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The Opioid Crisis – The Role of Healthcare Compliance

June 15, 2018

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- Dignity Health

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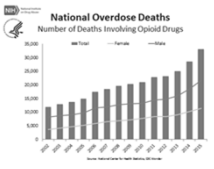
Agenda

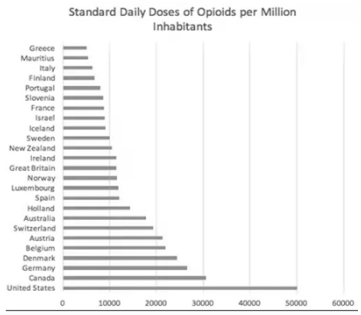
- Evaluate healthcare's contribution to the opioid crisis
- Analyze risks related to prescription drug diversions and abuse
- Present an overview of regulatory environment
- Offer proven drug –diversion solutions (policies, controls and compliance program)
- Provide investigative tools and data mining techniques

The Opioid Epidemic - Facts

- What are the facts (according to the Centers for Disease Control & America Society of Addiction Medicine):
  - On average, 115 Americans die every day from an opioid overdose
  - Drug overdose is the leading cause of accidental death in the U.S.
  - In 2014, nearly two million Americans either abused or were dependent on prescription opioid pain relievers
  - Overdoses from prescription opioids are a driving factor in the 16-year increase in opioid overdose deaths
  - The majority of drug overdose deaths (66%) involve an opioid



The Opioid Epidemic – Facts



Source: United Nations International Narcotics Control Board

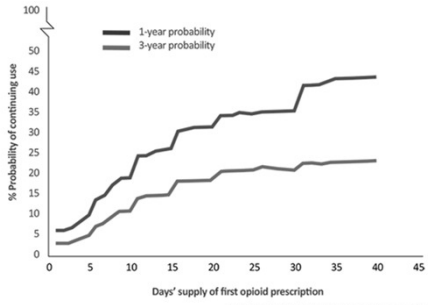
HealthCare's Contribution to the Epidemic

Healthcare's Contributions to the Epidemic - Post Surgery Scripts

- QuintilesIMS research firm as part of a national survey found:

	Nearly 3 million patients undergoing surgeries in 2016 became newly persistent opioid users
	Surgery-related overprescribing results in 3.3 BILLION unused pills available for misuse

New State Legislature Environment (as of April 2018)



Source: Centers for Disease Control and Prevention, 2017

Risks of Diversion & Abuse

What are the Risks?

Patients (Employee Diversion)	Patients (Patient Addicts)	Patient Sedation	Health Care Workers (Diverter)	Health Care Workers (Co-worker)	Hospital
Substandard Care	Patient becomes addict after surgery	Over sedating patients	Morbidity or Mortality	Disciplinary Action (for violation of P&P)	Loss of Revenue
Contamination	ED drug seekers continue their habit		Loss of Livelihood – loss of job, license	Mechanical Injury	Loss of Trust
Disease Spread	Patient addicts don't get help		Felony Criminal Prosecution	Infection (contaminated needles/broken vials)	Loss of Goodwill
Medication Errors	Patients go to Heroin due to opioid addiction		Civil Malpractice		Civil Liability
			Billing Fraud		Sanctions
					Negative Publicity
					Loss of Ability to Serve Community
					Additional Regulatory Scrutiny

Effingham Health System paying largest settlement ever for thousands of unaccounted Oxycodone tablets

Ineffective controls/failure to report timely

EFFINGHAM CO., GA (WTOC) - The Effingham Health System has agreed to pay the nation's largest penalty settlement of its kind to resolve allegations the health system failed to provide effective controls and procedures to guard against theft and loss of controlled substances, leading to significant diversion of opioids and failing to timely report the suspected diversion to the Drug Enforcement Administration.

The health system has agreed to pay $4.1 million $1 million to resolve the

The DEA launched the investigation in 2017 after receiving reports of diversion at Effingham Health System.

