



Diversion Prevention: What's a Pharmacy to Do?

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Disclosure

- The program chair and presenters for this continuing education activity have reported no relevant financial relationships.



Session Objectives

- Define the scope of the controlled substance diversion problem within United States hospitals and health systems
- Define the role of the pharmacy leader in controlled substance diversion, detection, and surveillance
- Design countermeasures to combat diverters within health systems
- Interpret and recommend interventions within your organization based on diversion scenarios
- Evaluate the common controlled-substance diversion hurdles and pitfalls when dealing with regulatory agencies after a diversion event



Getting to Know the Audience

How many people have a controlled substance diversion prevention program in place at your organization?



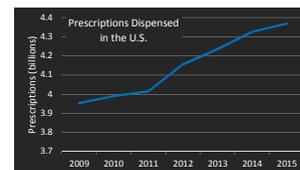
Getting to Know the Audience

How many pharmacy staff are dedicated to identifying controlled substance diversion at your organization?



Drug Abuse in the United States

- 2015: 4.36 billion prescriptions dispensed in the U.S.
 - Third most prescribed: 97 million hydrocodone prescriptions
- 2015 National Drug Threat Assessment by the DEA
 - 28% of law enforcement agencies say prescription drugs are the greatest drug threat
 - Up from 9.8% in 2009



Drug Abuse in the United States

- 2014 National Survey on Drug Use and Health by the Substance Abuse and Mental Health Services Administration (SAMHSA)
 - 7.6% of population report abusing pain relievers, tranquilizers, stimulants or sedatives in the past year
- 1.24 million ED visits involving nonmedical use of prescription medications
 - 29% involved narcotic pain relievers




Drug Abuse in Healthcare

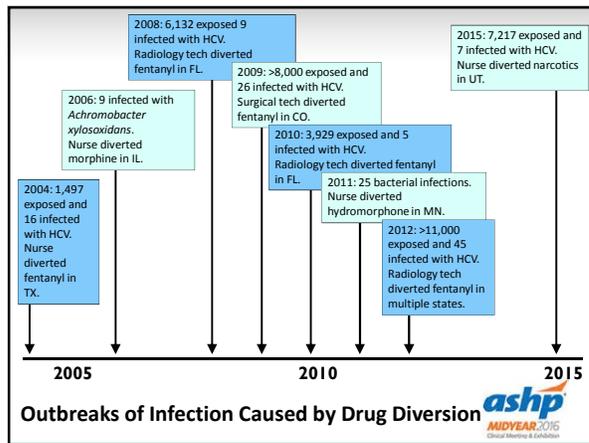
- Estimated that 10% –15% of healthcare workers develop substance addiction
 - Same incidence as the general population
- SAMHSA estimates that 103,000 healthcare workers abuse drugs each year
- Likely, these numbers are an underestimation
 - Easily hidden
 - Poorly policed
 - Look the other way




Abuse Implications

- Substance abuse affects people from all demographics equally
- When healthcare workers are involved in drug diversion, it may cause:
 - Sub-standard patient care
 - Infection risk to patients





Diversion Penalties and Lawsuits

The Boston Globe
 Mass. General to pay \$2.3 million over drug thefts

THE DENVER POST
 Class action suit filed in drug theft case at Swedish hospital that put thousands at risk for hepatitis, HIV

The Dallas Morning News
 Parkland hospital system fined for employees' drug thefts

FOX SEATTLE TACOMA
 Seattle Cancer Care Alliance settles investigation for \$250,000

Dignity Health Agrees To Pay \$1.55 Million In Civil Penalties To Resolve Controlled Substances Act Claims



Regulatory Response to Drug Abuse

- Secure and Responsible Drug Disposal Act of 2010
 - Gives DEA authority over the enforcement of drug disposal regulations
 - Controlled substances must be disposed in a fashion that renders them non-retrievable
- Hydrocodone reclassified as Schedule II, Tramadol reclassified as Schedule IV in 2014
 - DEA's attempt at curbing abuse
- CDC Guideline on Prescribing Opioids for Chronic Pain, 2016
 - Risks associated with opioids
 - When and what to prescribe




Speak Up, Save A Life

- Ongoing campaign:
 - To promote awareness of the gravity of the issue of substance abuse and diversion
 - To encourage reporting and dialogue

