

3.5.7 Automated Drug Delivery Systems

(a) Procedure Overview

Each Correctional Pharmacy shall establish a supply of medications with controlled access limited to designated licensed health care staff for the purpose of timely medication administration in the absence of a patient-specific supply. The Automated Drug Delivery System, also known as Automated Dispensing Cabinet (ADC), shall be an adjunct to medications delivered from the Correctional Pharmacy or California Department of Corrections and Rehabilitation-Central Fill Pharmacy (CDCR-CFP). ADCs shall be used to provide drug security and tracking for controlled substances to meet all federal and state requirements.

(b) Purpose

To provide guidelines for the use of ADCs for timely administration of medication in the absence of a patient-specific supply, while minimizing drug waste and providing secure medication storage and tracking to meet the United States Drug Enforcement Administration (DEA) and the California State Board of Pharmacy (BOP) standards for controlled substances.

(c) Responsibilities

(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:

- (A) Ensure administrative 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 implement this procedure.
- (B) Establish requirements and restrictions for issuance of a chart order pursuant to a protocol.
- (C) Establish circumstances in which chart orders generated pursuant to a protocol shall include auto-verification within the health record.

(2) The Systemwide Pharmacy and Therapeutics Committee

The Systemwide Pharmacy and Therapeutics (P&T) Committee shall:

- (A) Have overall responsibility for issuing restrictions and limitations on medication inventory and staff access rights for an ADC.
- (B) Establish authorized lists of medications available for Registered Nurse (RN) dispensing from an ADC or Licensed Correctional Clinic (LCC) stock as authorized by California Business and Professions Code, Division 2, Chapter 6, Article 2 - Scope of Regulation, Section 2725.1.
- (C) Issue standardized medication administration instructions for pre-printed labels to be used for RN dispensing when medications are to be administered as keep-on-person (KOP).

(3) The Statewide Chief of Pharmacy Services

The Statewide Chief of Pharmacy Services shall have:

- (A) Overall responsibility for ADC server and database oversight including user and drug databases.
- (B) Overall responsibility for maintenance of ADC settings including warnings.
- (C) Oversight of ADC purchases/lease contracts and service agreements.

(4) Institutional

(A) The Chief Executive Officer (CEO) has overall responsibility for ensuring the implementation and enforcement of this procedure including, but not limited to:

- 1. Providing plant requirements to support the placement of an ADC;
- 2. Compliance with state regulatory requirements, in collaboration with the Pharmacist-in-Charge (PIC), for location and registration of an ADC;
- 3. Purchasing of labels and consumables required for using an ADC; and,
- 4. Maintenance of a service contract in collaboration with the Statewide Chief of Pharmacy Services.

(B) The institutional health care leadership team as part of the quality management process has overall responsibility to review:

- 1. Overall quality of ADC processes;
- 2. Compliance with federal and state regulations;
- 3. Compliance with this procedure;
- 4. Assignment of consistent and adequate resources; and,
- 5. Licensed health care staff training.

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- (C) The Chief Nurse Executive (CNE) shall be responsible for:
1. The establishment and maintenance of nursing procedures to provide control and accountability for medications after removal from an ADC;
 2. The designations of Supervising Registered Nurse (SRN) II/III's responsible for emergency key possession, accessing of an ADC, and recordkeeping during ADC downtime procedures; and,
 3. Ensuring adequate training of all licensed health care staff in the proper routine use of an ADC and ADC downtime procedures.
- (D) The PIC shall be responsible for:
1. Establishment, maintenance, accountability, and accuracy of ADC inventory;
 2. Monthly review of storage locations and inventory organization within an ADC;
 3. Working in conjunction with the Statewide Chief of Pharmacy Services or designee to provide information needed for the maintenance of ADC databases;
 4. Registering ADCs with the California State BOP (this will change to a licensing process effective July 1, 2019);
 5. Preparation and review of ADC reports;
 6. Communication with the CEO regarding service and quality issues;
 7. Assisting in the annual training of all staff in regard to proper ADC use and ADC downtime procedures;
 8. Periodic cycle counts resulting in a:
 - a. Monthly inventory of all DEA-controlled substances within an ADC; and,
 - b. Quarterly inventory of all non-DEA-controlled medications within an ADC.
 9. Compliance with controlled substances reconciliation requirements pursuant to California Code of Regulations, Title 16, Division 17, Article 2, Section 1715.65, Inventory Reconciliation Report of Controlled Substances.
- (E) Licensed health care staff shall comply with this procedure including, but not limited to:
1. Proper use of an ADC;
 2. Proper disposition, storage, labeling, and return of medications after removal from an ADC;
 3. Completion of ADC training for designated staff prior to initial use and at least annually thereafter; and
 4. Compliance with statewide information technology security requirements and restrictions pursuant to the Annual Information Security Awareness Training located on the Information Technology webpage at: <http://lifeline/ExecutiveOperations/InformationTechnology/InformationSecurity/Pages/Home.aspx>.
 - a. All passwords shall be protected from use by persons other than to whom they belong.
 - b. All equipment shall be secured when not in use.

