Controlled Substance Diversion Prevention Programs – What Should You Do?

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Agenda

- Creating and maintaining a Drug Diversion Task Force, implementation of a response system and tracking and trending drug diversions throughout a hospital system
- Creating best practice in maintaining a reactive and proactive controlled substance diversion prevention program in a multi-disciplinary healthcare system
- Cultivating a Speak Up environment that prevents drug diversion and identifies resources for employees that require treatment for substance abuse

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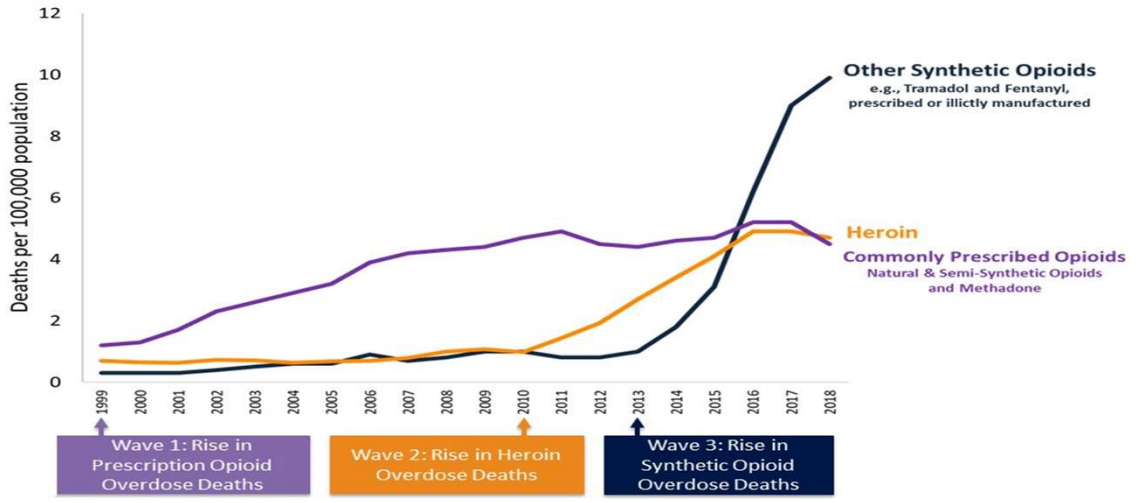
Diversion Defined

- Diversion:
  - CMS: Diverting drugs from legal and necessary uses towards uses that are illegal and typically not medically authorized or necessary.
  - This includes people they were not prescribed for and often use of prescription drugs for recreational purposes.
- Addiction:
  - Continued use despite harm

Diversion Defined (continued)

- Facility Drug Diversion:
  - Theft of medication, including "waste" from patients or other health care facilities for personal use or sale. Can include prescription pads.

3 Waves of the Rise in Opioid Overdose Deaths



SOURCE: National Vital Statistics System Mortality File.

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Opiate Overdose Deaths

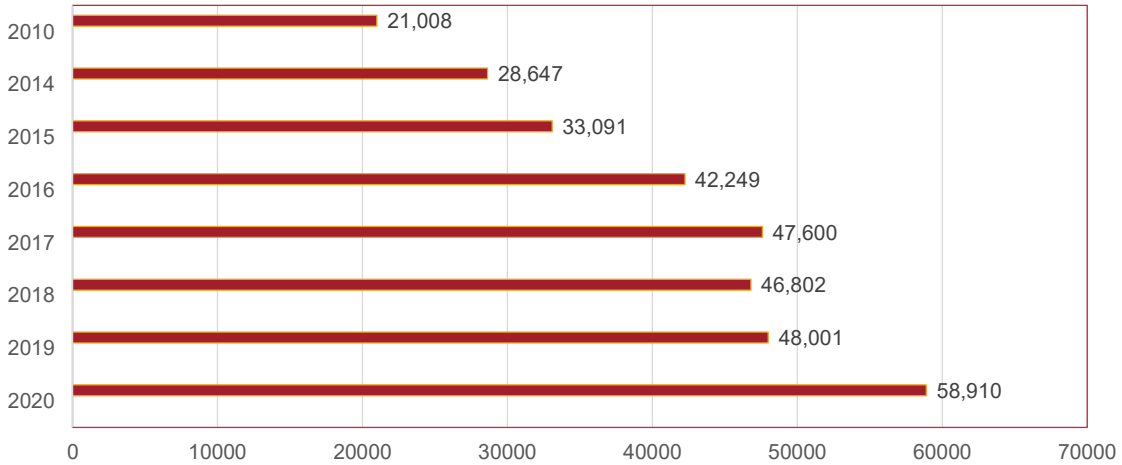

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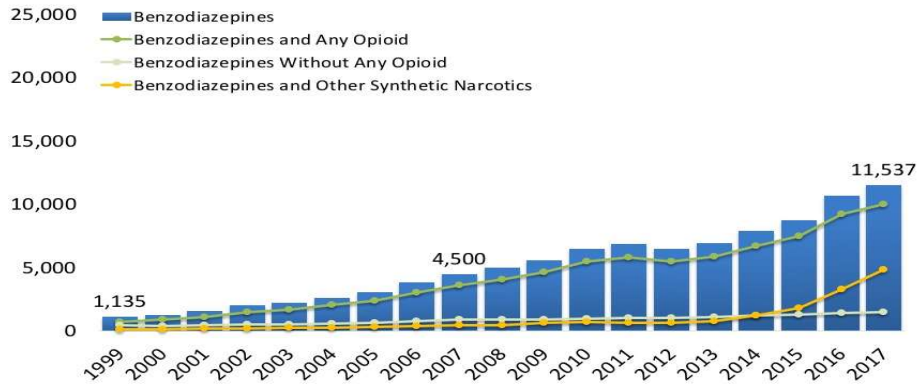
Figure 8. **National Drug Overdose Deaths Involving Benzodiazepines, by Opioid Involvement,** Number Among All Ages, 1999-2017



