

DEPARTMENT: Pharmacy

POLICY: PS-80

SUBJECT: Controlled Drugs: Distribution and Accountability (General)

PURPOSE: Controlled drugs shall be distributed, administered, and accounted for in accordance with state and federal laws, rules, and regulations. Controlled drugs include drugs listed in current Federal drug abuse prevention and control acts, and drugs designated by State of Montana regulations.

RESPONSIBILITY:

- Pharmacy Staff
- Nursing
- Medical Staff

POLICY:

All controlled substances in Frances Mahon Deaconess Hospital are under the control of the Director of Pharmacy. Policies and procedures will be developed to cover the handling of all control substances in the hospital. The controlled substances distribution system will provide an audit trail for controlled substances from the time they are received into the pharmacy to the time of use. Units that have automated dispensing machines will be stocked by pharmacy personnel on a regular basis. All controlled substances-stocking records will be kept electronically in the pharmacy. A perpetual daily pharmacy inventory will be kept on all controlled substances with an actual physical inventory performed at least monthly.

PROCEDURE:

- 1) Registration
 - a) FMDH will hold current registration with the Drug Enforcement Administration (DEA).
- 2) Procurement
 - a) Ordering, record-keeping, handling, dispensing, checking, and inventory will follow all applicable Federal and Montana laws.
 - b) Schedule II drugs will be ordered using a DEA form 222 or CSOS. The Pharmacist with POA/Administrator must sign the form. Once signed, the blue copy will be kept in the pharmacy pending the arrival of the ordered medication. The original and remaining copies will be sent to the vendor. Upon arrival of order, the quantity of medication received will be indicated on the blue copy by a designated staff person or pharmacist and will be entered into the perpetual inventory by a designated staff member or pharmacist.
- 3) Storage
 - a) Controlled substance storage areas without MedDispense Units are securely locked. All controlled substances must be double locked when left unattended except when an item requires refrigeration, and then it will be kept in the refrigerator in locked boxes. All compartments in the Automated Units will be kept closed when not being accessed.

- 4) Distribution: Automated Units
 - a) All controlled substances into the Automated Unit on a regular basis by pharmacy personnel. Each dose administered to the patient will be electronically documented through the automated cabinet.
 - b) The pharmacy technician will print a below par report daily for each MedDispense Unit. Controlled substances needed will be obtained and placed with the report to be checked. A Pharmacist must verify the correct drug and count before the drugs are taken to the floor. The technician will then stock the Automated Unit.
 - c) The pharmacist will review a daily printout of medications dispensed from the pharmacy and compare that to the list of medications entered into the floor Automated Units.
 - d) Narcotic usage (administered and wasted) will be documented through the automated Unit. Only one dose is to be given from each dosage unit removed from the machine. If any of the medication is to be wasted, it will be done immediately prior to or immediately following the administration of the correct dose to the patient, and will be witnessed by another individual at the time the drug is wasted. Both individuals must document the waste through the Automated Unit. The remainder of the package (vial, tablet, etc) must be wasted. Controlled drugs that are dispensed but then not used must be returned to the Automated Unit only if the seal has not been broken. If the seal has been broken (example: Carpuject syringes), the medication is to be wasted immediately and witnessed by another individual at the time the drug is wasted
 - e) Any discrepancies involving controlled drugs will be investigated and resolved through the automated Unit. If a discrepancy cannot be accounted for, the unit director or shift coordinator and Pharmacy must be contacted immediately and an Incident Report generated. Nursing floor staff must settle all discrepancies before shift's end.
 - f) All dispensing and restocking records are kept in the pharmacy electronically. These records will be kept according to Federal and State laws.

- 5) Distribution: NON-MedDispense Units
 - a) All floor stock controlled substances will be issued with an accompanying sign-out sheet. Refills will be issued only upon Pharmacy receiving the completed sign-out sheet. A person authorized to administer them will sign for all controlled substances. Discrepancies in the narcotic count are investigated thoroughly. If a discrepancy cannot be accounted for, the unit director or shift coordinator and Pharmacy must be contacted immediately and an Incident report generated; for C II substances, a DEA Form 106 must be executed.
 - b) The person receiving controlled substances must go directly to the appropriate nursing area.
 - c) When a drug is restocked before previously issued doses have been used; all remaining doses must be accounted for.

- 6) Nursing Unit Inventories
 - a) All discrepancies must be thoroughly investigated and records corrected before the staff leaves the floor.
 - b) If a discrepancy cannot be accounted for, the unit director or shift coordinator and Pharmacy must be contacted immediately and an Incident Report completed.

7) Pharmacy Inventory

- a) A perpetual inventory of all Schedule II, III, IV and V medications will be kept of drugs stored in the pharmacy. If a discrepancy cannot be resolved, it is documented and submitted to the DEA annually. If theft is suspected, the Director of Pharmacy should be notified, and the loss must be reported to the DEA. (FORM 106- available online)
- b) An annual inventory of all scheduled medications will be conducted in accordance with federal law.