(d) Local Operating Procedure Requirements

Each institution shall be required to maintain a local operating procedure (LOP) which permits continuity of care while using an ADC. The LOP shall include, but is not limited to:

- (1) Tracking of items located outside of an ADC.
- (2) Handling of unit-of-use medication for patient-specific KOP administration after removal from an ADC while awaiting pharmacy labeling.
- (3) ADC downtime procedures.
 - (A) Institutional process for management and possession of ADC keys.
 - (B) During regular business hours of the Correctional Pharmacy.
 - (C) During hours when the Correctional Pharmacy is closed.

(e) Procedure

(1) Preliminary Requirements for an Automated Dispensing Cabinet

(A) Legal requirements

1. Pursuant to California Business and Professions Code, Division 2, Chapter 9, Article 25, Section 4427.3, ADC placement in a CDCR institution is limited to licensed units pursuant to both California Code of Regulations, Title 22, Division 5 and California Business and Professions Code, Division 2, Chapter 9, Article 13.5, Section 4187.
2. An ADC shall be operated by a Correctional Pharmacy with a current and valid pharmacy license. Any drugs within an ADC are considered owned by the Correctional Pharmacy until they are dispensed or furnished from the ADC.

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3. Through June 30, 2019, the CEO, with the assistance of the PIC, shall complete Form 17A-100, Notification of Installation or Discontinuance of an Automated Drug Delivery System, which can be found on the California State BOP website at www.pharmacy.ca.gov. The completed form shall be submitted to the California State BOP within 30 calendar days of installation of the device and on an annual basis as part of the pharmacy's license renewal.
4. Beginning July 1, 2019, an ADC installed, leased, owned, or operated in California shall be licensed by the California State BOP. This license shall be renewed with applicable fees annually. The renewal date shall be the same as the correctional pharmacy license.
5. Beginning July 1, 2019, prior to issuance of an ADC license, the California State BOP shall conduct a pre-licensure inspection, within 30 calendar days of a completed application for an ADC license, at the proposed location of the ADC. Relocation of an ADC shall require a new application for licensure. Replacement of an ADC shall require notification to the California State BOP within 30 calendar days.
6. Policies and procedures related to an ADC shall be provided by the Systemwide P&T Committee to include appropriate security measures and the monitoring of the inventory to prevent theft and diversion. All policies and procedures shall be maintained in either electronic form or paper form at the location where an ADC is being used.
7. Effective July 1, 2019, pursuant to California Business and Professions Code, Division 2, Chapter 9, Article 25, Section 4427.7, the PIC, or designee, shall complete annual self-assessments for each ADC evaluating the pharmacy's compliance with pharmacy laws relating to the use of ADCs. All information regarding operation, maintenance, compliance, errors, omissions, or complaints pertaining to ADCs shall be included in the self-assessment.
8. Should a Correctional Pharmacy discontinue operation of an ADC, the PIC shall advise the California State BOP in writing within 30 calendar days.

(B) Physical requirements and installation

1. The CEO, in coordination with the Chief Medical Executive (CME), Chief Physician & Surgeon (CP&S), CNE, Supervising Dentist, Senior Psychiatrist, and PIC, shall determine licensed locations requiring an ADC.
2. The CEO shall ensure the security, adequate square footage, emergency power (battery backup), and computer connections required for proper functioning of an ADC.

(2) Automated Dispensing Cabinet Use

(A) Medications shall be removed from an ADC only after order verification by a pharmacist except when pharmacy services are unavailable as described below.

