

**“Starting a Pharmaceutical Program”**

St. Joseph’s Health Center

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”

### St. Joseph’s Health Center

*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 recently 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](http://www.volunteersinhealthcare.org) or call toll-free at 1-877-844-8442.*

#### **Who we are**

Our pharmacy is part of an indigent clinic operating as a department of a hospital. The clinic started out with three or four volunteer family practice physicians. This number quickly grew, and we now have over 70 physicians who volunteer. Most of these are family practice physicians, but we do have several orthopedic, ENT, cardiologist, urologist and GYN physicians who come to the clinic as well. We also have one ophthalmologist, who donated the equipment to have an eye exam room, and one optometrist. The clinic refers patients to physicians outside of the clinic for specialty care.

We are situated at an off-site location. Most financial support comes from the hospital. However, we do receive many private donations and community grants, but we do not receive any state or federal funds. In the past 12 months we filled 30,344 prescriptions (about 115/day). Our patient population is 2,036 and is geographically restricted to St. Joseph’s County. The patient population is 39% Caucasian, 39% African-American, 16% Hispanic and 6% from other racial groups.

At this time, for all eligible patients we fill prescriptions prescribed by clinic physicians, by physicians in our referral network and by physicians who have seen a patient in the St. Joseph emergency room. Eligibility requirements include having no Medicare or Medicaid, a household income within 150% of the Federal Poverty Level and not being a patient at the other sliding fee scale clinics in the city. The client may not have insurance through his employer or be eligible for reasonable insurance from employer. We consider reasonable insurance to be insurance that costs less than 5% of gross income. In many instances it might be suggested that a worker enroll in individual insurance through his or her employer, but bring his or her spouse to be seen at the clinic. Children would automatically qualify for Indiana Medicaid (CHIPS) under our financial guidelines. We have tried to provide the highest level of medical and pharmaceutical care with our limited resources.

Patients pay \$5 for an office visit, but nothing for medication. We have no medication caps. The most common problems seen at the clinic are diabetes, high blood pressure, chronic pulmonary diseases, gastrointestinal diseases, and muscular and arthritic diseases as well as acute infectious illness. We do not fill birth control pills (we are a Catholic institution) or certain “lifestyle” medications, e.g. Viagra. We do not fill controlled drugs on location, but do provide them to the patient through the hospital’s outpatient pharmacy at no cost.

#### **How we got started**

The decision to have an on-site pharmacy was more of an evolution than a decision. The clinic began in a small carriage house with three doctors and 50 patients. Physicians provided samples gleaned from their office

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*The St. Joseph Regional Medical Center in South Bend, Indiana is a hospital that operates a free clinic as part of its care system. Saint Joseph’s Health Center has operated the clinic since 1986. As part of its commitment to health care the clinic hosts an on-site medication room that provides medication to residents of St. Joseph’s county who are seen at the clinic, seen by a physician in the clinic’s referral network or seen at St. Joseph’s emergency room.*

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to supply the patient, and this expanded to what we do today. The doctors who staffed the clinic were of the mind that with a generous community effort, patients should be able to have the medications they needed regardless of their financial resources.

The decision was made to hire a pharmacist at our clinic eight years ago when nurses were trying to fill medications from a small medication room with samples. The physicians had already decided that patients would not pay for medication. Over-worked and under-trained nurses would do what they could, but if they did not have or could not find a specific medication, it was ordered from the outpatient pharmacy. Thousands of dollars were being spent this way unnecessarily. It was decided that a part-time pharmacist could be a cost saver as well as improve the quality of care. The part-time pharmacist evolved into a full-time position that could fill virtually all prescriptions, except controlled drugs, on site.

## **Pharmacy set-up**

The pharmacy has been organized basically in the same manner that a retail pharmacy might be organized. Drugs are arranged alphabetically on the shelves. The source of our stock can be easily determined—a “dot” sticker is placed on any medication received via indigent drug program, the wholesaler’s sticker distinguishes purchased medication, samples are stored separately (see below) in a room connected to the pharmacy, and controlled prescriptions (for pick up only) are stored in a lockable drawer. Over the years this balance has shifted because we now use many less samples and try to use indigent programs more, but the basic organization has not changed. Changes have evolved rather than come from specific, planned decisions.

