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Minimum Security and Safeguard Requirements for Storage and Handling of Controlled Substances

Sec. 21a-262-1. Definitions

(a) **Controlled Substances** means a drug, substance, or immediate precursor so designated as a controlled drug or controlled substance pursuant to state and/or federal drug laws and regulations.

(b) **Schedules of Controlled Substances.** For security purposes, each particular controlled substance shall be considered to be in the schedule as designated in each particular instance by applicable state and/or federal drug laws or regulations. In instances of conflict between state and federal drug laws or regulations, the controlled substances shall be considered to be in the schedule providing the highest degree of control.

(c) **Registrant** means any person of firm registered with the federal government for conduct of any business activity with controlled substances. The person signing the federal application for registration for controlled substances shall be considered to be the registrant for security purposes.

(d) **Classification of Registrants.** For security purposes, registrants shall be classified according to the business activity for which they are registered under the federal controlled substances act.

(e) **Controlled Substance(s) Units:** A controlled substance unit shall be a unit consisting of a quantity of controlled substance(s) which shall be determined according to the following formula:

#100 Tablets or Capsules—shall be 1 unit

One pint of a liquid—shall be 1 unit

$\frac{1}{8}$ ounce of a powder, crystal, flake, or granule—shall be 1 unit

One multiple dose vial—shall be 1 unit

Ten suppositories—shall be 1 unit

Ten single dose Ampules, Tubexes, Dosettes, Hyporettes, or other single dose package forms for injection whether powder or in solution—shall be 1 unit

The quantity of controlled substance(s) stocked by any registrant shall be determined for security purposes by totaling the number of controlled substance(s) units currently on hand. Partial containers of controlled substances shall be considered as being full when determining the total quantity of controlled substance stock. Larger package sizes shall be counted according to the number of controlled substance units they contain. Package sizes less than a full controlled substance unit shall be counted as the fraction of a controlled substance unit which the package size contains, i.e., #50 Tablets shall be counted as .5 controlled substance units.

(f) An approved safe or safe(s) as used in sections 21a-262-1 to 21a-262-10, inclusive, of the Regulations of Connecticut State Agencies means any safe(s) that has been approved prior to January 1, 1975 or any safe(s) which conforms to or exceeds all of the following standards:

(1) Underwriters Laboratories, Inc. certified with a minimum of a B Burglary Rate;

(2) Underwriters Laboratories, Inc. certification as being equipped with a relocking device;

(3) Weight of 750 pounds or more or rendered immobile by being securely anchored to a permanent structure of the building; and

(4) Adequate interior space to store all controlled substances required to be kept within.

(g) An approved vault as used in sections 21a-262-1 to 21a-262-4 inclusive, means a vault approved prior to January 1, 1975 or a vault constructed after January 1, 1975 and meeting the following specifications or equivalent:

(1) Walls, floors, and ceilings constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with 1/2 inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings.

(2) The door of the vault must contain a multiple-position combination lock or the equivalent, a relocking device or equivalent and steel plate with a thickness of at least 1/2 inch. (The GSA Class 5 rated steel door meets all the qualifications for the vault door.)

(3) The vault, if operations require it to remain open for frequent access, must be equipped with a "day gate" which is self-closing and self-locking or the equivalent. If the operation requires only that the vault be opened infrequently, such as to remove raw material in the morning and return raw material at night, and is always relocked immediately after use, a "day gate" is not required.

(4) The walls, floor, and ceiling of the vault must be equipped with an alarm which, when unauthorized entry is attempted, transmits a signal directly to a central station protection company, or a local or state police agency which has a legal responsibility to respond, or a 24-hour control station operated by the registrant. If necessary, due to local conditions or other problems, holdup buttons shall be placed at strategic points of entry to the perimeter area of the vault.

(5) The vault door must be equipped with a contact switch.

(6) The vault must have at least one of the following:

- a. Complete electrical lacing of the walls, floor and ceiling or
- b. Sensitive ultrasonic equipment within the vault or
- c. A sensitive sound accumulator system or
- d. Such other device designed to detect illegal entry as may be approved by the Commissioner of Consumer Protection.

(7) The electrical alarm system must be certified as being an Underwriters Laboratories, Inc., approved system and installation.

