The Opioid Crisis – The Role of Healthcare Compliance

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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

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The Opioid Epidemic – Facts

- Standard Daily Doses of Opioids per Million Inhabitants

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
Risks of Diversion & Abuse
What are the Risks?

<table>
<thead>
<tr>
<th>Patients (Employee Diversion)</th>
<th>Patients (Patient Addicts)</th>
<th>Patient Sedation</th>
<th>Health Care Workers (Diverter)</th>
<th>Health Care Workers (Co-worker)</th>
<th>Hospital</th>
</tr>
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<tbody>
<tr>
<td>Substandard Care</td>
<td>Patient becomes addict after surgery</td>
<td>Over sedating patients</td>
<td>Morbidity or Mortality</td>
<td>Disciplinary Action (for violation of P&amp;P)</td>
<td>Loss of Revenue</td>
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<tr>
<td>Contamination</td>
<td>ED drug seekers continue their habit</td>
<td>Patient addicts don't get help</td>
<td>Loss of Livelihood – loss of job, license</td>
<td>Mechanical Injury</td>
<td>Loss of Trust</td>
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<tr>
<td>Disease Spread</td>
<td></td>
<td></td>
<td>Felony Criminal Prosecution</td>
<td>Infection (contaminated needles/broken vials)</td>
<td>Loss of Goodwill</td>
</tr>
<tr>
<td>Medication Errors</td>
<td>Patients go to Heroin due to opioid addiction</td>
<td></td>
<td>Civil Malpractice</td>
<td>Civil Liability</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Billing Fraud</td>
<td>Sanctions</td>
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Patients (Employee Diversion) can lead to efficiencies, but also to risks such as patient addiction and substandard care. Patients (Patient Addicts) may continue their habits even after surgery, leading to over sedation and patient morbidity or mortality. Health Care Workers (Diverter) and (Co-worker) risk disciplinary action for violation of P&P, while the hospital could face loss of revenue.

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

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 than a four-year period, in violation of the hospital’s responsibilities under the Controlled Substances Act.” The settlement includes a $4.1 million payment to the government and an agreement to improve compliance with federal law.

The health system has agreed to pay $4.1 million to resolve allegations that it failed to report to the Drug Enforcement Administration (DEA) the diversion of oxycodone tablets. The settlement also includes a civil penalty of $100,000 and $175,000 in fines for two former employees who were charged with conspiracy to defraud the government.

Ineffective controls/failure to report timely led to the diversion of oxycodone tablets, which resulted in federal penalties and a large settlement for the hospital.

Effingham Health System has agreed to pay $4.1 million to resolve allegations of diversion of oxycodone tablets.

The system failed to provide effective controls and procedures to prevent diverted oxycodone tablets from entering the marketplace.
Patient Safety Risks:

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

Written by Alyssa Roga | 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.
Pharmacy Theft Risks:

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

"The DEA is committed to investigating hospitals that are not in compliance with the Controlled Substances Act (CSA)"

Financial / Reputation Risk – DEA Fine / Settlement Agreements:

• Dignity Health  
  2014  
  $1.25M

• Mass. Gen  
  2015  
  $2.3M

• CA Rideout Health  
  2016  
  $2.4M

• Intermountain Health  
  2017  
  $1M

• Effingham Health  
  2018  
  $4.1M
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.
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 variances 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

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 State Arizona Board of Pharmacy, or call the hotline for the Opioid Act. The Arizona Board of Pharmacy’s mission is to protect the public’s health, safety, and welfare through regulation, education, and information.

Who is required to review a patient record to PMP system?

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 totaling 90 days or more.

As of October 19, 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 substance prescription monitoring program’s control database tracking system at the beginning of each new course of treatment and at least quarterly while that prescription continues a part of the treatment.

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

Can prescribers continue to dispense controlled medication out of the office?

Beginning April 26, 2018, prescribers who wish to prescribe a controlled substance to patients who do not have access to the PMP system must use an alternative method of prescribing the controlled substance, must provide the same support for the patient’s medication as is required under the Arizona controlled substance prescribing and monitoring system, and must maintain the same level of accountability as under the Arizona controlled substance prescribing and monitoring system.

What are the new limits regarding the length of time opioids may be prescribed?

Beginning April 26, 2018, a health provider shall limit the initial prescription for a schedule II opioid to not more than a 30-day supply or an initial opioid prescription following a surgical procedure to a 14-day supply. (A.R.S. 32-2344).

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

- 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?

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<tbody>
<tr>
<td>• Comprehensive Drug Abuse Prevention and Control Act of 1970 • The Controlled Substances Act (CSA), Title II • DEA</td>
<td>• Boards of Pharmacy • Regulations/Laws vary by State</td>
<td>• 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</td>
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## DEA Question 1

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

a) Yes
b) No

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Answer #1 = b / NO

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

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

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

$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!!!!

2011
- DEA notified of loss
- DEA on site assessment of IP and OP sites

2012
- DEA fines notification
- Internal assessment of all pharmacies

2013
- Standardized processes
- Weekly calls
- Monthly attestations
- Site visits to 47 inpatient & outpatient pharmacies

2014
- DEA 2 yr. Settlement signed
- External Auditor reports submitted to DEA annually
- Internal audits
- President’s Scorecard
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 Filing System

Anomalous Usage Audits

Monthly Attestations

Routine Reconciliations

Self Audit Checklists

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 biennial 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
ReadilyRetrievableOptions

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

ProvenSolutions:ClosedLoopSystem

- 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.
Proven Solutions: Reconciliations

RECONCILE! RECONCILE!

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

Order

- Reconcile reverse distributor pick up to Automated Dispensing Machine (ADM) expired

Expire/Waste

- Reconcile ADM dispensings to administration and waste records.

Dispensing

- Reconcile Wholesaler Invoice to ADM Stocking Receipt

Receiving/Stocking

- Reconcile ADM dispensings to administration and waste records.

Transfer

- Reconcile Transfers to/from the floors

Proven Solutions: Control Examples

Continuous Preventative & Detective Controls

Ordering & Stocking Controls

- CSOS
  - Dual Receipt / Stocking Custody
  - Reconcile invoice to ADM Stocking

Transfers

- Reconcile transfers to/from floors
- Reconcile transfers to kit/PCAs/direct disp.
- Reconcile Reverse Distributor

Dispensing

- Diversion Monitoring
- Daily Discrepancy Resolution
- ADM audits to Order/MAR/Waste

Nursing Involvement
Proven Solutions: Security Requirements

Controlled Substance (CS) Inventory
- Perpetual inventory
- Terminate access timely
- Blind Counts
- All CS in ADM's
- Security Cameras

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
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

Detection Controls – All

- Accountability Audit – Hospital ADMs:

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

**THEFT OR SUBSTANTIAL LOSS**

- Notify DEA within one day via a letter
- If loss is verified, complete DEA Form 106 and submit.
- If no theft or loss, notify DEA in writing of this fact.
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 identify 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.
Thank you

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