VOLUME 9: PHARMACY SERVICES	Effective Date: 05/2007
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9.18 ORDERING, SECURING, AND DISPOSING OF DEA SCHEDULE II, III, IV, AND V CONTROLLED SUBSTANCES PROCEDURE	Attachments: Yes ☐ No ☒

I. PROCEDURE OVERVIEW

The 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, dispenses, administration, return, and destruction for security and audit purposes. All pertinent records and documentation shall be accurately completed and maintained.

The theft, loss, and waste of controlled substances shall be reported and documented to comply with federal and state regulations and Inmate Medical Services Policies and Procedures (IMSP&P), Volume 9, Chapter 21, Break-In, Theft/Loss From Pharmacy or Medication Storage Areas.

II. PURPOSE

To ensure that DEA 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.

III. DEFINITIONS

Chart Order (Order): An order, entered on the chart or health record of a patient by or on the order of a provider authorized by law to prescribe/order drugs, shall be authorization for the administration of the drug furnished by the pharmacy.

The order shall be considered a prescription if the medication is given to the patient to store with his/her possessions for self administration while inside a California Department of Corrections and Rehabilitation (CDCR) institution provided that the chart or health record of the patient contains all of the information required by California Business and Professions Code, Sections 4040 and 4070, and the order is signed by the provider.

Disposal: The handling of controlled substances that, due to expiration date, spoilage, or contamination, are no longer suitable for use or returnable to contracted prime or secondary pharmaceutical vendors.

Inventory Control Method: A record of all receipts, administration, and waste or return of controlled substances kept in the medication administration area. The Inventory Control Method (ICM) includes the following data elements:

- Date
- Time
- Patient name
- CDCR number
- Dose
- Amount of waste (if any)
- Reason for waste (when applicable)
- Administered by
- Co-signer (when applicable)
- Names of controlled substances

Medication Administration Area: Any place that stores medications that is located outside of the pharmacy (e.g., medication cart, medication room, nursing stations, or Triage and Treatment Area).

Par Level: An average fixed quantity of an item that must be kept on-hand for daily operations.

Perpetual Inventory Record: An inventory system that continually updates the inventory records to account for each addition to and each subtraction from the inventory.

Physical Inventory: A count of the actual number of units physically present (e.g., tablets/capsules, milliliters, vials).

Prescription: Oral, written, or electronic transmission that is given to the person for whom ordered and is issued by a physician, dentist, optometrist, podiatrist, naturopathic doctor, nurse practitioner, or physician assistant licensed in the State of California.

Procurement: Refers to the purchase of pharmaceuticals by the pharmacy. Various agencies may refer to a procurement as an order. To avoid confusion with the term chart order, "CII order" is used in this procedure regarding the procurement of controlled substances.

IV. PROCEDURE

A. Institution DEA Registration

1. Required registration
   a. The Pharmacist-in-Charge (PIC) and Chief Executive Officer (CEO) of each institution are responsible for keeping the DEA registration current and accurate.
   b. California Correctional Health Care Services (CCHCS) pharmacies must register with the DEA. The registration must be maintained at the registered location and be available for inspection.

c. The institution's CEO or designee shall be the certifying official and the PIC is the registrant on the DEA registration certificate. A separate DEA registration is required for each pharmacy license.
d. 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.

2. Additional Registrations for Substance Abuse Treatment and Detoxification
   a. A clinic engaged in substance abuse treatment and detoxification must obtain 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/.
   b. This activity also requires the approval and certification by the Center for Substance Abuse Treatment within the Substance Abuse and Mental Health Services Administration of the U.S. Department of Health and Human Services as well as the applicable state methadone authority.
3. DEA Renewals
   a. Renewal of the DEA registration is required every three (3) years. CDCR institutions are exempt from payment of the registration fees. The registrant shall receive a renewal notice approximately 60 days before the expiration date.
   b. The PIC or designee is responsible for the timely renewal of the DEA registration which can be completed online.

B. Authority to Prescribe/Order Controlled Substances

Note: Revisions to this section must be concurrently revised with Volume 9, Chapter 9, Prescription/Order Requirements Procedure, Section IV(G).

