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Crowe Healthcare Webinar Series

Healthcare Providers' Ongoing Challenges With Controlled Substances

Presented by:

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Course Objectives

As a result of participating in this session, you should be able to:

- Identify ways to detect gaps in your current processes and how to start development of an action plan to address them
- Explain the role that senior management and executives play in the controlled substance process
- Assess the organization's current crisis management and reporting processes and how to test their effectiveness
- Define strategies for managing and responding to DEA or other regulator audits in a timely and effective manner

Polling Question #1

What is your profession?

- a) CPA / Auditor
- b) Pharmacy Director
- c) Compliance
- d) Hospital Sr. Leadership
- e) Other

The Opioid Epidemic

- Public Health Emergency Declaration Signed October 2017

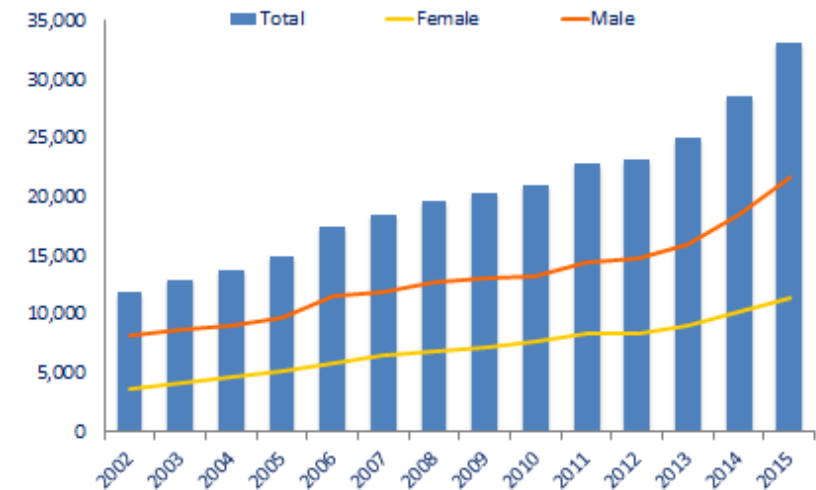


The Opioid Epidemic - Facts

- What are the facts (according to the Centers for Disease Control):
 - On average, 115 Americans die every day from an opioid overdose
 - 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 Number of Deaths Involving Opioid Drugs



Source: National Center for Health Statistics, CDC Wonder

The Opioid Epidemic – Areas of Impact





Hospital's Key Risks

What are your Specific Risks?

Patients	Health Care Workers (Diverter)	Health Care Workers (Co-worker)	Hospital
Substandard Care (Pain, Waking up during Surgery, Injury)	Morbidity or Mortality	Disciplinary Action (for violation of P&P)	Loss of Revenue
Contamination	Loss of Livelihood – loss of job, license	Mechanical Injury	Loss of Trust
Disease Spread	Felony Criminal Prosecution	Infection (contaminated needles/broken vials)	Loss of Goodwill
Medication Errors	Civil Malpractice		Civil Liability
	Billing Fraud		Sanctions
			Negative Publicity
			Loss of Ability to Serve Community
			Additional Regulatory Scrutiny

Where Within the Hospital Setting are Drugs Diverted?

Location

- Pharmacy – Inpatient and Retail
- Clinical Units
- Surgical Center
- Hospice
- Home Health

