Best Practices in Controlled Substances Management

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Disclosure Statement

• Nothing to disclose

Objectives

• Highlight key state, federal, and regulatory requirements for the management of controlled substances.
• Review ASHP Guidelines for successful development of a drug diversion prevention program.
• Discuss best practices for personnel management and investigation/reporting requirements when drug diversion has been detected or confirmed.

Massachusetts General Hospital

• Largest hospital in Massachusetts
• Largest teaching hospital of Harvard Medical School
• U.S. News and World Report Top Hospital (#3 in 2016)
• 999-bed medical center
• Annually:
  • Admits 48,000 inpatients 1.5 million outpatient visit
  • 100,000 emergency room visits
  • 42,000 operations

Massachusetts General Hospital

• October 4, 2011-April 1, 2015: Failed to make, keep, or furnish certain records and provide effective controls and procedures to guard against theft and loss of controlled substances
• $2.3 Million Dollar Settlement with the federal government
Claims against MGH

• Failure to report theft of controlled substances within one business day
• Failure to provide effective controls and procedures to guard against theft and diversion
• Failure to maintain complete and accurate records of all controlled substances received, sold, delivered, or otherwise disposed of

Claims against MGH

• Failure to document 358 transfers of Schedule II controlled substances using the required DEA 222
• Failure to
• 407 transfers of Schedule IV controlled substances with invoices
• Failure to conduct appropriate initial and biennial inventories
• Failure to maintain current and accurate records of controlled substances in automatic drug dispensing machines

Outcome

• Ordered to pay federal government $2.3M within 10 days
• Three-year Corrective Action Plan with Drug Enforcement Agency
• Implementation of Best Practices

Background

• To reduce the risk of patient harm
  – Inadequate pain relief
  – Inaccurate documentation
  – Infection disease exposure from contaminated needles and drugs
  – Impaired provider performance
• To reduce regulatory and legal risk to the organization
  – Fraudulent billing and liability
  – Improve community confidence

ASHP Draft Guidelines

PREVENTING DIVERSION OF CONTROLLED SUBSTANCES

Common Risk Points and Methods of Diversion

- Procurement
- Preparation and Dispensing
- Prescribing
- Administration
- Waste and Removal

Adapted from DRAFT ASHP Guidelines on Preventing Diversion of Controlled Substances (Accessed October 1, 2016)

Purpose of Guidelines

- Provide detailed on comprehensive framework to facilitate establishment of a CS Diversion Prevention Program (CSDPP)
- Emphasis need to comply with applicable Federal and State laws and regulations
- Highlights importance of technology and diligent surveillance, strengthened controls, and proactive prevention of diversion

Core Elements of CSDPP

- Core Administrative Elements
- System-Level Controls
- Provider-Level Controls

Legal and Regulatory Requirements

- Records Retention
- Biennial Inventory
- DEA registration and power-of-attorney designations
- Procurement requirements and forms
- Prescription authentication
- Surveillance
- Investigation and Reporting of CS diversion or loss
- Authorization to access, waste, and transfer

DEA Registration

- Appointment of registrant who will be accountable for enforcement of requirements
- Powers of attorney should be current and re-evaluated on a regular basis
- Procedures in place for reporting suspected or known diversion to the DEA and local authorities
- Ensure completeness and integrity of required documentation

Organization Oversight and Accountability

- Interdisciplinary controlled substances management program with committee
- Identification of healthcare workers which are authorized to access or handle controlled substances
- Designation of Diversion Officer who coordinates all aspects of program under existing compliance management program structure
- Establishment of Diversion Response Team
Key Members of CSDPP Committee

- Medical
- Anesthesia
- Pharmacy
- Nursing
- Security
- Human Resources
- Compliance
- Risk Management
- Administration
- Legal
- Media/Communication
- Information Technology
- Employee Health

Automation and Technology

- Implementation of technology in high risk areas
  - Main Pharmacy controlled substances vault
  - Anesthesiology
  - Procedural areas
  - Surgery centers
  - Remote locations
- Diligence in developing meaningful and readily retrievable reports, investigation of trends and variances, and review of the impact of changes in automation technology

