Facilitating Quality, Cost-effective Medication Access

Marisa Mancuso Barnes
Free Clinic Solutions

Medication Access in a Free Clinic Setting: Tremendous Need and Opportunity

For health care providers, diagnosing a disease is only one step toward helping the patient become healthy. Being able to treat the condition adequately is another. Every day free clinics across the country face the challenge of providing access to affordable medications for their patients. Some have rightfully said that free clinics are as much free pharmacies as they are clinics, given the high percentage of clinic patients in need of medications. Many of these patients are on multiple medications, requiring the clinic to be agile, resourceful, and efficient in making them available. A good medication access program typically contains multiple approaches to obtaining medications. This Guide focuses on proven methods and strategies for facilitating quality, cost-effective medication access in a free clinic setting.

A free clinic is a nonprofit, community-based or faith-based organization that provides health care services, either at little or no charge, to low-income, uninsured and underserved populations, relying heavily on volunteer health professionals and partnerships with other health organizations. Some of the information here may also pertain to organizations that prefer to describe themselves as "charitable" or "charity" clinics, which are entities that have all or most of the characteristics of free clinics except that they mandate or strongly encourage the patient's payment of fees (assessed either on a flat or a sliding-fee scale) and perhaps even bill Medicaid.

Patients with no health care coverage delay accessing medical care and forgo treatment for chronic conditions such as hypertension, diabetes, hyperlipidemia, and respiratory diseases. Almost half of all uninsured, nonelderly adults have a chronic condition.[1] Studies have shown

that up to one-third of individuals, both insured and uninsured, never fill the prescriptions given to them by their medical provider. Cost is certainly a factor. Retail prescription drug prices increased an average of 6.9% a year from 1997 to 2007, more than two and a half times the average annual inflation rate of 2.6% over the same period.[2] Lack of access to critically needed health care and medications results in little or inconsistent medication compliance for the treatment of chronic illnesses, and medical conditions are thus exacerbated. When patients' illnesses go untreated, they end up in the hospital emergency room, or worse, get admitted, for conditions that could have been avoided had medications been more readily available earlier.

Free Clinics and Their Provision of Medication Access

Primarily due to the struggling economy and the extremely high rate of unemployment, 89% of free clinics in the United States have seen an increase in the number of patient visits in the past one to three years, with more than 25% of clinics accommodating increases of 30% or more.[3] Most free clinics report offering medications from a dispensary (65.9%) rather than a licensed pharmacy (25.3%). These medications included free samples obtained from pharmaceutical manufacturers (86.8%), pharmaceuticals obtained with the assistance of corporate patient assistance programs (77.3%), and direct purchases from manufacturers (54.9%), or outside pharmacies (52.2%).[4] Most free clinics work very hard to assure that patients who receive a prescription from the clinic actually get it filled. Otherwise, the time and service that the volunteer provider has given to the patient goes for naught. In recent years a number of clinics have resorted to giving patients prescriptions for generic medications to get them filled for $4.00 (for a 30 day supply) at a local pharmacy. The downside of this approach is

that the clinic effectively loses the ability to assure that patients get their prescriptions filled, thus compromising patient outcomes and health improvement.

Considerations Before Starting a Medication Access Program

Implementing a medication access program within a free clinic requires a significant commitment of time, knowledge, and resources. The clinic needs to understand the plethora of sources of donated and low-cost medications, and be able to determine which of those make the most sense for the clinic, depending on its patient mix, prescriber preference, financial resources, and more. The clinic needs to be clear about what conditions it wishes to treat with medications. Examples are acute illnesses, chronic illnesses, mental illnesses, obesity management, substance abuse, skin conditions, and birth control. The clinic needs to decide whether the program will provide medication access for prescriptions written by clinic providers only, or whether it will also assist enrolled clinic patients with prescriptions written by outside providers or hospital emergency departments. The clinic needs to consider what financial resources are available, and as part of this, whether administrative fees or donations will be solicited from patients for medications obtained through the program. The clinic needs to develop a drug formulary, which is a list of medications that the clinic has determined that it will prescribe and provide. This is addressed in further detail later in the Guide.

Patient Assistance Programs (PAPs)

Many free clinics make strong use of pharmaceutical manufacturer patient assistance programs (PAPs, for short), which donate medications to low-income individuals who have no prescription drug coverage. Medications available through PAPs are usually brand-name

medications and require a manufacturer-specific application signed by the patient and the prescribing physician, individual patient eligibility documentation, and a physician's order or prescription. In order to receive free medication through a PAP, an individual must be determined eligible by the donating company.

Each pharmaceutical company has its own specific eligibility criteria. Almost all programs base eligibility on the individual's residency, income, and insurance status. Medications obtained through individual patient assistance programs are specific to the individual for whom the medication was filled and are not available for general pharmacy or other patient use. Currently, over 180 pharmaceutical companies sponsor patient assistance programs and provide over 2,500 brand-name medicines to eligible clients at no cost. Three excellent resources to determine what medications are available through manufacturer patient assistance programs are NeedyMeds (www.needymeds.org), RxAssist Plus (www.rxassist.org), and the Partnership for Prescription Assistance (www.pparx.org).