1. Each provider must have his/her own DEA registration to prescribe/order controlled substances.
2. 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 his/her DEA registration.
3. For mid-level 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.
4. Providers prescribing/ordering Food and Drug Administration approved controlled substances (e.g., methadone, suboxone) for maintenance and detoxification treatment must obtain an additional DEA registration. Emergency interim orders can be written without the additional registration if they do not exceed three (3) days and are not renewed.
5. All pharmacists have the responsibility to ensure that controlled substances prescriptions/orders have been issued by appropriately authorized providers.

C. Prescription/Order Requirements for Controlled Substances

Note: Revisions to this section must be concurrently revised with Volume 9, Chapter 9, Prescription/Order Requirements Procedure, Section IV(H).

1. Duration of Controlled Substance Orders
   a. Orders for CII controlled substances shall have a maximum duration of 60 days from the date written.

b. Orders for CIII-V controlled substances shall have a maximum duration of 150 days from the date written.

2. Controlled Substance Prescription for Parole or Discharge
   a. When a patient is given medication which is a DEA CII-V controlled substance, and the patient will be self administering the medication upon parole or discharge (outside of the institution), a California approved tamper-resistant prescription blank is required pursuant to California Health and Safety Code, Section 11162.1 of the California Uniform Controlled Substances Act.
   b. 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 pharmacy business hours.

D. Continuity of CII Controlled Substance Prescriptions/Orders

Note: Revisions to this section must be concurrently revised with Volume 9, Chapter 9, Prescription/Order Requirements Procedure, Section IV(I).

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 arrives at an institution and has a current prescription/order for a CII controlled substance, the intake nurse shall obtain either a new prescription/order or a discontinuation prescription/order.

E. Telephone Orders for CII Controlled Substances

Note: Revisions to this section must be concurrently revised with Volume 9, Chapter 9, Prescription/Order Requirements Procedure, Section IV(J).

1. As defined by the DEA, telephone orders are only permitted in emergency situations as follows:
   a. The immediate administration of the drug is necessary for proper treatment of the intended patient;
   b. No alternative treatment is available (including a drug which is not a CII controlled substance); and
   c. It is not possible for the prescribing provider to provide a written order for the drug at that time.
2. 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 substances prescribing privileges. When a provider is not on site, an emergency CII controlled substances telephone order may be given to a licensed nurse.
3. Emergency telephone CII controlled substances orders shall not exceed 72 hours in duration, and all orders must be signed or electronically authorized via Computerized Provider Order Entry (CPOE) by the provider within 48 hours or no later than the next business day following a weekend or holiday.
4. When the provider arrives on site 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.

F. Pharmacy Procurement, Accountability, and Disposal of Controlled Substances

1. Procurement
   a. 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 pharmacy hours.
   b. All CII-V controlled substance purchases shall be made through contracted vendors.
   c. Authorization to purchase CII controlled substances rests with the registrant (usually the PIC or pharmacist with Power of Attorney). A sample Power of Attorney form is located in the Code of Federal Regulations, Title 21, Chapter II, Drug Enforcement Administration, Department of Justice, Section 1305.05.
   d. Controlled substances 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 (3) years in accordance with state and federal regulations.
   e. All CII controlled substances shall be procured from the vendor using DEA Form 222 or Controlled Substance Ordering System (CSOS).
      1) Procurement Using DEA Form 222 (obtained by contacting the DEA)
         a) When completing a DEA Form 222 for procurement of CII controlled substances, the following shall be included:
            - The vendor's description of the drug being requested;
            - The number of line items to be procured; and
            - The registrant's or agent's signature.
         b) Forward the original DEA Form 222 and copy to the vendor for processing. Retain the requestor's copy (copy 3) to match with the vendor's invoice upon receipt of the drug. A "CII order" must be placed with the vendor that shall be matched up with the DEA Form 222 being submitted to the vendor. Expect a two (2) to three (3) day turnaround to receive the drug when using the paper process.
         c) When the "CII order" is received from the vendor, the actual number of packages received by the pharmacy shall be entered on the DEA Form 222 with the date they were received. 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.
      2) Procurement Using CSOS
         a) Pharmacists who sign electronic orders to procure CII controlled substances shall enroll with the DEA to acquire their own personal CSOS certificate.
         b) Each pharmacist with a CSOS certificate may procure CII controlled substances for the institution electronically via the CSOS program.
         c) Each pharmacist shall be responsible for utilizing the CSOS program appropriately.
         d) When the "CII order" is received, a copy of the invoice shall be kept in the institution's CII controlled substances procurement file.
      3) The PIC or designee is responsible for the receipt of the CII controlled substances.

a) 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 designee shall be notified immediately. The PIC or designee shall notify the vendor of the broken seal.
b) 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.