Source: : Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2017 on CDC WONDER Online Database, released December, 2018

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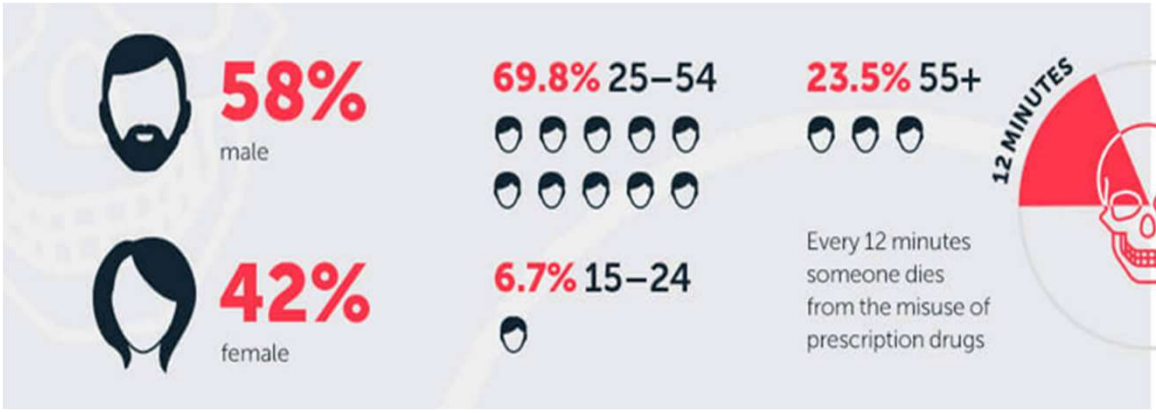
Demographics



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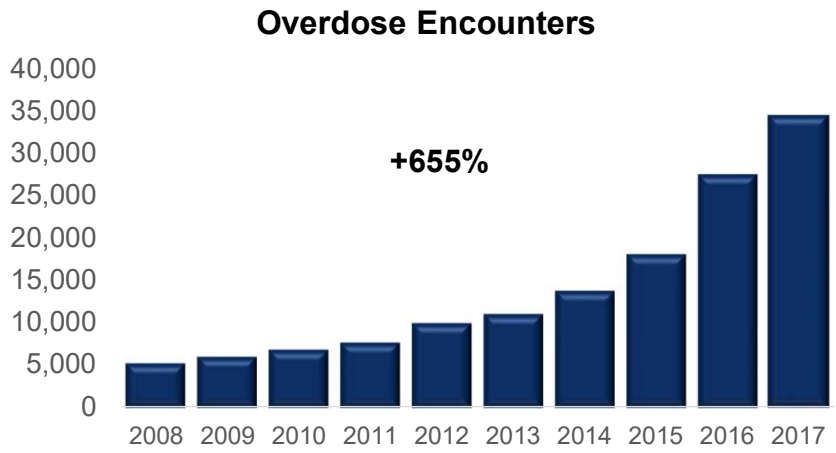
The Ohio Opioid Crisis



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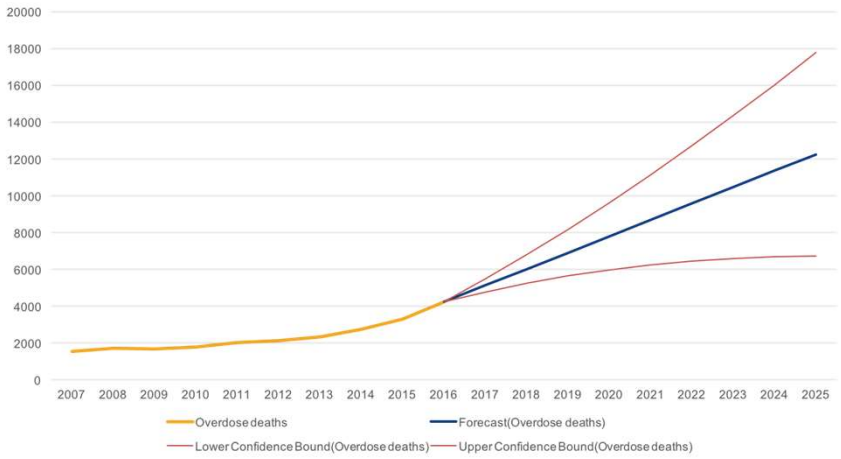
Overdose Deaths Projected



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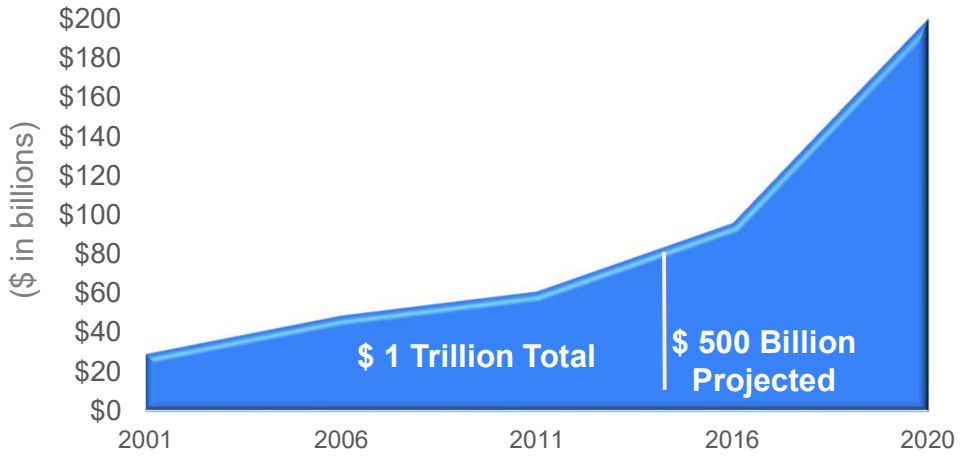
Total & Projected Costs of the U.S. Opioid Epidemic



