3.5.11 Medication Inventory Management, Labeling, and Storage

(a) Procedure Overview

Medications within California Correctional Health Care Services (CCHCS) and California Department of Corrections and Rehabilitation (CDCR) institutions shall be managed, labeled, packaged, and stored in compliance with applicable federal and state laws and regulations. Unusable medications shall not be stocked.

(b) Purpose

To ensure that medications within an institution are in compliance with applicable federal and state laws and regulations while being available, identifiable, and safe for use with proper labeling, packaging, and storage.

(c) Responsibility

(1) Statewide

CCHCS and CDCR departmental leadership at all levels of the organization, within the scope of their authority, shall ensure administrative, custodial, and clinical systems are in place and appropriate tools, training, technical assistance, and levels of resources are available so that licensed health care staff can successfully comply with this procedure.

(2) Regional

Regional Health Care Executives are responsible for compliance with this procedure at the subset of institutions within an assigned region.

(3) Institutional

(A) The Chief Executive Officer (CEO) shall be responsible for the overall management and storage of medications within all health care service areas.

(B) The Chief Support Executive (CSE) shall be responsible for ensuring medication storage areas and equipment (including, but not limited to, temperature monitoring) are available and maintained properly in accordance with manufacturer recommendations and policy in all health care service areas.

(C) The Pharmacist-in-Charge (PIC) shall be responsible for:

1. The management of medication inventory within the pharmacy.
2. The dispensing or furnishing of medications in compliance with applicable federal and state laws and regulations inclusive of product labeling and patient prescription labeling.
3. Processing of shipments to the state-contracted reverse distributor.
4. Monthly inspections of medication storage areas.

(D) The Chief Nurse Executive (CNE) shall be responsible for the management, accountability, administration, and issuance of medications in licensed correctional clinics (LCCs) or other nursing patient-care areas.

(E) The Supervising Dentist (SD) shall be responsible for the management, accountability, administration, and issuance of medications in dental LCCs.

(F) The CEO, CSE, PIC, CNE, and/or SD, or their designees, are responsible for correcting identified medication management deficiencies within their respective health care service areas.

(d) Procedure

(1) General Labeling Requirements

(A) Prescription labels shall comply with the requirements in applicable federal and state laws, including California Code of Regulations (CCR), Title 16, Section 1707.5 and Business and Professions Code, Sections 4076, 4076.5 and 4076.6.

1. Chemical symbols shall not be used.
2. Latin abbreviations are not acceptable on Keep-on-Person (KOP) labels.

(B) Patient-specific labels shall include the information listed below:

1. Name and address of the pharmacy dispensing the medication.
2. The date the prescription/order was issued.
3. The name of the patient (including the CDCR number).
4. The name of the provider.
5. Clear directions for use of the medication.
6. The name and the strength or dosage of the medication dispensed.
7. Liquid dosage forms shall include concentration as well as dosage.
8. The quantity of the medication dispensed.

9. The medication expiration date, not to exceed the pharmaceutical manufacturer's expiration date in accordance with Section (d)(6), Beyond-Use Dates.
10. Auxiliary labels as needed (e.g., precautionary labels).
11. Prescription number.
12. Pharmaceutical manufacturer.
13. Physical description of the product (e.g., tablet, capsule).
14. Medication prescription/order stop date.
15. The patient's housing and bed location.
16. The condition or purpose for which the medication was prescribed if the condition or purpose is indicated on the prescription/order.

(C) Non-legend (over-the-counter [OTC]) medications shall be labeled in conformance with federal and state laws, such as consumer-ready packaging, and do not require a prescription label from the pharmacy unless ordered as a prescription by a provider and dispensed by the pharmacy.

(D) Only persons licensed to dispense medications may apply or modify a prescription label. Persons licensed to dispense include, but are not limited to:
1. Providers authorized within the scope of their practice.
2. Pharmacists.
3. Registered Nurses working in an LCC pursuant to California Business and Professions Code, Division 2, Chapter 6, Article 2 - Scope of Regulation, Section 2725.1.

(E) It shall be the responsibility of the authorized prescriber to identify patients that require labeling or counseling in a language other than English and to identify the language required.

(2) General Packaging Requirements

(A) Medication Packaging

Medication containers must be provided that are consistent with CDCR Department Operations Manual, Section 54030.1, which specifies types of materials inmates may possess. Medication containers that are acceptable for use when dispensing/furnishing medications include, but are not limited to:
1. Amber pharmacy vials with snap-on lids.
2. Plastic zip lock bags (amber or clear) with medications in unit-dose packaging.
3. Unit-of-use drug cards (blister pack and bubble pack).
4. Unit-dose.
5. Medication vials with child-proof packaging dispensed to patients for family visits, the Community Prisoner Mother Program, or release.

