

### 3.5.7 Automated Drug Delivery System

#### (a) Procedure Overview

The California Department of Corrections and Rehabilitation (CDCR) and California Correctional Health Care Services (CCHCS) shall ensure each correctional pharmacy maintains 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 (ADDS), also known as an automated dispensing cabinet, shall be an adjunct to medications delivered from the correctional pharmacy or Central Fill Pharmacy (CFP). The ADDS 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 ADDS machines 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 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 apply this procedure.
- (B) Maintain requirements and restrictions for issuance of a chart order pursuant to a protocol.
- (C) Define 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 for an ADDS.
- (B) Maintain authorized lists of medications available for Registered Nurse (RN) dispensing from an ADDS or licensed correctional clinic (LCC) stock as authorized by California Business and Professions Code (BPC), 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 Systemwide Medication Management Subcommittee

The Systemwide Medication Management Subcommittee shall have overall responsibility for issuing restrictions and limitations on staff access rights for an ADDS.

##### (4) The Statewide Chief of Pharmacy Services

The Statewide Chief of Pharmacy Services shall have:

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

##### (5) Institutional

(A) The Chief Executive Officer (CEO) has overall responsibility for ensuring compliance with this procedure including, but not limited to:

- 1. Providing plant requirements to support the placement of an ADDS.
- 2. Continuing compliance with state regulatory requirements, in collaboration with the Pharmacist-in-Charge (PIC), for location and registration of an ADDS.
- 3. Purchasing of labels and consumables required for using an ADDS.
- 4. Retaining 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 ADDS processes.
- 2. Compliance with federal and state regulations.
- 3. Compliance with this procedure.
- 4. Assignment of consistent and adequate resources.

CALIFORNIA DEPARTMENT OF CORRECTIONS AND REHABILITATION  
CALIFORNIA CORRECTIONAL HEALTH CARE SERVICES  
Health Care Department Operations Manual

5. Licensed health care staff training.

(C) The Chief Nurse Executive (CNE) shall be responsible for:

1. Maintaining nursing procedures to provide control and accountability for medications after removal from an ADDS.
2. Designating the Supervising RN (SRN) II/IIIs responsible for emergency key possession, accessing of an ADDS, and recordkeeping during ADDS downtime procedures.
3. Ensuring adequate training of all licensed health care staff in the proper routine use of an ADDS and ADDS downtime procedures.
4. Ensuring completion of the CDCR 7543, Controlled Substance Reconciliation Mismatch Form.

(D) The PIC shall be responsible for:

1. Maintenance, accountability, and accuracy of ADDS inventory.
2. Reviewing of storage locations and inventory organization within an ADDS on a monthly basis.
3. Working in conjunction with the Statewide Chief of Pharmacy Services, or designee, to provide information needed for the maintenance of ADDS databases.
4. Licensing ADDS with the BOP.
5. Preparing and reviewing of ADDS reports.
6. Communicating with the CEO regarding service and quality issues.
7. Assisting in the annual training of all staff in regard to proper ADDS use and ADDS downtime procedures.
8. At minimum, conducting cycle counts as follows:
  - a. Weekly inventory of all DEA-controlled substances within the pharmacy.
  - b. Monthly inventory of all DEA-controlled substances within an ADDS.
  - c. Quarterly inventory of all non-DEA-controlled medications within an ADDS.
9. Maintaining records of medication reconciliation within the pharmacy for at least one year and a total of three years.
10. Identifying any trends of medication mismatch and reporting to the institution Medication Management Subcommittee.
11. Ensuring compliance with controlled substances reconciliation requirements pursuant to California Code of Regulations (CCR), Title 16, Division 17, Article 2, Section 1715.65, Inventory Reconciliation Report of Controlled Substances.
12. Ensuring pharmacy staff training and pharmacy implementation of the current Controlled Substances Accountability Training Manual.

