A Comprehensive Guide to Preventing Controlled Substance Diversion

An Interdisciplinary and Technological Approach

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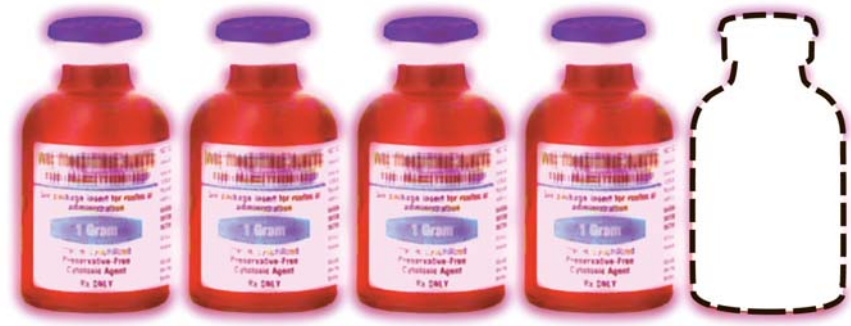

THE DRUG ENFORCEMENT AGENCY (DEA) AND STATE REGULATORY AGENCIES require pharmacies to demonstrate control and security over their controlled-substances inventory, document it accurately, and identify inventory movement or diversion in a timely and retrievable manner. Significant losses of controlled substances must be reported to the DEA, and the agency states that "the loss of a small quantity of controlled substances, repeated over a period of time, may indicate a significant problem." Always err on the side of caution: If there is a question as to whether a loss is significant, report it to the DEA. With the appropriate technology and systems, maintaining and demonstrating your facility's control over such substances should be a manageable process.

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Fostering a Culture of Responsibility

To prevent diversion, your institution must first establish standardized methods of documenting and handling controlled substances. Any and all staff members who handle controlled substances must be appropriately monitored and the seriousness of your diversion program must be communicated to them as well.

To foster a culture of responsibility surrounding controlled substances, it is imperative that all disciplines embrace this practice and share in discrepancy-resolution and diversion-prevention responsibilities. Working together, administration, physicians, nurses, and security should come to a consensus regarding the policies and procedures for handling controlled substances. Assigning anti-diversion roles to pharmacy and other hospital personnel is the key to success in managing diversion issues.

Using ADMs to Prevent Diversion

The appropriate use of automated dispensing machines (ADMs) can minimize the risk of diversion. The role-based access and functions that are available to employees using ADMs should be standardized. Uniform controlled-substances policies and procedures help to ensure a quicker resolution of discrepancies and errors, and a periodic review of system administrators can help prevent diversion issues.

Reports and Data Interpretation: ADMs offer several key reports that can aid in preventing and detecting controlled-substance diversion. A "controlled substances vault access" report states the user, date, time, drug, quantity, and compartment access in chronological order. An "all events" report states all user activity and transaction types within a time frame, and can be tailored to specific data requirements, such as individual drugs or users. A "controlled substances vault compare" report allows administrators to cross-reference the inventory that leaves the narcotic vault and arrives at the ADM on the patient care unit. Transactions that do not match show up on this report by patient care unit, medication, quantity, date, time, and user. A "review send" report provides detailed information regarding the removal of narcotics from the vault, specifying the user, time, date, medication, quantity, and intended destination. An "ADM" report provides detailed information regarding the transaction of narcotics at the patient care unit ADM, indicating the user, time, date, medication, quantity, and inventory movement at the machine. A "purchase history" report helps to trend the receipt of controlled substances into inventory and monitor drug-use patterns. And finally, a "proactive controlled substances diversion" report isolates above-average consumption of controlled substances, as determined by standard deviation.

Purchasing and Inventory-Management Systems

Targeted purchasing and inventory-management systems provide additional opportunities to increase control over controlled substances. Set your controlled-substances vault computer to generate a report based on the last three months of inventory movement in 10-day increments. Par levels for controlled substances should be set for a 10-day re-supply value,

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Narcotic-Diversion Warning Signs and Schemes:

Some patterns and behaviors to look out for

- The employee in question exhibits changes in work habits, attitude, physical appearance, and behavior.
- Pharmacy notices changes in patterns of narcotic-use quantities.
- Patients complain of poor pain management and the patient care record demonstrates erratic pain relief.
- Narcotics are pulled for excessive amounts of patients or larger doses than those ordered.
- Excessive amounts of leaking IV bags are returned to the pharmacy.
- An excessive pattern of broken vials and ampoules, explained as "accidents," develops. (Look for puncture marks on rubber stoppers of broken vials or for clean breaks without fragments.)
- Narcotic waste is thrown into the general trash where it is later picked up by the diverter.
- Returned capsules are missing powder or broken tablets are returned without all of their pieces.
- Diluent is substituted for active injectable narcotic in IV bags.
- Look-alike drugs are substituted for narcotics in pharmacy storage.
- Diverters may use heated needles to penetrate the bottom of ampoules and IV bags or curved needles to penetrate metal lids and rubber stoppers on vials.
- Fictitious user names are created and deleted to gain access to ADMs and narcotic vaults.
- Employees make drug transactions during off-shifts or unscheduled times.

