

PHARMACEUTICAL POLICY

&

PROCEDURE MANUAL

PHARMACEUTICAL POLICY AND PROCEDURE

This manual is designed to provide each site with the following information:

1. Policy for Sample Medication Distribution;
2. Policy for Recall Tracking;
3. Policy for Medication Errors;
4. Policy for Serious Adverse Drug Reactions;
5. Sample Medication Formulary;
6. Drug Product Problem Reporting Forms; and
7. Serious Adverse Drug Reaction Reporting Forms.

The Pharmacy and Therapeutics Committee add sample medications to the formulary after review of the efficacy, safety and cost. They are prescribed and dispensed by qualified professionals, according to organizational goals and in accordance with Local, State and Federal laws.

Medical Sales Representatives must have appointments with the providers at each site and at **no time** may deliver samples to the nursing staff without the approval of the provider. The sample medication must be logged into the sample medication book. The medical sales representative will complete this log to include the date, lot number, name of medical sales representative, name of medication, quantity and expiration date.

Each provider of medical services must complete the dispensing log. The purpose of the dispensing log is to allow for tracking of medications that may be recalled or have led to a serious adverse effect upon a patient.

The formulary of Sample Medications will be divided into therapeutic categories, as outlined below:

ACE INHIBITORS
ALPHA-BLOCKERS
ALPHA-BLOCKERS
ANTI-INFECTIVES
ANTIRETROVIRALS
ANTI-DEPRESSANTS
ANTI-PSYCHOTIC
ANGIOTENSIN II BLOCKERS

BETA-AGONIST INHALERS

CALCIUM CHANNEL BLOCKERS
CALCIUM CHANNEL BLOCKERS:
*WITH ACE INHIBITOR
CARDIOSELECTIVE BETA BLOCKERS:
*WITH DIURETIC *WITH ALPHA BLOCKER
CONTRACEPTIVES
COX-2 INHIBITORS
COUGH/COLD PREPARATIONS

DIURETICS

H2 ANTAGONISTS
HYPOGLYCEMICS

INHALED STERIODS

LIPID LOWERING AGENTS

NASAL STERIODS
NSAIDS

ORAL ANTI-ASTMATIC PREPS

PROTON PUMP INHIBITORS

TOPICALS

VITAMINS

Sample Medication Formulary

CUSTODY: Sample medications are in the custody of the physicians and other licensed practitioners with prescriptive authority, to whom the pharmaceutical representatives have officially provided the samples, in accordance with State Law and regulation. The pharmacist consultant may assist with the inventory and control of the medications, but the custody of the medications remains the responsibility of the physician or other provider to whom the medications were given. The pharmacist consultant maintains the integrity of the sample medication room through routine inspections.

SECURITY: All sample medications are stored in a locked room designated for medication storage. Access to this room is restricted to medical providers. This list includes: Physicians, Physician Assistants, Registered Nurses, Licensed Practical Nurses and Certified Nurse Midwives. Satellite clinics will use locked cabinets within a lockable room.

INVENTORY: Appropriate inventory controls will be conducted to assure proper security, storage, transportation and administration of sample medications. At least monthly, the sample medication room will be inventoried to remove all out-dated medications. Out-of-date medications will be discarded or disposed of in accordance with applicable State law and regulations. Medication is shelved according to disease state and within each category and the medication is alphabetized. All overstock will be reviewed monthly by the pharmacist consultant and/or medical personnel and added to inventory as space allows. The Pharmacy and Therapeutics Committee -- in consultation with the medical staff -- will determine which sample medications will be accepted by the program and stocked in the sample medication room or locked cabinet. This list may be specific to individual medications, or may describe broad categories of medications that the clinical staff has determined to be efficacious, affordable, and in other ways helpful to the patients. The program will not accept medications solely on the preference of the pharmaceutical representative.

RECALL TRACKING

All sample medications provided to patients will be recorded in the patient's medical record. Additionally, the patient's identifier (name, record number) along with the amount of medication given to the patient will be recorded on the sample medication log. The pharmaceutical representative is responsible for entering the name, date and lot number of the medication on the medication log that is brought into each facility.

The Pharmacist Consultant will notify providers of drug recalls. The consultant, along with a representative from the clinic (nurse), will review log files to identify patients who may have received recalled medication. The provider, nurse or consultant will notify the patient of the recall. Patients should be asked to bring in the recalled medications for return to the manufacturers unless directed otherwise by the manufacturer. All of the above must be documented in the patient's chart.

The nursing staff or pharmacist consultant will also check our shelves or locked cabinets for any of the recalled medication. The medication will either be returned to the manufacturer or discarded in a manner that is irretrievable.

MEDICATION ERRORS: The National Coordinating Council for Medication Error and Prevention defines a "Medication Error" as follows:

"A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient or consumer. Such events may be related to professional practice, procedures and systems, include prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring and use."

It is expected that providers and nursing staff will document all medication errors using the MEDICATION ERRORS REPORTING PROGRAM FORM. One copy will be placed in the patients' chart and a second copy will be placed in the medication error logbook. The Pharmacy and Therapeutics Committee will review the medication error logbook quarterly. A quarterly report, including any action taken, will be submitted to the performance improvement committee.

SIGNIFICANT ADVERSE DRUG REACTIONS

A significant adverse drug reaction logbook will be kept at each site of the Hill Health Center. In addition, the Columbus Avenue site will have a Pharmacy Manual and Significant Adverse Drug Reaction/Medication Error logbook in each department. (Internal Medicine, Pediatrics and OB/GYN).

The log must be completed in full. All relevant information must be included.

***“Examples of a significant adverse medication reaction include: Any situation in which the ingestion or application of a medication results in an emergency response that requires intervention from a medical provider to prevent permanent impairment or damage. This response may result not only in discontinuation of the medication but also additional therapies to alleviate the reaction. Ingestion of or application of a (prescription or non-prescription) medication that produces an allergic response is not considered a serious adverse medication reaction. Patients should be screened for allergies before the administration of a medication.*”**

“Outcomes of serious adverse events can be life-threatening, result in disability, congenital anomaly, hospitalization and/or death.”

If the adverse drug reaction is suspected to be the result of a drug product problem, the practitioner is encouraged to utilize the USP Drug Product Problem Reporting Program.

Patients will be instructed to bring in those medications so they can be discarded or the patient can be advised to discard them in a irretrievable manner (i.e., flushing them down the toilet). The provider may wish to send the drug back to the manufacturer for review.

The Serious Adverse Drug Reaction log will be reviewed quarterly by the Pharmacy and Therapeutics Committee and a summary, as well as any corrective action taken, will be presented quarterly to the Performance Improvement Committee.

FORMS

- For the “Medication Errors Reporting Form” ---
Call Toll Free for Additional Forms: 1-800-487-7776
or
Fax Request to: 301-816-8532;
- For the “MedWatch Drug Problem Reporting Form” -- Call Toll Free: 1-800-332-1088.

FORMULARY