3.5.16 DEA Schedule II-V Controlled Substances

(a) Procedure Overview

(1) The correctional pharmacy shall maintain a system of accountability for Drug Enforcement Administration (DEA) Schedule II, III, IV, and V (CII-V) controlled substances. This includes, but is not limited to, documenting purchases, receipt, storage, chart orders, prescriptions, dispensing, administration, return, and destruction for security and audit purposes. The correctional pharmacy shall complete a quarterly reconciliation of all CII controlled substances. All pertinent records and documentation shall be accurately completed and maintained.

(2) CII-V controlled substances shall be stored in automated drug delivery systems (ADDS), whenever possible to maximize security and control. All staff shall follow procedures defined in the Health Care Department Operations Manual (HCDOM), Section 3.5.7, Automated Drug Delivery Systems, for use of an ADDS. All CII-V controlled substances stored within an ADDS are considered correctional pharmacy inventory until they are issued for patient administration.

(3) The theft, loss, and waste of controlled substances shall be reported and documented to comply with federal and state regulations; the HCDOM, Section 3.5.21, Break-In, Theft/Loss From Pharmacy or Medication Storage Areas; and HCDOM, Section 5.1.4, Reporting of Actual or Suspected Incidents of Fraud, Errors, and Improper Governmental Activities.

(b) Purpose

To ensure that CII-V controlled substances are managed and accounted for in compliance with federal and state regulations, are not lost or diverted for misuse or abuse, and breaches of security or losses due to theft or another cause are addressed promptly.

(c) Responsibility

(1) Statewide

California Department of Corrections and Rehabilitation (CDCR) and California Correctional Health Care Services (CCHCS) departmental leadership at all levels of the organization, within the scope of their authority, shall ensure administrative and clinical systems are in place and appropriate tools, training, technical assistance, and levels of resources are available so that licensed health care staff can successfully implement this procedure.

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

The Systemwide P&T Committee shall have overall responsibility for issuing restrictions and limitations on medication inventory.

(3) Institutional

(A) The Chief Executive Officer (CEO) has overall responsibility for ensuring the implementation and enforcement of this procedure.

(B) The Chief Medical Executive shall be responsible for ordering, storage, and provider access to California-approved tamper-resistant prescription blanks.

(C) The Chief Nurse Executive (CNE) shall be responsible for the establishment and maintenance of nursing procedures to provide control and accountability for CII-V controlled substances issued as a patient-specific supply, removed from an ADDS, or obtained during ADDS downtime procedures.

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

1. Establishing and maintaining accountability for and accuracy of CII-V controlled substances within the correctional pharmacy and all ADDS.
2. Compliance with all federal and state laws pertaining to pharmacy and the ordering, storage, management, handling, dispensing, wasting and accountability for controlled substances.
3. Conducting a daily count of all DEA controlled substances which were accessed, received, wasted, dispensed, or removed from usable inventory on that business day.
4. Conducting a weekly count of all DEA controlled substances in the correctional pharmacy.
5. Conducting a monthly count of DEA controlled substances in each ADDS which shall be maintained in the Inventory Control Method (ICM).
6. 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.

7. Confirming prescriptions for CII-V controlled substances dispensed to released patients have been reported to the Controlled Substance Utilization Review and Evaluation System (CURES) in compliance with California Health and Safety Code (HSC), Division 10, Chapter 4, Article 1, Section 11165, Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Department of Justice.
8. Compliance with the Pharmacy Services Controlled Substances Accountability Manual.

(E) Providers authorized to prescribe controlled substances shall:
1. Obtain and maintain a current DEA registration for all controlled substance schedules within their scope of practice to prescribe.
2. Where applicable, obtain and maintain a current X-waiver or DATA waiver from the Substance Abuse and Mental Health Services Administration (SAMHSA) (https://buprenorphine.samhsa.gov/forms/select-practitioner-type.php).
3. Obtain and maintain access to CURES.

(F) Licensed nursing staff shall comply with this procedure including:
1. Proper use of an ADDS.
2. Proper disposition, storage, waste and return of CII-V controlled substances.
3. Proper use of a paper ICM as needed for CII-V controlled substances tracked outside of an ADDS and during ADDS downtime procedures.