The release from the United States Attorney's Office states, "DEA determined that tens of thousands of oxycodone 30mg tablets were unaccounted for, and were believed to have been diverted over more th n a four-year period, in violation of the hospital's responsibilities under the Controlled Subst es Act. DEA also determined that Effingham Health System failed to notify DEA of the su ed diversion within the time required by federal law."

Tens of thousands oxycodone diverted

"We would like to acknowledge today's news release from the Southern District of Georgia, U.S. Attorney's Office, regarding Effingham Health System. As that release states, Effingham Health System has agreed to settle a civil penalty related to alleged recordkeeping and notification violations of the Controlled Substances Act. The recordkeeping relates to pharmacy operations dating back to March of 2013 and does not reflect the current processes or procedures at the Hospital.

"We appreciate the cooperative nature of the United States Attorney's Office and Drug Enforcement Agency (DEA), for recognizing the efforts put forth since 2016 to improve pharmacy operations, "says Fran Baker-Hitt, CEO for Effingham Health System. "We were dismayed to find, through this investigation, vulnerabilities in our prior record keeping and reporting systems."

Former Billings Clinic nurse to admit stealing painkillers from patients for personal use

BILLINGS -- The former Billings Clinic nurse who was fired last year for allegedly diverting powerful painkillers intended for over 300 patients for his own personal use has indicated he will plead guilty to the charges.

An audit of the record keeping machine at the hospital revealed Mills made over 70 null transactions using his login from February through March.

Mills admitted he'd been carrying out the diversion scheme since February of 2017. He said he worked an average of four days a week and said he diverted two vials of Fentanyl most days that he worked.

Mills reported taking most of the Fentanyl out of vials using a syringe and replacing it with saline. When he did this, Mills said he made sure patients got a full vial along with whatever he switched out.

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Patient Safety Risks:

Police arrest Washington hospital nurse accused of infecting patients with hep C

Written by Alyssa Rege | May 07, 2018 | Print | Email

Police arrested a 31-year-old former MultiCare Good Samaritan Hospital nurse last week who may have infected at least two patients at the Puyallup, Wash., hospital with hepatitis C, according to *The News Tribune*.

Police booked Cora Weberg, RN, into Pierce County Jail early May 4. Authorities reportedly recommended prosecutors charge her with second-degree assault for allegedly knowingly infecting at least two patients and stealing injectable drugs from the hospital, according to the report. Ms. Weberg was released from jail May 5, according to *Kiro 7 News*.

Ms. Weberg has not been charged with a crime. However, a preliminary finding of probable cause filed by police and obtained by *The News Tribune* stated Ms. Weberg "intentionally contaminated medicine or another substance with her own blood; she then administered the medicine or other substance intravenously; Cora Weberg knew or reasonably should have known that her blood was likely to contain one or more blood-borne pathogens; and Cora Weberg's blood did, in fact, contain and transmit hepatitis C virus."

MultiCare Good Samaritan Hospital officials announced the possible infection of two patients last week, and issued a recommendation to 2,600 patients who were treated in the hospital's emergency room during an eight-month period between August 2017 and March 23 to receive testing for the infection.

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Pharmacy Theft Risks:

Pharmacist accused of stealing $10k worth of painkillers, amphetamines

By Andrea Hay | Posted: Thu 4:02 PM, Mar 08, 2018 | Updated: Thu 6:55 PM, Mar 08, 2018

GILLETT, Wis. (WBAY) - A former Gillett pharmacist faces felony charges, accused of stealing more than $9,000 worth of painkillers and amphetamines.

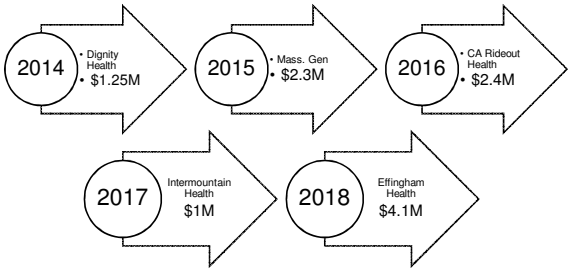
Angela Lane, 39, now lives in Green Bay, free on $10,000 bond. She's charged with theft and fraud for the illegal diversion of medication from the HSHS St. Clare Pharmacy in Gillett.