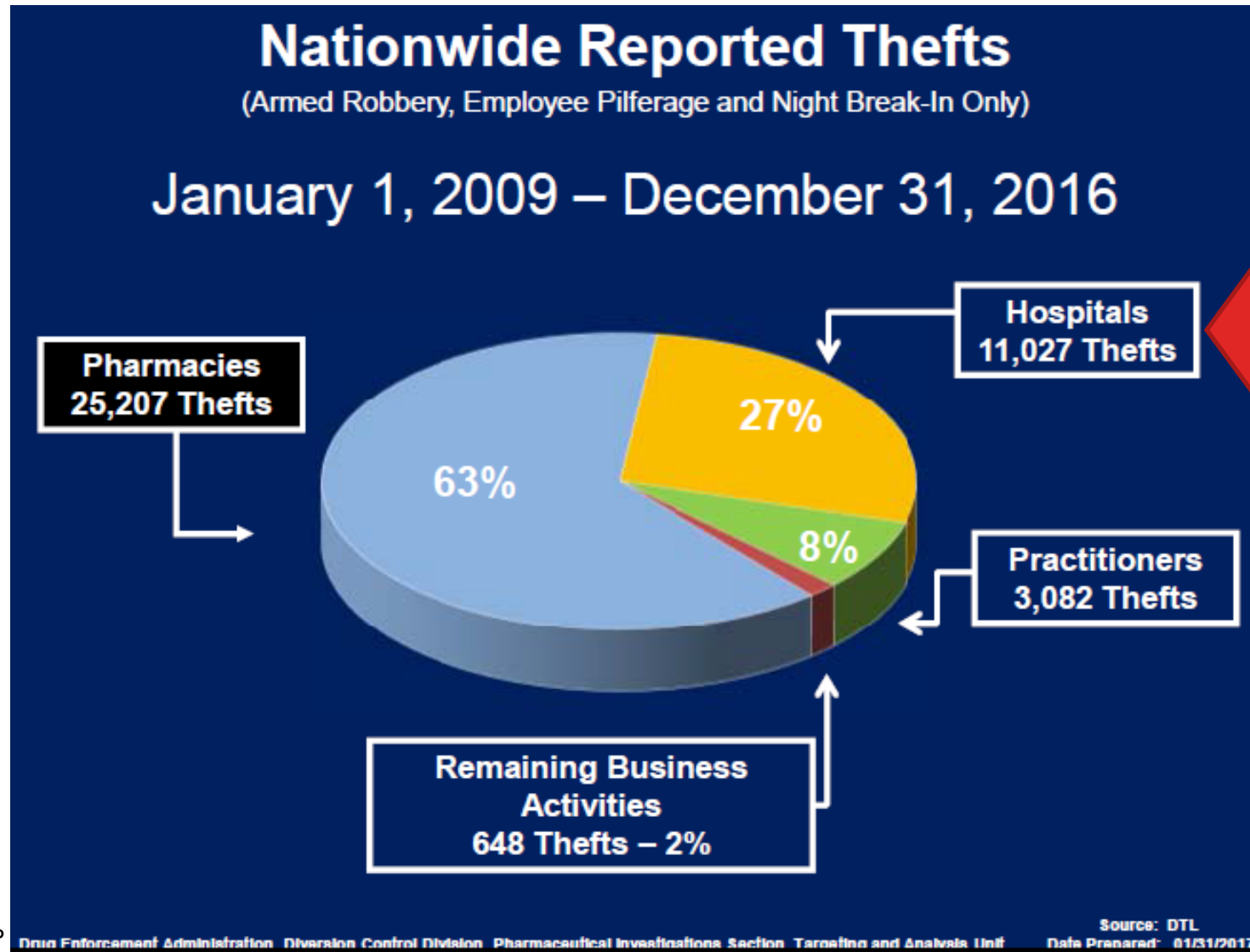
Where

- Med Rooms
- Refrigerators
- Vaults
- Med Carts
- ADMs
- Sharps Containers
- Return Bins
- Anesthesia Trays
- APCs
- IV Bags
- Expired Bins
- Waste (compounding, IV, Bin Waste)