A primary concern among medication access advocates has been whether pharmaceutical company patient assistance programs will still be in existence after 2014 when the Patient Protection and Affordable Care Act is implemented. The answer is likely to be yes. There is a solid consensus across the charitable section of the pharmaceutical industry that there will always be a need for patient assistance programs. Whether through direct product donation or copayment assistance programs, pharmaceutical manufacturers are likely to continue serving the needs of the ever growing and changing population of low-income people who cannot afford their medications.

While most PAPs are for brand-name medicines, there are some PAPs that have been established for generic medicines. Two resources that connect patients and providers to PAPs

for generics are Rx Outreach (www.rxoutreach.com) and Xubex Pharmaceutical Services (www.xubex.com). These companies purchase generic medications in bulk supply and dispense them for a nominal fee to qualifying individuals.

Necessary Resources for Utilizing PAPs Effectively

- ***Physical Resources***: Facilitating medication access via PAPs requires dedicated physical space, equipment, administrative supplies, and electronic capabilities. Staff need full access to a computer with internet access, fax machine, copier, and telephone. In order to streamline the PAP process, the area needs to be easily accessible to both patients and health care providers alike.
- ***Staffing Resources***: It is critical for the clinic to recruit and deploy dedicated staff to administer PAPs. Ideally, this would include at least one employee (part-time or full-time), to ensure program integrity and effectiveness as well as increased capacity through the training and coordination of volunteers. See a Medication Access Coordinator job description in the Additional Resources. Community workforce development programs, such as "Experience Works" www.experienceworks.org, local technical colleges, and certificate programs in allied health provide excellent resources for volunteer assistance. The number of staff required to successfully administer PAPs depends upon a number of factors including the number of patients enrolled in the clinic and the volume of prescriptions they are dispensed, the clinic's eligibility processes and procedures, whether the clinic uses PAP software or completes applications manually, and the clinic's overall operational structure.

- ***Financial Resources***: In addition to overhead costs and paid staffing, there are costs associated with supplies, equipment, and any information technology resources.
- ***Information Technology Resources***: A clinic will administer PAPs more efficiently, cost-effectively, and accurately, as well as have the ability to serve more patients, when it uses a PAP software program. See below for further information.
- ***Operational Resources***: A standard operating or policy and procedure manual is a critical component of any successful program that uses PAPs. In addition to the overall program guidelines, the manual should include procedures for implementing the PAP application process, record keeping and follow-up actions, receiving, storing, and dispensing PAP medication, and returning or disposing of PAP medication not dispensed or delivered to the specific patient. If a clinic does e-prescribing, the clinic will have to put in place a process to make certain hard copies of prescriptions bearing the prescribing provider's signature are available to mail in with the PAP application.

PAP Software Programs

An optimal PAP software program should meet the basic PAP application and tracking processes, be HIPAA-compliant, and have additional functions to provide comprehensive case management, streamlining and maximizing the medication access process. Some of the more widely used programs include:

- MedData Services - www.meddataservices.com
- PAPTracker - www.needymeds.org/indices/paprxtracker.htm
- DataNet Solutions - www.datanetsolutions.org/medservpap.aspx
- PDA USA - www.pdausa.org

- RxAssist Plus - www.rxassistplus.com
- RxHope - www.rxhope.com

Institutional Patient Assistance Program (IPAPs)

Some manufacturers donate free medication in bulk supply to a hospital, clinic, or other health care institution, rather than directly to a patient. This is called an IPAP. IPAPs may also be known as "bulk replenishment programs." In an IPAP, pharmaceutical companies enter into a contract with an eligible institution or clinic and ship their free product directly to the facility in bulk supply on a monthly basis to replace program product dispensed to qualified patients the previous month. IPAPs are available only to qualifying disproportionate share hospitals (DSH), federally qualified health centers (FQHC) and FQHC "look-alikes," non-profit "central fill" and charitable pharmacies, and free clinics with on-site pharmacy or dispensary. Each pharmaceutical company has its own specific eligibility criteria for patients served through their IPAPs, primarily basing eligibility on the individual's legal residency within the United States, income, and insurance status. Be advised that about 50% of pharmaceutical company Patient Assistance Programs require the eligible client to be a U.S. resident: either a U.S. citizen or a legal permanent resident (i.e. green card holder). A birth certificate, Social Security number, current driver's license, or Alien Registration Card may document this. Manufacturers establish a set of business rules that contracted facilities must follow. Facilities are required to maintain all required verifications of eligibility for each patient for a minimum of three years.

