

**POLICY AND PROCEDURE MANUAL
PHARMACY SERVICES**

CODE: 3.13.0
DATE: 1/4/85
REVISED: 7/17/17, 12/13/17, 4/19/22

SECTION: **INPATIENT PHARMACY SERVICES**

APPROVED: **Thinh Tran, Pharm. D**

SUBJECT: **CONTROLLED SUBSTANCE HANDLING**

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POLICY

The Rancho Los Amigos National Rehabilitation Center (RLANRC) Department of Pharmacy shall comply with all regulations of the Federal and State laws and regulations for controlled substances. This policy reviews the general procedures for the security and handling of controlled substances throughout the hospital. Separate procedures will address specific areas of controlled substances handling, such as procurement, storage, distribution and accountability.

PURPOSE

To establish policy and procedures to comply with the Controlled Substances Act and to provide full accountability of all controlled substances issued to patients within RLANRC.

PROCEDURES

1. Registration

RLANRC is registered with the Drug Enforcement Administration (DEA) as a Hospital/Clinic. The Director of Pharmacy approved Pharmacy designee, by virtue of a Power of Attorney, signs the DEA Form 222. The DEA numbers are available from the Pharmacy Administration for the Inpatient and Outpatient pharmacies.

2. Procurement

- a. Pharmacy orders all Controlled Substances.
- b. Scheduled II controlled drugs are ordered on-line by the narcotic pharmacist
The Narcotic Pharmacist (NP) runs a daily par level report to see which Schedule II controlled drugs need to be ordered. The NP calls the DHS Procurement office for a purchase order number. The order is placed through the online controlled substance ordering system (CSOS). After the order is placed, the Narcotic Pharmacist will digitally sign the order using the CSOS signing certificate. Only those individuals who have been issued a CSOS certificate by the DEA's CSOS Certification Authority may digitally sign for the electronic ordering of Schedule II controlled substances. In lieu of a CSOS certificate, the paper DEA 222 form can be used.
- c. Schedule III, IV and V drugs are procured using the same procurement procedures for non-controlled drugs. Procurement orders are sent to the DHS Procurement office where they are assigned a purchase order number. RLANRC pharmacy DEA numbers are on file with its wholesalers. The procurement assistant at RLANRC places the Schedule III-V drugs.
- d. When received, orders for all controlled substances are verified and entered in the perpetual inventory records by the Narcotic Pharmacist on the electronic DEA form 222 or hardcopy DEA 222 form.

3. Storage and Security

- a. Pyxis C-II Safe
 - i. All controlled substances in the Inpatient Pharmacy are stored in the Pyxis C-II Safe and the Inpatient Pharmacy Pyxis MedStation.

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- ii. Access is allowed only for Pharmacist via user ID and password. The Pyxis C-II Safe System Manager and Narcotic Pharmacist will be responsible for user ID entry, updates and changes. For user ID, first initial and last name (John Smith = jsmith). All users will sign the ID/Password Confidentiality Agreement.
 - iii. No other department , including Security, Safety, or Facilities, shall have access to the Pyxis C-II Safe.
 - b. Pyxis MedStations (Nursing Units, Operating room, Anesthesia ward, PACU and Special Procedures)
 - i. Controlled substances are stored in the Pyxis MedStations on the Nursing Units, and refilled to PAR levels by the Inpatient Pharmacy.
 - ii. The Nursing Administration is responsible for maintaining Pyxis MedStation access by their licensed nursing personnel (see nursing P&P). They will maintain their User ID/Password and Confidentiality Agreement.
 - iii. Administered doses of controlled substances are properly and promptly recorded, by the Registered Nurse, on the patient's Medication Administration Record (MAR). Medications dispensed from the Pyxis MedStation are also electronically recorded and maintained.
 - iv. RLANRC licensed personnel inventories and counts all controlled medications as defined in their Policy and Procedure.
 - v. Count discrepancies are reported to the Pharmacy via the Pyxis MedStation Console. Pyxis online discrepancies will be explained using free text. All discrepancies are to be resolved and documented before the end of the shift.
 - The Supervising Staff Nurse will audit the station's unresolved discrepancies prior to the change of shift. A resolution printout will be given to the Nurse Manager.
 - Discrepancies that cannot be resolved at the station will result in an event notification and follow narcotic loss/theft procedures.
 - Discrepancy resolutions are done on the unit when they occur. Upon resolution the station printout will be saved for the Nurse Manager.
 - vi. The Pharmacy will conduct random periodic, unannounced audits of controlled substances for proper accountability; comparing the Pyxis MedStation report with the patient's MAR. Any irregularities will be reported to the Nurse Manager and Pharmacy Supervisor.
 - vii. Unit dose tablets, capsules and single dose vials will be utilized to reduce the possibility of pilferage. The use of Multi-dose vials or bulk oral medications will be discouraged in the Inpatient Pharmacy.

