



CONNECTICUT DEPARTMENT OF
CONSUMER PROTECTION
DRUG CONTROL DIVISION

Extended Care Facility (ECF) Recommendations

Mobile Medication Carts

1. Mobile medication carts shall be of substantial construction and shall incorporate the following security features:
 - a. A separate, lockable, non-removable drawer or compartment for the storage of all controlled substances.
 - b. The key which locks the controlled substance drawer or compartment shall be different from the key(s) to all other locking devices on each cart and such keys shall not be interchangeable between carts within the same facility.
 - c. Locking mechanism(s) which will secure the entire contents of the cart without requiring the use of a key.
2. Mobile medication carts when not in use shall be locked and stored within a limited access locked and enclosed medication room or closet or other substantially constructed enclosed structure.
3. Mobile medication carts shall be securely locked at all times when unattended and locking devices shall be maintained in good working order. In addition, all medication and injection equipment shall be stored within the locked cart.
4. The separate controlled substance drawer or compartment shall be securely locked at all times except for the actual time required to remove or replace needed items or to conduct an audit.
5. The keys to the controlled substance drawer or compartment of each mobile cart shall be separated from the keys to the other locking devices of that cart and shall be carried personally by the nurse responsible for the required controlled substance audit during each nursing shift and no duplicate keys shall be available to other than specifically designated supervisory personnel.

Bi-Monthly Audits, Prescription Blanks and Storage Requirements

1. The director of nursing or his/her nursing supervisor designee shall conduct unannounced documented audits of all controlled substance stock on all units at least twice a month.
2. Practitioner prescription blanks, if kept on the premises, must be securely stored and safeguarded. Access to prescription blanks should be strictly limited and controlled and under no circumstances may pre-signed practitioner prescription blanks be kept or used.

3. All controlled substance stock shall be inventoried when received and immediately placed into the controlled substance drawer or compartment within the mobile cart. Quantities of patients' controlled substance stock stored within mobile medication carts shall be limited to the minimum quantities necessary to provide for normal efficient operation and shall be promptly removed for proper disposition when no longer needed by the patient.
4. Schedule II controlled substance stock in small amounts not exceeding the quantity necessary for normal efficient operation kept at any specific individual area or location shall be stored in a locked substantially constructed non-portable and immobile metal cabinet or metal container within another separate locked enclosure.
5. Schedule III, IV and V controlled substance stock in small amounts not exceeding the quantity necessary for normal efficient operation kept at any specific individual area or location shall be stored with the Schedule II controlled substance stock in compliance with the security measures set forth in #3 above or separately from other drugs and/or substances in a separate secure locked non-portable immobile substantially constructed cabinet or container.
6. Controlled substance stock requiring refrigeration should be secured in a locked refrigerator or locked immobile container within a refrigerator.
7. Access to controlled substance cabinets or containers shall be limited to a minimum number of authorized personnel essential for efficient operation.
8. Controlled substance storage locations shall be securely locked except for the actual time required to remove or replace needed items. Locks shall be kept in good working order with keys removed and said keys shall not be left in a location accessible to other than specifically authorized personnel.
9. Keys for controlled substance cabinets or containers must be kept on two separated holders.
10. Separate covered storage should be provided for medications requiring refrigeration that are stored in the same refrigerator along with foods and/or other non-drug items.
11. "External" use items should be stored separately from "internal" use items.
12. Used needles, syringes, hypodermic units and/or other contaminated injectable equipment should be placed directly into a leak-proof, rigid, puncture-resistant container. The container lid shall be a one-way system to prevent spillage and/or diversion. Disposal containers and contents shall be promptly and properly destroyed in a non-recoverable manner when filled.

Required Controlled Substance Records for Patients

1. Required receipt records for patients' controlled substance stock must be separately maintained and must indicate:
 - a. Date of receipt
 - b. Name and address of the supplier
 - c. Kind and quantity of controlled substance received

2. Required receipt records for patients' controlled substance stock must be separately maintained and must indicate:
 - a. Date of receipt
 - b. Name and address of the supplier
 - c. Kind and quantity of controlled substance received
3. Required disposition records for patients' controlled substance stock must be separately maintained and should indicate:
 - a. Date and time of administering or dispensing
 - b. Name of the patient
 - c. Name of the practitioner
 - d. Kind and quantity of controlled substance administered or dispensed
 - e. Signature of individual administering or dispensing the controlled substance
4. Required destruction records shall be maintained whenever partial or individual doses of controlled substance stock are discarded by nursing personnel and must indicate:
 - a. Name, form, strength and quantity of the controlled substance
 - b. Signature of another nurse witnessing such destruction
5. At the beginning of each work period or shift, a nurse must be assigned responsibility for the security of Schedule II controlled substance stock. Such responsibility shall be assumed by said nurse by preparing a signed inventory indicating:
 - a. Each kind and quantity of Schedule II controlled substance received
 - b. Time and date received
 - c. From whom received

This responsibility shall not be transferred or assigned to another nurse or person during the course of each work period or shift unless another signed inventory transferring responsibility is first prepared.

