

Distribution of Sample Medications/Formula

PURPOSE: Compliance with providing sample medications/formulas to patients in a safe manner requires a significant administrative effort. The physician office will practice dispensing sample medications/formulas to its patients, the practice will act as a pharmacy and is required to follow state and federal pharmacy regulations. The physician's office will address the following areas in: accepting and distributing sample medications/formulas to assure the physician's responsibility to the patient and the regulatory system has been met.

POLICY: The physician's office will address the following areas in: accepting and distributing sample medications/formulas to assure the physician's responsibility to the patient and the regulatory system such as keeping a Destruction and Expiration Log, Inventory Inspection Log, Refrigerator/Freezer Log, Patient Distribution Log, Patient Instruction Form.

PROCEDURE:

I. **Accepting Samples.**

A. All sample medications/formulas received from a pharmaceutical drug representative should be documented as received on a Drug Inventory Log, initialed by both the pharmaceutical drug representative and an office staff member. Pharmaceutical drug representatives should not be independently accessing samples and should be accompanied by staff when accessing the samples.

II. **Storage and Documentation**

- A. The practice is responsible for having a process in place for the storage, handling, removal, and distribution of samples. A specific person should be assigned responsibility for inspections, preferably, monthly.
- B. All sample medications/formulas should be stored in a locked room in a location inaccessible to patients. Medications/formulas should not be stored in exam rooms where patients are left unattended.
- C. The storage area should not be subject to extreme temperatures. All refrigerators containing medications/formulas should have daily temperature checks. For medications/formulas requiring refrigeration, processes need to be in place to notify if there has been a refrigerator or freezer (electricity malfunction when the office is closed. Logs of these checks should be maintained for five years.
- D. Lighting in the storage room should allow easy reading of medication names and dosages.
- E. Samples should be well-organized by drug or drug group. Medications/formulas with similar names or similar packaging should be located in separate areas.
- F. All medications/formulas in the practice should be stored according to manufacturer's instructions. They should be checked monthly for outdates, deterioration and appropriate location. Inspect all areas in which medications/formulas are stored including refrigerators.

- G. It is recommended that an inventory of sample medications/formulas be maintained. It may be helpful to use an inventory sheet for each type of sample medication. Maintain the log on file for five years. These sample logs are intended to provide your office practice with a methodology to track the sample medications/formulas that you dispense as well as aid you in identifying those that have expired and require disposal.
- The EXPIRATION AND DESTRUCTION LOG allows you to document expired medications/formulas when it is destroyed by a pharmacy. When sample medications/formulas is destroyed at a pharmacy, a pharmacist must sign off on the receiving sample medications/formulas on Expiration and Destruction Log. Expired sample medications/formulas should be discarded in accordance with federal, state and local laws. Drug take-back programs may be an alternative for practices to remove unwanted medicines from the practices. It is important to contact your state or the federal Department of Environmental Services for advice on medication disposal.
 - The INVENTORY INSPECTION LOG allows you to check all expiration dates at a glance to streamline your review and discard process.
 - The REFRIGERATOR/FREEZER TEMPERATURE LOG is a log to assist you in compiling the necessary temperature documentation for medications/formulas requiring refrigeration.
 - The PATIENT DISTRIBUTION LOG is a means to keep track of the patients who received the medication, along with the lot number of that medication. Use of this log will simplify the process of identifying your patients that have received a medication whose lot number has been recalled or has had other warnings or issues associated with it.
 - The provider must provide all the necessary drug information, patient instructions, education, and documented in member's list.

III. Access

- A. Sample medications/formulas should be stored in a secured location. Access to sample medications/formulas should be limited to specified medical personnel only.
- B. Employees should not be allowed to access or request free samples. Self-medication can lead to adverse events of which the practice could be held liable.

IV. Dispensing

- A. Only pharmacists, physicians and mid-level providers with prescribing authority may actually dispense medications/formulas. When the physician office practice dispenses sample medications/formulas to its patients, the practice is acting as a pharmacy and is required to follow state and federal pharmacy regulations.
- B. At times patients request refills of their sample medications/formulas. Sample medications/formulas may only be dispensed **after** a physician or mid-level provider with prescribing authority (physician assistant or nurse

practitioner) has authorized the refill. This information should be noted in the patient's record.

C. When retrieving sample medications/formulas, the authorized medical professional should:

- review the provider's order/authorization
- double check the name of the medication on the package
- confirm the expiration date of the medication
- verify the patient's allergies to medications/formulas

D. All medications/formulas should be labeled with the following:

- Patient's Name
- Medication Name
- Dosage
- Frequency or Time
- Route
- Form, i.e., liquid, tablet, drops
- Date Dispensed
- Lot Number

E. The provider should discuss with the patient the administration, storage, potential interactions, and side effects of the medication. All discussions with the patient regarding allergies, side effects, dosage, special procedures for taking medications/formulas and other related issues should be documented in the patient's medical record.

A SAMPLES DRUG FORM is a form for providing the medication information patient's may need after they leave the practice, as patients may not remember oral instructions. The form provides a place for patient/guardian signature acknowledging receipt of the medication information. A copy of this form should be retained in the patient's medical record.

F. A double check of the patient's name and second identifier, i.e., date of birth, should occur when providing the patient with the medications/formulas.

G. Documentation of the provision of sample medications/formulas should be placed in the patient's medical record to include the name of the medication, date, dose, frequency, route, form, date dispensed, lot number and written authorization by the provider. Any written information provided to the patient regarding the instructions and adverse reactions of medications/formulas prescribed should also be noted in the patient's medical record.

All physician practices that distribute sample medications/formulas should ensure mechanisms are in place for secure storage, patient distribution and education, appropriate record-keeping and regular monitoring. A detailed policy and procedure should support this process.