The Wisconsin Pharmacy Examining Board has suspended Lane's license to practice.

Court documents say Lane resigned from her position at the pharmacy after she was confronted by coworkers. Her boss told police she admitted to the theft right away.

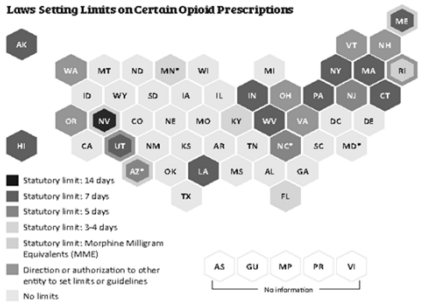
Financial / Reputation Risk – DEA Fine / Settlement Agreements:

"The DEA is committed to investigating hospitals that are not in compliance with the Controlled Substances Act (CSA)" Special Agent in Charge Michael J. Ferguson – 2015



Regulatory Response to Opioid Epidemic – What does this mean?

New State Legislature Environment (as of April 2018)



Joint Commission – New/Revised Pain Assessment and Management Standards

- Facility state PMP access
- Engage patients about pain management
- Patient education
- Referrals for addicted patients

New State Regulations – California BOP

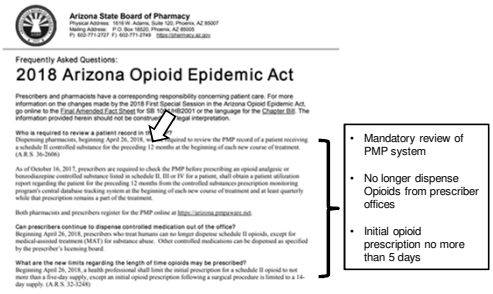
- Effective April 1, 2018

1715.65. Inventory Reconciliation Report of Controlled Substances

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.
(b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section.
(c) A pharmacy or clinic shall compile an inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This compilation shall require:
(1) A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section;
(2) A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report;
(3) A comparison of (1) and (2) to determine if there are any variances;
(4) All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form; and
(5) Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

- Quarterly inventory counts of CII
- Reconcile acquisitions and dispositions
- Explain variances
- Maintain reconciliation documentation

New State Regulations – Arizona Board of Pharmacy



Arizona State Board of Pharmacy
Physical Address: 1616 W. Adams, Suite 120, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
P): 602-771-2727 F): 602-771-2749 https://pharmacy.az.gov

Frequently Asked Questions:

2018 Arizona Opioid Epidemic Act

Prescribers and pharmacists have a corresponding responsibility concerning patient care. For more information on the changes made by the 2018 First Special Session in the Arizona Opioid Epidemic Act, go online to the Final Amended Fact Sheet for SB 1001/HB2001 or the language for the Chapter Bill. The information provided herein should not be construed as legal interpretation.

Who is required to review a patient record in the PMP?
Dispensing pharmacists, beginning April 26, 2018, are required to review the PMP record of a patient receiving a schedule II controlled substance for the preceding 12 months at the beginning of each new course of treatment. (A.R.S. 36-2606)

As of October 16, 2017, prescribers are required to check the PMP before prescribing an opioid analgesic or benzodiazepine controlled substance listed in schedule II, III or IV for a patient, shall obtain a patient utilization report regarding the patient for the preceding 12 months from the controlled substances prescription monitoring program's central database tracking system at the beginning of each new course of treatment and at least quarterly while that prescription remains a part of the treatment.

Both pharmacists and prescribers register for the PMP online at https://arizona.pmpaware.net.

Can prescribers continue to dispense controlled medication out of the office?
Beginning April 26, 2018, prescribers who treat humans can no longer dispense schedule II opioids, except for medical-assisted treatment (MAT) for substance abuse. Other controlled medications can be dispensed as specified by the prescriber's licensing board.