1. If pharmacy services are unavailable and an order has not been verified by a pharmacist and if, in the prescriber's professional judgment, delay in therapy may cause potential harm, a medication may be removed from an ADC and administered to a patient under the direction of the prescriber.
 - a. Pharmacy services shall be considered unavailable when the Correctional Pharmacy is closed and the CDCR-CFP after-hours service has not responded. A lack of response by the CDCR-CFP after-hours service shall occur when:
 - 1) A message has been sent within the Cerner Message Center to CF Pharmacy Rx Trfr Message Pool with a subject line that includes: "[facility name] - ADC removal," and
 - 2) A phone call has been placed to the CDCR-CFP after-hours service number, without response, as posted on the Pharmacy webpage at:
<http://lifeline/HealthCareOperations/MedicalServices/Pharmacy/Forms/After-Hours-Pharmacy-Services.pdf>.
 - b. For orders placed when pharmacy services are unavailable as indicated in Section (e)(2)(A)1.:
 - 1) For Computerized Provider Order Entry by the provider, the placement of the order with the inclusion of the start time shall be considered the exercising of the provider's professional judgment that delay in therapy may cause potential harm.
 - 2) For verbal orders given to a licensed nurse, a part of the nurse's verbal read-back to the provider shall include the start time. The provider's authorization to complete the medication order with inclusion of the start time shall be considered the exercising of the provider's professional judgment that delay in therapy may cause potential harm.

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2. The administration of medications removed from an ADC by licensed health care staff shall be documented in the health record. During downtime procedures, administration of medications removed from an ADC shall be documented on a paper Medication Administration Record.
- (B) When removing a high-alert or look-alike/sound-alike medication from the ADC, the ADC shall display appropriate alerts for the user.
- (C) Medications that have been removed from the packaging issued by pharmacy, appear tampered with, or are outdated, contaminated, mislabeled, or recalled shall be disposed of pursuant to the Health Care Department Operations Manual (HCDOM), Section 1.2.12, Disposal of Regulated Waste Generated by Health Care Staff; Section 3.5.11, Medication Inventory Management, Labeling and Storage; and Section 3.5.16, Ordering, Securing, and Disposing of DEA Scheduled II, III, IV, and V Controlled Substances.
- (D) Withdrawal of medications from an ADC by licensed health care staff shall occur as follows:
1. Medications shall be withdrawn from an ADC for one patient at a time and only after entering all required patient-specific information.
 2. Licensed health care staff shall complete all information requested by an ADC in the course of a medication withdrawal or pharmaceutical return. Failure to do so may originate in a null transaction.
 3. The ADC shall track a limited number of medications which are stored outside of the ADC cabinet. These medications shall be taken for administration only upon direction from the ADC after completing all required information. An institution's LOP shall identify storage locations for ADC-tracked medications located outside of the ADC.
 4. The Systemwide P&T shall authorize a limited number of medications which an RN is authorized to dispense from an ADC or LCC stock. An RN working at an LCC may dispense pursuant to California Business and Professions Code, Division 2, Chapter 6, Article 2 - Scope of Regulation, Section 2725.1.
 5. Controlled substances shall be withdrawn as follows:
 - a. Patient-specific information shall be entered into an ADC.
 - b. Licensed health care staff shall select the controlled substance from the patient-specific profile screen. Where the medication order is not presently listed, licensed health care staff shall enter the required controlled substance order information into the system. Verification by a pharmacist is required, or a medication order override shall be generated.
 - c. Licensed health care staff shall follow the prompt provided for locating and opening the compartment that contains the required medication. The ADC shall request the countback for all pills in the compartment prior to removing the dose. When the countback does not match the ADC anticipated count, a discrepancy will be created.
 - d. Should a licensed health care staff waste a dose of controlled substances, staff shall record the waste with a witness at the ADC machine as defined in the HCDOM, Section 3.5.16, Ordering, Securing, and Disposing of DEA Schedule II, III, IV, and V Controlled Substances. For instructions on the proper disposal of the medication, refer to the HCDOM, Section 1.2.12, Disposal of Regulated Waste Generated by Health Care Staff.
 6. Licensed health care staff shall withdraw a medication from an ADC in the following quantity:
 - a. When the pharmacy is closed and the medication is packaged as a unit-of-use item (e.g., eye drops, creams), a single unit-of-use package shall be removed from an ADC for the specific patient and retained for future medication passes. For RN-dispensed exceptions, refer to Section (e)(2)(E)2.
 - 1) If the medication order shall continue after the Correctional Pharmacy reopens and is desired to be given KOP, two orders shall be required. The first order shall be Nurse Administered/Directly Observed Therapy (NA/DOT) administration to cover the interim period, and the second order shall be KOP to continue until therapy is completed. A pharmacist shall place this label upon the medication which is stored at the LCC. Once labeled, the unit-of-use medication can be given to the patient for KOP administration. The medication shall not be given to the patient for self-administration until the Correctional Pharmacy has properly labeled it.
 - 2) If the medication order shall discontinue prior to the Correctional Pharmacy reopening or if the order is intended to be NA/DOT for the entire duration, the medication shall be ordered as a single NA/DOT order and the medication shall not be given to the patient for self-administration.