Key Elements of Automation and Technology

- Interdisciplinary team that participates in selection and implementation of automated systems
- Vendor collaboration to provide adequate solutions
  - Support control, surveillance, and auditing functions through entire chain of custody
- Readily retrievable records with information necessary to conduct investigations
- Use of specialized systems in high-risk areas with high-volume controlled substances use
- Healthcare workers are adequately trained regarding roles and responsibilities in the use of automation and technology
- Designated pharmacist with oversight of automated dispensing devices
- Policies and procedures that address access, security, and documentation

Human Resources Management

- Written substance abuse policy
- Healthcare worker education and awareness program
- Supervisor training program
- Employee and Physician assistance program
- Peer support and systems, such as pharmacist recovery networks
- Requirements for drug testing
- Sanctions for performance and diversion violations

Staff Training and Education

- Initial orientation and annual education on institution’s awareness program
- Requirement to be educated on medication diversion and controlled substances policies prior to granting authorization to access controlled substances
- Awareness of random compliance checks
- Manager training on signs and symptoms of abuse and diversion

The Role of Human Resources

- Active Employee Assistance Program (EAP)
  - Mandatory referral program
  - Reporting to relevant State Boards
  - Contract for return to work
- Drug testing for cause
- Policies when patient care may be impacted and further testing is warranted
- Policies and procedures for overdose or death in the workplace
Potential Warning Signs of Substance Abuse

<table>
<thead>
<tr>
<th>Vague or Dramatic Illnesses &amp; Excuses</th>
<th>Poor Job Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difficulty following work assignment</td>
<td>Slower reaction time</td>
</tr>
<tr>
<td>Illogical charting/medication errors</td>
<td>Wearing long sleeves all the time</td>
</tr>
<tr>
<td>Poor concentration and/or judgement</td>
<td>Easily argumentative and defensive</td>
</tr>
<tr>
<td>Diaphoretic</td>
<td>Frequent accidents</td>
</tr>
</tbody>
</table>

Warning Signs of Potential Diversion

<table>
<thead>
<tr>
<th>Volunteers for overtime often</th>
<th>Frequent trips to bathroom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Willing to float or stays late often</td>
<td>Long trips out of work area</td>
</tr>
<tr>
<td>Comes into work when not assigned or scheduled</td>
<td>Discrepancies between patient reports of pain relief and charted medications</td>
</tr>
<tr>
<td>Readily volunteers to medicate other patients</td>
<td>Frequent breakage and unwitnessed spills</td>
</tr>
<tr>
<td>Volunteers to waste medication that was not administered</td>
<td>Signing out maximum amount of narcotics</td>
</tr>
<tr>
<td>Asks for witness of waste after it has already occurred</td>
<td></td>
</tr>
</tbody>
</table>

Monitoring and Surveillance

- Relies on the availability and use of data and information, including timely access to actionable reports that support an effective surveillance and detection system
- Assesses comprehensiveness and level of documentation and response to suspected diversion events and compliance with established policies and procedures
- Automated systems and diversion monitoring software are recommended for high-risk or high-volume locations
- Oversight by CSDPP Committee
  - Surveillance measures
  - Thresholds of variance that require action
  - Reporting frequency
  - Surveillance procedures

Recommended Surveillance Practices

- Pharmacist with adequate support staff and dedicated time for surveillance monitoring
  - Optimization of automated dispensing devices and diversion monitoring software reporting capabilities
- Processes for procurement and surveillance
  - Audits of purchase history (variations)
  - Purchase invoice compared to orders and receipt into perpetual inventory
  - Identification of usual peaks in quantity or frequency of purchases

