

Ambulatory Clinic Policy and Procedure

Title: STORAGE AND DISPOSAL OF DRUGS AND BIOLOGICALS	Policy Number: EP 4.1
Regulation: Joint Commission; United States Controlled Substances Act; Code of Federal Regulations; Texas Controlled Substances Act; Texas Higher Education Coordinating Board	Effective Date: 01/2026

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, vaccines, 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. For instruction on obtaining controlled medications, see Management of Controlled Substances (EP 4.4).
2. List of Stock Medication
 - a. Each clinic will maintain a list of all stock medications and biologicals, including strength and dosage, for in-clinic dispensing and administration. The aggregate of these lists will be considered the list of "clinics stock medications".
 - b. The P&T Committee will review and approve the list throughout the clinics annually and have a full list readily available.
 - c. To add medication to the organization's list, a Request for Addition or Revision of Medication Formulary Form (EP 4.1A) must be completed. The P&T Committee will review the medication for approval.
3. Storage
 - a. Medications will be maintained and stored in areas according to the manufacturer's recommendations.
 - b. Medications must not be readily accessible to patients or unauthorized individuals.
 - c. Rooms or storage areas where medications are kept will be secured in a locked cabinet or room when not supervised. The Department of Quality Improvement will conduct quarterly reviews to ensure access is restricted to personnel with an operational need.
 - d. Drugs, vaccines, and biological material will be stored separately from miscellaneous solutions (i.e., Betadine, Gentian Violet, Clorox, etc.).
 - e. All stored medications and the components used in their preparation are labeled with the contents, expiration date, and any applicable warnings.
 - f. All expired, damaged, and/or contaminated medications or vaccines must be removed, labeled, and stored separately from medications available for administration.
4. Refrigeration
 - a. Medications requiring refrigeration must NOT be stored with food items or specimens.

Ambulatory Clinic Policy and Procedure

- b. Digital thermometers also known as data loggers will be placed in refrigerators and freezers to verify temperature levels.
 - Refrigerator temperatures are to be maintained between 36.0°F to 46.0°F.
 - Freezer temperatures are to be maintained between -58°F to 5°F.
 - Note: Please review the manufacturer's storage instructions carefully to ensure proper handling of medications stored in your refrigerator or freezer unit.
 - c. Temperatures are to be monitored and logged twice daily, once in the morning and once in the afternoon, utilizing the Temperature Recording Form for Refrigerator (EP 4.1C) and Temperature Recording Form for Freezer (EP 4.1D).
 - d. Min/Max values should be cleared when morning values are recorded to ensure accurate monitoring is taking place. Values will be recorded on appropriate temperature recording forms.
 - e. Temperatures recorded during the weekend will be reviewed when morning values are recorded on the first working day of the week.
 - f. Digital thermometers must include high/low alarm set to notify clinics of temperatures that have fluctuated above or below acceptable ranges.
 - g. If temperature fluctuates above or below acceptable ranges:
 - An occurrence report must be submitted.
 - A Temperature Excursion Report (EP 4.1E) must be submitted and attached to occurrence report.
 - The clinic will contact the manufacturer of all medications, vaccines, and/or biologicals stored in the specific location affected to receive direction for the medications that were exposed to the out-of-range temperatures and attach to occurrence report.
 - h. Refrigerators/freezers should be plugged into a backup power source.
 - i. It is preferred that only one refrigerator or freezer unit is plugged in per electrical outlet. However, if the clinic anticipates connecting multiple units into a single duplex outlet, facilities must be notified and must review the configuration prior to use.
 - Post "DO NOT UNPLUG" signs at the outlets and on the drug, vaccine, or biological storage unit.
 - j. Any refrigerator or freezer that is used should have enough space to store the largest inventory expected at the busiest point in the year without crowding.
 - Dormitory-style combined units are not used to store any vaccines.
 - k. Annual or as needed cleaning of units should be done to discourage bacterial and fungal growth. Cleaning must be done strategically to minimize the risk of temperature excursions.
 - l. Defrost manual-defrost freezers when the frost exceeds either 1 cm or per manufacturers recommendations.
5. Confused Drugs, High Alert, and Hazardous Medications
- a. Confused drugs (also known as look-alike/sound-alike medications), high alert medications, and hazardous medications will be identified and listed. These lists will be reviewed and updated annually, and as needed, and will be readily available.
 - b. These medications will be segregated in different bins or spaces.
 - c. These medications will be distinguished by using "TALL MAN LETTERING".
 - d. Stickers will be used on medication containers to identify confused drugs and, high alert, and hazardous medications.
 - e. Departments may utilize the Institute for Safe Medication Practices (ISMP) as a resource for identifying Confused Drug Names or the National Institute for Occupational Safety and Health (NIOSH) for identifying hazardous drugs.
6. Controlled (Scheduled) Substances

