

Controlled substances Identifying risks and internal audit focus areas



Introduction

With a mission focused on improving the health of patients and taking care of the sick, health care providers face unique challenges when dealing with responsibilities associated with controlled substances. Drugs and other substances that are considered controlled substances under the Controlled Substances Act (CSA) are divided into five schedules depending upon the drug's acceptable medical use and the drug's abuse or dependency potential:

- **Schedule I Controlled Substances (CI):** Substances in this schedule have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.
- **Schedule II/IIIN Controlled Substances (2/2N) (CII):** Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence.
- **Schedule III/IIIN Controlled Substances (3/3N) (CIII):** Substances in this schedule have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence.
- **Schedule IV Controlled Substances (CIV):** Substances in this schedule have a low potential for abuse relative to substances in Schedule III.
- **Schedule V Controlled Substances (CV):** Substances in this schedule have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics.¹

The Drug Enforcement Administration (DEA) is charged with enforcing the CSA. Special areas of risk and concerns specific to inventory management and regulatory compliance need to be considered when dealing with controlled substances. Diversion of such materials can be difficult to detect considering the number of different access points and variety of individuals involved in the medication distribution of controlled substances. Furthermore, there are additional special considerations for diversion activities specific to injectable drugs that can have dire consequences that affect patient safety.

Health care providers face unique challenges when dealing with responsibilities associated with controlled substances.

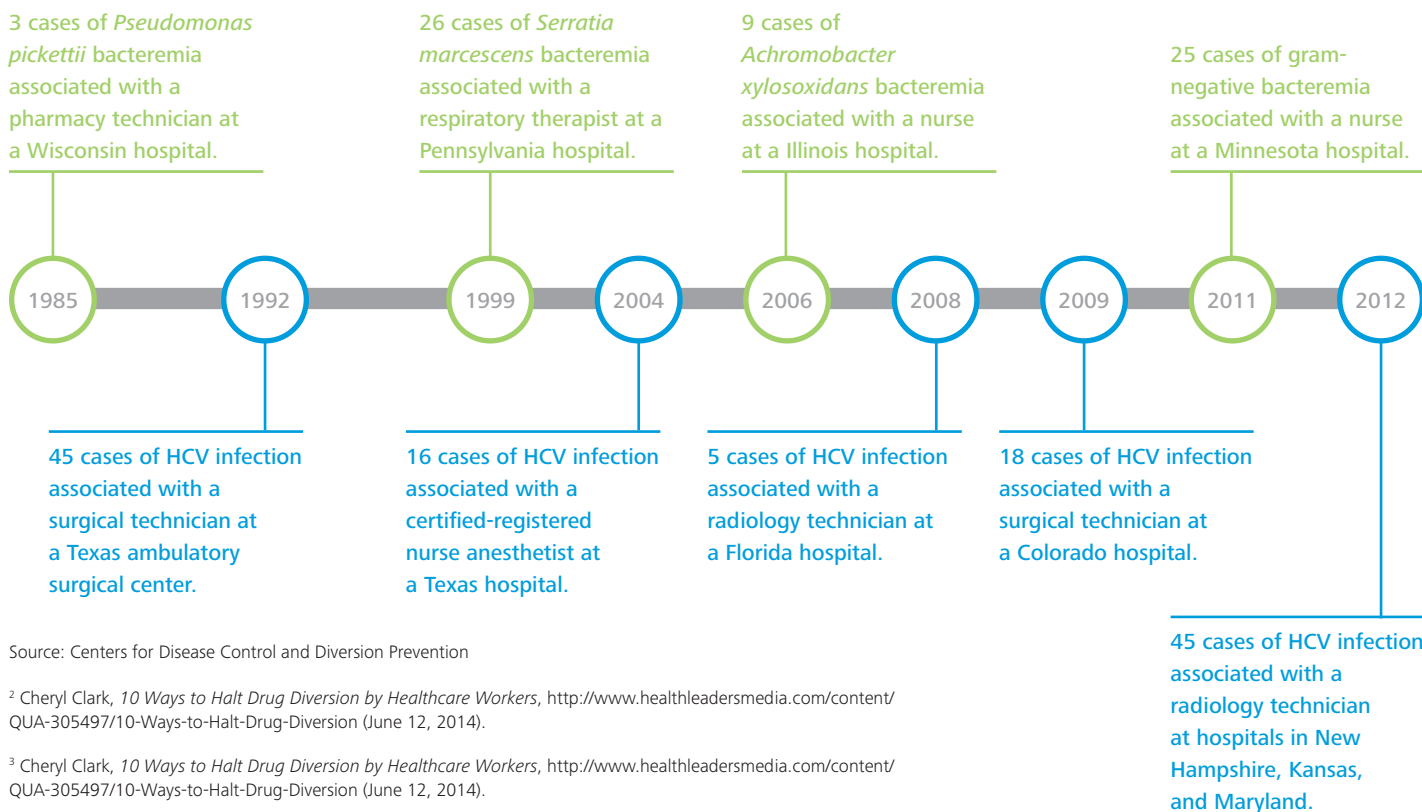
¹ U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control, <http://www.dea/diversion.usdoj.gov/schedules/>