Healthcare Diversion – Organizational Risk

- Financial Harm
- Reputational Harm
- Clinical Harm

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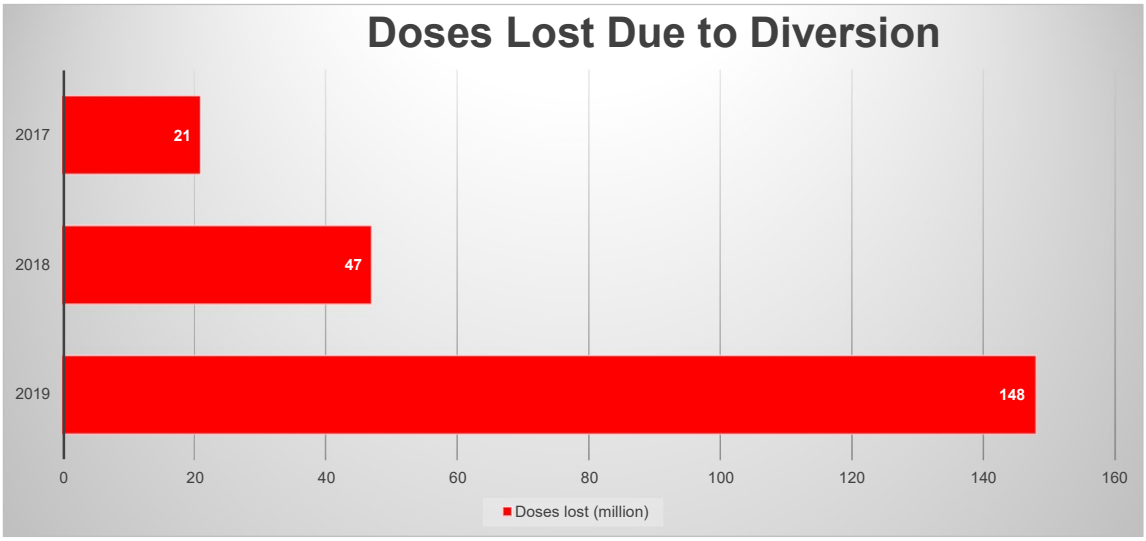

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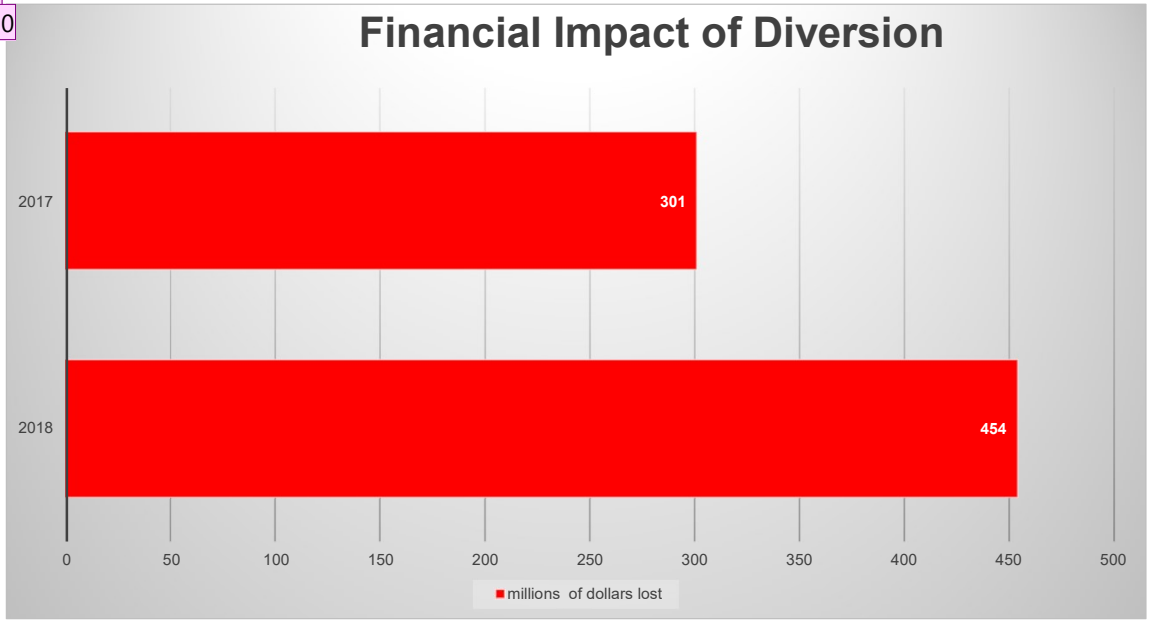