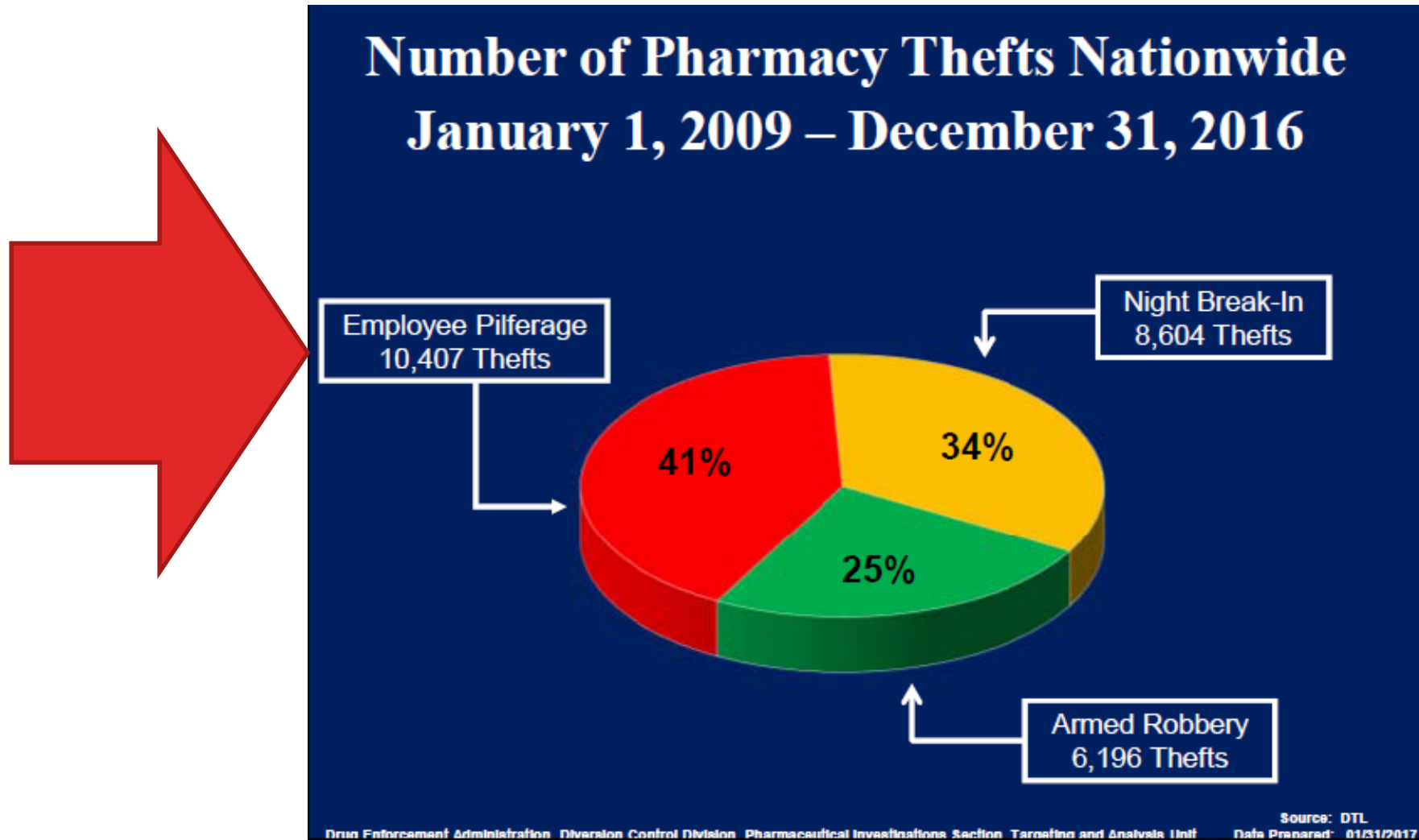
Your Hospital's Drug Diversion Risks

- Is your hospital identifying diversions?
- Are controls in place at each stage the drugs move?
- Are controls in place for each storage point?
- Is there continuous monitoring of employees or persons with controlled substance access?

Hospital's Controlled Substance Thefts (27%)



Controlled Substance Thefts (Employee Pilferages = 41%)

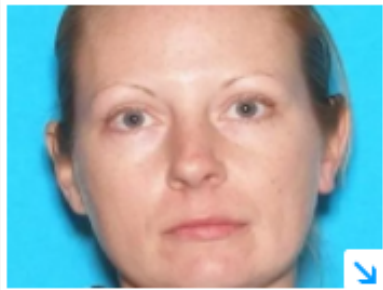


Hospital's Drug Diversion Risks

Nurse charged with forging prescriptions after yearlong investigation

By Terri Sanginiti, The News Journal

Published 12:00 p.m. ET March 24, 2014 | Updated 3:16 p.m. ET March 24, 2014



(Photo: Submitted)

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A nurse who worked at the Delaware Hospital for the Chronically Ill up until last spring was arrested Friday following a nearly yearlong investigation into her having forged prescriptions to obtain oxycodone for her personal use, authorities said Monday.

Danielle M. Tharp-Strouse, 31, of the 6100 block of Mud Mill Road near Camden, was charged Friday with three counts of felony obtaining a controlled substance by misrepresentation or fraud, seven counts of second-degree forgery and once count of falsifying a business record, said Jason Miller, spokesman for the state Attorney General's Office.