(d) Procedure

(1) Institution DEA Registration

(A) Required Registration
1. The PIC and CEO of each institution are responsible for keeping the correctional pharmacy's DEA registration current and accurate.
   a. CCHCS pharmacies must register with the DEA. The registration must be maintained at the registered location and be available for inspection.
   b. The CEO, or designee, shall be the certifying official, and the PIC shall be the registrant on the DEA registration certificate. A separate DEA registration is required for each correctional pharmacy license.
   c. Scanned copies of all DEA registrations and renewals shall be provided to the Statewide Chief of Pharmacy Services via e-mail at pharmacyreports@cdcr.ca.gov.
   d. The PIC shall list their email address with the DEA as the institution contact.
   e. The PIC and CEO are responsible for the timely renewal of the DEA registration which shall be completed online.
2. Where non-patient-specific CII-V controlled substances are to be stored at a licensed unit outside of an ADDS, the location shall possess its own DEA registration. The CEO, in collaboration with the PIC, shall be responsible for keeping a licensed unit's DEA registration current and accurate.
3. Renewal of the DEA registration is required every three years. CDCR institutions are exempt from payment of the registration fees. The registrant shall receive a renewal notice approximately 60 calendar days before the expiration date.

(B) Additional Registrations for Substance Abuse Treatment and Detoxification

A clinic engaged in Schedule II substance abuse treatment and detoxification must obtain:
1. A separate DEA registration as a Narcotic Treatment Program via a DEA Form 363 which may be completed online at the following link: http://www.deadiversion.usdoj.gov/.
2. A completed Narcotic Treatment Program Initial Application (DHCS 5014) with the Department of Health Care Services.
3. Approval and certification by the Center for Substance Abuse Treatment within the SAMHSA (https://www.samhsa.gov/) of the U.S. Department of Health and Human Services as well as the applicable state methadone authority.

(2) Training

All pharmacy staff shall complete the Controlled Substance Learning Management System Training upon hire and annually.

(3) Authority to Prescribe/Order Controlled Substances

(A) Each provider must have their own DEA registration to prescribe/order controlled substances.

(B) Only those providers registered with the DEA and authorized by their respective State of California licensing board shall prescribe/order controlled substances. It is the provider's responsibility to notify the CCHCS Credentials Verification Unit of any changes to their DEA registration.

(C) For advanced practice providers to have authority to prescribe/order controlled substances, they must have a DEA registration, have met applicable State of California licensing board requirements, and prescribe/order within their scope of licensure.

(D) Providers prescribing/ordering Food and Drug Administration approved Schedule III, IV, and V (CIII-V) controlled substances (e.g., buprenorphine) for maintenance and detoxification treatment must obtain an X-waiver or DATA waiver and may only treat up to their patient limit. It is the responsibility of the ordering provider not to exceed the assigned patient limit. A provider may apply for the X-waiver or patient limit increase through SAMHSA at https://buprenorphine.samhsa.gov/forms/select-practitioner-type.php.

1. Institution leadership shall monitor to ensure that a provider does not exceed their X-waiver patient limit.
2. Pursuant to Code of Federal Regulations (CFR), Title 21, Part 1306, Section 1306.07, emergency interim orders can be written without the additional registration if they do not exceed three calendar days and are not renewed.
3. For patients admitted to a licensed Correctional Treatment Center for treatment of a condition other than addiction, providers without an X-waiver may continue approved controlled substances (e.g., methadone, buprenorphine) for maintenance and detoxification treatment. Patients shall continue on the dose as prescribed by the Narcotic Treatment Program; dose may be rounded to the nearest 5-mg dose prescribed and converted to a different formulation.

(E) All pharmacists have the responsibility to ensure that controlled substance prescriptions/orders have been issued by appropriately authorized providers. Pharmacists are unable to dispense controlled substances without the provider bearing the prerequisite valid credentials.

(4) Prescription/Order Requirements for Controlled Substances

(A) CII-V controlled substances shall always be administered under Direct Observation Therapy (DOT) and shall only be dispensed as Keep-On-Person (KOP) for medications at the time of release, following the techniques outlined in the HCDOM, Section 3.2.4, Medication Administration.

(B) Duration of Controlled Substance Orders

Prescription orders that exceed the maximum duration may be changed by the pharmacist to be filled at the maximum allowable duration. The pharmacist shall notify the ordering provider of any change to the prescription order.

