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Drug Diversion Enforcement on the Rise…and an RX for Prevention

The general counsel fidgeted nervously with her pen as the hospital's Audit Committee Chair, CEO, and senior management team entered the conference room. It was a hastily called meeting, with the email indicating only that a critical issue needed to be discussed urgently. Certainly the experienced general counsel had dealt with False Claims and Stark Law allegations in the past without calling an "all hands on deck" meeting; but this was a matter which risked not only regulatory, but severe reputational harm and embarrassment for one of the country's leading academic medical centers. After everyone was seated, the general counsel described the issue that had recently come to light in bare terms; a significant quantity of the hospital's controlled substances inventory was "unaccounted for", the cause or source of the disappearance was unknown, and the DEA would need to be notified and would certainly investigate. In short, it's the type of meeting that no general counsel or organization wants to hold. While past investigations have focused on the role of individuals in drug diversion cases, future government enforcement activities will focus on the organization's responsibility for preventing drug diversion and related liability when it occurs. The good news is that there are a number of proactive steps that organizations can take to prevent or detect drug diversion.

Drug diversion

Drug diversion is the illegal distribution or abuse of prescription drugs or their use for unintended purposes. Drug diversion contributed to a fourfold increase in substance abuse treatment admissions from 1998 to 2008 for individuals ages 12 and over. Further, since 2009, more people in the United States have died each year from drug poisoning than from motor vehicle crashes.[1] Health care providers (e.g., hospitals) are one of the leading sources of diverted drugs, given the types and quantities of drugs purchased, and the multiple personnel routinely involved in the purchase and distribution of drugs. For these reasons and more, it's likely that the Drug Enforcement Administration (DEA) and other agencies will increase their enforcement activities in this area; not only to take guilty individuals to task, but to hold hospitals, nursing homes, pharmacies and other organizations that purchase and maintain drugs accountable for a lack of proper oversight and diligence when diversion in their facilities occurs.

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Drug diversion sources

Drugs can be diverted in multiple ways, including but not limited to:

- From automated dispensing systems.
- By substituting or changing medications provided to patients.
- Through theft of sample medications.
- By re-directing expired medications for use or distribution elsewhere.
- By altering or falsifying medical record documentation.
- By "wasting" of medications.
- By forged or counterfeit prescriptions.
- By diverting large drug quantities when they're purchased or during delivery and receipt.

1 CMS Medicare Learning Network: "*Medicaid Program Integrity — What is a Prescriber's Role in Preventing the Diversion of Prescription Drugs?*" — ICN 909010 March 2014

As the diversion of prescription drugs is — by necessity — a clandestine activity, it is incumbent that organizations take several steps to proactively detect and prevent drug diversion.

As the use of automated dispensing units ("ASDUs") increased over the past 25 to 30 years, many providers were lulled into a false sense of security that these devices prevented diversion, when in reality they no more prevent diversion than the "old days" of locked cabinets or drawers if access and use isn't carefully monitored.

Reasons for increased enforcement

The DEA's Office of Diversion Control oversees and investigates diversion matters, while federal (21 CFR, Part 1300) and state regulations (e.g., state pharmacy boards) govern the handling, security, and reporting requirements for controlled substances and potential diversion incidents. Along with more stringent penalties for false claims violations in the Accountable Care Act (ACA) (including the submission of false information related to the ordering or prescribing of prescription drugs), Office of Inspector General (OIG) investigations of drug diversion are on the rise. A contributing factor may be that this type of fraud can be lucrative. In Northern California, for example, OIG agents report that a bottle of 30mg Oxycodone tablets are trafficked at a price of $1,100–$2,400 a bottle, which is up to 12 times the normal price of a legally filled prescription.[2]

In addition, the proliferation of pain clinics has led to an increase in the illegal distribution of expired or counterfeit medications which are ultimately billed to Federal Health Care Programs (e.g., Medicare, Medicaid), thereby implicating the False Claims Act.