What are the new limits regarding the length of time opioids may be prescribed?
Beginning April 26, 2018, a health professional shall limit the initial prescription for a schedule II opioid to not more than a five-day supply, except an initial opioid prescription following a surgical procedure is limited to a 14-day supply. (A.R.S. 32-3248)

- Mandatory review of PMP system
- No longer dispense Opioids from prescriber offices
- Initial opioid prescription no more than 5 days

What are the Laws, Regulatory Bodies and Agencies Governing Drug Diversion?

What are the Laws, Regulatory Bodies and Agencies Governing Drug Diversion?

Federal	State	The Code of Federal Regulations (CFR)
• Comprehensive Drug Abuse Prevention and Control Act of 1970 • The Controlled Substances Act (CSA), Title II • DEA	• Boards of Pharmacy • Regulations/Laws vary by State	• Title 21 of the CFR deals with Food and Drug rules and regulations within the United States for the following agencies: • Food and Drug Administration (FDA) • Drug Enforcement Administration (DEA) and • Office of National Drug Control Policy (ONDCP) • Codes under Title 21 specific to Drug Diversion fall under sections: • 1301- Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances • 1304 - Records and Reports of Registrants • 1306 - Prescriptions

DEA Question 1

1. Does the DEA require controlled substance inventory discrepancy reviews?

a) Yes
b) No

Answer #1 = b / NO

1. Does the DEA require controlled substance inventory discrepancy reviews?

NO

- The Office of Diversion Control Controlled Substances Security Manual requires all registrants to provide ***effective physical security controls*** and operating procedures to guard against theft and diversion of controlled substances.
- The framework of the Controlled Substance Act (CSA) requires that all controlled substance transactions are to take place within a "closed system" of distribution. Within this "closed system" ***strict accounting for all controlled substance transactions*** must be maintained.
- The DEA Pharmacist Manual specifies that healthcare professionals and pharmacists share responsibility for ***preventing prescription drug abuse and diversion***.

DEA Question 2

2. Are hospital DEA fines calculated primarily on the lack of controls?

a) Yes
b) No

Answer #2 = b / NO

2. Are hospital DEA fines calculated primarily on the lack of controls?

NO

"It is the responsibility of any DEA registrant to **maintain accurate records** and safeguard controlled substances." Gary G. Grindelwald, DEA Special Agent

"The nation is in the midst of an opioid crisis and all entities that distribute controlled substances must hold the frontline. Regulatory compliance and **accurate recordkeeping are key** in a pharmacy's ability to prevent prescription drug diversion," stated DEA Special Agent in Charge John J. Martin

"One purpose of the CSA is to ensure that pharmacies **maintain accurate records** to minimize the chance of diversion of powerful and potentially addictive drugs, which wreak havoc on our communities and destroy lives," U.S. Attorney Talbert said.

DEA is a law enforcement agency that has the ability to assess civil and criminal penalties

$10,000* / *$25,000 per violation

Massachusetts General DEA Claims = $2.3 Million

- Failure to report theft / loss within one business day
- Failure to maintain complete and accurate records of all controlled substances
- Failure to document transfers of Schedule IIs
- Failure to document transfers of Schedule III-Vs
- Failure to conduct initial inventory
- Failure to conduct biennial inventory
- Biennial inventory was incomplete

Documentation

- Failed to provide effective controls and procedures to guard against theft / diversion

Access **Controls**

$10,000 per violation

DEA Findings – Ah Ha Moments

- Biennial inventory is whole house, one day and physical count
- Indicate "open or close of business" on biennial inventory
- Date received indicated on each invoice
- Power of Attorney (POA) cannot be sub-granted (only the registrant can grant access)
- ALL Controlled Substance records must be segregated

$10,000
per violation

Dignity Health's DEA Journey

Dignity Health's Journey

2012 Dignity Health facing over $10M fine!!!!

Dignity Health's Journey

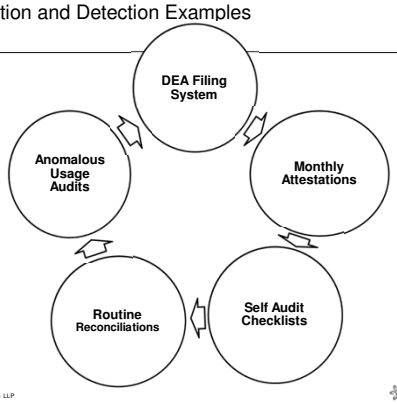
Culture Prior to DEA Agreement

- Pharmacy System Leadership was "Advisory"
  - No System Requirements
- Regulation compliance focus (vs. prevention and detection controls)
- Relied on Pharmacist in Charge (PIC) license for effective controls