Differences Between PAPs and IPAPs for Free Clinics

Individual PAPs require separate applications for each medication for each patient. In an IPAP, the application or contract is between the pharmaceutical company and the clinic itself. Individual patient applications are not required. Individual PAPs require patient eligibility documentation be submitted with each medication request and application. In an IPAP, clinics document patient eligibility just once a year. This may coincide with the clinic's own eligibility policies. If determined eligible for a traditional PAP program, depending on the manufacturer's process, it may take two to six weeks before patients receive their PAP medications. IPAP medications are available for immediate dispensing to qualified patients. In individual PAPs, the medication is shipped directly to the patient's home or to the clinic in the patient's name. The medication is for that individual patient's use only. IPAP medication is shipped in bulk directly to the clinic to be dispensed to all eligible patients as prescribed. Although a traditional PAP program benefits from a dedicated administrative staff person, an IPAP program requires the direct supervision and administration of a licensed pharmacist. In an IPAP, pharmaceutical companies no longer incur the substantial costs of processing thousands of individual patient assistance program forms or the expense of individually dispensing, packaging, and shipping thousands of individual prescriptions. IPAP programs save time and resources currently allocated to completing individual applications for medication assistance. Many clinics report a 40-90% reduction in costs per patient compared to traditional PAP programs.

Qualifying and Applying for an IPAP Contract

Successfully entering into an IPAP agreement with a pharmaceutical company takes time and considerable preparation on the part of the free clinic. Companies expect the clinic to be

operating professionally and within best practice standards, and to complete the application and provide all requested documentation in a timely manner. The clinic will need to provide the following documents:

- Copy of the IRS letter designating organizational status as a 501(c)(3) or 509(a)(1)
- Copy of the most recent IRS Form 990 or audited financial statement
- Organization's standard operating procedures, including patient eligibility criteria, patient determination and enrollment process, and record retention policy
- Pharmacy's standard operating procedures, including security, access controls, inventory management (receipt, storage, dispensing, delivery, patient education, and product destruction), procedures to prevent product diversion, tracking, record keeping, and reporting capabilities
- Copy of the pharmacy's state license or permit
- Copy of the state license of the designated pharmacist-in-charge or medical director's DEA number and license to dispense, if applicable

Once the pharmaceutical company receives the application and accompanying documentation, many companies arrange for an on-site audit to ensure that the clinic is in the best position to comply with the IPAP's business rules. Successfully negotiating an IPAP contract from the first contact to the initial product delivery may take a clinic up to two years to achieve.

Requirements for a Free Clinic to Maintain an IPAP Contract

Following initial stocking by the manufacturer, clinics are required to submit their replenishment orders on a monthly basis, providing detailed, patient-specific data on the products

dispensed and delivered to eligible patients the previous month. Clinics submit monthly reports electronically either through a web-based portal or on computer disc depending on each manufacturer requirements. Most pharmaceutical companies conduct annual and "for cause" audits of IPAP facilities in order to ensure compliance with the contract and the company's business rules. Clinics are required to maintain all required verifications of eligibility for each patient for a minimum of three years.

Free Clinics and On-Site Pharmacies

For many clinics, a natural service expansion is to consider providing medications to patients through an on-site pharmacy. Having a licensed pharmacy on-site allows a clinic to expand its available medication inventory beyond the individual PAP medications and donated physician samples. A free clinic with an on-site pharmacy may be eligible to participate with pharmaceutical company IPAPs and/or purchase medications directly from manufacturers through a variety of means. One primary benefit of having an on-site pharmacy is that, if the medication is available on the shelf, the patient's prescription may be filled immediately following his or her medical appointment. This saves time and provides added convenience for the patient, and provides added assurance to the clinic that the patient's medication needs are being met. Another benefit is that prescribers and the pharmacist on duty can consult with each other directly if they need to discuss a particular medication or treatment regimen. There are several points to consider when making the decision whether or not to have an on-site pharmacy:

1. What is the current system for obtaining medications within the community? Is it adequate? If not, why not?

2. Is there a sufficient number of pharmacists in the community who will agree to volunteer? Is there one who will agree to be the pharmacist-in-charge?
3. What is the patient mix of the clinic? The target population may indicate what types of drugs, medication inventory requirements, and acquisition methods would best meet those needs.
4. What is the anticipated number of patients to be served? For clinics that serve a large number of patients, treating both acute and chronic conditions, having an on-site pharmacy may provide easier access to prescription medicines and may increase the ability to serve many more individuals.

Resource Requirements for an On-Site Pharmacy

- ***Physical resources***: A pharmacy requires dedicated space, equipment, security, and electronic and data capabilities including some type of inventory management system.
- ***Staffing resources***: At a minimum, a licensed pharmacist must be present any time the pharmacy is open. For licensure, there needs to be a designated pharmacist-in-charge (PIC). A clinic should base staffing size on the anticipated number of prescriptions to be dispensed. Pharmacy technicians should be considered, so as to maximize the time and effort of the pharmacist(s) on duty.
- ***Information technology Resources***: A clinic will operate its pharmacy more efficiently, cost-effectively, and accurately, as well as have the ability to serve more patients, using a pharmacy software program. One of the leading pharmacy software vendors serving free clinics is QS/1.