Major changes have occurred due to inspections by Joint Commission on Accreditation of Healthcare Organizations (JCAHO), which we are subject to as part of a hospital system. As part of our JCAHO inspection in 1999, it was determined that a “drug room” should now become a licensed pharmacy. (The pharmacy became licensed as a Retail I class pharmacy in May of 2000.) A pharmacist JCAHO inspector made the recommendation based on the scope of the dispensing activities—i.e., we were already functioning as a pharmacy without the regulation—and partly because the number of prescriptions being filled per day. Since we already had a pharmacist in place, this was not a major task. We also needed to reorganize the way we handle samples. State and federal laws required that samples must be stored in a separate “sample room” accessible to physicians and nurses as well as the pharmacist. This amounted to partitioning off a room separate from the remainder of the pharmacy. The pharmacy is only accessible to the pharmacist.

Because of these changes we also hired a part-time pharmacy technician. This gave us more time to refine the way we applied for medications through pharmaceutical patient assistance programs, and thus allowed us to apply to more programs. Both pharmacist and pharmacy technician have become equally knowledgeable in these programs, allowing us to work as a team.

## ***Recommendations/observations:***

We would say there are three main considerations in beginning a program and deciding whether to dispense on-site: organization, time, and help. Instead of jumping in you must make decisions about how you will organize your program considering these factors:

- **Organization**

Plan what your objectives will be for providing medications:

- what medical conditions will you provide medication—chronic, acute, both?
- how many patients will you be serving?
- will you use samples and pharmaceutical patient assistance programs?
- will you purchase medications to be dispensed?
- do you have space to store medication?

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- **Time**  
Consider the amount of time it will take to achieve your objectives:
  - to dispense medications
  - to organize samples
  - to order and receive indigent drugs
- **Consider the reliable assistance you can depend on:**
  - do you have trained staff and/or volunteers that you can rely upon to help you achieve your objectives?

It is our experience that with the right amount of good help, it is very feasible to provide about half of medications via pharmaceutical patient assistance programs and samples.

## **Procuring medications**

We obtain our medications from four sources: patient assistance programs, samples, bulk purchases from the hospital's internal pharmacy, and from the hospital outpatient pharmacy. Our first goal is to fill all of our patients' medications and our second is to do this in the most cost efficient manner. We try to decide the best way to pursue a specific medication. For example, it is simply not time and cost efficient to use patient assistance programs for drugs we can purchase cheaply as generics. For the same reason, we use the hospital's outpatient pharmacy to fill prescriptions only under certain circumstances (see below).

### ***Drug samples***

We can only solicit samples from manufacturer's representatives, due to JCAHO regulations. We keep a card file on the various reps. If we need samples, we call the rep, let them know what we need and let them know when a doctor will be available for a signature. Some reps are very attentive and stop by unsolicited. We find that we have a corps of reps who are more than happy to be "welcomed" into a doctor's office. Recently the pharmacy secretary, who schedules the displays in the doctor's lounge in the hospital, began to check with us. If reps wish to schedule a display, they need to be a regular donor to the clinic. In the past we had been quite successful in soliciting sample donations from physician's offices. However, because there is loss of "tracking" and a possibility of diversion, JCAHO regulations require that we can now only obtain samples directly from manufacturer's representatives. In addition, we are also required to maintain an inventory of receipts and dispersal of samples. Therefore, dispensing samples has become a very time consuming process. For these reasons, the number of medications that we dispense from samples has been greatly reduced. We now fill about 6% or about 145 prescriptions per month from samples.

We use samples primarily for meeting acute needs, probably because we do not receive as many samples as we used to. For example, in the past we received so many Merck samples, that we did not need to bother with Merck's patient assistance program. Now we find that most often samples are "fill-ins" until we can receive an indigent supply. Samples are especially helpful in filling prescriptions for our patients who do not have legal residency. Developing a good network and relationship with the various reps is essential. If they feel welcomed, they will tend to leave more samples and will be more responsive to your calls.