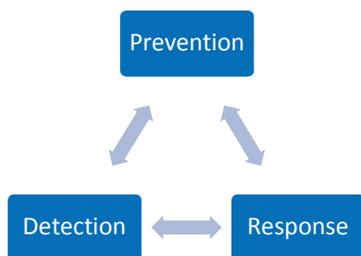


Diversion Prevention Team (DPT)

- **Program Manager:** Carol P. - RN
 - Clinical experience: inpatient & outpatient nursing
 - Formal nursing leadership experience
 - Extensive Lean & process improvement work
- **Project Manager:** Andrew B. – former pharmacy technician
 - Pharmacy tech experience, addiction work, research/statistical analysis
- **Data Analysts:**
 - Steve H. – RN
 - Sarah M. - Criminal Justice
 - Karrie T. - Pharmacy technician



Diversion Prevention Program: Key Areas of Responsibility



Prevention

- **Education**
 - Annual & ongoing; all UMHS staff
 - Leadership: case studies, etc.
- **Communication**
- **Audits**
 - Quarterly; focus on CS security / compliance
- **Root Cause Analysis**
 - Implement practice changes as needed
- **Medication Safety Rounds**
 - Understand unit practice / barriers
 - Build partnerships with leaders & staff



Detection

- **Data Analytics / Suspicious Activity Monitoring**
 - Anomalous Use: outlier data*
 - Diversion Prevention Program Database*
 - Controlled Substance Tool reports*
 - Manager Requests
 - RL6 - Event Reports
 - Security Reports
 - Discrepancies
- *proactive monitoring tools

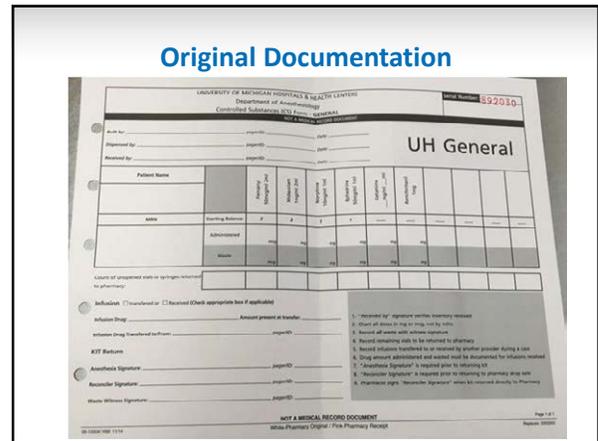
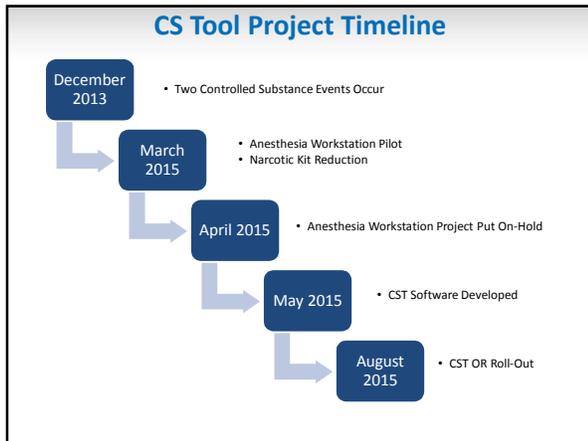


Response

- **Real-time response: page 24/7**
- **Diversion Prevention Review Team (DPRT)**
 - Multi-disciplinary team that reviews cases and makes the decision to FCT data driven cases
- **Investigatory Interviews**
 - Program Manager leads all investigatory interviews related to suspected diversion



2016 Midyear Clinical Meeting & Exhibition Diversion Prevention: What's a Pharmacy to Do?



CST Case Documentation

Substances	Count	Amt	Adm	Loss	Total	Unopened	Returned
Ephedrine 50mg/ml(1ml)	1	50	0	0	50 mg	0	0
Fentanyl 50mcg/ml(2ml)	3	300	100	0	200 mcg	0	0
Midazolam IV 3mg/ml(2ml)	2	4	1	0	3 mg	0	1 mg
Morphine 10mg/ml(1ml)	1	10	0	0	10 mg	0	0

CST Homepage

Kit #	Kit Type	Patient Name	Current Provider	Status
89429	Adult General	ADP		View Details
89478	Adult General		Unused	View Details
89479	Adult General		Unused	View Details
89480	Adult General		Unused	View Details
89481	Adult General		Unused	View Details
89482	Adult General		Unused	View Details
89483	Adult General		Unused	View Details
89484	Adult General		Unused	View Details
89485	Adult General		Unused	View Details
89486	Adult General		Unused	View Details

