

Building and Maintaining a Formulary

A formulary is a list of medications that your organization wants to encourage physicians and patients to use. It includes the medication's therapeutic class, the brand name, the generic name, and the available dosages or strengths

Once the decision has been made to include an on-site pharmacy in your health clinic, you need to decide what medications will be available for your providers to prescribe to patients. This is best completed by reviewing the current system for medication access throughout the present safety-net structure, including existing prescribing and ordering practices and identifying the medications most frequently prescribed by safety-net providers.

In addition, you will want to work with the medical community, practitioners, and pharmacists to determine the primary medication needs of the population you have elected to serve. For example, if your clinic will be focusing predominantly on chronic care, you may learn that the top five disease categories currently treated in your service area are Diabetes, Hypertension, Lipid Management, Asthma or similar pulmonary conditions, and Allergies. Your formulary should reflect an adequate supply of medications most frequently prescribed to treat these and other chronic disease conditions.

In addition, you will want to have a wide range of:

- Analgesics
- Anti-infective agents (both oral and topical)
- Antihistamines
- Decongestants
- Respiratory agents for the acute cases that present
- Agents with multiple indications
 - Ibuprofen
 - Diphenhydramine
 - Prednisone

Regardless of your clinical focus, acute care, chronic care, specialty, or full service, it is vitally important to establish a formulary. Medications placed on the formulary are selected for a variety of reasons. In order to minimize expenditures, prescription medications are usually determined and evaluated based on cost,

safety, and efficacy. Is the medication the least expensive medication available and still equally effective and clinically appropriate for the indicated diagnosis and treatment plan?

Further, formularies may be designed to reflect the philosophy and mission of the clinic. Based on your guiding principles, your organization may want to exclude certain medications from the approved formulary list. Such as:

- Narcotics
- Psychotropics
- Appetite suppressants
- Infertility medications
- Medications used for cosmetic purposes (wrinkles, hair loss, acne, etc.)
- Erectile dysfunction medications
- Oral contraceptives or other contraceptive devices
- Injectable Medications (with the exception of Insulin)
- Experimental and Investigational (including off-label use) medications
- Some types of vitamins (non-prenatal)

More to Consider

Additionally, you will need to decide if your formulary will contain Over the Counter (OTC) medications for dispensing, such as Tylenol, Motrin, vitamin and mineral supplements, etc. Will you provide medical supplies like syringes, glucometers, test strips, lancets, or spacers for inhalers?

Clearly, as a significant component of any efficient pharmacy operation, establishing a standard and consistent formulary is essential to ensuring quality patient care and to enhancing provider satisfaction. Unlike a retail pharmacy, as the only medications available for ordering and dispensing to clinic patients are those that have been approved by the organization and are available on the pharmacy shelf, On-Site Pharmacies are often considered to have “closed” formularies. A closed formulary is a formulary that restricts the medications available within an institution or available under a third-party plan. There is generally a formal, objective review and approval process required before changes

in the formulary may occur. Further, a closed formulary may be developed as either a “positive” or “negative” formulary.

1) A positive formulary begins with a blank piece of paper and medications are added to it after discussion, review, and approval.

- Building a positive formulary may be more challenging initially because each medication must be considered and added to the list individually. However, this is probably the best method for limiting the medications that are available and thereby may control costs more efficiently.

2) A negative formulary starts with a comprehensive list of medications and medications are removed from the list that is deemed unnecessary, duplicative, or not aligned with the clinic mission.

- A negative formulary, because it starts out with a larger number of medications, is most likely to result in a larger formulary of approved medications

Either method of formulary development is satisfactory.

Optimally, a small committee should be developed to oversee the On-Site Pharmacy operations. The committee should consist of the clinic medical director, a licensed pharmacist, a staff or volunteer healthcare provider, and the organization’s Executive Director. In addition to other duties, this committee may act as a Pharmacy-and-Therapeutics (P&T) committee for all decisions regarding the clinic formulary and will serve as the primary communications link between the pharmacy, the medical staff, and the Board. The P&T committee is responsible for all matters related to the use of medications in the clinic, including ordering, storing, and dispensing procedures, and the development and maintenance of the formulary. The basic objectives of a P&T committee are to determine medications of choice based on the uniqueness, medical necessity, efficacy, safety, and cost of each product reviewed. In many cases, a P&T committee may recommend a type of formulary system using “step therapy.” This requires providers and patients to first try well-established, low cost medications before moving on to newer and often more expensive medication treatment therapies if the first treatment plan proves to be ineffective or unsuccessful.

Other influence to formulary development is the anticipated source or sources of medications. Clinics may obtain medications for pharmacy use from Institutional Patient Assistance Programs (IPAP) sponsored by pharmaceutical companies, through purchased stock, and from physician sample donations. Medications obtained through Individual Patient Assistance Programs are for the specific individual and are not available for general pharmacy use. Purchased product and, as a rule, IPAP donated medications may be the most consistently available in your pharmacy. Once contracts and agreements to purchase product are secured, these medications would be listed on your formulary. Donated physician samples may be inconsistently available and, similar to purchased product, have specific record this maintains requirements that are regulated by both federal and state laws. If your clinic decides to accept physician sample donations, donations should be sorted and only those sample medications listed on the approved clinic formulary should be inventoried and stored in the clinic pharmacy. All other donated physician sample medications should be passed on to other community healthcare programs. This policy is critical in order to support your healthcare providers and maintain consistency in treatment plans for your patients. It is an unnecessary disruption to the providers if they must constantly look and guess what is stocked on the pharmacy shelves prior to prescribing it to their patient. Further, having to constantly change medications because donated medication samples may or may not be available interferes with your patient's prescribed treatment plan and may impact their health outcomes.

Creating and maintaining an approved formulary is a fundamental building block to successful On-Site Pharmacy operations. Most importantly, by establishing a formulary, you will make clear to your prescribers what medications are available. Continuous monitoring of the formulary is also of vital significance to therapeutic selection. Any changes in the formulary or to product availability should be communicated immediately to your healthcare providers.

Using Drug Company Patient Assistance Programs (PAPs)

In an effort to make medications available to those in need, many pharmaceutical companies provide free medications to individuals with low incomes who have no prescription drug coverage. These donated medications are provided through pharmaceutical company Patient Assistance Programs (PAPs). Medications