Recommended Surveillance Practices

- Verification of a perpetual inventory with frequency consistent with the controls to limit the timeframe for discovery
  - Blind count implementation on automated dispensing cabinets
  - Monthly counts of automated dispensing cabinet
  - Inventory conducted at each shift change when outside of automated dispensing devices
  - Biennial physical inventory with documentation per DEA requirements
  - Movement across organization is traced with all transactions reconciled
- Prescribing practices and trends are evaluated
- Automated dispensing device reports are reviewed at least monthly by pharmacy and patient care managers
  - Compare device activity with administration records
  - Patient response to medication is evaluated against medication administration, documentation of response, and patient interview
  - Compare shift-to-shift administrations
- Nursing management to conduct random patient interviews
  - Verify receipt of medication and pain control
  - Compare responses to nursing patient assessment notes and medication administration records
  - Review of cases where product integrity may be compromised
- Process for discrepancy resolution and time in which they should be resolved
  - End of shift or with pharmacy involvement within 24-72 hours
**Recommended Surveillance Practices**

- Designated pharmacist reconciles when an unaccountable discrepancy is discovered
- Trend of poor documentation practices are reviewed for possible diversion
- Pharmacy reconciles controlled substances in high-risk areas by comparing the amount dispensed with the amount documented
- Identify specific high-risk controlled substance medications that are randomly assayed (random testing of waste)

**High-Risk Areas**

- Organization should identify high-risk areas and include an assessment of risk for diversion, ease of detection, and probability of harm
- Includes areas where the same provider is prescribing, obtaining, preparing, and administering the medication—Surgery centers, operating rooms, and procedural and anesthesia areas
- Locations where high volumes of controlled substances are ordered, prescribed, stored, and dispenses within the same location (main pharmacy)

**High-Risk Area: Anesthesia and Operating Rooms**

- Documentation of doses administered in health record should be routinely reconciled with documentation of dose dispensed and return quantities as well as prescribed dose
- Pharmacist responsible for all drugs and controlled substances dispensed and distributed in the setting
- Pharmacy technicians may be assigned most of the responsibility but be supervised by a pharmacist

**High-Risk Area: Satellite Pharmacy**

- Staffed whenever surgery and anesthesiology areas are normally staffed
- Establish mechanism for after-hours drug supply
- Supply levels should be checked, reconciled, and replenished daily
- Dedicated pharmacy resources within perioperative area
- ASHP Guidelines on Surgery and Anesthesiology Pharmaceutical Services

**Investigation and Reporting of Suspected Diversion**

- Any unaccountable discrepancy should be considered a possible diversion and escalated to an investigation
- Director of Pharmacy or designee and diversion officer should be notified immediately and participate in all active investigations

**Investigation and Reporting Procedure Elements**

- Identification of who will coordinate the investigation, appropriate team members, leadership and organization legal counsel notification, documentation of the investigation, and coordinating internal and external reporting
- Investigations are conducted as thoroughly and completely as possible
- Upon arrest of a healthcare worker for illicit use of controlled substances all transactions should be reviewed to determine if diversion has occurred
- Process for determining actions of suspension, transfer, termination, or other action is predefined
- Immediately removal of access privileges if diversion is suspected
- Guidelines for engaging others including DEA, licensure boards, laboratories, and local law enforcement
- Defines when DEA Form 106 should be filed
### Chain of Custody

- Must ensure that chain of custody is maintained at all times and at all points of transfer between individuals
- Depend on ability to reliably audit the trail of transfer
- Prohibit delegation of access
  - Sharing of electronic medical record, automated dispensing cabinet, or pharmacy door passcodes, not providing key access and entry to unauthorized individuals
- Secure, lockable, and tamper-evident delivery containers for offsite locations
- Fully executed DEA Form 222 when providing controlled substances for emergency medical services

### Storage and Security

- Controlled substances are stored in a locked and secured location at all times
- Camera surveillance should be considered in high risk locations
- Storing controlled substances in transportable lock boxes or “fanny packs” is avoided
- Lock-out times for electronic locks on carts are limited to narrowest window based on setting
- Defined process to ensure that only authorized individuals have access to controlled substances (consideration of separation)

### Storage and Security

- Procedure to track keys, secure keys after hour, replace lost keys, and change locks
- Video surveillance and recording of secure locations
- Automated dispensing device technology utilized in high-volume areas, anesthesia and surgery locations, high-volume clinics, and outpatient procedure areas

