

OBJECTIVES

Discuss	Discuss recent headline cases of drug diversion
Identify	Identify the link between drug diversion prevention and patient safety initiatives
Review	Review the key themes from the 2022 ASHP Guidelines on the Prevention of Controlled Substance Diversion

RELEVANT FINANCIAL RELATIONSHIP DISCLOSURE

The following person in control of this activity's content have relevant financial relationships:

Amanda Hays: employee and shareholder of Becton and Dickinson and Company

 As defined by the Standards of Integrity and Independence in Accredited Continuing Education definition of an ineligible company. All relevant financial relationships have been mitigated prior to the CPE activity

RECENT HEADLINES

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Wednesday, November 16, 2022

Man Convicted for Health Care Fraud and Prescription Drug Diversion Scheme

A federal jury convicted a California man yesterday for his role in an approximately \$723,000 health care fraud and prescription drug diversion scheme involving two Southern California pharmacies.

Thousands of doses of fentanyl, other drugs reported missing from local hospital

McLaren Health and feds reach record \$7.75M settlement of drug allegations



Published 5:40 p.m. ET Jan. 19, 2021 | Updated 6:13 p.m. ET Jan. 19, 2021

For Immediate Release

RECENT HEADLINES



November 30, 2021

Contact: Cynthia M. Velazquez Phone Number: 571-324-7481

UT Southwestern to Pay \$4.5 Million to Resolve Alleged Controlled Substance Act Violations That Permitted Drug Diversion by

NEWS > INVESTIGATIONS

Two nurses died of overdoses inside a Dallas hospital. What went wrong?

The nurse lay in a bathroom stall, a syringe in her hand and track marks on her arm. She died from an overdose of fentanyl, a potent painkiller meant for patients. It was a rare accident two years ago at UT Southwestern's Clements hospital in Dallas. Until it happened again.

How did 7 gallons of fentanyl go missing from a hospital? Regulators launch investigation

Mackenzie Bean and Erica Carbajal - Updated Friday, June 10th, 2022

RECENT HEADLINES

DANVILLE, Va. (WSET) — SOVAH Health has reached a settlement with the U.S. Dept. of Justice for \$4.36 million related to violations of the Controlled Substance Act.

In two separate incidents between 2017 and 2020, SOVAH employees diverted controlled substances from the healthcare facility.

In the first, from 2017 to 2019, Paulette Toller, a pharmacy technician at SOVAH Health Danville, admitted to finding a "loophole" in the hospital's automated dispensing system that allowed her to withdraw controlled substances under codes that were no longer valid. An affidavit showed Toller illegally obtained two syringes of oxycodone liquid and a total of 13,422 controlled substance pills. She was sentenced to 13 months in prison.

Northeast Hospital Agrees to Pay \$1.9 Million To Resolve Allegations of Controlled Substance Recordkeeping Violations

BOSTON – Northeast Hospital Corporation (Northeast), part of Beth Israel Lahey Health, has agreed to pay \$1.9 million in civil penalties to resolve allegations that Northeast violated the Controlled Substance Act (the CSA) by failing to keep accurate records of controlled substances, including opioids.

The CSA requires accurate inventorying and tracking of each controlled substance in circulation, from the manufacturer to the ultimate user. The recordkeeping requirements are intended, in part, to prevent misuse of controlled substances and avoid overdoses or other harms.

Northeast does business as Beverly Hospital in Beverly, Mass.; Lahey Outpatient Center Danvers in Danvers, Mass.; BayRidge Hospital in Lynn, Mass.; and Addison Gilbert Hospital in Gloucester, Mass. Each of these four locations is separately registered with the Drug Enforcement Agency (DEA) to handle controlled substances.

The DEA began investigating Northeast after it reported on March 22, 2018, that an employee had stolen 17,846 dosage units of controlled substances, including fentanyl, Percocet, oxycodone, dextroamphetamine and MS Contin, over more than a year. Northeast discovered the diversion in the course of implementing improvements to its pharmacy operations and controlled substances accountability procedures, and promptly suspended the employee.