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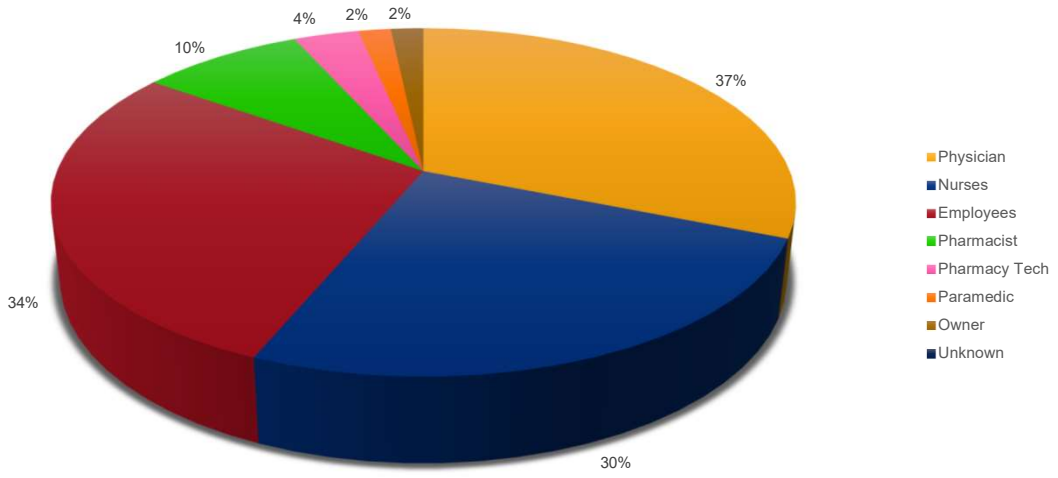
Role in Diversion



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Occupational Factors

- Ease of access to medications
- Legitimate use and chronic conditions
- Physical and emotional demands of job
- Knowledge and sense of control
- Suppression of feelings and emotions
- Vicarious trauma (2nd victim)

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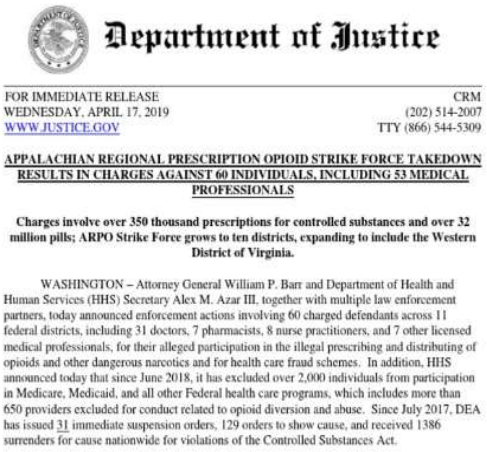
Easy Access to Drugs

- Most diversions occur in outpatient settings, where majority of prescription drugs are used
- Most common drugs diverted are opioids, with Benzodiazepines increasingly common, along with stimulants.
- Professions with easy access to controlled substances, such as anesthesiology, pharmacy and nursing, have higher rates of addiction
- The American Nurses Association has estimated that 1 in 10 nurses is struggling with drug or alcohol addiction

Methods of Diversion

- Methods used by healthcare workers to divert controlled substances include:
  - Theft of vials or syringes or directly from IV bags
  - Under-dosing patients
  - Theft of waste
  - Raiding sharps and/or RX disposal containers
  - Tampering with patient medications
  - Falsification of verbal order
  - Removal for duplicate dose
  - Theft of physical prescriptions

In the News



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APPALACHIAN REGIONAL PRESCRIPTION OPIOID STRIKE FORCE TAKEDOWN RESULTS IN CHARGES AGAINST 60 INDIVIDUALS, INCLUDING 53 MEDICAL PROFESSIONALS

Charges involve over 350 thousand prescriptions for controlled substances and over 32 million pills; ARPO Strike Force grows to ten districts, expanding to include the Western District of Virginia.

WASHINGTON – Attorney General William P. Barr and Department of Health and Human Services (HHS) Secretary Alex M. Azar III, together with multiple law enforcement partners, today announced enforcement actions involving 60 charged defendants across 11 federal districts, including 31 doctors, 7 pharmacists, 8 nurse practitioners, and 7 other licensed medical professionals, for their alleged participation in the illegal prescribing and distributing of opioids and other dangerous narcotics and for health care fraud schemes. In addition, HHS announced today that since June 2018, it has excluded over 2,000 individuals from participation in Medicare, Medicaid, and all other Federal health care programs, which includes more than 650 providers excluded for conduct related to opioid diversion and abuse. Since July 2017, DEA has issued 31 immediate suspension orders, 129 orders to show cause, and received 1386 surrenders for cause nationwide for violations of the Controlled Substances Act.

Single largest Prescription opiate law enforcement operation in history

- 4 months after the inception of the task force
- 31 physicians, 7 pharmacist, 8 Nurse Practioners and 7 others
- 32 Million pills
- 350,000 prescriptions
- 7 states
- 1.75M pills from one pharmacy

Examples

- Anesthesiologist from Hazelton, PA stole drugs from patients who then underwent surgery with no anesthesia
  - Lawsuits included statements from patients who had suffered through the surgery while paralyzed from medications but feeling almost all the surgery sensations
  - Physician would create drug mixtures containing trace amounts of necessary drugs, steal the remainder, and document to create a legitimate paper trail
- Nurse and an Anesthesia Resident overdose at major medical center on the same night, only fatally from stolen opiates, resulting in a 5 year DEA investigation and 4.3 Million dollar settlement.

