

Drug diversion prevention and detection

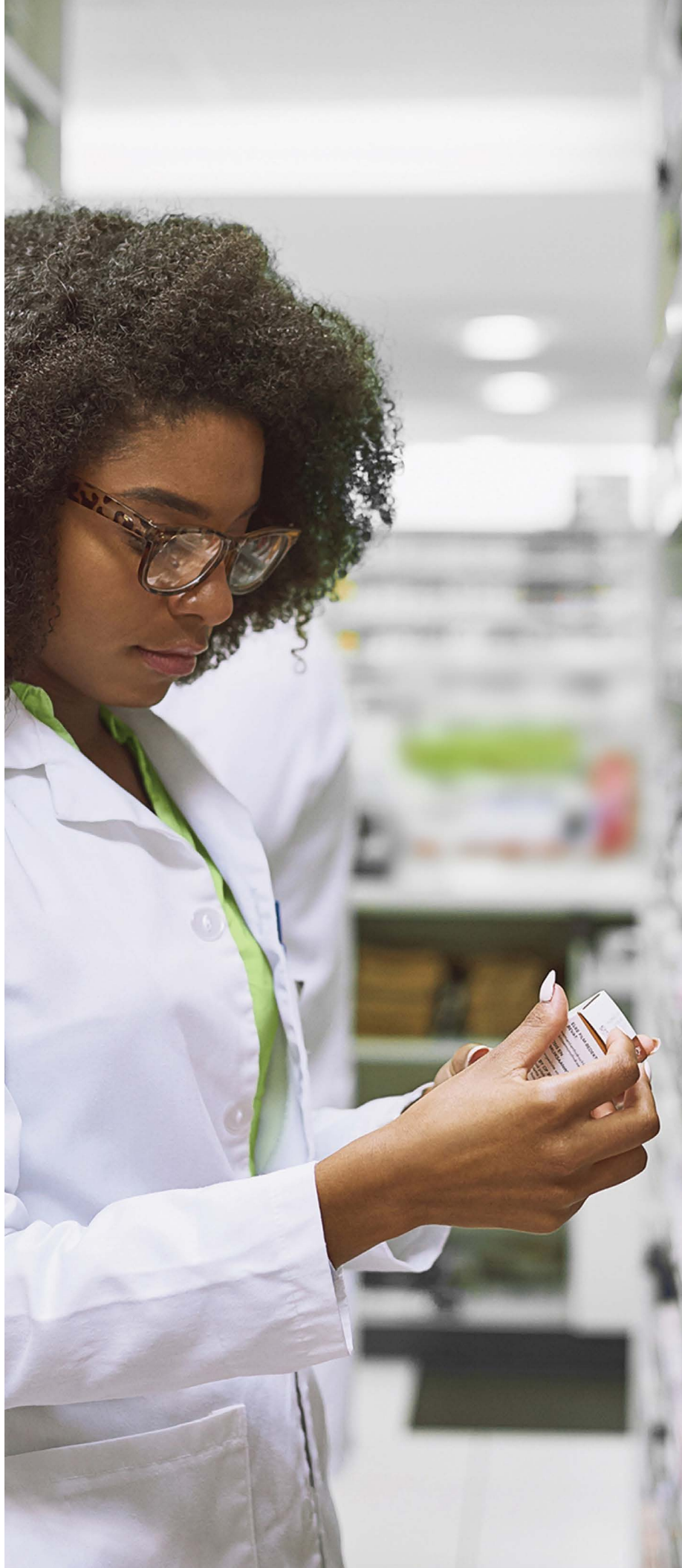
Using a comprehensive
risk and internal audit
approach

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Director, Risk, Internal Audit and
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 **bakertilly**
now, for tomorrow.





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The escalation of drug diversion

The United States Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) report that opioids killed more than 42,000 people in 2016. In 2016, 66 percent of drug overdose deaths involved an opioid and 40 percent of all opioid overdose deaths involved a prescription opioid. ^{(1) (2)}

Now consider that approximately 10 to 15 percent of all healthcare professionals will misuse drugs or alcohol at some time during their career. Although the rates of substance abuse and dependence are similar to those of the general population, the prevalence is disturbing because healthcare professionals serve as the caregivers responsible for the health and well-being of the general population. ⁽³⁾ Drug diversion by healthcare workers can cause serious harm to patients (particularly if the worker is impaired while delivering care) or to themselves.

Healthcare organizations face serious legal, financial, operational and reputational risks and regulatory fines resulting from worker drug diversion and inadequate internal controls. Every healthcare organization, in partnership with its operations, compliance and internal audit functions, must ensure a comprehensive interdisciplinary drug diversion management program is functioning. To effectively address drug diversion issues, a comprehensive program must include rigorous controls and monitoring.

The OPIOID EPIDEMIC by the number

IN 2016

116

people died every day from opioid-related drug overdoses

11.5m

people misused prescription opioids¹



42,249

people died from overdosing on opioid²



2.1 million

people had an opioid use disorder¹



948,000

people had an opioid use disorder¹



170,000

people used heroin for the first time¹



2.1 million

people misused prescription opioids for the first time¹



17,087

deaths attributed to overdosing on commonly prescribed opioids²



19,413

deaths attributed to overdosing on synthetic opioids other than methadone²



15,469

deaths attributed to overdosing on heroin²



504 billion

in economic costs³

Sources: 1-2016 National Survey on Drug Use and Health, 2-Mortality in the United States, 2016 NCHS Data Brief No. 293, December 2017, 3-CEA Report: The underestimated cost of the opioid crisis, 2017

What is drug diversion?