1. All initial (new start) orders for CII-V controlled substances shall have a maximum duration of seven calendar days from the date written.
2. The patient shall be evaluated by the primary care team for any change in condition prior to placing an order for additional CII-V controlled substances.
3. Orders for stable CII controlled substances shall have a maximum duration of 30 calendar days and may be written or renewed up to seven calendar days in advance.
4. Taper orders for CII-V controlled substances may be written in their entirety up to and including discontinuation.
5. Hospice or palliative care orders for CII controlled substances shall have a maximum duration of 60 calendar days and may be written or renewed up to seven calendar days in advance.
6. Orders for stable CIII-V controlled substances shall have a maximum duration of 90 calendar days and may be written or renewed up to seven calendar days in advance.

(C) Selection of Controlled Medication

Orders for extended release opioids must be preceded by a trial of an immediate-release formulation unless explicit rationale is given and documented in the health record for departure from this protocol.

(D) Controlled Substance Prescription for Release to an Outside Facility (Transfer, Out-to-Court, Hospital Visit, Probation, Parole, Discharge, Re-entry Program)

1. For controlled substance prescriptions for patients released to an outside facility (including interfacility transfers, out-to-court, hospital visits, probations, paroles, discharges, and re-entry programs), the ordering provider shall first enter the order via computerized provider order entry (CPOE) as soon as feasible, in addition to fulfilling the legal requirements established in federal and state laws.

2. DEA CII controlled substances
   Pursuant to CFR, Title 21, Part 1306, Section 1306.11(a), when a patient is given medication which is a DEA CII controlled substance for administration outside of the institution, it is incumbent on the pharmacist to procure from the prescriber either a DEA compliant Electronic Prescription pursuant to 21 CFR 1311 et seq or a California-approved tamper-resistant prescription blank pursuant to HSC, Section 11162.1 of the California Uniform Controlled Substances Act before dispensing.
3. DEA CIII-V controlled substances
   Pursuant to CFR, Title 21, Part 1306, Section 1306.21(a), a pharmacist may only directly dispense a CIII-V controlled substance pursuant to a DEA compliant electronic prescription, a paper prescription signed by a practitioner on a California-approved tamper-resistant prescription blank or a verbal prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required in Sec. 1306.05, except for the signature of the practitioner.
   a. For verbal prescriptions, the provider shall subsequently call the pharmacy. If the provider has yet to call a pharmacist to deliver the verbal prescription, it is incumbent on the pharmacist to contact the provider to obtain the verbal prescription with readback to ensure a timely dispense.
   b. When accepting a verbal prescription, the pharmacist shall ensure that a verbal order with readback is obtained and reduced to writing. Documentation must include all elements as required by the Pharmacy Services Controlled Substances Accountability Manual. The hard copy of this prescription shall be retained for at least three years.
4. The Chief Medical Executive at each institution shall be responsible for ensuring that California-approved tamper-resistant prescription blanks are procured and secured within the institution and available during correctional pharmacy business hours.

(5) Continuity of Controlled Substance Prescriptions/Orders

(A) Continuity of CII Controlled Substance Prescriptions/Orders

1. Federal law does not permit the transfer of CII controlled substances prescriptions/orders between institutions; therefore, a new prescription/order is required for CII controlled substances prior to administration when a patient transfers from one institution to another.
2. When a patient transfers between CDCR institutions and has a current order for a CII controlled substance, the pharmacist conducting the transfer shall notify the provider or on-call provider for a controlled substance review. The provider at the receiving institution shall be responsible for performing the controlled substance review. If medication continuation is appropriate, the provider must enter a new order.
3. If the pharmacist cannot reach the provider, the pharmacist shall notify the receiving facility's Receiving and Release (R&R) nursing staff via Message Center.
4. The R&R nurse shall contact the provider or on-call provider to complete the controlled substance review. If medication continuation is appropriate, the provider must enter a new order or provide the order to the nurse (telephone with readback for a maximum of 72 hours).

(B) Continuity of CIII-V Controlled Substance Prescriptions/Orders
The Electronic Health Record System is an electronically shared "real-time, online database" shared by all correctional pharmacies. Therefore, prescriptions/orders for CIII-V controlled substances may be transferred for the duration of the active order as permitted by law and the prescriber's authorization pursuant to CFR, Title 21, Chapter II, Part 1306, Section 1306.25, Transfers between Pharmacies of Prescription Information for Schedules III, IV, and V Controlled Substances for Refill Purposes.