Hospital's Drug Diversion Risks

- December 2017 Intermountain Health System fined \$1 Million



| Courtesy Intermountain Healthcare
Intermountain Medical Center in Murray.

Utah-based Intermountain Healthcare to pay feds \$1 million after former employee diverted thousands of pills for eight years

Hospital's Drug Diversion Risks

- September 2015 Massachusetts General \$2.3 fine
- 3 year DEA Settlement Agreement

MGH Settles Drug Theft Case For \$2.3 Million

September 29, 2015

By Michael Norton, State House News Service



Massachusetts General Hospital has agreed to pay the United States \$2.3 million to resolve allegations that lax controls enabled MGH employees to divert controlled substances such as oxycodone for personal use.

The Justice Department [announced the settlement](#) Monday afternoon, calling it the largest of its kind involving allegations of drug diversion at a hospital.

Hospital's Drug Diversion Risks

- December 2016 Hospitals fine \$2.4M for record keeping.

Monday, December 12, 2016

California Facilities Owned By Rideout Health to Pay Civil Monetary Penalties and Agree to 3-Year Compliance Plan to Resolve Controlled Substance Act Claims

The Drug Enforcement Administration (DEA) is becoming more aggressive about enforcing recordkeeping and other rules for controlled substances in hospitals, surgery centers, urgent care clinics and so on. We have handled audits by the DEA and fines are a significant part of their enforcement. A recent case shows what can happen to health care facilities when the recordkeeping rules are not followed. This case also shows that even with cooperation the fines can be significant.



On December 6, 2016, Rideout Health entered into a settlement agreement in which it will pay the United States \$2,425,000 to settle the federal claims of alleged violations of the Controlled Substances Act including record keeping. The alleged violations were by three of Rideout Health's facilities in Yuba and Sutter Counties: Rideout Memorial Hospital, Fremont Medical Center, and Feather River Surgery Center. There were no allegations of diversion or improper prescribing.

Hospital's Drug Diversion Risks

- January 2017 Hospital pays \$510,000 Fine

Hospital Fined \$510,000 After Pharmacist's Illicit Prescription Drug Diversion

JANUARY 13, 2017

Jennifer Barrett, Assistant Editor



A Pennsylvania hospital has agreed to pay \$510,000 in fines after an inpatient pharmacist stole controlled substances. The pharmacist, Renata Dul, was found to have stolen more than 35,000 units of a controlled substance, including oxycodone, on 85 occasions from 2010 to 2013.

Abington Memorial Hospital (AMH) disclosed the pharmacist's actions to the DEA after detecting a discrepancy during inventory, which prompted an investigation that revealed pill count discrepancies, missing or incomplete medication inventories, and altered or missing drug records. An internal investigation pinpointed Dul's ability to exploit a gap in the software used to track prescription medications, where he then altered or destroyed related records, *Philly.com* reported.

Hospital's Drug Diversion Risks

DEA executes warrant at hospital pharmacy

December 29, 2014

By Mark Lowery, Editor

Agents from the Drug Enforcement Administration (DEA) recently searched records at a Virginia hospital pharmacy in connection with stolen narcotics with an estimated street value close to \$1.4 million.

According to an [article](#) by the *News & Advance*, federal agents copied thousands of pages of pharmacy records regarding dispensing, ordering, and distribution of controlled substances at Lynchburg General Hospital.

What You Need to Know – State Board of Pharmacy Regulatory Risks

- Pharmacy Director Arrested and Charged:

**Office of the Special Narcotics Prosecutor
for the City of New York**

Bridget G. Brennan, Special Narcotics Prosecutor

80 Centre Street, Sixth Floor
New York, NY 10013
212-815-0400, Gen
212-815-0440, Fax

**For Immediate Release
July 8, 2014**

Contacts:

Kati Cornell
Special Narcotics Prosecutor's Office
(212) 815-0525

**Former Pharmacy Director at Beth Israel Medical Center charged in
theft of narcotic painkillers from hospital: Pills worth over \$5.6 million
on black market**

BRIDGET G. BRENNAN, New York City's Special Narcotics Prosecutor, announced today the indictment and arrest of ANTHONY D'ALESSANDRO, former Director of Pharmacy Services for Beth Israel Medical Center in Manhattan, for stealing and illegally possessing nearly 200,000 oxycodone pills, which he allegedly obtained from his place of employment since approximately 2009. These pills carried a street value of approximately \$5.6 million.