- ***Financial resources***: In addition to previously mentioned overhead costs, there will be costs associated with initial and annual licensure renewal, dispensing supplies (e.g. vials, lids, labels) and equipment, and purchased medications, if any.
- ***Medication resources***: It is essential that there be a sufficient supply of medications available in the pharmacy, through either purchase or donation, in order for the pharmacy to adequately meet the medication needs of the patients and prescribers.
- ***Operational Resources***: A standard operating or policy and procedure manual is a critical component of any pharmacy operation and is required for licensure.

Pharmacy Licensure Requirements

Each state board of pharmacy sets the rules and regulations for operating a licensed pharmacy within the state. An on-site pharmacy typically requires sufficient physical space, equipment, security, and storage area. Some of the legal requirements can be waived by the state board of pharmacy, upon request by the applicant organization. Although pharmacies operating in free clinics must be licensed by the state board of pharmacy, the board may issue a special or limited-use pharmacy permit when the scope, degree, or type of pharmacy practice or service to be provided is of a special, limited, or unusual nature as compared to a retail or hospital pharmacy. In addition, the Board may approve a pilot program for a set period as provisional transition to full licensure. Examples of physical standards that may be regulated are:

- Minimum square footage of the pharmacy or prescription department
- Security and restricted access
- Schedules or types of drugs to be maintained by the pharmacy.
- Presence of a sink and refrigerator within the secured space.

- Inventory control processes

Options for Purchasing Medications for an On-Site Pharmacy

One approach is to purchase medications from a local independent pharmacy that agrees to sell the medications at a reduced cost. A clinic should not enter into any such agreement until it has given all the potentially interested pharmacies in the community, within proximity of the clinic, an opportunity to submit a proposal. This will ensure that the clinic is getting the best price and service available. Another approach for the clinic is to buy medications on contract from a wholesale distributor. Some of the leading major national distributors are AmerisourceBergen, Cardinal, McKesson, Henry Schein, and Quest (which sells only generics). Still other clinics have negotiated to purchase medications from their local nonprofit hospital at their cost, with possibly the addition of a small administration fee. Hospitals are able to use their purchasing power to get some of the lowest pricing available. Clinics should inquire of their nonprofit hospital partners whether they would be open to such an arrangement. A Federal Trade Commission advisory opinion in 2004 (see Additional Resources) provided legal clearance for this kind of transaction. Free clinics in some states (e.g. Virginia) have been authorized to purchase pharmaceuticals from the state's pharmaceutical buying contract. Check with your state central pharmacy to see if this option may exist.

Formularies and Why a Free Clinic Should Have One

Creating and maintaining an approved drug formulary is a fundamental building block to a successful medication access program. A formulary is, "a continually updated list of medications and related information, representing the clinical judgment of physicians,

pharmacists and other experts in the diagnosis and/or treatment of disease and promotion of health."[5] The principal value of a formulary is that it enables a clinic to address the medication needs of its patients in an organized manner while also controlling costs and maximizing the use of free or low-cost medications where feasible. A formulary may include both brand-name and generic medications and helps provide access to quality, affordable prescription drugs. The formulary may allow prescribers to implement "step therapy". This is the practice of starting medication therapy with the most cost-effective and safest drug therapy for the disease condition and progressing to other more costly or risky therapies only if the first treatment plan proves to be ineffective or unsuccessful. An approved formulary assists with determining the safest, most cost-effective medications for patients; providing consistency and rationality to prescribers; minimizing conflicts of interest for providers during medication selection (this is particularly important when prescribing medications available through institutional patient assistance programs); managing in-house medication supply inventory; and, keeping the clinic or organization in line with its philosophy, mission, and guiding principles.

Developing and Maintaining a Formulary

It is optimal to have a team of professionals determine the medications to be included in a clinic's formulary. This team is sometimes referred to as a Pharmacy & Therapeutics (P&T) Committee. The P&T Committee should consist of the medical director, a licensed pharmacist, at least one more staff or volunteer medical provider, the medication access coordinator (if applicable), and the clinic's executive director. Medications that are included on the formulary should not only represent an important therapeutic treatment plan, but also be clinically equivalent and possibly more cost-effective than other medications not on the formulary. Treat

the formulary as a living document, a work in progress. It is best to review and update the formulary at regular intervals to ensure optimal health care treatment and cost-effectiveness. Any changes in the formulary should be communicated immediately to the clinic's health care providers. There is agreement in the medical community that a drug formulary is more useful when accompanied by a system to support it. A drug formulary system is "an ongoing process whereby a health care organization, through its physicians, pharmacists, and other health care professionals, establishes policies on the use of drug products and therapies, and identifies drug products and therapies that are the most medically appropriate and cost-effective to best serve the health interests of a given patient population."[5] For more information on the principles of a sound drug formulary system, go to http://www.pbm.va.gov/LinksAndOtherResources/FormularyPrinciplesCoalition.pdf.