### ***Retail or other pharmacies***

The hospital outpatient pharmacy is the only pharmacy with which we have an arrangement for filling prescriptions. Because we are all part of the same organization, the presumption is that they will provide us with the best discount—the equivalent of an "employee" discount. The pharmacy "bills" our account monthly to be charged against our budget. This is the most expensive way to obtain medication, because

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we always pay a markup of some kind, except for medications filled through patient assistance programs. We use the hospital's outpatient pharmacy for dispensing controlled drugs (which we are not licensed to dispense), filling prescriptions from voucher based patient assistance programs (e.g. Glaxo SmithKline), or providing starter amounts for a patient (two week's worth of medication that will hold a patient over until medication from patient assistance programs arrive). About 126 prescriptions are filled per month at the outpatient pharmacy. At one point when we were having many billing and other operational problems with this set-up we briefly considered approaching other pharmacies about providing these medications. We thought a pharmacy might make a donation to the pharmacy in the form of a "credit" to be used towards filling patient prescriptions. This has never been pursued, although it may be a good idea for the future.

## ***Bulk purchasing***

About 1196 (45 %) of prescriptions are filled from drugs we purchase directly from the hospital's internal pharmacy through a local wholesaler. We place an order daily, and the medication is delivered the next day. The pharmacy inventory coordinator from the hospital places the order. The advantage of this is that she can scan the computer for the cheapest product or the one with a contract price. For the most part, we order the bulk generics that we use, i.e., amoxicillin, furosemide, HCTZ, etc. from this source, but we also purchase brand name medication as well. We may need to order other medications that cannot be easily obtained by samples or patient assistance programs and also glucose meter strips. Obviously, we try to limit those purchases as much as possible, but if we do need an item it is often significantly discounted due to contract pricing. There are a few brand medications that are so inexpensive that we do not bother with patient assistance programs. Unfortunately, sometimes drugs go off contract with what seems to be no warning! That is why it is helpful to have the inventory coordinator available to alert us to the change. Once again, this amount is billed to our account.

It is a great convenience to be able to get items very quickly. Since we can always get something in a day, we can keep on hand a very limited inventory of the more expensive items and thus limit our cost. We have found that this contract pricing is even lower than prices offered by generic wholesalers.

## **Program Operations**

### ***Staffing***

Because we are a licensed pharmacy, we must have a pharmacist available at all times that the pharmacy is open. The pharmacist is a paid, full-time position; we have never been able to recruit pharmacists to volunteer with any regularity. The pharmacist dispenses all medication (with the assistance of the technician) from processing refills to filling new prescriptions from the patient chart after the patient sees the physician. The pharmacist counsels all patients on new medications with written and verbal instructions. Counseling is documented in the chart. Counseling is offered on refills when requested by the patient or the pharmacist. The pharmacist assists the physician in the monitoring of blood work for patients on Coumadin, Avandia and Actos, methotrexate and anti-convulsants. The pharmacist also alerts the physician of possible drug interactions. Diabetic patients who have problems with glucose monitoring, diabetic complications, and medications may see the pharmacist when the diabetic educator is not available. The pharmacist also prepares an updated list of each patient's medications for the chart before each doctor's appointment. The pharmacist interacts with the other health care professionals about patient care. In addition, the pharmacist works with the technician in applying and re-submitting requests for patient assistance programs, maintaining the computer system, supervising technician and volunteers, removing outdated medications from the shelves, and preparing a monthly report of medications received and dispensed.

We also have on staff a full-time pharmacy technician. Her duties are to assist the pharmacist in filling prescriptions, ordering medications from the hospital pharmacy, calling pharmaceutical reps for samples, maintaining

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the inventory of samples, maintaining records, and ordering medications through the patient assistance programs. We have four senior citizen volunteers. They volunteer anywhere from 3 to 15 hours per week only in the pharmacy. At present, they check in most medications received from patient assistance programs and our daily orders from the hospital pharmacy. They record expiration dates for all drugs in the expiration log and record and sticker the medications. They will also help prepare forms, stock shelves, and reorder bottles.

## **Formulary**

In the beginning, we took medications from any and all sources. We have tried to accommodate the physicians with whatever medications the physician felt was necessary. Most often, however, the physician would come to the pharmacist or vice versa to offer guidance in selecting a medication. For example, if the physician wished to order an ace inhibitor, the pharmacist could recommend one that was readily available either with samples or through patient assistance programs. On the other hand, if the physician ordered a medication that we did not have, the pharmacist would suggest an alternative and most often the physician would agree.

