

“Starting a Pharmaceutical Program”

WV Health Right

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

PHARMACEUTICAL

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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 website at www.volunteersinhealthcare.org or call toll-free at 1-877-844-8442.

Who we are

WV Health Right, established in 1982, is a free clinic serving the uninsured and underinsured in Charleston, WV. As part of its commitment to health care, the clinic provides medication for free, both to its patients and to individuals referred by physicians in the Charleston area. The clinic's pharmaceutical access program enjoys support from local pharmacists, physicians, hospitals, and the City of Charleston.

WV Health Right is open 66 hours per week. The clinic provides care to over 13,000 uninsured and under-insured patients with a household income below 100% of the Federal Poverty Level. (Medical expenses are deducted from household income.) For the under-insured population we provide only items not covered by the patient's insurer, i.e., medications for the Medicare population. Patients do not have to be seen at WV Health Right in order to receive services, and physicians in the community routinely refer patients to our pharmacy.

During 2000, the pharmacy dispensed 91,072 prescriptions valued at \$7.8 million Average Wholesale Price (AWP). Medications are dispensed for acute and chronic illness. Patients with chronic conditions receive a two-month supply of medications. The top three chronic conditions of clinic patients are: cardiovascular disease, diabetes, and pulmonary disease. The pharmacy occupies 560 square feet out of the clinic's total of 14,400 square feet.

How we got started

For the uninsured poor, diagnosis without treatment/medications is pointless. Therefore, medication access has always been a part of the services offered. (We do not dispense controlled drugs such as strong painkillers, diet drugs, etc.) Health Right's decision to operate a pharmaceutical program on site was quite simple. The clinic could not afford to buy every medication needed by every patient nor could it pay the retail price at pharmacies for medications ordered by its providers. In addition, initially, Health Right was only open during evening hours, and many retail pharmacies were not open as late as the clinic. Finally, medication availability was seen as a method to get the patients to return to the clinic for follow-up care and/or health education. Therefore, an on-site pharmacy offered the best financial control, was easier for the patient, and addressed the issue of patient compliance without increased cost.

Initially, Health Right dispensed mostly physician samples and physician stock bottles. This was before the days of pharmaceutical patient assistance programs. Also, some medications were purchased through

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the state's medication contract (no longer available to non-state agencies). In addition, drugs were purchased through several generic drug manufacturers and on a limited basis through a local independent pharmacy at its cost and without a dispensing fee. Times have changed and currently, Health Right uses patient assistance programs, physician samples, drug company donations, and direct purchase at Public Health Service (PHS) prices through several different manufacturers. (PHS pricing, also known as the 340B program, is a pricing structure negotiated by the federal government with pharmaceutical manufacturers. Some organizations that receive federal funding are eligible to receive discounted pharmaceuticals through this program. WV Health Right has negotiated prices with the pharmaceutical companies that mirror those of PHS pricing.) Other potential sources for donated drugs are: when a manufacturer agrees to shipments of a near-dated product (within six months) or when another company has acquired the drug/company necessitating a change in all packaging. Even mergers of companies call for a change in labeling/marketing of samples and stock bottles.

Improving operations

Over the years Health Right has changed pharmacy operations in two basic ways: changes in clinical policies and changes to increase cost effectiveness or efficiency. An example of the former is pre-dispensing of medications for selected groups of patients to reduce the pharmacy load from busy days to those when fewer patients are being served. Health Right initiated two programs, Mega-Med and Mini-Med, to decrease pharmacy flow during peak hours. Patients who are seen by an external provider (that is, those that are not Health Right clinic clients) and who are on more than 8 medications per month become part of the Mega-Med program. Those on three or fewer per month are part of the Mini-Med program. Medications for these patients are filled in advance of the patient's visit during "off-peak" hours. This makes it much easier to dispense these medications quickly. Patients in these programs are required to contact the clinic one week in advance of picking up their medications and to have a valid prescription on file at the clinic pharmacy.

Clinical policies and protocols may change as the result of changes in drug development. For example, sometimes after a drug has been in use for a while, the manufacturer will recommend that new—and often more complex—protocols be followed when a patient is using a certain drug. This may result in additional laboratory tests for that patient. At this point the clinic needs to assess whether it can continue offering the drug. Or, a new drug may cause a different kind of change in clinical protocol. For example, initially no nerve medications were available for patients unless the patient was under the care of a Health Right psychiatrist. However, this policy was changed when a new drug class, Selective Serotonin Re-uptake Inhibitors was developed that included such mild antidepressants such as Zoloft, Paxil, and Prozac.

