3.5.39 Furnishing or Dispensing Medication to Legally Authorized Persons or Entities: Licensed Correctional Clinics

(a) Procedure Overview

This procedure describes the process for furnishing or dispensing medications by the institution's correctional pharmacy or California Department of Corrections and Rehabilitation (CDCR) Central Fill Pharmacy (CFP) to persons or entities as authorized by law.

(b) Purpose

To ensure the furnishing or dispensing of medication is in compliance with federal and state requirements and community standards of practice and to establish a procedure for the furnishing of medications to licensed correctional clinics (LCC).

(c) Responsibility

(1) Statewide

CDCR and California Correctional Health Care Services (CCHCS) departmental leadership at all levels of the organization, within the scope of their authority, shall ensure administrative and clinical systems are in place and appropriate tools, training, technical assistance and resources are available to ensure the:

(A) Furnishing or dispensing of medication from the correctional pharmacy and the CFP are in compliance with federal and state requirements and community standards of practice.

(B) Availability of medication or devices to authorized personnel and health care treatment areas when necessary for the treatment of CDCR patients in compliance with federal and state requirements.

(2) The Systemwide Pharmacy and Therapeutics (P&T) Committee

The Systemwide P&T Committee is responsible for:

(A) Developing and maintaining policies and procedures pertaining to the provision of medication management.

(B) Identifying medications permitted at an LCC for the purpose of performing a diagnostic or treatment procedure whose access shall be restricted to providers only.

(3) Institutional

(A) The Chief Executive Officer (CEO) shall be responsible for ensuring the:

1. Furnishing or dispensing of medication is in compliance with federal and state requirements and community standards of practice within all institutional health care areas.
2. Identification and licensing of all health care treatment areas as LCCs where the provision of medication or devices are necessary for the treatment of CDCR patients, and medications or devices are not being furnished to a licensed unit pursuant to licensure by California Department of Public Health (CDPH) under California Code of Regulations (CCR), Title 22.

(B) The CEO, Chief Medical Executive (CME), Chief Physician and Surgeon (CP&S), Supervising Dentist (SD), and Chief Nurse Executive (CNE), shall be responsible for limiting the use of furnished dangerous drugs or dangerous devices to those locations in compliance with federal and state requirements within applicable health care areas.

(d) Procedure

(1) Furnishing or Dispensing by the Correctional Pharmacy or CFP

(A) All correctional pharmacies and the CFP shall comply with the following requirements:

1. California Business and Professions Code (BPC), Division 2, Chapter 9, Articles 1-24.
2. California Code of Regulations (CCR), Title 16, Division 17, Articles 1-11.
3. California Health and Safety Code (HSC), Division 10, Chapters 1-5.
4. All requirements of the Federal Food and Drug Administration and the Drug Enforcement Administration (DEA) as deemed applicable.

(B) All correctional pharmacies shall furnish or dispense medications as follows:

1. A pharmacist shall review any medications furnished to a licensed location prior to it leaving the pharmacy.
2. Nonprescription medications shall be furnished as packaged by the manufacturer or distributer with appropriate labeling in accordance with applicable federal and state medication labeling requirements. Repackaged nonprescription medications shall be labeled with a prescription label for the patient and shall be handled as prescription medication.

3. Prescription medications shall be dispensed to a patient pursuant to a prescriber's order or prescription and shall be labeled pursuant to BPC, Division 2, Chapter 9, Article 2, Section 4076. Exceptions to this requirement include the furnishing of medication to:
   a. A physician, dentist, podiatrist, or optometrist for use in diagnosing or treating patients.
   b. A Correctional Treatment Center, Skilled Nursing Facility, or other facility currently licensed under Division 2 of the HSC.
   c. an LCC currently licensed under BPC, Division 2, Chapter 9, Article 13.5, Sections 4187-4187.6.

(2) Licensed Correctional Clinics

(A) The CEO in coordination with the CME, CNE, SD, Senior or Chief Psychiatrist, and Pharmacist-in-Charge (PIC) shall determine the locations within the institution, codified in a local operating procedure (LOP), that require the availability of medications or devices for the treatment of CDCR patients.