(E) Licensed health care staff shall comply with this procedure including, but not limited to:

1. Proper use of an ADDS.
2. Proper disposition, storage, labeling, and return of medications after removal from an ADDS.
3. Completion of ADDS training prior to initial use and at least annually thereafter.
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 ADDS. The LOP shall include, but is not limited to:

- (1) Tracking of items located outside of an ADDS.
- (2) Handling of unit-of-use medication for patient-specific KOP administration after removal from an ADDS while awaiting pharmacy labeling.
- (3) Providing ADDS downtime procedures.
  - (A) Institutional process for management and possession of ADDS 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 Drug Delivery System**

**(A) Legal Requirements**

1. Pursuant to BPC, Division 2, Chapter 9, Article 25, Section 4427.3, ADDS placement in a CDCR institution is limited to licensed units pursuant to both CCR, Title 22, Division 5 and BPC, Division 2, Chapter 9, Article 13.5, Section 4187.
2. An ADDS shall be operated by a correctional pharmacy with a current and valid pharmacy license. Any drugs within an ADDS are considered owned by the correctional pharmacy until they are dispensed or furnished from the ADDS.
3. An ADDS installed, leased, owned, or operated in California shall be licensed by the BOP. This license shall be renewed with applicable fees annually. The renewal date is the same as for the correctional pharmacy license.
4. Prior to issuance of an ADDS license, the BOP shall conduct a pre-licensure inspection, within 30 calendar days of a completed application for an ADDS license, at the proposed location of the ADDS. Relocation of an ADDS shall require a new application for licensure. Replacement of an ADDS requires notification to the BOP within 30 calendar days.
5. Policies and procedures related to an ADDS shall 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 ADDS is being used.
6. Pursuant to BPC, Division 2, Chapter 9, Article 25, Section 4427.7, the PIC shall complete a self-assessment for each ADDS evaluating the pharmacy's compliance with pharmacy laws relating to the use of ADDS annually before July 1 of each year and within 30 days of a newly installed PIC, a newly issued ADDS license, or a change in address of a licensed ADDS location. All information regarding operation, maintenance, compliance, errors, omissions, or complaints pertaining to an ADDS shall be included in the self-assessment. For any deficiencies identified through the self-assessment, the PIC shall provide a written corrective action plan and timeframe to correct the issues. Completed self-assessments shall be retained for a minimum of three years from the date performed.
7. Should a correctional pharmacy discontinue operation of an ADDS, the PIC shall advise the 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 ADDS.
2. The CEO shall ensure the security, adequate spacing, emergency power (battery backup), and computer connections required for proper functioning of an ADDS.
3. An ADDS shall be located in a licensed unit within a secured medication storage area, free from clutter, distractions, and interruptions.

**(2) Administrative Requirements**

- (A)** Only licensed health care staff lawfully authorized to administer or dispense the drug may use their own unique identification to utilize an ADDS for completing this task. Each user shall maintain only one permanent user profile.
- (B)** The PIC, or designee, is considered the legal administrator of the ADDS. The PIC shall be responsible for providing information to the Statewide Chief of Pharmacy Services, or designee, for maintenance of ADDS databases.
- (C)** The PIC in conjunction with the Statewide Chief of Pharmacy Services, or designee, shall maintain the permanent staff access file within an ADDS. Access to an ADDS 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 ADDS.
  2. The employee's supervisor, or designee, shall submit a completed Application Access Request via the CCHCS Service Portal for the PIC to approve. Once approved, the form will be routed to the Statewide Chief of Pharmacy Services, or designee, to enter the employee into the ADDS staff access database.

CALIFORNIA DEPARTMENT OF CORRECTIONS AND REHABILITATION  
CALIFORNIA CORRECTIONAL HEALTH CARE SERVICES  
Health Care Department Operations Manual

3. The Statewide Chief of Pharmacy Services, or designee, shall designate the access parameters for each licensed health care staff granted access to an ADDS.
  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.
- (D) The PIC and CNE, or respective designees, shall be responsible for training their staff in the use of an ADDS and in LOP downtime procedures, including use of the emergency keys. The PIC and CNE shall review training records of all licensed pharmacy and nursing staff annually.
- (E) The CNE or SRN II/III may grant temporary access that will expire in three days. If access is granted over a weekend or holiday, the CNE or SRN II/III shall grant temporary access every three days until the correctional pharmacy reopens. Where continuing access is required, refer to Section (e)(2)(C) above.
- (F) Information security practices shall apply and be enforced for ADDS 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>.

