

DRUG DIVERSION PREVENTION

in Healthcare



Kimberly New, BSN, JD, RN

Drug Diversion in Healthcare

Kimberly New, BSN, JD, RN

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About the Author

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Kimberly New, BSN, JD, RN is a consultant to healthcare institutions on the subject of drug security and diversion. She is the founder and principal consultant of Diversion Specialists, a firm that specializes in the prevention, detection, and response to drug diversion by healthcare personnel. New advises institutions on issues of controlled substance security and Drug Enforcement Administration regulatory compliance and helps healthcare facilities set up and expand their drug diversion programs with the goal of protecting patients, staff, and facilities from the harm frequently associated with diversion. She is a nurse and an attorney, with extensive clinical experience as a nurse as well as many years of experience as a healthcare lawyer. She has also worked as a compliance officer at both a large long-term care company and an academic medical center.

New is a frequent author and national speaker on the subject of health facility diversion. She is the executive director of the International Health Facility Diversion Association. New has been featured in *USA Today* and *The Wall Street Journal* and has served as a guest author for the Centers for Disease Control and Prevention Safe Healthcare and Department of Health and Human Services aids.gov blogs.

Preface

Drug diversion by healthcare personnel is a pervasive problem. All healthcare facilities, clinics, and offices that use controlled substances face this issue at one time or another. Unfortunately, there are few resources available to assist facilities in addressing diversion. This book is a guide for healthcare institutions seeking to build or improve their diversion programs or those dealing with discoveries related to diversion.

Every institution is vulnerable to diversion and must have a robust program to address it. While isolated practices to prevent and detect diversion, such as end-of-shift counts, have been used for many years, attention has focused recently on the need to have more elaborate programs involving a multidisciplinary effort to address more subtle tactics used by diverters. Regulatory agencies have increasingly stringent requirements for the structure and content of programs; settlements between the Drug Enforcement Administration and institutions investigated for diversion generally include a requirement that the institution's diversion program be altered to conform to a defined set of criteria.

Although many institutions undertake isolated efforts to develop a diversion program, my experience suggests that a comprehensive and adequate program is present at a minority of facilities. Obstacles to the implementation of an adequate program include a lack of support from executives, a lack of resources, a lack of understanding of the risks, a lack of necessary expertise, and a fear of negative publicity or regulatory scrutiny that might result from the discovery of diversion.

Insufficient attention to diversion is not confined to one type of institution. Facilities ranging from critical access hospitals and long-term care facilities to large and prestigious academic medical centers have been penalized for inadequate diversion controls within the past decade.

Chapter 1

Introduction to Drug Diversion

Diversion is the theft of drugs. Most diversion is of controlled drugs, so when the term is used, it is often understood to refer to theft of controlled substances; but not all diverted drugs nor all abused drugs are controlled substances. This book deals chiefly with diversion of controlled drugs, but many of the principles apply to theft of other drugs as well.

A number of diversion-related requirements exist with which healthcare facilities must comply. Most states have detailed Board of Pharmacy regulations, which may impose more restrictive controls than federal law requires for some medications. Federal laws and regulations, such as the Controlled Substances Act, dictate numerous drug security and accountability measures. The Secure and Responsible Drug Disposal Act of 2010 and, in many cases, municipal waste handling regulations set requirements for disposing of some types of pharmaceutical waste. The Medicare *Conditions of Participation (CoP)* and survey agencies have established standards to which facilities must adhere relating to patient safety, nursing practice, pharmacy operations, and medical staff processes.

Drug diversion almost certainly occurs in every facility where controlled substances are handled and stored. The perpetrators of diversion may be nurses, pharmacists, anesthesiologists, other physicians, midlevel providers, nonclinical staff, patients, impostors, and even visitors and patients' family members. The diverter is not necessarily a person with legitimate access to medications. Our focus is on diversion by institutional staff, especially nurses, pharmacists, and anesthesia staff.