(6) Emergency Telephone Orders for CII Controlled Substances

(A) Pursuant to CFR, Title 21, Chapter II, Part 1306, Section 1306.11, Requirement of Prescription, telephone orders are only permitted in emergency situations as follows:

1. The immediate administration of the medication is necessary for proper treatment of the intended patient.
2. No alternative treatment is available (including a medication which is not a CII controlled substance).
3. It is not possible for the prescribing provider to provide a written order for the medication at that time, because a provider is not on site.

(B) Emergency telephone orders for CII controlled substances shall not be permitted if there is a provider on site at the institution with DEA CII controlled substance prescribing privileges. When a provider is not on site, an emergency CII controlled substance telephone order may be given to a licensed nurse.

(C) Emergency telephone CII controlled substance orders shall not exceed 72 hours in duration, and all orders must be signed or electronically authorized via CPOE by the provider within 48 hours or no later than the next business day following a weekend or holiday.

(D) When the provider arrives onsite to sign an order or electronically authorize a CPOE order, a new order for continued therapy shall be written and signed or entered via CPOE when appropriate.

(7) Pharmacy Procurement, Accountability, and Disposal of Controlled Substances

(A) Procurement

1. The PIC shall ensure that a pharmacist, who has the ability to order controlled substances to meet the needs of the institution, is on duty during correctional pharmacy hours.
2. All CII-V controlled substance purchases shall be made through contracted vendors.
3. The CEO, as the certifying official on the DEA registration, must appoint pharmacists with Power of Attorney in sufficient number, in addition to the PIC, to ensure that the institution can order controlled substances without issue. A sample Power of Attorney form is located in the CFR, Title 21, Chapter II, Drug Enforcement Administration, Department of Justice, Section 1305.05 (https://www.deaecom.gov/poa.html).
4. The PIC shall maintain current Power of Attorney forms in the correctional pharmacy's Board of Pharmacy Compliance binder at all times.
5. Controlled substance invoices must be kept separately from other invoices and additionally split into a file for CII controlled substances and a file for CIII-V controlled substances. Purchase records shall be retained for three years in accordance with federal and state regulations.
6. All CII controlled substances shall be procured from the vendor using preferably Controlled Substance Ordering System (CSOS) or, if unavailable, a DEA Form 222.
    a. Procurement Using CSOS
        1) Pharmacists who sign electronic orders to procure CII controlled substances shall enroll with the DEA to acquire their own personal CSOS certificate.
        2) Each pharmacist with a CSOS certificate may procure CII controlled substances for the institution electronically via the CSOS program.
        3) Each pharmacist shall be responsible for utilizing the CSOS program appropriately.
        4) When the "CII order" is received, a copy of the invoice shall be kept in the institution's CII controlled substances procurement file.
    b. Procurement Using DEA Form 222 (obtained by contacting the DEA)
        1) When completing the single-sheet DEA Form 222 for procurement of CII controlled substances, the following shall be included:
            a) The vendor's name and address.
            b) The vendor's description of the drug being requested.
            c) The number of packages and package size being requested for each drug.
            d) The name and strength of each item being requested.
            e) The total number of line items entered on the DEA Form 222.
            f) The registrant's or agent's printed name, signature, and date of DEA Form 222 completion.
        2) The purchaser shall make and retain a copy of the DEA Form 222 and send the original to the supplier.
        3) The purchaser should expect a two to three calendar day turnaround to receive the drug when using the paper process. The supplier shall record its DEA registration number and the number of packages shipped and report the transaction to the DEA.
        4) When the order is received, the purchaser shall record the number of packages received for each item and the date the shipment was received on their copy of the DEA Form 222.
        5) The DEA Form 222 and the corresponding invoice shall be stapled together and filed separately from other invoices in a CII controlled substances procurement file for auditing purposes.
    c. The PIC, or pharmacist designee, is responsible for the receipt of the CII controlled substances.
        1) When receiving the "CII order," a pharmacist shall inspect the "CII order" to ensure the containers are sealed. If the seal is broken, the PIC, or pharmacist designee, shall be notified immediately. The PIC or pharmacist designee shall notify the vendor of the broken seal.

2) The pharmacist receiving the "CII order" shall check the "CII order" against the invoice and sign the invoice indicating the receipt and the date received.