(Effective July 27, 1984; amended April 3, 2007)

Sec. 21a-262-2. Security requirements

(a) Requirements for minimum security and safeguard standards for storage and handling of controlled substances may be determined for each registrant by the Commissioner of Consumer Protection after consideration of the protection offered from an overall standpoint in instances wherein other security measures provided exceed those specifically stated. If the registrant has provided other safeguards which can be regarded in toto as an adequate substitute for some element of protection required of such registrant such as supervised watchman service, full electrical protection of the building, electric alarms, etc., such added protection may be taken into account in evaluating overall required security measures. In cases where special hazards exist such as extremely large stock, exposed handling, unusual vulnerability to loss, theft, diversion, or robbery, additional safeguards will be required by the Commissioner of Consumer Protection which may include approved vault(s), approved safe(s), electrical alarm protection, and/or hold up button(s).

(b) In all instances, registrants shall maintain all stocks of controlled substances in all schedules in a secure area or location accessible only to specifically authorized personnel. Such specific authorization should be given by registrants only to the minimum number of employees absolutely essential for efficient operation. All

controlled substances should be stored in such a manner as to prevent theft or diversion of these preparations.

(c) In all instances, registrants shall maintain all equipment used for storage of controlled substances such as approved vault(s), approved safe(s), caged areas, cabinets, enclosures, etc., 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 therefrom. Keys to the locks shall not be left in a location accessible to other than specifically authorized personnel.

(d) Any controlled substance(s) stored at any location not stored in compliance with section 21a-262-1 through section 21a-262-10 inclusive, or at a location other than that for which the person, firm, or business activity is registered under the Federal Controlled Substances Act shall be subject to seizure by the Commissioner of Consumer Protection. This action of seizure shall be considered as being in the best interests of the general public and said Commissioner shall not be held liable for any loss of revenues suffered by the person surrendering the drugs.

(e) Any wholesaler, manufacturer, or laboratory licensed by the Commissioner of Consumer Protection, who after due process, has his license revoked or suspended by said Commissioner, or who does not within 30 days apply for relicensure shall upon loss of said license dispose of his entire stock of controlled substances under conditions approved by the Commissioner or surrender his entire supply of controlled substances to said Commissioner. Any Licensed Pharmacy or any Practitioner who has his license revoked or suspended by his respective Licensing Board or who does not apply for relicensure, shall dispose of his entire stock of Controlled Substances under conditions approved by the Commissioner of Consumer Protection or shall surrender his entire stock of Controlled Substances to said Commissioner. This action of surrender shall be considered as being in the best interest of the general public, and said Commissioner shall not be held liable in any way for any loss of revenue suffered by the person surrendering these drugs.

(f) If any case where a loss, theft, burglary, or diversion of controlled substances has occurred, the Commissioner of Consumer Protection may require additional security safeguards which may include storage of any controlled substance(s) in an approved vault, approved safe, separate locked caged area, locked room or enclosure, or a substantially constructed locked steel or wood cabinet, or under effective electrical protection within 90 days of any such occurrence. In the case of hospitals, 180 days shall be allowed for this purpose.

(g) Registrants shall not maintain any stock of controlled substance(s) in excess of the quantity actually required for normal, efficient operation.

(Effective July 27, 1984)

Sec. 21a-262-3. Disposition of drugs

(a) Disposal of undesired, excess, unauthorized, obsolete, or deteriorated controlled substances shall be made by a registrant, person having title to, enforcement or court official, executor of an estate, or any other person in the following manner:

(1) By transfer to a person or firm registered under the Federal Controlled Substances Act and authorized to possess such controlled substances providing all state and federal required procedures are complied with.

(2) By following procedures as outlined in Sections 307.21 of the Code of Federal Regulations.

(3) By the following manner in the case of hospital pharmacies where small quantities of less than No. 10 controlled substance units are involved on any separate occasion:

(a) By destruction in such a manner as to render the controlled substance(s) nonrecoverable.

(b) By destruction conducted by a Connecticut licensed pharmacist in the presence of another Connecticut licensed pharmacist acting as a witness.

(c) By maintaining a separate record of each such destruction indicating the date, time, manner of destruction, the type, strength, form, and quantity of controlled substance(s) destroyed, and the signatures of the pharmacist destroying the controlled substance(s) and the pharmacist witness.

(4) By a manner rendering the controlled substance(s) nonrecoverable in cases where such controlled substance(s) are legally possessed by a person for his/her own personal use pursuant to a bonafide medical condition.

(5) By surrender without compensation of such controlled substance(s) to the Commissioner of Consumer Protection in all other instances.