- ### Other Achievements
- Formation of executive oversight committee
 - Pre-employment drug testing initiated
 - Compliance hotline to allow anonymous reporting
 - Reviewed/updated all CS policies
 - Developed comprehensive CS audit plan
-

- ### Other Achievements
- UMHS Practitioner Impairment Policy revised to include all Medical School Faculty
 - Physician Wellness Committee established
 - Expanded use of UBC's to off-site locations
 - Annual mandatory on-line learning – all staff
 - Engaged two external consultants
 - Unrecoverable method deployed for CS waste
-

Other Achievements

- Developed software to reconcile EHR and UBC
- Hired 10 people at UM devoted to diversion prevention/detection
- Added cameras & card readers in many areas
- Required use of biometric ID on UBC's
- PCA key accountability



Other Achievements

- Developed purchase vs. dispense reports – monthly monitoring
- Narcotic drip management – only locked pumps can be used for CS infusions
- Increased nurse manager involvement: monthly review of RN activity with follow up and collaboration with the DPT



DEA – lessons learned

- Agents do not know how hospitals work or what systems we use
- Focused on the basics and letter of the law
- Only ask questions; don't give direction or advice
- Can be intimidating
- Can be reasonable



Next Steps

- Implement OP pharmacy CS storage systems
- Renovate vault storage area
- Camera and card access expansion
- Continue communications & safety rounds
- Refine diversion monitoring process
- Consider system-wide random testing
- Offer site visits to other health systems
- Optimize Automated Dispensing Cabinet functionality



Summary

- Significant progress in 3 years
- Organizational commitment to ongoing improvements to ensure accountability and patient safety – need commitment from the top
- **Our Goal:** To be the leaders and best in diversion prevention and detection and safe use of controlled substances



Scenario #2:

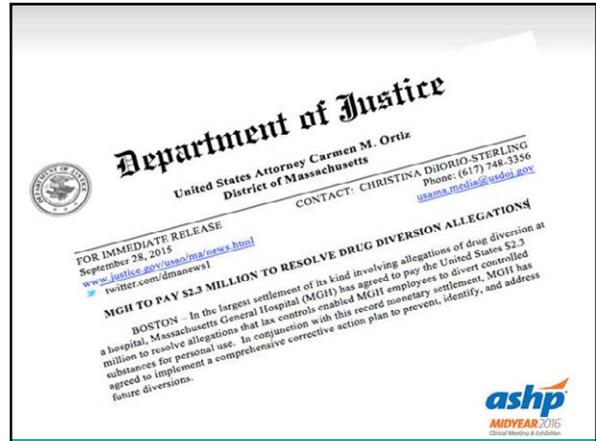
A pharmacy technician is found dead at home and medications are found at the scene with your hospital's labels on them.

- How would you handle the immediate situation?
- What steps could you take to prevent this in the future?



Drug Diversion and the DEA at Mass General Hospital

Christopher Fortier PharmD, FASHP
 Chief Pharmacy Officer
 Massachusetts General Hospital
 Boston, MA



DEA Violations at MGH

- Major nurse diversion
- Failure to report within timeframe
- No biennial inventory
- Not utilizing DEA 222 for off-site license transfer
- Unable to provide 2 years worth of readily-retrievable ADC records



Mass General Hospital

- 1,000 bed academic medical center and clinics across Boston-metro area
- 2 million control substances dispensed annually
- 30,000 employees
 - 2,400 physicians
 - 380 pharmacy employees
 - 3,800 nurses
 - 450 anesthesia providers
- Automation
 - 200 automated dispensing machines
 - 90 anesthesia workstations



Drug Diversion Task Force



The Basics

- **2-years readily retrievable data**
- **DEA binder**
 - Hospital licensed sites
 - Biennial inventory
 - Power of Attorney forms
 - DEA/DPH licenses
 - Suspicious monitoring
 - BAA
 - DEA 106 filings
- **Files**
 - CSOS order/invoice matching
 - DEA 222 forms
 - Reverse distributor
 - Weekly narcotic inventories
- **Narcotic vault**
 - Limited access and hours
- **Process to remove employees from system**
- **Nationally certified techs**