Examples Cont'd

- A nurse was caught hiding a bag of fentanyl and pulling narcotics at a significantly higher rate than other nurses in her unit. A search of her locker turned up "intravenous start kits, IV needles with blood on them, empty needle packages and 10 ml syringes that appeared to be used," according to documents from the licensing department
- In 2009, a pt. at Johns Hopkins undergoing a routine heart cath develops Hepatitis C from unknown source. After years of collaborative investigation, it was determined that a medical tech, that worked in 18 hospitals in 7 states over 9 years, was swapping syringes of pain medication with ones he used, containing saline. He was hepatitis C positive. He exposed over 6,000 people and at least 46 are now positive and 1 dead, due to his diversion. Resulted in the largest hepatitis C outbreak in US history. He is serving 39 years.

Examples Cont'd

- A nurse anesthetist "regularly" stole liquid opioid medications for his own use. According to documents from the licensing department, he collapsed in the operating room while performing a general anesthesia procedure in 2005 and tested positive for fentanyl, meperidine and normeperidine
- Nurse admitted to stealing hydrocodone, oxycodone and hydromorphone from his employer, a rehab center in, throughout 2012 and 2013. He recorded that he had given them to patients when in fact he was ingesting them himself, "often while still at work," according to the licensing department's documents

Examples of issues identified

- Medications diverted from carts
- Medications found in locker rooms, floors, bathrooms or ceilings
- Partial doses in omnicell (syringe and pill)
- Tampered PCAs
- Medication cart control issues
- Blood splatter and paraphernalia in bathrooms
- Fake urines
- Rx theft – inpatient and outpatient and from execs
- Rxs on Instagram
- Drugs found in ORs
- Stolen meds for suicide attempts
- Patient diversion
- Retail pharmacy theft

Why establish a Diversion Prevention Program?

- Protect the organization
- Increase patient safety
- Protect your staff
- Protect your community

Impact on Your Hospital

- Civil liability
- Regulatory Concerns (CMS, DEA)
- Conditions of Participation (State Operations Manual Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals)

DEA

- 21 CFR 1301.90 Employee Screening Procedures (non-practitioners)
- DEA position that obtaining certain information by non-practitioners is vital to assess the likelihood of an employee committing a drug security breach
- “Need to Know” is a matter of business necessity, essential to overall controlled substance security

DEA

- 21 CFR 1301.92 – Illicit activities by employees
  - Employees who possess, sell, use, divert controlled substances will subject themselves not only to State or Federal prosecution
  - Employer will immediately determine status of continued employment by assessing the seriousness of the violation, the position of responsibility held by the employee and past record of employment

Conditions of Participation

- § 482.13 (c)(2) – The patient has the right to receive care in a safe setting
  - Hospital must:
    - Protect vulnerable patients
    - Identify and evaluate problems and patterns of incidents

Conditions of Participation

§ 482.25(a)(3) –**Current and accurate records must be kept of the receipt and disposition of all scheduled drugs**

- Records of all scheduled drugs must be maintained and any discrepancies in count reconciled promptly
- Must be capable of quickly identifying loss or diversion of controlled substances and determining the extent of the diversion
- Must have policies and procedures in place which minimize scheduled drug diversion

Conditions of Participation

§ 482.25(b)(2)(i-ii) - All drugs and biologicals must be kept in a secure area, and locked when appropriate

- Storage procedures must prevent unmonitored access by unauthorized individuals
- Mobile nursing medication carts, anesthesia carts, epidural carts and other medication carts containing Schedule II, III, IV, and V drugs must be locked within a secure area
- If tampering or diversion occurs, or if medication security otherwise becomes a problem, the hospital must evaluate its current medication control policies and procedures, and implement the necessary systems and processes to ensure that the problem is corrected, and that patient health and safety are maintained

Joint Commission

The hospital must safely:

- Manage high alert medications
- Store medications
- Control medications brought from home
- Dispense and administer medications
- Manage returned medications; and
- The hospital must evaluate the effectiveness of medication management system

Reporting is Essential

- Must report to DEA immediately (Ohio Board of Pharmacy)
- Law Enforcement (if applicable)
- FDA/OIC (if tampering)
- OIG (if applicable, i.e., potential fraud)

Reporting

Three agencies place responsibility for security of all drugs in the healthcare setting on the Pharmacy

- Drug Enforcement Agency (www.deadiversion.usdoj.gov)
- The Joint Commission (www.jointcommission.org)
- American Society of Health-System Pharmacists (www.ashp.org)

Ohio:

- Ohio Board of Pharmacy
- Ohio Board of Medicine (if applicable)
- Ohio Board of Nursing (if applicable)

DEA Reporting

§ **21 CFR 1301.91** Employee responsibility to report drug diversion

• Reports of drug diversion are necessary part of employee security program but also serve the public interest at large

• 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

Conditions of Participation

§ 482.25(b)(7) - Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate

- Controlled drug losses must be reported to DEA
- Some states mandate reporting of a crime or drug related crime

Potential Consequences of Non-Reporting

- Alleged diverter is dismissed/employment terminated or allowed to quit
- Potential of rehabilitation near zero
- Violates laws and regulations
- Disregards the well being of the diverter
- No reported history will bypass preventive screening at next employer

Consequences

Civil and Criminal Penalties

- In 2015, a Massachusetts hospital agreed to pay $2.3 million to settle allegations that lax controls enabled hospital employees to divert controlled substances for personal use
- A California health system paid $2.42 million to settle claims that three of its facilities violated the Controlled Substances Act. The hospital system failed to provide sufficient security controls to prevent diversion
- 5/18 - A Georgia heathy system had a penalty of $4.1 million enforced after DEA investigation revealed that tens of thousands of 30mg oxycodone tablets were unaccounted for. DEA also found healthcare system failed to notify DEA in time required by federal law
- 8/18 - A Michigan Hospital system was fined $4.3 million for violations of the Controlled Substances Act. This system experienced 2 staff drug overdoses in the same day

