Drug Diversion Prevention, Detection and Response: The Compliance Professional’s Role

John Burke, President, IHFDA
Kimberly New, Executive Director, IHFDA

Understanding Diversion

- All facilities face this issue
- Substantial safety, quality, regulatory compliance and legal risk
- Mitigate risk with formal program, transparency and culture change
Culture: Ongoing Awareness, Education and Accountability

Program Essentials

Diversion Specialist

- Daily operations-surveillance/education
- Database
- Institutional resource
- Diversion risk rounds
- Community, LE and regulatory liaison
Program Essentials

Response Team

- Objective
- Consistent
- Cumulative

Oversight Committee

Diversion Committee

- Anesthesia
- Nursing (general, procedural)
- Pharmacy (med safety, narc)
- Security
- Risk Management
- Accreditation
- Chief Medical Officer
- Compliance

- Infection prevention
- Human Resources
- Employee Health
- Finance
- Laboratory
- Research
- COO or other C-Suite rep
- Ad hoc
Key Aspects of Program

- Policies to prevent, detect and properly respond to diversion
- Stakeholder collaboration
- Method of auditing/transaction review
- Prompt attention to suspicious data
- Collaborative relationship with external agencies
- Education for all staff
- Diversion risk rounds

Key Regulatory Considerations
Screening For Risk

21 CFR 1301.90 Employee screening procedures

- Obtaining certain information is vital to assess the likelihood of an employee committing a drug security breach
- Need to know is a matter of business necessity, essential to overall controlled substances security
- Conviction of crimes and unauthorized use of controlled substances are activities that are proper subjects for inquiry

Screening for Risk

21 CFR 1301.93 Sources of information for employee checks

DEA recommends that inquiries concerning employees' criminal records be made as follows:

- Local inquiries. Inquiries made by name, date and place of birth, and other identifying information, to local courts and law enforcement agencies for records of pending charges and convictions.
- DEA inquiries. Inquiries furnished to DEA Field Offices along with written consent from the concerned individual for a check of DEA files for records of convictions. The Regional check will result in a national check being made by the Field Division Office.
Security from Procurement to Administration and Disposal

42 CFR §482.25(a) Standard: Pharmacy Management and Administration

- The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

- The hospital's pharmacy service must ensure safe and appropriate procurement, storage, preparation, dispensing, use, tracking and control, and disposal of medications and medication-related devices throughout the hospital, for both inpatient and outpatient services.

Controls and Safeguards

42 CFR §482.25(b) Standard: Delivery of Services

- In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

- Safe dispensing of medications must be in accordance with accepted standards of practice and includes, but is not limited to:

- Reviewing all medication orders (except in emergency situations) for appropriateness by a pharmacist before the first dose is dispensed.
Controls and Safeguards

42 CFR §482.25(b)(1) - Medications must be dispensed by the hospital in a manner that is safe and meets the needs of the patient:

- Quantities of medications are dispensed which minimize diversion and potential adverse events while meeting the needs of the patient;

Security

42 CFR §482.25(b)(2)(i) - All drugs and biologicals must be kept in a secure area, and locked when appropriate.

- Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons
- If there is evidence of tampering or diversion, or if medication security otherwise becomes a problem, the hospital is expected to evaluate its current medication control policies and procedures, and implement the necessary systems and processes to ensure that the problem is corrected, and that patient health and safety are maintained
- All controlled substances must be locked.
• Are medication storage areas periodically inspected by pharmacy staff to make sure medications are properly stored?

• Determine that security features in automated medication distribution units are implemented and actively maintained, e.g., that access authorizations are regularly updated to reflect changes in personnel, assignments, etc.

Staff Reporting

21 CFR §1301.91 Employee responsibility to report drug diversion

• Reports of drug diversion by fellow employees is necessary and also serves the public interest at large

• An employee with knowledge of drug diversion from his employer by a fellow employee is obligated to report to a responsible security official of the employer

• Confidentiality for those reporting

• Employer shall inform all employees concerning this policy
External Reporting

21 CFR §1301.76 Other security controls for practitioners

- Registrants required to notify the DEA Field Division Office in their area, in writing, of the theft or significant loss of any controlled substance within one business day of discovery of such loss or theft.

- Also complete and submit to the Field Office, DEA Form 106, "Report of Theft or Loss of Controlled Substances" regarding the theft or loss.

