



Controlled Substance Diversion: Active and Proactive Solutions

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MGH TO PAY \$2.3 MILLION TO RESOLVE DRUG DIVERSION ALLEGATIONS

BOSTON – In the largest settlement of its kind involving allegations of drug diversion at a hospital, Massachusetts General Hospital (MGH) has agreed to pay the United States \$2.3 million to resolve allegations that lax controls enabled MGH employees to divert controlled substances for personal use. In conjunction with this record monetary settlement, MGH has agreed to implement a comprehensive corrective action plan to prevent, identify, and address future diversions.

...down to pay
the report
reinforced and added

DEA SETTLEMENTS

- **California- 2014**
 - ❖ Settlement: \$1.55 million to resolve claims it mishandled control substances
 - ❖ Violations:
 - Theft of between 20,000 – 30,000 hydrocodone tablets from its outpatient pharmacy in 2010 and 2011.
 - Numerous recordkeeping errors, such as missing signatures on delivery slips and inventory adjustments, as well as missing invoices.
- **Oklahoma - 2011**
 - ❖ Settlement: \$1,000,000,
 - ❖ Violations:
 - Inconsistencies in narcotic inventories resulting from pharmacy transfers to Surgical center.
 - Disclosed discrepancies to Board of Pharmacy and DEA.
 - Distributed methadone to medical facility not registered
 - Failed to maintain proper methadone records and inventories.
- **Indiana - 2007**
 - ❖ Settlement: \$2 million
 - ❖ Violations:
 - Investigation began based on allegations a pharmacy tech was stealing hydrocodone.
 - DEA discovered that the hospital was unable to account for 623,843 hydrocodone tablets.
 - Failed to keep accurate records and make accurate reports designed to safeguard the public against diversion.

MGH DEA VIOLATIONS

- ❖ 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 ADM records



MGH CORRECTIVE ACTION PLAN

- ❖ Drug diversion compliance officer
- ❖ Mandatory annual training
- ❖ Anesthesia workstations
- ❖ OR post-case reconciliations
- ❖ Conduct daily review of anomalous usage reports
- ❖ Quarterly review of trend and pattern reports
- ❖ Self-evaluation of all DEA registered facilities
- ❖ Unannounced accountability audit by external auditor



COMPREHENSIVE PROGRAM

- ❖ Staff training
- ❖ Surveillance
- ❖ Auditing
- ❖ Automation and technology
- ❖ Ordering, receiving, distribution, storage, dispensing, administration, and returns
- ❖ Multidisciplinary collaboration
- ❖ Peri-operative
- ❖ Ambulatory areas
- ❖ Waste disposal/returns
- ❖ Reporting
- ❖ Investigation
- ❖ Human Resources



“It is extremely important that pharmacies be prepared to meet this challenge by focusing closer attention on prescriptions dispensed, ensuring that hiring policies and accountability policies and procedures are sufficient to detect, discover, and respond to recent opioid drug crisis, as well as identify impaired health care workers and assist them in seeking appropriate programs for recover.”

- Ruth Carter, DEA spokesperson, October 2015



DEA considering rulemaking on suspicious order reporting. <http://www.fda.gov/oc/2015/08/27/082715dea-considering-rulemaking-on-suspicious-order-reporting.html>. Accessed August 27, 2016.



PRE-MEETING SURVEY RESULTS



SURVEY OF ACADEMIC MEDICAL CENTERS

❖ Pharmacy

- An automated vault is used for storage of controlled substances **87.3 %**
- Audit of controlled substance purchases against products added to pharmacy inventory is performed at least quarterly - **68.4 %**
- Individual who submits a controlled substance purchase order is not responsible for receiving the order - **80.7 %**
- Discrepancies are reviewed by an individual not routinely involved in controlled substance handling - **70.9 %**
- Person-to-person transfers of controlled substances are audited, including transfers to non-automated storage areas **70.1 %**
- Cameras directed at controlled substance storage areas **55.2 %**

McClure SR, O'Neal BC, Grauer D, et al. Compliance with recommendations for prevention and detection of controlled substance diversion in hospitals. *Am J Health-Syst Pharm.* 2011; 68:689-94.