Hospital Employees Speak about the Crisis

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Potential Impact on Patients

- Impairment and addiction places patients at risk
- Potential of denying patients appropriate pain relief
- Potential to expose patients to blood borne pathogens
- Potential falsification of records (Fraud)
- Theft
- Potential tampering

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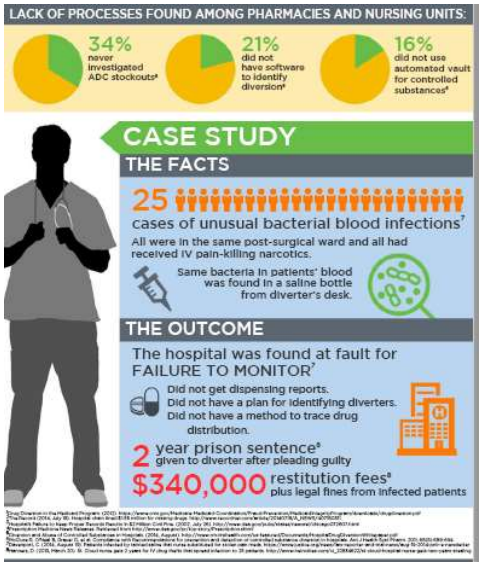
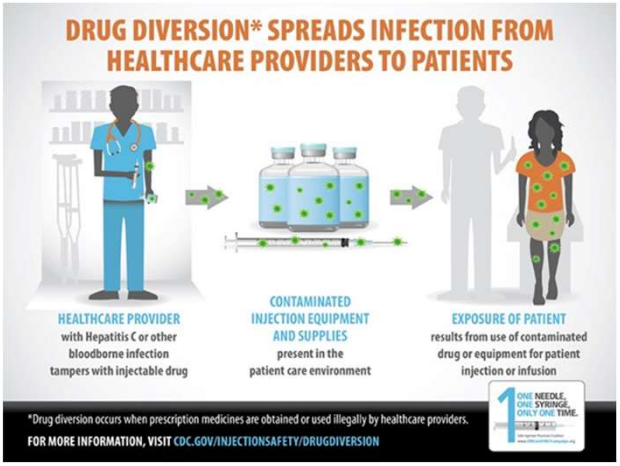


Patient Impact



Recognition of Patient Harm

- Diversion does not always result in patient harm, but red flags to look for:
  - Diversion of scheduled doses
  - Documentation of pain at time medication is diverted
  - Evidence of substitution and tampering
  - Impairment resulting in patient harm or reckless endangerment

How do you prevent this from happening to your organization?

- Build an Organizational Culture of awareness
- Education, and more education
- Speak up Culture
- Multidisciplinary Team Approach
- Drug Diversion Response Team
- Diversion Specialist or Lead

How to Build The Program

- Starting from scratch
- Evolution of an established system.

Effective Program

- Must establish a formal, system wide approach
- Includes safeguards to reduce ability of employees to divert prescription drugs
- Appropriate systems for detecting activity and dealing with workers who are addicted to prescriptions drugs
- Incorporates all disciplines where employees come into contact with prescription drugs, not just pharmacy
  - This includes medical staff, nursing, human resources, legal and regulatory compliance, and security

Effective Program Cont'd

- Requires top down hospital buy in to be effective
- Comprehensive risk assessment to identify areas where there may be a breakdown in policies and where monitoring, controls and security may need to be strengthened (Gap analysis and risk rounds)
- Written policies to regulate all aspects of the purchase, storage, and dispensing of controlled substances
- Clear policies on the administration and waste of all prescription drugs
- Internal audits should be regularly be conducted, especially in high risk areas such as pharmacy and anesthesia

Internal Controls

- Lack of internal controls can lead to diversion.
- Must be:
  - Preventative
    - Example: policies and procedures for security of drugs
  - Detective
    - Example: audit capabilities
  - Automated / Manual
    - Example: Routine audit by staff; key inventory

Policies and Procedures

- Pre-employment screening
- Drug handling (licensure)
- Surveillance
- “Reasonable suspicion” drug testing
- Suspected diversion
- Confirmed diversion (as a result of audit or witnessed)

Identification

- Medication Storage System audits (Omnicell, Pyxis, etc.)
- Routine monitoring
- Personal observation – Speak Up Culture
- Education
  - New employee and annual
  - Clinical Staff and Managers
    - Methods of diversion
    - Behavior clues
    - Physical Signs

Identification

- Tardiness, unscheduled absences, etc.
- Frequent disappearances from work and/or taking frequent or long trips to restroom
- Patterns of removal of controlled substances near or at end of shift
- Heavy or no documented “wastage” of medications
- Patterns of holding waste until change of shift
- Patterns of ordering and inventory trends in pharmaceutical purchasing

Inventory Management

- Physical Controls
  - Location of workstations and accessibility by non-users
  - Computer screens locked when inactive
- Automated Medication Unit Security
  - Passwords
  - Unsuccessful log ins
  - Default sign off
  - Overrides (when and where appropriate)

Inventory Management (cont'd)

- Scheduled drug are secure at all stages and at all times.
- Analysis of dispensing, override and waste reports
- Physical Security:
  - Cameras
  - Facility Secured Badge Access
  - Terminated Employee Process

UH - Incident Response

- March 2017-creation of the **Drug Diversion Task Force**
  - Included System Leadership, Pharmacy, Compliance, Human Resources, Legal, Quality and Risk, UH PD, Employee Assistance Program, Corporate Health, Internal Audit
- Reviewed existing policies and determined processes that needed to be strengthened and/or consolidated
- Identified that incident response needed to be created