Risks realized

About 15 years ago, one hospital realized and starting addressing the fact that they were sending at least one anesthesia worker a year into treatment for fentanyl addiction.² Additional instances of healthcare worker drug abuse were discovered by another provider when a patient died from a hepatitis C infection caused by a radiology technician diverting drugs.³ A recent article published by Elsevier illustrated the growing problem of patient harm stemming from diverting injectable drugs. Over the past 10 years, outbreak investigations related to health care provider drug diversion have documented more than 100 infections and nearly 30,000 patients potentially exposed to blood borne or bacterial pathogens. The frequency with which these events have been detected appears to be increasing".⁴

The Centers for Disease Control and Diversion Prevention (CDC), along with state and local health authorities, have assisted investigating infection outbreaks stemming from drug diversion activities that involved healthcare providers who tampered with injectable drugs. A summary of recent outbreaks is illustrated in the following timeline.⁵

As the frequency of diversion activities has increased, it brings even more attention. Without a solid prevention program in place, healthcare providers are playing a high risk game with patient lives and addicted healthcare workers. This brings both reputational and financial implications to the organization.



Source: Centers for Disease Control and Diversion Prevention

² Cheryl Clark, *10 Ways to Halt Drug Diversion by Healthcare Workers*, <http://www.healthleadersmedia.com/content/QUA-305497/10-Ways-to-Halt-Drug-Diversion> (June 12, 2014).

³ Cheryl Clark, *10 Ways to Halt Drug Diversion by Healthcare Workers*, <http://www.healthleadersmedia.com/content/QUA-305497/10-Ways-to-Halt-Drug-Diversion> (June 12, 2014).

⁴ CDC Report: *Patients Harmed After HealthCare Providers Steal Patients' Drugs*, <http://www.elsevier.com/about/press-releases/research-and-journals/cdc-report-patients-harmed-after-health-care-providers-steal-patients-drugs> (June 2, 2014).

⁵ Centers for Disease Control and Diversion Prevention, *Risks of Healthcare-associated Infections from Drug Diversion*, <http://www.cdc.gov/injectionsafety/drugdiversion/> (June 2014).

○ Bacterial outbreak
○ Hepatitis C virus (HCV) outbreak

Program requirements

The handling of controlled substances is subject to numerous regulations, starting with the requirement that pharmacies and the providers hold licenses that are up to date and in proper standing with the licensing authorities. Upon acquisition of these medications, tracking the chain of custody is necessary for operations and compliance accountability. Part of the chain of custody involves segregated storage of these medications in locked areas with restricted access. When dispensing these medications, a perpetual inventory must account for all allocations (dispensed/returns/waste) of these medications.

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Per regulation and hospital policy, only certain healthcare professionals are allowed to handle controlled substances in efforts to minimize diversion and improper handling. Additional training should be provided and documented to establish that the persons are qualified for the handling of these types of medications. Records of inventory, training, and licenses must be retrievable during a federal, state or other external audit that show appropriate handling and accounting for the drugs has occurred. Automated dispensing devices and software applications have made compliance with tracking and accountability requirements more user friendly for health care organizations. However, periodic internal audits should be conducted to determine if employees are following policies and that robust tracking of medication is occurring facility wide.



Considerations when conducting an internal audit

The following are some example activities to consider when conducting an internal audit:

- Perform business process walkthroughs, inquiries and document reviews to assess whether procedures and internal controls exist to comply with controlled substance requirements.
- Assess compliance with registration requirements:
 - Does the person/site have a current and valid DEA registration?
 - Is the DEA registration specifically for the location that is being reviewed?
 - Is the current and valid registration kept on site or is there a letter to the DEA requesting a central recordkeeping site?
 - Is the re-registration application signed by the current DEA Registrant?
 - Is a current and valid state registration on site?
 - Are any drug compounds at the site and/or activities being performed that are not supported by the current and valid registration?
- Assess compliance with the physical security requirements:
 - If the storage area contains/holds any CI through CV compounds, are the physical security controls in compliance with 21 CFR Part 1301.72 (Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas)?
 - If the registrant is a clinical researcher, are the physical security controls in compliance with 21 CFR Part 1301.75 (Physical security controls for practitioners) for storage areas that contain/hold any CI through CV compounds?
- Review alignment of employee screening recommendations per 21 CFR Part 1301.90 (Employee screening procedures):
 - Is there an employee screening procedure in place?
 - Is this employee screening procedure company-wide?
- Assess compliance with records and reporting requirements:
 - Does the site have records for the last two years on site, or is there a DEA-approved central recordkeeping site where the records are kept?
 - Has the site performed an inventory of records and reports in the last two years per 21 CFR Part 1304.11 (Inventory requirements)?
- If yes, does the inventory reflect all material “on hand” and delineated by material which is on site versus that which is kept elsewhere?
 - For changes in re-scheduling of a controlled substance, are there any compounds handled at the site that were re-scheduled and are either not included in an initial inventory at the time of being re-scheduled or are not part of the biennial inventory?
 - Are the records in compliance with 21 CFR Part 1304.11 (Inventory requirements)?
 - Are the continuing records in compliance with 21 CFR Part 1304.21 (General requirements for continuing records)?