(B) Licensing of Correctional Clinics
1. Where the identified locations are not presently operated pursuant to a license issued by the CDPH under HSC, Title 22, correctional clinic licenses shall be obtained from the California State Board of Pharmacy pursuant to BPC, Division 2, Chapter 9, Article 13.5 Sections 4187-4187.5.
2. The CEO shall be the administrator on all correctional clinic licenses for that institution. The PIC with responsibility for that institution shall be the consultant pharmacist for each of the correctional clinic licenses for that institution.
3. When the CEO or PIC positions are vacant, the institution has 30 calendar days to determine a replacement and submit license changes to the California State Board of Pharmacy.
4. Licenses issued to a correctional clinic by the California State Board of Pharmacy shall be displayed at the clinic location and are to be renewed annually.
5. If the license renewal form has not been received 30 calendar days prior to the expiration, the CEO shall:
   a. Use the form found on the California State Board of Pharmacy website or obtain the form from CDCR/CCHCS Pharmacy Division at: CCHCSHQPharmacyAdminServices@cdcr.ca.gov.
   b. Submit the license renewal form to the California State Board of Pharmacy for timely renewal.

(C) Pharmacy policies and procedures and LOPs pertaining to an LCC.
1. Pharmacy policies and procedures shall be developed and approved by the Systemwide P&T Committee as defined in the Health Care Department Operations Manual (HCDOM), Section 1.2.11, Systemwide Pharmacy and Therapeutics Committee.
2. All institution LCCs shall adopt the Systemwide P&T Committee policies and procedures. Pharmacy procedures required while awaiting Systemwide P&T Committee passage of statewide policy and procedures may be implemented via LOP with acknowledgement and approval by the Statewide Chief of Pharmacy Services or designee. An LOP shall neither contradict nor be inconsistent with statewide policies and procedures.
3. Approvals of pharmacy policies and procedures and LOPs shall be memorialized by designated institution staff on the CDCR 7300, Licensed Correctional Clinic Policy and Procedure Acknowledgement. Approval of LOPs shall be memorialized by the Statewide Chief of Pharmacy Services or designee on the CDCR 7300 as indicated above.
4. All policies and procedures shall be available in paper copy or electronic form at each LCC location.

(D) Once licensed, an LCC may obtain medications from a correctional pharmacy, the CFP, or from another LCC within the same institution for administration or dispensing to patients eligible for care at the correctional facility.

(E) All medication storage within an LCC shall comply with the HCDOM, Section 3.5.11, Medication Inventory Management, Labeling, and Storage.

(F) LCC Stock
1. Medications provided to an LCC for administration shall include:
   a. Patient-specific medications.
   b. CFP-repackaged medications in stock cards or unit doses.

c. Correctional pharmacy-repackaged medications pursuant to the HCDOM, Section 3.5.23, Repackaging and Compounding of Non-Sterile Medications.
d. Unit-of-use, unit dose, or bulk packaging supplied by the manufacturer.
e. Sterile intravenous compounds prepared pursuant to BPC, Division 2, Chapter 9, Article 7.5, Compounded Sterile Drug Products.
f. Non-sterile compounds prepared pursuant to BPC, Division 2, Chapter 9, Article 7.7, Outsourcing Facilities.

2. All medications shall be labeled pursuant to applicable federal and state laws and applicable US Pharmacopeia chapters pertaining to the type of medication provided.
3. Any medications provided to an LCC shall be labeled with a barcode to permit validating against the Electronic Health Record System (EHRS) order for accuracy prior to administration.

(G) Medications shall be dispensed or administered from an LCC pursuant to:
1. An order or valid prescription, or
2. A statewide-approved protocol.

(H) Stock Medications Restricted to a Provider
1. Stock levels shall be determined by the CEO, CME, CNE, Senior or Chief Psychiatrist, SD, and PIC based upon standards of practice and patient need.
2. A limited number of medications stocked at an LCC may be restricted for use by a provider to perform a diagnostic or treatment procedure conducted within the clinic.
3. Medications for this purpose shall be restricted to those identified by the Systemwide P&T Committee. Use of these medications within the LCC shall be recorded in the treatment records of the EHRS. Medications include, but are not limited to:
   a. Local and topical anesthetics.
   b. Ophthalmic mydriatic drops.
   c. Fluorescein drops.
   d. Hydrogen Peroxide or Betadine for surgical preparation or wound care.
   e. Topical antibiotic ointment for wound dressing application.

(I) Dispensing of Medications to a Patient
1. The dispensing of medications shall only be performed by a physician and surgeon, a dentist, a pharmacist, or other person lawfully authorized to dispense medications in a clinic setting. Notwithstanding any other provision of law, a registered nurse (RN) working at an LCC may dispense drugs or devices upon an order by a licensed physician and surgeon or an order by a certified nurse-midwife or an advanced practice provider if the RN is functioning within a licensed primary care clinic (e.g., LCC) pursuant to BPC, Division 2, Chapter 6, Article 2, Section 2725.1.
2. When medications are given to patients for Keep-on-Person (KOP) use, they shall be labeled in accordance with the requirements of the HCDOM, Section 3.5.5, Prescription/Order Requirements and Medication Availability, and BPC, Division 2, Chapter 9, Article 4, Sections 4076-4076.6. Protocol medications for KOP use must be given to the patient in the manufacturer-supplied, over-the-counter package to include all boxes and materials that include FDA-approved labeling.

