



Department of Pharmacy POLICY AND PROCEDURE

POLICY NUMBER: 889
VERSION: 1

SUBJECT: Controlled Substances Management

PURPOSE:

To establish guidelines and compliance regarding the acquisition, dispensing, administering, record keeping, security, monitoring, and inventory of Controlled Substances

POLICY:

High Desert Regional Health Center Pharmacy shall comply with all Federal and State regulations in the management of Controlled Substances.

PROCEDURE:

1. ORDERING CONTROLLED SUBSTANCES:

- a) All requests for controlled drugs must be made on properly completed pharmacy pink order forms and signed by 2 licensed persons, the requester and the approving nurse.
- b) Schedule II controlled drugs for use in the Clinics (ASC and Urgent Care) shall be ordered by filling out a triplicate DEA 222 order form.
- c) A completed DEA 222 form signed by the Nurse in charge or Nurse Manager, Registered Nurse with power of attorney shall be delivered to pharmacy. The bottom blue copy will be kept at the Clinic, and the top two copies will be sent to the wholesale distributor.
- d) Pharmacy will send the top two copies of the DEA 222 order form to the wholesaler using procedure established for ordering medications for ASC.
- e) For the Urgent Care Clinics, pharmacy will fill the order according to the procedure of Controlled Drugs transfer between licensed pharmacies within High Desert Regional Health Center. Pharmacy will keep the brown copy of DEA222 form and mail the green copy to DEA after filling the order.

- f) Schedule III-V shall be ordered by sending a completed approved narcotic order form signed by the Nurse in Charge of the ASC or designee to the Pharmacy.
- g) For the Urgent Care Clinics, a narcotic refill order will be printed by the Pyxis and the pharmacist will fill the order.

2. TRANSFER CONTROLLED SUBSTANCES :

- a) Controlled substances may be transferred between licensed pharmacies within High Desert Regional Health Center. Schedule II shall be transferred appropriately with DEA 222 form.
- b) Only licensed persons with Power of Attorney in file can sign for the DEA 222 form.
- c) The stock transfer must be entered in the inventory book and in the computer by the pharmacy supplying the controlled substances.
- d) The request (pink) form must be used for the transfer of controlled substances with signatures of the requester and the pharmacist who fills the order.

3. RECEIVING CONTROLLED SUBSTANCES:

a) For the ASC:

- A Pharmacist will receive and sign for delivery of controlled drugs, ensure that all containers are sealed and intact, check stock received against wholesalers invoice, and record lot number and expiration date of each medication received.
- Pharmacy will deliver the medications and invoice to the ASC. Pharmacy will keep a photocopy of all order forms and invoices.
- Quantity of drugs received shall be added to the inventory book by the ASC nurse who will accept and cosign for the transaction.
- Nurse Manager/Charge Nurse will date the blue copy of the DEA222 order form and indicate quantity of each medication received. The DEA 222 form will be kept at the ASC together with the invoice.

b) For the Urgent Care Clinics:

- Only licensed nursing personnel may receive an order for controlled substances. Pharmacy technician will deliver the controlled substances to the clinics. The nurse shall verify the Pyxis refill order form with the medications; sign and check for correctness before the pharmacy technician fill the Pyxis. Pharmacy technician will

sign and enter the drawer and pocket number where he put the controlled drugs.

4. STORAGE AND SECURITY OF CONTROLLED SUBSTANCES:

- a) All controlled substances shall be stored in a locked cabinet or in an Automated Dispensing Machine (Pyxis). If drugs require refrigeration, it will be stored in a locked refrigerator or separate locked box in the refrigerator.
- b) Pharmacy will restock the Pyxis with the controlled substances refill form printed by the Pyxis.
- c) In the ASC, only the nurse in charge or designee will have the keys to access to controlled substances locked in the cabinet.
- d) In the clinics, only licensed personnel, with access to the Pyxis, can remove controlled substances from the Pyxis.
- e) In the Pharmacy, only the Director of Pharmacy, Pharmacy Supervisor, and Staff Pharmacists will be provided with the keys for the Pharmacy Controlled Substance Cabinet and the combination of the Narcotic safe cabinet.
- f) The Narcotic Safe Cabinet and the Controlled Substance Cabinet in the Pharmacy will be kept locked at all times, except when drugs are received, inventoried, dispensed or logged. The Narcotic safe Cabinet and the Controlled Substances Cabinets in the Pharmacy are never to be left open indiscriminately.

5. ADMINISTRATION AND RECORD KEEPING OF CONTROLLED SUBSTANCES;

- a) A Registered Nurse, Licensed Vocational Nurse, CAN, Physician, Nurse Practitioner may administer a Controlled substance only when a signed, legibly written provider order is present in the patient's record.
- b) Records of all controlled substances received, administered or otherwise disposed of shall be kept in each clinic by the Nurse Manager or designee and shall be available for inspection by authorized agencies. These records shall be stored for seven years (BPC Section 4180F2)
- c) Record of Schedule II is to be separate from Schedule III, IV, and V.
- d) All transactions in the Pharmacy must be recorded in the pharmacy log book.

