

Ambulatory Clinic Policy and Procedure

Title: MANAGEMENT OF CONTROLLED SUBSTANCES	Policy Number: EP 4.13
Regulation Reference: 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	Effective Date: 2/2020

Policy Statement:

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

Scope and Distribution:

This policy applies and will be distributed to all Texas Tech Physicians of El Paso ambulatory clinics.

Definitions:

Controlled substances – substances 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 Controlled Substances Act (CSA) – regulates the manufacture, importation, possession, use and distribution of certain narcotics, stimulants, depressants, hallucinogens, anabolic steroids and other chemicals. The CSA lists controlled substances in five scheduled 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 (DEA) – enforces federal controlled substance regulations.

Texas Department of Public Safety (DPS) – enforces state requirements outlined in the Texas Controlled Substances Act (TCSA). A memorandum of understanding between the DPS and Texas Higher Education Coordinating Board exempts higher education institutions from many state requirements, though federal requirements are unaffected.

Procedure:

I. PRESCRIBING CONTROLLED SUBSTANCES

1. A practitioner, as defined in the TCSA, §481.002(39)(A), must issue a written prescription for a **Schedule II** controlled substance only on an official Texas prescription form or through an electronic prescription that meets all requirements of the TCSA. This subsection also applies to a prescription issued in an emergency situation. A prescription for a controlled substance must be dated and signed on the date when issued. The prescription must include the patient's full name and address, and the practitioner's full name, address, and DEA registration number. The prescription must also include:



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- a. Drug name
 - b. Strength
 - c. Dosage form
 - d. Quantity prescribed
 - e. Directions for use
2. Schedule II controlled substance prescriptions should be filled out, completed, and signed by the prescribing physician/provider.
 3. Schedule II prescriptions completed on paper forms must be recorded and scanned into the electronic medical record.
 4. The practitioner is responsible for ensuring that the prescription conforms to all requirements of the law and regulations, both federal and state.
 5. A prescription for a controlled substance may only be issued by who is:
 - a. Authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practice :
 - i. physician,
 - ii. dentist,
 - iii. podiatrist,
 - iv. veterinarian,
 - v. mid-level practitioner,
 - vi. or other registered practitioner
 - b. Registered with DEA or exempted from registration
 - c. An agent or employee of a hospital or other institution acting in the normal course of business or employment under the registration of the hospital or other institution which is registered in lieu of the individual practitioner being registered provided that additional requirements as set forth in the CFR are met.
 6. An unused official prescription form is invalid and the unused form(s) must be returned to the Texas Board of Pharmacy with an appropriate explanation not later than the 30th day after the date:
 - a. The practitioner's license to practice or DEA number is cancelled, revoked, or suspended, denied or surrendered or amended to exclude the handling of all Schedule II controlled substances; or
 - b. The practitioner is deceased
 7. A practitioner who obtains from the board an official prescription form is accountable for each numbered form and is responsible to meet all the requirements of federal and state law to account for and manage these forms.
 8. While an official prescription blank is not in immediate use, a practitioner may not maintain or store the forms at a location easily accessible for theft or other misuse.
 9. **Beginning March 1, 2020**, pharmacists and prescribers (other than a veterinarian) will be required to check the patient's Prescription Monitoring Program (PMP) history before dispensing or prescribing opioids, benzodiazepines, barbiturates, or carisoprodol.



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II. CONTROLLED SUBSTANCES IN CLINIC

1. Decisions regarding availability of Schedule II-V controlled substances made available in clinical departments will be made by the Department Chair based on clinical need with input from faculty, the department administrator, the nurse manager, the Office of Claims Management, and the Office of Quality Improvement.
2. Controlled substances will be included in the list of stock medications maintained by each clinic site.
3. All schedule II-V controlled substances will be ordered as needed by the clinical departments' purchasing designee through approved vendors.
 - a. Required order forms will be completed, including completion of DEA Form 222 when appropriate.
 - b. The clinical departments will designate an individual to receive controlled substances and maintain documentation of received controlled substances.
 - c. A second licensed staff member 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 designees will verify that the controlled substances log (attachment A) is updated completely and accurately reflected the new stock added.
 - d. Records will be maintained for the current fiscal year plus two additional years.
4. All controlled substances will be stored in a locked cabinet in a secure location of the clinic away from patient treatment areas.
 - a. Clinical departments will identify staff who have access to the controlled substance cabinet.
 - b. Clinical departments will maintain a current, updated list of individuals who have access to the substance cabinet.
 - c. The controlled substances cabinet/inventory will be reconciled at the end of each day controlled substances were administered, and weekly regardless of usage.
 - d. 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.
 - e. If the discrepancy cannot be resolved the head nurse, department administrator, Medical Director, and Director of Claims Management shall be notified and an occurrence report must be completed.
 - f. TTUHSC El Paso will report abuses and losses of controlled substances, in accordance with law and regulation, to the Texas Tech Police Department.
 - g. 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 A).
 - 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.
5. Only licensed staff may administer controlled substances as outlined in section I.5.a.
 - a. Standard medication administration processes will be followed as per policy EP 4.3.
6. If wastage of a partial dose is required, the controlled substance designee must contact the Department of Safety Services to ensure proper disposal procedures are followed.



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- a. The controlled substances log must be updated appropriately to reflect such wastage/disposal. Primary and secondary designees must sign the log to verify accurate information.
 - b. Controlled substances must never be thrown in the toilet or sink.
7. The Office of Quality Improvement will monitor compliance with processes and documentation as outlined in this policy no less than every six months.

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Signatory approval on file by: Juan Figueroa, M.D. Director of Clinical Operations Clinic Operations Committee, Chair Paul L. Foster School of Medicine	