Drug diversion is the transfer of a prescription drug from a lawful to an unlawful channel of distribution or use. The estimated cost of controlled prescription drug diversion and abuse to both public and private medical insurers

is approximately \$72.5 billion a year. Among healthcare providers, it is estimated that 15 percent of pharmacists, 10 percent of nurses and eight percent of physicians are challenged with alcohol and/or drug dependency. ⁽⁴⁾

Drug diversion's impact on patients

Patients seeking care are being harmed by varying types of healthcare workers who are drug diverters. Patients may suffer increased pain if their medications are diverted and could be exposed to a lower quality of care if a caregiver is impaired. Mayo Clinic physicians Keith Berge and William Lanier reviewed medical research and CDC records related to outbreaks of infections due to drug diversion by healthcare personnel in the U.S. from January 2000 through December 2013. The researchers identified six infectious outbreaks over a 10-year period beginning in 2004; all occurred in hospital settings. Implicated healthcare professionals included three technicians and three nurses – one of whom was a nurse anesthetist.

Infections spread via tampered injectable controlled substances. Two outbreaks

involved tampering with opioids administered via patient-controlled analgesia pumps and resulted in gram-negative bacteremia in 34 patients. The remaining four outbreaks involved tampering with syringes or vials containing fentanyl, which resulted in the hepatitis C virus infection transmittal to 84 patients. In each of these outbreaks, the implicated healthcare professional was infected with the hepatitis C virus and served as the source. This resulted in nearly 30,000 patients who were potentially exposed to blood-borne pathogens and targeted for notification advising testing. ⁽⁵⁾

The chart (found on the next page) from the CDC depicts a summary of infectious outbreaks from 1983 to 2013 that resulted from drug diversion activities involving healthcare workers that tampered with injectable drugs. ⁽⁶⁾

Drug diversion's impact on healthcare organization

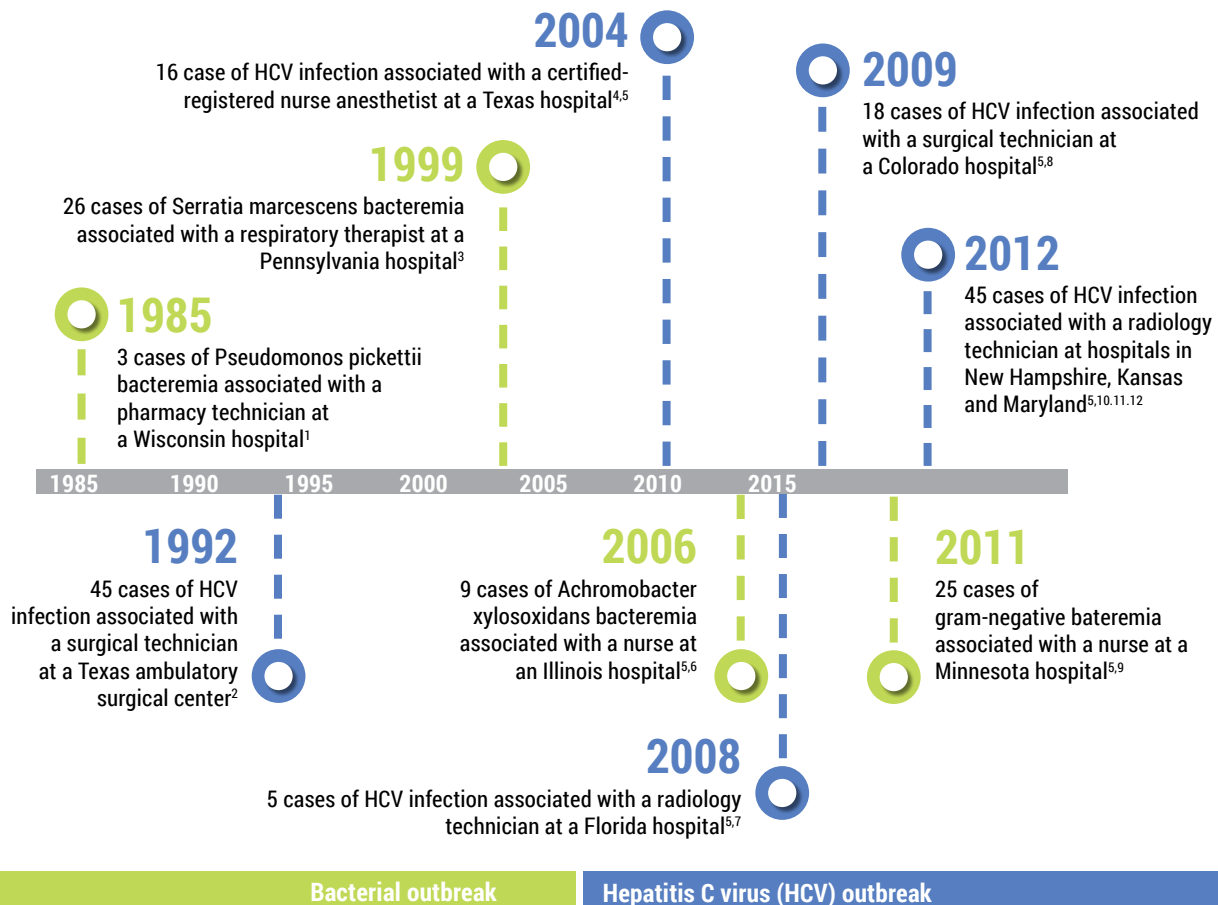
Many incidents of health workers diverting controlled substances have been reported in the news media and to regulatory agencies, resulting in grave legal and regulatory consequences for the organizations that employed these workers.