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- b. When multi-dose vials are withdrawn from an ADC, the beyond-use date shall be written on the vial pursuant to the HCDOM, Section 3.5.11, Medication Inventory Management, Labeling and Storage. The remainder of the vial shall be kept at a licensed unit for future patient-specific administrations.
- c. All other medications shall be removed in the quantity required for a single administration of the medication with nursing staff returning to the ADC for each medication pass.

(E) Medications removed from an ADC shall be administered as follows:

- 1. With the exception of medications authorized by the Systemwide P&T for RN dispensing, medications removed from an ADC shall have an administration type of NA or DOT.
 - a. When the Correctional Pharmacy is closed and a valid order exists as KOP but the licensed health care staff must remove a medication from an ADC to administer it NA/DOT, a new order of short duration by a provider is required within the health record to permit the recording of medication administration.
 - b. The CFP after-hours service shall assist in generating the bridging orders to allow for temporary NA/DOT administration. The following process shall be used to obtain CFP after-hours assistance:
 - 1) A message shall be sent within the Cerner Message Center to CF Pharmacy Rx Trfr Message Pool with a subject line that includes: “[facility name] – Bridging order needed,” and
 - 2) A phone call shall be placed to the CFP after-hours service number, as posted on the Pharmacy webpage at:
<http://lifeline/HealthCareOperations/MedicalServices/Pharmacy/Forms/After-Hours-Pharmacy-Services.pdf>
 - 3) Refer to Section (e)(2)(A)1.a. for CDCR-CFP after-hours lack of response.
- 2. For RN dispensing of unit-of-use packages, medications shall be KOP using the following procedures:
 - a. California Business and Professions Code, Division 2, Chapter 9, Article 4, Sections 4076 and 4076.5 define label requirements for medications dispensed to a patient. The Systemwide P&T Committee shall define labeling procedures in addition to the approved drugs for RN dispensing.
 - b. The RN shall:
 - 1) Ensure that the instructions on the medication label correspond to the instructions within the medication order or statewide leadership-approved protocol.
 - 2) If the instructions do not match, the medication shall not be furnished to the patient without obtaining a consistent medication order or applying an appropriate statewide leadership-approved protocol.
 - 3) In the absence of a medication order consistent with the administration directions as printed on the prescription label, medications shall be administered pursuant to Section (e)(2)(E)2.
 - c. The RN shall complete the electronic health records system (EHRS) medication administration process to record the dispensing of the KOP medication to the patient in the quantity consistent with the unit-of-use package.

(F) Pharmaceutical Returns

- 1. Each ADC machine shall be equipped with an ADC return bin. Any medication removed from an ADC which remains acceptable for use then becomes a pharmaceutical return and shall be returned to an ADC return bin.
- 2. Nursing staff shall identify the patient and the medication and then choose the medication return button. This will then instruct the nurse to place the doses in the medication return bin.
- 3. When the medication has been crushed or otherwise becomes unsuitable for use, staff shall dispose of the medication pursuant to the HCDOM, Section 1.2.12, Disposal of Regulated Waste Generated by Health Care Staff, for proper disposal of pharmaceutical waste and shall then record wasted doses at the ADC.
- 4. The PIC, or designee, shall refer instances of pharmaceutical waste being placed in the ADC return bin to the CNE or designee for appropriate training.

(3) Troubleshooting

(A) Reporting ADC Failure

- 1. Any issues with the function or contents of an ADC shall be reported to the PIC and the SRN II/III on duty upon discovery.

