3.5.25 Inspecting Medication Storage Areas

(a) Procedure Overview

The Pharmacist-in-Charge (PIC), or designee, shall regularly inspect all medication storage areas for compliance with licensing requirements, federal and state laws, statewide policies and procedures, and local operating procedures (LOPs). United States Drug Enforcement Administration (DEA) and the California State Board of Pharmacy-identified controlled substances shall be accurately maintained, documented, inventoried, and reconciled. All medications shall have current dates, be in useable condition, and be properly labeled. Storage areas shall be clean, uncluttered, well-lit, secured, and contain only properly authorized medications.

(b) Purpose

To ensure that unusable medications are not available for patient use and that medications are stored safely and under the proper conditions pursuant to national and state medication storage standards (e.g., United States Pharmacopeia, Centers for Disease Control and Prevention, California Code of Regulations Title 22, California Business and Professions Code Division 2, Chapter 9, Article 13.5).

(c) Procedure

(1) Medication Quality Assurance Rounds

(A) The PIC, or designated pharmacist, shall make Medication Quality Assurance Rounds to inspect all medication storage areas inside and outside of the pharmacy at least monthly, or as often as needed as determined by the local Pharmacy and Therapeutics Committee and the PIC to comply with California Correctional Health Care Services policy and applicable federal and state requirements.

(B) The pharmacist completing the medication storage area inspection shall complete the CDCR 7477, Medication Storage Area Inspection Checklist, print their name, and sign and date the form.

(C) The Registered Nurse (RN), Licensed Vocational Nurse (LVN), or Psychiatric Technician (PT) present at the completion of the medication storage area inspection for health care treatment areas and licensed units shall acknowledge receipt of the CDCR 7477 by printing their name, and signing and dating the form. The pharmacist shall provide a copy of the CDCR 7477 to the RN, LVN, or PT who signed the form. The copy shall be processed pursuant to the LOP.

(D) For dental clinics, the dentist present at the specific clinic shall acknowledge receipt of the CDCR 7477 by printing their name, and signing and dating the form. The pharmacist shall provide a copy of the CDCR 7477 to the dentist who signed the form. The copy shall be processed pursuant to the LOP.

(E) For a Correctional Pharmacy, the CDCR 7477 shall be signed by the pharmacist completing the inspection and signed by the PIC.

(F) The PIC shall review all completed CDCR 7477s for all medication storage areas, print their name, and sign and date the form. A copy of all completed CDCR 7477s shall be provided to the Chief Executive Officer (CEO) or designee.

(2) Inspection Requirements

(A) A DEA controlled substances audit shall be included in the monthly rounds. This audit shall include the following:

1. A DEA Schedule III-V medication audit which shall include:
   a. A physical inventory performed and compared against the balance shown in the Inventory Control Method.
   b. Verify that:
      1) Each dose of the controlled substance is properly documented.
      2) Damaged or refused medications already issued for patients are disposed of properly in accordance with the Health Care Department Operations Manual (HCDOM), Section 1.2.12, Disposal of Regulated Waste Generated by Health Care Staff, and Section 3.5.16, DEA Schedule II-V Controlled Substances.
2. A DEA Schedule II medication audit which shall include:
   a. Using the reconciled on-hand inventory from the prior month's count, which shall become the starting inventory for the present audit.
   b. Verifications of additions to stock-on-hand which shall include, but is not limited to:

1) Pharmacy stock received from vendors (Note: DEA controlled substances schedule II can only be moved from one registered location to another registered location via a DEA 222 Form).
2) DEA-registered licensed unit stock received from pharmacy (Note: DEA controlled substances schedule II can only be moved from one registered location to another registered location via a DEA 222 Form).
3) Licensed-unit stock received from DEA-registered licensed units within the same institution (Note: DEA controlled substances schedule II can only be moved from one registered location to another registered location via a DEA 222 Form).
4) Pharmacy stock received from DEA-registered licensed units (Note: DEA controlled substances schedule II can only be moved from one registered location to another registered location via a DEA 222 Form).
5) Stock transfers between the Correctional Pharmacy and any Automated Dispensing Cabinet (ADC) which it registers and operates (Note: in this case, all movement is considered to occur within the same DEA-registered pharmacy, therefore a DEA 222 Form is not required for drug movement).

