



*Ambulatory Clinic Policy and Procedure*

<p>Title: <b>STORAGE AND DISPOSAL OF DRUGS AND BIOLOGICALS</b></p>	<p>Policy Number: <b>EP 4.1</b></p>
<p>Regulation Reference: Joint Commission MM.03.01.01., MM.01.01.03, MM.01.02.01, United States Controlled Substances Act; Part 21, Code of Federal Regulations, Chapter II, DEA, Part 1300-End; Texas Controlled Substances Act; Memorandum of Understanding between the Texas Department of Public Safety and The Texas Higher Education Coordinating Board</p>	<p>Effective Date: <b>9/2022</b></p>

**Policy Statement:**

This policy shall stand as a guide for qualified faculty, staff, and residents to appropriately acquire, maintain, and administer stock drugs and biologicals in the clinical areas.

**Scope and Distribution:**

This policy applies to all Texas Tech Physicians of El Paso (TTP-EP) ambulatory clinics that stock drugs and/or biologicals.

**Procedure:**

**1. OBTAINING MEDICATIONS**

- a. The Clinic designee is responsible for ordering necessary drugs and biological material for the clinical areas.
- b. These will be ordered as needed by the clinic purchasing designee through approved vendors.
- c. Decisions regarding availability of Schedule II-V controlled substances made available in each clinic will be made by the Clinic Medical Director based on clinical need with input from the Office of Claims Management and the Office of Quality Improvement.
- d. When obtaining controlled substances:
  - Required order forms will be completed, including completion of DEA Form 222 when appropriate.
  - The clinic will designate a licensed individual to receive and maintain documentation of received controlled substances.
  - A second licensed individual will review and reconcile the order forms, actual controlled substances, quantities, and packing slips prior to them being placed in the locked controlled substance cabinet. The primary and secondary licensed designees will verify that the controlled substances log (attachment A) is updated and accurately reflects the new stock added.
  - If the second licensed staff member is unavailable, the clinic designee will represent and abide by the rules set forth.
  - Records will be maintained for the current fiscal year plus two additional years.

**2. LIST OF STOCK MEDICATION**

- a. Each Clinic will maintain two separate written lists of all controlled and stock medications respectively to include strength and dosage, for in-clinic dispensing and administration. The aggregate of these lists will be considered the list of “clinics stock medications”.



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- b. The Medication/Equipment Committee will review and approve the list throughout the clinics annually and have a full list readily available.
- c. Before a medication is added to the organization's list, the Medication/Equipment Committee will review the medication for approval.
- d. At least two designated staff members must count clinic stock medications weekly. Expiration dates will be checked during each count.

### **3. STORAGE**

- a. Medications will be maintained and stored in areas according to the manufacturer's recommendations and not readily accessible to patients. Rooms or storage areas where medications are kept will be secured in a locked cabinet or room when not supervised.
- b. Drugs/biological material will be stored separately from miscellaneous solutions (i.e., Betadine, Gentian Violet, Clorox, etc.).

### **4. REFRIGERATION**

- a. Medications requiring refrigeration must NOT be stored with food items or specimens.
- b. Digital thermometers will be placed in refrigerators and freezers to verify temperature levels. Refrigerator temperatures are to be maintained between 35°F-46°F.
- c. Temperatures are to be monitored and logged daily when clinics are open by an individual designated by the clinic. Min/Max values should be cleared after the morning values are recorded and after the afternoon values are recorded to ensure accurate monitoring is taking place.
- d. Refrigerators/freezers should be plugged into a backup power source.
- e. Thermometers used in refrigerators/freezers containing medications should record the highest and lowest temperatures and include a high/low alarm (recorded on log) utilizing the Medication Refrigerator Temperature Log 4.1A.

When temperatures fluctuate above or below acceptable ranges, it needs to be determined how long the medications may have been out of range. The clinic will contact the manufacturer of all medications stored in the specific location affected to receive guidance on what to do with the medications that were exposed to the out-of-range temperatures.

### **5. LOOK-ALIKE/SOUND ALIKE DRUGS AND HIGH ALERT/HAZARDOUS MEDICATIONS**

- i. Will be identified and listed and these lists will be reviewed and updated annually, and as needed, and will be readily available.
- ii. Will be segregated in different bins or spaces.
- iii. Will be distinguished by using "TALL MAN LETTERING" i.e. upper case letters
- iv. Stickers will be used on medication containers to identify Look-alike/Sound alike drugs and High Alert/Hazardous medications

### **6. STORAGE AND INVENTORY OF CONTROLLED SUBSTANCES**

- a. Controlled substances will be stored in a locked cabinet in a secure location of the clinic away from patient treatment areas using at least two differently keyed locks at all times.
- b. Controlled substances must be stored in a keyed lockbox, safe, or steel cabinet and must have an inner and outer door with the locks for each door keyed differently.



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- c. If safe or steel cabinet is less than 750lbs, the safe or steel cabinet must be mounted, secured, or bolted to a wall, the floor, or base imbedded in the concrete.
- d. If stored in keyed lockboxes, keys must be stored separately from each other, away from lockbox, and stored in a drawer or cabinet that is either part of a bench or cabinet that is mounted to the wall or floor, and secured at all times with a hasp and padlock.
- e. Only individuals licensed to administer the drugs may have access to the storage cabinet and each clinic will keep a list of those individuals.
- f. Licensed individuals removing controlled substances from the locked cabinet will do the following:
  - i. Reconcile controlled substance doses physically present with the controlled substances log (attachment 4.1 B).
  - ii. Remove the needed medication and document the following in the log; date, patient name, E#, expiration date, amount removed, and the balance remaining. The individual will then sign the log.
  - iii. If wastage of a partial dose is required, the dose will be disposed of in the mediwaste bin with neutralizing agent. The wastage must be verified and signed by the licensed primary and secondary designated staff member, and the controlled substance log will be updated to reflect such waste/disposal appropriately.
  - iv. Reconciliation, removal, and waste of a controlled substance will be witnessed by the primary and secondary licensed individual. If a second licensed individual is unavailable, reconciliation, removal, and wastage of a controlled substance will be witnessed by the clinic designee.
- g. The controlled substances cabinet/inventory will be reconciled at the end of each day by at least two designated staff members regardless of usage.
- h. The individuals counting the drugs must sign, date, and record time of day drugs were counted
- i. The count form will be maintained in a secure location and will adhere to the Texas document retention schedule.
- j. If a discrepancy is discovered, the head nurse or controlled substance designee will research each situation on a case-by-case basis to resolve the discrepancy.
- k. If the discrepancy cannot be resolved, the head nurse, Medical Director, and Director of Claims Management shall be notified and an occurrence report must be completed.
- l. TTUHSC El Paso will report abuses and losses of controlled substances, in accordance with law and regulation, to the Texas Tech Police Department.

### **7. DISPOSAL:**

- a. All stock medications (including multi-dose vials) will be checked by clinics at least monthly for expiration dates and discarded appropriately as per policy OP 75.17.
  - b. 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. .
  - c. If large amounts of medications need to be disposed of, contact Safety Services for approved disposal procedures.
  - d. Medications should be discarded as per policy and not down the sink or toilet.
8. For vaccines provided through the Texas Vaccines for Children program, the ambulatory clinic should use the forms and methods provided by the Texas state health department.



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