4. Dispensing of Controlled Substances

- a. Inpatient Pyxis MedStations orders for controlled substances are determined by the Pyxis Refill Delivery Report. After controlled drugs have been refilled into the MedStations, the Narcotic Pharmacist runs a "Pyxis vs. C-II Safe Compare Report",

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which verifies the integrity of the movement of medications between Pyxis C-II Safe and Pyxis MedStations. Any variances will be resolved and documented by the Narcotic Pharmacist.

- b. Only pharmacists are allowed to dispense controlled substances from the Inpatient Pharmacy. The pharmacist screens orders for appropriate quantity, dispenses the correct medication, and keeps a perpetual inventory of all controlled substances. The perpetual record is accessible through the Pyxis C-II Safe. The System Manager and Narcotic Pharmacist will be responsible for maintaining the C-II Safe medication database.
5. Controlled Substance Inventory
 - a. The Narcotic Pharmacist shall perform monthly inventory for all controlled substances in the inpatient pharmacy.
 - b. A Pyxis C-II Safe Discrepancy Report shall be submitted to the pharmacy supervisor whenever a discrepancy is discovered.
 6. Controlled Substance Records
 - a. The following records shall be kept on file for a minimum of 3 years:
 - Controlled Substances Refill form
 - Pyxis MedStation activity receipts (refills, load, unload, outdate etc.)
 - Pyxis C-II Safe Controlled Substances inventory record (stored as an electronic database)
 - Receipts for return of CDAR sheets
 - All C-II Safe Events report
 - Pyxis verses C-II Safe comparison report.
 - b. The following records must be kept on file for a minimum of 3 years:
 - Controlled Drug Administration Record
 - Controlled Substances Salvage Log
 - DEA Form 106 & 222
 - Biennial Controlled Substances Inventory
 - Reference No. 706.1 - Missing/Expired Narcotic Form
 7. Disposition of Controlled Substances
 - a. In the Pharmacy
 - i. Expired controlled medications will be handled by a DEA approved pharmaceutical return processor. RLANRC Department of Pharmacy uses a County approved pharmaceutical waste management company to handle wastage, returns and credit. DEA Form 222 (for C-II only) will be used for transfer of ownership to the approved vendor.
 - ii. Damaged and or contaminated medications will be disposed of in the presence of two pharmacists and documented on the "Controlled Substance Salvage Log" sheet; if the second pharmacist is not available a pharmacy technician can serve as a witness.

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- b. Nursing Units
 - i. Partial doses and full doses not given to the patient (i.e., patient refuses, damaged medication, medication dropped on the floor etc.) shall be disposed of by two licensed nursing personnel. One licensed nurse disposes the medication and the second one acts as the witness. The documentation will be recorded in the Pyxis MedStation under the patient's profile..
 - ii. Upon filling the Pyxis MedStation the earliest outdate will be recorded in the machine. Outdate reports will be generated by the Pharmacy weekly and corrective action taken. The Pharmacy will track and replace all medications as their expiration date approach.
 - c. Anesthesia, Special Procedure, Outpatient Surgery and PACU
 - i. Return controlled substances to the Pyxis MedStation internal return bin. Every Monday, the pharmacy technician empties the MedStation return bin and returns all controlled drugs to the Narcotic Pharmacist.
 - ii. Partial doses not given to the patient shall be disposed of by two licensed personnel. One licensed personnel disposes the medication and the second one acts as the witness. The documentation will be recorded in the Pyxis MedStation.
 - d. Discrepancies
 - i. All dispensing MedStation (Nursing Units, Operating room, Anesthesia ward, PACU and Special Procedures) discrepancies must be resolved as defined in their Policy and Procedure.
 - ii. All filling MedStation and Pyxis C-II Safe discrepancies must be resolved by the Narcotic Pharmacist ASAP.
 - iii. All unresolved discrepancies involving controlled substances must be reported to the pharmacy managers as soon as they are suspected or identified.
8. Reporting Theft or Loss of Controlled Substances
- a. Each licensed nurse/anesthesiologist/Pharmacy staff employed at RLANRC must exercise sufficient judgment to assure safety in the ordering, securing, administering and controlling of controlled substances, and to seek appropriate guidance when necessary.
 - b. Report immediately any improper use or suspicion of improper use of controlled drugs, to respective nurse manager, clinical nursing director, or administrative nursing supervisor.
 - c. If drug diversion is suspected, the Pharmacy Supervisor will investigate and report to the Pharmacy Chief and Facility Police. The incident will be investigated and evaluated such that a corrective action can be taken. The Pharmacy Chief will report the incident to the State Board of Pharmacy and the DEA using online (www.deadiversion.usdoj.gov/webforms/dtlLoginSolicit.do) DEA Form 106.