### Storage and Security

- Utilization of witness or other verification process upon restocking or pulling returns
- Process to monitor pharmacy inventories
  - Manually inventoried by rotating, licensed, or authorized individuals weekly
  - In high-volume or high-risk areas more frequent verification audits are completed potentially more frequently
  - Without automation inventory is conducted once weekly
- Controlled substance counts are managed by automated dispensing devices or done manually through blind count during each access

### Storage and Security

- Inventory is conducted by two authorized healthcare workers if blind counts have not been performed within one week on automated dispensing cabinets
  - Occurs at beginning and end of every shift when area is open for services when automated dispensing cabinet is not used
- Patient-specific continuous infusions are contained in a secured, locked box utilizing no-port tubing unless under constant surveillance
- Documentation used to procure and prescribe controlled substances are secured and monitor to prevent theft or loss

### Patient Own Medications

- Patients should be encouraged to return their own medications to home via family member
- Should only be accepted when they are to be administered pursuant to a medication order
- Documentation is key:
  - Medication name
  - Quantity inventoried
  - Signatures verifying healthcare workers and patients received and returned to patient
- Provide public receptacle for disposal by patients
- Notify local authorities when patients present with illicit substances
Internal Pharmacy Controls

Procurement

Preparation

Dispensing

Internal Control: Procurement

• Safeguards in place that prohibit ordering of controlled substances by those not authorized by the organization
• Electronic CS ordering system (CSOS) is utilized
• When paper forms are used, DEA 222 forms are locked in a secure location and are recorded on a perpetual inventory log
• Separation of duties exists between ordering and receipt of controlled substances
  – Two authorized individuals count and check-in received product and confirm that order, invoice, and product-received match (at least one licensed)
• Investigate and remedy discrepancies with wholesaler or other distributor

Internal Control: Preparation & Dispensing

• Perpetual inventory is maintained with blind-count process
• Access to inventory is limited, with controls to identify who accessed the inventory, when the inventory was accessed, and what changes were made to the inventory
• Drug products are inspected for alteration or tampering, discrepancies are investigated for possible diversion

Internal Control: Preparation & Dispensing

• Purchase in unit dose packaging whenever possible, put controls in place when repackaging is required
• Delivery and restocking of patient care and procedures areas requires a second witness, with verification of delivery and receipt
• Returns from patient care and procedural areas have a second witness, with verification of return

Prescribing & Administration

• Restricted to licensed authorized prescribers with DEA authorization
• Use of electronic means when appropriate
• Mechanism to track and secure prescriptions and paper used to print prescriptions
• Valid order must exist for all controlled substances administered, overrides are minimized
Prescribing & Administration

- Process in place to identify and verify authorized prescribers (including medical residents)
- Pharmacists clarify orders for which the prescriber or order is questionable with regard to prescriber identity or legitimacy
- Active prescriptions and orders are re-evaluated regularly and discontinued when patient transfer to different level of care
- Establishment of automatic stop orders

Prescribing & Administration

- Retrieval from inventory by authorized healthcare worker responsible for administration and documentation
- Avoid preemptively drawing up medication into syringes in advance
- Avoid use of multi-dose vials or syringes
- Establish policies and procedures that address documentation of controlled substances issued but not used

Returns, Waste, and Disposal

- Controlled substances should be stocked in ready-to-use form when possible and in lowest commercially available units
- Waste procedures should maintain chain of custody at all times
- Waste should occur immediately or as close to the time of administration as possible
- Independent witness with at least one being licensed individual

Returns, Waste, and Disposal

- Witness should verify:
  - Product label
  - Volume or amount being wasted matches drug product in documentation
  - Wasting occurs per policy for safe disposal and in a manner that makes the substance irretrievable
- The entire process of drawing up and wasting from the vial should be witnessed

Returns, Waste, and Disposal

- All issued but unused controlled substances that may be potentially reusable are returned to the pharmacy or to a designated, secure return location
- Unless selected for random assay, unusable products should be immediately wasted and witnessed by authorized individuals per specific organization procedures
- Partially used preparation or containers not returned to the pharmacy for disposal except for purposes of random assay
- In high-risk areas waste should be witnessed and reconciled with an authorized pharmacy healthcare workers
- Returns or destruction of expired controlled substances should occur at least quarterly

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