

Methods, Trends and Solutions for Drug Diversion

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Introduction

Drug abuse in the United States has reached epidemic proportions. Drug overdoses are one of the leading causes of death for Americans under the age of 50. According to a 2017 study by the Centers for Disease Control and Prevention (CDC), overdoses killed approximately 64,000 people in the United States in 2016.¹ This represents an increase of more than 22 percent over the 52,404 drug deaths recorded in 2015. Almost 50,000 of those deaths were attributed to opioid drugs, including prescription opioids like OxyContin and Vicodin and synthetic opioids like fentanyl and heroin.²

Drug Diversion Overview

Drug diversion is the unlawful distribution or use of prescription drugs in any manner not intended by the prescriber. With an ever-growing population of drug abusers, demand for prescription drugs, and controlled substances in particular, is skyrocketing. Prescription drugs are valued by abusers because of their purity and uniform strength. Street values for many controlled substances are significantly higher than their retail value. In addition, pharmaceutical manufacturers continue to develop new specialty and lifestyle drugs, which often come with high retail prices. The financial gains from reselling these drugs make them attractive targets for diversion.

The drugs with the highest potential for drug diversion and abuse are controlled substances, which are classified as such by the U.S. Drug Enforcement Administration (DEA) based on their intended medical use as well as their potential for dependence or abuse. Drugs in this class include opioids, anabolic steroids, depressants, hallucinogens and stimulants.³ The public health consequences of drug diversion are significant. Drug diversion has contributed to the increase in drug-related hospitalizations, substance abuse admissions, and drug overdose deaths, which in turn contribute to rising medical and insurance costs. Diversion can also be a driver of disease outbreaks, as in cases of infected addicts spreading disease through the sharing of needles and other drug paraphernalia.

Methods for prescription drug diversion are varied. Patients become engaged in drug diversion by selling their legally obtained prescription drugs, “doctor shopping” by soliciting multiple physicians using false pretenses to receive prescriptions for controlled

¹ U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, *Vital Statistics Rapid Release, Provisional Drug Overdose Death Counts*, November 2017, <https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm>, (accessed December 15, 2017).

² Ibid.

³ U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, *What is a Prescriber's Role in Preventing the Diversion of Prescription Drugs?* January 2014, <https://www.cms.gov/medicare-medicare-coordination/fraud-prevention/medicaid-integrity-education/provider-education-toolkits/downloads/prescriber-role-drugdiversion.pdf> (accessed December 21, 2017).

substances, or altering a prescription to obtain an unlawful quantity of a controlled substance. Diversion also occurs when prescription pads are stolen or forged in order to obtain drugs fraudulently. Physicians and other providers can become actively involved in drug diversion by operating pain clinics, or “pill mills,” and intentionally prescribing unnecessary medications or prescribing larger quantities than is medically necessary.

Consequences of Drug Diversion in Hospitals

In healthcare settings, prescription drugs can be diverted at any point along the supply chain as they are moved from manufacturers to distributors to pharmacies to hospitals and other healthcare organizations, and finally to the patient. Hospitals are at high risk for drug diversion, because of the ready access to prescription drugs in these facilities.⁴ Most diversions of drugs occur in outpatient settings, where the majority of prescription drugs are used. The most common drugs diverted from healthcare facilities are opioids.⁵

Addiction is the primary cause of controlled substance diversion among healthcare professionals.⁶ Professions with easy access to controlled substances, such as anesthesiology and nursing, have higher rates of addiction. For example, the American Nurses Association has estimated that one in 10 nurses is struggling with drug or alcohol addiction.⁷ Methods used by healthcare workers to divert controlled substances include theft of vials or syringes, under-dosing patients, taking waste for personal use, raiding sharps disposal containers, and tampering with patient medications by replacing controlled substances with another product, such as saline.

Hospital workers who divert drugs for personal use are a significant threat to patient safety. Impaired practitioners put patients at risk of harm as a result of diminished judgment and slower reaction time. Diversion can also result in patients receiving lower doses of needed pain medications. Tampering with injectable medications can expose patients to bloodborne pathogens or to other unsafe substances.⁸ In one case in 2016, 16 patients in two hospitals became infected with hepatitis C after a nurse diverted drugs

⁴ Gregory Burger and Maureen Burger, *Drug Diversion: New Approaches to an Old Problem*, *Am J Pharm Benefits*, 2016; 8(1):30-33, http://www.ajpb.com/journals/ajpb/2016/ajpb_januaryfebruary2016/drug-diversion-new-approaches-to-an-old-problem (accessed January 24, 2018).