(B) Central Fill Packaging

When feasible and if the medication is available through the Central Fill Pharmacy, filling should be processed through the Central Fill Pharmacy's automated, high-volume dispensing equipment to ensure efficiency and to reduce waste. Solid oral dosage forms provided by Central Fill Pharmacy shall be packaged in either blister cards containing quantities in increments of 30 or in unit-dose packaging.

(C) Patient-specific Medication Quantity

Medication shall be issued in the quantity necessary to complete prescriptions/orders except as noted below:
1. Routinely administered medications limited to a 30-day supply per dispense. Exceptions may be permitted as determined by the Systemwide Medication Management Committee.
2. Unit-of-use medications in multiples of package size may be dispensed utilizing the nearest manufacturer package size subject to the pharmacist's judgment.
3. PRN (as needed) medications limited to a 30-day supply per dispense in multiples of 30 tablets or capsules (for oral dosage forms) shall be provided unless indicated otherwise in the prescription/order.
4. Prescriptions/orders for patients housed in temporary locations, correctional treatment centers (CTC), or other inpatient areas may be dispensed in quantities less than a 30-day supply.
5. During downtime procedures, when prescriptions/orders are recorded on a CDC 7221, automatic stop prescriptions/orders applies to licensed inpatient beds only in accordance with the HCDOM, Section 3.5.9, Additional Requirements Pertaining to Licensed Inpatient Facilities.

(3) Storage Requirements and Inventory Management

(A) General Requirements

1. Medications shall not be left exposed to the environment (i.e., out of containers or in containers with lids left off overnight) or left unsecured.
2. Breaches of security or losses shall be handled pursuant to HCDOM, Section 3.5.21, Break-In, Theft/Loss from Pharmacy or Medication Storage Areas.
3. Containers shall be clean, intact, and closed securely.
4. Medication for internal use in liquid, tablet, capsule, or powder form shall be stored separately from medication for external use.
5. Test agents, germicides, disinfectants, and other household substances shall be stored separately from medication.
6. Each patient's medications shall remain in the original package and with the labeling originally received from the pharmacy until the time of administration.
7. Floor stock medication, or non-patient specific medication excluding OTC medication in consumer-ready packaging used for nursing protocols and medication provided via an automated drug delivery system (ADDS), shall only be maintained in licensed units (e.g., CTCs, skilled nursing facilities, hospices, and correctional clinics).
8. No outdated medications shall be stored with usable medications.
9. Every effort shall be made to keep the quantity and variety of medications maintained in inventory at a level to ensure appropriate availability but also to prevent waste and unsafe storage conditions.
10. The electronic health record system (EHRS) shall be used to order floor stock from a correctional pharmacy. When EHRS is unavailable, all floor stock medications and supplies shall be ordered from the correctional pharmacy on a CDCR 7244, Drug Order.
11. Storing or consuming food and drink, chewing gum or tobacco, and applying cosmetics are prohibited in areas where medications are prepared or administered.
12. Food, drink, and laboratory specimens shall not be stored in the medication refrigerator/freezer.

(B) Unusable Medications

1. Medications that no longer meet federal and state requirements are unusable and shall be removed from stock that is available for use. Staff removing the medication from active inventory shall remove any confidential patient information from the packaging. The medication shall be handled as follows:
   a. Controlled substances waste shall be witnessed and limited to contaminated and partial doses only. Complete doses no longer necessary shall be returned to the pharmacy for appropriate re-dispensing, and expired medications shall be returned to the pharmacy for reverse distribution as defined in the HCDOM, Section 3.5.16, Ordering, Securing, and Disposing of DEA Schedule II, III, IV, and V Controlled Substances.
   b. All medication that has become outdated within the pharmacy shall be quarantined and disposed of as waste or shipped to the state-contracted reverse distributor pursuant to Section (d)(7) below. All medication that has become outdated within a health care location shall be disposed of pursuant to the HCDOM, Section 1.2.12, Disposal of Regulated Waste Generated by Health Care Staff.
   c. All medications that are not Drug Enforcement Administration (DEA) scheduled controlled substances and are unusable shall be placed in the appropriate disposal container pursuant to the HCDOM, Section 1.2.12, Disposal of Regulated Waste Generated by Health Care Staff.
   d. Health care staff receiving medications returned by patients shall remove confidential patient information and immediately place in the appropriate disposal container pursuant to the HCDOM, Section 1.2.12, Disposal of Regulated Waste Generated by Health Care Staff.
2. Medications dispensed in error including, but not limited to, the following reasons, shall be returned to the pharmacy:
   a. The medication container has been filled with the wrong medication, dose, and/or quantity.
   b. The container has been mislabeled (e.g., wrong administration method).
   c. The medication is a duplicate order/issue.