The Basics

- **Biennial inventory**
 - Open or close of business
 - Ideally all on same day
 - Physical inventory
 - Pharmacist/tech sign off
- **Control substance online database files**
 - DPH and DEA filing
 - Investigation documents



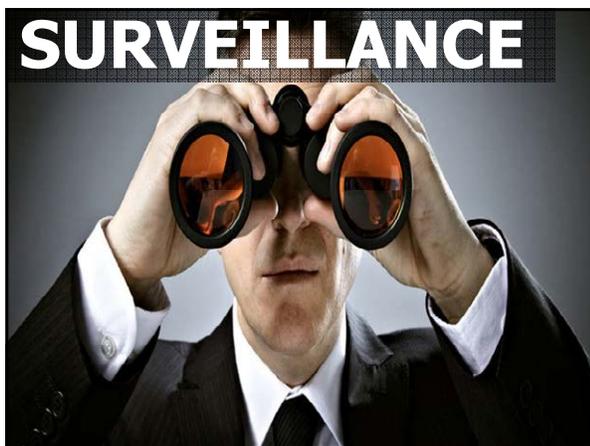
Staff Education

- **Pharmacy, nursing, anesthesia**
 - Annual mandatory training
- **Signs and symptoms, diversion practices**
- **Targeted education**
 - Control substance electronic surveillance training
 - Nurse managers
 - Waste documentation, witness, disposal
 - Discrepancies
 - Override list changes, policies



Staff Education

Wasting complete doses	Removal under someone else
Withdrawing without an order	Giving less than what was ordered
Dropping/breaking containers	Canceled transactions
Removal for discharged patient	Duplicative doses
Withdrawing for patient who do need pain meds	Asks a colleague to witness a waste that has already been wasted
Volunteers for overtime often	Frequent trips to bathroom
Willing to float or stay late often	Long trips off unit
Comes into work when not assigned or scheduled	Discrepancies between patient reports of pain relief and charted meds
Readily volunteers to medicate other patients	Consistently signing out maximum amount of narcotics
Volunteers to waste medication that was not administered by him/her	

Organizational Dashboard

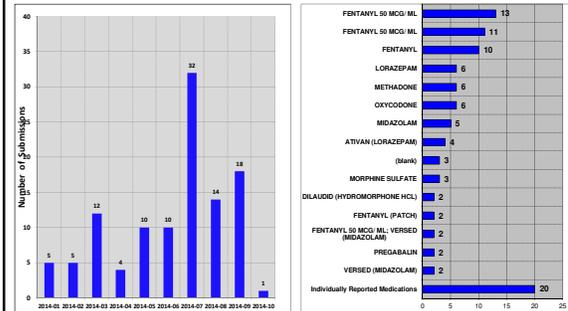
Nursing Measures
Anomalous User and User Activity Checks. (Daily)
Activity and User Checks (S-S-H)
Shift Discrepancy Checks
Pharmacy / Anesthesia Measures
Post Case Reconciliation Compliance (Daily)
Pharmacy Measures
DEA 106 Filings
Destock-Null Transactions (Daily)
Destock-Null Transactions (Weekly)
Discrepancy Checks (Daily)
Dispense >5 Report (Daily)
DPH Filings
Global List Transaction Review (Weekly)
Inventory Integrity Checks- Endoscopy (Monthly)
Override Report (Daily)
Suspicious Order Monitoring (Monthly)
Terminated Employee ADM Removal (Monthly)
Annual Inventory
Site Visits

Audit

- **Trending reports**
 - Medication, location, user
 - Post-case reconciliation
 - Employee volume comparisons
- **Accountability audits**
 - 6 selected drug by independent auditor annually
- **On-site record audits of all DEA licenses**
 - Biennial inventory, powers of attorney, 222 forms, DEA 106's, invoices
- **Pharmacy employees**
 - Null transactions, destock, overrides
- **Suspicious monitoring**



Report Trending



Automation/Technology

- **Understanding how technology works/limitations**
 - ADC, anesthesia workstation, surveillance systems, pharmacy CS inventory system
 - e.g. When patients are discharged from system
- **System configurations**
- **Upgrades/system enhancements**
- **Access to quick and usable data**
 - 2 years worth of readily retrievable data