**(3) Contents of the Automated Drug Delivery System**

- (A) General guidelines for ADDS contents include:
1. Medications stored in an ADDS shall conform to federal and state laws and regulations.
  2. Medication labels shall include: medication name, strength, expiration date, and quantity (if not apparent from the container).
  3. The preferred method for delivery of controlled substances shall be non-patient-specific from an ADDS. All non-patient-specific controlled substances shall be stored in an ADDS. Where the product characteristics do not permit storage in an ADDS, the medication shall be issued as patient-specific.
  4. Over-the-counter nurse protocol medications shall not be stored in an ADDS.
  5. Inventory within an ADDS shall conform to the requirements, restrictions, and limitations issued by the Systemwide P&T and Systemwide Medication Management Committees.
  6. Pharmacy labels pre-printed for RN Dispense medications shall conform to the standard administration instructions as specified by the Systemwide P&T Committee.
  7. When stocking controlled substances, high alert medications, and look-alike/sound-alike medications within an ADDS, each medication shall be stored in a compartment limited to a single medication with a locking lid.
  8. Pharmacy shall identify the locking lid bins containing controlled substances for easy recognition during ADDS downtime (e.g., colored labels, dots, or other distinct markings on the locking lid).
  9. Recalled medications shall be removed from the ADDS by the pharmacy for disposition in accordance with the Health Care Department Operations Manual (HCDOM), Section 3.5.11, Medication Inventory Management, Labeling, and Storage.
- (B) The PIC and the institution Medication Management Subcommittee, 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 ADDS to meet the reasonable needs of the institution.
- (C) The contents of an ADDS shall be reviewed by the PIC in collaboration with the staff listed in Section (e)(3)(B) above for appropriateness on a regular basis but not less than annually.
- (D) The PIC, or designee, shall restock an ADDS up to the established par level at intervals determined by the electronic prompting of an ADDS. The stocking and restocking of an ADDS shall be performed by a pharmacist or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist.
- (E) When stocking an ADDS, the pharmacist or pharmacy technician shall:
1. Select the medication being restocked from an ADDS inventory list.
  2. Follow the ADDS 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.

CALIFORNIA DEPARTMENT OF CORRECTIONS AND REHABILITATION  
CALIFORNIA CORRECTIONAL HEALTH CARE SERVICES  
Health Care Department Operations Manual

- b. For locking lid compartments, follow the ADDS prompts to ultimately open the correct compartment and barcode scan the medication.
- (F) Where the correctional pharmacy has the Omnicell Controlled Substances Manager<sup>®</sup> (CSM), the PIC, or designee, shall review the “CSM Exception Report” by the end of the business day pursuant to the HCDOM, Section 3.5.16, DEA Scheduled II-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 service providers including, but not limited to dentists, optometrists, and 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 ADDS, which the specialized service provider 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.
- (4) Issuing Medications from an Automated Drug Delivery System**
- (A) Medications on the Acceptable Override Medications List (found on the Pharmacy webpage at <http://lifeline/HealthCareOperations/MedicalServices/Pharmacy/Forms/AcceptableOverrides2020.pdf>) when used as part of a medical procedure, as a diluent, or in an emergent situation may be removed from an ADDS before a pharmacist has verified the order. This removal will flag as an override in the system and will require a succinct explanation.
- (B) Any other medications shall be removed from an ADDS only after a pharmacist has verified the order 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 ADDS 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 after-hours Central Pharmacy Services has not responded. A lack of response by the after-hours Central Pharmacy Services shall occur when:
      - 1) A message has been sent within the Cerner Message Center to CFP Pharmacy Transfer Message Pool with a subject line that includes: “[facility name] - ADDS removal,” and
      - 2) A phone call has been placed to the after-hours Central Pharmacy Services 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)(4)(B)1:
      - 1) For computerized provider order entry, 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 to the patient.
      - 2) For verbal orders given to a licensed health care staff, a part of the verbal read-back to the provider shall include the start time in addition to the complete order and alerts as needed. 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 to the patient.
  - 2. The administration of medications removed from an ADDS by licensed health care staff shall be documented in the electronic health records system (EHRS) Medication Administration Wizard or electronic Medication Administration Record (MAR). During downtime procedures, administration of medications removed from an ADDS shall be documented on a paper MAR.

