TEXAS TECH UNIVERSITY
HEALTH SCIENCES CENTER™
EL PASO

Ambulatory Clinic Policy and Procedure

Title: **SAMPLE DRUG CONTROL, VENDOR SAMPLE CONTROL**	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: **2/2019**

Policy Statement:

Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) 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 TTUHSC El Paso 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. Department Clinical 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 TTUHSC El Paso 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 Log Sheet with the date of acquisition, lot number, and running total of the inventory updated.

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

   e. See EP 4.2 A. (sample medication log sheet) for more detail.

2. Dispensing/Recording:

a. The sample log 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 log 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. A sheet including patient instructions should be given to the patient with the sample medication and one copy placed in the medical record attached to the appropriate progress note or scanned in to the Electronic Medical Record (EMR). In lieu of placing a copy in the medical record, documentation of samples dispensed may be written or dictated into the progress note.
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 instructions sheet.

3. Storage:

a. Sample medications are stored appropriately as outlined in Policy EP 4.1 Management of Clinic Stock 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: The log will serve as a running count of inventory. The quantity physically on hand should be reconciled with the log on a quarterly basis by a clinic designee. Expiration dates, integrity of the containers, and integrity of the medication are to also be checked during inventory.

5. Disposal:

a. Outdated or unwanted sample medications should be disposed of as outlined in Policy EP 4.5 Disposal of Medications. Drugs should not be disposed of in the toilet, sink or sharps container.
b. Disposal of sample medication is then recorded on the log 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.
c. Non-drug samples should be disposed by the clinics according to their hazardous content if any.

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Signatory approval on file by:	Juan Figueroa, M.D. Director of Clinical Operations Clinical Operations Committee, Chair Texas Tech University Health Sciences Center El Paso		