⁵ Keith Berge, et al., *Diversion of Drugs Within Health Care Facilities, A Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention*, *Mayo Clin Proc.* 2012 Jul; 87(7): 674-682, July 2012, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3538481/> (accessed December 20, 2017).

⁶ Barry Abramowitz, *Drug Diversion in Healthcare*, *The Journal of Global Drug Policy and Practice*, Vol. 8, Issue IV, Winter 2014, http://www.globaldrugpolicy.org/Issues/Vol%208%20Issue%204/Drug%20Diversion%20in%20Healthcare_Commentary.pdf (accessed December 17, 2017).

⁷ Mary Ann B. Copp, “Drug Addiction Among Nurses: Confronting a Quiet Epidemic,” *Modern Medicine*, April 2009, <http://www.modernmedicine.com/modern-medicine/news/modernmedicine/modern-medicine-feature-articles/drug-addiction-among-nurses-con?page=full> (accessed January 14, 2018).

⁸ U.S. Department of Health and Human Services, Kimberly New, *Drug Diversion in Health Care Settings Can Put Patients at Risk for Viral Hepatitis*, May 2014, <https://www.hhs.gov/hepatitis/blog/2014/05/02/drug-diversion-in-health-care-settings-can-put-patients-at-risk-for-viral-hepatitis.html> (accessed December 22, 2017).

for personal use and then used the same needles as the patients.⁹ When a patient is harmed as a result of drug diversion by a hospital worker, a lawsuit may be filed against the hospital, which can result in substantial liability and/or consequences.

Hospitals found to have inadequate controls in place are at risk for both criminal and civil penalties. Several recent cases have resulted in multimillion dollar settlements. In 2015, Massachusetts General Hospital agreed to pay \$2.3 million to settle allegations that lax controls enabled hospital employees to divert controlled substances for personal use.¹⁰ More recently, a California health system paid \$2.42 million to settle claims that three of its facilities violated the Controlled Substances Act. In that case, the system for distributing controlled substances between the three hospitals failed to provide sufficient security controls to prevent diversion.¹¹

Hospital workers who divert drugs risk harming themselves and their professions. Substance abusers may suffer from physical and mental ailments, and their involvement in diversion puts them at risk of addiction, exposure to communicable diseases, overdose, and even death. They risk the loss of their job or their provider license, and may face state or federal prosecution as well as civil malpractice actions. Drug diversion also harms the reputation of the medical profession, especially when patient safety is compromised. Coworkers, meanwhile, may be exposed to uncapped contaminated needles, broken glass vials, and other risks created by the drug abuser.¹²

Regulatory Framework

All prescription products in the United States are subject to federal and state regulation. Controlled substances are more heavily regulated due to their higher potential for addiction and abuse. Unlawful possession or distribution of drugs can result in criminal prosecution.

Controlled Substances Act

The Controlled Substances Act (CSA) has been the primary federal drug law regulating the manufacture and distribution of controlled substances since 1970. The CSA requires every person who orders, handles, stores or distributes controlled substances to be

⁹ Shenefelt, Mark, “Investigators: 16 hepatitis C cases identified at McKay-Dee and Davis Hospitals,” Standard Examiner, April 4, 2016, <http://www.standard.net/News/2016/04/04/State-announces-results-of-hepatitis-C-investigation.html>, (accessed January 25, 2018).

¹⁰ U.S. Department of Justice, U.S. Attorney’s Office, District of Massachusetts, *MGH to Pay \$2.3 Million to Resolve Drug Diversion Allegations*, September 28, 2015, <https://www.justice.gov/usao-ma/pr/mgh-pay-23-million-resolve-drug-diversion-allegations> (accessed January 5, 2018).

¹¹ U.S. Department of Justice, U.S. Attorney’s Office, Eastern District of California, *Rideout Health to Pay Civil Monetary Penalties to Resolve Controlled Substances Act Claims*, December 6, 2016, <https://www.justice.gov/usao-edca/pr/rideout-health-pay-civil-monetary-penalties-resolve-controlled-substance-act-claims> (accessed January 5, 2018).