MGH Corrective Action

- Employ a full time Drug Diversion Compliance Officer
- Establish a drug diversion team
- Conduct mandatory annual training for all staff
- Purchasing controlled substance surveillance software
- ADC's having timed password-reset (90 days) and biometrics
- Requiring the MGH Department of Pharmacy to conduct daily operating room post case reconciliation of controlled substances dispensed, used or wasted.
- Requiring at least one nursing leader per clinical area to:
 - Conduct weekly reviews of all controlled substance surveillance software anomalous usage reports for ADC's in that clinical area
 - Conduct daily M-F reviews of controlled substances dispensed from the ADC's in that clinical area



MGH Corrective Action

- Requiring clinical nursing supervisors to review certain ADC reports on Saturdays, Sundays and holidays
- Requiring Associate Chief Nurses to conduct monthly compliance checks on their nursing leader direct reports
- Requiring trend and pattern reports to be reviewed quarterly by the DDTF
- During each year of this CAP, MGH will conduct a self evaluation of all its DEA registered facilities to review compliance with all requirements of the ACT
- MGH will maintain reports of disciplinary actions taken against employees found to have lost a significant quantity of controlled substances or found to have stolen or diverted controlled substances.
- MGH will complete biennial inventories of all of its DEA-registered facilities using physical counts (including all ADCs) witnessed by 2 individuals



MGH Corrective Action

- **MGH will take the following corrective actions in addition to the enhanced controls:**
 - MGH will hire external auditors to conduct unannounced audits at all MGH facilities with active DEA registrations of 5 Schedule CII-V randomly chosen by the auditors.
 - Each audit report will be reviewed and signed by the pharmacist in charge or the registrant's DEA-designated person
 - MGH will have 30 days to cure/resolve any deficiencies identified in the audit report and efforts to cure will be documented in the report
 - If the auditors find any discrepancies/losses, MGH will send the audit report within 5 days of the end of the 30 day period
 - MGH will maintain audit records and make them available for the DEA upon request for up to a 2 years after the CAP expires



Lessons Learned

- Are you looking hard enough?
- Multidisciplinary collaboration is critical
- Variety of surveillance and audit tools
- Resources dedicated to sustaining program
- Program visibility is major deterrent



Scenario #3:

Over the last month at 3 of your hospitals: Nurse is caught stealing controlled substances from your automated dispensing cabinets, Anesthesia provider caught "Huffing" gases and Physician tested positive for cocaine.

- How would you handle the situation?
- What steps could you take to prevent this in the future?



Lessons Learned from an Integrated Health System

**Robert Fink, PharmD, MBA, FACHE, FASHP, BCHSP,
BCPS**
VP – Ancillary Services & Chief Pharmacy Executive
Quorum Health



System Approach to CS Accountability

- Corporate President, Chairman, & CEO sets the tone and establishes accountability
- Hospital CEOs held accountable and lead facility accountability
- Standardized (no-deviation) policies & procedures, standardized forms, standardized reporting
- Standardized automation and equipment (corporate funded mandates)
 - ADCs, IV/PCA pumps, drop boxes, refractometers, surveillance software
- Standardized "on-boarding" of new hospitals and MD clinics
- Support of corporate legal counsel, compliance, and internal audit



RN found after overdose

- Standardize policies and procedures for controlled substance compliance
- Standardize controlled substance accountability records (CSARs) and other forms
- All large volume CS waste and used fentanyl patches returned to the pharmacy. Verified using refractometry.
- Standardized diversion reporting process and standardized diversion report (internal use)
- Submission of DEA 106 reports (reports to state board of pharmacy, board of nursing, other state agencies as required)
 - Define significant loss for consistent reporting



Standardized Forms

- Consecutively numbered
- Colored ink
- Watermarked security paper
- Standardized for use across multiple facilities to reduce printing costs
- “Generic” Rx pads are prohibited
 - ED physicians must use their own pre-printed pads or e-prescribe
- Maintain Rx pads and Rx paper in locked storage
 - Install locks on Rx printer paper trays



Internal Diversion Reporting

- Stolen Rx forms
- Stolen DEA-222 forms
- Forged Rx
 - Written
 - Verbal
- Reports related to potential inappropriate prescribing
- Diversion of non-controlled substances
 - Theft of medications from crash carts
 - Do not maintain CS within crash carts



Internal Diversion Reporting

- Theft of patients own medication
 - Occurs when patients bring their own CS to the ED
 - Discourage or prohibit use of patient’s own CS when admitted
- Report theft of CS during shipment (wholesalers may use overnight shippers or contract drivers)



Nursing Responsibilities

- All CS must be inventoried daily (or daily if required by nursing policy)
 - Recommend inventory between night shift and day shift
 - Different nursing personnel should conduct inventory (could be a challenge for small hospitals or specialty units)
- All partial dose CS waste must be witnessed by licensed personnel (those personnel allowed by state law to administer medications).
 - Do not place into sharps container
 - Fentanyl patches should be handled with gloved hands as drug is readily absorbed through the skin – can result in positive drug screens (violation of glove policy can result in termination)
- May need to discuss impact with nursing unions, but they cannot deny participation as these are legal requirements.