- In September 2015, Massachusetts General Hospital (MGH) agreed to pay \$2.3 million to resolve allegations that lax controls enabled MGH employees to divert controlled substances for personal use. Two nurses had stolen large volumes of controlled substances (nearly 16,000 pills, mostly oxycodone) from automated dispensing machines. The subsequent U.S. Drug

Enforcement Administration (DEA) audit of MGH's controlled substances revealed pill count discrepancies totaling over 20,000 missing or incomplete medication inventories and hundreds of missing drug records. ⁽⁷⁾

The estimated cost of controlled prescription drug diversion and abuse to both public and private medical insurers is approximately \$72.5 billion a year.

Infectious Outbreaks Resulting From Drug Diversion Activities Involving Healthcare Workers Tampering With Injectable Drugs 1983-2013



- In March 2016, the Augusta Chronicle reported that Emory University Hospital Midtown was fined \$200,000 and its pharmacy license was placed on probation for three years by the Georgia Board of Pharmacy. This was the result of two pharmacy technicians having diverted more than one million doses of controlled substances between October 2008 and July 2013. It was reported that “the scheme was perpetuated through coordinated illicit activity, including misappropriating credentials from a pharmacy buyer; exploiting use of an electronic function in the hospital’s system to conceal the unauthorized purchases, and bypassing the receiving/inventorying process.”⁽¹¹⁾
- In November 2016, the Denver Post reported that a surgical technologist was sentenced to prison for theft of a syringe filled with fentanyl from Swedish Medical Center in Englewood, CO. The technician was reported to be addicted to drugs and HIV positive. Previously, he was court-martialed in 2011 (while enlisted in the Navy) after admitting to stealing vials of fentanyl. He was fired from at least five healthcare facilities in California, Arizona and Washington before Swedish hired him in August 2015. Swedish Medical Center incurred a cost of \$800,000 to test patients for infections fearing they might be infected with HIV or hepatitis.⁽⁸⁾
- In October 2017, the Detroit Metro Times reported that a Detroit pharmacist was convicted of stealing nearly \$6.2 million from healthcare agencies, a felony for which he received 42 months in prison. From October 2009 to April 2014, he was found to be fraudulently charging health insurers for prescriptions that were never dispensed.⁽⁹⁾
- In January 2017, the Philly Voice reported that Abington Hospital agreed to pay \$510,000 to settle allegations that its controls and practices enabled a staff pharmacist to take more than 35,000 pills, including oxycodone, for illegal use. A subsequent DEA audit revealed the pill count discrepancies, missing or incomplete medication inventories and altered or missing drug records.⁽¹⁰⁾

Taking action to prevent drug diversion

Drug diversion activity creates multiple victims, with potential harm to the diverter, patients, colleagues and the organization that employs them. Significant gaps can exist in a healthcare organization's

drug diversion prevention and detection efforts. How can leadership, compliance and internal auditors within healthcare organizations work together to best detect and prevent drug diversion?

I: Identify where diversion occurs in the healthcare environment

Diversion prevention and detection requires many functions and efforts to work effectively, including: accountability, an interdisciplinary approach, significant controls, technology, training, monitoring, surveillance and investigation, along with judicious behavioral observation. Today, organizational practices to prevent and detect diversion vary from refined, proactive programs to haphazard efforts.

Individual facilities within an organization can have a great deal of operational variability. Integrated delivery systems (IDS) vary in size. There are large metropolitan hospitals, teaching facilities and many organizations which have acquired smaller rural facilities over time. Today, healthcare organizations can span multiple states. These organizations may struggle with migrating geographically dispersed and size-varying facilities on to the same technologies





and to operate under the same policies and procedures. Smaller facilities may lag behind with technology implementation. Policies and procedures can differ across the enterprise. Given tight operating budgets, there are often scarce resources for training, monitoring and surveillance of drug diversion.

From procurement to waste and/or removal, common vulnerabilities or gaps exist in controlled substance processes for drug diversion to occur. The chart on the next page (adapted from the American Journal of Health Systems Pharmacists report) documents phases of the controlled substance lifecycle with common points of risk and methods of diversion frequently seen in healthcare. ⁽¹²⁾

II: Identify workers at risk for drug diversion

Organizations need to identify health workers at risk for controlled substance abuse and drug diversion, beginning with improved screening of new healthcare workers.

To aid in the identification of at-risk workers, the CDC reports that some risk factors may make people particularly vulnerable to prescription opioid abuse and overdose, including:

-  Obtaining overlapping prescriptions from multiple providers and pharmacies.
-  Taking high daily dosages of prescription pain relievers.
-  Having mental illness or a history of alcohol or other substance abuse.
-  Living in rural areas and having a low income. ⁽¹³⁾

Screening and assessment – Human resources screening efforts should provide validation of previous employment, reference checks and candidate vetting with state licensing boards to learn if past violations exist. Special attention should be focused on workers coming from another state or those who have moved from state to state. A careful assessment should be conducted during new employee physical exams to those who report injuries or conditions with chronic pain. Those applying for positions in high drug diversion risk areas, such as pharmacy and anesthesia, should be carefully reviewed. Finally, all new hires should be screened for drugs.

