DRUG DIVERSION IN HEALTH CARE

JUNE 2023

Drug diversion is defined as "any criminal act or deviation that removes a prescription drug from its intended path from the manufacturer to the patient."¹ While drug diversion can occur in a variety of settings and be committed by anyone, it is particularly likely to occur in healthcare settings by healthcare workers due to the ease in which they can access prescription drugs.² Drug diversion in health care is a serious issue that can result in patient harm, financial loss to the healthcare entity, and civil and criminal litigation based on the perpetrator's actions.

HOW DRUG DIVERSION IN HEALTH CARE OCCURS

Some researchers estimate that as many as 10 to 15 percent of all healthcare workers divert drugs at least once in their careers.³ In general, medications diverted from healthcare settings are used to support the use (or misuse) of the drug by the healthcare worker or, less frequently, resold to a third party for financial gain. Because of the availability of, and access to, medications inside of healthcare organizations, prescription drug diversion by healthcare workers can be difficult to detect. In fact, experts believe that only a fraction of individuals who divert drugs in healthcare settings are ever caught. It is often not until patient harm occurs that the diversion is discovered.

While any medication is at risk of being diverted, certain drugs are more commonly diverted than others. These medications include anti-anxiety drugs and sedatives, pain pills, stimulants, sleep aids, and anesthetics. Fentanyl is the most diverted drug in the healthcare setting. A healthcare worker can divert drugs through several mechanisms: (1) false documentation (*e.g.*, stating in a patient's medical record that the worker gave the patient the drug without doing so, or falsely listing a medication as wasted); (2) scavenging wasted medication (*e.g.*, removing residual medication from used syringes or the trash); or (3) theft by tampering (*e.g.*, substituting or diluting medication with a similar looking substance, such as saline). Signs that a healthcare worker may be diverting drugs include: (1) delays between the time the worker obtains a drug from the pharmacy or automated dispensing cabinet (ADC) and the time the worker administers it to the patient; (2) frequent ADC overrides or irregular ADC reports; and (3) wasting large amounts of drugs or not properly documenting drug waste.⁴ Patients reporting high pain scores or complaining of pain after being administered pain medication may also be a sign of drug diversion by workers.

Drug diversion in the healthcare setting can harm patients in a variety of ways. Patients may receive poor quality of care from an impaired healthcare worker. The impairment could be in the form of the healthcare worker being acutely intoxicated, or alternatively, being distracted about obtaining the next dose. Moreover, drug diversion can lead to patients not receiving essential medications, which can result in pain and suffering. In November 2021, seven former patients of the Yale University Reproductive Endocrinology and Infertility clinic (REI clinic) sued Yale

¹ "Healthcare-Associated Infections (HAI) Drug Diversion Planning and Response Toolkit for State and Local Health Departments," *Council of State and Territorial Epidemiologists*, June 2019, 9,

https://cdn.ymaws.com/www.cste.org/resource/resmgr/pdfs/pdfs2/Drug_Diversion_Toolkit_LiveL.pdf.

 $^{^{2}}$ The term "healthcare worker" in this factsheet encompasses both clinical (*e.g.*, physicians, nurses, pharmacists, and allied health professionals.) and non-clinical (*e.g.*, environmental, administrative, or technical) staff. Drug diversion in health care settings is not limited to clinical staff.

³ "Questions about Drug Diversion," HealthcareDiversion.org, accessed December 9, 2022, <u>https://healthcarediversion.org/faq/</u>.

⁴ An automated dispensing cabinet (ADC) is a locked medication cabinet that allows a healthcare worker to obtain prescription drugs only after inputting a unique user identification code. The ADC provides the worker with only the drugs requested and each transaction is electronically recorded. *See* Wu Yi Zheng, et al., "The Impact of Introducing Automated Dispensing Cabinets, Barcode Medication Administration, And Closed-Loop Electronic Medication Management Systems on Work Processes and Safety of Controlled Medications In Hospitals: A Systematic Review," *Research in Social and Administrative Pharmacy* 17, no. 5 (May 2021): 833, https://doi.org/10.1016/j.sapharm.2020.08.001.

University in state court after allegedly undergoing painful surgeries and procedures with little to no analgesic due to drug diversion by a nurse.⁵ The nurse stole fentanyl from the REI clinic for her own use and admitted in her criminal case that she used a syringe to withdraw fentanyl from vials and then reinjected saline to cover up the tampering.⁶

Another way patients can be harmed by drug diversion is exposure to infectious agents. A worker's tampering of injectable medications may place a patient at risk for infection because the worker substitutes unsterile substances, such as tap water, for a sterile drug or by the worker exposing the patient to used syringes. The latter can directly expose a patient to HIV and the hepatitis B and C viruses. Exposure to bacterial pathogens can lead to sepsis and, in some cases, death. This results in increased healthcare costs due to the need for longer hospital stays and additional treatments. The U.S. Centers for Disease Control and Prevention has a <u>webpage</u> listing U.S. outbreaks associated with drug diversion by healthcare workers between 1983 to 2018. In some years, the number of cases associated with such outbreaks exceeds 40.