For mobile cart distribution systems, these requirements are extended to include Schedule III, IV and V controlled substance stock in addition to Schedule II controlled substance stock.

Patient Medication

1. Medications belonging to one specific patient should not be "borrowed" or just taken for administration to a different patient. To minimize or prevent "borrowing", the following should be reviewed and improvements enacted as necessary:
 - a. Drug procurement procedures
 - b. Expediency of receipt of medication orders
 - c. Range of availability of emergency drug supplies

2. The containers of patients' medications obtained pursuant to practitioners' prescriptions must be labeled with the following information:

- a. Name of the patient
- b. Name of the practitioner
- c. Name and address of the pharmacy supplier
- d. Name and strength of each dose

When a pharmacist dispenses a substitute drug product, the label must bear the name of the dispensed drug and if said dispensed drug product does not have a brand name, the label shall indicate the generic name of the drug product dispensed along with the name of the drug manufacturer.

- e. Serial number and date of the prescription or date refilled, if applicable

The printing on the aforementioned labels should be legible and pharmacy suppliers should be immediately advised of those deficiencies that need correction.

3. A policy should be established and maintained to ensure that expired medications will be immediately removed and replaced where indicated.
4. Patient medications which are discontinued, unauthorized or no longer needed for other reasons should be immediately removed from nursing unit locations and properly documented and stored while awaiting appropriate disposition.

Stock Medication (Medication that does not belong to any specific patient)

1. Stock items of over-the-counter medications and/or medical devices should be routinely checked to insure:
 - a. Proper labeling
 - b. Absence of illegibly labeled containers
 - c. Absence of excessive suppliers
 - d. Absence of prescription required non-emergency approved items
 - e. Proper storage conditions (light, temperature, etc.)
 - f. Adequate stock rotation

Emergency Drug Supply – Required Records & Storage Requirements

1. The medical director or practitioner responsible for the controlled substance emergency stock must have a current certificate of registration for this facility from the State of Connecticut Department of Consumer Protection's Drug Control Division, 450 Columbus Boulevard, Suite 901, Hartford, CT 06103 (860-713-6065).
2. The medical director or practitioner responsible for the controlled substance emergency stock must have a current certificate of

registration for this facility from the Federal Drug Enforcement Administration, 716 Brook Street, Rocky Hill, CT 06067 (860-257- 2601) or JFK Federal Building, Room E-400, 15 New Sudbury Street, Boston, MA 02203 (Main Number: 617-557-2100)(Registration Unit: 617-557-2200 or 2201)(Diversion Unit: 617-557-2191).

3. The practitioner registered for the controlled substance stock at this facility is legally responsible for all required controlled substance records and security safeguards pertaining to emergency controlled substance supplies procured pursuant to his/her registration. This applies whether or not the actual procedural steps are delegated to other persons.
4. Required emergency drug supply records (i.e. inventories, receipts and dispositions) must be maintained separately for audit and inspection purposes and cannot be filed with the required records of patients' drug supplies.
5. An annual controlled substance inventory for the controlled substance emergency stock must be conducted on or about May 1st of every year and should include:
 - a. Name, strength, type and amounts of all controlled substances on hand
 - b. Name, address and DEA registration number of the registrant
 - c. Whether the inventory was taken at the opening or closing of business
 - d. Signature of person conducting the inventory

Schedule II controlled substance stock shall be listed separately from Schedule III, IV and V controlled substance stock and said inventory record must be kept in a separate and readily available manner for three years.

6. Required receipt records for the controlled substance emergency stock must be complete, accurate and separately maintained and must be inclusive of:
 - a. Date of receipt
 - b. Name and address of the supplier
 - c. Kind and quantity of controlled substance received
7. Required disposition records for the controlled substance emergency stock must be complete, accurate and separately maintained and must be inclusive of:
 - a. Date and time of administering or dispensing
 - b. Name of the patient
 - c. Kind and quantity of controlled substance administered or dispensed
 - d. Signature of the individual administering or dispensing the controlled substance
8. Required destruction records of unwanted/unusable controlled substance emergency stock must be maintained in a form and manner separate from the required records of destruction of patients' controlled substance stock.