(b) Reporting of loss, theft, or unauthorized destruction of controlled substances. Any loss, theft, or unauthorized destruction of any controlled substance(s) must be reported by a registrant within 72 hours of discovery of any such occurrence to the Commissioner of Consumer Protection as follows:

(1) Where through breakage of the container or other accident, otherwise than in transit, controlled substance(s) are lost or destroyed, the registrant shall make a signed statement as to the kinds and quantities of controlled substance(s) lost or destroyed and the circumstances involved. The statement shall be forwarded to the Commissioner of Consumer Protection and a copy retained by the registrant.

(2) Where controlled substance(s) are lost by theft or otherwise lost or destroyed in transit, the consignee, and the consignor if within this state, shall forward to the Commissioner of Consumer Protection a signed statement which details the facts, includes an accurate listing of the controlled substance(s) stolen, lost, or destroyed and specifies that the local authorities were notified. A copy of the statement shall be retained by the registrant.

(Effective July 27, 1984)

Sec. 21a-262-4. Manufacturers, wholesalers, distributors, importers, and exporters

(a) Schedule II Stock if less than No. 250 controlled substance units shall be stored in an approved safe. If No. 250 or more controlled substance units all schedule II controlled substances shall be stored in an approved vault.

(b) Schedule III, IV, V Stock shall be stored in an approved vault, approved safe equipped with a separate effective electrical alarm system, or separate secure locked caged area, room, or enclosure equipped with a separate effective electrical alarm system. If a caged area or enclosure is used, such caged area or enclosure must be completely enclosed. If a caged area is used, construction must be of heavy gauge wire mesh having openings smaller than the smallest controlled substance(s) containers stocked.

(c) All controlled substances in the process of manufacture, distribution, transfer, or analysis shall be stored in such a manner as to prevent diversion; shall be accessible only to the minimum number of specifically authorized personnel essential for efficient operation; and shall be returned to the required security location immediately after completion of the procedure or at the end of the scheduled business day. If a manufacturing process cannot be completed at the end of a working day, the processing area or tanks, vessels, bins, or bulk containers containing controlled

substances must be securely locked inside an area or building which affords adequate security.

(Effective July 27, 1984)

Sec. 21a-262-5. Licensed pharmacies

(a) Schedule II Stock, if less than No. 150 controlled substance units a substantially constructed completely enclosed locked wood or metal cabinet shall be used for storage of all schedule II controlled substance stock. If No. 150 or more controlled substance units an approved safe shall be used for storage of all schedule II controlled substance stock. Pharmacies newly licensed and/or relocating after Jan. 1, 1975 shall be required to store all schedule II controlled substances in an approved safe.

(b) Schedule III, IV, V Stock shall be stored in an approved safe, substantially constructed locked metal or wood cabinet, or dispersed throughout stock within the pharmacy prescription compounding area providing requirements of Section 21a-262-2 (b) are complied with and a loss, theft, or diversion of any controlled substance in any schedule has not occurred.

(c) In every case where loss, theft, burglary, or diversion other than armed robbery during regular scheduled business hours of any controlled substance in any schedule has occurred from a licensed pharmacy, an approved safe shall be required within 90 days of such occurrence for the storage of all schedule II and III controlled substance stock, and additional safeguards shall be required from schedule IV and V controlled substance stock.

(d) The Commissioner of Consumer Protection may require any licensed pharmacy(ies) to store any controlled substance stock in an approved safe, or locked substantially constructed cabinet for security purposes when overall conditions warrant additional safeguards.

(Effective July 27, 1984)

Sec. 21a-262-6. Practitioners including but not limited to medical doctors, dentists, veterinarians, osteopaths, and podiatrists

(a) Schedule II and III Controlled Substance Stock, if total is No. 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 stock is more than 15 controlled substance units, such stock shall be stored in an approved safe. In the case of veterinary practitioners an additional No. 25 controlled substance units of schedule II or III controlled substance stock of the barbiturate-type, for use solely for animal anesthesia or animal euthanasia, may be stored in a locked substantially constructed steel or wood cabinet.

(b) Schedule IV and V Controlled Substance Stock shall be stored in a locked substantially constructed steel or wood cabinet or in a securely safeguarded location.

(c) In no case shall a practitioner's controlled substance stock be left unsecured or unattended in an examining room, treatment room, automobile, or in any other location assessable to nonauthorized persons.