RECENT HEADLINES

PRESS RELEASE

Former Nurse Sentenced for Tampering with Fentanyl Vials Intended for Patients at Fertility Clinic

Tuesday May 25, 2021

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For Immediate Release

U.S. Attorney's Office, District of Connecticut

Leonard C Boyle, Acting United States Attorney for the District of Connecticut, announced DONNA MONTICONE, 49, of Oxford, was sentenced today by U.S. District Judge Janet C. Hall in New Haven for tampering with fentanyl vials intended for patients at the fertility clinic where she was employed. Monticone was ordered to serve three years of supervised release, four weekends of incarceration, and three months of home confinement.

According to court documents and statements made in court, Monticone was a nurse employed by the Yale Reproductive Endocrinology and Infertility clinic "Yale REI clinic") in Orange. As part of her responsibilities at the Yale REI, Monticone ordered and inventoried a variety of narcotics used by the clinic, including fentanyl, which is a component of a cloner of drugs used by Yale physicians during outpatient surgical procedures to anesthetize patients and protect them from feeling pain.

In June 2020, Monticone began stealing fentanyl for her own use. She accessed secure storage areas and took vials of fentanyl, used a syringe to withdraw the narcotics from the vials, and reinjected saline into vials so that it would appear as if none of the narcotics were missing. The investigation revealed that approximately 75 percent of the fentanyl given to patients at the Yale REI clinic from June to October 2020 was adulterated with saline. Some of the vials contained diluted fentanyl, while others contained no drug at all and contained just saline.

Monticone knew that the adulterated vials of fentanyl she replaced at the Yale REI clinic would be used in surgical procedures, and that the absence of an anesthetic during an outpatient procedure may cause serious bodily injury to the patient. Monticone initially injected herself with the fentanyl while working at the Yale REI clinic and eventually began taking the vials home. She would refill the vials with sterile saline at home, bring them back to the clinic, and reintroduce them into the stock of fentanyl available for used during surgical procedures. On approximately November 1, 2020, Monticone brought approximately 175 vials of

The Reverberations of Pain and Its Dismissal

On 'The Retrievals,' a new podcast presented by Serial Productions and The New York Times, a dozen women speak about their traumatic experiences at a fertility clinic, where pain medication was secretly swapped out for saline. WIIIV WE ALE

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For Immediate Release



Drug Enforcement Administration

Brian D. Boyle Special Agent in Charge New England @DEANewEnglands June 22, 2023

Contact: Kristen Govostes Phone Number: (617) 557-2100

Cheshire Medical Center to Pay \$2 Million to Settle Allegations of Controlled Substances Act Violations

CONCORD, N.H.-U.S. Attorney Jane E. Young announces today that Cheshire Medical Center (CMC) in Keene will pay \$2 million to resolve allegations that it violated the Controlled Substances Act (CSA) by failing to keep accurate records of controlled substances, including opioids.

"Cheshire Medical Center's failure to fulfill its obligations under the Controlled Substance Act enabled the theft of prescription narcotics—including powerful opioids such as fentanyl, which led to a shockingly high percentage of drugs missing from CMS's inventory. The failures uncovered warranted a multi-million-dollar penalty and a stringent corrective action plan," said U.S. Attorney Jane Young. "This is one of the largest settlements of drug diversion claims against a hospital in the country."



Drug Enforcement Administration

Michael A. Davis Special Agent in Charge St. Louis @DEAStLouisDive March 09, 2023

Contact: Andree Swanson Phone Number: (571) 362-5149 For Immediate Release

Nurse at St. Louis County Hospital Sentenced to Four Years of Probation for Fraudulently Obtaining Fentanyl

ST. LOUIS – U.S. District Judge Stephen R. Clark on Thursday sentenced a former nurse at a St. Louis County, Missouri, hospital to four years of probation for fraudulently obtaining fentanyl for her own use.