What You Need to Know – Federal Regulatory Risks

DEA Special Agent in Charge John J. Bryfonski stated “The public expects our health professionals to honor their oath and follow both regulations and the law to assure the health and safety of the people they treat. When these professionals depart from their oath and the law by diverting controlled substance-pharmaceuticals from legitimate medical uses to illegal uses, DEA will investigate and hold them accountable.”

The Opioid Epidemic – Hospital's Current State

A USA TODAY review shows more than 100,000 doctors, nurses, medical technicians and health care aides are abusing or dependent on prescription drugs in a given year, putting patients at risk.



Hospital's Role in the Opioid Epidemic

Hospital's Role: Take Action!

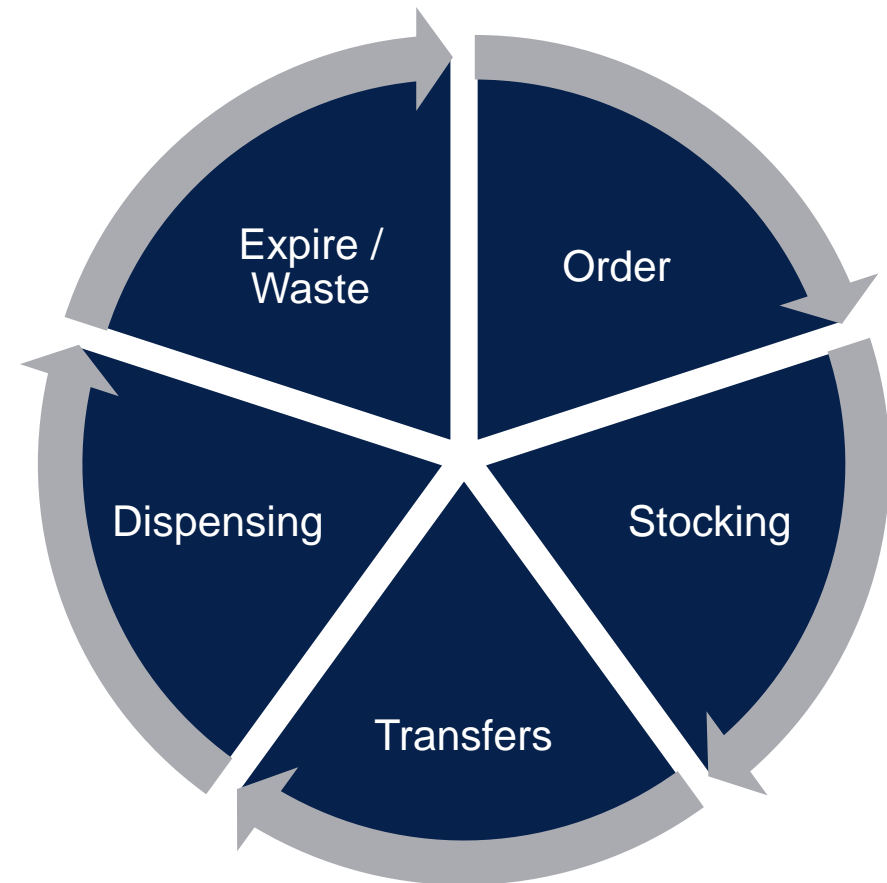
Stop diversion before it starts!!