Institutional diversion is diversion that occurs in healthcare institutions, including hospitals, nursing homes, and other care facilities. This type of diversion differs from diversion in the community in several ways. One distinguishing feature is that, in institutions, the diverters are chiefly healthcare personnel, although anyone within an institution may divert if there is access and availability. Addressing diversion within institutions requires a thorough understanding of the methods used to access medications legitimately, as well as the methods diverters use to conceal their theft. Most diversion within institutions is for personal use, particularly at the hands of direct care providers. Diversion for resale is slightly more common among pharmacists and pharmacy staff, largely because pharmacy diversion can be more difficult to identify and quantities of controlled drugs available to a savvy diverter can be substantial.

The risk factors for diversion among clinical personnel are many, including regular access to controlled substances, job stress, sleep deprivation or irregular sleep, empathy burnout, and stresses brought in from outside the workplace. Many individuals who divert have injuries or medical conditions that cause chronic pain. They may divert in an attempt to self-medicate or to supplement a legally prescribed opioid that they feel is inadequate to their need. Healthcare personnel caught diverting frequently recall that a one-time theft led to an ever-increasing need and habit of diversion. A nurse at one institution, who was legally prescribed an opioid for a painful medical condition, found that the prescription was not sufficient to her need; she ultimately resorted to stealing opioids from her facility, forging prescriptions, and doctor-shopping.

Besides needing to alleviate the stresses of work and life, personnel who regularly handle and administer controlled drugs such as opioids may become inured by familiarity to the risks posed by such drugs and lose the inhibition that unfamiliarity normally provides. It is not uncommon for staff members who regularly handle controlled drugs to admit they handle them casually. In one institution I visited, preoperative nursing staff members reported that they treated a benzodiazepine they commonly used “like water.”

Among medical specialists within institutions, anesthesiologists are at highest risk for diversion, both because of access and because of their familiarity with potent controlled substances. Diversion is an occupational hazard for anesthesiologists, and fatalities due to abuse of prescription drugs are not uncommon in the profession. A survey of anesthesiology residency programs from 1991 to 2001 found that 80% of programs had recognized impairment in at least one of their residents. A resident fatality due to substance abuse was reported by 19% of programs (Collins, McAllister, Jensen, & Gooden, 2005).

Drugs targeted for diversion are chiefly controlled drugs, but other drugs may be involved, especially drugs that mitigate the adverse effects of the primary diverted drugs. For example, a person experiencing nausea from abuse of opioids might divert ondansetron or promethazine to alleviate the nausea. When diversion is for personal use, each diverter will usually have a preferred drug or perhaps two or three favorite drugs. Because the effect of opioids decreases with increasing exposure, the quantity of an opioid diverted by any individual will always increase with time.

Scope of the Problem

A question I am often asked at consultation with institutions is, “How many diverters should we expect to find? What proportion of nurses/pharmacists/other staff divert drugs?” Unfortunately, a well-founded answer to that question is not available. Diversion is, by its nature, a clandestine activity, and any estimation of its prevalence requires both discovery and reporting. Many institutions lack the tools and resources to conduct effective ongoing surveillance for diversion.

No thorough studies have addressed the prevalence of diversion among nurses or hospital pharmacists, and the studies that have been done among anesthesiologists acknowledge significant barriers

to the collection of data. Information on the prevalence of diversion at long-term care facilities is also scarce. Because of the vulnerability of the patient population and the lack of automated drug security at many long-term care facilities, diversion is probably at least as widespread there as at acute care hospitals.

Diversion has also been reported to occur at prison infirmaries as well as at schools, where school nurses steal medications kept for individual special-needs students. Diversion is also common in the home health and hospice settings, where there is little or no direct supervision and often liberal use of opioids. In these settings outside of dedicated healthcare institutions, the odds of a diverter being caught are extremely low, since security and accountability measures are comparatively weak.