Recently, we have begun the process of implementing a formulary that has been put to paper. We are making a greater effort to control our costs and are in the process of introducing the formulary to the physicians who volunteer their time at the clinic. It is far too early to assess the actual dollar savings we will realize. It may also be necessary in the future to ask patients to pick up some of the cost of some of their medications, especially if the patient does not agree with our formulary choices.

The director of pharmacy at the hospital has made the decisions of what medications are on the formulary. Factors for inclusion on the formulary are: 1) effectiveness; 2) side effects and safety profile; and 3) cost. In general, most drugs on the list are available through patient assistance programs, or they are inexpensive generics. However, there have been some choices made where proven effectiveness outweighs immediate cost considerations. In these cases it is felt that the long-term outcome of using an expensive drug may actually save money. An example of this is Levaquin, which we may or may not have available to us as samples.

The formulary is meant to be a "living document," i.e., we will change the formulary to reflect any changes in necessary to help us decrease costs and still maintain a high level of care. There are several reasons for changes in the formulary: 1) Drugs move off patent to generic. In this case, drugs may now be unavailable through patient assistance programs. Generic versions may or may not be "affordable." 2) Drugs are newly introduced. Supplies of these drugs are often readily available as samples and also through patient assistance programs. 3) Changes in patient assistance programs may make it easier or more difficult to obtain medication. 4) New drugs may be introduced that may be simply be deemed as important enough to place on formulary. 5) Drugs may move from contract pricing to off, or vice versa.

## **Computer system**

We have been using a licensed pharmacy software system, Datastat, for the past seven years. However, this system has become obsolete, so we are in the process of deciding whether to choose a new system or to upgrade the present system. Datastat is an online system that is used by pharmacies and is, therefore, meant to be used for billing insurance companies. Since we do not do any billing, it has been a very expensive program due to the monthly maintenance fees (\$50/month). We use the computer system as follows: 1) fill and refill all medications; 2) maintain medication records on each patient which are readily retrievable; 3) provide clinical interactions when filling prescriptions; 4) generate monthly reports; 5) produce a patient medication record that can be placed in the chart for the physician's review; and 6) create a patient list for drugs to be ordered on patient assistance programs.

## **Budget**

The annual clinic budget for the year 2000-2001 is \$850,000, which includes all expenses related to the pharmacy. We have no direct way of predicting medication expenses. However, based on previous months'

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expenditures and the fact that we continue to diligently work to obtain as many drugs as possible through patient assistance programs, we estimate that costs run \$12,000 to \$15,000 per month (or about \$6 per prescription filled). As mentioned before, we are now instituting an official formulary that will allow us to cut even more of our costs.

We value most medications using Average Wholesale Price (AWP), which tends to be on the high side, but is most commonly used. However, prescriptions filled at the outpatient pharmacy are priced higher than AWP and medications purchased in bulk from the internal hospital pharmacy are lower than AWP. Each month we track costs and savings in several categories, including:

- value of drugs received from all sources
- average number of prescriptions filled daily
- average number and % of total prescriptions filled from all sources
- average AWP value and % of total AWP value from all sources
- average AWP value per prescription from all sources
- total contract value of glucose strips dispensed per month

Fifty percent of the prescriptions filled are from donated medication (samples and patient assistance programs); however, these medications represent almost seventy-five percent of the AWP value.

## Lessons learned

Our best and first advice is to make sure that you use the services of a pharmacist to help organize your program. Pharmacists know drugs and manufacturers, and have the skill to organize a pharmacy or drug room. Without a pharmacist, you may spend unnecessary dollars on medications you already have or could easily obtain generically or substitute to a similar product. A pharmacist consultant can help you easily organize a very workable pharmaceutical access program. Even if you would have to pay a pharmacist, it would be well worth your money! Secondly, if you have the resources, a computer system is invaluable. A computer system can generate readable labels. Being able to retrieve records is invaluable day-to-day, as well as when you try to organize and order your program. We do not believe the most sophisticated system is necessary, however. Finally, make the most effective use of your help. If you have reliable volunteers, train them to do certain tasks that will relieve you. Well-trained volunteers are invaluable for prepackaging monthly quantities of medications, checking in orders, and filling out forms.

## For more information, contact:

Carla Bice  
Clinical Director  
St. Joseph's Health Center  
326 South Chapin Street  
South Bend, IN 46601  
Phone: (219) 232-4070

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111 Brewster Street  
Pawtucket, RI 02860  
1-877-844-8442

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