Impact Throughout System

- Additions to daily duties for PIC and staff
- Additions to daily duties for Nursing
- New System oversight and accountability
- External and Internal audits
- New Key Performance Indicators (impact to Hospital Presidents Incentives)
- Added staffing to entire organization

Prevention and Detection Examples



DEA Findings - Recordkeeping

Published

DEA investigators also looked at the inpatient side of the house. "The accountability audit revealed material variances in counts for the majority of controlled substances evaluated, including most hydrocodone strengths. The investigation also revealed numerous record-keeping deficiencies at St. Joseph's inpatient and outpatient pharmacies, including failure to maintain complete and accurate records of receipt of controlled substances," failure to document the date of receipt on invoices and failure to finish a biennual inventory, which all were required by statute, the settlement alleged. Some of these problems, which are violations of the Controlled Substances Act, existed at several other Dignity facilities, the U.S. attorney alleges.

The DEA audit identified numerous infractions in recordkeeping requirements with each infraction fined at $10,000 / infraction.

- Poor Recordkeeping
- Failure to maintain accurate records of receipt
- Failure to maintain required inventory

Proven Drug Diversion Solutions

DEA File

Readily Retrievable Options

Spreadsheet

Paperwork / Documentation	Area Kept	Comments
Invoices, Previous Year (Jan - Dec) **CIII - CIV, CV**	Narcotic Room	Prior years in Director's office
Invoices, Previous Year (Jan - Dec) **CII**	Narcotic Room	Prior years in Director's office
Invoices, Current Year **CIII - CIV, CV**	Narcotic Room	
Invoices, Current Year **CII**	Narcotic Vault	
DEA 222 Forms, Unused	Director's office	
DEA 222 Forms, Executed	222s are separate in Narcotic Room - Current year	Prior years in Director's office
DEA 222 Forms, Executed - CSOS	Electronic	Carol's computer
CII Log Book	Electronic	Omnicell
Inventory Records of Controlled Substances	Electronic	Omnicell
Inventories, Initial and biannual, dated as beginning and close of business	Biannual -Board of Pharmacy book - dispensing pharmacist area	Others - Director's office
Records of Controlled Substances distributed	Electronic	Omnicell Record
Sales to other registrants; **returns** to vendors; **distribution** to reverse distributors	Carol's office	Returns only, no sales
Record of Controlled Substances dispensed (prescriptions, Schedule V logbook) - placeholder if electronic	Clinical office, wire rack outside Director's office	Omnicell Delivery record
DEA 106 Forms (Report of Theft or Loss of Controlled Substance)	Director's office	
DEA 41 Forms (Registrants Inventory of Drugs Surrendered - Spillage, loss, breakage, damage/ destruction)	Carol's office	with returns documents

- Binder with reference to "other" locations
- Binder with a spreadsheet to "other" locations

Directing staff to location

Located in Director of Pharmacy file cabinet:
- Unused DEA 222 Forms
- All Inventory Records of controlled substances (monthly, biennial)
- Records of Transfers of controlled substances between pharmacies (currently, none exists)
- Sales to other registrants, returns to vendors, distribution to reverse distributors
- DEA 106 Forms (Report of Theft or Loss of Controlled Substance)
- DEA 41 Forms (Registrants Inventory of Drugs Surrendered-Spillage, loss, breakage, damage/destruction)
- CHAN Report or internal audit report
- Current Power of Attorney (POA) paperwork/PIC charge
- Annual fiscal inventory paperwork
- DEA/BOP inspections/documents
- PIC change inventory paperwork/documents