CALIFORNIA DEPARTMENT OF CORRECTIONS AND REHABILITATION  
CALIFORNIA CORRECTIONAL HEALTH CARE SERVICES  
Health Care Department Operations Manual

- (C) Withdrawal of medications from an ADDS by licensed health care staff shall occur as follows:
1. Medications shall be withdrawn from an ADDS for one patient at a time and only after entering all required patient-specific information. Licensed health care staff shall select the medication from the patient-specific profile screen. If the medication order is not presently listed, licensed health care staff shall enter the required order information into the system, and a medication order override will be generated.
  2. Licensed health care staff shall complete all information requested by an ADDS over the course of a medication withdrawal. Failure to do so may result in a null transaction.
  3. The ADDS may track a limited number of medications which are stored outside of the ADDS cabinet. These medications shall be taken for administration only upon direction from the ADDS after completing all required information. An institution's LOP shall identify storage locations for ADDS-tracked medications located outside of the cabinet when implemented.
  4. The Systemwide P&T Committee shall authorize a limited number of medications which an RN is authorized to dispense directly to the patient to KOP from an ADDS or LCC stock. An RN working at an LCC may dispense pursuant to BPC, Division 2, Chapter 6, Article 2 - Scope of Regulation, Section 2725.1.
  5. Additionally, controlled substances shall be withdrawn as follows:
    - a. Licensed health care staff shall follow the prompt provided for locating and opening the compartment that contains the required medication. The ADDS shall request the countback for all pills in the compartment prior to removing the dose. When the countback does not match the ADDS anticipated count, a discrepancy will be created.
    - b. Should a licensed health care staff waste a dose of controlled substances, staff shall record the waste with a witness at the ADDS cabinet as defined in the HCDOM, Section 3.5.16, DEA Schedule II-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 ADDS 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 ADDS for the specific patient and retained for future medication passes. For RN Dispense exceptions, refer to Section (e)(4)(D)2.
      - 1) If the medication order shall continue after the correctional pharmacy reopens and is desired to be given KOP, two orders are 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.
    - b. When multi-dose vials are withdrawn from an ADDS, 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 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 ADDS for each medication pass.
- (D) Medications removed from an ADDS shall be administered as follows:
1. With the exception of medications authorized by the Systemwide P&T Committee for RN dispensing, medications removed from an ADDS 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 ADDS 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 after-hours Central Pharmacy Services shall assist in generating the bridging orders to allow for temporary NA/DOT administration. The following process shall be used to obtain assistance from after-hours Central Pharmacy Services:

CALIFORNIA DEPARTMENT OF CORRECTIONS AND REHABILITATION  
CALIFORNIA CORRECTIONAL HEALTH CARE SERVICES  
Health Care Department Operations Manual

- 1) A message shall be sent within the Cerner Message Center to CFP Pharmacy Transfer 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)(4)(B)1.a. for CFP after-hours lack of response.
2. For RN dispensing of unit-of-use packages, medications shall be KOP using the following procedures:
- a. The correctional pharmacy shall affix labels onto eligible RN Dispense medications. The labels must be approved by the Systemwide P&T Committee.
  - b. The RN shall handwrite the patient’s name and other required information on the label so that it completes all requirements specified in the BPC, Division 2, Chapter 9, Article 4, Sections 4076 and 4076.5.
  - c. The RN shall:
    - 1) Ensure that the instructions on the medication label correspond to the instructions within the medication order.
    - 2) If the instructions do not match, the medication shall not be furnished to the patient without obtaining a consistent medication order.
    - 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)(4)(D)1.
  - d. The RN shall complete the EHRS medication administration process to record the dispensing of the KOP medication to the patient.
- (E) Medications that have been removed from the packaging issued by pharmacy; appear tampered with; are outdated, contaminated, mislabeled, altered (e.g., crushed), or recalled; or otherwise becomes unsuitable for use shall be disposed of pursuant to the 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, DEA Scheduled II-V Controlled Substances. Licensed health care staff shall then record wasted doses at the ADDS.
- (F) Pharmaceutical Returns
1. Each ADDS cabinet shall be equipped with a return bin. Any medication removed from an ADDS which remains usable shall be returned to an ADDS 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. The PIC, or designee, shall refer instances of pharmaceutical waste being placed in the ADDS return bin to the CNE, or designee, for appropriate training

