

<b>Institutional Handbook of Operating Procedures Policy 03.02.11</b>	
Section: Department of Pharmacy	Responsible Vice President: EVP & COO Clinical Enterprise
Subject: Notification of Theft or Significant Loss of Controlled Substances	Responsible Entity: Department of Pharmacy

**I. Title**  
*Controlled Substance Theft or Significant Loss Reporting*

**II. Policy**

The purpose of this policy is to require appropriate reporting to the U.S. Drug Enforcement Administration (DEA) and State Agencies of any Theft or Significant Loss of Controlled Substance.

The Diversion Prevention Task Force (DPTF) will manage the investigation of all reports of suspected Controlled Substance diversion. The DPTF Team will include representatives from Compliance, UTMB Police, Human Resources, Nursing, Physician, Pharmacy, Legal Affairs, and Leadership.

If DPTF concludes it is highly probable that there has been a Theft or Significant Loss of a Controlled Substance (a “Finding”), the Director of Pharmacy or designee must ensure that, within **one business day** of the date the Finding is made, the facility sends an initial notification letter to the Local DEA Office. If at the conclusion of the investigation, the “Finding” is the same, the facility must file a DEA Form 106.

In addition, a Theft must be reported to local law enforcement, and any Theft or Significant Loss must be reported to the Texas State Board of Pharmacy by mailing a notification letter along with DEA Form 106.

**III. Procedures**

*A. Internal Reporting*

1. If the DPTF suspects or concludes that Controlled Substance diversion has occurred or probably occurred, the following notifications will be made:
  - a. If an employee or licensed healthcare provider is suspected of diverting CS while on duty, notify the employee’s supervisor/department chair/program director
  - b. If a UTMB house resident or student is suspected of diverting CS within the scope of their training, notify the Dean or Administrator of the appropriate school
  - c. Compliance will notify the appropriate billing department to determine whether modifications should be made to bills related to affected medical care
  - d. Information Technology department will be notified to halt access to internal email and Electronic Health Record (EHR)
  - e. Security will be notified to suspend badge access to relevant buildings, departments, and medication storage areas
  - f. Employee health will be notified to determine the need for a fit-for-duty evaluation and “for cause” drug test
  - g. Quality and Safety will be notified to ensure that patient safety is not compromised.

## B. External Reporting

If a Controlled Substance is determined to have been diverted by ANY individual, the UTMB Executive Pharmacy Leader or Designee will ensure that appropriate reports are made to:

1. Drug Enforcement Agency (DEA)
  - a. Initial notification letter must be mailed, emailed or faxed to the Local DEA Office within **one (1) business day** of discovery of a suspected Theft or Significant Loss of a Controlled Substance.
  - b. Must complete the DEA Form 106 if CS diversion is confirmed at the conclusion of the investigation.
  - c. If, after the initial notification to DEA, the investigation of the Theft or Significant Loss determines no such theft or loss of Controlled Substances occurred, a DEA Form 106 does not need to be filed. However, for complete and accurate records, pharmacy should notify the DEA in writing of this fact in order to resolve the initial report and explain why no DEA Form 106 was filed regarding the incident
2. Texas State Board of Pharmacy (TSBP)
  - a. The Theft or Significant Loss of any Controlled Substance must be reported in writing to the TSBP on the discovery of such theft or loss
  - b. Pharmacy shall be in compliance by submitting to the board a copy of the DEA report of theft or loss of Controlled Substances, DEA Form 106, or by submitting a list of Controlled Substances stolen or lost.
3. Law Enforcement
  - a. If a UTMB employee is determined to have committed CS diversion, UTMB Police will report the diversion to the local police department. This report will be made regardless of whether the diversion occurred within the scope of the employee's employment or training, or while the employee was a patient or visitor.
  - b. In the event of CS diversion by a patient, or visitor who is not a UTMB employee, the Legal Department in collaboration with UTMB police will determine whether the report the diversion to the local police department.
4. State Licensing Board
  - a. Chief Nursing Officer/Associate Chief Nursing Officer or Designee will report Controlled Substance diversion by nurses
  - b. Chief of the Medical Staff will report Controlled Substance diversion by Staff Physicians per [IHOP 08.01.07- Evaluation and Treatment of Impaired Physicians](#).
  - c. The Dean of the applicable School or designee will report Controlled Substance diversion by fellow, residents or students
  - d. Directors of each campus Pharmacy or designee will report Controlled Substance diversion by Pharmacy staff
  - e. The applicable supervisor or other Departmental leader or designee will report Controlled Substance diversion by all other licensed or registered health care providers
5. Patient Notification
  - a. If any patient is harmed by a Controlled Substance diversion, the patient will be informed of the circumstances of CS diversion and its impact on the patient. The patient's primary physician will be responsible for ensuring that this communication occurs.
  - b. If Controlled Substance diversion is confirmed but it is unclear whether the diversion caused patient harm or placed one or more patients at risk of harm, the DPTF in collaboration with the UTMB Legal Department will determine whether patient notification will serve the best interests of potentially affected patients.