9. Quantities and types of emergency use drugs and medical devices should be limited to the maximum amount deemed sufficient to provide for the immediate medical needs of the patient(s) during an emergency period. Routine reviews of all emergency use drugs and medical device supplies actually on hand and routine re-evaluation of the approved listings should be conducted to insure absence of excessive stocks.
10. Reserve supplies of the duly registered practitioner's Schedule II and III controlled substance emergency stock, if the total is 15 controlled substance units or less, shall be stored in a locked substantially constructed steel or wood cabinet in a securely safeguarded location. If the total quantity of Schedule II and III controlled substance emergency stock is more than 15 controlled substance units, such stock shall be stored in an approved safe.

A controlled substance unit shall be a unit consisting of a quantity of a controlled substance which shall be determined according to the following formula:

#100 tablets or capsules
#1 pint of liquid
½ ounce powder (crystal, flake or granule)
#1 multiple-dose vial
#10 suppositories
#10 single-dose ampules, tubex, dosettes, hyporettes or single-dose package forms

11. Reserve supplies of the duly registered practitioner's Schedule IV and V controlled substance stock shall be stored in a locked substantially constructed steel or wood cabinet in a securely safeguarded location.
12. In no case shall a practitioner's controlled substance emergency stock be left unsecured or in any location accessible to unauthorized persons.
13. Schedule III, IV and V controlled substance stock in small quantities intended for emergency use only, may be stored within an emergency drug kit or on emergency crash carts equipped with disposable locking or sealing devices, provided adequate security measures for such controlled substance stock are maintained and required record-keeping procedures are complied with.
14. Each container of emergency drugs shall be labeled with the:
 - a. Original stock label of the drug manufacturer or
 - b. Name, strength, form and quantity of the drug, expiration date and drug lot number

Unit dose packaging is recommended whenever available.

15. A system of documented checks should be implemented on a scheduled basis to insure the integrity of nursing unit emergency drug supplies. The expiration date of the earliest expiring medication should be clearly labeled on the outside of emergency drug containers, seals should be intact and used items should be promptly replaced.

16. Emergency drug stock (i.e. controlled substance stock, non- controlled substance stock, prescription required medical devices) must be procured by the medical director and said stock must be limited in type and quantity to those specifically documented and authorized by the medical director for use as emergency stock in the facility.
17. Emergency drug stock must only be obtained from a duly licensed pharmacy or wholesaler and a DEA order form is required for the purchase of Schedule II controlled substance stock.

Drug Destructions

1. Controlled substance stock that is no longer required and was obtained pursuant to a practitioner's prescription for an individual patient shall be securely kept and safeguarded until properly disposed of.
2. Non-controlled substance stock that is no longer required and was obtained for use by a specific patient should be securely kept and safeguarded until properly disposed of.
3. Access to controlled substance stock awaiting destruction shall be strictly limited and under no circumstances shall such stock be accessible to other than authorized personnel specifically responsible for security, documentation and insuring proper destruction procedures. Keys/combinations must be kept secure and inaccessible to unauthorized persons.

For each extended care facility, two or more of the following persons may jointly dispose of excess controlled substance stock:

- a. Nursing home administrator
- b. Consultant pharmacist
- c. Director of Nursing Services
- d. Assistant Director of Nursing Services

Such facility shall maintain documentation of any such destruction and disposal for a period of three years and such documentation shall be maintained in a separate log and on a form prescribed by the Department of Consumer Protection.

4. Access to non-controlled substance stock awaiting destruction shall be strictly limited and under no circumstances shall such stock be accessible to other than authorized personnel specifically responsible for security, documentation and destruction of such drugs.
5. Medications no longer needed and not scheduled for return to the individual patient(s) shall be destroyed in a non-recoverable manner. Under no circumstances shall any such drugs be returned to the supplier nor shall any such drugs be retained for the use of any other person.
6. All drugs intended for destruction should be reconciled with the corresponding record(s) to ensure the correct quantities and types are received. Verification should be accomplished before such drugs are placed in the required security location.

7. The list(s) of all drugs intended for destruction shall be maintained current to include all such drugs on hand. Such listings shall indicate:
 - a. Name of the patient
 - b. Name of the supplier
 - c. Prescription number
 - d. Name of the practitioner
 - e. Name, strength and quantity of drug
 - f. In the case of generic medications, the generic name of the drug should be indicated on the listing(s)
8. The list(s) of all drugs awaiting destruction should be kept in a secure location separate from the drugs.
9. The frequency with which the destruction of non-controlled substance and controlled substance stock is made should be closely monitored to insure adequate security and to prevent the accumulation of excessive amounts of such drugs.
10. All records of the destruction of the patients' non-controlled substance and controlled substance stock must be kept for a period of three years and said records must be kept separate from all other records and be readily available for inspection.