Ambulatory Clinic Policy and Procedure

- a. Controlled substances will be identified and listed. These lists will be reviewed and updated annually, and as needed, and will be readily available.
- b. Please refer to Management of Controlled Substances (EP 4.4).
7. Sample Medications
 - a. Sample medications will be identified and listed. These lists will be reviewed and updated annually, and as needed, and will be readily available.
 - b. Please refer to Management of Sample Medications (EP 4.2).
8. Patient Specific Medications
 - a. Patient specific medications will be identified.
 - b. Please refer to Management of Patient Specific Medications (EP 4.5).
9. Disposal
 - a. All stock medications will be checked by clinics weekly for expiration dates and discarded appropriately as per Disposal of Expired Medications (HSCEP OP 75.17).
 - b. Expired or unused portions of medications, vaccines, or biologicals in small amounts should be placed in appropriate container 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.
10. Recalled Medications
 - a. Clinics will follow regulatory guidelines for safe disposal or return of recalled medications to the manufacturer or designated agency.
 - b. Records for any recalled medication will be maintained for the current fiscal year plus two additional years.
 - c. Clinics will document recall on appropriate medication log.
11. Returned Medications
 - a. Clinics will not accept returned, unused, or expired medications from patients under any circumstances to ensure patient safety, maintain regulatory compliance, and uphold proper handling and disposal practices.
 - b. Patients are encouraged to follow local guidelines for the safe disposal of medications.
12. Vaccine and Medication Transport
 - a. Transport involves the movement of a vaccine or medication over a short time frame and distance between sites. Medications, vaccines and/or biologicals will be delivered directly to the facility where it will be used or housed. During emergencies such as power outages or natural disasters that put drugs, vaccines and/or biologicals in jeopardy, these actions should take place to protect these pharmaceutical supplies.
 - b. Transport of vaccines or medications should always be completed by two individuals.
 - c. Follow (EP 4.1F), for guidance on how vaccines and medications should be transported, and consult the manufacturer's instructions for any specific requirements and recommendations.
 - d. Off-site vaccine transportation:
 - Total transport time should not exceed 8 hours total.
 - Diluents will accompany their corresponding vaccines.
 - Transport only the number of medication, vaccines and/or biologicals needed for the event, workday, or situation.
 - If a non-commercial vehicle must be used, place the transportation containers in the passenger compartment, not the trunk.
 - e. Emergency transportation of medication, vaccines, and/or biologicals:

Ambulatory Clinic Policy and Procedure

- Ensure alternative pharmaceutical storage facility has ample storage and can accommodate the medication, vaccines, and/or biological.
 - Only open the storage unit door when medication, vaccines, and/or biologicals are ready to be packed into the transportation containers.
- f. Storing medications, vaccines, and/or biologicals at the destination site:
- Upon arrival to the off-site location, medication, vaccines and/or biologicals will be stored in an appropriate storage unit with a temperature monitoring device and will adhere to guidance from this policy on recording medication, vaccines, and biological storage unit temperatures.
- g. If medication or vaccines cannot be stored in an on-site storage unit, keep medication and/or vaccines in a portable vaccine storage unit with the container closed as much as possible and with a temperature monitoring device placed as close as possible to the medications/vaccines.
- Temperature monitoring devices such as digital data loggers should have a buffered temperature probe because they match vaccine temperatures more closely than those measured by standard thermometers.
 - Check and record temperatures hourly while stored in a portable vaccine storage unit.
13. Other
- a. 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.

References:

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- Chapter 6: Vaccine Administration. (2024, April 8). Epidemiology and Prevention of Vaccine-Preventable Diseases. <https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-6-vaccine-administration.html>
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- Texas Higher Education Coordinating Board. (2020, June 11). Department of Public Safety (DPS) and Texas Higher Education Coordinating Board (THECB) controlled substance memorandum of understanding (MOU). Texas Higher Education Coordinating Board. <https://reportcenter.highered.texas.gov/agency-publication/policies-and-procedures/department-of-public-safety-dps-and-texas-higher-education-coordinating-board-thecb-controlled-substance-memorandum-of-understanding-mou/>
- Texas Legislature. (n.d.). Health and Safety Code Chapter 481: Texas Controlled Substances Act. Retrieved May 28, 2025, from <https://texas.public.law/statutes/tex. health and safety code title 6 subtitle c chapter 481>
- The Joint Commission. (2024). Medication Management (MM). In The Joint Commission Comprehensive Accreditation Manual for Ambulatory Care (p. MM-1-MM-22).

Ambulatory Clinic Policy and Procedure

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U.S. Department of Justice, Drug Enforcement Administration. (2025, May 27). 21 CFR Part 1301—Registration of manufacturers, distributors, and dispensers of controlled substances. Electronic Code of Federal Regulations. <https://www.ecfr.gov/current/title-21/chapter-II/part-1301>

U.S. House of Representatives. (n.d.). 21 U.S.C. § 801 et seq. Retrieved May 28, 2025, from <https://uscode.house.gov/view.xhtml?req=granuleid%3AUSC-prelim-title21>

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