Licensing

In 1998, the West Virginia Board of Pharmacy determined that it had authority over the free clinics as these clinics were dispensing medications. The free clinics fought this determination, and took the issue to the state legislature. The Legislature clarified the law and free clinics are now specifically exempt from oversight by the state Board of Pharmacy. The State Department of Health and Human Resources has established standards for pharmacies within clinics.

Recommendations/observations

- **MOST IMPORTANT:** Find out if you will fall under your state Board of Pharmacy, as statutory and regulatory requirements can be considerable if you do come under the pharmacy board. (Charging patients for medications will likely place you under most state Boards of Pharmacy, as it is comparable to a retail drug store.)
- Decide what medications are needed and their availability through drug manufacturers' patient assistance programs. Use this as your base formulary and expand it with low cost generic drugs. Set a pharmaceutical budget and live within it.

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- Inquire into having a volunteer clinician apply for a “second site” DEA license using the address of the clinic. This will cost \$210 for three years. Most pharmaceutical manufacturers require a DEA # and will ONLY send to a physical address.
- No controlled drugs; word travels fast if these are available.
- For any provider that does not charge for its services a crucial issue is COST. If all resources are spent on medications, nothing is left for other budget items. Despite cost, some brand name, life-sustaining medications **must be** purchased rather than have the patient go without. No matter how efficient the clinic, this will happen and cost incurred on a drug that could have been provided for free. However, having prefaced this with practical budgetary considerations, **THE most important** fundamental issue in this decision-making process has to be that the medical care and treatment (including drug availability) should be **patient focused**.
- Many manufacturers destroy millions of dollars of sample medications, for example, when companies merge. Should you hear of these developments, immediately contact the reps and find out what they have been asked to do with their samples. Most appreciate assigning them over to a clinic rather than sending them back to the company to be incinerated.

Procuring medications

Drug samples

Health Right receives samples from many physician offices in our immediate coverage area. We regularly update our formulary and provide it to physicians along with a request for doctor samples. Although many physicians bring samples to the clinic when they volunteer we also have a pick-up system staffed by volunteers. This system is coordinated through the doctor’s office manager or nurse responsible for their drug closet. The nurse or office manager is usually responsible for calling in prescriptions to our clinic pharmacy and therefore is knowledgeable about our process, thankful of our formulary, and appreciative of having their samples picked up so they don’t have to deliver the drugs to the clinic or wait until the drug expires and have them destroyed.

Drug representatives deliver medications to Health Right. In addition, physicians are asked to:

- Request that samples be delivered to the free clinic rather than their offices.
- Ask the drug representative to deliver medications to the clinic the next time the doctor is scheduled to volunteer.
- Ask the drug reps to volunteer at the clinic and help out in the pharmacy.
- Request that any drug company honorarium they receive (for example, for speaking at a seminar) be given to Health Right.

All of these efforts illustrate to the drug reps that we have the support of the medical community.

Support and networking among the free clinics is a part of our system in West Virginia. We regularly e-mail each other regarding excess medications, needs for specific drugs, drug manufacturer program changes, etc. When a new clinic opens the existing free clinics pool resources to stock its pharmacy.

Recommendations/observations

1. Utilize volunteers and non-volunteer physicians to get the word to the drug reps.
2. We have found that physician samples are decreasing and that paperwork is increasing for programs wanting to accept and distribute samples.

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3. Remember, samples are a marketing tool, so it is the new—and most likely expensive— drugs that will be marketed this way. Samples are provided to encourage the doctor to try these drugs and then continue them. Their primary purpose is not to provide poor patients with medication.

Retail or other pharmacies

Health Right has only one arrangement (without a written agreement) with a retail pharmacy. It is an independent drug store, non-chain retail pharmacy. Medications are purchased from this one retail pharmacy on a VERY limited basis. The retail pharmacy is reimbursed at its cost for the drug. If the pharmacy buys a bottle of 1,000 and Health Right sends a patient for 100 pills, we pay 10% of the cost of the bottle of 1,000. We do not pay a dispensing fee. This pharmacy, and its pharmacists, have been involved with Health Right for nineteen years and believe in the mission of the clinic. The head pharmacist is on our Board of Directors and regularly volunteers. He is a compassionate and caring individual who daily sees the impact of medication costs on the poor.

