The Opioid Crisis – The Role of Healthcare Compliance

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Candace Fong, PharmD
• System Director of Pharmacy and Medication Safety
• Dignity Health

Tamara Metts, CIA
• Crowe Horwath Healthcare Risk Consulting Senior Manager
• Pharmacy/Controlled Substance – Subject Matter Expert
• Dignity Health Internal Auditor

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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

National Overdose Deaths

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The Opioid Epidemic – Facts

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)

Risks of Diversion & Abuse

What are the Risks?
**Patient Safety Risks:**

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

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 Sara Vleker, 31, into Pierce County Jail early Saturday. Authorities reportedly recommended prosecutors charge her with second-degree assault for illegally injecting at least two patients and stealing medication from the hospital, according to the report. Vleker was released from jail July 5, according to King 5 News.

Vleker has not been charged with a crime. However, a preliminary finding of probable cause filed by police and obtained by The News Tribune states Vleker “illegally obtained medication or another substance from the hospital, and then administered the medication or other substance in an unsterile manner.”

MultiCare Good Samaritan Hospital officials announced the possible infection of two patients last week, and urged a recommendation to 2,662 patients who were treated in the hospital’s emergency room during an eight-month period between August 2017 and March 2018 to receive testing for the infection.
Pharmacy Theft Risks:

Financial / Reputation Risk – DEA Fine / Settlement Agreements:

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

New State Regulations – California BOP
### New State Regulations – Arizona Board of Pharmacy

- 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?

**Federal**
- Comprehensive Drug Abuse Prevention and Control Act of 1970
- The Controlled Substances Act (CSA), Title II
- DEA

**State**
- 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).
- Codex, under Title 21 specific to Drug Diversion fall under sections:
  - 1201 - Registration of Manufacturers, Distributors and Dispensers of Controlled Substances
  - 1204 - 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

DEA Question 2

2. Are hospital DEA fines calculated primarily on the lack of controls?
   a) Yes
   b) No
6/11/2018

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.

$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
- 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

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
- Monthly Attestations
- Anomalous Usage Audits
- Routine Reconciliations
- Self Audit Checklists
DEA Findings - Recordkeeping

Published

DEA investigations also looked at the inventory side of the house. The accountability void revealed material variances in costs for the majority of controlled substances evaluated, including most hazardous strengths. The investigation also revealed numerous recordkeeping infractions at 35 complex inhalant sites.表扬 the patient
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 Cayuga 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 records of receipt
- Failure to maintain required inventory

Proven Drug Diversion Solutions

DEA File
Readily Retrievable Options

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

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.

Proven Solutions: Reconciliations

- Reconcile Power of Attorney's to CII orders
- Reconcile CII order receipts to completed DEA 222 forms
- Reconcile wholesaler invoice to ADM Stocking Receipt
- Reconcile ADM dispemings to administration and waste records
- Reconcile transfers to / from the floors
Proven Solutions: Control Examples

Continuous Preventative & Detective Controls

- Ordering & Stocking
  - CSOS
  - Dutu Receipt / Stocking Custody
  - Reconcile receipt to ADM Stocking

- Transfers
  - Reconcile transfers to/from floor
  - Reconcile transfers to kit/PCAs/direct disp.

- Reconciliation
  - Reconcile Reverse Distributor Dispensing

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

- Nursing Involvement

Proven Solutions: Security Requirements

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

  Terminate access timely

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
• Bedside 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>Transaction Type</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>+ Floor Dispensed</td>
</tr>
<tr>
<td>+ Returns</td>
</tr>
<tr>
<td>+ Returned Pickups</td>
</tr>
<tr>
<td>+ Floor Pickups</td>
</tr>
<tr>
<td>+ Expired Pickups</td>
</tr>
<tr>
<td>- Floor Dispensed</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>
</tr>
</tbody>
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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…..

- 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

THEFT OR SUBSTANTIAL LOSS

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 withdrawals 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.