Texas Tech Physicians of EL PASO

Ambulatory Clinic Policy and Procedure

Title: **MANAGEMENT OF SAMPLE MEDICATIONS**	Policy Number: **EP 4.2**
Regulation: Texas Health & Safety code, Dangerous Drug Act, Federal Anti-Kickback statute, 42 U.S. Code § 1320a-7b	Effective Date: **09/2022**

Policy Statement:

Texas Tech Physicians of El Paso (TTP-EP) recognizes the value of vendor supplied sample medications and other products as we strive to meet the needs of our patients which includes a significant indigent population. It is the policy of TTP_EP that all physicians or practitioners who hold a license to distribute dangerous drugs will comply with all state and federal laws by maintaining records of the acquisition and disposal of prescription drug samples. In addition, vendors supply many products free of charge to clinics that are potentially beneficial to our patients, distribution of these products must be tracked to avoid potential entanglement with the Federal Anti-Kickback statute (42 U.S. Code § 1320a-7b). The ultimate duty to oversee the maintenance of the records associated with prescription drugs is the responsibility of the physician or practitioner and failure to do so may result in a criminal penalty. Each Clinic Administration is responsible for tracking the acquisition and distribution of non-prescription vendor samples. This policy is in accordance with the Dangerous Drug Act, Texas Health & Safety code, § 483.001, 483.022-483.025, 483.049 and the Federal Anti-Kickback statute, 42 U.S. Code § 1320a-7b.

Scope and Distribution:

This policy applies and will be distributed to all TTP-EP ambulatory clinics. It also applies to clinical departments without ambulatory clinics when they are direct recipients of vendor samples with patient use.

Procedure:

1. **Acquisition:**

    a. Physicians are responsible for signing for and obtaining sample prescription medications from pharmaceutical representatives. A signed form (**acquisition form**), excluding electronic signatures, is obtained from the pharmaceutical companies and a copy of this form should be kept on file in the clinic.

    b. Designated staff are responsible for signing for non-prescription vendor samples upon receipt from the representatives or upon delivery. A signed form (**acquisition form**), excluding electronic signatures, is obtained from the vendor companies and a copy of this form should be kept on file in the clinic

    c. Each clinic or clinical department is required to maintain a log system to track acquisition, dispensing, and disposal of drugs and non-drug samples. The acquisition forms and sample medication logs should be kept for no less than **two (2) years**. The amount received is recorded on the **Sample Medication Log Sheet** (4.2A) with the date of acquisition, lot number, and running total of the inventory updated. (See EP 4.2A Sample Medication Log Sheet for more detail.)

    d. Upon acquisition, the acquisition form shall be visibly marked with the date of receipt. Sample medication containers must be visibly marked as samples.

2. Dispensing/Recording:

a. The **Sample Medication Log Sheet** will serve as a record of sample meds acquired and dispensed as well as a reference of lot numbers in the event of a recall. There must be a log for each type of sample drug obtained with the drug name and strength clearly indicated. The process is the same for non-drug samples.

b. As sample drugs are dispensed to patients, the **Sample Medication Log Sheet** is to be updated with the date the sample was dispensed, patient name, medical record number, lot number, expiration date, and the number dispensed. The process is the same for non-drug samples.

c. The **Sample Medication Instruction Sheet** (Form 4.2B) including patient instructions should be completed and given to the patient and one copy will be scanned in to the Electronic Medical Record (EMR).

d. Medication Samples must be labeled with the patient's name and date of birth, medication name, strength, amount, and expiration date if not apparent from the packaging.

e. The provider, or a nurse following a physician order, shall be the one to hand the medication to the patient along with the Sample Medication Instructions Sheet (4.2B).

3. Storage:

a. Sample medications are stored appropriately as outlined in Policy EP 4.1 Storage and Disposal of Drugs and Biologicals.

b. Sample medications should be secured and not readily accessible to patients or visitors.

c. Sample medications are not to be stored in providers' offices or outside the approved area for medication storage in the clinics.

4. Inventory:

a. The Sample Medication Log Sheet will serve as a running count of inventory.

b. The sample medications must be counted at the end of each shift by at least two persons, and weekly regardless of use.

c. The individuals counting the sample medications must sign, date, and record time of day drugs were counted.

d. Expiration dates, integrity of the containers, and integrity of the medication are to also be checked during inventory.

5. Disposal:

a. Expired or unused portions of medications in small amounts should be placed in the cardboard bin labeled "Pharmaceutical Waste" and a disposal request will be submitted through the Safety Services website. Sample medications should be discarded as per policy 4.1, and not be disposed of in the toilet, sink or sharps container.

b. If large amounts of medications need to be disposed of, contact Safety Services for approved disposal procedures.

c. Disposal of sample medication is then recorded on the Sample Medication Log Sheet by indicating date the drug was discarded, the amount discarded, the reason for discarding the medication, and the name of the person disposing of the drug.
d. If non-drug samples need to be disposed of based on the hazardous content, please discard appropriately as per policy OP 75.17.

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Signatory approval on file by: Juan Figueroa, M.D. Director of Clinical Operations Clinic Medical Directors Committee, Chair Texas Tech Physicians of El Paso