**(5) Overrides**

- (A) Each business day, the PIC, or designee, shall review medication order overrides from an ADDS for the appropriateness and completeness of an order as specified in the HCDOM, Section 3.5.5, Prescription/Order Requirements and Medication Availability, 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 or to refer any identified training issues to the CNE or designee.

**(6) Discrepancies**

(A) Discrepancy Resolution and Daily Guided Cycle Counts

1. Any discrepancies shall be resolved by licensed health care staff within the same shift. If unable to resolve, the issue shall be referred to the SRN II/III immediately for resolution within the same shift.
  2. At least once every day for each ADDS in use that day, nursing staff shall perform a DEA controlled substances guided cycle count of all locked bins that have been opened since the last guided cycle count.
  3. For discrepancies unable to be resolved by the SRN II/III or line staff, notify the CNE and PIC, and refer to the HCDOM, Section 3.5.21, Break-In, Theft/Loss from Pharmacy or Medication Storage.
- (B) The Pharmacy Administrator shall schedule the ADDS Discrepancy Report and the Cycle Count Non-compliance Report to be generated at least daily and e-mailed to the health care executive team and the PIC or their respective designees.

CALIFORNIA DEPARTMENT OF CORRECTIONS AND REHABILITATION  
CALIFORNIA CORRECTIONAL HEALTH CARE SERVICES  
Health Care Department Operations Manual

- (C) Each business day, the PIC, or designee, shall review discrepancy transactions from an ADDS.
  - 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 ADDS no later than the next business day.
  - 2. If an ADDS has been manually opened during downtime procedures, pharmacy staff shall perform a complete inventory of the ADDS, correlating the last known inventory for ADDS contents against the present inventory of ADDS contents. Differences in inventory shall be accounted for by using a paper Inventory Control Method (ICM) process as specified in the institution's ADDS LOP. All discrepancies shall be identified and reviewed.
- (D) Discrepancy reports shall be reviewed at least 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.
- (E) Unresolved discrepancies or missing medications from an ADDS 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.

**(7) Reconciliation of Controlled Substances**

**(A) Controlled Substances Inventory Managed in an ADDS CSM**

- 1. Whenever possible, controlled substances stored in a pharmacy shall have the inventory managed in an ADDS CSM.
- 2. Upon procurement of new controlled substances from the wholesaler, a physical inventory count shall be performed. The physical count shall be reconciled against the invoice; and all discrepancies are immediately documented on the invoice, reported to the PIC, and corrected with the pharmaceutical wholesaler. Only medication that has been physically counted shall be entered as received into the CSM.
- 3. Each business day, the PIC, or designee, shall reconcile all medication quantities entered into the CSM against the invoice to ensure all controlled substances purchased have been properly added to inventory. Any unresolved reconciliations shall be immediately resolved before the close of the business day.
- 4. Unresolved reconciliations or missing medications from a CSM shall be handled as a theft/loss and immediately reported by the discovering staff to the PIC pursuant to the HCDOM, Section 3.5.21, Break In, Theft/Loss from Pharmacy or Medication Storage Areas.