(B) Correctional Pharmacy Controlled Substances Inventory and Reconciliation

1. The PIC is responsible for maintaining all records pertaining to the acquisition and disposition of controlled substances.
2. A Perpetual Inventory Record (PIR) for each controlled substance shall be maintained in either paper or electronic form.
3. The PIC, or pharmacist designee, shall conduct periodic controlled substances inventory and reconciliation functions pursuant to federal and state laws, HCDOM, Section 3.5.25, Inspecting Medication Storage Areas, and the Pharmacy Services Controlled Substances Accountability Manual.
   a. The PIC, or pharmacist designee, shall ensure that a pharmacist conducts a weekly physical count of all controlled substances that are located within the correctional pharmacy and a monthly inventory of all controlled substances contained within an ADDS operated by the correctional pharmacy.
   b. The PIC, or pharmacist designee, shall also conduct a monthly physical inventory of controlled substances in all medication storage areas of the institution where controlled substances are stored outside of an ADDS.
   c. All controlled substance counts used to satisfy the monthly medication storage area, including the inspection of the correctional pharmacy, or ADDS inspection shall occur at the time of the monthly medication area inspection and shall be documented on the CDCR 7477, Medication Storage Area Inspection Checklist.
4. Inventory Reconciliation
   Pursuant to CCR, Title 16, Division 17, Article 2, Section 1715.65, Inventory Activities and Inventory Reconciliation Reports of Controlled Substances, each correctional pharmacy and every licensed correctional clinic shall perform inventory activities and prepare inventory reconciliation reports to detect and prevent the loss of federal controlled substances at least once per quarter.
   a. The PIC, or pharmacist designee, shall review all inventory activities performed and inventory reconciliation reports prepared, and shall establish and maintain secure methods to prevent losses of federal controlled substances. For more information, refer to the frequently asked questions, which can be found at the following link:
      http://www.pharmacy.ca.gov/laws_regs/1715_65_inv_rec_rpt_faq.pdf.
   b. Each inventory reconciliation report shall include all of the following:
      1) A physical count, not an estimate, of all quantities of each federal controlled substance covered by the report that the pharmacy or clinic has in inventory. Where a physical count of an ADDS has been performed pursuant to HCDOM 3.5.25, Inspecting Medication Storage Areas, less than 35 days prior to the inventory reconciliation, the PIC, or pharmacist designee, may utilize the count reported by the ADDS rather than a physical count for the reconciliation being performed;
      2) A review of all acquisitions and dispositions for each federal controlled substance covered by the report since the last inventory reconciliation report covering that controlled substance;
      3) A calculation of expected count on hand which takes the end count from the prior report, adds all acquisitions and subtracts all dispositions;
      4) A comparison between the actual count on hand and the expected count on hand to determine whether discrepancies exist. Records for resolved discrepancies shall be maintained with the inventory reconciliation report. Any remaining discrepancies shall be reported as a loss pursuant to California Code of Regulations, Title 16, Division 17, Article 2, Section 1715.6, Reporting Drug Loss; HCDOM 3.5.21, Break-In, Theft/Loss From Pharmacy or Medication Storage Areas; and the Pharmacy Services Controlled Substances Accountability Manual;
      5) This report and all records used to compile the report shall be maintained in the pharmacy for three years in a readily retrievable form;
      6) Identification of each individual involved in preparing the report; and
      7) Possible causes of overages.
   c. In addition to the pharmacist conducting the reconciliation, the inventory reconciliation report shall be dated and signed by the PIC. Where the PIC conducted the reconciliation, the PIC shall sign indicating

that they performed the reconciliation and that they reviewed the report. An individual may use a digital or electronic signature or biometric identifier in lieu of a physical signature under this section if, in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report. The statement shall be dated and signed and retained on file for three years.

d. A new PIC of a correctional pharmacy shall complete an inventory reconciliation report for all federal controlled substances described within 30 calendar days of becoming the PIC; and whenever possible, an outgoing PIC shall complete an inventory reconciliation report for those controlled substances prior to their departure.
e. For each physical location which stores controlled substances, the PIC shall complete a separate inventory reconciliation report therefore maintaining separate reports for the correctional pharmacy as well as individual reports for each of the ADDS.