Our process works as follows: if the medication is unavailable in our pharmacy but the patient immediately needs it, the pharmacy staff brings the request to the administrator or assistant administrator. Then we call the pharmacy to check on availability and cost. Health Right can usually have medications on site the next day, therefore cost, quantity, and a patient's access to Health Right are all factors taken into consideration when calling our retail pharmacy supporter. When using the local pharmacy, Health Right runs a label for the medication on our computer, places it on an empty vial, and sends the patient with the vial to the retail pharmacy. We are billed and the patient is not. We have been known to order 2 pills for immediate dispensing, and have the patient return to the clinic the next day (if possible) to receive the full prescription which the clinic would fill through direct purchase from the drug manufacturer or wholesaler.

Recommendations/observations

1. Approach an independent pharmacy, chains are less receptive or not interested.
2. Make your system easy for the retail pharmacy and do not pay a dispensing fee.
3. It is reassuring to the volunteer physicians and pharmacists that a needed medication can be provided even when the drug is not available at the clinic.
4. Purchasing medications through a retail pharmacy is very expensive and could easily get out of hand. Be sure there is a process in place for approval. In most instances another drug on site can be substituted.

Donations from hospitals/other health care institutions

Several different arrangements are in existence at Health Right.

1. A local community hospital donates \$30,000 worth of medications to the clinic annually (adjusted for clinic growth each year). We order generic medications from their pharmacy on an as needed basis. The hospital pharmacy tracks the medications and deducts their cost of the drug from our annual allowance. We use this arrangement based upon our dispensing needs, cost of the drug (comparison with our cost through other methods of purchase), and how quickly we can receive the medication. If we call the hospital pharmacy by 4PM we can have the medications in our pharmacy the next day. We have this arrangement with one local community hospital.
2. Some hospitals do not choose to donate medications but do want to support our medication needs. These hospitals send us a check annually. Currently, Health Right has six hospitals choosing this route of support for medications.

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3. Other medical supply companies and providers supply the clinic with pharmacy vials, blank pharmacy labels, laboratory supplies, orthopedic/diabetic equipment, etc. In addition, many local medical institutions support Health Right financially.

Contacts were made to initiate the above arrangements by the administrator of Health Right, a member of the Board of Directors, or someone who knew the company contact person. Community support was always documented and the contact person within the company was in a position to make the decision on our request. Frequently, this contact was the CEO or owner. The amount of time for each approval varied upon the request. The pharmacy computer took the longest at about 6 months.

Recommendations/observations

1. Track patient data on inpatient and ER hospital utilization and which hospital the patient would use in the event of an emergency. This will assist in getting hospital support.
2. Illustrate community support.
3. Plan on several months in the approval process. Some local hospitals may take years to approve.
4. For profit hospitals are less likely to support your efforts. Therefore, plan on additional work, pressure, and documentation.

Bulk purchasing

Bulk purchasing of medications is a necessity for drugs that we cannot access through other means. Health Right buys generic drugs but pricing varies significantly, and sometimes Public Health Service 340B pricing is not always the lowest price we can get for a drug. We have several different arrangements with manufacturers and/or wholesalers; as such, it is important to be able to “research” a price to get the best deal. In addition to “drawing down” from our pharmacy account (as described above), we mostly use two sources: 1) We participate in a consortium called Ameri-net, which is a huge national purchasing cooperative which includes hospitals, nursing homes, clinics, and others. As such, they get huge discounts on medications and other items and 2) Par-Med is a drug wholesaler that we also use. We price check and sometimes ask them to under-bid other prices we have been quoted.

Recommendations/observations

1. DO NOT assume that a published discounted price is the lowest. Based on quantities a company may significantly discount their price. Volume purchases or sales promotions will bring the prices down as well. I usually ask the salesperson to check with her supervisor on a lower price.

Drug company donations

Health Right has replenishment arrangements with Eli Lilly and Co., Parke-Davis, Jansen Pharmaceutical, Ortho-McNeil, and Ortho Pharmaceuticals. In these arrangements companies will replenish medications in bulk as requested by the clinic. These programs are a great way to receive medications. They are less time consuming and significantly less costly to the clinic AND to the drug manufacturer. In addition, by sending these drugs to a non-profit instead of an individual provider or patient the manufacturer can receive a tax deduction or write-off for their donation. However, Health Right has had to invest considerable time to ensure that the process works properly. These arrangements were approved by management level personnel and NOT by those running the patient assistance programs.

WV Health Right’s request for bulk shipments or drug replenishment arrangements included: a detailed explanation of the clinic, proof of tax exempt/not-for-profit status, whom the clinic serves, what services are provided, number of volunteer physicians, listing of medications requested, estimate of quantities of drug, statement that

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all medications are free of charge, need for start-up stock, how documentation can be provided on quantities of medications dispensed, establish frequency of the requests, and a statement that patients getting the drugs are uninsured, ineligible for Medicaid, and impoverished. Remember the manufacturer does not want to give away medication to anyone who might be able to afford the drug. Involve the local reps if you think it will help move the process along. This can take several months to establish, so do not stop enrolling patients until you get your first shipment. Getting the name of the individual within the company who has the power to make the decision takes considerable time.