LAWS AND REGULATIONS RELATED TO DRUG DIVERSION

Healthcare facilities and workers must comply with several federal laws and regulations pertaining to drug diversion. The 1983 Federal Anti-tampering Act (Anti-tampering Act) provides that "[w]hoever, with reckless disregard for the risk that another person will be placed in danger of death or bodily injury and under circumstances manifesting extreme indifference to such risk, tampers with any consumer product that affects interstate or foreign commerce, or the labeling of, or container for, any such product, or attempts to do so" will be fined and/or imprisoned.⁷ The statute's definition of "consumer product" includes food, drugs, medical devices, and cosmetics as defined by the Federal Food, Drug, and Cosmetic Act.⁸ In 2021, a court sentenced Donna Monticone, the nurse from the REI clinic example above, to three years of supervised release, four weekends of incarceration, and three months of home confinement after she pleaded guilty to a one count violation of the Anti-tampering Act.⁹

Per a federal regulation pertaining to manufacturers, distributors, and dispensers of controlled substances, employees "who possess, sell, use, or divert controlled substances will subject themselves not only to state or federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment."¹⁰ Additionally, the U.S. Drug Enforcement Administration (DEA) notes that its "position [is] that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer."¹¹ The failure of an employee to report knowledge of a co-worker's drug diversion to an employer can jeopardize his or her continued employment in a drug security area.¹²

As a condition of participation in Medicare and Medicaid, the Centers for Medicare and Medicaid Services requires a hospital to report abuses and losses of controlled substances—in accordance with applicable federal and state laws—to the individual responsible for pharmaceutical services at the hospital and the chief executive officer.¹³ The failure of a hospital to properly detect and report drug diversion could jeopardize its participation in Medicare and Medicaid. A jurisdiction may have specific laws and rules that regulate the reporting of drug diversion in healthcare settings. For example, North Carolina law states that "[e]very licensee has a duty to report in writing to the [state Medical] Board within 30 days any incidents that [the] licensee reasonably believes to have occurred involving . . . fraudulent

⁵ *Melissa Cowan, et al. v. Yale University*, Connecticut Superior Court, Judicial District of Waterbury, Case No. UWY-CV21-6063194-S (suit filed November 17, 2021).

⁶ Id.

⁷ 18 U.S.C. § 1365(a) (2023).

⁸ Id.; 21 U.S.C. § 321 (2023).

⁹ "Former Nurse Sentenced for Tampering with Fentanyl Vials Intended for Patients at Fertility Clinic," The United States Attorney's Office, District of Connecticut, May 25, 2021, <u>https://www.justice.gov/usao-ct/pr/former-nurse-sentenced-tampering-fentanyl-vials-intended-patients-fertility-clinic</u>.

¹⁰ 21 C.F.R. § 1301.92 (2023).

¹¹ 21 C.F.R. § 1301.91 (2023).

¹² *Id.*

¹³ 42 C.F.R. § 482.25(b)(7) (2023).

prescribing, drug diversion, or theft of any controlled substances by another person licensed by the [Medical] Board."¹⁴ Additionally, in Utah "[a]n individual is guilty of a class B misdemeanor if the individual: (1) knows that a practitioner is involved in diversion; and (2) knowingly fails to report the diversion to a peace officer or law enforcement agency."¹⁵

Simply put, drug diversion in healthcare settings places healthcare facilities and workers at legal and financial risk. Healthcare facilities face civil litigation, fines, loss of eligibility for Medicare and Medicaid reimbursement, and loss of public trust. Healthcare workers who divert substances put themselves at risk for criminal prosecution, civil malpractice suits, and administrative discipline, including the loss of their professional license(s).

HOW TO PREVENT DRUG DIVERSION

All healthcare facilities should have policies and procedures in place to deter drug diversion and identify drug diversion and intervene when it occurs. Such policies and procedures should be comprehensive and created through collaboration between multiple stakeholders, including healthcare staff, pharmacy services, safety and security personnel, legal counsel, human resources, and industry loss-prevention experts. Requiring periodic counts of medication inventory and implementing monitoring systems can help deter drug diversion and identify suspect behaviors, such as workers sharing ADC passwords or IDs, pocketing medications, and removing used medications from sharps and waste containers. Policies should also address the length of time between when a healthcare worker obtains a medication from the pharmacy or ADC and administers that medication; under what circumstances a complete dose of a medication can be discarded; and how soon any leftover medication should be disposed of after a dose is administered to a patient.