3. Medications that are overstocked or considered of a quantity not needed for use in the health care setting shall be handled as follows:
   a. DEA scheduled controlled substances shall be returned to the pharmacy for inspection, destruction, or redistribution as appropriate.
   b. All other prescription or OTC medication may be returned to the pharmacy for redistribution or moved from one LCC to another LCC within the same institution pursuant to Business and Professions Code, Section 4187.
   c. Health care staff shall make every effort to minimize the loss of medications due to outdating by attempting to locate other health care settings that may utilize this medication prior to becoming outdated.
   d. Every medication storage area shall have a return bin for returning medications to the pharmacy. Where a storage area has a medication refrigerator or freezer, there shall be a separate return bin for the refrigerator, the freezer, and room temperature medications. Each return bin shall be clearly labeled "Pharmacy returns only; medication waste prohibited."

(C) Temperature Requirements
1. Medications that do not require refrigerated or frozen storage shall be stored at controlled room temperature.
   a. Controlled room temperature is between 20°C and 25°C (68°-77°F); excursions permitted between 15° and 30° C (59°–86°F) (refer to United States Pharmacopeia [USP] Controlled Room Temperature).
2. Medications that require refrigerated or frozen storage shall be stored as follows:
   a. Refrigeration temperature shall be maintained between 2°C and 8°C (36°-46°F).
   b. Freezer temperature shall be maintained between -50°C and -15°C (-58°-5°F).
3. The medication manufacturer recommendation for storage temperature shall be adhered to when different from above.

(D) Temperature Monitoring
1. Room Temperature
   a. All medication storage locations shall have a thermometer to monitor room temperature.
   b. Logging procedures shall be performed daily in any area where medications are stored (with or without an ADDS. Additionally, any interruption in the functioning of an air-conditioned area or any area identified as possibly exceeding acceptable medication storage conditions shall require immediate corrective action (see Temperature Excursions, Section (d)(2)(E) below).
   c. The room temperature shall be recorded at the beginning of the shift on the CDCR 7217, Medication Storage Temperature Log for each medication storage area staffed for third watch. The room temperature shall be recorded at the end of the second watch shift for medication storage areas closed for third watch but open for second watch. The temperature log shall indicate the area as being "closed" for medication storage areas not staffed for either shift.
   d. The room temperature shall be recorded on the CDCR 7217 at the time of the pharmacy closing (or in the early evening) to reflect the hottest temperature of the day for each pharmacy. If closed for the day, the temperature log shall indicate the area as being "closed."
   e. Each completed temperature log shall remain in a designated location for pharmacy staff to review monthly. Once reviewed, pharmacy staff shall file the temperature logs in the designated location. Each institution shall determine a location for storing completed room temperature logs which shall be maintained for three years.
2. Refrigerator and Freezer
   a. Temperatures shall be monitored with accurate thermometers twice daily during hours of operation. In areas that are not open every day, the use of a digital data logger or the use of minimum/maximum thermometers shall be utilized. The thermometer shall be checked as soon as the area re-opens. The temperature excursion process shall be followed if any out of range temperatures are shown to have occurred.
   b. All refrigerated or freezer medication storage shall utilize a digital data logger or the CDCR 7217. Each institution shall establish the following:
      1) A process for storing completed logs which shall be maintained for three years.
      2) A process to maintain and monitor equipment performance.

c. A digital data logger shall be used for any refrigerator or freezer storing vaccines. Digital data loggers are the preferred temperature recording method for all refrigerated and freezer medication storage.
d. When a digital data logger is used, CDCR 7217 is not required if the recorded temperature data is auditable electronically.
   1) At a minimum, the data logger must be audited once daily and the minimum/maximum temperature shall be reviewed.
   2) Data loggers with notification capability shall notify the area supervisor in the event of a temperature excursion. The temperature excursion process shall be followed if any out of range temperatures are shown to have occurred.
   3) At least once monthly during the medication room inspection, the monthly temperature log shall be reviewed for appropriate medication storage and temperature excursions.