Determining What Medications to Include on a Formulary

When developing a formulary, it is best to determine the primary medication needs of patient population. If a clinic focuses predominantly on treatment of chronic conditions, for example, the formulary should reflect an adequate supply of medications most frequently prescribed to treat chronic disease conditions. In an acute care clinic, the formulary should contain a wide range of analgesics, anti-infective agents (both oral and topical), antihistamines and decongestants, and respiratory agents. Consideration should be given to whether the formulary includes over the counter (OTC) medications, such as Tylenol, Motrin, vitamin and mineral supplements, and medical supplies like syringes, glucometers, test strips, and lancets, or spacers for inhalers. A clinic's current or anticipated sources of medications, and certainly what they cost, influences the formulary. For security reasons, it is prudent that a clinic not include

narcotics on its formulary. The clinic needs to have a policy governing or restricting the prescribing of medications not listed on the formulary. Based on its mission, values, or guiding principles, the clinic may want to exclude certain other medications from its formulary. Examples may include:

- Appetite suppressants
- Infertility medications
- Medications used for cosmetic purposes (wrinkles, hair loss, acne, etc.)
- Erectile dysfunction medications
- Smoking cessation products
- Oral contraceptives or other contraceptive devices
- Injectable medications (with the exception of insulin)
- Allergy serums
- Experimental and investigational (including off-label use) medications

The formulary should include relevant drug details in order to facilitate ease of use and ensure adherence. It should include the following information:

- Therapeutic Category
- Drug Name (brand name and generic name)
- Drug Strength
- Drug Dosage Form
- Relative Cost Indication, if available
- Quantity Limitations, if any
- Procurement Source (sample, PAP, IPAP, purchase, etc.)
- Tier (if implementing a tiered drug formulary system)

- Drug Location (this is especially helpful in clinics using a "drug closet" or a physician-dispensed pharmacy)

Contracting with an Outside Pharmacy

Can a free clinic do this? Yes! In these situations, the pharmacy agrees to fill prescriptions written by clinic providers, typically at a reduced cost (e.g. some percentage off average wholesale price, or sometimes much lower). In addition, they may waive any dispensing fees. The pharmacy may bill the clinic monthly for reimbursement or may simply set up its own formulary of reduced cost generic medications and accept a small co-payment from the patient. The clinic should review the monthly bill for accuracy, to ensure that all customers served are in fact patients of the clinic and the patients actually got their prescriptions filled. Besides providing a valuable community service, these pharmacies enjoy the benefit of increased retail traffic from customers who may not normally patronize their store.

Other Options for Facilitating Access to Medications

Volunteers in Health Care, in their guide to Starting a Pharmaceutical Access Program, lists a variety of approaches to providing medication access within a community.[5] In addition to the in-house approach, they list:

1. Creating a pharmacy where anyone meeting the eligibility requirements may receive medication. Frequently, this is known as a "charitable pharmacy." An example is St. Vincent de Paul Charitable Pharmacy in Cincinnati: http://www.svdpcincinnati.org/Programs_and_Services/Charitable_Pharmacy.

2. Creating a stand-alone service that is separate from any health care program that helps individuals apply for medications from existing PAP programs. A good example of this is WVRx (http://www.wvrx.org). Although jointly administered by West Virginia Health Right in Charleston and Beckley Health Right (which are both free clinics), WVRx is a statewide charitable mail order pharmacy that is open to all residents of West Virginia who are between 18 and 64 years of age who have no prescription drug coverage and who have a family income at or below 200% of FPL. WVRx also assists seniors age 65 and over to apply for Low Income Subsidy and to submit PAP applications to drug manufacturers who help Medicare recipients in the donut hole.
3. Creating a medication access program within a provider network so that patients from different organizations may use the program. More than one organization shares responsibility for program operations.
4. Creating a medication access program that is part of a statewide or regional referral network. Examples of these programs are:
    - Kentucky Pharmacy Providers Program - www.healthkentucky.org/providers
    - Cenla (Lousiana) Medication Access Program - www.cmaprx.org
    - Welvista (South Carolina) - www.welvista.org
    - Dispensary of Hope (Tennessee) – www.dispensaryofhope.org

There are also some national organizations that facilitate access to donated prescription medications. Leading examples of these are AmeriCares (www.americares.org) and Direct Relief International (www.directrelief.org).