Common points of risk and methods of drug diversion seen in healthcare's controlled substance lifecycle

Procurement

- Purchase order and packing slip removed from records
- Unauthorized individual orders for CS on stolen DEA Form 222
- Product container is compromised

Preparation and dispensing

- CS are replaced by product of similar appearance when prepackaging
- Removing volume from premixed infusion
- Multidose vial overfill diverted
- Prepared syringe contents are replaced with saline solution

Prescribing

- Prescription pads are diverted and forged to obtain CS
- Prescriber self-prescribes CS
- Verbal orders for CS created but not verified by prescriber
- Written prescriptions altered by patients

Administration

- CS are withdrawn from an ADD on discharged or transferred patient
- Medication documented as given but not administered to patient
- Waste is not adequately witnessed and subsequently diverted
- Substitute drug is removed and administered while CS is diverted

Waste and Removal

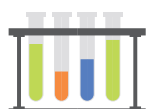
- CS waste is removed from unsecure waste container
- CS waste in syringe is replaced with saline
- Expired CS are diverted from holding area

Note: *CS =controlled substances, DEA = Drug Enforcement Administration, ADD = automated distribution device.

Below are six best practices your organization should consider when developing a drug testing program:



Develop a written policy and process. This is critical as it provides a protocol for the organization to follow and makes the procedures transparent to employees. The policy should adhere to all applicable state and federal compliance requirements and be reviewed by an employment attorney.



Drug testing is more effective when used for both pre-employment background check and ongoing employment screening. Ongoing periodic drug testing helps to deter workers from using drugs. Individuals should be selected at random for drug testing and testing should be conducted as soon as possible from the time of notification to minimize the opportunity for tests to be falsified.



Drug testing can be conducted using urine, oral fluid and/or hair samples. Organizations should evaluate all three specimen types to determine which will best meet their needs. To decide among testing methods, employers should consider cost, whether testing should be done on or off site, the organization's level of risk tolerance, the organization's priorities for candidate experience and the length of the drug detection window. For example, when considering pre-employment screening options, hair testing works well since it offers up to 90 days of visibility into the candidate's drug history. For situations requiring same-day or ongoing screening, urine or oral fluid may be best since it provides a one-week window of detection.



Drug testing requirements vary depending on industry and job functions. Positions that involve driving or operating machinery may be more safety-sensitive than administrative roles. In a healthcare environment, where employees may have access to medications, it's important to conduct drug tests on all workers with such access on an ongoing periodic basis. Build a testing program that meets the organization's needs and clearly identifies in the policy which roles require drug testing.



Document the entire drug testing process, this is critical to help organizations protect themselves in the event of litigation or a regulatory audit. An organization should document every step in the process – from notification to results analysis. It's helpful if the human resources (HR) information system creates an automated digital audit trail for every step in the drug screening process since this helps show that the organization is conducting unbiased testing according to its drug testing policy.



Contact the organization's insurance providers to see if the organization qualifies for rebates based on its drug testing policies. Many workers' compensation, medical and liability insurance providers offer incentives for employers that conduct drug screening. In fact, a number of states currently require worker's compensation insurance providers reward organizations with discounts or rebates if they implement drug testing according to state guidelines. ⁽¹⁴⁾

Behaviors – What behaviors in employees should raise concern? Addicts can exhibit a range of potentially troubling behaviors when under the influence of or addicted to drugs, such as: impulsiveness, compulsiveness, inability to deal with stress, low self-esteem, impatience and antisocial conduct. Healthcare leaders, managers and

co-workers need to be observant. Has someone on your team discussed a previous addiction? Has an employee's behavior recently changed? Does an employee want to work alone, experience mood swings, become quick to anger or despondent when that was not normal behavior before?



Training and monitoring – For currently employed health workers, organizations need to provide training, support programs, policy and procedures that address diversion behavior, including reporting to the DEA, state licensing boards and law enforcement. Organizations need to consider drug screening for cause along with

random drug testing with existing employees. Vigilant monitoring is required by managers who employ healthcare workers practicing on a limited license for adherence to the limitations and for relapse behavior

A comprehensive HR approach supporting an interdisciplinary drug diversion management program should, at a minimum, include:

- Written employee and provider substance abuse policy
- Worker education and awareness program
- Supervisor training program
- Employee and provider assistance program
- Peer support and systems
- Requirements for drug testing, including a for-cause policy for drug testing
- Return-to-work policies for healthcare workers
- Sanctions for performance and diversion violations.⁽¹²⁾



Has someone on your team discussed a previous addiction? Has an employee's behavior recently changed? Does an employee want to work alone, experience mood swings, becomes quick to anger or despondent when that was not normal behavior before?

III: Define a comprehensive drug diversion program

A layered and comprehensive program is required to detect and prevent drug diversion in healthcare organizations.