2. Pharmacy Controlled Substances Inventory
   a. The PIC is responsible for maintaining all records relating to the acquisition and disposition of controlled substances. This includes, but is not limited to, invoices and quantities received, dispensed, returned, or destroyed.
   b. A perpetual inventory record (PIR) for each controlled substance shall be maintained in both paper and electronic form.
   c. The PIC or designee shall ensure that a pharmacist conducts a monthly physical inventory of all controlled substances in the pharmacy.
   d. The PIC or pharmacist designee shall ensure that there is a monthly physical inventory of controlled substances in all medication administration areas of the institution. This shall occur at the time of the monthly medication area inspection and shall be documented on the CDCR 7477, Medication Area Inspection Checklist.
   e. On the first business day of July each year, the PIC or pharmacist designee shall conduct a physical inventory of all controlled substances stored in the pharmacy.
      1) The inventory shall be conducted at the beginning or end of the business day with the time noted on the inventory sheet.
      2) Any discrepancies shall be investigated by the PIC or pharmacist designee, and discrepancies that cannot be resolved shall be reported as detailed in Volume 9, Chapter 21, Break-In, Theft/Loss from Pharmacy or Medication Storage Areas.
      3) The inventory record must be signed and dated by the PIC or pharmacist designee.
      4) One (1) copy of the physical inventory shall be maintained within the pharmacy for audit purposes, and one (1) copy shall be submitted via e-mail to pharmacyreports@cdcr.ca.gov.
3. Disposal
   a. Controlled substances that require disposal due to expiration date, spoilage, or contamination shall be sent to the contracted vendor for potential credit and/or disposal using the vendor's procedures.
   b. The quantity of controlled substances to be sent to the contractor shall be deducted from the PIR and the pharmacy database.
   c. Controlled substances for disposal that can no longer be used shall be segregated from active stock and entered on a destruction/return PIR and signed by the pharmacist for tracking until they are sent to the 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.
   d. For CII controlled substances, the vendor shall provide DEA Form 222 copies one (1) and two (2) to the pharmacy and retain copy three (3) for the vendor's record.

The pharmacist shall confirm the quantity for each line item by initialing the line and entering the date the shipment is physically sent to the vendor on both copies of the DEA Form 222. Copy one (1) of the DEA Form 222 shall be attached to the CII controlled substance destruction/return PIR and placed in a pharmacy CII controlled substances file. Copy two (2) of the DEA Form 222 shall be sent to the designated DEA office.

4. For guidance on the DEA process for movement of CII controlled substances inventory between CCHCS pharmacies, refer to the DEA Pharmacist's Manual at http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/.

G. Medication Administration Area Ordering, Receiving, and Administration of Controlled Substances

1. The PIC, in collaboration with the Chief Nurse Executive (CNE), shall establish par levels for each medication area where controlled substances are stored and administered to patients.
2. The par levels shall be reviewed on a regular basis [not less than once every six (6) months] by the PIC and CNE at the institution to minimize stock levels and ensure adequate levels of controlled substances.
3. Licensed nursing staff shall use a CDCR 7244, Drug Order, to request controlled substances at an interval agreed upon by the PIC and CNE.
4. Controlled substances shall be securely stored under double lock in the medication area at all times. The CNE shall be responsible for ensuring limited access, key control, and drug accountability for all controlled substances stored in medication administration areas.
5. The ICM shall be used for tracking controlled substances in medication administration areas. The CNE shall ensure use of the ICM by licensed nursing staff.
6. The blank ICM shall be issued by the pharmacy to each medication administration area and each issue shall be tracked by the pharmacy. The completed ICM shall be returned to the pharmacy and maintained for three (3) years from the date of the last entry in accordance with state and federal law.
7. Controlled substances shall be provided by the pharmacy. At the time of the controlled substances delivery, pharmacy staff shall enter each drug and the amount provided into the ICM, and a licensed nursing staff shall verify the quantity of each controlled substance. The pharmacy staff and the licensed nursing staff shall both sign the entry.
8. At every shift change, two (2) licensed nursing staff shall conduct a physical inventory of the controlled substances for accuracy and accountability.
   a. If the count is correct, then both licensed nurses conducting the count shall sign the ICM.
   b. If the count is not correct, it shall be immediately reported to the Supervising Registered Nurse II (SRN II) on duty. The discrepancy shall be handled in accordance with Volume 9, Chapter 21, Break-in, Theft/Loss from Pharmacy or Medication Storage Areas.
9. Each institution shall establish a process for the handling of wasted, contaminated, or expired controlled substances in non-pharmacy medication storage areas. This