Donated Medication Samples

Pharmaceutical companies provide physicians with samples of their products primarily for marketing purposes, not to fill gaps in medication access for the uninsured. Samples are often the newest drugs, which often mean that they are the most expensive. There is little value in starting a patient on a very expensive medication in limited supply via donated samples if there is another, equally effective and less expensive alternative available, even if it must be purchased. Clinics are unable to count on a steady and consistent supply of samples; therefore, providing a patient with samples is generally not practical for the ongoing treatment of chronic disease conditions. Having to constantly change medications because samples may or may not be available interferes with a patient's prescribed treatment plan and may adversely impact their health outcomes. Collecting and accounting for donated samples is challenging and time consuming. Often, there is limited control over what products are donated. A licensed, healthcare professional should sort through the donated medications to remove any products that have expired or that are not prescribed by the clinic or included on the approved formulary. Under no circumstances should a provider or clinic dispense medications that have expired. Clinic must arrange for destruction, according to state law, when any product becomes outdated (expired), damaged, or compromised.

Considerations for Free Clinics in Using Donated Samples

Used appropriately, in the manner intended by the manufacturers, physician samples may help patients avoid unnecessary medication costs or treatment delays. It is often helpful to begin a patient on a sample of medication for a brief period to determine if there are any side effects or

to establish therapeutic levels. Samples may be a temporary option for patients currently waiting to receive the same product through individual PAPs. There are specific rules and regulations mandating how sample medications are received, stored, handled, dispensed, and destroyed. These rules and regulations are monitored and enforced by both federal and state laws. The U.S. Food and Drug Administration released the updated Donation of Drug Samples to Charitable Institutions ruling in April 2011. A copy of the Regulation is available in the Additional Resources. Future updates to Section 203.39: Donation of drug samples to charitable institutions regulation may be found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm. Exemptions granted to free clinics by the FDA reflect federal requirements only. Clinics still must comply with all state pharmacy laws and regulations governing the use of physician samples.

Resources for Free or Low-Cost Diabetic Supplies

Program Name	Services Provided	Service Area
ACCU-CHEK Patient Assistance Program	Medical Supplies	National
BD Insulin Syringe Assist Program	Medical Supplies	National
Bionime	Medical Supplies	National
Charles Ray, III Diabetes Association	Medical Supplies	National
Henry Schein	Medical Supplies	National
Invacare Supply Group	Medical Supplies	National
IPump.org, Inc	Medication and Supplies	National
Meijer Supermarkets	Medication and Supplies	All Locations
RxOutreach	Medication and Supplies	National
Xubex Free Diabetes Kit & Supplies	Medical Supplies	National

Caution Against Generic Glucose Strips

Too often, glucometers require one specific type of test strips for monitoring blood glucose levels. Generic glucose reagent strips are test strips developed by companies (third parties) other than the one that manufactured the glucometer. They are less expensive than the manufacturer's recommended test strips. The FDA strongly advises that patients use third-party test strips with caution, as there have been thousands of adverse events, including fatalities, reported due to the use of these generic strips. One issue is that manufacturers may change their blood glucose meters and test strips. If third-party strip manufacturers are not informed or aware of these changes, then third-party test strips may be incompatible and render inaccurate results. The amount, type, and/or concentration of the chemicals on the test strip may be different, or the actual size and shape of the strip itself may vary. As blood glucose meters are sensitive and react to these features of test strips, they may not work accurately if not manufactured to work correctly with the specific glucometer.

About the Author

Marisa Mancuso Barnes has more than 20 years of experience in the health care, human service, and pharmaceutical industries. She possesses extensive knowledge of the principles, best practices, and promising solutions in the field of medication access for uninsured populations, as well as a strong background in clinic management, efficiency, and productivity. As a member of the Free Clinic Solutions consulting team and with her own company, MMB Advantages, Marisa has assisted numerous organizations in developing and optimizing their medication access programs. Currently, she provides special project assistance to Rx Partnership, an innovative and award-winning public/private partnership dedicated to increasing access to free prescription medications for Virginia's eligible uninsured. Since its inception in 2004, Rx Partnership has facilitated direct access to over $50 million in free medications from pharmaceutical partners to the 20 Affiliate free clinics and community health centers throughout Virginia.

In addition, Marisa has provided consultation and program development services to the Heinz Family Philanthropies/PS2, a non-profit corporation with a commitment to developing preventive and primary care alternatives to help decrease the costly use of emergency room care while at the same time providing quality care options for uninsured Americans. Prior to launching her consulting career, Marisa served nine years as Assistant Director with the Fairfax County Department of Health Community Health Care Network (CHCN). Through three neighborhood Health Centers, this NACo award-winning program provides comprehensive and continuing primary care to over 15,000 low-income, uninsured residents of Fairfax County, Virginia. She graduated *magna cum laude* from George Mason University with a Bachelor's degree in psychology.

About Free Clinic Solutions

Established in 2006, Free Clinic Solutions is a national organization that provides strategic consulting, training, coaching, research, writing, and public speaking to free clinics and charitable clinics across the U.S., their associations, and other organizations that support and partner with them. Services are provided by a team of professionals who have extensive experience in the health care safety net and subject matter expertise in relevant disciplines. Founder and Principal Mark R. Cruise served as Executive Director of the Virginia Association of Free Clinics from 1997-2006. For more information, visit www.freeclinicsolutions.com or call (804) 306-3975.