(E) Temperature Excursions
1. Room Temperature Excursions
   a. Record the out-of-range temperature on the CDCR 7217.
   b. Notify the supervisor and the PIC or designee.
   c. Document initial actions taken to correct temperature variance on the Temperature Excursion Action Record. For example:
      1) Alert the supervisor and pharmacy of the out-of-range temperature.
      2) Adjust the thermostat.
      3) Notify Plant Operations that the medication storage area requires immediate attention.
   d. If the temperature excursion is expected to exceed 24 hours, portable air conditioning units shall be made available.
   e. In the event that portable air conditioning units are not available, a plan shall be immediately implemented to move medications to a secured air conditioned area during non-medication pass times.
   f. Room temperature logging shall continue at least twice a day until the temperature excursion is resolved.
2. Refrigerator/Freezer Temperature Excursions
   a. Record the out-of-range temperature on the CDCR 7217 or on the data logger software.
   b. Alert the supervisor and pharmacy of the out-of-range temperature.
   c. Take immediate actions to correct medication storage. These may include:
      1) Temperature adjustment of the refrigeration unit.
      2) Moving all medications to a functional refrigerator/freezer.
      3) If vaccines are present, immediately implement emergency vaccine storage and handling process.
3. Emergency Vaccine Storage and Handling
   a. Quarantine any vaccines in a separate container in the refrigerator or freezer with a "do not use vaccines" notice until pharmacy staff can retrieve and/or manufacturer guidance can be obtained, if:
      1) The refrigerator temperature is warmer than 8°C (46°F).
      2) The freezer temperature is warmer than -15°C (5°F).

(4) Pharmacy Security

(A) Possession of a key or electronic access to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist. Access to one additional pharmacy key for emergency purposes shall be maintained in a tamper evident manner pursuant to CCR, Title 16, Section 1714(e).

(B) Each pharmacist, while on duty, shall be responsible for the security of the pharmacy including provisions for effective control against theft or diversion of medications.

(C) A pharmacist shall be responsible for any individual who enters the pharmacy for the purposes of performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the pharmacy. The pharmacist shall remain present in the pharmacy during all times the authorized individual is present. Temporary absences of the pharmacist are only permitted in accordance with the HCDOM, Section 3.5.33, Temporary Absence of the Pharmacist.

(D) Institution locksmiths shall not access pharmacy locations without the presence and direct supervision of a pharmacist.

(5) Non-Pharmacy Medication Area Security

The CEO and CNE, or designee, shall ensure that medications stored in the nursing units, LCCs, or other nursing patient care areas are properly secured. The CEO and SD, or designee, shall ensure that medications stored in the dental clinics are properly secured.

(A) Doors to medication areas shall remain locked unless in use by authorized personnel.

(B) Medications shall be stored in locked rooms, cabinets, drawers, or carts of sufficient size in an orderly manner to prevent crowding. Locked mobile medication storage (e.g., carts) shall be secured in a locked room when unattended.

(C) Keys to the medication rooms, cabinets, drawers, or carts shall be restricted to licensed nursing, dental, and pharmacy staff who shall be personally accountable for them.

(D) Keys shall not be left in drawers, hung on walls, given to patients, or given to non-medical personnel.

(E) Institution locksmiths shall not access medication storage areas without the presence and direct supervision of health care staff.

(F) Each institution shall establish a process for the transfer of keys (medication cabinets, drawers, carts, or medication rooms) among licensed nursing, dental, and pharmacy staff that precludes involvement of non-health care personnel.

(G) Controlled substances shall be securely stored in an ADDS and must be under double lock in the medication areas at all times until withdrawn for administration. The CNE shall be responsible for ensuring limited access, key control, and medication accountability for all controlled substances.

(H) Any unlicensed individuals in the medication area (e.g., housekeeping staff, patients being treated) shall be under the direct observation of licensed nursing, dental, or pharmacy staff.

(I) Pharmacists shall conduct monthly inspections of medication storage areas in collaboration with licensed nursing or dental staff. A report of identified deficiencies shall be provided to the CEO and the CNE, SD, or Health Program Manager III as applicable.

(6) Beyond-Use Dates

(A) Medications supplied in the manufacturer's original packaging and stored appropriately shall be usable until the expiration date (considered to be midnight of the last day of the month indicated, unless otherwise stated) on the package unless otherwise stated in the CCHCS Guideline for Calculating Beyond-Use Date.

(B) Repackaged and dispensed medications shall comply with the Food and Drug Administration requirements and USP guidelines for determining beyond-use dates.