Nursing Responsibilities (continued)

- All suspected tampering or diversion must be immediately reported
- Nurses to inspect integrity of drug packaging with daily inventories
- Unresolved discrepancies must be reported immediately to CNO and Pharmacy Director
- Shift counts must be correct before personnel are allowed to leave facility
 - Drug screens obtained
- Monitor agency/traveling nurses



Example Anesthesia Proof-of-Use Form



Pharmacy Responsibilities (continued)

- CS waste returned to pharmacy must be destroyed by two pharmacists
 - If second pharmacist is not available – professional licensed to administer medications (e.g., RN, CRNA)
- Use refractometer to verify returned waste
 - All large volume (e.g., morphine drips, fentanyl cassettes)
 - Random for CS returned from the OR
 - Maintain logs of verified waste
 - Consider analyzing waste returned by an anesthesia provider for a week at a time or all for a locum tenens



Example CS Waste Verification Audit Form



Non-CS Accountability

- Alcohol permit or liquor license, if applicable.
 - Tax-exempt containers require “cradle-to-grave” accountability. Empty containers must be destroyed.
- Treat propofol as a controlled substance (optimally as a C-II)
 - Maintain secure inventory of all product
 - Either in ADS or remote locked storage with key controlled through ADS.
 - Require waste to be witnessed or returned to the pharmacy
 - Be aware of potential substitution with IV fat emulsion



Non-CS Accountability (continued)

- Maintain all gases in secured storage and within locked anesthesia carts
- Consider having pharmacy techs refill vaporizers
- Dispense anesthesia gas using a bottle exchange program
 - Affix serially numbered detection evident labels to each bottle and log dispensing date
- Be aware that once narcotics and propofol are controlled, anesthesia gases will be abused if not controlled.
- Remove cocaine from physician practices
- Remove cocaine from hospital formulary



Non-CS Accountability (continued)

- Maintain ketorolac as a controlled substance
 - Prevents RNs from substituting ketorolac for narcotics
- Add promethazine, diphenhydramine to watch list or treat as a controlled substance
- Maintain control of other drugs with high abuse/diversion potential
 - Sildenafil, cyclobenzaprine, tramadol, carisoprodol



Detection and Deterrents

- Standardized education modules
 - Computer-based training to document completion
 - Required for all new hires, including employed physicians
 - Includes pharmacists, pharmacy technicians, nurses, all ancillary clinicians (e.g., respiratory therapy, lab, dietitians), administrators



Detection and Deterrents (continued)

- **Auditing process**
 - From physician order to medication administration
 - Can be completed by pharmacy technicians or nurses
 - Nurses may not audit their own department
 - Include patient interviews
 - Verify orders with prescriber
 - Should include all anesthesia providers each quarter
 - Should include all nursing departments each year
 - Monitor discharged patients from the ED
 - Monitor ADC over-rides
 - Reconcile all orders/proof-of-use from the ED, OR, and procedural areas
 - Include Internal Audit department to verify compliance



Detection and Deterrents (continued)

- **Physician practices**
 - No controlled substances administered unless procedurists (e.g., endoscopy, oral surgeons)
 - Monitor all drug purchases/wholesaler reports
 - No controlled substances dispensed to patients
 - No controlled substance sample medications
 - Prescriptions pads must be secured
 - Monitor verbal prescriptions
 - No pre-signed prescription forms
 - Control passwords to EMR (e-prescribe platforms)
 - Monitor EMR reports



Detection and Deterrents (continued)

- Controlled substance drug screening
 - Pre-employment
 - Reasonable cause
 - Random
 - When diversion is suspected
 - All staff involved
 - Follow medical staff by-laws