Bibliography

1. Davidoff, A and Kenney, G. *"Uninsured Americans with Chronic Health Conditions: Key Findings from the National Health Interview Survey."* The Urban Institute and the University of Maryland. May 2005. Available at: http://www.urban.org/publications/411161.html.

2. Kaiser Family Foundation calculations using data from the National Association of Chain Drug Stores, "Industry Facts-at-a-Glance," http://www.nacds.org (based on data from IMS Health), and Consumer Price Index, US City Average, All items, from the Bureau of Labor Statistics, http://www.bls.gov, May 8, 2008).

3. AmeriCares. *Addressing Resource Gaps in the U.S. Health Care Safety Net: An Assessment of the Free Clinic Network.* April 2011.

4. Darnell, JS. *Free Clinics in the United States: A Nationwide Survey*, Archives of Internal Medicine, 2010.

5. *Principles of a Sound Drug Formulary System*. Washington, DC: Pharmacy Benefits Management Services, Medical Advisory Panel, VISN Pharmacist Executives and MSCoE Directors, Veterans Health Administration, Department of Veterans Affairs; October 2000.

6. Walton, JM. *Starting a Pharmaceutical Access Program: A Volunteers in Health Care Guide*. Volunteers in Health Care. 2002, 2004.

Additional Resources

Medication Access Coordinator
Roles and Responsibilities

Implement Medication Access Program process to streamline access to the most appropriate and cost-effective medications for enrolled patients.

Process pharmaceutical company Patient Assistance Program applications for enrolled clinic patients.

Establish a case management system to ensure patients have streamlined and consistent access to medications.

Orient enrollment staff to Patient Assistance Program eligibility verification criteria to expedite application process.

Work directly with all prescribers to facilitate increased use of pharmaceutical company Patient Assistance Programs (PAP) for patients who are prescribed brand medications.

Administer the Medication Sample Program including solicitation, procurement, and inventory control and support. Explore option of registering with on-line sample ordering website through the Henry Schein Rx Samples Service: https://www.henryscheinrxsamples.com/default.aspx

Maintain the electronic medication selection guide to assist physicians with the medication access process.

Oversee the Patient Assistance Program software system. This includes updates, reporting requirements, report requests, etc.

Liaison with community pharmacists and health safety-net providers to ensure optimal communication and partnership achievement

Federal Regulation of Donated Drug Samples to Charitable Institutions

[Code of Federal Regulations]
[Title 21, Volume 4]
[Revised as of April 1, 2011]
[CITE: 21CFR203.39]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER C--DRUGS: GENERAL

PART 203 -- PRESCRIPTION DRUG MARKETING

Subpart D--Samples

Sec. 203.39 Donation of drug samples to charitable institutions.

A charitable institution may receive a drug sample donated by a licensed practitioner or another charitable institution for dispensing to a patient of the charitable institution, or donate a drug sample to another charitable institution for dispensing to its patients, provided that the following requirements are met:

(a) A drug sample donated by a licensed practitioner or donating charitable institution shall be received by a charitable institution in its original, unopened packaging with its labeling intact.

(b) Delivery of a donated drug sample to a recipient charitable institution shall be completed by mail or common carrier, collection by an authorized agent or employee of the recipient charitable institution, or personal delivery by a licensed practitioner or an agent or employee of the donating charitable institution. Donated drug samples shall be placed by the donor in a sealed carton for delivery to or collection by the recipient charitable institution.

(c) A donated drug sample shall not be dispensed to a patient or be distributed to another charitable institution until it has been examined by a licensed practitioner or registered pharmacist at the recipient charitable institution to confirm that the donation record accurately describes the drug sample delivered and that no drug sample is adulterated or misbranded for any reason, including, but not limited to, the following:

(1) The drug sample is out of date;

(2) The labeling has become mutilated, obscured, or detached from the drug sample packaging;

(3) The drug sample shows evidence of having been stored or shipped under

conditions that might adversely affect its stability, integrity, or effectiveness;

(4) The drug sample is for a prescription drug product that has been recalled or is no longer marketed; or

(5) The drug sample is otherwise possibly contaminated, deteriorated, or adulterated.

(d) The recipient charitable institution shall dispose of any drug sample found to be unsuitable by destroying it or by returning it to the manufacturer. The charitable institution shall maintain complete records of the disposition of all destroyed or returned drug samples.

(e) The recipient charitable institution shall prepare at the time of collection or delivery of a drug sample a complete and accurate donation record, a copy of which shall be retained by the recipient charitable institution for at least 3 years, containing the following information:

(1) The name, address, and telephone number of the licensed practitioner (or donating charitable institution);

(2) The manufacturer, brand name, quantity, and lot or control number of the drug sample donated; and

(3) The date of the donation.