**(B) Controlled Substance Removed from ADDS for Administration**

- 1. All actions performed on an ADDS generate a transaction record (e.g., issuance, return, waste).
- 2. All ADDS transaction records must be reconciled daily.
- 3. At least once daily, an SRN II/III shall review a report of the previous day that reflects the ADDS transaction of controlled substances versus all administrations as recorded on the MAR in EHRS.
- 4. The SRN II/III shall report on the CDCR 7543 each occurrence of a mismatch between the total units of a controlled substance withdrawn from the ADDS and the total units documented as administered on the MAR. The CDCR 7543 shall be forwarded to the pharmacy once completed. The SRN II/III shall work with the medication line staff to resolve the incident and prevent future incidents.
- 5. The SRN II/III shall compile and review the CDCR 7543 data to identify trends that may indicate process deficiencies. The institution Nursing Subcommittee shall provide oversight, review reported deficiencies, and implement corrective action plans as necessary.
- 6. The PIC, or designee, shall maintain all CDCR 7543 forms in a readily retrievable format. The PIC shall report any concerns about controlled substance medication reconciliation to the institution Medication Management Subcommittee.
- 7. If upon review of the CDCR 7543, a controlled substance reconciliation mismatch cannot be resolved, it shall be considered a true loss. For all true losses, a corrective action plan shall be implemented to prevent future losses.
- 8. All true losses shall be handled as a theft/loss and immediately be reported to the CNE and PIC pursuant to the HCDOM, Section 3.5.21, Break-In, Theft/Loss from Pharmacy or Medication Storage.

**(8) Troubleshooting**

**(A) Reporting ADDS Failure**

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



CALIFORNIA DEPARTMENT OF CORRECTIONS AND REHABILITATION  
CALIFORNIA CORRECTIONAL HEALTH CARE SERVICES  
Health Care Department Operations Manual

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 pharmacy business day.

(B) ADDS Downtime Procedures

1. In the event that a single ADDS malfunctions, the SRN II/III shall post a sign on the cabinet indicating “out of order” and direct licensed health care staff to an alternate ADDS.
  - a. The inoperable ADDS shall remain secured until repaired without accessing the emergency ADDS keys whenever there is a working ADDS within the same or nearby licensed unit.
  - b. As the last resort, the institution shall activate the Total ADDS Downtime Procedures in the LOP.
  - c. When it is necessary to access an ADDS using the ADDS keys, it is the SRN II/III’s responsibility to notify the PIC of emergency access to the ADDS so that the PIC can address the issue the next 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 Omnicell Help Desk at 1-800-910-2220 and provide the serial number located inside the top cabinet of the ADDS. CCHCS maintains a service and repair contract that requires rapid repairs to malfunctioning ADDS machines.
3. In the event of ADDS 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 ADDS within the same or nearby licensed unit, the inoperable ADDS shall remain secured until repaired without accessing the emergency ADDS keys.
  - b. For rare instances when medications are not available without accessing an inoperable ADDS, the LOP shall include the process for accessing emergency ADDS keys. As an ADDS is legally considered part of the correctional pharmacy, these keys must be maintained with the strictest of control.
  - c. Emergency key access to the ADDS
    - 1) The SRN II/III on duty shall be notified of the need for emergency access to the ADDS using the ADDS keys. All SRN II/III shall be trained in the use of keys to access an ADDS during downtime procedures.
    - 2) The CNE, or designee, shall designate the SRN II/III responsible for operation and security of an ADDS opened during downtime procedures. The designated SRN II/III shall maintain and retain all records of transactions during the ADDS downtime until:
      - a) Relieved of their post by another designated SRN II/III; or
      - b) The ADDS unit has been reassembled and secured.
    - 3) Emergency access keys shall be maintained within a tamper-evident, limited-access key box. This key box may be kept by Central Key Control or kept in a location occupied by the CNE or designee.
      - a) If Central Key Control maintains the tamper-evident key box, then routine key control processes shall be followed for checking both the key box and maintenance of the key checkout log.
      - b) If the CNE, or designee, maintains the tamper-evident key box, then it shall be secured with a tamper-evident numbered seal. 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. The CNE, or designee, shall check the seal on the tamper-evident key box each shift to confirm its integrity and record the checking of the tamper-evident seal in a key log. 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/III 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.

