FEATURE

Increased Diversion Resources? Avoid a false sense of security

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Over the past few years, many healthcare systems have increased their number of dedicated drug diversion specialists and implemented more robust drug diversion software. Systems that have a drug diversion specialist, team or software might think that is all they need for a successful drug diversion program. In some cases, the changes and levels of dedicated resources have led to a false sense of security, especially if drug diversion specialists are inexperienced and software still requires significant manual intervention.

Diversion is expensive and prevalent. Diversion costs the U.S. <u>\$78.5 billion annually</u>. A <u>2022 study</u> indicated that 18 percent of nurses showed signs of substance use problems, while one-third of this population qualified as having a substance use disorder.

Look at these five key areas to help reveal whether your organization's sense of security is false:

- Drug Enforcement Administration (DEA) regulatory complexity
- Knowledge gaps
- Lack of a drug diverter mindset
- Resources not focused on highest risks
- Lack of monitoring and follow-through processes

DEA regulatory complexity

DEA regulations can be complex and difficult to understand. Also, healthcare leaders often are not focused on whether their hospital drug diversion teams and auditors have the knowledge and experience to implement and manage robust prevention and detection according to the regulations.

Many hospitals do not report any diversions or report only one or two diversions each year. And the reported diversions are often identified not through drug diversion programs but through internal or external alarms such as other providers or the local police department raising concerns. Citations to entities involving their noncompliance with DEA regulations can lead to <u>multimillion-dollar settlements</u>. But if the entity that reports—or misreports—a diversion is a member of a health system, the DEA and law enforcement may inspect other locations and assess practices throughout the entire organization.

A few of the DEA regulations that can be particularly complex to understand and properly implement follow.

Power of attorney (POA) compliance

The POA must be executed by the DEA registrant. The registrant will vary depending on the type of organization. For example, if the organization is a corporation, then the registrant must be an officer of the corporation. However, a registrant may authorize another individual to sign applications for the registrant by filing a power of attorney for that individual with the <u>Registration Unit of the DEA</u>. Because DEA regulations on this topic are not very clear and can be easily misinterpreted, many pharmacy directors inappropriately grant POAs.

DEA Form 41 (Registrant Record of Controlled Substances Destroyed)

<u>DEA Form 41</u> must be used for controlled substance destruction to maintain the closed-loop system for accountability. For example, if a vial of a controlled substance is dropped and spillage occurs and is clearly observed, but the controlled substance is not recoverable, that information must be documented on a DEA Form 41.

INCREASED DIVERSION RESOURCES?

Diverters are savvy—they learn of the areas that have oversight and divert in other areas that lack controls.

However, the regulation is not clear on controlled substances destroyed by compounding processes or other pharmacy-controlled substances destruction. In addition, when controlled substances are destroyed at a registrant's location, two employees must personally witness the destruction until the controlled substance is rendered nonretrievable.

DEA Form 106 (Report of Theft or Loss of Controlled Substances)

The DEA must be notified in writing within one business day of discovery of a theft or significant loss. Your organization's reporting can be done to the local DEA field office or through the submission of a DEA Form 106.

The notion of *discovery* can be confusing. However, the DEA explains that if an organization is involved in an ongoing investigation, the DEA can be notified in writing (without submitting a DEA Forum 106) within one day of discovery of a theft or significant loss. The DEA Form 106 is not required until the investigation is complete and only if the loss was validated. If the drugs were located during the investigation, then the DEA Form 106 does not need to be submitted, but the DEA should be advised of that fact in writing.

Another option is to simply submit the DEA Form 106 within one business day of discovery. Since DEA is silent on defining *discovery*, you should validate that the DEA Form 106 was filed within one business day of any documentation on the theft or significant loss.

Knowledge gaps

Because of siloed practices, lack of shared lessons, overreliance on software applications, and unfamiliarity with industry leading practices, healthcare systems often have undesirable variations in their compliance practices. And staff may lack expertise in and knowledge about the complexities surrounding controlled substance and drug diversion regulations. In addition, various DEA field offices can have different views.

Healthcare facilities often work in silos, so while one hospital might go through a DEA settlement agreement and consequently implement robust controls, another hospital within the same healthcare system or same town might have no idea about the controls applied. Facilities within a healthcare system or similar geography should work together to share lessons learned and leading practices implemented. The need to prevent drug diversion across the entire healthcare system should outweigh the discomfort or embarrassment of not having thorough knowledge of DEA regulations and leading practices.

Organizations might rely too much on drug diversion software applications or the premise of a robust drug diversion program. Many great computer applications are available, but caution should be taken in completely relying on the technology as the sole source for drug diversion oversight. Areas often overlooked within these applications include clinical procedural areas, manual documentation of drug administrations and pharmacy diversions.

Outside expertise also should be considered, especially at the onset of creating a drug diversion specialist position or team. Often these positions or teams are created from within the hospital and do not receive specialized training to perform their new job responsibilities.