5. Annual Inventory
On the first business day of August each year, the PIC, or pharmacist designee, shall conduct an annual physical inventory of all controlled substances that are part of the correctional pharmacy inventory. This includes controlled substances located within the correctional pharmacy and controlled substances contained within an ADDS operated by the correctional pharmacy.
a. The inventory for the correctional pharmacy shall be conducted at the beginning or end of the business day with the date and time noted on the inventory sheet. The inventory for an ADDS shall likewise be noted with the date and time.
b. The inventory record shall be organized as follows:
1) Location (correctional pharmacy vs. each ADDS)
a) CII medications
b) CIII-V medications
2) Details for the controlled substances reconciliation by location
c. The annual inventory shall be conducted in August of each year, and the controlled substances reconciliation shall be considered the reconciliation for the quarter that contains August of each year.
d. If operational barriers exist to performing the annual physical inventory on the first business day of August, written permission from the Statewide Chief of Pharmacy Services, or designee, and regional pharmacy services manager, or designee, shall be obtained. Written permission shall include a specified date by which the inventory shall be performed.
e. The most recent annual inventory conducted shall be used for the biennial inventory required by the DEA pursuant to the CFR, Title 21, Chapter II, Part 1304, Section 1304.11 Inventory Requirements.
f. The inventory record must be signed and dated by the pharmacist conducting the inventory and by the PIC or pharmacist designee.
g. One copy of the physical inventory shall be maintained within the correctional pharmacy for audit purposes, and one copy shall be submitted via e-mail to pharmacyreports@cdcr.ca.gov.

6. Reporting Discrepancies
Any discrepancies shall be investigated by the PIC or pharmacist designee, and discrepancies that cannot be resolved shall be reported as detailed in the HCDOM, Section 3.5.21, Break-In, Theft/Loss from Pharmacy or Medication Storage Areas.

(C) Tracking Movement of Controlled Substances

1. When a licensed unit has an ADDS supplied by the correctional pharmacy, controlled substances shall be stored in the ADDS to the extent possible. Controlled substances not stored in the ADDS shall be provided with patient-specific labeling for individual patient administration.
2. A correctional pharmacy shall use electronic tools as directed by the Statewide Chief of Pharmacy Services, when available, to track all controlled substance transactions relating to the correctional pharmacy controlled substance supply. Transactions tracked include, but are not limited to, the following:
a. Purchases received from wholesaler.
b. Returns sent to wholesaler or reverse distributor.
c. Stock transactions sent to ADDS.
d. Return transactions from ADDS.
e. Patient-specific dispenses or returns by the correctional pharmacy.

f. Patient-specific dispenses from a non-CDCR facility and its immediate destruction within the correctional pharmacy.

3. During downtime procedures, transactions shall be kept on a paper ICM.
4. Controlled substances which have become waste shall be disposed of pursuant to the HCDOM, Section 1.2.12, Disposal of Regulated Waste Generated by Health Care Staff, and recorded electronically with a witness.

(D) Disposal of Controlled Substances from the Correctional Pharmacy

1. Controlled substances removed from an ADDS that require disposal due to expiration date, spoilage, or contamination shall be returned to the correctional pharmacy. These controlled substances shall be added to the controlled substances already stored in the correctional pharmacy for disposal.
2. The correctional pharmacy shall send expired medications to the contracted return vendor for potential credit and/or disposal pursuant to the contracted return vendor's procedures.
   a. The quantity of controlled substances to be sent to the contracted return vendor shall be deducted from the PIR and, when applicable, the pharmacy database.
   b. Controlled substances for disposal that can no longer be used shall be segregated from active stock and inventory for this stock shall be maintained as part of the pharmacy's destruction/return (PIR. This inventory shall be inventoried at least weekly until they are sent to the contracted return vendor. The PIC, or pharmacist designee, shall keep a destruction/return PIR for CII controlled substances and a separate destruction/return PIR for CIII-V controlled substances. The PIC, or pharmacist designee, shall indicate on the destruction/return PIR the date the shipments were sent to the contracted return vendor and, if the shipment is a CII, the number on the DEA Form 222 provided by the contracted return vendor.
   c. For CII controlled substances, the contracted return vendor shall provide the pharmacy with a DEA Form 222. A pharmacist shall include the national drug codes, the quantity for each line item returned, and the date the shipment is physically sent to the contracted return vendor. The pharmacy shall submit the DEA Form 222 to the DEA either by mail to the Registration Section or by email to DEA.Orderforms@usdoj.gov by the close of the month and retain the original copy in its CII file.