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2. In the event the Correctional Pharmacy is unavailable, the SRN II/III on duty shall be notified immediately, and the SRN II/III on duty shall send notification to the PIC or designee for follow-up the next Correctional Pharmacy business day.
- (B) ADC Downtime Procedures
1. In the event that a single ADC malfunctions, the SRN II/III shall post a sign on the ADC indicating “out of order” and direct the licensed health care staff to an alternate ADC.
 - a. The inoperable ADC shall remain secured until repaired without accessing the emergency ADC keys whenever there is a working ADC within the same or nearby LCC.
 - b. As the last resort, the institution shall activate the Total ADC Downtime Procedures specified in the LOP.
 - c. When it is necessary to access an ADC using the ADC keys, it is the SRN II/III’s responsibility to notify the PIC of emergency access to the ADC, so the PIC can address the issue the next Correctional Pharmacy business day.
 2. For mechanical issues unrelated to institutional events (e.g., flood, fire, riot, power failure), the SRN II/III on duty shall notify the 24-Hour Ommicell Help Desk at 1-800-910-2220 and provide the serial number located inside the top cabinet of the ADC. CCHCS maintains a service and repair contract that requires rapid repairs to malfunctioning ADC machines.
 3. In the event of ADC failure across the entire institution, the institution shall access after-hours pharmacy services pursuant the HCDOM, Section 3.5.8, After-Hours Pharmacy Services.
 - a. Whenever there is a working ADC within the same or nearby LCC, inoperable ADCs shall remain secured until repaired without accessing the emergency ADC keys.
 - b. For rare instances when medications are not available without accessing an inoperable ADC, the LOP shall include the process for accessing emergency ADC keys. As an ADC is legally considered part of the Correctional Pharmacy, these keys must be maintained with the strictest of control.
 - c. Emergency key access to the ADC
 - 1) The SRN II/III on duty shall be notified of the need for emergency access to the ADC using the ADC keys. All SRN II/III shall be trained in the use of keys to access an ADC during downtime procedures.
 - 2) Emergency access keys shall be maintained within a tamper-evident, limited-access key box. This key box may be kept by custody or kept in a location occupied by the CNE or designee.
 - a) If custody maintains the tamper-evident key box, then routine custody processes shall be followed for both the checking of the tamper-evident key box and the maintenance of the key checkout log.
 - b) It is the PIC, or designee, who retains unused tamper-evident numbered seals and who shall seal key boxes whenever the tamper-evident seal has been broken. The PIC, or designee, shall track the seal number used on the tamper-evident key box at all times.
 - c) If the CNE, or designee, maintains the tamper-evident key box, then the seal on the tamper-evident key box must be checked each shift to confirm its integrity. The CNE, or designee, shall maintain a key log in which the checking of the tamper-evident seal shall be recorded. Pharmacy shall be notified when the tamper-evident seal has been broken. When the tamper-evident seal has been broken, the log shall include:
 - i. The date and time of issue
 - ii. Printed name and signature of the staff signing out the key
 - iii. Date and time the keys are passed
 - iv. Printed name and signature of the SRN II/IIIs giving and receiving keys upon issue and upon passing until Pharmacy takes possession.The SRN II/III on duty shall be the only authorized person to access the keys from a tamper-evident, limited-access key box.
 - 3) The CNE, or designee, shall designate the SRN II/IIIs responsible for operation and security of ADCs opened during downtime procedures. The designated SRN II/III shall maintain and retain all records of transactions during the ADC downtime until:
 - a) Relieved of their post by another designated SRN II/III; or

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- b) The ADC unit has been reassembled and secured.
- d. Once the emergency has been resolved and the emergency ADC keys are no longer necessary, the SRN II/IIIs on duty shall pass the keys to the next oncoming SRN II/III retaining possession and control of the keys until the PIC or designee takes possession. The keys shall be returned to a key control location once the tamper-evident key box has been repaired or Pharmacy has replaced the tamper-evident seal.
- e. Audit Procedures during ADC Downtime
 - 1) The SRN II/III using the emergency ADC keys to access an ADC shall conduct an initial controlled substance inventory with any available licensed health care staff. This inventory shall be the initial quantity entered into the paper Inventory Control Method (ICM).
 - 2) Should the SRN II/III secure the ADC, they shall conduct a final controlled substance inventory with any available licensed health care staff. This inventory shall be the final quantity entered into the paper ICM.
 - 3) The paper ICM shall be reviewed by the PIC or designee on the next Correctional Pharmacy business day.

(4) Contents of the Automated Dispensing Cabinet

(A) General guidelines for ADC contents include:

