CCM has run its program long enough and has an active involvement of volunteer physicians that most in our area are aware of our need for samples and will provide them if possible. We have a volunteer coordinator in charge of five volunteers who makes arrangements with other volunteer “runners” to pick up the medications from the physician’s office for delivery back to our pharmacy. Physicians in both private practice and at area hospitals call us and request someone to pick up the medications. The number of physicians who donate medications varies month to month; however, there is a core of 25 or so private practice physicians who donate samples given to them by pharmaceutical representatives. Medications are picked up and delivered weekly. We plan to implement a physician solicitation program to increase the base of providers of sample medications.

Retail or other pharmacies

The procedure we have recently started using is to fax a request for a certain medication to be dispensed for a certain client and authorizing payment. Every month the independent pharmacy sends us an itemized bill for the medications dispensed to our clients. During the search for an outside source to dispense medications, we contacted two of our local retail chains. Neither of the chains was willing to accept an arrangement for billing purposes like we have with the independent pharmacy. We have not formally negotiated discounts with the independent pharmacy; however, they do give us 10% off as a professional courtesy. We also do not have a formal legal or written arrangement with the pharmacy.

Donations from drug companies

There are four drugs that we get in a bulk shipment from Parke-Davis. A drug usage report is collected quarterly from our database and submitted to the manufacturer along with prescriptions signed by a physician from our Clinical Advisory Board. We identified these institutions by the medications we use the most, and the physicians on our Clinical Advisory Board solicited drug company representatives to get this medication. Occasionally we

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will ask a physician on our clinical advisory board to request a specific medication from a pharmaceutical representative. The argument is usually posed in terms of benefits of donated drugs to the indigent populations in our community. The primary barrier to this source is that solicitation and maintenance of the relationship is labor-intensive.

Bulk purchasing

We currently purchase from Cardinal Wholesaler and Quest Pharmaceuticals, Inc., both of which we approached over the phone. The medications we purchase from Cardinal are brand name drugs, specifically maintenance medications such as those for hypertension such as Accupril, Lotensin, etc. The medications that we purchase from Quest consist of generic drugs and vary from antibiotics to just about any drug that currently has a generic equivalent formulation such as Enalapril, HCTZ, etc. We have been purchasing medications through Cardinal since opening operations in 1987 and through Quest since 1993. The prices for generics at Quest tend to be lower as it is specifically a generics clearinghouse, and we would recommend using such a clearinghouse.

Program operations

Staffing

The majority of the medications dispensed are by the Director of the Pharmacy, a licensed pharmacist and full-time employee. We also have volunteer pharmacists who help with dispensing. Recently, the North Carolina Board of Pharmacy gave approval for continuing education credits for pharmacists volunteering at free clinics or pharmacies, so this has strengthened our volunteer pharmacist recruitment efforts. We also have one full-time pharmacy technician and two paid part-time staff involved in volunteer oversight and patient assistance programs. They also assist in client screening and evaluations. Volunteers also serve as couriers and provide front-desk assistance.

Formulary

We did not establish a formulary in advance of our program; it evolved as the program grew. We initially used whatever medications we could get donated. As the program grew, cost considerations necessitated the development of a formulary in order to serve clients with the greatest need, while keeping costs reasonable. We developed a list of "life sustaining" medications we would carry or purchase. Under the "non-life-sustaining" category, we included any drugs that were not essential to a client's sustenance and decided that we would dispense these if we had donated samples on hand but would not purchase them if we did not have samples.

Every prescription medication that goes onto our shelves is verified as to quantity, type, dosage, expiration date, etc. When we run low on a medication, we reorder it. We also ask patients to call their refills in three days in advance, which allows us enough time to order the necessary medications from Cardinal or Quest. The volume and particular cost of prescriptions dispensed during the day helps the Pharmacy Director decide which medications need ordering. Our daily budget for dispensed medications is approximately \$1,500. If medications dispensed exceed this amount on a particular day and we are low on a particular medication, the Pharmacy Director will defer purchases in order to remain within budget.

Computer system

Our prescription database gives us a picture of what "goes out" of the CCM pharmacy. We use VIP Pharmacy Management System, which we purchased for \$10,600 in 1993. A subsequent upgrade in 1997 cost \$2,600. VIP runs under Xenix/Unix (the newer version runs under Linux) and meets our needs quite well. It provides us with demographic profiles of our client base and allows us to generate profiles of the medications we have dispensed. We often generate drug usage reports to identify demand for a particular medication.

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Pharmacy budget

The current pharmacy budget (excluding the value of in-kind products) is \$511,622, with \$360,000 budgeted for medicine purchases and \$151,622 for salaries and benefits. Originally, our pharmacy budget was essentially nothing because the pharmacy was run entirely by volunteers, including pharmacists. As the pharmacy grew, we hired a director to provide daily oversight of pharmacy operations. Safety in prescription fulfillment became paramount as we served more and more clients. The director's salary came out of our general operating fund for program services.

Funding sources

Our first funding sources included local churches, foundations, and individual donations, which also comprise the majority of our funding for our other service programs. In the late 1980s, the pharmacy grew to the extent that we needed to add space for the program. Consequently, we conducted a successful capital campaign and many foundations and individuals donated to this "one-time" cause. We have a restricted fund for our pharmacy but many of our general support grants and donations also cover pharmacy costs as the pharmacy is considered among our core services. We usually can predict monthly medication costs based upon a previous period's activity, although we have found no thoroughly accurate forecaster. Our general policy for cost containment is the rule that if a prescription is "life-sustaining," we will exert all possible energies to provide it if we can. If we cannot, or if the drug is not "life-sustaining," we will fill the prescription if we happen to have donated samples available.

Lessons learned

If you are a currently existing organization, conduct an organizational assessment to ascertain in-house skills, abilities, and availability of staffing or volunteers. If you are a new organization, decide which model to use, based upon resources available (volunteer, financial, etc.) at start-up.

Lastly, tour successful facilities.

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