Hospital's Role: Define a Process

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

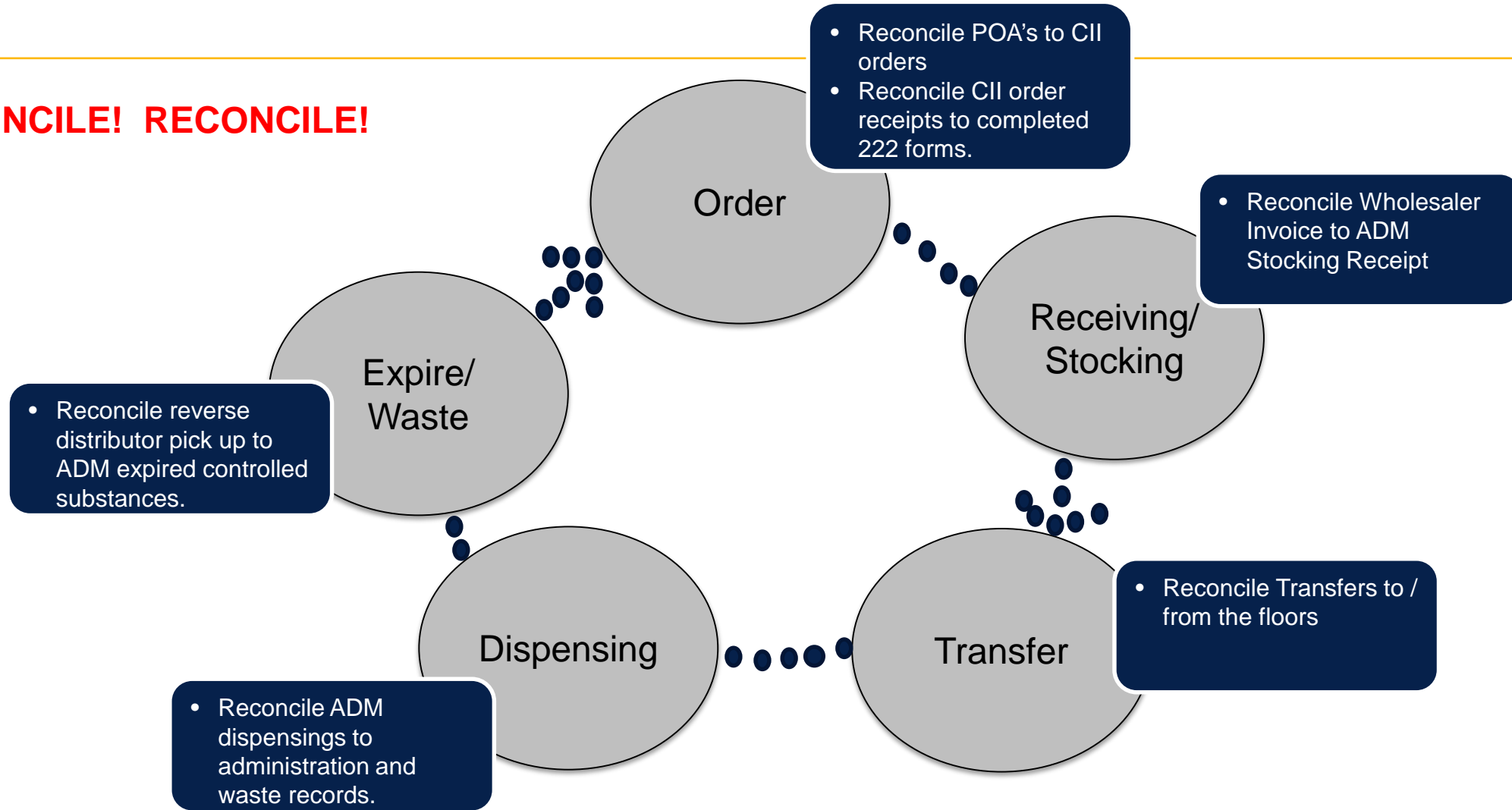
*The framework of the **Controlled Substance Act (CSA)** requires that all controlled substance transactions are to take place within a “closed system” of distribution.*

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



Hospital's Role: Reconciliations

RECONCILE! RECONCILE!