Directing staff to location

Located in Storage Cage (Basement):
- Jan – Dec (CIII-CIV, CV) invoices
- Jan – Dec (CII) invoices
- Executed DEA 222 Forms with invoices attached
- Records of controlled substances distributed
- Outdated CII return documents
- Outdated CIII-CV return documents

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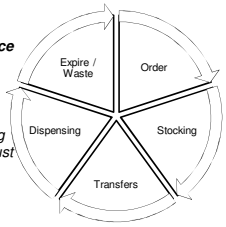
Proven Solutions: Closed Loop System

- Implement preventative and detective controls during every phase of the closed loop system

*The framework of the **Controlled Substance Act (CSA)** requires that all controlled substance transactions are to take place within a "closed system" of distribution.*

Within this "closed system" strict accounting for all controlled substance transactions must be maintained.



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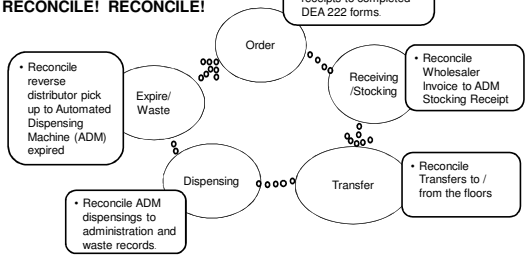
Proven Solutions: Reconciliations

RECONCILE! RECONCILE!

- Reconcile Power of Attorney's to CII orders
- Reconcile CII order receipts to completed DEA 222 forms.



- Reconcile reverse distributor pick up to Automated Dispensing Machine (ADM) expired
- Reconcile Wholesaler Invoice to ADM Stocking Receipt
- Reconcile Transfers to / from the floors
- Reconcile ADM dispensings to administration and waste records.

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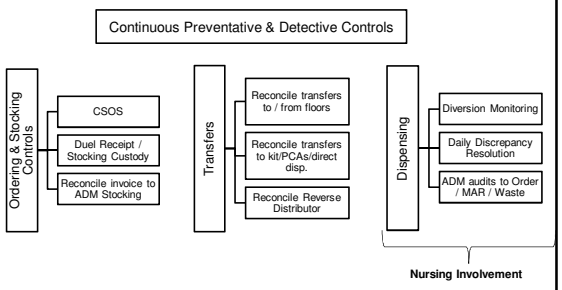
Proven Solutions: Control Examples



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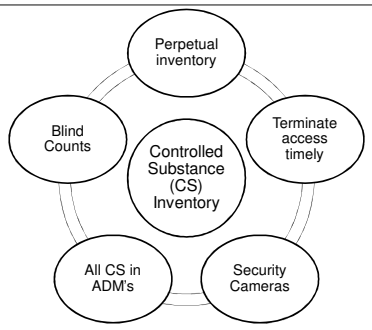
Proven Solutions : Security Requirements



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Preventative Controls

Automation:

- Perpetual inventory system
- Automated Dispensing Machines
  - ✓No generic / common ID access
  - ✓All CS maintained in ADM
  - ✓Profiled
  - ✓All waste require a witness
  - ✓Anesthesia carts
- Bar code scanning
  - ✓From receipt to bed side wrist band scanning
- Surveillance video monitoring

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Detection Controls - Nursing

Monitoring – NURSING

- High user employees
- Same witness / wasting habits
- Frequent discrepancies and null transactions
- Anesthesia box/trays reconciliation by pharmacy
- Bed side scanning exception reports (between withdraw and administration times and dosage)
- Audits of orders, administration, waste and returns
- Audits of overrides to orders

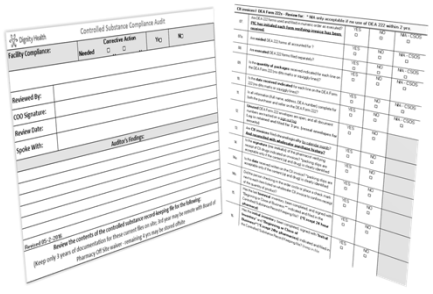
Detection Controls - Pharmacy

Monitoring – PHARMACY

- Reconcile online vendor purchases to invoices/stocking receipts/ADM receipts
- Review matching report of transports to / from floors
- Reconcile expired reverse distributor reports
- Audit and reconcile withdraws not dispensed to floor
- Reconcile expired controlled substances to vendor reports