It is also possible to make special arrangements with companies outside of their usual policy. For example, if a drug manufacturer is located in your state, contact should be made regarding donations. Don't forget generic drug manufacturers. Also, several manufacturers will send samples of medications if the following conditions occur: near dated drugs, a drug company name change, no longer sampling the medications, etc. WV Health Right has received medications under these circumstances.

WV Health Right also uses patient assistance programs which are by far the most time consuming, labor intensive, and costly method of securing donations. They are also a major source of medications. Significant volunteer training and time is spent to enroll patients for medications one patient at a time, one drug at a time.

Program Operations

Staffing

The pharmacy is run by a Pharmacy Coordinator (a paid pharmacy technician) and during hours of operation is staffed by three other paid pharmacy technicians, a volunteer pharmacist, and generally one volunteer counting medications. (Pharmacists are recruited by staff and volunteers; local hospitals support this effort as well.) Patient assistance program applications are handled by three FTE's: one paid staff and several volunteers. The Pharmacy Coordinator makes sure that the top 50 medications dispensed by the pharmacy are always available for dispensing.

The pharmacy computer tracks patient medication, with a copy of the information maintained in the patient's chart. Any potential drug interactions are flagged by our pharmacy computer software. Patient follow-up is done every time the patient returns for medications. If a patient is habitually non-compliant the patient is asked to return more frequently for education on the medication, the disease/condition or other aspects of patient care/treatment.

Formulary

WV Health Right established a formulary soon after the clinic opened. The formulary is modified every couple of months. It is based on medications provided free of charge and those we purchase. The formulary lists those drugs that are nearly always available at the clinic, although drugs not listed on the formulary are also dispensed. The decision on which medications to make available is made by staff based upon availability of the drug. (As changes in patient assistance programs may impact medication availability drugs may be deleted from our formulary.)

Computer system

The Health Right pharmacy computer, software, and technical support were donated to the clinic twelve years ago. This was made possible by area pharmacies and pharmacists who volunteered at the clinic. First, we found that the pharmacy computer system used by most of the area pharmacies and hospitals was Renlar. We prepared a letter for the signature of every hospital and pharmacy that used Renlar and sent the letter to their corporate headquarters asking that a pharmacy computer be donated. After Renlar donated the system, software updates were handled the same way. Cardinal Health has since acquired Renlar and our agreement (non-written) is still in existence. Recently one of our dot-matrix label printers went down. Cardinal Health

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over-nighted the clinic a refurbished printer. Another free clinic in West Virginia had its pharmacy computer donated by Kroger (the food store).

WV Health Right uses Medi-Span, software that is used by many local pharmacies and hospitals, for patient medication tracking. Updates are provided free of charge.

Pharmaceutical budget

Health Right has a pharmaceutical line item in its general operating budget for \$35,000 in FY01. Over time this budget item, outside support, number of prescriptions filled and the annual value of medications dispensed have increased. Actual expenditures have been: FY98=\$19,166, FY99= \$30,512, FY00=\$30,957.) Prescriptions dispensed have increased as well: FY98=57,215 valued at \$3,665,830, FY99 = 65,640 valued at \$4,663,669, FY00=76,440 valued at \$5,924,375. During fiscal year 2000, WV Health Right paid for only 2% of the total prescriptions dispensed, with the balance donated. The City of Charleston recently increased its support from \$10,000 to \$20,000 for medications for the current fiscal year.

We do not have a set amount to be spent each month. If we run over budget we take the overage out of another line item, write a grant request, or call local supporters. Although the budget is adopted by the Board in June of each year, it is continually tracked by the administrator of WV Health Right. If it appears we are exceeding the line item the Board will adjust the line item upward. The Board of Directors places a very high priority on medications. They have always approved an increase in the line item even if it requires their involvement to assist in securing additional funds to cover the increase.

There is no co-pay, cap, deductible, or limit on prescriptions. We ask that the patient donate \$1.00 per prescription filled, although it is not required and not all patients give.

Lessons learned

Set a budget, attempt to live within it, learn the free drug programs, maintain a sense of humor in dealing with their frequent changes in program requirements, call others for help, get samples and pharmaceuticals from anywhere you can, then just START! If you try to make the pharmacy perfect, you will never begin. Your program will grow and changes will be made frequently. After 19 years of a free pharmacy program, we still make changes.

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