1. For non-sterile solid and liquid dosage forms that have been repackaged into single-unit and unit-dose containers, the beyond-use date shall be one year or less unless stability data or the manufacturer's labeling indicates otherwise.
2. For all other types of non-sterile dosage forms, the beyond-use date is one year or the time remaining of the expiration date, whichever date arrives first unless otherwise stated in the CCHCS Guideline for Calculating Beyond-Use Date.

(C) Any medication whose beyond-use date varies from the manufacturer's expiration date shall be handled as follows:

1. Pharmacy shall communicate the beyond-use date to the appropriate staff.
2. The health care staff member that initially opens the container shall calculate the beyond-use date. This date and the staff's initials shall be written on the medication label or container. No medication shall be used once it has reached the beyond-use date.
3. The health care staff that opens or needle-punctures a multi-dose vial shall identify the date 28 days from the present (or sooner if the manufacturer specifies differently) and write this beyond-use date and their initials on the label or vial.
4. All single dose injectables shall be discarded after their first opening, including sterile water for injection, regardless of remaining solution.

(7) Use of Master Contracts by Pharmacy for the Return of Medications

(A) The PIC, or designee, shall supervise the disposition of outdated, discontinued, or overstocked medications within the pharmacy.

(B) The pharmacy shall store outdated medications separate from active medication stock until disposition. The outdated medication storage area shall be clearly labeled.

(C) The pharmacy shall utilize vendors contracted through master contracts for the destruction/credit of controlled and non-controlled substances and for the return/credit or destruction of medications that are unusable.

(D) The pharmacy shall retain records of return, credit, and certificates of destruction documents for a period of three years.

(8) Medication Recalls

(A) All recalled medications in licensed units (including, but not limited to, CTC, LCC, and ADDS) shall be returned to the pharmacy for disposition as soon as possible.

(B) The pharmacy shall ensure that the recalled medication is unavailable for use and is either sent back to the manufacturer or destroyed per the recommendation of the manufacturer.

(C) When a medication is recalled by the manufacturer, the PIC shall determine whether the recall has been extended to the pharmacy level or to the patient level.

1. Pharmacy Level:
   a. If the recall is limited to the pharmacy level, the PIC, or designee, shall inspect all pharmacy and all patient care areas, including ADDS. Medications affected by the recall shall be returned to the pharmacy for disposition.
   b. The pharmacy shall maintain a record of pharmacy-level recalls. This record shall be kept for a period of three years from the date of the recall.
2. Patient Level:
   a. If the recall extends to the patient level, the PIC shall identify all patients who may be in possession of the recalled medication(s).
   b. The PIC shall notify the CME, the CNE, prescriber, and nursing staff in patient care areas where medication may have been administered or distributed to patients.
   c. Most medications stored in an ADDS were dispensed dose-by-dose and would have already been fully consumed. For affected unit-of-use medications, the PIC shall notify the Chief CME, the CNE, prescriber, and nursing staff in patient care areas where medication may have been administered or distributed to patients.
   d. The pharmacy shall coordinate with Nursing for retrieval and replacement of all medications affected by the recall.
   e. The pharmacy shall maintain a record of patient-level recalls including a list of potentially affected patients and disposition. This record shall be kept for a period of three years from the date of the recall.

References

- California Business and Professions Code, Division 2, Chapter 6, Article 2, Section 2725.1
- California Business and Professions Code, Division 2, Chapter 9, Article 3, Section 4064.5
- California Business and Professions Code, Division 2, Chapter 9, Article 4, Sections 4076, 4076.5, and 4076.6
- California Business and Professions Code, Division 2, Chapter 9, Article 7, Section 4119.5, Transfer or Repackaging Dangerous Drugs by Pharmacy
- California Business and Professions Code, Division 2, Chapter 9, Article 13.5, Sections 4187-4187.6
- California Code of Regulations, Title 16, Division 17, Article 2, Section 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements
- California Code of Regulations, Title 16, Division 17, Article 2, Section 1714(e)
- California Code of Regulations, Title 22, Division 5, Chapter 1, Article 3, Section 70263. Pharmaceutical Service General Requirements
- 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 3.5.9, Additional Requirements Pertaining to Licensed Inpatient Facilities
- 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

- Health Care Department Operations Manual, Chapter 3, Article 5, Section 3.5.33, Temporary Absence of the Pharmacist
- Food and Drug Administration Drug Quality Assurance – Drug Repackagers and Drug Relabelers https://www.fda.gov/media/75182/download
- United States Pharmacopeia, USP 32, General Notices and Requirements
- United States Pharmacopeia, USP 797, Pharmaceutical Compounding – Sterile Preparations

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