Third-party specialists can help build out an effective drug diversion audit program and assist with the oversight, auditing procedures and training. Also, drug diversion specialists should be consistently expanding their knowledge about current drug diversions identified across the country as well as examining thought leadership articles from outside experts. Insights from external sources might identify gaps that can be mitigated before

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they are exploited. In addition, sharing diversion risks and experiences with peers across healthcare systems and communities is vital.

Lack of a drug diverter mindset

Individuals operating or auditing a drug diversion program must think like a diverter. They must step out of their role and ask themselves: If I wanted to divert, where could I do it? Thinking like a diverter also involves asking those who are responsible for controlled substances that same question. Who better to ask than the individuals who stock, transfer, administer and waste controlled substances every day? Detecting drug diversion within a hospital needs to incorporate multiple departments, including pharmacy, nursing, information technology, security and human resources.

Diverters are focused on concealing their diversion and getting their next drug. They often know where management is focusing drug diversion efforts and already have considered and planned multiple other avenues for their diversion. Diversion can occur at any point where controlled substances are accessed or stored.

Diverters typically begin with diversions of small quantities of a particular drug. Diversion of wasted drugs is a common method and can take many forms, such as wasting entire doses, removing a larger dose than necessary, and diverting from medical waste containers. The diverters' need might escalate as dependence on the drug increases. To conceal the diversion, they might progress to different methods of diverting such as removing medication for a patient who has been discharged, removing a duplicate dose, inputting fictitious orders, and tampering with or substituting medication.

If a health system focuses its drug diversion program on reviewing overrides of automated dispensing cabinet transactions, for example, then no one will divert in overrides. But if no oversight exists for drug withdrawals for John/Jane Doe (unidentified) emergency department trauma patients, then that is probably where diversion will occur. Diverters are savvy—they learn which areas have oversight and divert in other areas that are lacking controls.

Resources not focused on highest risks

Facilities often rely on the same manual oversight processes

that have been in place for years. Even after implementing the latest closed-loop software, the manual oversight processes continue. For example, comparison reports for controlled substances transported between the pharmacy and nursing, anomalous usage reports, and inventory discrepancy reviews are typically manual and often consume a significant amount of a diversion program's resources.

Manual processes typically cover only the specific areas of technicians transferring to nursing floors, nurses using a lot of the same drug or having high volumes of withdrawals, and nurses outright stealing from automated dispensing machines. Unfortunately, dozens more methods exist for diversion.

Diversion gaps that often are ignored include a lack of standardized tracking and review protocols for inconsistent pain scales for drug administrations, increased titration of doses by specific nurses, overrides, and waste not documented. Even if some of these reviews are automated by diversion monitoring software, investigation of the software exceptions is critical.

If drug diversion software is not being used to its full capabilities, under-utilization can be similar to the diversion team being notified of a potential diversion but not responding. Drug diversion specialists might lack diversion investigation experience, which also can hinder necessary or effective action.

Drug diversion specialists should have a multifaceted focus on controlled substances recordkeeping compliance, regulations, internal controls and investigations. They should plan and execute efforts that go beyond policies, procedures and software reporting by incorporating all areas where controlled substances are stocked, accessed or used. Reviews in areas that have had longtime manual and effective controls might be reduced to random or intermittent reviews because employees are aware of the oversight and thus will look elsewhere to divert.

Lack of monitoring and follow-through processes

Once the right knowledge, mindset and focus are in place, the right processes need to be implemented to guide the program. Implementing the right processes is a critical step that should not be underestimated. Without proper direction

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and accountability, the knowledge, mindset and focus are not complete and fully supported.

Defining the ongoing monitoring procedures to be conducted should not be a one-time exercise. Diverters will adapt as new monitoring is put in place. Consequently, drug diversion specialists must continually assess the environment to determine risks and whether monitoring processes need to be updated or changed.

Follow-through processes need to be implemented and monitored:

- Expectations for nursing staff to review reports and conduct audits should be documented and tracked.
- A disciplinary escalation process should be in place if audits are not conducted timely or correctly.
- Tracking and trending of outliers should be ongoing to shed light on repeat situations or individuals.
- Multidisciplinary rounding of hospital departments for proper drug practices can keep the practices in the forefront of everyone's mind and allow for on-the-spot re-education and training.
- A diversion committee should be established with oversight and regular meetings to assist with follow-through and increased accountability.

Beyond a false sense of security

Drug diversion continues to plague healthcare providers across the country. Prevention and detection require considerable knowledge and expertise as well as constant learning. Healthcare systems might be working under a false sense of security created by having a drug diversion specialist, team or software. A drug diversion program requires so much more. Your internal audits are perhaps never more meaningful than when testing controls that keep patients and staff safe from harm and addiction. Drug diversion programs can save lives, especially when effectively managed and audited. **NP**



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In law a man is guilty when he violates the rights of others. In ethics he is guilty if he only thinks of doing so. - Immanuel Kant