(f) Each recipient charitable institution shall maintain complete and accurate records of donation, receipt, inspection, inventory, dispensing, redistribution, destruction, and returns sufficient for complete accountability and auditing of drug sample stocks.

(g) Each recipient charitable institution shall conduct, at least annually, an inventory of prescription drug sample stocks and shall prepare a report reconciling the results of each inventory with the most recent prior inventory. Drug sample inventory discrepancies and reconciliation problems shall be investigated by the charitable institution and reported to FDA.

(h) A recipient charitable institution shall store drug samples under conditions that will maintain the sample's stability, integrity, and effectiveness, and will ensure that the drug samples will be free of contamination, deterioration, and adulteration.

(i) A charitable institution shall notify FDA within 5 working days of becoming aware of a significant loss or known theft of prescription drug samples.

Advisory Opinion from Federal Trade Commission Regarding Purchasing Medications from a Hospital

UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Bureau of Competition
Jeffrey W. Brennan
Assistant Director
Health Care Services & Products
Direct Dial
(202) 326-3688

January 6, 2004

Judy Erb
Vice President
Dunlap Memorial Hospital
832 South Main Street
Orrville, Ohio 44667

Dear Ms. Erb:

This letter responds to your request on behalf of Dunlap Memorial Hospital for an advisory opinion whether Dunlap's provision of pharmaceuticals to the Viola Startzman Free Clinic would fall within the scope of the Non-Profit Institutions Act (NPIA). The NPIA exempts from the Robinson-Patman Act "purchases of their supplies for their own use by schools, colleges, universities, public libraries, churches, hospitals, and charitable institutions not operated for profit."[1] For the reasons explained below, we have concluded the NPIA would apply to pharmaceuticals transferred by Dunlap to the Free Clinic.

As we understand the facts based on the information you provided, Dunlap is a non-profit hospital. The Free Clinic is a non-profit institution, funded entirely by donations, grants, and unpaid services of volunteer physicians, that provides free medical care to adults in and around Wayne County, Ohio. Dunlap purchases pharmaceuticals through Amerinet, a hospital purchasing group. The hospital pays a lower price than is currently available to the Free Clinic, which purchases drugs prescribed by Clinic doctors from a local pharmacy at the average wholesale price plus a dispensing fee. You have asked whether the NPIA would apply to drugs purchased by Dunlap and then transferred to the Free Clinic, where they would be dispensed to patients of the Clinic. You also ask whether Dunlap could charge a fee to cover its cost of providing the pharmaceuticals to the clinic.

The NPIA applies only to pharmaceuticals purchased by a hospital for its "own use" – that

---

[1] 15 U.S.C. § 13c.

is, for use in the care the hospital renders to its patients.[2] Since the patients of the Free Clinic are not Dunlap's patients, the NPIA would not apply to pharmaceuticals dispensed directly by the hospital to those individuals. The Commission, however, has concluded that the Act covers the transfer of supplies, at cost, from a non-profit hospital to another organization that is entitled to NPIA protection for its own purchases, so long as those supplies are for the receiving institution's "own use" within the meaning of the NPIA.[3]

The Free Clinic appears to be a non-profit charitable institution entitled to purchase supplies under the NPIA, and it will use the pharmaceuticals that it receives from Dunlap for its "own use" in the care of Clinic patients. Accordingly, Dunlap's purchase of pharmaceuticals for transfer to the Free Clinic at its cost would be covered by the NPIA.

The Commission's reasoning in the *St. Peter's* opinion would not apply if Dunlap sold pharmaceuticals to the Free Clinic at a profit. The Commission's staff has concluded, however, that an institution making a transfer to another NPIA-eligible institution may charge the receiving institution not only its acquisition cost for the materials but also a fee sufficient to cover any additional costs it incurs as a direct result of making the transfer (but not overhead expenses that the institution would incur without regard to the transfer).[4] Dunlap will retain the protection of the NPIA, therefore, if it transfers pharmaceuticals to the Free Clinic at a price that does not exceed its direct costs in purchasing and transferring the materials.

This letter sets out the views of the staff of the Bureau of Competition, as authorized by the Commission's Rules of Practice. Under Commission Rule § 1.3(c), 16 C.F.R. § 1.3(c), the Commission is not bound by this staff opinion and reserves the right to rescind it at a later time. In addition, this office retains the right to reconsider the questions involved and, with notice to the requesting party, to rescind or revoke the opinion if implementation of the proposed program results in substantial anticompetitive effects, if the program is used for improper purposes, if facts change significantly, or if it would be in the public interest to do so.

Sincerely yours,

Jeffrey W. Brennan
Assistant Director

---

[2] *Abbott Laboratories v. Portland Retail Druggists Assn*, 425 U.S. 1, 14 (1976).

[3] *St. Peter's Hospital of the City of Albany*, 92 F.T.C. 1037 (1978).

[4] Letter from Michael D. McNeely to Sheldon Klein (*North Ottawa Community Hospital*) (October 22, 1996).