- 1. Medications stored and dispensed from an ADC shall conform to federal and state laws and regulations. All medications shall be administered or dispensed pursuant to a valid prescription order pursuant to the HCDOM, Section 3.5.5, Prescription/Order Requirements, or statewide leadership-approved protocols.
 - 2. The preferred method for delivery of controlled substances shall be non-patient-specific from an ADC. All non-patient-specific controlled substances shall be stored in an ADC. Where the product characteristics do not permit storage in an ADC, the medication shall be issued as patient-specific.
 - 3. Over-the-counter nurse protocol medications shall not be stored in an ADC.
 - 4. Inventory within an ADC shall conform to the requirements, restrictions, and limitations issued by the Systemwide P&T Committee.
 - 5. Pharmacy labels pre-printed for RN-dispensed medications shall conform to the standard administration instructions as specified by the Systemwide P&T Committee.
 - 6. When stocking controlled substances, high alert medications, and look-alike/sound-alike medications within an ADC, each medication shall be stored in a compartment limited to a single medication with a locking lid.
 - 7. Medication labels shall include: medication name, strength, expiration date, and amount (if not apparent from the container).
 - 8. Controlled substances in an ADC shall only be stocked in locking lid bins. Pharmacy shall identify the locking lid bins containing controlled substances for easy recognition during ADC downtime (e.g., colored labels, dots, or other distinct markings on the locking lid).
- (B) The PIC and the local P&T Committee, in consultation with the CME, CP&S, CEO, CNE, Chief Psychiatrist or Senior Psychiatrist, and Supervising Dentist, or their respective designees, shall prepare, update, and approve the types, dosages, and quantities of drugs stocked in an ADC to meet the reasonable needs of the institution.
- (C) The contents of an ADC shall be reviewed by the PIC in collaboration with the staff listed in Section (e)(4)(B) above for appropriateness on a regular basis but not less than annually.
- (D) The PIC, or designee, shall restock an ADC up to the established par level at intervals determined by the electronic prompting of an ADC. The stocking and restocking of an ADC shall be performed by a pharmacist or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist.
- (E) When stocking an ADC, the pharmacist or pharmacy technician shall:
- 1. Select the medication being restocked from an ADC's inventory list.
 - 2. Follow the ADC prompts to locate the correct medication compartment.
 - a. For matrix drawer compartments, scan the barcode on the medication and the barcode within the compartment to ensure the medication is being restocked into the correct compartment.
 - b. For locking lid compartments, follow the ADC prompts to ultimately open the correct compartment and barcode scan the medication.
- (F) Where the Correctional Pharmacy has the Omnicell Controlled Substances Manager® (CSM), the PIC, or designee, shall review the "CSM Exception Report" not less than weekly pursuant to the HCDOM, Section

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3.5.16, Ordering, Securing, and Disposing of DEA Scheduled II, III, IV, and V Controlled Substances. Where exception transactions exist on the report, the PIC, or designee, shall resolve the exception by the end of the business day. Where exception transactions cannot be resolved, the transaction shall be handled pursuant to the HCDOM, Section 3.5.21, Break-In, Theft/Loss from Pharmacy or Medication Storage Areas.

- (G) Specialized services including, but not limited to dentists, optometrists, respiratory therapists, shall be restricted to only accessing medications consistent with their scope of practice by:
1. Identifying a single drawer or compartment of an ADC, which the specialized service shall access,
 2. Specifying the access level for the provider such that the drug can identify whether this provider is to have access, or
 3. Licensing the office(s) for the specialized service as an LCC, where medications will be stocked consistent with their specialized scope of practice. The pharmacy shall monitor requisitions to ensure compliance with the specialized scope of practice.

(5) Administrative Requirements

- (A) An ADC shall be located in a licensed unit within a secured medication storage area, free from clutter, distractions, and interruptions.
- (B) Only licensed health care staff lawfully authorized to administer or dispense the drug may use his or her own unique identification to utilize an ADC for completing this task.
- (C) The PIC, or designee, is considered the legal administrator of the ADC. It is the PIC's responsibility to provide information to the Statewide Chief of Pharmacy Services or designee for maintenance of ADC databases.
- (D) The PIC in conjunction with the Statewide Chief of Pharmacy Services, or designee, shall maintain the permanent staff access file within an ADC. Access to an ADC shall occur as follows:
1. A new employee shall complete information system requirements for access and use of computers to include required access to an ADC.
 2. The employee's supervisor shall provide the PIC at the institution with a completed Clinical or System Access Request (CSAR) Form for the PIC to sign. Once signed, the PIC shall provide the CSAR to the Statewide Chief of Pharmacy Services or designee at CDCRCHCSOmicellCF@cdcr.ca.gov to enter the employee into the ADC staff access database.
 - a. The CSAR Form can be accessed on Lifeline on the Information Technology webpage at: <http://lifeline/ExecutiveOperations/InformationTechnology/Forms/CSAR-Form.pdf>.
 3. The Statewide Chief of Pharmacy Services, or designee, shall designate the access parameters for each licensed health care staff granted access to an ADC.
 4. The CNE, or designee, shall provide periodic personnel updates of designated licensed health care staff to the PIC, who shall provide it to the Statewide Chief of Pharmacy Services or designee.
 5. The CNE, or designee, shall notify the PIC when access needs to be revoked. The PIC shall provide it to the Statewide Chief of Pharmacy Services, or designee, who shall remove access of that staff by close of business the next business day.
- (E) The PIC and CNE, or respective designees, shall be responsible for training their staff in the use of an ADC and in LOP downtime procedures. The PIC, or designee, shall participate in the training of all staff.
- (F) The CNE or SRN II/III may grant temporary access that will expire no later than 72 hours from when granted. If access is granted over a weekend or holiday, the CNE or SRN II/III shall grant temporary access every 72 hours until the Correctional Pharmacy reopens. Where continuing access is required, refer to Section (e)(5)(D)2. above.
- (G) Information security practices shall apply and be enforced for ADC use and access pursuant to the Annual Information Security Awareness Training located on the Information Technology webpage at: <http://lifeline/ExecutiveOperations/InformationTechnology/InformationSecurity/Pages/Home.aspx>.