From Jan. 18, 2020 to Feb. 2, 2020, Lindsay J. Maupin, of Cape Girardeau, Mo., fraudulently obtained fentanyl from a Pyxis machine for her own use on multiple occasions. Maupin was working at Mercy Hospital South in St. Louis County at the

Pharmacy staff flagged Maupin for withdrawing two to three times more fentanyl than her peers, and she tested positive for fentanyl, court documents say.



Phone Number: 17 3, 693-3329

Austin Pharmacy to Pay \$200,000 in Civil Penalties for Alleged Violations of the Controlled Substances Act

AUSTIR, Texas People's Pharmacy inc. has agreed to pay \$200,000 in pivil penalties to resolve allegations that it violated applicance the Controlled Substance And USA.

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HEALTHCARE WORKER DRUG DIVERSION



10-15% experience drug or alcohol dependence

Only a fraction of those go on to divert from their employer but the exact number is unknown

Risks to patients include inadequate pain relief and exposure to infectious disease



Co Occurring Disease

Depression and post-traumatic stress disorder (PTSD)

Fatigue

Stress



Impact of COVID-19

Increase in substance use due to rise in depression and mental health disorders

Focus shift to frontline care needs

Ref:

The Joint Commission, Drug diversion and impaired health care worker. Quick Safety, Issue 48, April 2019
 Baldisserri MR. Impaired healthcare professional. Crit Care Med 2007; 35(suppl):S106-16.

^{2.} balasserri Mk. impaired nearincare professional. Crit Care Med 2007; 33(suppl):3100-10.

WHAT KEEPS ME UP AT NIGHT?



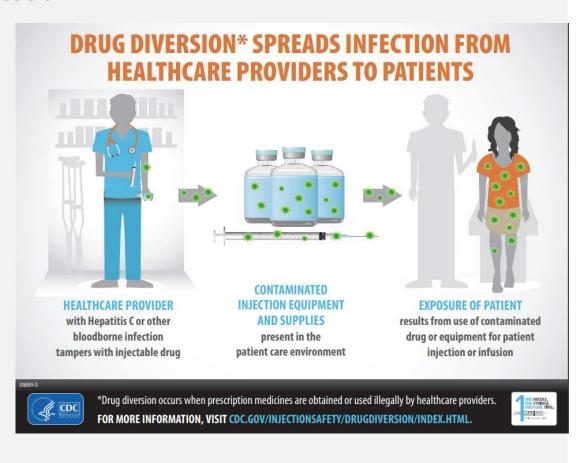
Employee is diverting medications and tampers with medication using non-sterile technique, or otherwise unsafe injection practices



Employee has an infectious disease



Infectious disease spreads to patients



DRUG DIVERSION IMPACT PATIENT SAFETY



Pain

Patients not receiving pain medications due to delay, underdosing, or non-dosing

Treatments/surgical intervention without adequate pain relief

- Joint Commission Quick Safety Brief. Drug Diversion and Impaired Health Care Workers. April 2019
- 2. CDC. Viral Hepatitis Outbreaks Related to Health Care.
- 3. Medical Professionals Reference, July 7, 2017
- 4. MMWR 2019;68 (16):374-6
- 5. The Washington Post, Aug 8, 2019
- 6. JAMA Network Feb 27, 1991



Viral Infections²

Hepatitis and HIV

2008 – 2019: 4 outbreaks by HCV-infected health care providers – with at least 90 outbreak-associated cases of HCV and 28,989 persons notified for screening²

Long incubation period + (typically) asymptomatic illness with HBV and HCV = underdetected and underreported²



Other Bacterial Infections³⁻⁶

- Achromobacter xylosoxidans
- Serratia marcenses
- Sphingomonas paucimobilis
- Pseudomonas picketti
- Ochrobactrum anthropic
- Stenotrophomonas maltophilia

RECOGNITION OF DRUG DIVERSION AS A PATIENT SAFETY **THREAT**





Drug diversion and impaired health care workers

In every organization, drug diversion is a potential threat to patient safety. Risks to patients include inadequate pain relief and exposure to infectious diseases from contaminated needles and drugs, compounded by potentially unsafe care due to the health care worker's impaired performance. Furthermore, diversion may cause undue suffering to patients who don't receive analgesic relief, can be costly to an organization by damaging its reputation, and may lead to major civil and criminal monetary penalties.