(E) For guidance on the DEA process for movement of CII controlled substance inventory between CCHCS pharmacies, refer to the DEA Pharmacist's Manual at the following link: https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-046R1)(EO-DEA154R1)_Pharmacist's_Manual_DEA.pdf.

(8) Licensed Units Ordering, Receiving, and Administering Controlled Substances

Pursuant to the HCDOM, Section 3.5.39, Furnishing or Dispensing Medication to Legally Authorized Persons or Entities: Licensed Correctional Clinics, controlled substances within licensed units shall be handled as follows:

(A) Licensed units are NOT permitted to have stock controlled substances without possessing a DEA registration.

(B) In the absence of a DEA registration, controlled substances for use by the licensed units shall be:

1. Dispensed as patient specific by the correctional pharmacy pursuant to an order and shall bear a label restricting its use to the identified patient; or
2. Maintained within the licensed unit ADDS. All controlled substances within an ADDS are considered a part of the correctional pharmacy and fall under its DEA registration. Furnishing of controlled substances from an ADDS shall occur pursuant to the HCDOM, Section 3.5.7, Automated Drug Delivery Systems.

(9) Controlled Substances in an ADDS

(A) Controlled substances shall only be stored in locking bins within an ADDS and shall be replenished by the correctional pharmacy during pharmacy business hours based upon electronic prompting.

(B) The ICM shall be updated with the data input required prior to removal of controlled substances from the ADDS.

(C) When controlled substances, for any reason, have not been administered to the patient for whom they were withdrawn and the medication remains usable for its intended purpose without being opened or crushed, the medication shall be returned to the ADDS electronic return bin.

(D) When a dose of controlled substance removed from an ADDS is no longer usable for its intended purposes, the waste transaction shall be recorded at an ADDS. The medication shall be disposed of pursuant to the HCDOM, Section 1.2.12, Disposal of Regulated Waste Generated by Health Care Staff. Following which, the disposal shall be recorded by the nurse wasting the controlled substance and the witness at the ADDS.

(E) At the beginning of every controlled substance withdrawal, the licensed nursing staff shall verify the count within the compartment of the ADDS.
1. If the count entered matches the ADDS expectation, then the withdrawal from the compartment occurs and the transaction is complete.
2. If the count entered does not match the ADDS expectation, then a discrepancy is created. A discrepancy message shall be sent via e-mail to designated supervisory staff determined by the institution PIC and CNE. The withdrawal transaction shall be permitted to occur; however, the discrepancy must be addressed as outlined below.
3. All discrepancies shall be addressed and either resolved or verbally reported to the SRN II or Unit Supervisor on duty on the shift in which they were created or found. When the SRN II or Unit Supervisor is unable to resolve a discrepancy, the discrepancy shall be handled in accordance with the HCDOM, Section 3.5.21, Break-in, Theft/Loss from Pharmacy or Medication Storage Areas.

(F) Pharmacy staff shall conduct a physical inventory of all controlled substances in each ADDS no less than once every month. When a discrepancy is discovered, a transaction history and a discrepancy report shall be generated. Any discrepancies discovered during the physical inventory shall be reported to the SRN II or Unit Supervisor on duty. When the pharmacy staff and SRN II or Unit Supervisor are unable to resolve a discrepancy, the discrepancy shall be handled pursuant to HCDOM, Section 3.5.21, Break-in, Theft/Loss from Pharmacy or Medication Storage Areas.

(10) Controlled Substances Utilization, Review and Evaluation System

(A) Pharmacy responsibilities under CURES
1. Pursuant to HSC, Division 10, Chapter 4, Article 1, Section 11165(d), Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Department of Justice, for each prescription for a CII-IV controlled substance, the dispensing pharmacy shall report the specified information to the Department of Justice CURES Program as soon as reasonably possible but not more than one business day after the date a controlled substance is dispensed. Orders written for patients admitted to CDCR institutions are exempt from this requirement until prescriptions are written for a patient leaving the institution such as for release.
2. Up to a 30-day supply of controlled substances may be given to patients at release from CDCR institutions. Controlled substances shall be dispensed pursuant to a written California approved tamper-resistant prescription blank from the provider at the time of release in accordance with the HCDOM, 3.5.28, Medication Continuity with Patient Movement: Transfer/Parole/Discharge/Re-entry Program.
3. Controlled substances dispensed pursuant to a written California approved tamper-resistant prescription blank for CII-IV controlled substances written for the release of a CDCR patient shall be reported within one business day as part of the CURES program.
4. CURES reporting occurs electronically. Information regarding CURES reporting is available on the State of California Board of Pharmacy website.