Theft and Loss

- Diversion is theft, not loss

- Updates every 30 days

- For loss, no single objective standard, but instead view in context of a registrant's business activity and environment

- When in doubt, registrants should err on the side of caution in alerting the appropriate law enforcement authorities, including DEA, of thefts and losses of controlled substances
Theft and Loss

Determining significance of loss:

- Actual quantity of controlled substances lost in relation to the type of business;
- The specific controlled substances lost;
- Whether the loss can be associated with access by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
- A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
- Whether the specific controlled substances are likely candidates for diversion;
- Local trends and other indicators of the diversion potential of the missing controlled substance.
Health Facility Diversion

- Significant number of HF do not report diversion
- Offender dismissed/fired allowed to quit
- Violates laws and regulations
- Disregards well being of the patient!
- Offending healthcare employee gravitates to other institutions
- Will continue addiction and collaborative damage
- Liability issues can become overwhelming

Health Facility Diversion

- HF must realize these are crimes!
- In most states the diversion of Rx drugs is a felony
- Federal crime also
- Losses/thefts need to be reported like any other criminal activity
- HIPAA exclusionary rules apply
- LE and court involvement will require serious rehabilitation attempts
Health Facility Diversion

- HF seriously impede meaningful rehabilitation by not reporting
- The lower the addiction levels the better chance of rehab success
- Caring, responsible HF address problem head on and “do the right thing”

Hospital Obstacles

- Failure to report loss/theft of CS
- Attempted legal blockades
- Overprotection by Human Resources (Criminal Investigation)
- Interference attempts by unions
- Pressure on staff to overlook or disregard diversion
- General lack of cooperation with LE
Health Professional Investigations

• 30% of PDS arrests were health professionals
  
  • Average health professional arrest every 6 days
  
  • Almost 70% of those arrests were nurses
  
  • Average nurse arrest every 8 days

Health Professional Investigations

• Statistics reveal 50 nurse arrests per year per 400,000 population (Cincinnati)

• Using 300,000,000 as U.S. population

• Pushes it out to 3,750 potential arrests per year nationwide

• Average of 10.2 nurse diversion arrests per day should occur!

• Based only on those cases discovered not the overall total
Investigative Techniques

- What is history at the diversion site?
- Has there been a personnel change at the diversion site?
- Are there any overt personal issues with the personnel at the site?
- Has there been an access to the site change?

Investigative Techniques

- Thoroughly gather pertinent information from nursing supervisor
- Thoroughly gather pertinent information from pharmacy
- Assess the timeline of the thefts
- Identify personnel changes
- Identify nursing personnel working during the...
Investigative Techniques

- Criminal/Traffic background of nursing personnel
- Check PMP if able
- Medical or emotional issues
- Relationship or finance problems
- Agency nurses
- Utilize available computer dispensing databases
- Work with HF staff during investigation

Investigative Techniques

- Particular attention to PRN patient administration
- Check promethazine usage
- Consider order for urine screen of patient (when applicable)
- Approach suspect on last working day upon exiting facility, if possible
- Good interrogation techniques essential
Response

Timing is Everything!

Diversion Response Team

- May consist of person from pharmacy, nursing, security, HR, legal, other
- Meet when discrepancy occurs with CS and cannot be resolved (24 Hrs)
- Meet when outright theft of CS
- Unresolved CS issues notify LE
- Provide info to LE and work closely with them to resolve case
Diversion Response Team

- Select LE member carefully
- Oftentimes best available is a plainclothes detective
- Familiar with investigations in general
- Travels health facility w/o a uniform
- LE selected MUST want to be on team
- Must be willing to learn and work with non-LE
- Find this person before your first diversion

Diversion Response Team

- Team should debrief after each reported diversion incident
- What did we do right and wrong?
- How can we improve the next time?
- Is the team made up of the correct members?
- Do we need to add a member/s?
- Was the outcome the best for the healthcare employee and patient?
Culture of Safety

A culture of safety provides the means for robust reporting of errors and near misses, as well as the feedback loop to inform staff of what was done to prevent recurrence. It is a learning environment, where adverse events do not get hushed up, but instead are shared throughout the organization to educate all. It is a culture that does not punish human error, but that does address unprofessional and disruptive behavior that can undermine safety.

Regulatory Climate-Focus on Hospitals

- Inpatient processes
- Formal program
- Accountability and tracking
- Awareness
- Following policies and procedures
- Evidence of work being done
Thank you!

Kimberly New jd bsn rn
John Burke
kimberly@diversionspecialists.com
burke@rxdiversion.com

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