¹² Keith Berge, et al., *Diversion of Drugs Within Health Care Facilities, A Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention*, Mayo Clin Proc. 2012 Jul; 87(7); 674-682, July 2012.

registered with the DEA in order to perform these functions. Registrants must maintain accurate inventories and records, and must have specific security controls and operating procedures in place to guard against theft and diversion.¹³ In addition, the CSA requires that all prescriptions for controlled substances be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of medical practice.¹⁴ Registrants must have a system in place to identify suspicious orders of controlled substances.¹⁵

The CSA categorizes drugs into one of five schedules (I-V), based on each drug's medical use and its potential for abuse or dependency. The most harmful substances are placed in Schedule I, and the rest appear in descending order accordingly. Examples of drugs included in each schedule are:

- Schedule I: heroin, ecstasy, LSD, marijuana
- Schedule II: morphine, cocaine, methamphetamine
- Schedule III: Vicodin, anabolic steroids
- Schedule IV: Ambien, Soma, Valium
- Schedule V: Lyrica, cough suppressants¹⁶

Both the DEA and the Food and Drug Administration (FDA) have authority to add or remove drugs from the different schedules. The CSA's system of schedules makes it easier for state legislatures to enact criminal drug statutes by referencing the schedules rather than listing all substances subject to the law. It also makes it easier to update drug laws all at once, since individual drugs can be added or removed from the schedules as necessary without the need to amend all other drug laws.

The DEA is the enforcement arm of the CSA. The agency is responsible for ensuring that registrants comply with the recordkeeping, security and storage requirements of the CSA. DEA investigators use recordkeeping systems to help identify suspicious movements of controlled substances. The DEA frequently acts on leads from pharmacists, prescribers, patients and members of the public. It also works closely with the FDA, as well as state and local law enforcement, on task forces to stop drug trafficking and drug violence.

Individuals who violate the CSA may be subject to criminal, civil and administrative penalties. Criminal penalties can include prison sentences and fines. Persons involved in diverting controlled substances may also be subject to civil fines or forfeiture actions on the proceeds obtained from the unlawful sale of the drugs. Administrative penalties may include suspension or revocation of DEA registration.

¹³ 21 CFR 1301.71(a)

¹⁴ 21 CFR 1306.04(a)

¹⁵ 21 CFR 1301.74(b)

¹⁶ U.S. Department of Justice, Drug Enforcement Administration, *Drug Scheduling*, <https://www.dea.gov/druginfo/ds.shtml>, (accessed December 29, 2017).

Patient Protection and Affordable Care Act

The Patient Protection and Affordable Care Act (ACA) contains several provisions that address the opioid epidemic and drug diversion. The ACA created stronger penalties for submitting false claims or knowingly false information related to the ordering of prescription drugs. It requires state Medicaid agencies to suspend payments to physicians and other providers when there is credible evidence of fraud. In addition, if providers are terminated for cause by Medicare or any state Medicaid agency, they must also be terminated by Medicaid and the Children's Health Insurance Program (CHIP) in all states.¹⁷

In addition, the ACA improved mental health care and made drug addiction treatment more accessible by requiring addiction treatment to be covered by health insurance policies. It also mandated that addiction coverage be on par with treatments for other chronic diseases. The ACA expanded prescription drug coverage for eligible Medicare and Medicaid patients. According to the U.S. Department of Health and Human Services, the number of uninsured patients seeking care for addiction has declined since the enactment of the ACA. In states that expanded Medicaid under the ACA, the number of uninsured hospitalizations for substance abuse and mental health disorders dropped from 20 percent in 2013 to about 5 percent in 2015.¹⁸

State Regulations

Possession or distribution of illegal drugs is a crime under state laws and most municipalities. In most states, it is a felony to attempt to divert drugs by misrepresentation, fraud, forgery or deception. Drug convictions can result in heavy fines and/or prison sentences. Providers may also have their licenses suspended. The severity of the penalties typically depends on the drug's schedule, the quantity of drugs involved, and whether the offender has previous convictions for similar crimes.

Hospital Drug Diversion Programs

Drug diversion is an ongoing problem for hospitals that can threaten patient safety and create significant liability. An effective program to prevent drug diversion includes safeguards to reduce the ability of employees to divert prescription drugs, as well as appropriate systems for detecting such activity and dealing with workers who are addicted to prescription drugs. A comprehensive plan incorporates all of the disciplines where employees can come into contact with prescription drugs, not just the pharmacy. This

¹⁷ U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, *What is a Prescriber's Role in Preventing the Diversion of Prescription Drugs?* January 2014.