(J) LCC Records
1. The CEO in coordination with the CNE and SD, as applicable, shall ensure that records of acquisition, transfer, administration, and dispensing are kept at each LCC location for all medications.
2. All records pertaining to the acquisition, transfer, administration, and dispensing of medications shall be maintained for a minimum of three years and shall be available for inspection by authorized personnel and the institution PIC or designee. Records of acquisition, transfer, administration, and dispensing for an LCC shall be as follows:
   a. Records of acquisition and transfer shall be by electronic requisition and distribution.

1) The LCC requesting the medication shall determine the appropriate location from which the required medication will be obtained. The primary location for obtaining medication shall be the correctional pharmacy.
2) In the event that the medications are needed before the correctional pharmacy can provide them to the LCC, the LCC may requisition medications from another LCC within the same institution.
   a) The LCC requesting the medication shall complete a requisition directed to the correctional pharmacy or to the LCC within the same institution providing the medication.
   b) The correctional pharmacy or the LCC within the same institution providing the medication shall confirm the amount of medication being provided and complete the distribution.
   c) No medications shall be moved until this requisition and distribution process is completed.
   d) The LCC receiving the medication shall complete the in-transit review which will close the requisition.
3) When the electronic requisition process is unavailable, approved downtime procedures shall be followed. Copies of paper records generated shall be stored at both providing and requesting LCC or correctional pharmacy.

b. All LCC records of administration and dispensing shall be kept by the EHRS electronic Medication Administration Record (eMAR) for medications provided by the LCC to the patient pursuant to a prescriber's order or statewide-approved protocol. Reports shall be available to track use of medications from the LCC stock based upon the eMAR.
c. When the eMAR is not available for recording administration and dispensing, a paper MAR shall be used. The resulting paper MAR shall be scanned into the EHRS for the identified patient.

3. Use of correctional clinic stock medications by health care providers for diagnostic or treatment procedures conducted within the LCC, as described in section (d)(2)(H) above, shall be recorded using the treatment records of the EHRS. No other tracking records shall be required.

(K) Automated Drug Dispensing System or Automated Dispensing Cabinet within an LCC

1. Medications for an LCC may be stored within an automated drug dispensing system (ADDS), also known as an Automated Dispensing Cabinet. Medications stored within an ADDS are considered inventory of the correctional pharmacy until removed for dispensing or for administering to a patient pursuant to a prescriber's order or statewide-approved protocol.
2. The CEO in coordination with the CME, CP&S, CNE, SD, Senior or Chief Psychiatrist, and PIC shall determine the quantities and contents of the ADDS.
3. Refer to the HCDOM, Section 3.5.7, Automated Drug Delivery Systems, for information regarding proper use of an ADDS.

(L) Controlled Substances

1. LCCs are NOT permitted to have stock controlled substances without possessing a DEA registration.
2. Controlled substances for use by the LCC shall be maintained within the LCC ADDS or shall be dispensed for the patient by the correctional pharmacy as a patient-specific order bearing a label restricting its use to the identified patient. All controlled substances within an ADDS are considered as a part of the correctional pharmacy and fall under its DEA registration.
3. Refer to the HCDOM, Section 3.5.16, Ordering, Securing, and Disposing of DEA Schedule II, III, IV, and V Controlled Substances, for information regarding proper handling of controlled substances.

References

- California Business and Professions Code, Division 2, Chapter 6, Article 2, Section 2725.1
- California Business and Professions Code, Division 2, Chapter 9, Articles 1-24.
- California Health and Safety Code, Division 2, Chapter 1, Article 1 Section 1206(b)
- California Health and Safety Code, Division 10, Chapters 1-5
- California Code of Regulations, Title 16, Division 17, Articles 1-11
- Health Care Department Operations Manual, Chapter 3. Article 5, Section 3.5.5, Prescription/Order Requirements and Medication Availability
- Health Care Department Operations Manual, Chapter 3. Article 5, Section 3.5.7, Automated Drug Delivery System

- Health Care Department Operations Manual, Chapter 3. Article 5, Section 3.5.11, Medication Inventory Management, Labeling, and Storage
- Health Care Department Operations Manual, Chapter 3. Article 5, Section 3.5.16, DEA Schedule II-V Controlled Substances

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