CALIFORNIA DEPARTMENT OF CORRECTIONS AND REHABILITATION  
CALIFORNIA CORRECTIONAL HEALTH CARE SERVICES  
Health Care Department Operations Manual

- d. Once the emergency has resolved and the emergency ADDS keys are no longer necessary, the SRN II/IIIs on duty shall pass the keys to the next oncoming SRN II/III 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 ADDS Downtime
  - 1) The SRN II/III using the emergency ADDS keys to access an ADDS 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 ICM.
  - 2) Should the SRN II/III secure the ADDS, 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 pharmacy business day.

**(9) Inspections**

(A) At least weekly, the correctional pharmacy staff shall:

- 1. Audit, review, inspect, and restock medications from the “return bin” of an ADDS. Pharmaceutical returns shall be handled as follows:
  - a. After auditing the quantity of each medication against the expected returns, 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 be disposed of pursuant to the HCDOM, Section 1.2.12, Disposal of Regulated Waste Generated by Health Care Staff.
    - 2) 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 or designees 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) Medications issued by pharmacy as patient-specific shall not be returned to an ADDS return bin. If found, any patient-identifying information shall first be removed. Unusable medications 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.
    - 4) RN Dispense medications issued patient-specific from an ADDS may be returned to the ADDS external return bin if licensed health care staff documents on the label that the medication has not been in the hands of the patient. If found, any patient-identifying information shall first be removed before reissuing.
  - 2. Review null transactions from an ADDS 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, or more frequently as necessary, 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 ADDS.
- 3. Conduct a physical inspection of the drugs to ensure that medications in an ADDS continue to meet drug dating, labeling, and storage requirements (including proper location).
- 4. Inspect an ADDS 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 seven-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 ADDS. Medications shall be

CALIFORNIA DEPARTMENT OF CORRECTIONS AND REHABILITATION  
CALIFORNIA CORRECTIONAL HEALTH CARE SERVICES  
Health Care Department Operations Manual

restocked to ensure that adequate supplies are available for continuity of care and for urgent/emergent patient needs.

- a. When on-hand quantities have fallen below the minimum par level set, the pharmacy shall restock to bring inventory close to maximum par level.
  - b. When on-hand quantities are significantly more than usage, the PIC shall consider reduction of inventory and par levels within the ADDS
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 ADDS 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 ADDS 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 ADDS.
  2. Review items that have not been used recently to determine whether the aging inventory should still occupy a space in the ADDS.
  3. Complete controlled substance recordkeeping, inventory, and reconciliation pursuant to CCR, Title 16, Division 17, Article 2, Section 1715.65, Inventory Reconciliation Report of Controlled Substances and the HCDOM, Section 3.5.16, DEA Scheduled II-V Controlled Substances. Any inconsistencies identified in the reconciliation process shall be handled according to Sections (e)(6)(C) and (e)(6)(D).
- (D) Upon notification from the PIC, or designee, an SRN II/III shall review ADDS reports for appropriate ADDS 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)(6).
  3. Overrides occurring during correctional pharmacy or CFP after-hours service availability, refer to Section (e)(5).
- (E) All reports shall be retained for a minimum of three years.

## 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 4017.3
- California Business and Professions Code, Division 2, Chapter 9, Article 2, Section 4026
- 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 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 1715.1
- California Code of Regulations, Title 16, Division 17, Article 2, Section 1715.65, Inventory Reconciliation Report of Controlled Substances
- 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

CALIFORNIA DEPARTMENT OF CORRECTIONS AND REHABILITATION  
CALIFORNIA CORRECTIONAL HEALTH CARE SERVICES  
Health Care Department Operations Manual

- 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 and Medication Availability
- 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, 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 3.5.25, Inspecting Medication Storage Areas
- Food and Drug Administration Drug Quality Assurance – Drug Repackagers and Relabelers, <https://www.fda.gov/media/75182/download>
- Form 17M-111, Application Instructions Automated Drug Delivery System (ADDS) License at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)
- Form 17A-114, Notification of Discontinuance or Replacement of an Automated Drug Delivery System (ADDS) at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)
- 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](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: 05/2022