Sample Medications Policy and Procedure – SAMPLE

Purpose: To establish guidelines for the control of all sample medications received from pharmaceutical representatives at [*insert name of practice/clinic*]

A medication is defined as any substance, other than food or devices, that may be used on or administered to persons as an aid in the diagnosis, treatment or prevention of disease or other abnormal conditions. This policy addresses procuring, storing, maintaining and dispensing sample medications and managing related recalls.

Definitions:

Class I – Food and Drug Administration (FDA) recalls include "dangerous or defective products that predictably could cause serious health problems or death."[1]

Class II – FDA recalls include "products that might cause a temporary health problem, or pose only a slight threat of a serious nature."[2]

Class III – FDA recalls include "products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing laws."[3]

Responsibility:

A. All office clinical personnel are responsible for monitoring the receipt, storage, and prescribing practitioner distribution of sample medications, as outlined in these procedures.

B. When a prescribing practitioner dispenses a sample medication to a patient, the practitioner is responsible for also providing instructions to the patient regarding expected effects of the medication, possible side effects, food or drug interactions, when to notify the practice if the medication is ineffective or if there is a serious side effect, contraindications related to alcohol and food, and directions for use.

C. The practice manager or compliance coordinator is responsible for immediately notifying staff members regarding urgent Class I recalls and providing periodic summary reports regarding Class I, II and III product recalls issued by the FDA, as reported by the FDA in its weekly *Enforcement Report*. The practice manager or compliance coordinator will print off the *Enforcement Report* from the FDA website each week and review the report to determine if the practice is maintaining a recalled medication.

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D. If a sample medication is recalled, the prescribing practitioners are responsible for determining if replacement medicines need to be issued and will take appropriate steps to do so.

E. The practice manager or designee is responsible for reviewing sample medication logs and sample stock medications, taking appropriate action to notify patients who received a recalled medication, and removing stock medications from shelves.

Procedures:

A. A prescribing practitioner must sign the professional sample form or ledger, which is provided by the pharmaceutical sales representative, at the time the professional samples are received.

B. [*Insert name of practice/clinic*] will not accept samples of controlled substances.

C. [*Insert name of practice/clinic*] will not accept samples that are expired or nearly expired.

D. [*Insert name of practice/clinic*] will not accept samples or medication donations from individuals or other organizations.

E. All sample medications dispensed are recorded in a sample medication log (see Exhibit A - *Sample Medication Log*). The following information is to be recorded:
1. Patient name
2. Medication name
3. Lot #
3. Date medication is dispensed
4. Strength
5. Quantity

F. A label (Exhibit B) containing the following information is affixed to the sample medication:
1. Prescriber's name and telephone
2. Patient's name
3. Patient's date of birth
4. Medication name, strength, and dosage form
5. Date medication is dispensed
6. Route of administration in plain language; for example, by mouth rather than oral
7. Frequency of administration
8. Reason for taking the medication
9. Special precautions; for example, may cause drowsiness, take with food or after fasting for a specified period of time

10. Expiration date

G. Written or verbal instructions regarding the proper use of each new sample medication shall be provided to each patient. The instructions and education provided to the patient shall be documented in the patient's medical record.

H. All sample medication expiration dates will be checked monthly. Any expired medications will be separated from the sample inventory and discarded according to the applicable regulations.
   1. Medications are considered to be "expired" on the first day of the month/year following the month/year indicated on the sample package.
   2. Expired drugs/supplies are not suitable for charitable donation.

I. In the event of urgent Class I product recall notification, an audit of sample stock and all logbooks will take place.
   1. Sample medication logs will be reviewed for distribution of the recalled medication.
   2. Any patient who has received a recalled medication will be notified immediately by phone or letter and arrangements will be made to provide replacement medications, if the provider determines that a replacement medication is necessary.
   3. All recalled samples will be removed from stock.
   4. Those patients having received medication with recalled lot numbers and recalled medications removed from stock shall be discarded in accordance with the manufacturer's recall notice.
   5. For Class I medication recalls, documentation of the medication recalled and replacement will be made in the medical record of each pertinent patient.

J. For Class II and III product recalls that do not necessitate contact with patients who may have received the recalled medication:
   1. The sample stock will be reviewed for the presence of the recalled medication.
   2. Recalled samples will be removed from stock and discarded in accordance with the recall notice.

References:

1. U.S. Food and Drug Administration (FDA), "FDA 101: Product recalls – From First Alert to Effectiveness Checks," Page last updated October 14, 2014, http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm, 02/24/2015.
2. Ibid.
3. Ibid.