SURVEY OF ACADEMIC MEDICAL CENTERS

- ❖ Operating Rooms
 - Controlled substances dispensed for an OR case are always reconciled by pharmacy against products documented as administered or returned to the pharmacy for ~~wasting~~ **56.8%**
 - Controlled substances not used in an OR case are returned to the pharmacy for ~~wasting~~ **48.7%**
- ❖ Nursing Units
 - Biometric fingerprint scan for access to automated dispensing machines **62.2 %**
 - Locking cases used to secure non-PCA controlled substance infusion containers while being administered – **35.6 %**

McClure SR, O'Neal BC, Grauer D, et al. Compliance with recommendations for prevention and detection of controlled substance diversion in hospitals. *Am J Health-Syst Pharm.* 2011; 68:689-94.



WORKSHOP OUTLINE

- ❖ Introduce yourselves to each other stating your position and which institution you are from
- ❖ Identify both a scribe and someone who will facilitate the discussion with the group
 - The facilitator will also be the person to provide the final plan report out to the larger group
- ❖ Review the assignment and begin having an interactive discussion sharing your experiences around some best practices and limitations with drug diversion
- ❖ You will have about 30 minutes to complete the assignment
- ❖ Report out will take place following lunch



CASE SCENARIO

- ❖ Seeing in the news and hearing from your colleagues about the numerous drug diversion cases taking place in hospitals across the country
- ❖ You have dealt with diversion incidents as they arise but with all the competing priorities developing a comprehensive drug diversion program has not been a strategic priority for the department or the organization
- ❖ Your boss asks in your one-on-one meeting if you think your Department of Pharmacy has a comprehensive drug diversion program and what you are doing proactively around drug diversion surveillance and compliance

WHAT IS YOUR RESPONSE?



WORKSHOP OUTLINE

- ❖ Develop a strategic and practical plan around active and proactive strategies
- ❖ Prioritize (lowest work-highest value) the initiatives and identify implementation timelines for each



SCENARIO #1

Peri-operative and Procedure Areas

ASSIGNMENT: Develop a strategic and practical plan around active and proactive strategies for the peri-operative and procedure area. Prioritize (lowest work-highest value) the initiatives and identify implementation timelines for each. Within your plan make sure to address the following items:

- Active and proactive surveillance methods
- Implementation and/or optimization of technology and automation
- Waste validation processes
- Storage and transfer of controlled substances between areas
- Metrics for analysis and data to be audited
- Strategies to engage anesthesia and anesthesia leadership
- Staff education and training
- Other areas you feel should be included



Peri-operative and Procedure Areas

- ❖ Technology, Automation, and Procedures
 - Automated dispensing machines (ADM) for distribution within procedural suites and/or core for after-hours use
 - Minimize person-to-person handoffs with closed-loop automation dispensing where possible
 - Chain of custody documentation exists for person-to-person handoffs during procedures
 - Cameras are in use in high-risk areas
 - If trays or boxes are used, quantities are minimal and specific for a single patient
- ❖ Waste Validation
 - Ensure that all individuals involved in controlled substance handling during procedures have waste validated no less than quarterly
 - Potential methods
 - Refractometry
 - UV-vis spectroscopy
 - Internal or external laboratory analysis



Peri-operative and Procedure Areas

- ❖ Metrics and Auditing
 - Audit to detect any open transactions between inventory locations
 - Audit to identify significant fluctuations in distribution of controlled substances at the line item level
 - Reconcile controlled substance quantity dispensed against quantity documented as administered on procedure notes and/or dispensing record
 - Ensure that quantities returned (for re-use or waste) are correct
 - Internally benchmark quantities used by a given practitioner against peers in similar cases
 - Include propofol in analyses



SCENARIO #2

Supply chain and Internal Pharmacy Storage

ASSIGNMENT: Develop a strategic and practical plan around active and proactive strategies for the supply chain and internal pharmacy storage. Prioritize (lowest work-highest value) the initiatives and identify implementation timelines for each. Within your plan make sure to address the following items:

- Active and proactive surveillance methods
- Implementation and/or optimization of technology and automation
- Metrics for analysis and data to be audited
- Physical controls
- Expired medication and waste processes
- Strategies around purchasing privileges and processes
- Surveillance methods of pharmacy technicians and pharmacists
- Staff education and training
- Other areas you feel should be included



Supply Chain and Internal Pharmacy Storage

- ❖ Physical Controls and Technologies
 - Evaluation of security prior to arrival in pharmacy
 - Cameras
 - Ensure at least 3-4 weeks of DVR storage
 - Badge access to pharmacy storage areas
 - Access limited to pharmacy employees
 - Regular review of access list
 - Automated physical vault for storage of all controlled substances schedules
 - Limit vault privileges to those with a need for access
 - Secure storage of refrigerated and expired controlled substances
 - Ensure chain of custody is maintained and witness of transfer is documented in reverse distribution transactions