In 2017, the American Journal of Health Systems Pharmacists published the report, "ASHP Guidelines on Preventing Diversion of Controlled Substances," which outlined a comprehensive controlled

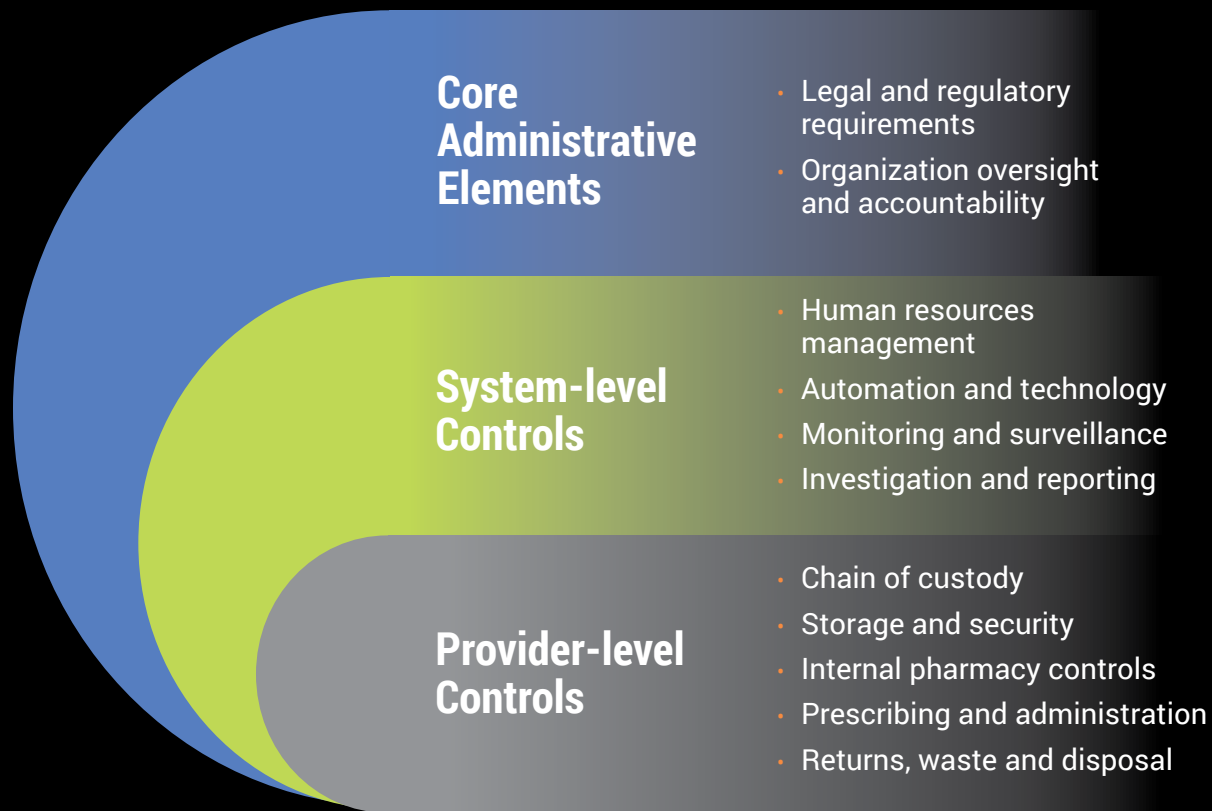
substance diversion prevention program (CSDPP).

A comprehensive CSDPP incorporates: core administrative elements, system-level controls and provider-level controls. The illustration below depicts the essentials elements of a CSDPP program.⁽¹²⁾

With a well-defined comprehensive program, building a strong interdisciplinary CSDPP leadership team will

IV: Engage leadership

Key components of a controlled substance diversion prevention program (CSDPP)



help to define, support and guide the program. With policy and procedure development comes the need for supervisor and worker training, assessment of existing controls, active monitoring systems, surveillance, and timely and routine reporting on the results of the program. A designated drug diversion officer should also be appointed and

hold primary responsibility for coordination of drug diversion monitoring and surveillance in collaboration with compliance, internal audit and pharmacy leadership.

V: Tap into technology

The use of electronic health record systems in conjunction with automated distribution devices and prepackaging devices aid in the implementation of controls and monitoring. The implementation of these applications and devices will involve an interdisciplinary team of information technology (IT), pharmacy and nursing professionals. Pharmacy leaders must lead the way and ensure that technology surrounding medication ordering, dispensing

and administration is established to support diversion control, monitoring, surveillance and regulatory needs. One cannot, however, rely solely on technology to prevent or detect diversion. The previously reported diversion examples depict how shrewd and deceptive a diverter can be. Some diverters use the technology designed to prevent diversion to their advantage and in ways others would not consider.

VI: Incorporate approach into culture and training

Worker and supervisor training and diversion management programming needs to support a “see something, say something” culture. Patient safety is paramount. While 10-15 percent of our healthcare workforce may be at risk for substance abuse, the remaining 85 percent of the workforce can provide the first line of defense in protecting patients and the organization. Healthcare workers must be educated to know what to look for in co-worker behavior and then feel empowered to act immediately and address situations as they arise.

Case in point: A health system reported to the U.S. Food and Drug Administration (FDA) a significant diversion of anesthetic medications by a nurse anesthetist. The nurse anesthetist was identified by a co-worker. The co-worker offered to witness drug wasting if the nurse anesthetist needed assistance. The nurse anesthetist responded casually with, “I take care of that myself.” Upon hearing this, the co-worker became alarmed and reported the comment to management.

A review was conducted of the paper anesthesia narcotic administration records documented by

the nurse anesthetist. The review found that the anesthetist was documenting the initials of a fictitious person as having witnessed the wasting of controlled substances. This documentation was handwritten and varied in appearance from the nurse anesthetist’s handwriting. The director of pharmacy who reviewed the documents was verifying that there were two signatures witnessing wasting. The director did not, however, realize that the second initials on the documentation did not belong to anyone working in the surgery or anesthesia areas.