(B) Prescriber responsibility under CURES
1. All providers authorized to prescribe controlled substances are required to have access to CURES and consult CURES pursuant to HSC, Division 10, Chapter 4, Article 1, Section 11165.4, CURES: Prescribers' Duty Required to Consult CURES.
2. If the first time a provider prescribes a controlled substance to a patient occurs within 12 months of their incarceration, the provider shall consult CURES to review the patient's history of controlled substances.
3. When prescribing a controlled substance for a patient upon release, the provider shall consult CURES.
4. More information regarding mandatory use of CURES for prescribers can be found at the following link: https://www.mbc.ca.gov/Resources/Medical-Resources/CURES/Mandatory-Use.aspx.

References

- Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, United States Code, Title 21, Section 801 et seq.
- Controlled Substances Act, United States Code, Title 21, Section 829, subsection (a)
- Code of Federal Regulations, Title 21, Chapter II, Section 1305.05, Power of Attorney

- Code of Federal Regulations, Title 21, Part 1305, Subpart B, Section 1305.13, DEA Form 222
- Code of Federal Regulations, Title 21, Part 1306, Section 1306.07, Administering or Dispensing of Narcotic Drugs
- Code of Federal Regulations, Title 21, Chapter II, Part 1306, Section 1306.11(d), Requirement of Prescription
- Code of Federal Regulations, Title 21, Chapter II, Part 1306, Section 1306.25, Transfers between Pharmacies of Prescription Information for Schedules III, IV, and V Controlled Substances for Refill Purposes
- Code of Federal Regulations, Title 21, Chapter II, Section 1311.115, Additional Requirements for Two-Factor Authentication
- Code of Federal Regulations, Title 21, Chapter II, Section 1311.116, Additional requirements for Biometrics
- California Business and Professions Code, Division 2, Chapter 9, Article 2, Section 4019
- California Business and Professions Code, Division 2, Chapter 9, Article 2, Section 4036.5
- California Business and Professions Code, Division 2, Chapter 9, Article 2, Section 4040
- California Business and Professions Code, Division 2, Chapter 9, Article 4, Section 4070
- 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 Code of Regulations, Title 16, Division 17, Article 2, Section 1715.6, Reporting Drug Loss
- California Code of Regulations, Title 16, Division 17, Article 2, Section 1715.65, Inventory Activities and Inventory Reconciliation Reports 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 10, Chapter 4, Article 1, Section 11162.1
- California Health and Safety Code, Division 10, Chapter 4, Article 1, Section 11165, Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Department of Justice
- California Health and Safety Code, Division 10, Chapter 4, Article 1, Section 11165.4, CURES: Prescribers' Duty Required to Consult CURES
- Drug Enforcement Administration, Pharmacist's Manual, Section IX, Valid Prescription Requirements
- State of California Board of Pharmacy website: http://www.pharmacy.ca.gov/
- State of California Board of Pharmacy, FAQs: Inventory Reconciliation Regulation, http://www.pharmacy.ca.gov/laws_regs/1715_65_inv_rec_rpt_faq.pdf
- Infinite Solutions, Controlled Substances Utilization, Review and Evaluation System, http://www.4Infinitesolutions.com/cures/
- 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 1, Article 4, Section 1.4.4, Advanced Practice Provider
- 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 3.5.7, Automated Drug Delivery Systems
- 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 3.5.19, Medications Brought from a Non-CDCR Facility
- 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
- Health Care Department Operations Manual, Chapter 3, Article 5, Section 3.5.28, Medication Continuity with Patient Movement: Transfer/Parole/Discharge/Re-entry Program
- Health Care Department Operations Manual, Chapter 3, Article 5, Section 3.5.39, Furnishing or Dispensing Medication to Legally Authorized Persons or Entities: Licensed Correctional Clinics
- Health Care Department Operations Manual, Article 1, Section 5.1.4, Reporting of Actual or Suspected Incidents of Fraud, Errors, and Improper Governmental Activities

- Pharmacy Services Controlled Substances Accountability Manual
  https://cdcr.sharepoint.com/sites/cchcs_lifeline_pharmacy/SitePages/Best-Practices.aspx

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