Incident Response Cont'd

- Met with local government Drug Task Forces to discuss cooperation between hospitals and local law enforcement
- Held **Root Cause Analysis** for Drug Diversion
- Led to the creation of a "Drug Diversion Specialist" position (1 FTE)
  - Included system leaders from Nursing, HR, Pharmacy, Legal, and Physicians

RCA Example

Applicable Internal Controls	Effectiveness of Internal Controls	Recommended Action Items	Owner	Time Line
Physical security of drug dispensing carts (e.g., Omnicell)	System architecture build underway. Not all controlled substances in locked carts; there are narcotics in the code boxes; anesthesia drug boxes not included. Opportunity to standardize across system.	Place all controlled substances in locked drug carts; undertake gap assessment of anesthesia (Internal Audit has done some work in this area); audit whether passwords are shared and ensure all passwords are individual; audits/education regarding need to log out; look at PCA pumps. Standardize time out review for access (e.g., those who have not accessed for several months--turn off access); identify best practice for reviewing overrides. Perform sweeps of emergency/code boxes with drugs.		
Limits on who can access drugs in drug dispensing carts	Challenges with floats, terminating access for terminated employees and those who have transferred roles and no longer need access, and those who are suspended for a substance abuse issue/placed on fitness for duty.	Come up with process for terminating access for those who transfer roles and those who are terminated or suspended. Also need to deal with existence of multiple badges.		
Audit trail of who accesses drug dispensing carts	Currently, we don't have integration between Omnicell (or other drug care dispensing systems, such as PIXIS and Accudose). It's a manual process to link order, documentation and pulls.	Explore cost and effectiveness of technology to integrate technologies.		
Standard deviation reports	They do pick up issues but those who don't work full-time, including but not limited to PRNs, don't tend to get picked up. Deviation Report standards differ across system. Need more resources.	Standardize across system. Come up with process for PRNs and those who work less than full time. Hire full-time person to review standard deviation reports on daily basis?		
Random audits	Not standardized throughout system.	It was suggested that we look at every nurse twice /year. Include others, such as those who work in anesthesia? Audits reveal many issues, including sloppy documentation that does not meet SOC.		

Education

- On-line, In person
  - Large audiences, small practices, individual providers
- Risk management education days
- Rolled out Controlled Substance Toolkit
  - Employed providers and office staff
  - Hospital-affiliated providers and office staff
- Mandatory annual training
  - All prescribers
  - All Staff
  - All new residents
- Extends beyond patient-facing population to broader System & Community
- Larger Consortium Education program

Drug Diversion Response System

- Drug Task Force determined that better incident response was necessary
- All disciplines that had a role to play in drug diversion included on a call when a concern arises
- Conference Call (10-15 minutes)
  - Call roll, establish A/C privilege
  - Presentation of facts
  - Questions and discussion
  - Each participant list his/her department's targets/tasks

Drug Diversion Response System Education

- Rolled out at all hospitals through management forums, senior leadership team meetings, rounding with hospital employees
- Message to managers and staff: Observe, examine, question without assumptions, and Speak Up
- Call Compliance or the Drug Diversion Specialist directly to discuss any suspicions of drug diversion
- Education is ongoing through compliance trainings, leadership meetings, and department huddles

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SPEAK UP CULTURE

15% OF PHARMACISTS,
10% OF NURSES,
AND 8% OF PHYSICIANS
SUFFER FROM
ADDICTION

Ohio has the second-highest rate of drug overdoses in the U.S.

Concerns regarding controlled drugs?

Possible impaired coworker?

SEE SOMETHING – SAY SOMETHING!

UH SUPPORTS A SPEAK-UP CULTURE

For the safety of our staff and our patients contact:

CONFIDENTIAL HOTLINE

1-800-227-6934
UHhospitals.org/Ethics
Diversion Specialist pager 33629

University Hospitals

Diversion Investigations

- When diversion suspected
  - Diversion Specialist is notified and investigates the issue
  - Review of medical records(s) and drug cabinet records
  - Diversion team put on alert (Diversion Call)
  - Verification of data and analysis of composite picture
  - Initial interview conducted
  - Employee immediately removed from patient care; drug access discontinued
  - Drug screen (if applicable)
  - Suspension pending completion of investigation
  - Assessment and referral to care

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When Diversion is Confirmed

- Determine employment disposition
- Report to Boards and/or law enforcement
- Place administrative hold on bills pending review
- Conduct PHI audit

Obstacles:

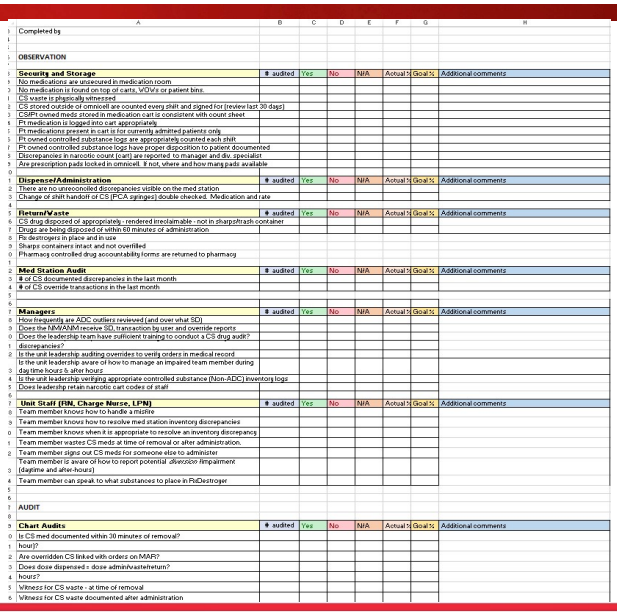
- No one wants to Speak Up on their 20 year colleague if they think response will only be punitive (loss of employment, criminal charges, etc.)
  - Make sure they know they are **saving a life**, and potentially many others
  - Make sure they know there is a road to recovery
  - Drug addiction is classified as a disease. If not a hospital system, then who will address the problem as such?