¹⁸ U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Continuing Progress on the Opioid Epidemic: The Role of the Affordable Care Act*, January 11, 2017, <https://aspe.hhs.gov/pdf-report/continuing-progress-opioid-epidemic-role-affordable-care-act> (accessed December 28, 2017).

would include the medical staff, nursing, human resources, legal and regulatory compliance, and security.¹⁹

Hospital leadership should review its drug diversion program regularly. A comprehensive risk assessment can help hospitals identify areas where there may be a breakdown in policies and procedures, or areas where monitoring, controls and security may need to be strengthened. A thorough review of controlled substances and the drug inventory process can help identify gaps in the dispensing and administering of controlled substances to patients and can develop solutions. Security managers have an important role to play in preventing and reducing drug diversion, and should work with hospital management to identify gaps in security and controls, and ensure the effectiveness of the diversion program.

Policies and Procedures

Hospitals must have policies and procedures in place to control access to prescription drugs and minimize the opportunities for diversion. Written policies should regulate all aspects of the purchase, storage and dispensing of controlled substances. It is important for there to be a clear division of duties in procurement, stocking and dispensing. Invoices must be carefully reviewed to ensure consistency between what is ordered, signed for and received into stock. Staff should be required to verify dispensing and receipt of controlled substances, and there should be a clear chain of custody throughout the dispensing process. Review and restocking of returns should be done by two staff members.

Hospitals also need procedures regarding the handling, storage, and disposal of controlled substance pharmaceutical waste, and disposal must comply with federal, state and local laws. Some of these procedures might include:

- Hospital staff should be monitored when disposing of controlled substances.
- Pharmaceutical waste containers should be attached to a wall with small openings so devices and waste cannot be easily retrieved.
- Access to waste containers should be limited to only a few staff members.
- Security patrols should include regular monitoring of areas where pharmaceutical waste containers are located.

¹⁹ Keith Berge, et. al., *Diversion of Drugs Within Health Care Facilities, A Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention*, Mayo Clin Proc. 2012 Jul; 87(7):674-682.

Audits

Internal audits play a vital role in identifying and preventing diversion, especially in high-risk areas such as pharmacies and procedural areas. This includes inventory management of controlled substances, daily audits of controlled substance data, and concurrent review of medical records. Prescription auditing software is an important tool for examining usage trends and activities by individual staff. Audits should be conducted by two or more individuals so that analyses are not limited to a single perspective and gaps in monitoring resulting from staffing changes can be avoided.²⁰

Physical Controls

Hospitals use numerous physical controls to prevent unauthorized access to controlled substances, including storing the drugs in locked cabinets and pharmacy vaults. Security personnel play an important role in monitoring these areas. Hospitals should also require regular counts of controlled substances and documentation when removing them from storage locations.

Automated dispensing cabinets (ADCs) are used in most hospitals to improve patient safety, inventory management and medication security. ADCs are computerized and store and dispense controlled substances near the point of care. They are a useful tool for monitoring and restricting access to controlled substances. ADCs track user access and can provide real-time drug inventory reports.

Security and Monitoring

Hospitals need strong security measures and close monitoring of all employees with access to controlled substances. Controlled substances must be secured, whether in the pharmacy or in procedural areas, operating rooms, or anesthesia work areas. Cameras should be placed in all areas where controlled substances are stored or accessed and at all entry points. Surveillance video should be readily available to investigators and security personnel whenever a diversion incident is suspected.

Education and Training

Hospitals should have education and training programs in place to educate staff on drug addiction and the dangers of substance abuse. Hospital staff need to be made aware of the risk of controlled substance diversion and the resulting threats to patients and the hospital. Staff should receive regular training on all hospital policies and procedures to reduce diversion, including steps they should follow when diversion is suspected.

Healthcare professionals have an ethical duty to protect patients by reporting impaired professionals. An effective training program can help hospital staff to recognize when a colleague may have a drug problem. Signs of addiction may be difficult to detect, but they

²⁰ Gregory Burger and Maureen Burger, *Drug Diversion: New Approaches to an Old Problem*, Am J Pharm Benefits, 2016; 8(1):30-33.

can include reduced productivity or missed work days, changes in personal appearance, mood swings or irritability, and complaints from patients of ineffective pain medications. Creating a culture of safety and accountability can help make staff feel more comfortable with recognizing the potential warning signs of drug diversion and reporting any behaviors of concern to the proper authority.

Human Resources

The human resources function plays an important role in reducing the risk of drug diversion. Criminal and financial background checks can help a hospital assess the likelihood that a prospective employee may become a drug diverter. Pre-employment screening should include questions about whether the candidate has ever been disciplined or terminated because of drug diversion or other mishandling of controlled substances.²¹ Regular drug testing of employees with access to prescription drugs, combined with supervisor awareness of warning signs, are also helpful in detecting employees with a drug problem.