Controlled Substance Control Examples

Continuous Preventative & Detective Controls

Ordering & Stocking Controls

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

Transfers

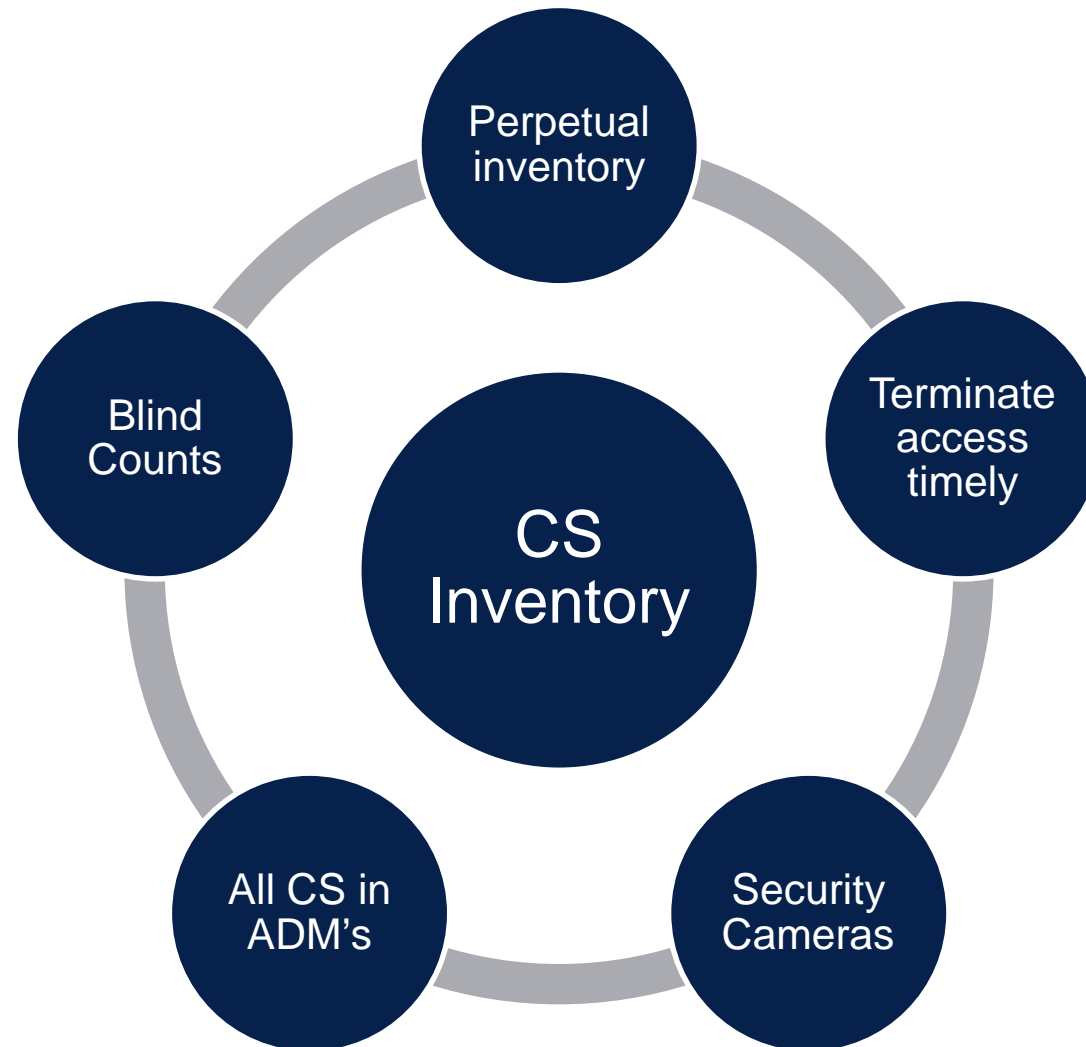
- Reconcile transfers to / from floors
- Reconcile transfers to kit/PCAs/direct disp.
- Reconcile Reverse Distributor

Dispensing

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

Nursing Involvement

Hospital's Role: Security Requirements





Hospital's Regulatory Risks

Polling Question

2. Does the DEA require controlled substance inventory discrepancy reviews?
- a) Yes
 - b) No

Polling Answer #1

2. 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**.

Polling Question

3. Are hospital DEA fines calculated primarily on the lack of controls?
- a) Yes
 - b) No

Polling Answer

3. 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. Olenkiewicz, 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

DEA Security / Controls Regulation

Title 21 Code of Federal Regulations

PART 1301 — REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

SECURITY REQUIREMENTS

§1301.71 Security requirements generally.

(a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in Secs. 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in Secs. 1301.72, 1301.73 and 1301.75 may be used in lieu of the materials and construction described in those sections.