6. The Diversion Prevention Task Force will evaluate all incidents of Controlled Substances and determine whether additional external reports should be made, such as reports to the Department of Public Health or the Food and Drug Administration.

#### IV. Definitions

*Controlled Substances*: medications classified as Schedule I through V by the Federal Drug Enforcement Agency ([21 C.F.R. §§ 802 \(6\), 812](#)) and/or [Texas Controlled Substance Act](#).

*Drug Diversion*: is defined as the diversion of licit drugs for illicit purposes. It involves the diversion of drugs from legal and medically necessary uses towards uses that are illegal and typically not medically authorized or necessary.

*DEA*: the U.S. Drug Enforcement Administration

*DEA Form 106*: the official DEA Form 106 (Report of Theft or Loss of Controlled Substances), submitted through the DEA's online submission system

*Finding*: means the Diversion Prevention Task Force (DPTF) has determined that it is highly probable a Theft or a Significant Loss has occurred.

*Initial DEA Report*: a short-written notification (Letter), sent by fax, email, or letter, stating that a Theft or Significant Loss of a particular Controlled Substance has been discovered and that a DEA Form 106 will be submitted, if warranted, once the investigation is complete.

*Local DEA Office*: the DEA Field Division Office in the Houston area where the facility is located.

*Purchased Unit*: the unit of measure in which the Controlled Substance is purchased by the facility. For example, the Purchased Unit for Norco 5/325 (Hydrocodone Bitartrate 5mg/Acetaminophen 325mg) is 100. This definition does not include single-dose vials.

*Theft*: means it is highly probable that a person has stolen a Controlled Substance from the facility. A finding of theft requires actual, real, or specific evidence, either direct or circumstantial, that would make a reasonable person believe that theft is highly probable. In deciding whether a theft has occurred, the facility should consider all the available evidence and, when viewed as a whole, determine if the evidence would make a reasonable person believe that it is highly probable that a Controlled Substance has been stolen.

*Significant Loss*: means the standard of Theft has not been met, but a Controlled Substance cannot be accounted for, even after reasonable efforts have been taken to find it, and that loss is "Significant." For purposes of this policy, "Significant" means either a) the quantity lost is greater than one Purchased Unit or (b) the quantity lost is greater than 5% of the total inventory of the specific controlled substance missing at a particular location, or b) there is a pattern of losses associated with a particular healthcare provider.

#### V. Relevant Federal and State Statutes

[21 C.F.R. §§ 802 \(6\), 812](#)

[21 C.F.R § 1301.76 \(b\)](#)

[Texas State Board of Pharmacy Rule 291.3 \(f\)](#)

[Texas Controlled Substance Act](#)

**VI. Related UTMB Policies and Procedures**

[IHOP 03.07.01-Fitness for Duty](#)

[IHOP 08.01.07-Evaluation and Treatment of Impaired Physicians](#)

**VII. Dates Approved or Amended**

<i>Originated: 11/26/2024</i>	

**VIII. Contact Information**

Department of Pharmacy

409-772-1174