Obstacles Cont'd

- Requires collaboration with local law enforcement
  - Drug courts, diversion plans, probation plans
- Requires robust Employee Assistance Program/Corporate Health programs
- Until they are no longer employees, they are **our employees**

Conclusion

- Drug Diversion Defined
  - Scope of problem
  - Profile and predisposing factors
  - Impact on hospital and patients
  - Regulations
- Reporting Requirements
- Components of a diversion prevention, detection and response program
- Examples/UH Approach



	A	B	C	D	E	F	G	H
1	Completed by							
2								
3								
4	OBSERVATION							
5								
6	**Security and Storage**	# audited	Yes	No	N/A	Actual %	Goal %	Additional comments
7	No medications are unsecured in medication room							
8	No medication is found on top of carts, VCVIs or patient bins.							
9	CS waste is physically witnessed							
10	CS stored outside of omnicell are counted every shift and signed for (review last 30 days)							
11	CS/Pt owned meds stored in medication cart is consistent with count sheet							
12	Pt medication is logged into cart appropriately							
13	Pt medications present in cart is for currently admitted patients only							
14	Pt owned controlled substance logs are appropriately counted each shift							
15	Pt owned controlled substance logs have proper disposition to patient documented							
16	Discrepancies in narcotic count (cart) are reported to manager and div. specialist							
17	Are prescription pads locked in omnicell. If not, where and how many pads available							
18								
19	**Dispense/Administration**	# audited	Yes	No	N/A	Actual %	Goal %	Additional comments
20	There are no unreconciled discrepancies visible on the med station							
21	Change of shift handoff of CS (PCA syringes) double checked. Medication and rate							
22								
23	**Return/Waste**	# audited	Yes	No	N/A	Actual %	Goal %	Additional comments
24	CS drug disposed of appropriately - rendered irreclaimable - not in sharps/trash container							
25	Drugs are being disposed of within 60 minutes of administration							
26	Rx destroyers in place and in use							
27	Sharps containers intact and not overfilled							
28	Pharmacy controlled drug accountability forms are returned to pharmacy							
29								
30	**Med Station Audit**	# audited	Yes	No	N/A	Actual %	Goal %	Additional comments
31	# of CS documented discrepancies in the last month							
32	# of CS override transactions in the last month							
33								
34								
35	**Managers**	# audited	Yes	No	N/A	Actual %	Goal %	Additional comments
36	How frequently are ADC outliers reviewed (and over what SD)							
37	Does the NM/AM receive SEL transaction by user and override reports							
38	Does the leadership team have sufficient training to conduct a CS drug audit?							
39	discrepancies?							
40	Is the unit leadership auditing overrides to verify orders in medical record							
41	Is the unit leadership aware of how to manage an impaired team member during day time hours & after hours							
42	Is the unit leadership verifying appropriate controlled substance (Non-ADC) inventory logs							
43	Does leadership retain narcotic cart codes of staff							
44								
45	**Unit Staff (RN, Charge Nurse, LPN)**	# audited	Yes	No	N/A	Actual %	Goal %	Additional comments
46	Team member knows how to handle a misfire							
47	Team member knows how to resolve med station inventory discrepancies							
48	Team member knows when it is appropriate to resolve an inventory discrepancy							
49	Team member wastes CS meds at time of removal or after administration.							
50	Team member signs out CS meds for someone else to administer							
51	Team member is aware of how to report potential *diversion /*impairment (daytime and after-hours)							
52	Team member can speak to what substances to place in PixDestroyer							
53								
54								
55	AUDIT							
56								
57	**Chart Audits**	# audited	Yes	No	N/A	Actual %	Goal %	Additional comments
58	Is CS med documented within 30 minutes of removal?							
59	hour)?							
60	Are overridden CS linked with orders on MAR?							
61	Does dose dispensed = dose admin/waste/return?							
62	hours?							
63	Witness for CS waste - at time of removal							
64	Witness for CS waste documented after administration							

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Diversion Call Checklist

Diversion Specialist Notified of Suspected Diversion:	
Employees Name, title and Division	
Call date & time:	
Initial Actions: • Roll Call (Law Department identified first and establishes privilege) • If threat of immediate harm exists (patients, employee, UH staff)-HR discloses facts in support immediately after privilege established • Meeting Facilitator: • Scribe:	☐ Drug Diversion Specialist: ☐ Legal ☐ Risk ☐ Compliance ☐ UH PD/Security ☐ Pharmacy ☐ Employee health ☐ Employee assistance ☐ Human resources ☐ Leadership
Diversion Specialist/HR: Brief Summary • Where and when the incident occurred • Specific employee suspected • First notification of the incident-Time/Date/Reporter • How diversion was identified (i.e. deviation report, medical supplies missing, etc.) • Scope/Duration of diversion • Type of drug diverted • Quantity of the drug diverted • Duration-how long has the suspected diversion been occurring • Identify circumstances that permitted diversion to occur • Identify employee's next shift start time • Identify other individuals involved • Identify employee's supervisor-and if they have been notified	

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Questions?