Statistics from both the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) and the American Nurses Association (ANA) suggest that about 10 percent of health care workers are abusing drugs. Due to the availability of and access to medications in health care organizations, diversion of controlled substances can be difficult to detect and prevent without a comprehensive controlled substances diversion prevention program

The Drug Enforcement Administration (DEA) recognizes five classes of drugs that are frequently abused: opioids, depressants, hallucinogens, stimulants, and anabolic steroids. A major driver of drug diversion is opioid abuse, which in recent years has reached epidemic proportions. Chain of custody

· Returns, waste, and disposal

Human resources management
 Automation and technology
 Monitoring and surveillance

Essential components of a controlled substances diversion prevention program

Legal and regulatory requirements
 Organization oversight and accountability

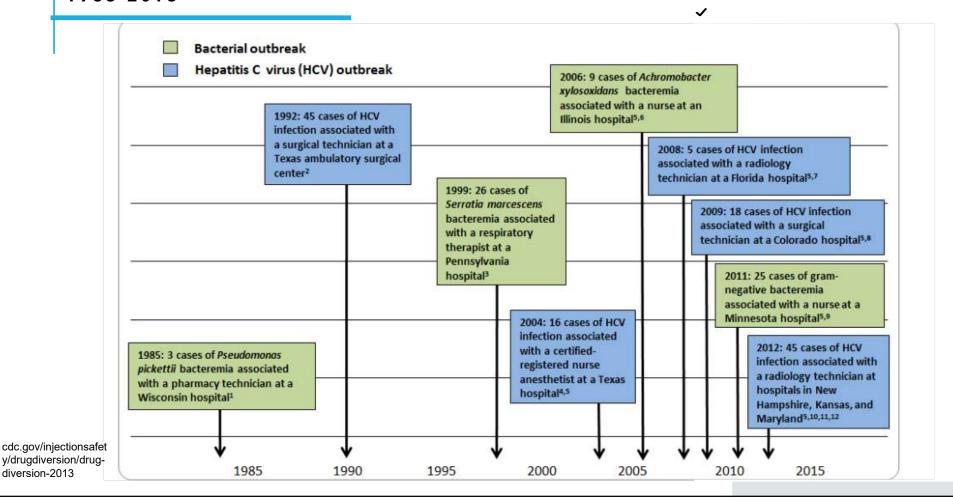
Fentanyl — one of the most potent opioids — is the most commonly diverted drug, and is the lead opioid in causing deaths due to opioid overdoses. Diversion of opioids in injectable and oral forms is seen across all levels of an organization, from chiefs to frontline staff, and across all clinical disciplines.

Experts believe that only a fraction of those who are diverting drugs are ever caught, despite clear signals—such as abnormal behaviors, altered physical appearance, and poor job performance. Direct observation is vital to detecting diversion and may be the only way to identify an impaired colleague. In organizations where controlled substances are used, all staff should be educated about CSDPP, including leadership rsight, legal and regulatory requirements, monitoring and surveillance, automation and technology, and

The organization's culture must support empowerment of staff to stop, question and act. Health care workers must be expected and empowered to speak up when something seems abnormal or unsafe.

