TEXAS TECH UNIVERSITY
HEALTH SCIENCES CENTER™
EL PASO

Ambulatory Clinic Policy and Procedure

Title: **SAMPLE DRUG CONTROL**	Policy Number: **EP 4.2**
Regulation Reference: Texas Health & Safety code, Dangerous Drug Act, Joint Commission	Effective Date: **2/2017**

Policy Statement:

Texas Tech University Health Sciences Center El Paso (TTUHSC El Paso) recognizes the value of sample medications 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. The ultimate duty to oversee the maintenance of these records is the responsibility of the physician or practitioner and failure to do so may result in a criminal penalty. This policy is in accordance with the Dangerous Drug Act, Texas Health & Safety code, § 483.001, 483.022-483.025, 483.049.

Scope and Distribution:

This policy applies and will be distributed to all TTUHSC El Paso ambulatory clinics.

Procedure:

1. **Acquisition:**

    a. Physicians are responsible for signing for or obtaining sample medications from pharmaceutical representatives. A signed 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. Each clinic is required to maintain a log system to track acquisition, dispensing, and disposal of drugs. 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.

    c. Upon acquisition, the request 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 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.

    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.

    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. 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 shall be the one to hand the medication to the patient.

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.

Policy Number:	**EP 4.2**	Original Approval Date:	**1/2014**
Version Number:	**2**	Revision Date:	**2/2017**
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		