

Drug Diversion Detection: Prevention, Identification, and Reporting– Policy

Effective Date:

Sites: The University of Kansas Health System - Enterprise Wide

Purpose: To provide a systematic, coordinated, and timely approach to the prevention, recognition, and reporting of suspected drug diversion to ensure safe medication practices, a safe employee environment, and to prevent patient harm.

Definitions

Controlled Substance (CS): A drug or other substance, or immediate precursor, included in Schedule I, II, III, IV, or V of part B of 21 U.S.C. §802(6). The term does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.

Diversion Oversight Committee: A multidisciplinary group of leaders, with representation from nursing, pharmacy, anesthesia, risk management and human resources, that ensure the safe use of controlled substances throughout the health system.

Drug: As defined by 21 U.S.C. §321(g)(1) – (A) articles recognized in the official United States Pharmacopoeia,[1] official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

Drug Diversion: Any identified theft of Health System supplied or approved drugs (controlled and non-controlled substances) at any point in the workplace supply chain, likely used for illicit purposes, such as supporting the individual's addiction, an associated person's addiction, or to sell for financial gain.

Policy

1. All staff are required to comply with state and federal laws and regulations regarding medication handling and security, including controlled substances.
2. All staff are responsible for internally escalating any known or suspected drug diversion or theft to their supervising manager as soon as possible.
3. Suspicion and investigation of drug related diversion may arise from a variety of circumstances, including but not limited to, the following:
 - a. A witnessed incident of probable drug diversion
 - b. Behaviors that may indicate an impaired care provider/practitioner
 - c. Suspicious activity identified during routine monitoring and/or proactive surveillance
 - d. Self-disclosure of drug diversion by an individual
 - e. Notification of suspected drug diversion from an external source, such as local law enforcement or a family member of a suspected drug diverter
 - f. Online Event Reporting System
4. Any employee who reports suspected drug diversion of another individual, honestly and in good faith, will be protected from retaliation.
5. Drug Diversion by an employee is grounds for termination as defined in *Drug/Alcohol Abuse, Diversion, and Testing, 702 Policy*.
6. The prevention, detection, investigation, and external reporting of drug diversion is the responsibility of the Diversion Detection Response Team (DDRT@kumc.edu).
 - a. The Diversion Detection Response Team (DDRT@kumc.edu) includes, but is not limited to:

- i. Site specific Pharmacist-in-Charge (PIC) or Drug Enforcement Agency (DEA) registrant
 - ii. Director of Pharmacy
 - iii. Pharmacy Manager – Controlled Substance Compliance
 - iv. Diversion Detection Pharmacist
 - v. Diversion Detection Quality Nurse
 - vi. Diversion Oversight Committee Members (when applicable)
7. All suspected incidents of drug diversion will be investigated as outlined in sections II and III below.
8. Confirmed drug diversion will be reported to all appropriate agencies within the specified time required by the DEA and applicable State Board of Pharmacy.

Procedures

I. Prevention

a. Pre-Employment Screening

- i. Refer to the *Drug/Alcohol Abuse, Diversion, and Testing, 702 Policy*

b. Education

- i. All pharmacy staff will be educated on medication handling and diversion procedures.

c. Auditing and Surveillance

- i. The University of Kansas Health System will maintain a drug diversion auditing and surveillance program to enable the prompt identification of loss or diversion of controlled substances and to identify quickly the individual(s) responsible for any drug diversion.
- ii. Auditing and surveillance techniques include, but are not limited to:
 1. Reports generated from automated dispensing system (ADS) technology
 2. Third Party diversion detection software (i.e. Omnicell Analytics, Rx Auditor)
 3. Auditing pharmacy purchase records and controlled substance transfers between DEA licensed sites
 4. Routine inventory counts of controlled substances
 5. Chart reviews within the electronic health record
 6. Online Event Reporting System review

II. Investigation

- a. An investigation begins promptly after diversion is suspected. Each suspected diversion event will be investigated under the discretion of the Diversion Detection Response Team (DDRT@kumc.edu).
- b. Escalation of the suspected diversion will be determined after an initial review by a member of the Diversion Detection Response Team (DDRT@kumc.edu). The Diversion Detection Response Team (DDRT@kumc.edu) will determine if the suspected diversion warrants further investigation, or if the diversion threat is invalid.
- c. The actions conducted in an investigation include, but are not limited to:
 - i. Reports that correspond to the ADS machines
 - ii. Chart review in the electronic medical record
 - iii. Surveillance camera review
 - iv. Employee badge access records
 - v. Time-card information access
 - vi. Fact finding interviews with health system employees
 - vii. Testing of recovered medications for purity via third-party vendors
 - viii. Review of medication purchasing records
 - ix. Review of reverse distribution records
- d. If the diversion threat warrants further investigation, the suspected diverter may be tested for drugs/alcohol in compliance with the *Drug/Alcohol Abuse, Diversion, and Testing, 702 Policy*.
 - i. At the time a drug test is completed:
 1. The PIC must be notified immediately upon completion.

2. The PIC will submit a provisional DEA 106 form for any controlled substance(s) that is unaccounted for related to the investigation during normal business hours.
 3. The PIC will also notify the appropriate state Board of Pharmacy, including the provisional DEA 106 form, for any controlled substance(s) that is unaccounted for related to the investigation during normal business hours.
- ii. If the urine drug screen results as positive and corresponds to the unaccounted-for controlled substance, the DEA 106 form will be finalized.
 - iii. If the urine drug screen results as negative, the DEA 106 and subsequent notice to the State Board of Pharmacy will be redacted unless there is otherwise enough evidence to substantiate the theft of controlled substances.
 - iv. Refer to *Controlled Substance Significant Loss and Reporting Policy* if the incident resulted in theft or loss of controlled substances.
- e. The procedures and evidence of all investigated diversion events will be documented in an easily retrievable manner.

III. Reporting

a. Internal Reporting

- i. If there is suspicion or known drug diversion that has occurred or probably occurred, the following notifications will be made:
 1. Pharmacist-In-Charge & DEA registrant
 2. The employee's supervisor
 3. Human Resources department
 4. Chief Compliance and Internal Audit Officer
- ii. The Chief Compliance and Internal Audit Officer will be notified to also determine whether modifications should be made to claims related to affected medical care.

b. Reporting to Law Enforcement, Licensing Boards and Government Agencies

- i. If a controlled substance is determined to have been diverted by any individual, the Diversion Detection Response Team (DDRT@kumc.edu) will ensure that the appropriate reports are completed for the following agencies:
 1. DEA Office of Diversion Control, DEA form 106
 2. Kansas State Board of Pharmacy (if applicable)
 3. Missouri State Board of Pharmacy (if applicable)
- ii. The DEA and appropriate State Board of Pharmacy will be notified of all diversion events as soon as the investigation has determined diversion or significant loss is the most likely explanation for the discrepancy in controlled substance records. Further reporting will be completed, as appropriate, upon completion of a urine drug test or identification of further evidence.
- iii. In collaboration with the Chief Compliance and Internal Audit Officer, the respective director in which the employee reports up to, will report the drug diversion by licensed or registered healthcare providers to the appropriate licensing board(s).
- iv. The Diversion Detection Response Team (DDRT@kumc.edu), in collaboration with the Chief Compliance and Internal Audit Officer, may report diversion to local law enforcement. This report may 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. The report may be made after the employee's employment period if additional information regarding diversion is found.

Supporting Documents:

- **Controlled Substance Handling Policy**
- **Controlled Substance Significant Loss and Reporting**
- **Controlled Substance Discrepancy Resolution**
- **Drug/Alcohol Abuse, Diversion, and Testing, 702**