Drug diversion often involves criminal enterprises and networks. In addition to patients, providers, and pharmacies, these networks may include patient recruiters, money launderers, and street dealers and gangs. Some of these culprits have violent criminal histories, increasing the challenges and risks to law enforcement agents investigating these cases.[3] Combating these criminal enterprises and drug diversion has become a top law enforcement priority, and a major reason why there has been a 9% increase in the 2016 DEA budget devoted to Diversion Control.[4]

Proactive drug diversion detection and prevention

As the diversion of prescription drugs is — by necessity — a clandestine activity, it is incumbent that organizations take several steps to proactively detect and prevent drug diversion. These detection and prevention steps mirror the seven elements of an effective compliance program, including but not limited to:

- Training and education.
- Hotline reporting for suspected violations, including anonymous and confidential communication when needed.
- Job rotation and mandatory vacations for pharmacy purchasing managers.
- Electronic prescriptions for controlled substances.
- Developing written policies and procedures required by state and federal regulations for:
  - Policies and procedures on the wasting of controlled substances.
  - Policies and procedures on the destruction of expired drugs.
  - Discrepancy identification, reporting, investigation and resolution.
  - Ordering drugs from wholesalers and vendors.
  - Segregation of duties in the ordering, receipt, inventory, and storage process.
  - Receiving drugs from vendors.
  - Stocking drugs in the pharmacy vault and on floors/units.
- Reporting questionable transactions or events to an immediate supervisor and/or pharmacy director. For example:
  - An individual request by a physician for controlled substances.
- Properly securing and reconciling DEA-222 forms used for ordering Class II controlled substances.
- Reconciling drug orders to drug receipts to drug stocking.

2 https://oig.hhs.gov/newsroom/spotlight/2013/diversion.asp
3 Ibid
4 U.S. DEA FY 2016 Performance Budget Congressional Submission

- Securing the delivery process:
  - The wholesale vendor should deliver controlled substances directly to the pharmacy, where a pharmacist should sign a receipt and take delivery.
  - In addition, drugs should be delivered from the pharmacy to individual floors/ units in a secured manner.

- Limiting, securing and monitoring access to the pharmacy vault in which controlled substances are stored.

- Investigating and reviewing discrepancies on a timely basis. For example, staff working on a unit in which an unexplained discrepancy occurs may be asked to remain at the end of their shift until the discrepancy is appropriately resolved.

- Training and educating employees on the proper use of ASDUs.
  - Physical access to the units.
  - Use of system screens and software.

- Tracking key data produced by the ASDU system, including:
  - High frequency of discrepancies by certain individuals or service areas (including the pharmacy).
  - Higher than expected wasting.
  - Questionable transactions — Examples include higher than expected utilization of a controlled substance on a particular floor or unit. In certain instances, a review of related medical records may be needed to confirm both the physician order of the drug and the administration to the patient.

- Limiting the number of individuals with access to controlled substance ASDU bins.

- Limiting the number of personnel with "Super User" status in the ASDU system — these users have the ability to modify inventory counts, and add or delete users.

- Establishing more frequent and unscheduled inventory counts.
  - Although DEA regulations require physical inventory of controlled substances once every two years, consider increasing the cycle count frequency for selected drugs. For example, pharmacy personnel may wish to select a small number of controlled substances and/or high-cost drugs for weekly pharmacy inventory counts, while individual units should be prompted to count back and record beginning inventory when removing a controlled substance from the ASDU.

- Educating relevant employees on identifying, detecting and reporting potential drug diversion.

In addition, the recently enacted FDA Drug Supply Chain Security Act ("track and trace"), while established primarily to prevent distribution of harmful drug products, can also aid in the investigation of drug diversion by providing an "e-pedigree" which can be used to follow diverted drugs.[5]

While the analogy is not perfect, think of your drug dispensing units and inventory as "cash registers" of the corner store, in which you should be able to properly reconcile cash on hand at the beginning of the day (i.e., drug inventory), sales (i.e., proper drug disbursements), and the cash balance at the close of the business day. Proper auditing and monitoring activities can assist in preventing or detecting shoplifting or employees stealing money from the "cash register" (i.e., drug diversion).

Conclusion

With an increased DEA budget and heightened concerns regarding the type, amount and frequency of drugs being illegally distributed, drug diversion enforcement will likely increase, and organizations will be held liable along with the individuals involved. However, providers can take several steps to mitigate the risk of drug diversion in their facilities, and should strive to do so proactively before a problem occurs. As President Kennedy once said, "The time to repair the roof is when the sun is shining."

5 Daigle, Lisa — "*Following Pharmaceutical Products Through the Supply Chain*" — August 2012 American Society of Health-System Pharmacists (ASHP) Policy Analysis

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