Regulations don't require specific preventative / detective internal controls

DEA Record Keeping Regulations



DEA Record Keeping Regulation

Drug Enforcement Administration Pharmacist's Manual

SECTION VI – RECORDKEEPING REQUIREMENTS

Required Records

The records which must be maintained by a pharmacy are:

1. Executed and unexecuted official order forms (DEA Form 222) or the electronic equivalent
2. Power of Attorney authorization to sign order forms
3. Receipts and/or invoices for schedule II controlled substances
4. Receipts and/or invoices for schedules III, IV, and V controlled substances
5. All inventory records of controlled substances, including the initial and biennial inventories, dated as of beginning or close of business
6. Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors)
7. Records of controlled substances dispensed (i.e., prescriptions, schedule V logbook)
8. Reports of Theft or Significant Loss (DEA Form 106), if applicable
9. Inventory of Drugs Surrendered for Disposal (DEA Form 41), if applicable
10. Records of transfers of controlled substances between pharmacies
11. DEA registration certificate
12. Self-certification certificate and logbook (or electronic equivalent) as required under the combat Methamphetamine Epidemic Act of 2005

DEA Record Keeping Regulation

RESOURCES > Title 21 Code of Federal Regulations > Part 1304 > 1304.21

Title 21 Code of Federal Regulations

PART 1304 — RECORDS AND REPORTS OF REGISTRANTS

CONTINUING RECORDS

§1304.21 General requirements for continuing records.

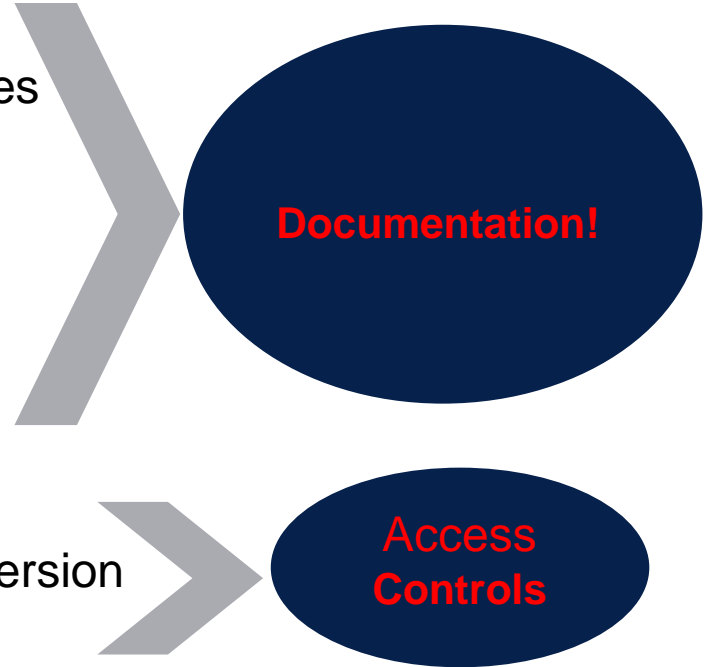
- Example:

(d) In recording dates of receipt, distribution, other transfers, or destruction, the date on which the controlled substances are actually received, distributed, otherwise transferred, or destroyed will be used as the date of receipt, distribution, transfer, or destruction (e.g., invoices or packing slips, or DEA Form 41).

\$10,000 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

Elements of DEA Inspection

- Accountability Audit
- Record and Documentation Request and Review
- Evaluate Security
- Evaluate Due Diligence Procedures



Common DEA Violations

- Inventory Records
 - No inventory taken within two years
 - Inventory not whole house
 - Inventory not on one day
 - Inventory missing required elements
 - Schedule II not segregated from Schedule III-V records
- Receiving
 - Date received not on invoice
 - Invoices not maintained / readily retrievable
- Electronic 222 Forms
 - Failure to record # of received and date
 - Not retaining CSOS Subscriber Agreement
 - Not achieving electronic 222's



Polling Question

4. What is the best time to implement a controlled substance monitoring program?
- a) After a drug diversion is identified
 - b) After a DEA visit
 - c) Now
 - d) All of the above



How Can We Help?

Access Your Risks

- Control Design Audit: From Order to Dispense / Waste / Reverse Distributor
- Accountability Audit
- Diversion Investigations
- Assistance with potential BOP and/or DEA investigations or Settlement Agreements

Thank you

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