Remember that some diverters show no signs at all.

Drugs of Concern

Cocaine (ADD)	Hydromorphone
Dextromethorphan (ADD)	Ketamine
Fentanyl	Oxycodone
Hydrocodone	Tramadol

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or the amount of inventory needed to cover consumption over a period of 10 days. Faster-moving items can be purchased in 20-day supplies. Purchasers should obtain co-signatures on drug orders to increase accountability, and consider using Web-based ordering to allow for easy documentation of purchase times, dates, and quantities.

Packaging Types: Controlled substances should be packaged in tamper-proof or tamper-evident unit-dose packaging whenever possible, and choose vials over ampoules, as they are stronger and less prone to breakage. For bulk products, use tamper-proof tape to label and initial the amount of doses remaining in each bottle.

Acquisition and Documentation: Enlist two people to receive narcotics: one to receive the shipment from the wholesaler and the other to receive it at the narcotic vault. Both of these individuals can be charged with matching the purchase invoice with the delivery invoice, and one should confirm the inventory count upon delivery, while the other should perform a blind count in the narcotic vault. In addition, required co-signatures for received inventory will provide accountability and accuracy of the vault refill.

Distribution and Documentation: A different pharmacist should distribute narcotics than the one who receives the wholesaler inventory. A designated pharmacist should pull, blind count, and document a narcotic batch pull, and then bag it by nursing unit. Next, a designated technician should deliver the narcotics to the ADM, and then sign a delivery receipt and staple an ADM receipt to it, confirming that the amount pulled by the designated pharmacist matches the amount filled at the ADM. Delivery signature receipts and ADM receipts should be reviewed and then filed for one week.

Confirming the Integrity of Your Narcotic Inventory: There are certain key elements to the secure movement of narcotic inventory. First, designate a pharmacist other than the receiver or distributor of the inventory to generate a "narcotic vault compare" report to verify send-and-receive transactions. This pharmacist can generate various reports to resolve any inquiries or questionable transactions. Second, conduct a daily, staggered, blind-count inventory of your narcotic vault, so that the entire inventory has been reviewed over the course of a month. Enlist your corporate security officer to generate a proactive diversion report as a standard deviation check for ADM users that exhibit atypical activity. Monitor unresolved narcotic discrepancies on a daily basis, and quickly identify and provide assistance to resolve discrepancies in the narcotic vault and on the patient-care units. A designated pharmacist should review the discrepancy-resolution report to confirm that the reasons for the discrepancies are accurate and legitimate. Lastly, be sure to set par levels and monitor your narcotic inventory turns.

Patient Care Unit Storage and Documentation: Employees that access patient care area storage should perform a blind count of the storage unit's inventory after they access it, and a daily inventory blind count should be performed in the presence of a witness. Perform a discrepancy check on a twice-daily basis. Discrepancies must be resolved before the end of the shift. A joint policy between pharmacy and nursing can delineate the handling, administration, and wasting of narcotics and controlled substances.

Handling and Documenting Expired and Wasted Narcotics: Make use of a locked drop box to secure expired and/or wasted narcotics in the pharmacy, and require that narcotic waste be documented and co-signed. Using a "medication pending destruction" report, match waste entries with inventory collected, and then assign at least two pharmacists to verify, document (DEA 41), and destroy the narcotics upon authorization from the Bureau of Drug Enforcement/Control.

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Employee Discipline: If an employee is suspected of diversion, present him or her with facts and solid documentation of the suspected problem. Give the employee an opportunity to admit to his or her problem, and encourage admitted diverters to join an employee-assistance program. Employees who do not admit to diversion, risk harming themselves and their patients, and should be referred to the appropriate regulatory agencies.

Conclusion

A systemic approach to the handling of controlled substances in your facility can lead to a decrease in diversion and increased safety and comfort for your patients. Enlist the efforts of members of different departments across the health system to maximize the benefits of your diversion-prevention program. P&P

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Anti-Diversion Roles at Saint Barnabas Medical Center

Assistant Director of Pharmacy: DEA 222, ordering, receiving, discrepancy-resolution support

Information Systems Pharmacist: narcotic vault compare report, hardware and software support of ADM equipment

Purchasing Coordinator: receives narcotics from wholesaler

Night Shift Pharmacist: nursing unit narcotic batch fill

Transport Technician: delivers nursing unit narcotic batch fill

Pharmacy Supervisor: co-signs narcotic receipt into vault

Director of Pharmacy: oversees narcotics operations, reviews discrepancy resolution reports, and performs a weekly audit comparing ADM withdrawals with anesthesia patient-care records

Corporate Security Officer: reviews and investigates unresolved discrepancies, proactive diversion reports, and employee narcotic diversion issues

Designated nurses: daily inventory and discrepancy checks at the ADM

Patient Care Unit Managers: review unit specific discrepancy report and discrepancy resolution clarification requests