In the ASC:

- a) An entry in the Perpetual Inventory Narcotic (PIN) sheet will be recorded every time a medication is added or subtracted.
- b) Entry in the PIN sheet shall contain the following information:
 - Date and time
 - Name , strength, quantity of the controlled drug
 - Patient's name and medical record number
 - Signature of the person administering the drug
 - Signature of witness if there is wastage
 - Verified inventory count.

Verification of controlled substance inventory count at the beginning and/or end of each shift shall be documented on the PIN sheet signed by two licensed persons. Any discrepancy shall be reported to the Nurse Manager and Medical Director. In addition, a Patient Safety Net (PSN) report will be filled out.

In the Urgent Care Clinics:

- a) All transactions are recorded in the Automated Dispensing Machine (Pyxis).
- b) Two licensed persons verify inventory count at the beginning and end of shift.
- c) A weekly transaction report will be generated and reviewed by a pharmacist for all controlled substances removed and compared with patient's chart.
- d) Any discrepancies shall be reported to pharmacy supervisor and nurse manager to follow up and resolve the discrepancy.

6. UNUSED DOSES, WASTE, LOSS, THEFT, DISPOSAL OF CONTROLLED SUBSTANCES:

Unused doses:

- The nurse will return the item to the Pyxis if the item was not opened.
- Controlled substances removed from their containers, but not administered to patient, drugs accidentally spilled, broken or damaged shall be wasted with a licensed witness in the pharmaceutical waste container and accounted for by documenting in the Pyxis or on the PIN sheet with signatures of two licensed persons.
- For partial unused dose, the nurse shall document the waste with another licensed practitioner in the Pyxis, or on the PIN sheet in ASC.

Expired Controlled Substances

- Expired controlled substances shall be accounted for by deducting them from the inventory with the signatures of two licensed persons and removing them from the inventory.
- Expired drugs will be counted, clearly marked and recorded in the salvage book with signatures of two licensed persons, and stored in a separated area and returned to pharmacy.
- Pharmacy will contact pharmaceutical waste contractor (EXP) for proper disposition.
- Controlled substances picked up by EXP will be listed on form provided by vendor for schedule III, IV or V, or DEA 222 form for schedule II drugs.
- The pharmacy will keep the vendor report for schedule III, IV and V, the brown copy of DEA 222 form for 3 years, and mail the green DEA 222 form to DEA.
- Pharmacy supervisor will check the vendor report and DEA form with the invoice, credits or incineration forms from EXP to ensure that all expired controlled substances are accounted for.

Loss or Theft:**In the pharmacy:**

- If a shortage of a controlled drug is noted in the pharmacy, The Pharmacy Supervisor and the Director of Pharmacy shall be notified immediately.
- Pharmacy Supervisor will conduct an audit trail for the controlled substance to detect and resolve the discrepancy.
- If the audit trail fails to account for the discrepancy, the Director of Pharmacy will issue a "Loss of Controlled Drug Number" noting the kind and quantity of controlled drug missing and the circumstances on the "Lost Controlled Drug Log Sheet"
- The pharmacist in charge will fill in the "lost Controlled Drug Reporting Form" completely and sign the form. The original is kept in the Pharmacy. A copy will be sent to the Medical Director.

In the ASC and the Clinics:

- A controlled substance report shall be filled out for any discrepancy in the controlled substance inventory count, and the discrepancy shall be reported to the Nurse Manager and Medical Director.
- The Nurse Manager and Medical Director shall attempt to resolve the discrepancy by reviewing the records and interviewing personnel involved.

- If the discrepancy cannot be resolved, the Nurse Manager will fill out the “Lost Controlled Substance Report Form” and enter all information in the “Lost narcotic book” or contact the pharmacy to obtain a “Loss narcotic Number”.

Unresolved loss or theft for the pharmacy, the ASC, or the Clinics, will be reported to:

- The DEA
- California State Board of Pharmacy
- Administration
- Medical Director
- Safety Police

7. CONTROLLED SUBSTANCES INVENTORY:

In the Pharmacy:

Monthly inventory of all schedule controlled substances is to be performed by the pharmacist when doing monthly inspection of the pharmacy.

A complete inventory of all schedules II, III, IV and V drugs will be completed by the end of each fiscal year. The annual inventory will be kept on file for a period of at least three years.

In the ASC and Clinics:

The nurse or anesthesiologist dispensing a controlled substance shall verify the count for the medication during the transaction.

Two licensed persons must verify the count and inventory of controlled substances at the beginning and end of shift.

Any discrepancy must be promptly reported to the Nurse Manager or Medical Director.

A biennial inventory of all controlled substances in the pharmacy and all nursing units will be done every even year with initials of the persons who did the inventory and records will be kept for Pharmacy State Board inspection.

Approved By: Romina Panoussi (PHARMACY SERVICES CHIEF II)	
Date: 06/10/2014	Original Date: 04/30/2003
Reviewed: 06/10/2014	Next Review Date: 06/10/2015
Supersedes:	