Controlled Substances and Dangerous Drugs Compliance: Building Blocks for Success

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Expecting compliance without a proper foundation is like...

Building a house with a deck of cards!
In this presentation

Why compliance matters

The law

Responsibilities of the Registrants

Ongoing Training
The Federal and State Regulations are designed to operate within a closed system of distribution for the protection of public health safety and to prevent the **diversion** of controlled substances into the illicit market.

Drug diversion is the **illegal distribution or abuse/use of prescription drugs** away from the intended end user or a legitimate source.

Each Registrant must do what the law requires so that the drugs stay in the closed system of distribution and the drugs are not diverted onto the streets!
Drug Diversion: It would never happen here!

99% of the time Diversion happens from the inside.

The #1 reason - People’s life circumstances change in an instant

What is Diversion?

Diversion Case Review
What is Diversion?

Drug diversion is the illegal distribution or abuse of prescription drugs or their use for purposes not intended by the prescriber.
Every Employee has a responsibility to report

Every employee has a responsibility to report diversion.

Reports of drug diversion by fellow employees is not only a necessary part of an overall drug security program but also serves the best interest of the public. DEA requires that an employee who has knowledge of diversion by a fellow employee report the information either to DEA or an Emory official. Emory will treat all reports as confidential and will take all reasonable steps to protect the confidentiality of the information and the identity of the employee reporting the information.

Employees who don't feel comfortable reporting to their Supervisor/Department Head or HR may report to the Office of Research Integrity and Compliance (ORIC@emory.edu) or they may contact the EMORY TRUST LINE. The Trust Line is operated by an independent third party who will maintain the caller's anonymity while ensuring that the caller's report is routed to the proper individuals within the University. Contact the Emory Trustline:

CALL: 888.550.8850
ON THE WEB: EmoryTrustLine.com
Occupational and Personal Risk Factors that may lead to diversion
Common behaviors associated with drug diversion

The following behaviors **may** be associated with drug diversion:

- Demonstrates absenteeism or isolation
- Exhibits underperformance or behavioral changes (hyper or hypo activity)
- Lacks ability to concentrate or has frequent accidents
- Spends time near drug supply; volunteers to waste or medicate other patients
- Comes in when not scheduled; offers to work OT
- Makes frequent trips to the restroom and/or long trips off unit
- Conceals drugs or syringes; places personal bags near workstation
- Involved in drug-related discrepancies and/or poor documentation
- Wears cold weather clothing in warm weather

It's important to avoid unintentional or unconscious bias.
- Suspicion does not automatically equate to diversion.
- Good employees are not immune to diversion.
Record settlement reached in University of Michigan hospital drug diversion civil penalty case

DETOUR - The Drug Enforcement Administration and United States Attorney's Office for the Eastern District of Michigan today announced that the University of Michigan Health System has agreed to pay the United States $4.3 million as part of a settlement resolving allegations that UMHS violated certain provisions of the Controlled Substances Act, 21 U.S.C. §§ 801-904. The settlement, which is civil in nature, resulted from a years-long Drug Enforcement Administration investigation of UMHS's handling of controlled substances. It is the nation's largest settlement of its kind involving allegations of drug diversion at a hospital.

DEA began its investigation after two tragic incidents occurred in December 2013 involving two UMHS employees—a nurse and an anesthesiology resident. Both overdosed on opioids, including fentanyl, at a UMHS facility. The nurse's overdose was fatal.
https://emorywheel.com/drugs-scam-costs-university-health-system-millions/
Federal Requirements (DEA Registrants only)—21 CFR Part 1300 to end

State Regulations (All Registrants) – O.C.G.A Title 16, Chapter 13, Articles 1-3, O.C.G. A Rule 480-7-04

Each licensee is responsible for knowing and complying with all the regulations required by the license.
Researcher Responsibility:
Keeping drugs inside the closed system of distribution
Drug Accountability
Know the Laws & Penalties
Understand ALL the Regulations
Proper Recordkeeping
Drug Accountability
Due Diligence
Registration
Procedures
Security Requirements
Policy
Standards
Reporting
100% Compliance
Future Training Topics:

- Obtaining Proper Licensing – Pre-Registration Assistance & Proper Security
- What do I do once I receive my license? Setting up my drug binders
- What’s a controlled substance and what’s a dangerous drug?
- How do I conduct an Inventory? (Initial, Biennial or Annual)
- Ordering and Receiving Drugs Properly
- Current Use Forms. Which forms do I use?
- Disposing of Drug Properly
- Maintaining Drug Accountability
- Theft/Loss Reporting? It is a BIG Deal!
- Who do these controlled substances belong to? Abandoned drugs
- Conducting Self Inspections
- What happens when I retire or leave Emory?
Managing Controlled Substances & Dangerous Drugs in Research

You can choose to attend one or more of the following sessions.

- Nov 8, 2023 12:00 PM
- Dec 13, 2023 12:00 PM
- Jan 10, 2024 12:00 PM
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Thank you! Any Questions?