Supply Chain and Internal Pharmacy Storage

- ❖ Metrics and Auditing
 - Purchase versus receipt into inventory
 - Purchase versus charge
 - Investigation of signification fluctuations in purchase volumes
 - Reconciliation of actual expired bin contents against expected expired bin contents
 - Expired inventory against reverse distributor manifests
- ❖ Purchasing Controls
 - CSOS (Controlled Substance Ordering System)
 - Invoice matching
 - Limit number of individuals with purchasing authority
 - Segregation of duties in purchasing and receiving processes
 - Physical security and logging of DEA Form 222s



SCENARIO #3

Inpatient Pharmacy Operations

ASSIGNMENT: Develop a strategic and practical plan around active and proactive strategies for the inpatient pharmacy operations (exclude sterile compounding). Prioritize (lowest work-highest value) the initiatives and identify implementation timelines for each. Within your plan make sure to address the following items:

- Active and proactive surveillance methods
- Implementation and/or optimization of technology and automation
- Metrics for analysis and data to be audited
- Strategies around distribution to automated and manual areas
- Return processes to the pharmacy
- Repackaging and compounding processes
- Surveillance methods of pharmacy technicians and pharmacists
- Staff education and training
- Other areas you feel should be included



Inpatient Pharmacy Operations

- ❖ Metrics and Auditing
 - Distribution to non-automated destinations
 - Patient-specific transactions
 - Audit for chain of custody and presence of an order and administration
 - Controls around pneumatic tube distributions
 - Sales outside of institution
 - Transfers to and from floor stock inventory locations
 - Reconcile quantities distributed against quantities received into floor stock inventory along with transfers back to automated vault



Inpatient Pharmacy Operations

- ❖ Metrics and Auditing
 - Distribution to automated destinations
 - Thorough and appropriate investigation of open transactions
 - Repackaging and compounding transactions
 - Purchase in unit dose containers when possible
 - Reconciliation of source ingredient quantities against end product quantities
 - Inspection for alteration or tampering
 - Review of pharmacy discrepancy resolutions and adjustments to inventory counts
- ❖ Secure transfer to patient care units during delivery



SCENARIO #4

Retail pharmacy

ASSIGNMENT: Develop a strategic and practical plan around active and proactive strategies for the retail pharmacy operation. Prioritize (lowest work-highest value) the initiatives and identify implementation timelines for each. Within your plan make sure to address the following items:

- Active and proactive surveillance methods
- Implementation and/or optimization of technology and automation
- Metrics for analysis and data to be audited
- Physical controls
- Strategies around purchasing privileges and processes
- Processes for storage, dispensing, and return to stock
- Surveillance methods of pharmacy technicians and pharmacists
- Staff education and training
- Other areas you feel should be included



Retail Pharmacy

- ❖ Physical Controls
 - Cameras, alarms, and badge access
 - Vault storage for all schedules, volume permitting
 - Need for both manual inventory log and perpetual electronic inventory
- ❖ Purchasing and Other Controls
 - CSOS, limited number of personnel with privileges, segregation of duties, and secure storage of 222s
 - Limited availability of prescription pads
 - Regular validation of controlled substance inventory quantities
 - Restrict ability to adjust electronic inventory and require witness if allowed by pharmacy information system



Retail Pharmacy

- ❖ Metrics and Auditing
 - Validation of Schedule II prescriptions from manual log
 - Investigation of variances between electronic and physical inventory
 - Purchase versus receipt into inventory
 - Purchase versus distribution via prescription
 - Investigation of signification fluctuations in purchase volumes



SCENARIO #5

Sterile Products/Compounding

ASSIGNMENT: Develop a strategic and practical plan around active and proactive strategies for the supply chain and internal pharmacy storage. Prioritize (lowest work-highest value) the initiatives and identify implementation timelines for each. Within your plan make sure to address the following items:

- Active and proactive surveillance methods
- Implementation and/or optimization of technology and automation
- Metrics for analysis and data to be audited
- Strategies around distribution to or from sterile products area
- Waste process and handling of overfill/residuals
- Surveillance methods of pharmacy technicians and pharmacists
- Staff education and training
- Other areas you feel should be included



Sterile Products and Compounding

- ❖ Physical Controls
 - Consider ADM in proximity to sterile product area
 - Cameras
 - Lock boxes (in the absence of ADM utilization)
 - Security of refrigerated products
 - Avoid use of multi-dose vials where possible
 - Overfill should be considered unusable and should be documented as waste
- ❖ Metrics and Auditing
 - Line item reconciliation of:
Quantity transferred to sterile products area
 - Quantity used in preparations
 - Quantity wasted
 - = Quantity on-hand
 - Random validation of orders
 - Track flow of batched products to automated destinations