Patterns and trends that indicate potential diversion
Leaders have a responsibility to establish processes that support staff while enabling rapid detection of
diversion. While all staff potentially may be implicated in diversion, evidence suggests that those employees
with the greatest access to controlled substances are at the highest risk.² The focus of surveillance should be
on patterns and trends, including:

U.S. OUTBREAKS ASSOCIATED WITH DRUG DIVERSION BY HEALTHCARE PROVIDERS, 1983-2013



13

DRUG DIVERSION WITH TAMPERING IMPACT HEALTH CARE IN THE UNITED STATES



28,000

Patients in a Mayo Clinic study were put at risk of Hepatitis C over a 10-year period¹



5

Patients that developed Serratia marcescens due to tampering in a PACU in Wisconsin²



12

Confirmed patients with Hepatitis C due to an ER nurses' unsafe injection practices and diversion in Washington state³



6

Roswell Park Comprehensive
Cancer Care patients reported
to have contracted
Sphingomonas paucimobilis due
to nurse tampering⁴



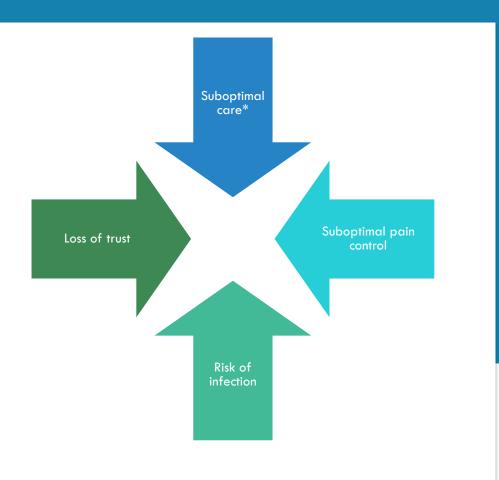
9

Patients impacted by tampering of fentanyl in the OR after developing Pseudomonas picketti

Recent Cases

- I. Mayo Clinic Proceedings, July 2014.
- . Medical Professionals Reference, July 7, 2017
- MMWR 2019;68 (16):374-6
- 4. The Washington Post, Aug 8, 2019
- 5. JAMA Network Feb 27, 1991

HEALTHCARE DIVERSION IS A PATIENT SAFETY ISSUE



THE SERIAL INFECTOR- HEPATITIS C



16 charges



46 infected



Fired 4 times



8 states



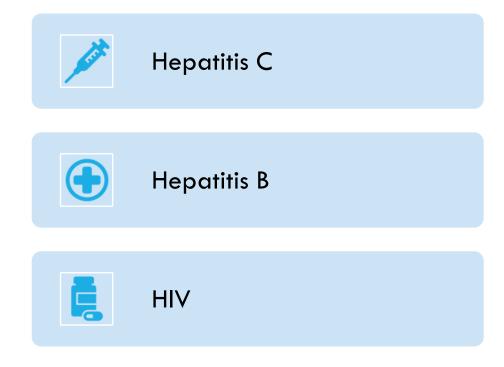
Injectable Fentanyl



39 years in prison

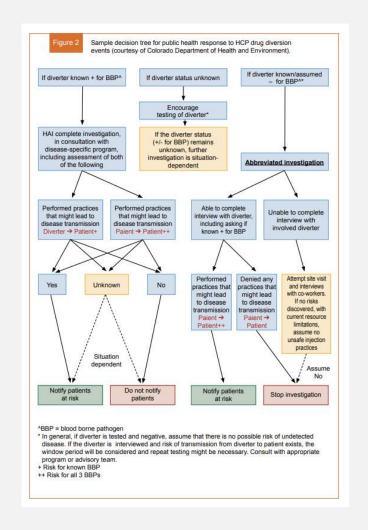
INFECTIOUS COMPLICATIONS

- Atypical Infections:
 - Achromobacter xylosoxidans
 - Serratia marcenses
 - Sphingomonas paucimobilis
 - Pseudomonas picketti
 - Ochrobactrum anthropic
 - Stenotrophomonas maltophilia