c. Verification of deductions to stock-on-hand which shall include, but is not limited to:
1) Pharmacy stock transferred to an ADC (Note: in this case, all movement is considered to occur within the same DEA-registered pharmacy, therefore a DEA 222 Form is not required for drug movement).
2) Pharmacy stock sent to a reverse distributor (Note: DEA controlled substances schedule II can only be moved from one registered location to another registered location via a DEA 222 Form).
3) Pharmacy stock transferred to a DEA-registered licensed unit (Note: DEA controlled substances schedule II can only be moved from one registered location to another registered location via a DEA 222 Form).
4) Pharmacy dispenses to a patient pursuant to a valid prescription or computerized physician order entry (CPOE) (Note: CPOE only valid with two-factor authentication).
5) Pharmacy stock transferred to another licensed pharmacy (Note: DEA controlled substances schedule II can only be moved from one registered location to another registered location via a DEA 222 Form).
6) ADC inventory dispensed for patient administration.
7) DEA-registered licensed unit stock being transferred to a different DEA-registered licensed unit within the same institution (Note: DEA controlled substances schedule II can only be moved from one registered location to another registered location via a DEA 222 Form).
8) DEA-registered licensed unit stock administered to patients.
9) Controlled substances dispensed for patient administration of which drug is wasted.
10) DEA-registered licensed unit stock being transferred to pharmacy.

d. Using the starting inventory plus additions to stock, minus deductions from stock which shall be the expected inventory on-hand.
e. A physical inventory of stock on-hand shall be conducted and compared with the expected inventory on-hand for each medication.

3. All discrepancies shall be identified and resolved. Any discrepancy which cannot be resolved shall be handled pursuant to the HCDOM, Section 3.5.16, DEA Schedule II-V Controlled Substances, and Section 3.5.21, Break-In, Theft/Loss from Pharmacy or Medication Storage Areas.

(B) All medication storage areas shall be inspected for unusable medications and the storage of unauthorized floor stock items, all of which shall be removed and disposed of pursuant to the HCDOM, Section 1.2.12, Disposal of Regulated Waste Generated by Health Care Staff, and Section 3.5.11, Medication Inventory Management, Labeling, and Storage.

(C) All look-alike/sound-alike medications, high-alert medications, and hazardous medications shall be properly identified and stored.

(D) Heat, light, and moisture requirements shall be appropriate for the medications stored.

1. Health care staff shall record room, refrigerator and freezer (where applicable) temperatures pursuant to the HCDOM, Section 3.5.11, Medication Inventory Management Labeling, and Storage.

2. The Chief Support Executive (CSE) shall be responsible for ensuring the availability and proper maintenance (including, but not limited to, temperature monitoring) of medication storage areas and equipment, in accordance with manufacturer recommendations and policy in all health care service areas. If a temperature problem arises outside of the pharmacy, nursing staff shall notify the pharmacy immediately for oversight to ensure that medications are maintained in good condition or replaced.
3. Evidence of excess moisture in the refrigerator shall be noted and reported to the CSE during normal business hours (or to the Supervising Registered Nurse II if after hours) if this will affect the condition or safety of stored medications.

(E) Medication areas shall be clean and free of vermin.

(F) All shelves, cabinets, drawers, dressing carts, and medication carts shall be opened for inspection to ensure proper labeling and storage of medications. Medications shall be stored only in authorized areas, and only authorized floor stock items or patients' medications that are properly labeled shall be stored in these areas.

(G) In accordance with California Health and Safety Code, Title 22, no medications may be left at bedside within licensed inpatient units with the exception of sublingual or inhalation forms of emergency drugs specifically ordered for "bedside use" by an authorized provider pursuant to the HCDOM, Section 3.5.13, Rescue Medications.

(H) For licensed units with an emergency medication storage unit, the drawer, cabinet, or cart shall be reviewed monthly and the review shall be documented on the CDCR 7477.

(3) Reporting Requirements

(A) Medication inspection reports shall be completed with inspection dates and observations. Additional notes concerning any problems or suggestions shall be listed. The report shall be sent to the CEO or designee and other supervisory staff or committees as appropriate and kept on file by the pharmacy for three years.

(B) Corrective action plans shall be developed by the CEO, or designee, with the assistance of the supervisor responsible for the medication area where a deficiency was found. Corrective action plans shall include how the problem will be resolved, implementation date, monitoring mechanism, and target resolution date. Progress shall be monitored by the ongoing monthly inspections.

References

- Centers for Disease Control and Prevention: http://www.cdc.gov/
- United States Pharmacopeia Section: Preservation, Packaging, Storage and Labeling
- California Business and Professions Code, Division 2, Chapter 9, Article 13.5 Correctional Clinics
- California Code of Regulations (CCR), Title 22, Division 5
- Health Care Department Operations Manual, Chapter 1, Article 2, Section 1.2.12, Disposal of Regulated Waste Generated by Health Care Staff
- Health Care Department Operations Manual, Chapter 3, Article 5, Section 3.5.6, Emergency Drug Supplies
- Health Care Department Operations Manual, Chapter 3, Article 5, Section 3.5.11, Medication Inventory Management, Labeling, and Storagee
- Health Care Department Operations Manual, Chapter 3, Article 5, Section 3.5.13, Rescue Medications
- Health Care Department Operations Manual, Chapter 3, Article 5, Section 3.5.16, DEA Schedule II-V Controlled Substances
- Health Care Department Operations Manual, Chapter 3, Article 5, Section 3.5.21, Break-In, Theft/Loss from Pharmacy or Medication Storage Areas

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