The DEA considers pre-employment screening vital in assessing the likelihood of an employee committing a drug security breach.¹⁶ Therefore, healthcare facilities should conduct pre-employment screening on all new hires. The DEA recommends that such screening include: (1) a criminal background check; (2) verification of licenses, if applicable; (3) drug screening; and (4) a written, signed response to the question "have you ever been disciplined, terminated, allowed to resign, or denied employment because of mishandling a controlled substance or a drug diversion issue?" Healthcare facilities should also advocate for state laws that provide immunity to employers of healthcare workers when they share potentially negative information about a former employee as part of the employment vetting process. For example, Maryland has a law that provides immunity to an employer who, acting in good faith, discloses any information about the job performance or the reason for employment termination of an employee or former employee to a prospective employer or if requested or required by a federal, state, or industry regulatory authority.¹⁷ Additionally, Colorado law states that "[i]n response to a request by a prospective or current employer of a healthcare worker, it is neither unlawful nor a violation of the prohibitions against blacklisting for an employer, when acting in good faith, to disclose information known about any involvement in drug diversion, drug tampering, patient abuse, violation of drug or alcohol policies of the employer, or crimes of violence by the healthcare worker who is an employee or a former employee of the responding employer."¹⁸ These types of laws can help prevent employers from hiring an individual previously terminated for suspicion of drug diversion at another facility.

¹⁴ N.C. GEN. STAT. ANN. § 90-5.4 (West 2022).

¹⁵ UTAH CODE ANN. § 76-10-2204 (West 2023). The law defines "practitioner" as an individual: (1) licensed, registered, or otherwise authorized by the appropriate jurisdiction to administer, dispense, distribute, or prescribe a drug in the course of professional practice; or (2) employed by a person who is licensed, registered, or otherwise authorized by the appropriate jurisdiction to administer, dispense, distribute, or prescribe a drug in the course of professional practice; or prescribe a drug in the course of professional practice or standard operations.

¹⁶ 21 C.F.R. § 1301.90 (2022).

¹⁷ MD. CODE ANN., CTS. & JUD. PROC. § 5-423 (West 2022).

¹⁸ COLO. REV. STAT. ANN. § 8-2-111.6 (West 2023).

Drug diversion in healthcare settings is an issue that can harm patients, healthcare facilities and workers, and the public in a variety of ways. When drug diversion is suspected within a healthcare facility, it is important for staff to promptly report concerns, assess the potential harm to patients, and collaborate with relevant internal and external stakeholders. Drug diversion can only be detected, however, when proper controls are in place. Comprehensive policies and procedures can help to ensure compliance with federal and state laws and regulations and prevent patient harm.

RESOURCES

https://healthcarediversion.org/.

"Healthcare-Associated Infections (HAI) Drug Diversion Planning and Response Toolkit for State and Local Health Departments," *Council of State and Territorial Epidemiologists*, June 2019, <u>https://cdn.ymaws.com/www.cste.org/resource/resmgr/pdfs/pdfs2/Drug_Diversion_Toolkit_LiveL.pdf</u>.

Berge, Keith H., et al. "Diversion of Drugs Within Health Care Facilities, a Multiple-Victim Crime: Patterns of Diversion, Scope, Consequences, Detection, and Prevention," *Mayo Clinic Proceedings* 87, no. 7 (July 2012): 674-682, https://doi.org/10.1016/j.mayocp.2012.03.013.

Nyhus, Julie. "Drug Diversion in Healthcare: Prevention and Detection for Nurses," *American Nurse Journal* 15, no. 5 (May 2021): 26-30, <u>https://www.ismp.org/sites/default/files/attachments/2021-05/an5-Drug%20Diversion-406a%20%282%29.pdf</u>.

The Joint Commission. "Drug Diversion and Impaired Health Care Workers." *Quick Safety* 48 (April 2019), <u>https://www.jointcommission.org/-/media/tjc/newsletters/quick_safety_drug_diversion_final2pdf.pdf</u>.

ABOUT LEGISLATIVE ANALYSIS AND PUBLIC POLICY ASSOCIATION

The Legislative Analysis and Public Policy Association (LAPPA) is a 501(c)(3) nonprofit organization whose mission is to conduct legal and legislative research and analysis and draft legislation on effective law and policy in the areas of public safety and health, substance use disorders, and the criminal justice system.

LAPPA produces timely model laws and policies that can be used by national, state, and local public health, public safety, and substance use disorder practitioners who want the latest comprehensive information on law and policy as well as up-to-the-minute comparative analyses, publications, educational brochures, and other tools ranging from podcasts to fact sheets. Examples of topics on which LAPPA has assisted stakeholders include law enforcement/community engagement, naloxone laws, alternatives to incarceration for those with substance use disorders, medication for addiction treatment in correctional settings, and the involuntary commitment and guardianship of individuals with alcohol or substance use disorders.

For more information about LAPPA, please visit: https://legislativeanalysis.org/.

© Legislative Analysis and Public Policy Association – This project is funded by a grant from the Office of National Drug Control Policy. Neither the Office of National Drug Control Policy, nor any other federal instrumentality operate, control, or are responsible for, or necessarily endorse this project.