Healthcare workers must be educated to know what to look for in co-worker behavior and then feel empowered to act immediately and address situations as they arise.

What can comprehensive audits reveal?

Consider all of the following examples:



1. Segregation of duties

Audits conducted of the controlled substance lifecycle reveal issues in multiple areas. Pharmacy issues include a lack of segregation of duties with controlled substance procurement, sloppy record keeping and missing DEA 222 forms and order receipt documentation. Staff shortages on later shifts are often noted as the reason for the lack of duty segregation. The use of a nursing supervisor with a licensed pharmacy team member could help to remedy such situations.



2. Blind count documentation and reviews

Observation of pharmacy-controlled substance vault blind counts reveal numeric documentation on the side of containers which suggests that true blind counts are not always being conducted.



3. Discrepancy reviews

Discrepancy reports for nursing care ADD units are not routinely reviewed to assess unresolved discrepancies. The lack of attention by pharmacy and diversion control personnel to unresolved discrepancy reports establishes an environment where diversion can happen and go undetected for long periods of time.



4. Nursing medication administration audits

Audits of nursing medication administration often reveal a lack of basic handwashing and failure to verify medication expiration dates. Automated systems (EHR and pharmaceutical dispensing units) and the use of bar code medication administration consistently promote strong adherence to the five rights of medication administration (commonly used by nursing staff). Nursing documentation reveals an increase in documentation of pain on a pain scale and the patient response to medication administration. The right documentation, rationale for administration and patient response to the medication signal use of the expanded eight rights of medication administration. ⁽¹⁵⁾



5. Discrepancy management

Today, there is a tendency to blame the ADD unit or the pharmacy technician who filled the prescription for the discrepancy: “Oh, the pharmacist will come by later and figure it out.” Nurse managers and charge nurses may not know how to investigate discrepancies nor use the display capabilities of the ADD units. In some organizations, nurse managers are not involved in discrepancy management and do not have access to discrepancy reporting.



6. Scheduling and diversion management

Nursing staff on care units are frequently working both eight-hour and twelve-hour shifts. These scheduling patterns add complexity to diversion management on the units. Let's say the eight-hour shift leaves at 7:00 PM and the shift created a discrepancy. The discrepancy is not identified until the narcotic count is completed at 11:00 PM. There is an attempt to resolve the discrepancy, but sometimes it requires talking with staff that left at 7:00 PM who are now home sleeping. Someone takes responsibility to follow up with the staff off duty in the coming days regarding the discrepancy. Often the discrepancy is resolved; however, sometimes it is forgotten and goes unresolved.



7. Paper-based workflow

The comingling of automated and paper-based workflow in surgery and procedural care areas can be a source of issues. Old paper-based forms are not kept up-to-date, do not accommodate multiple signatures to witness waste or chain of trust documentation with drop-off and return of controlled substance lock boxes. The paper documents often use abbreviations for new medications that are not referenced on document legends and are difficult to decipher on audit. Many small to medium-sized facilities have not implemented ADD units in the surgery and procedural areas while electronic record documentation have become mainstream.



8. Resources and diversion prevention program management

Finally, there are scarce resources in some facilities to develop a formal diversion prevention program and conduct the required monitoring and surveillance activities. Larger facilities often have a defined controlled substance diversion prevention program, compliance and internal audit support, and a designated diversion control officer. Smaller facilities often must rely on the director of pharmacy, nursing leadership and quality management to perform monitoring and surveillance along with other duties.

Best practices for drug diversion prevention and detection

Multiple departments in a healthcare organization must be involved in controlled substance management. Controlled substance management encompasses ordering, receiving, storing, prescribing, dispensing, transporting, administering, wasting, return and disposal. Effective controls are required in all work processes involving controlled substances.

The table below lists some of the best practices to prevent and detect controlled substance diversion in a healthcare organization's pharmacy, procedural and nursing areas. These best practices were compiled from pharmacy internal audit experiences and a review of multiple industry resources. The list's focus was placed on best practices for an inpatient pharmacy versus an outpatient or retail pharmacy. ^(12, 16)

Pharmacy

Procurement

1. Use of an electronic Controlled Substance Ordering System (CSOS). If an electronic ordering system is not used, a log of the DEA form 222 is kept to ensure all orders are accounted for.
2. If paper DEA Form 222s are used, the forms are stored in an organized manner in a secure location and accessible only to personnel authorized to order controlled substances.
3. A limited number of designated personnel are authorized by the organization and registered with the DEA to order controlled substances. Only designated personnel can access the CSOS.
4. There is separation of duties in the procurement process, the individual who submits a controlled-substance purchase order is not responsible for receiving the order.
5. Orders received are dated and signed by both witnesses. One of the order receivers must be a licensed pharmacy professional.
6. Procurement orders are verified for complete and accurate documentation.
7. Chain of custody procedures are implemented, for the receipt, transfer and transportation of controlled substances within the organization. Documentation of the chain of custody is maintained.
8. If controlled substances arrive within the organization for which there is no order or Form 222, an investigation is conducted to determine how this discrepancy occurred with the wholesaler or pharmaceutical distributor.
9. Audit of controlled substance purchases against products added to pharmacy inventory is performed at least quarterly.
10. Controlled substances are purchased in unit dose packages whenever possible to minimize repacking requirement, multiuse vials and the potential for diversion.