DRAFT ASHP Guidelines on Preventing Diversion of Controlled Substances



SCENARIO #6

Patient Care Areas and Use of ADM

ASSIGNMENT: Develop a strategic and practical plan around active and proactive strategies for the patient care areas (nursing). Prioritize (lowest work-highest value) the initiatives and identify implementation timelines for each. Within your plan make sure to address the following items:

- Active and proactive surveillance methods
- Implementation and/or optimization of technology and automation
- Metrics for analysis and data to be audited
- Practices around documentation, discrepancies, waste and handling
- Physical security controls
- Surveillance methods specifically for nurses
- Staff education and training
- Other areas you feel should be included



Patient Care Areas and ADM Utilization

- ❖ Physical Controls
 - Encourage cameras in medication rooms
 - ADMs
 - Biometrics
 - Limited quantities of controlled substances and/or single-dose dispensing
 - Lock boxes around patient-controlled analgesics and controlled substance drips and syringes
 - Security and accountability of keys
 - One-port tubing
 - Avoid use of lock boxes or cabinets for storage of multiple products



Patient Care Areas and ADM Utilization

- ❖ Metrics and Auditing
 - Transactions by user by drug per month and per shift worked
 - Investigate users who are greater than 3-4 standard deviations beyond peers
 - Interviews of patients by nurse leaders to assess adequacy of pain management
 - Waste pairings
 - Discrepancy management
 - Quantity of discrepancies created relative to peers
 - Validation of discrepancy resolution statements
 - Controlled substance overrides
 - Quantity of override transactions relative to peers
 - Audit overrides for presence of an order and documentation of administration
 - ADM removals occurring after discharge or transfer of patient, while still active in ADM system
 - ADM removals occurring on manually-admitted patient profiles
 - Audit for ADM removals of dosage strength that exceeds quantity needed



SCENARIO #7

Multidisciplinary Event Response Process

ASSIGNMENT: Develop a strategic and practical plan around active and proactive strategies for the multidisciplinary event response process. Prioritize (lowest work-highest value) the initiatives and identify implementation timelines for each. Within your plan make sure to address the following items:

- Composition of team
- Functions and responsibility of team
- Active and proactive surveillance methods
- Interrogation processes and practices
- State and federal reporting processes
- Metrics for analysis
- Employee support offerings
- Other areas you feel should be included



Multi-Disciplinary Event Response Process

- ❖ Team Composition
 - Pharmacy (lead)
 - Medical staff
 - Nursing
 - Anesthesia
 - Human Resources/Employee Health
 - Hospital Administration
 - Risk Management/Compliance
 - Legal
 - Internal Audit
 - Security
- ❖ Function and Responsibility
 - Addresses prevention control, diversion detection, incident investigation, and reporting
 - Regular and ad hoc review of audits, transaction data, and/or subjective observations and reports
 - Coordination of investigation and interrogation processes
 - Some level of training in conducting interrogations

DRAFT ASHP Guidelines on Preventing Diversion of Controlled Substances



THE BASICS

- ❖ 2-years worth of readily
- ❖ Biennial inventory
- ❖ Power of attorney forms
- ❖ Process to remove employees from systems
- ❖ Business associates agreement
- ❖ Define "significant"
- ❖ DEA 106 documentation files
- ❖ Annual staff training
- ❖ Understand automation functionality
- ❖ Non-pharmacy DEA licensed locations



KEY TAKEAWAYS

- ❖ Multidisciplinary collaboration
 - Pharmacy leading the way
- ❖ Proactive and multiple surveillance methods
- ❖ Drug Diversion team
- ❖ Consistent record auditing and trend analysis
- ❖ Understanding software and automation functionality
- ❖ Staff education, creating culture
- ❖ Reporting to agencies
- ❖ Secured storage
- ❖ Limited access
- ❖ Policies
- ❖ Waste processes and disposal



STRATEGIC PRIORITIES

Write down 5 strategic control substance diversion priorities that you plan to begin to implement when you return to your organization

Share with the audience 2-3 of those strategic priorities



RESOURCES

- ❖ ASHP Guidelines on Preventing Diversion of Control Substances
- ❖ ASHP Controlled Substances Diversion Prevention Program Elements of Implementation



QUESTIONS