Monthly Self Audits

- Complete monthly
- COO to sign
- Maintain in a file


Controlled Substance Compliance Audit

Facility Compliance:

Corrective Action Needed

YC NC

Reviewed By:

COO Signature:

Review Date:

Spoke With:

Auditor's Findings:

Review the contents of the controlled substance record keeping file for the following:

(Keep only 3 years of documentation for these current files on site; 3rd year may be stored with Board of Pharmacy Off Site request - ensuring 3 yrs max for most cases)

Detection Controls – All

• Accountability Audit – Hospital ADMs:

Beginning Inventory
+ Purchases Vendor #1
+ Purchases Vendor #2
+ Purchases Vendor #3
- Floor Dispensed
+ Returns
- Expired Pickups
- Direct Fills
- Charges / Admin records (floor/cart stock if not in ADM)
- Transfers to another DEA Registrant
- Misc., i.e. purchasing shortages, DEA 106, DEA 41
- Ending Inventory
= (Loss) / Overage

What Healthcare Compliance Needs to Know

Employee Screening

- A critical first step in diversion prevention is employee screening.
- The screening program should include a careful evaluation of the applicant's personal and previous employment references.
- Criminal background checks with local law enforcement authorities and with DEA are equally important.

Employee Responsibility to Report

- It is the position of DEA that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer.

Identify a loss? What to do…..

Drug Enforcement Administration
Pharmacist's Manual

A. Notify DEA and Local Police

The theft of controlled substances from a registrant is a criminal act and a source of diversion that requires notification to DEA. A pharmacy must notify in writing the local DEA Diversion Group (Appendix K) within one business day of discovery of the loss or theft of a controlled substance. Although not specifically required by federal law or regulations, the registrant should also notify local law enforcement and state regulatory agencies. Prompt notification to enforcement agencies will allow them to investigate the incident and prosecute those responsible for the diversion. If there is a question as to whether a theft has occurred or a loss is significant, a registrant should err on the side of caution and report it to DEA and local law enforcement authorities.

DEA must be notified directly. This requirement is not satisfied by reporting the theft or significant loss in any other manner. For example, a corporation which owns or operates multiple registered sites and wishes to channel all notifications through corporate management or any other internal department responsible for security, must still provide notice directly to DEA in writing within one business day upon discovery and keep a copy of that notice for its records. The notice must be signed by an authorized individual of the registrant.

Notify DEA within one day via a letter

THEFT **OR** SUBSTANTIAL LOSS

If loss is verified, complete DEA Form 106 and submit. If no theft or loss, notify DEA in writing of this fact

Drug Enforcement Administration
Pharmacist's Manual

C. If Investigation Finds No Theft or Loss

If, after the initial notification to DEA, the investigation of the theft or loss determines no such theft or loss of controlled substances occurred, a DEA Form 106 does not need to be filed. However, the registrant must notify DEA in writing of this fact in order to resolve the initial report and explain why no DEA Form 106 was filed regarding the incident.

Identify a loss? What to do…..

- Cooperate with Board of Pharmacy / DEA
- Have clear documented processes and polices for record keeping, preventative and detective controls
- Have an established diversion task force / response team with a Diversion Oversight Committee

Investigation Techniques

- Diversion Task Force / Response Team
  - Strong informatics skills to quickly identify patterns
  - Data mine all controlled substances for the identified employee for 6-12 months to start
  - Good interrogation techniques / consider urine screening
  - Example Investigative Techniques:
    - Nursing:
      - Match drug withdraws to medical record order, administration / waste
      - Review waste patterns with nursing to identity abnormalities, i.e. delayed waste, full vial waste, same nurse witness
      - Review discrepancy reports for volume of discrepancies and null transactions
    - Pharmacy:
      - Match wholesaler controlled substances purchase to ADM add to stock
      - Match ADM removals to floor add to stock, compounding, kit stocking, etc.

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Dignity Health

Thank you

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