(6) Inspections

- (A) At least weekly, the Correctional Pharmacy staff shall:
1. Review, inspect, and restock medications from the "return bin" of an ADC. Pharmaceutical returns shall be handled as follows:
 - a. Medications shall be inspected to ensure that they remain usable for their intended purpose.
 - 1) If the returned medications are no longer usable (e.g., crushed or outdated), a transaction history shall be obtained and the issue referred to the CNE or designee for training. The medication shall

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be disposed of pursuant to the HCDOM, Section 1.2.12, Disposal of Regulated Waste Generated by Health Care Staff.

- 2) If the returned medications are DEA controlled substances schedule II-V, pharmacy staff shall run a transaction history and reconcile the quantity identified as returned against the quantity present in the return bin. Any count discrepancies shall be referred to the PIC and SRN II/III on duty for resolution. Any count discrepancies that cannot be resolved shall be handled pursuant to the HCDOM, Section 3.5.21, Break-In, Theft/Loss from Pharmacy or Medication Storage Areas.
 - 3) If the medications have a patient-specific label indicating a patient name and CDCR number, pharmacy staff shall review the label. If the label indicates KOP administration, the medication shall be presumed to have been in the hands of the patient. Any patient-identifying information shall be removed, and the drug shall be disposed of by pharmacy staff pursuant to the HCDOM, Section 1.2.12, Disposal of Regulated Waste Generated by Health Care Staff. A transaction history shall be generated and the specific entry referred to the CNE or designee for training.
- b. Medications shall be restocked to ensure that adequate supplies are available for continuity of care and for urgent/emergent patient needs.
 - 1) When on-hand quantities have fallen below the minimum par level set, the pharmacy shall restock to bring inventory close to maximum par level.
 - 2) When on-hand quantities are significantly more than usage, the PIC shall consider reduction of inventory and par levels within the ADC.
 2. Review null transactions from an ADC for suspicious behavior.
 - a. The PIC, or designee, shall provide the SRN II/III with a copy of each report of null transactions involving nursing staff.
 - b. The PIC, or designee, shall review each null transaction report to assess procedural causes on the part of pharmacy staff and to identify needs for additional training.
- (B) At least monthly, a pharmacist at the Correctional Pharmacy shall:
1. Review transaction records to verify the security and accountability of the system.
 2. Conduct a cycle count of DEA controlled substances in each ADC.
 3. Conduct a physical inspection of the drugs to ensure that medications in an ADC continue to meet drug dating, labeling, and storage requirements (including proper location).
 4. Inspect an ADC machine for cleanliness.
 5. Review the Omnicell PAR vs. Usage Report to look for par levels that may need to be increased or decreased. When a maximum par level is significantly above the monthly usage (or 7-day maximum dosing for urgent/emergent medications not presently being used), the par level and on-hand quantity shall be reduced. Failure to review the Omnicell PAR vs Usage Report and adjust par levels and on-hand inventory increases the likelihood that medications expire within the ADC.
 6. Complete an inspection report pursuant to the HCDOM, Section 3.5.25, Inspecting Medication Storage Areas.
 7. Check the seal to the tamper-evident, limited-access key box to ensure that the ADC emergency keys have not been accessed. If the seal has been broken:
 - a. Review the log to identify the date and time that access occurred.
 - b. Check all inventory at the ADC to ensure that medications are accounted for.
 - c. Report the access to the CNE or designee to ensure adequate training in maintenance of the tamper-evident key box.
 - d. Missing medications shall be handled pursuant to the HCDOM, Section 3.5.21, Break-In, Theft/Loss from Pharmacy or Medication Storage Areas.
- (C) At least quarterly, the PIC, or designated pharmacist, shall:
1. Conduct a cycle count of the non-DEA-controlled medications in each ADC.
 2. Review items that have not been used recently to determine whether the aging inventory should still occupy a space in the ADC.
 3. Complete controlled substance recordkeeping, inventory, and reconciliation pursuant to California Code of Regulations, Title 16, Division 17, Article 2, Section 1715.65, Inventory Reconciliation Report of Controlled Substances and the HCDOM, Section 3.5.16, Ordering, Securing, and Disposing of DEA

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Scheduled II, III, IV, and V Controlled Substances. Any inconsistencies identified in the reconciliation process shall be handled according to Sections (e)(8)(C) and (e)(8)(D).