Implementation Across the Enterprise

- Cover memo from the President, Chairman, & CEO
- Toolkit – CBT, Policies & Procedures, Forms
- Corporate funding – Automation (ADS, IV pumps), Surveillance software, Instruments, Drop Boxes
- Webinars and Face-to-Face Education – CE programs, Expert speakers (Practitioners, DEA agents)
- Legal support (Including expert counsel)
- Accountability (Attestation statements, On-site inspection, Internal Audit)



Pearls or Key Take Aways

- Executive (CEO) ownership
- Culture of safety
- Zero tolerance
- Use automation for surveillance/detection/accountability
- Think outside the four walls – MD practices, ASCs, FSEDs
- Project cost of compliance across the enterprise



ASHP Guidelines on Diversion Prevention

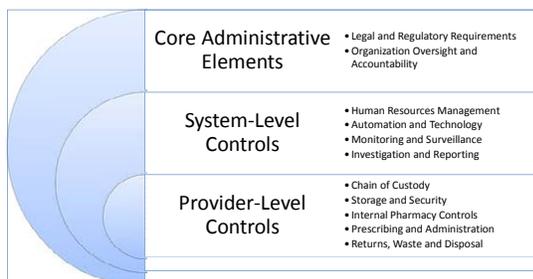


Purpose and Scope of ASHP Guidelines

- Controlled substance diversion:
 - Risk of harm to patients
 - Regulatory and legal risk to the organization
- Guidelines provide a comprehensive framework to support organizations in developing a controlled substance diversion prevention program (CSDPP)
 - Meets federal and state laws
 - Applies technology and diligent surveillance
 - Build tight control and establish checks and balances
 - Develop procedures for prompt intervention



Core Elements of a CSDPP



Common Risk Points and Methods of Diversion

- | | |
|-----------------------------------|--|
| Procurement | <ul style="list-style-type: none"> Purchase order and packing slip removed from records Product container is compromised |
| Preparation and Dispensing | <ul style="list-style-type: none"> CS are replaced by product of similar appearance Multi-dose vial overfill diverted |
| Prescribing | <ul style="list-style-type: none"> Verbal orders for CS created, but not verified by prescriber Prescriber self-prescribed CS |
| Administration | <ul style="list-style-type: none"> Medication documented as given but not administered Waste is not adequately witnessed |
| Waste and Removal | <ul style="list-style-type: none"> CS waste is removed from unsecure waste container Expired CS are diverted from holding area |



Legal and Regulatory Requirements

- Incorporate state-level initiatives and procedures
- Collaborate with quality, safety and compliance stakeholders within your organization
- Establish a process to report suspected or known diversions to the DEA



Organization Oversight and Accountability

- A CSDPP should discourage diversion, strengthen accountability, and increase identification of suspected diversions
- Establish an interdisciplinary CS management program and a diversion response team



Human Resources Management

- Create a written employee substance abuse policy
- Establish a healthcare worker education and awareness program
 - Assistance programs, peer support groups, etc.
- Determine criteria for drug testing
- Outline return to work policies for healthcare workers
- Identify sanctions for performance and diversion violations



Automation and Technology

- An interdisciplinary team should be involved in determining automated medication-related systems
- Automation systems must track waste, identify discrepancies, and have capability of report generation



Investigation and Reporting of Suspected Diversions

- Document all personnel involved in a review process
- If a healthcare worker is arrested for use of CS, an immediate investigation should follow
- Establish criteria for contacting outside authorities
- Define when a DEA 106 form should be completed



Storage and Security

- Record retrievable evidence of CS chain of custody at all times
 - Internally and externally
- Utilize lock-out times on electronic stations
- Limit CS access to authorized healthcare personnel
- Utilize biometric ID for password access
- Identify camera surveillance opportunities in high-risk areas



Internal Pharmacy Controls

- Utilize CSOS rather than DEA 222 forms
- Pharmacy owns all CS procurement
- Implement and maintain a perpetual inventory throughout all locations in the health-system



Returns, Waste, and Disposal

- Stock all CS in as ready-to-use form as possible
- Require an independent witness and documentation for wasting of all CS
- Define what constitutes complete and timely documentation of waste
- Waste containers are made non-retrievable for oral and IV medications



Key Takeaways

1. Recognize that controlled substance diversion is a growing problem and should be a priority for pharmacy leaders.
2. ASHP Guidelines on Preventing Diversion were created to support organizations in developing a controlled substance diversion prevention program.
3. Perform a gap analysis within your organization and implement drug diversion prevention strategies.



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