SAMPLE WORKFLOW FOR DRUG DIVERSION EVENTS

1. Council of State and Territorial Epidemiologists Healthcare-Associated Infections Drug Diversion Planning and Response toolkit for State and Local Health Departments; June 2019



EXAMPLES OF DIVERSION

www.healthcarediversion.org

Drug wholesaler courier theft

Pharmacy technician theft of returns

Emergency Medicine
Technicians tampering with
vials on ambulances

Falsified prescriptions

Falsification of waste

Hospital visitor theft

Tampering with PCAs or continuous infusions

CURRENT HEALTHCARE CHALLENGES



ASHP GUIDELINES ON PREVENTING DIVERSION OF CONTROLLED SUBSTANCES



FOCUSED AREAS OF UPDATE

Governance and Culture

- Leadership support (including resources)
- Culture of safety
- Culture of recovery

Scope- Expanded

- Community and mail order pharmacy
- Acute and outpatient areas

Resources- Expanded

- Advance analytics
- Automated dispensing cabinets (ADCs)
- Security
- Audit resources

Is drug diversion prevention an organizational priority?

If not, why?



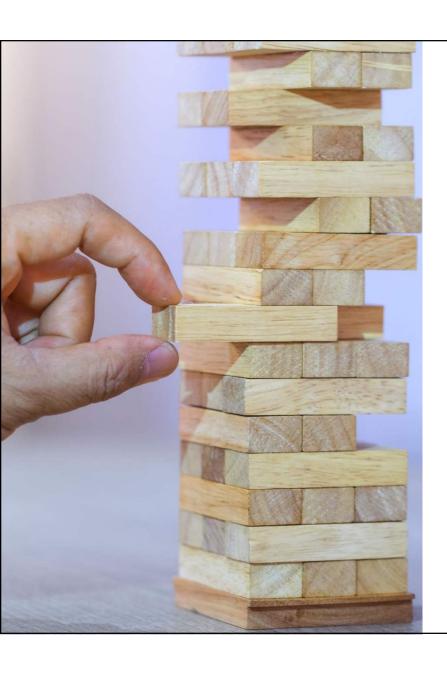
Refocus on the "why" behind diversion prevention initiatives

Patient harm

Regulatory, legal, financial, and reputational risks

Patient Experience

GOVERNANCE



GOVERNANCE

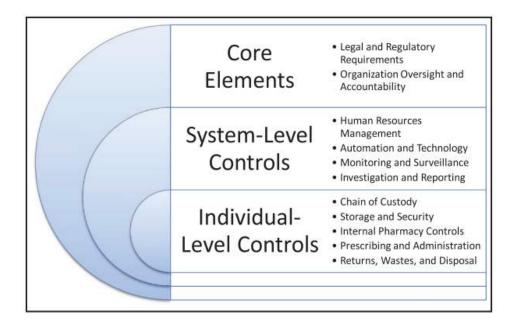
Gaps in resource investment continue in many organizations

- Advanced analytics
- Automated dispensing cabinets
- Security (camera or other)
- Auditing resources

Focus on relationships

- Nursing
- Medical staff
- System administration
- Staff awareness/signs of diversion or impairment

CONTROLLED SUBSTANCES DIVERSION PREVENTION PROGRAM (CSDPP)



https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-diversion-of-controlled-substances.ashx

MEDICATION USE SYSTEM- RISK POINTS

https://www.ashp.org/-/media/assets/policyguidelines/docs/guidelines/preventing-diversion-ofcontrolled-substances.ashx

Procurement and Storage

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

Prescribing

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

Preparation and Dispensing

- · CS are replaced by product of similar appearance when prepackaging
- · Removing volume from pre-mixed solutions
- · Multi-dose vial overfill is diverted
- · Prepared syringe contents replaced with saline solution

Administration

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

Waste, Removal, and Destruction

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

CULTURE

Culture of Safety

 Speak up culture supports culture of reporting for suspected diversion

Culture of Recovery

- Rehabilitation of healthcare workers with SUD
- Employee assistance programs
- Professional assistance programs
- Treatment success