Storage

11. A perpetual inventory is kept for all medications and blind counts are used when removing or adding substances to the pharmacy controlled substance inventory.
12. An automated vault is used for storage of controlled substances in the Pharmacy.
13. Biometric fingerprint scan is used for vault access.
14. Controlled substance vault access is limited, the vault software program controls and records every access, access date and time, what medication was accessed and the changes to the inventory.
15. Cameras are installed and directed at controlled-substance storage areas.
16. Personal belongings are banned from drug storage areas.
17. Person-to-person transfers of controlled substances are audited, including transfers to non-automated storage areas.
18. Controlled substance pharmacy vault inventory is conducted monthly.
19. Controlled substance packing is routinely inspected for evidence of tampering or alteration.

Dispensing controlled substances

20. An inventory is conducted at the end of every shift for a controlled substance that are not stored in an automated vault.
21. Controlled substance infusions are stored in a secured lock box and no-port tubing is used.
22. Controlled substances are never left unattended outside of the pharmacy vault.
23. Controlled substances counts are conducted with two individuals (one licensed) prior to transportation from the inpatient pharmacy to a patient care area.
24. Controlled substances are dispensed whenever possible in single unit dose tamper event packaging that utilize bar code scanning.
25. Secure, locked, non-transparent medication delivery carts/ containers are used to deliver CS and accessible only by authorized individuals.
26. Delivery and receipt are documented by pharmacy staff and a licensed staff member in the receiving department.
27. All discrepancies are investigated to resolution or reported.
28. Use of a system capable of electronically identifying discrepancies between the central pharmacy vault withdrawals and nursing unit-based ADD receipts.

Return, wasting and disposal

29. Controlled substances returned to the pharmacy from a patient care areas are verified and documented.
30. Approved methods for wasting a controlled substances are defined per federal, state and county laws and regulations.
31. Witness and documentation is required for wasting of all controlled substances.
32. Use and waste of multi-dose vials of controlled substances are audited.
33. Controlled substances returned to the pharmacy are inspected for package integrity.
34. Random audits are conducted of unused controlled substances to verify the content.
35. If a reverse logistic pharmaceutical processor is used, a DEA form 222 provided by the processor is reconciled against the central pharmacy vault inventory for returns and recalls.
36. A facility DEA authorized employee supervises all processes related to disposal with a third party reverse logistics processor.
37. Chain of custody is maintained and documented with all returns, waste and disposal processes.
38. Use of waste containers renders the controlled substance irretrievable or unusable.
39. Lock sharps and pharmaceutical waste containers to the wall or secure to other stationary equipment that cannot be easily removed from a clinical unit. Secure all keys to replace a container, and limit access to just a few designated staff.

Physical security – Pharmacy

40. Electronic access to control and monitor entry into the hospital pharmacy for all doors.
41. Audit of access is completed monthly.
42. After-hours access to the pharmacy by non-pharmacy personnel is prohibited.
43. Camera surveillance of any doors that are not secured by electronic access.
44. Camera surveillance of the inpatient pharmacy entrance, vault and dispensing areas.
45. If key access to the main pharmacy or storage areas exists, keys should be clearly stamped "Do Not Replicate" and distribution should be strictly limited to only essential personnel.

Surgical and procedural areas

- 46. Controlled substances dispensed for a surgical case are reconciled by pharmacy against the products documented as administered or returned to the pharmacy.
- 47. Secure controlled substances in the operating room, procedural areas and anesthesia work areas during and between surgical cases.
- 48. The syringes prepared from multi-dose vials are labeled and kept under the control of the person preparing the syringes until administered.
- 49. Controlled substances not used in a surgical a case are wasted by the healthcare worker who administered them along with a licensed witness who verified the amount of waste.
- 50. Opaque bags are not used in surgical and procedural areas.

Provider prescribing

- 51. Electronic systems are used to prescribe and communicate controlled substances orders.
- 52. All verbal orders require authorized prescriber signature.
- 53. If written prescriptions are used, watermark paper is leveraged, prescription pads are secured and tracking controls are implemented.
- 54. Controlled substances are prescribed by only licensed providers with DEA authorization.
- 55. Use of order sets to prescribe controlled substances with dosing alerts and documentation of indication or clinical need.
- 56. Maintain a listing of authorized prescribers and validation of their DEA authorization status.
- 57. Pharmacy review and clarification with prescribing provider for any controlled substance orders that comes into question.
- 58. Definition of an automatic order stop is defined after an established period of time or number of doses of a controlled substance.

Nursing care units

- 59. Controlled substances brought by the patient from home should be inventoried, documented and recorded in the patient medical record by two licensed nursing personnel.
- 60. Controlled substances brought from home should be returned to home by a family member. The patient and family member should sign that they have received the medication and have verified its quantity. If medication can't be sent home, it should be stored in a locked safe in the pharmacy department.
- 61. Policies and procedures should be documented to address the disposal of controlled substances brought by the patient that are no longer needed and illegal substances brought in by a patient.
- 62. Decentralized ADD are used for controlled-substance distribution.
- 63. Use of "blind" count (ADD user is forced to enter inventory count when accessing a pocket).
- 64. ADD discrepancy resolution explanations are investigated in a timely manner per policy.
- 65. ADD discrepancies are analyzed to identify individuals most frequently involved in discrepancies.
- 66. ADD stock outages are investigated for potential diversion.
- 67. Locking cases are used to secure non-PCA controlled-substance infusion containers while being administered.
- 68. Diversion detection software flags users for controlled-substance ADD transaction counts significantly above peer group mean.
- 69. Alert (email, voice mail and pager) sent to pharmacy leaders when a specified ADD per-transaction threshold is exceeded.

