Ambulatory Clinic Policy and Procedure

<table>
<thead>
<tr>
<th>Title:</th>
<th>Controlled Substances Management</th>
<th>Policy Number:</th>
<th>4.05</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation Reference:</td>
<td>United States Controlled Substances Act</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Part 21, Code of Federal Regulations, Chapter II, DEA, Part 1300-End</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Texas Controlled Substances Act</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Memorandum of Understanding between the Texas Department of Public Safety and The Texas Higher Education Coordinating Board</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Version Number:</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Effective Date:</td>
<td></td>
<td></td>
<td>3/2015</td>
</tr>
<tr>
<td>Original Approval:</td>
<td></td>
<td></td>
<td>3/2015</td>
</tr>
</tbody>
</table>

POLICY STATEMENT:

It is the policy of Texas Tech University Health Sciences Center (TTUHSC) Ambulatory Clinics to promote patient safety and standardization of processes and documentation in all matters relating to controlled substances.

Controlled substances are identified by the federal Controlled Substances Act (CSA) as pharmaceuticals or chemical precursors with a high degree of danger to humans and a significant probability of abuse. The CSA lists controlled substances in five schedules based on their hazard level, propensity for abuse, and known medical uses. Schedule I substances offer no accepted medicinal benefit and are considered highly addictive, whereas Schedule V substances offer known medicinal benefits and are considered the least at risk for abuse. The CSA also outlines registration, security, and record-keeping requirements for institutions and individuals in order to mitigate the risk of diversion (i.e., theft) or illegal manufacture of controlled substances. The CSA requires all practitioners (i.e., veterinarians, scientific researchers, and physicians) handling controlled substances to be registered with the Drug Enforcement Agency, unless exempted by law.

The Drug Enforcement Agency is tasked with enforcing federal controlled substance regulations, while the Texas Department of Public Safety enforces additional state requirements outlined in the Texas Controlled Substances Act. A memorandum of understanding between the Texas Department of Public Safety and the Texas Higher Education Coordinating Board exempts higher education institutions from many state requirements, though federal requirements are unaffected.

The medical benefits of controlled substances make their usage an important part of achieving TTUHSC’s mission of improving health through high quality education and medical care.

SCOPE:

This policy applies to all TTUHSC Ambulatory Clinics operated through its Schools.

PROCEDURE:

1. **Planning.** Decisions regarding availability of Schedule II-V controlled substances to be available in the Clinical Departments will be made by the Clinical Chair of the Department based on clinical need, with input from Faculty, the Administrator, and the Nurse Manager. Controlled substances will be included in the list of stock medications annually reviewed at a Departmental Faculty meeting to assess continued need to maintain the medication in the Clinic.
2. **Storage.** All controlled substances will be stored in a locked cabinet in a secure location of the clinic away from patient treatment areas. Clinical departments will identify staff who have keys to the controlled substance cabinet.

3. **Ordering.**
   a. All Schedule II – V Controlled Substances will be ordered as needed by the Clinical Departments’ (controlled substances) purchasing designee through the Texas Tech University Health Sciences Center Pharmacy. Order Forms required by TTUHSC Pharmacy will be completed, including completion of DEA Form 222 when appropriate.
   
   b. The Clinical Department's (controlled substances) designee will pick up the ordered controlled substances from the TTUHSC Pharmacy when ready and take them to the clinical department with the Department’s copies of the ordering forms provided by the pharmacy.
   
   c. Another clinical department licensed individual will review the ordering forms, drugs, and quantities received prior to them being placed in the locked cabinet in the Clinic and the two individuals will update the controlled substances log with date, “stock added,” the new “balance” of medication, and co-sign the log.
   
   d. Records will be maintained for a minimum of two calendar years beyond the current year (in 4.05.A, Controlled Substances Tracking Log).

4. **Preparing and Dispensing.**
   a. Only licensed staff may administer injectable controlled substances.
   
   b. Clinical Departments will identify individuals who may administer oral controlled substances.
   
   c. Individuals removing the medication from the locked cabinet will do the following:
      1) Reconcile the number of pills or vials of the medication with the 4.05.A, Controlled Substances Tracking Log.
      
      2) Remove the needed medication and document the following in the Log; Date, Patient Name, Medical Record number, Lot, Expiration Date, number dispensed, and the balance remaining, and sign (see 4.05.A, Controlled Substances Tracking Log).

5. **Administration.**
   a. The person administering the medication will make sure there is a written order for the medication.
   
   b. The person administering the medication will use two identifiers to ensure the medication is being administered to the correct patient.
   
   c. The person administering the medication will engage the “Seven Rights of Medication Administration” as follows:
      1) Right medication
      
      2) Right patient
      
      3) Right dosage
      
      4) Right route
      
      5) Right time
      
      6) Right reason
      
      7) Right documentation
6. **Wastage.**
   a. If wastage of a partial dose is required, two individuals must directly observe the wastage by a means to render them unrecoverable (e.g. down a sink) and cosign the wastage in 4.05.A, Controlled Substances Tracking Log, immediately after the patient encounter.
   b. Expired controlled substances will be returned to the TTUHSC Pharmacy and the Chief Pharmacist will date and sign the log with an entry stating, “expired medication received by the pharmacy” and amend the balance of medication remaining.

7. **Monitoring.**
   a. The Controlled Substances cabinet/inventory will be inventoried/reconciled at the end of every day on days when controlled substances were administered.
   b. If a discrepancy is discovered, the nurse or designee will research each individual situation to resolve the discrepancy.
   c. If the discrepancy cannot be resolved, the Nurse Manager, Administrator, Medical Director of the Clinical Department, and Director of Nursing Services (or designee) shall be notified and an Occurrence Report completed and submitted to the Director of Performance Improvement who will notify the TTUHSC Chief Pharmacist and bring the issue to Risk Management Committee.
   d. Texas Tech Physicians reports abuses and losses of controlled substances, in accordance with law and regulation to the Texas Tech Police Department.

8. **Evaluation.** The Director of Nursing or the Director of Performance Improvement will monitor compliance with processes and documentation as per the Controlled Substances Policy every six months and report compliance findings to the Risk Management Committee.

**APPROVAL AUTHORITY:**

This policy shall be recommended for approval by the Joint Ambulatory Policy Committee to the Council of Deans.

**RESPONSIBILITY AND REVISIONS:**

It is the responsibility of the Joint Ambulatory Policy Committee to review and initiate necessary revisions based on collaboration and input by and through Quality Improvement/Performance Improvement, Risk Management and the Office of Institutional Compliance.

**RIGHT TO CHANGE POLICY:**

TTUHSC reserves the right to interpret, change, modify, amend or rescind this policy in whole or in part at any time to reflect changes in policy and/or law.

**CERTIFICATION:**

This policy was approved by the Council of Deans on March 12, 2015.

**ATTACHMENTS:**

4.05.A – Controlled Substances Tracking Log