Prescriber and Pharmacist Practices

Prescribers can play an important role at the front end to prevent drug addiction and drug diversion. Clinical protocols regarding pain management can help reduce the overall number of controlled substance prescriptions.²² Prescriber guidelines prepared by the CDC recommend against the use of opioids as first-line or routine therapy for chronic pain. Instead, providers should start with alternative therapies, such as anti-inflammatories and muscle relaxers, to help patients relax and ease their pain. When opioid treatment is started, providers should begin with lower doses of immediate-release opioids, prescribe no more than what is needed for acute pain, and regularly follow up with patients to reevaluate the risk of harm.²³

Pharmacists also play a vital role in combatting drug addiction and diversion. When a prescription is presented by a patient or doctor's office, a pharmacist is not obligated to fill it.²⁴ The pharmacist first has the responsibility under the CSA to ensure that the prescription is legitimate.²⁵ The DEA has identified numerous red flags for potential diversion, including:

²¹ 21 CFR 1301.90

²² U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services, *What is a Prescriber's Role in Preventing the Diversion of Prescription Drugs?*, January 2014.

²³ U.S. Department of Health and Human Services, Centers for Disease Control & Prevention, National Center for Injury Prevention and Control, *CDC Guideline for Prescribing Opioids for Chronic Pain*, CDC Morbidity & Mortality Weekly Report, March 15, 2016, www.cdc.gov/drugoverdose/prescribing/guideline.html (accessed December 15, 2017)

²⁴ U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control, *DEA Trends and Update, August 13, 2017*, https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/conf_2017/aug13_2017/carrion.pdf (accessed January 25, 2018).

²⁵ 21 CFR 1306.04(a)

- Numerous customers receiving the same combination or strength of prescriptions
- Many customers paying cash for their prescriptions
- Many customers with the same diagnosis codes written on their prescriptions
- Individuals driving long distances to visit physicians and/or fill prescriptions
- Customers coming to the pharmacy in groups to fill the same prescriptions written by the same physician
- Prescriptions for controlled substances written by physicians not associated with pain management²⁶

Hospital Responses to Suspected Drug Diversion

Hospitals should have a clear plan in place to respond to suspected drug diversion or discrepancies in controlled substance inventory. Many hospitals have a centralized diversion response team with well-defined roles that include investigations, communications and reporting. Each suspected drug diversion incident must be thoroughly investigated to determine if federal or state regulations have been violated and if the healthcare worker has committed a crime.

The organization must also determine whether its own internal policies and procedures were violated. The employee may be required to undergo a drug screen and may be suspended pending the conclusion of the investigation. If diversion is confirmed, the hospital must assess the seriousness of the employee's violation, the position of responsibility held by the employee, the employee's record of employment, and other relevant factors in determining whether to suspend, transfer, terminate or take other action against the employee.²⁷

The hospital must report drug diversion incidents to all relevant federal and state agencies. The DEA must be notified immediately in the event of the theft or significant loss of a controlled substance. State laws vary, but reporting is mandatory in a majority of states. Often, reporting is made to the state Board of Medicine, Board of Pharmacy or other state regulatory body.²⁸ The DEA also recommends that hospitals immediately notify local law enforcement, since missing controlled substances might be disseminated in the community.²⁹

²⁶ 21 CFR 1306.04(a)

²⁷ 21 CFR 1301.92

²⁸ National Alliance for Model State Drugs, *State Laws/Regulations Requiring Hospitals, Nursing Homes, and Pharmacies to Report the Theft or Loss of Controlled Substances*, April 4, 2016, <http://www.namsdl.org/library/A6E61ABB-F923-A510-F44FA458B898567B/> (accessed January 22, 2018).

²⁹ U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control, *DEA Trends and Update*, August 13, 2017.

Conclusion

Drug diversion is a significant issue for hospitals, and the problem is growing as rates of drug abuse and addiction rise nationally. Drug diversion raises the risk of harm to patients and can result in increased regulatory scrutiny of healthcare facilities and workers. Hospitals also face potential liability and negative publicity if a patient is harmed by an impaired employee. To prevent drug diversion, hospitals should have a comprehensive drug diversion program that has full cooperation and support from all relevant disciplines. Security leadership plays an important role in working with hospital administration to ensure the effectiveness of the program.

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