- 70. Inventory is conducted at the end of every shift of the ADD pockets accessed.
- 71. Biometric fingerprint scan used for ADD access.
- 72. Medications are retrieved just prior to administration.
- 73. Wasting is completed with a second licensed staff member prior to administration of the medication.
- 74. Medications removed from the ADD are never left unattended.
- 75. ADD override capability is limited.
- 76. Prohibit drawing more than a single dose of a controlled substance into a syringe and saving partial doses in syringes at the bedside.
- 77. Medication administration can be correlated to the patient assessment or pain scale.
- 78. Integrity of medication packing is inspected.
- 79. Medication expiration date is verified.
- 80. Electronic verification via bar code scanning of the patient, medication, dose, route and time with administration.
- 81. Follow medication administration with documentation of administration location, reason for administration, noting the pain scale measure and resulting patient response.
- 82. All unused medication is witnessed, wasted immediately and documented.
- 83. All discrepancies are resolved upon discovery, no later than end of shift. Discrepancies which cannot be resolved are jointly reviewed by pharmacy and patient care leadership with resolution within 24 hours.

Organization

- 84. Organization has established an interdisciplinary CSDPP leadership team to define, support and guide the program and oversee the comprehensive controlled substance diversion prevention program. In addition, a designated diversion officer is identified within the organization.
- 85. Organization has defined a response team to respond to any suspected diversion that includes patient care manager, pharmacy, human resources and security personnel.
- 86. Process is established, documented and assigned to generate controlled substance data on a monthly basis.
- 87. Processes are established, documented and assigned to review and analyze controlled substance data on a monthly basis.
- 88. Mechanisms are defined to share the results of controlled substance analysis with the interdisciplinary leadership team defined to provide oversight to the comprehensive controlled substance diversion prevention program.
- 89. A standard process has been established and documented to investigate potential diversion cases.
- 90. Investigations are conducted in response to any suspected diversion.
- 91. DEA registrant or their designee reports all controlled substance thefts or significant loss to the DEA and as required by federal and state laws.
- 92. Drug diversion response in the organization includes assessment of harm to patients, consultation with public health officials when tampering with injectable medication is suspected, and prompt reporting to state and federal enforcement agencies.

A comprehensive audit approach

While monitoring and surveillance is management's primary role within a CSDPP, all relevant data regarding the controlled substance lifecycle management should be evaluated for trends, variances and improvement opportunities. A comprehensive CSDPP leadership team can work together to design, monitor and provide continuous audit feedback.

Audits of management monitoring and surveillance activities should include compliance reviews with federal and state regulations and organizational policies and procedures. Surveillance reporting, metrics and thresholds need to be identified and assessed. The frequency of reviews, audits and responsibilities must also be determined.

Audits should be conducted of diversion investigations to determine if the defined standard investigation approach is being followed. Further, documentation of investigations, completeness and reporting of investigations should be assessed. Internal audits should assess and confirm that corrective actions were taken as a result of investigations and reporting analysis.

All "systems of control" in the controlled substance lifecycle – from procurement to disposal – should be audited. The outcomes of a comprehensive audit approach may identify areas of non-compliance and often help in identifying opportunities to improve systems, processes and procedures.

A comprehensive audit approach can also provide assurance and advice through independent evaluation of an organization's drug diversion program, including assessment of policies and procedures, controls, monitoring, enforcement and continuous improvement. For example, in considering the "actions to prevent drug diversion" outlined in this whitepaper, a comprehensive auditing approach could provide assurance and advice with the following example reviews:

- **Review management controls over preventing and detecting drug diversion for common points of diversion risks**
- **Inspect HR and drug diversion management program policies and practices for inclusion of appropriate elements, such as:**
 - Written employee and provider substance abuse policy
 - Worker education and awareness program
 - Supervisor training program
 - Employee and provider assistance program
 - Peer support and systems
 - Requirements for screening and drug testing, including a for-cause policy for drug testing
 - Return-to-work policies for healthcare workers
 - Sanctions for performance and diversion violations
- **Compare the organizational drug diversion program to the CSDPP**
- **Assess management's controls and documentation of the organizational drug diversion program for evidence of effective and timely execution of training, monitoring, surveillance, timely investigation and routine reporting**
- **Test IT general controls for relevant drug inventory and diversion monitoring systems including application and automated controls, access to key configurations and transactions, system segregation of duties and change management.**

The outcomes of a comprehensive audit approach may identify areas of non-compliance and often help in identifying opportunities to improve systems, processes and procedures.

Taking a comprehensive approach with internal audit and risk management

Controlled substance diversion strategies have matured over the past five years. Significant improvements were made in the secure storage, dispensing, administration and monitoring of controlled substances. These improvements have evolved with the implementation of electronic health record systems, ADD units and bar code medication administration, but more must be done to prevent and mitigate risks. The opioid crisis and increase in drug diversion activity in

healthcare organizations will continue to spur support for definition and implementation of strong comprehensive diversion prevention programs. The risks to patient safety along with organizational financial, legal operational and reputational risks are too great to ignore. Internal audit along with your organization's other risk management functions have a significant opportunity to assist management to ensure the effectiveness of its drug diversion program.

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