GUIDELINE SCOPE:

COMMUNITY & MAIL ORDER PHARMACY



Community and mail delivery pharmacy was covered in initial guidelines (but not in depth)

- Additional information on registration requirements (drug receptacle collection, pseudoephedrine)
 - Receptacles- chain of custody, security, shipping package inspection

Security- included information on cameras, panic button/safe rooms, locked compartments for refrigerated CS

Auditing systems to track and validate inventory adjustments; automated dispensing

Specific risks- will call, meds to beds, canceled and return to stock

Fraudulent prescriptions

GUIDELINE SCOPE: CARE CONTINUUM



- Ambulatory surgery
- Nursing homes/closed door pharmacy
- Long-term care
- Home infusion
- Hospice
- Clinics
- Specialty pharmacy
- Free-standing ED or Urgent Care

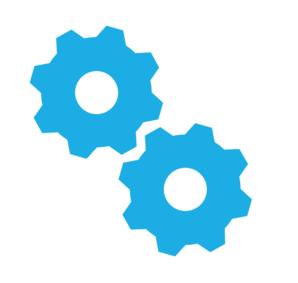
RESOURCES

Gaps in resource investment continue

- Advanced analytics- implement to reduce manual audit load (end to end coverage)
- Automated dispensing cabinets- coverage to alternate sites of care
- Security (camera or other)
- Auditing resources

Automation and Technology

- Increased focus on control, surveillance, and auditing
 - Chain of custody- end to end
 - Inventory- Automated Dispensing Cabinet (ADC) weekly if not blind counted each time, change of shift outside of ADC
 - Product with practice- focus on vial sizes needed for high risk injectables
 - Reduce-product specific dispensing



RESOURCES

Monitoring and Surveillance

- Coverage for all sites of care
 - Manual or automated auditing
 - To and From
- "The Basics"
 - Review medications obtained in non-pharmacy reviewed situations (overrides)!
 - Discrepancy investigations
 - Pain assessment/reassessment
 - Reconciliation (order to administration)



KEY PROCESS INDICATORS

Diversion risk point	Key process indicators
Procurement and inventory	Random inventory audits (to ensure the perpetual inventory count is correct) Inventory adjustment reasons and user Destocks Inventory statistics (amount dispensed, top movers, top issued medications, etc) Missing medication alerts
Preparation and dispensing	Overrides Quantity purchased vs. dispensed Discrepancies/time (day, month, etc) Discrepancy resolution by user Types of medications with top discrepancies Will-call audits (community-based prescriptions) Destock transactions Dispenses "off the clock" Dispensing consistent with pain scales Destock and null transactions Suspicious order monitoring Post-case reconcilling Time between event and detection Time between event and resolution Dispenses post discharge or transfer from unit Temporary patient additions
Prescribing	Verify active prescriber DEA license Only authorized prescribers are ordering CS (audit) Review and trend CS verbal orders that have not been cosigned Prescribing patterns trends compared to peers Suspicious order monitoring

Administration	Overrides
	User unlinked orders in relation to overrides
	Cancelation patterns/null transactions
	Returns
	Sole user (dispense, waste, return or issue)
	Out of area/unit dispensing/global list transactions
	Anesthesia post case reconciliation
	Anomalous user activity checks
	Gaps in documentation
	Delays in administration
	Delays in documentation
	Verbal read back or no cosign by location
Waste and	Waste patterns
removal	Waste witness patterns
	Time to document waste
	Delayed waste documentation from time of administration
	High waste products
	High waste procedures
	Full waste transactions
Overall process integrity	Post-case reconciliation
	Tracer audits (from the last biennial to a random day)
	Control substance safety reporting
	Submission information for DEA 106 reports
	State control substance filings
	Outstanding discrepancies
	Time to resolve discrepancies
	DEA/significant loss reports
	Expired CS trends