Even when diversion is discovered, it often goes unreported outside the institution where it occurs. Some healthcare facilities rationalize a lack of reporting by asserting that they don't want to harm the individual. Hospitals and other institutions commonly avoid reporting diversion out of a fear of negative publicity, legal action, or inviting the scrutiny of regulatory agencies. Unfortunately, such fears may be well-founded; the understanding of diversion investigation by regulatory agencies and the media may be less than perfect. In some cases, state regulatory agencies have threatened to impose immediate jeopardy of loss of licensure, based on an erroneous belief that any hospital that discovers diversion must have a substantial internal problem.

Estimates of the prevalence of diversion vary widely. Such estimates are generally no more than educated guesses, but they vary between 6% and 20% of nurses. Most of the estimates are probably lower than the reality. In my experience developing a diversion program at an academic hospital with a staff of approximately 1,000 nurses, after an initial period of catching 3 or 4 diverters each month, the baseline rate of discovered diversion settled down to an average of 1 or 2 per month. Even that rate probably underrepresented the actual rate of diversion, since the resources allotted to diversion surveillance were limited.

Controlled substances (in this context synonymous with controlled drugs) are drugs that are subject to special controls on their access and use. In the United States, most such drugs are identified by federal regulations on five schedules, named Schedule I, II, III, IV, and V, abbreviated C-I through C-V. A few drugs, including propofol at this writing, are not identified by federal schedules but are controlled by separate regulation in some states. The schedules are defined as follows:

- Schedule I drugs have a high addictive potential, no accepted medical purpose, and cannot legally be prescribed, dispensed, or administered except in certain pharmaceutical research
- Schedule II drugs include certain narcotics and stimulants that are considered to have a strong potential for abuse
- Schedule III drugs are considered to have a moderate potential for abuse
- Schedule IV have a lower abuse risk
- Schedule V drugs are considered to have the lowest abuse potential among controlled drugs

In the United States, all controlled substances must be handled with special consideration for security; it is a common misconception that the additional security requirements apply only to drugs in certain schedules.

It is clear that diversion by healthcare personnel impacts patients and institutions across the United States and elsewhere on a daily basis. For example, as of August 2016, more than 12,000 patients across the United States have been notified that they may have been exposed to a bloodborne pathogen as a result of a diversion scheme involving tampering and substitution of injectable drugs by a healthcare worker at the facility where they received care. The recognition of diversion in the United States has led that in other developed countries, but there has been an increase in media reports of institutional diversion outside the United States in the past several years as well. There have been reports of nurses stealing propofol and tampering with hydromorphone vials in Canada, “borrowing” pills in the United Kingdom, and stealing narcotic waste at a correctional institute in New Zealand, to name a few. It is certain that the increase in institutional diversion seen in the United States is occurring in other countries as well.

The understanding of drug diversion by those who investigate it has progressed considerably in recent years. Two decades ago, hospitals that performed end-of-shift counts of controlled drugs were considered to have adequate diversion programs, and any hospital that could resolve all its discrepancies was thought not to have diversion. It is now recognized that methods of diversion exist that simple counts would not discover, and regulatory agencies no longer accept end-of-shift counts as sufficient diligence with regard to diversion. With increasing sophistication of investigators and drug transaction analytics programs, diverters have become more sophisticated in outwitting the investigators. Investigators must be perpetually innovative to stay ahead of the diverters.

The brief answer to the question posed at the beginning of this section is: “It depends on how hard you look.” Certainly any institution that is not discovering diverters with some regularity is not looking hard enough. Whether a program is effective does not depend on the number of diverters discovered but on the thoroughness of the methods used to prevent, detect, and respond to diversion.

Risks Associated With Diversion

Diversion of drugs is not a victimless crime. The victims include patients but also the institution, the diverters’ colleagues, the diverters themselves, third-party payers, and the community at large. The harm done to each type of victim can take many forms.