- Assess compliance with order form requirements:
 - Are unexecuted DEA 222 forms secured in a locked or restricted access area?
 - Are there any log entries for CI or CII compounds that do not have an accompanying DEA 222 form or that do not qualify for DEA 222 exceptions?
 - Are there any DEA 222 forms that are signed by someone other than an authorized Power of Attorney (POA), and is the POA authorized by the current DEA Registrant?
 - Are the DEA 222 forms executed in compliance with 21 CFR Part 1305.06 (Persons entitled to fill orders for Schedule I and II controlled substances)?
- Assess destruction and/or disposal requirements:
 - Do destruction records/ DEA 41 forms for the last two years align with Automation of Reports and Consolidated Orders System (ARCOS) reports for the same time period?
 - If on-site destruction is performed, is there a valid DEA authorization letter on file?
 - If off-site destruction is performed, have all DEA stipulations been met?
- Review training programs in place:
 - Does the site indicate current training records for the employees handling controlled substance materials?
 - Does training occur for:
 - All new employees at the beginning of employment?
 - New employees who are likely to handle controlled substances materials?
 - Annually for all employees?
 - On a supervisor-specified basis?
 - Does the training program recognize on-the-job experience as a substitute for formal re-training?
 - Is training evaluated by written testing and performance?
- Review loss/ diversion reporting:
 - Do implemented systems sufficiently and quickly detect loss or diversion?
 - Is there an electronic database used for capturing and tracking controlled substances material movement within the site and additional areas?
 - Are there any documented situations of unaccounted losses or potential diversion of product that was not reported to the DEA?
 - Has the site experienced any losses/diversions of controlled substances materials with use of outside contractors?



Additional prevention considerations

In addition to following compliance rules, regulations, and guidelines, the following are further considerations for enhancing the safety of patients and employees:

- Has a zero tolerance policy been instituted for theft of any controlled substances?
- Is a 24-hour diversion hotline employed for workers to report suspicious behavior?
- Has a medication diversion prevention team been formed, which includes a full-time coordinator who is either a pharmacist or a certified pharmacy technician?
- Is a waste retrieval system available everywhere injectable opioids are used in patient care?
- Are areas throughout your organization that are most vulnerable, from the loading dock to the incinerator tracked and updated/modified as new diversion schemes are detected?
- Has a policy been implemented that the hospital has an obligation to report to the DEA when an employee is found to be diverting controlled substances.
- Is treatment offered if an employee is caught and terminated?

Developing and maintaining a robust program to track and prevent diversion activities should be a top priority, not only for the health and safety of patients, but for the health and safety of the organization's health care professionals.

With patient's health and safety being of paramount concern for health care providers, it should be clear that the risks related to diversion activities of controlled substances must not be taken lightly. Developing and maintaining a robust program to track and prevent diversion activities should be a top priority, not only for the health and safety of patients, but for the health and safety of the organization's health care professionals.

References

U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control, <http://www.deadiversion.usdoj.gov/schedules/>.

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Contacts

AHIA

Mark Eddy, CPA

HCA Healthcare
Mark.Eddy@
HCAHealthcare.com

Glen Mueller, CPA (Chair)

Scripps Health
Mueller.Glen@
scrippshealth.org

Debi Weatherford, CPA

Piedmont Healthcare
debi.weatherford@
piedmont.org

Deloitte

Kevin Wijayawickrama

Principal
Deloitte & Touche LLP
kevinw@deloitte.com

Karolyn Woo

Senior Manager
Deloitte & Touche LLP
kwoo@deloitte.com

Michael Fabrizio, CPA

Carolinas Healthcare
System
michael.fabrizius@
carolinashealthcare.org

Mark Ruppert, CPA

Cedars-Sinai Health System
Mark.Ruppert@cshs.org

Neetu Khilnani

Senior Manager
Deloitte & Touche LLP
nkhilnani@deloitte.com

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