TAMPERING RED FLAGS¹



Product specific signs:

Missing, manipulated or broken tamper-evident seals

Behavioral/physical signs:

- Long sleeves in warm weather
- Frequent bathroom trips
- Disappearing for long periods of time
- Employee physically in areas where they do not belong/volunteering to do tasks associated with narcotic transactions/supplies
- Signs of withdrawal
 - Anxiety, agitation, nausea, vomiting, abdominal pain
 - Emotional outbursts or verbal response

Transaction signs:

- Canceled transactions
- Higher than expected waste by specific employee
- Using narcotic when other medications may be more appropriate

Patient complaints

SUGGESTED STRATEGIES

Educate staff on drug diversion signs/symptoms and safe injection practices

See something, say something

- Reusing syringes
- Accessing single dose vials multiple times

Talk to patients about their pain

Ensure your CSDPP has all the correct stakeholders

- Infection prevention
- Patient advocacy (complaints)
- Risk management



KEY TAKEAWAYS

Discuss

- Discuss your current state of drug diversion prevention initiatives with leadership
 - Focus on the "why" and the "why now"

Assess

- Use the gap analysis as a starting place (appendix B)
- Focus on resource gaps
- Evaluate for sites of care across your organization where Controlled Substances are used

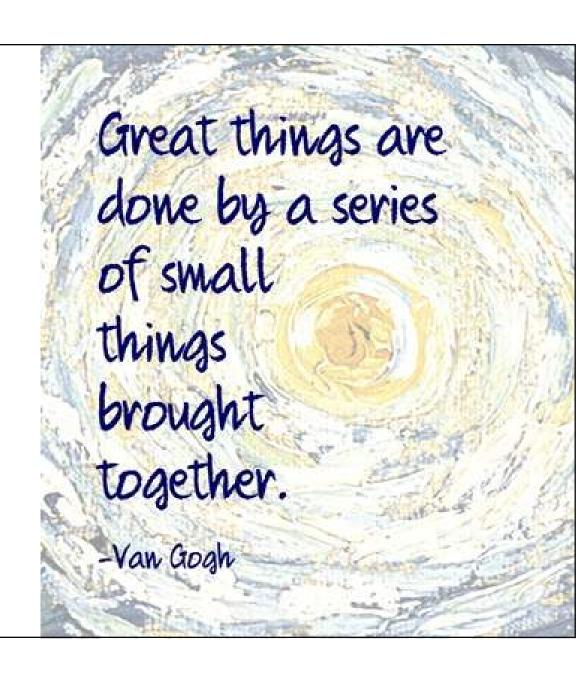
Develop

- Establish KPIs (table 1)
- Develop a culture of "see something, say something" to support earlier detection

QUESTIONS?

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- 3. Industry voices- as COVID-19 flare-up continue, healthcare organizations must double down on drug divers. T. Knight, Fierce Healthcare 2020
- 4. www.heatlhcarediversion.org
- 5. Culbertson N. July 15, 2020. "The Additional Crisis in America's Hospitals: Clinical Drug Diversion." Pharmacy Times. https://www.pharmacytimes.com/view/the-addiction-crisis-inamericas-hospitals-clinical-drug-diversion (accessed July 11, 2022).
- 6. A hospital staffer diverted drugs, which gave me hepatitis C. That happens more often than you think. Available at https://www.statnews.com/2019/12/20/drug-diversion-hospitals-hepatitis/. Accessed March 10, 2022.
- 7. Health Care Diversion Incident 33918. Available at https://healthcarediversion.org/incident-33918/. Accessed March 10, 2022.
- 8. Drug Diversion Puts Patients at Risk for Healthcare-Associated Infections. Available at: www.cdc.gov/injectionsafety/drugdiversion. Accessed February 25, 2022.
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- 10. Clark et al. ASHP Guidelines on Preventing Diversion of Controlled Substances, Am J Health Sys Pharm, 79, 24 (2022) 2279-2306.