(D) Upon notification from the PIC, or designee, an SRN II/III shall review ADC reports for appropriate ADC use and medication use on the part of nursing staff and to identify needs for additional training. Reports shall include, but are not limited to:

1. Null transaction reports
2. Discrepancy reports, refer to Section (e)(8).
3. Overrides occurring during Correctional Pharmacy or CFP after-hours service availability, refer to Section (e)(7).

(7) Overrides

(A) Each business day, the PIC, or designee, shall review medication order overrides from an ADC for the appropriateness and completeness of an order as specified in the HCDOM, Section 3.5.5, Prescription/Order Requirements, and for the appropriateness of bypassing the pharmacist's review.

(B) At least quarterly, the PIC, or designated pharmacist, shall review override reports to identify and address barriers to the pharmacist's review of the medication order prior to medication administration.

(8) Discrepancies

(A) The Pharmacy Administrator shall schedule the ADC Discrepancy Report to be generated daily and e-mailed to the CNE and the PIC or their respective designees.

(B) Each business day, the PIC, or designee, shall review discrepancy transactions from an ADC.

1. If CDC 7221, Physician's Orders, has been used during downtime of EHRS, the pharmacist shall review the orders for medications withdrawn from an ADC pursuant to Section (e)(2) no later than the next business day.
2. If an ADC has been manually opened during downtime procedures, pharmacy staff shall perform a complete inventory of the ADC, correlating the last known inventory for ADC contents against the present inventory of ADC contents. Differences in inventory shall be accounted for by using a paper ICM process as specified in the institution's ADC LOP. All discrepancies shall be identified and reviewed.

(C) Discrepancy reports shall be reviewed daily by an SRN II/III for nursing staff issues and the PIC for pharmacy staff issues. A copy of the resolved discrepancy report shall be submitted to the CNE and the PIC or their respective designees.

(D) Unresolved discrepancies or missing medications from an ADC shall be handled as a theft/loss and immediately reported by the discovering nursing or pharmacy staff or SRN II/III to the CNE and PIC pursuant to the HCDOM, Section 3.5.21, Break-In, Theft/Loss from Pharmacy or Medication Storage Areas.

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 2, Section 4024, Dispensing
- California Business and Professions Code, Division 2, Chapter 9, Article 2, Section 4026, Furnish
- California Business and Professions Code, Division 2, Chapter 9, Article 2, Section 4036.5
- California Business and Professions Code, Division 2, Chapter 9, Article 4, Section 4076
- California Business and Professions Code, Division 2, Chapter 9, Article 4, Section 4076.5
- California Business and Professions Code, Division 2, Chapter 9, Article 6, Section 4105.5
- California Business and Professions Code, Division 2, Chapter 9, Article 13, Section 4186
- California Business and Professions Code, Division 2, Chapter 9, Article 13.5, Sections 4187-4187.6
- California Business and Professions Code, Division 2, Chapter 9, Article 23, Section 4400
- California Business and Professions Code, Division 2, Chapter 9, Article 25, Section 4427-4427.8
- California Code of Regulations, Title 16, Division 17, Article 2, Section 1715.65, Inventory Reconciliation Report of Controlled Substances
- Form 17A-100, Notification of Installation or Discontinuance of an Automated Drug Delivery System at www.pharmacy.ca.gov
- California Code of Regulations, Title 22, Division 5, Licensing and Certification of Health Facilities, Home Health Agencies, Clinics, and Referral Agencies
- California Health and Safety Code, Division 2, Chapter 2, Article 1, Section 1261.6

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- 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 3.5.5, Prescription/Order Requirements
- Health Care Department Operations Manual, Chapter 3, Article 5, Section 3.5.8, After-hours Pharmacy Services
- 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, Ordering, Securing, and Disposing of DEA Schedule II, III, IV, and 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 3.5.25, Inspecting Medication Storage Areas
- Food and Drug Administration Drug Quality Assurance – Drug Repackagers and Relabelers, <https://www.fda.gov/media/75182/download>
- ISMP® 2009 Medication Safety Self-Assessment® for Automated Dispensing Cabinets, Page 4
- ISMP® 2011 Medication Safety Self-Assessment® for Hospitals, Page 2
- Omnicell® 2013 Recommended OmniCenter Reports for Pharmacy, http://www.orangeboxstudio.com/Winter_2013_Handouts/Omni_Rec_Reports_Pharmacy_v2.2.pdf
- Annual Information Security Awareness Training
<http://lifeline/ExecutiveOperations/InformationTechnology/InformationSecurity/Pages/Home.aspx>.

Revision History

Effective: 06/2002

Revised: 05/2019