process shall include utilizing the ICM for tracking and requires two (2) signatures from licensed nursing staff, pharmacists, or providers in any combination.

H. Controlled Substances in Automated Dispensing Cabinet (ADC, also Known as Omnicell)

1. Controlled substances shall not be maintained in the ADC without the written permission of the Statewide Chief of Pharmacy Services.
2. Where permission has been granted for an ADC to contain controlled substances, the above processes shall be modified to include the following:
   a. Controlled substances shall only be maintained in the locking bin area of the ADC and shall be replenished by pharmacy during pharmacy business hours based upon electronic prompting.
   b. The ICM shall be replaced by the data input required prior to removal of controlled substances from the ADC.
   c. At the beginning of every controlled substance withdrawal, the licensed nursing staff shall verify the count within the compartment of the ADC.
      1) If the count entered matches the ADC expectation, then the withdrawal from the compartment occurs as typical, and the transaction is complete.
      2) If the count entered does not match the ADC expectation, then a discrepancy is created. A discrepancy notification receipt shall print at the ADC and a 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 on duty on the shift in which they were created or found. When the SRN II is unable to resolve a discrepancy, the discrepancy shall be handled in accordance with Volume 9, Chapter 21, Break-in, Theft/Loss from Pharmacy or Medication Storage Areas.
   d. Pharmacy staff shall conduct a physical inventory of all controlled substances in each ADC no less than once every work week. Any discrepancies discovered during the physical inventory shall be reported to the SRN II on duty. When the pharmacy staff and SRN II are unable to resolve a discrepancy, the discrepancy shall be handled in accordance with Volume 9, Chapter 21, Break-in, Theft/Loss from Pharmacy or Medication Storage Areas.

I. Controlled Substances Utilization, Review and Evaluation System (CURES)

1. Up to a 30-day supply of controlled substances may be given to patients at parole/discharge 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 parole/discharge in accordance with IMSP&P, Volume 9, Chapter 28, Parole and Discharge Medications.
2. Controlled substances dispensed pursuant to a written California approved tamper-resistant prescription blank for CII-IV controlled substances shall be reported weekly as part of the CURES program. This requirement applies only to medications the patient takes upon parole, discharge, or transfer from CDCR custody.
3. CURES reporting occurs electronically. Information regarding CURES reporting is available on the State of California Board of Pharmacy website.

V. 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, 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 4040
- California Business and Professions Code, Division 2, Chapter 9, Article 4, Section 4070
- California Health and Safety Code, Division 10, Chapter 4, Article 1, Section 11162.1
- Drug Enforcement Administration, Pharmacist's Manual, Section IX, Valid Prescription Requirements
- State of California Board of Pharmacy website: http://www.pharmacy.ca.gov/
- Infinite Solutions, Controlled Substances Utilization, Review and Evaluation System, http://www.4Infinitesolutions.com/cures/
- California Correctional Health Care Services, Inmate Medical Services Policies & Procedures, Volume 4, Chapter 27B, Physician Assistant Procedure
- California Correctional Health Care Services, Inmate Medical Services Policies & Procedures, Volume 4, Chapter 28B, Nurse Practitioner Procedure
- California Correctional Health Care Services, Inmate Medical Services Policies and Procedures, Volume 9, Chapter 9, Prescription Requirements
- California Correctional Health Care Services, Inmate Medical Services Policies and Procedures, Volume 9, Chapter 21, Break-in, Theft/Loss From Pharmacy or Medication Storage Areas
- California Correctional Health Care Services, Inmate Medical Services Policies and Procedures, Volume 9, Chapter 28, Parole and Discharge Medications