The most immediate victims of diversion are patients. If opioid analgesics intended for patients end up diverted, the patients are denied the intended relief of pain. Habitual diverters become so concerned about obtaining their supply of drugs that they cease to be concerned about the welfare of patients. For example, in one case, a nurse anesthetist withheld opioids from a patient undergoing surgery and was willing to continue to withhold the medications even though the patient cried out in pain at the commencement of the procedure. In another case, a nurse siphoned fentanyl from the infusions of

critically ill patients and substituted saline for the diverted volume. The nursing staff members were baffled when several patients showed signs of pain despite receiving ongoing infusions. It was some time before the diversion scheme was ultimately discovered.

Patients also experience harm in other ways. Most diverters cannot avoid using their drugs during times of work, so patients receive care from an impaired provider. Many schemes involve falsification of medical records to cover the diverter's tracks, so the patient suffers from an inaccurate medical record. In an extreme case, the record may falsely indicate that the patient is opioid tolerant, and providers on a later shift may consequently use too high a dose.

In the most egregious form of diversion, tampering and substitution, the diverter removes the drug from a vial or other container; substitutes an inactive substance such as saline, tap water, or even water drawn from a toilet bowl; conceals the fact that the container has been opened; and returns the container to stock or to another location where it will be used on a patient. Such behavior obviously puts patients at risk for infection and harm in the form of unrelieved pain. If the substituted material is contaminated, the contaminated material is administered to patients. In several widely publicized events, diversion by substitution has resulted in infection of multiple individuals with bacterial pathogens or hepatitis C virus.

Institutions may be harmed by negative publicity, civil and regulatory liability, and low staff morale. Owing to a lack of understanding of the universal prevalence of diversion, diversion cases may be used by the press as evidence that an institution is subpar, while in reality, patients are much safer in institutions that regularly catch diverters as opposed to those that claim they have never had a case. Negative publicity may in turn undermine the trust of the community in the institution. Facilities may be sued by patients, and they may face substantial regulatory fines and corrective action plans. Criminal and civil cases arising from a diversion scheme may go on for years. Staff often become discouraged and suffer as a result of ongoing unfavorable public attention on the institution.

Diverters face a myriad of issues, including civil liability, loss of employment and license, detrimental health and social effects of opioid abuse, and overdose and death. Unfortunately, the gravest outcomes are not uncommon, and many institutions have lost a staff member as a result of an overdose death. Between 1999 and 2014, more than 165,000 people died in the United States as a result of a prescription opioid overdose (CDC, 2016). Healthcare personnel are not exempt from this statistic.

The community may also be impacted when healthcare personnel divert. Diverting personnel typically use the medication they are diverting throughout their shift. When they leave the facility, they operate a vehicle while under the influence of the drugs they have diverted. There have been several reported cases of healthcare personnel causing car accidents while driving impaired and being found to have diverted drugs with them in the vehicle (2016). In one such case, a Georgia anesthesiologist admitted to stealing and using propofol when she seriously injured five people in a car crash (2016).

In my own experience, unpublished cases of automotive injuries and accidents related to drug diversion are common. In one case, a nurse admitted injecting herself with powerful opioids prior to

driving home from work each day. Her reasoning was that she didn't want to arrive home in a state of withdrawal and draw suspicion from her family. In another case, a nurse consuming diverted oral benzodiazepines while driving on a busy highway passed out and caused a serious multivehicle accident. A patient care assistant gained access to a powerful opioid due to lax controlled substance handling where he worked. He injected himself prior to driving on a crowded freeway and was ultimately found passed out on the side of the road with his car still running.

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Theft of controlled substances at hospitals has always been a problem of paramount importance, but even with increased security measures, it still occurs. ***Drug Diversion Prevention in Healthcare*** discusses the issue of drug diversion in detail and demonstrates the components of a solid prevention plan. Loaded with tools and checklists, this book is designed to help hospital security officials create awareness of the drug diversion problem. You will learn how to design a program to keep staff accountable for drug administrations, as well as audits that monitor drug distribution from delivery to patient administration.



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