(Effective July 27, 1984)

Sec. 21a-262-7. Laboratories other than hospital clinical laboratories

(a) Schedule I and II Controlled Substance Stock shall be stored in an approved safe except where schedule II stock of the barbiturate type is used solely for its sedative or anesthetic effect on animals and not more than No. 10 Controlled Substance units are stocked, in which cases security as outlined for schedule III controlled substances in Section 21a-262-7 (b) will apply. In instances in laboratories

where schedule I or II stock may be unstable, of extremely small quantity, or of such a nature as to require special storage conditions, the Commissioner of Consumer Protection may approve of other security safeguards on an individual basis in lieu of those required by section 21a-262-1 through 21a-262-10 inclusive.

(b) Schedule III, IV or V Controlled Substances Stock shall be stored separately from other drugs and substances in an approved safe or separate secure locked location accessible only to the minimum number of specifically authorized personnel essential for efficient operation.

(c) Controlled Substances in the process of testing, use, or research shall be immediately returned to the required storage location upon completion of each such process.

(Effective July 27, 1984)

Sec. 21a-262-8. Pharmacies or other areas wherein controlled substances are stored, prepared, or dispensed exclusive of those specifically referred to in section 21a-262-9 and section 21a-262-10 located within licensed hospitals, mental health hospitals, mental retardation facilities, training schools, correctional institutions, juvenile training or youth services facilities, educational institutions, health maintenance organizations, health facilities, and within other care giving institutions or establishments including those which are private, state, or municipally operated, and including hospital drug rooms, hospital satellite pharmacies, and hospital clinical laboratories

(a) Schedule II and III Controlled Substance Stock in quantities of less than No. 150 controlled substance units shall be stored separately from other drugs and substances in a separate secure substantially constructed locked metal or wood cabinet. In the case of Hospital Clinical Laboratories, Schedule II Controlled Substance stock shall be stored in an approved safe.

Schedule II and III controlled substance stock in quantities of No. 150 controlled substance units or more but less than No. 1000 controlled substance units shall be stored in an approved safe.

Schedule II and III controlled substance stock in quantities of No. 1000 controlled substance units or more shall be stored in a completely enclosed masonry room or equivalent equipped with a vault-type steel door with horizontal or vertical locking bolts, having a three-tumbler combination lock and a relocking device. The completely enclosed masonry room or equivalent, if operations require it to be opened for frequent access, must be equipped with a "day gate" which is self-closing and self-locking or the vault type steel door must be equipped with a key locking device or an equivalent day locking device.

Completely enclosed masonry rooms or equivalents constructed after January 1, 1975, must be equipped with an electrical alarm system which, when unauthorized entry is attempted, transmits a signal directly to a central station protection company, or a local or state police agency which has a legal responsibility to respond, or a 24-hour control station operated by the registrant.

(b) Schedule IV and V Controlled Substance Stock shall be stored in a secure location within the pharmacy prescription compounding area or drug room.

Schedule IV and V Controlled Substance Stock stored within hospital clinical laboratories shall be kept in a separate secure locked location.

(c) Controlled Substance Stock within any such pharmacy shall not be accessible to other than specifically authorized pharmacy personnel, and shall be handled by authorized pharmacy personnel only.

(Effective July 27, 1984)

Sec. 21a-262-9. Hospital patient care areas, hospital nursing stations, other hospital drug storage locations, chronic and convalescent nursing homes, rest homes with nursing supervision, children's nursing homes, and areas and locations within correctional and/or juvenile training facilities, youth service facilities, mentally retarded facilities, and any other location other than pharmacies, hospital clinical laboratories, satellite pharmacies, or drug rooms, wherein drugs are stored, prepared, or dispensed not specifically referred to in section 21a-262-1 through section 21a-262-10 inclusive

(a) Schedule II Controlled Substances in small amounts not exceeding the quantity necessary for efficient operation kept at any specific individual area or location shall be stored in a locked substantially constructed nonportable and immobile metal cabinet or metal container within another separate locked enclosure. Keys shall not be the same for each of these locks and such keys shall be kept on two separated key rings or holders. Not more than one set of keys for the schedule II controlled substance cabinets shall be available to nonsupervisory personnel.

(b) 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 each said nurse who shall prepare a signed inventory indicating each kind and quantity of schedule II controlled substance received, the time and date received, and 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 systems regulated under subsection (h) of this section, the requirements of this subsection shall be extended to include schedule III, IV and V controlled substance stock in addition to schedule II controlled substance stock.

(c) Schedule III, IV, V Controlled Substance Stock in small amounts not exceeding the quantity necessary for normal efficient operation of each individual unit shall be stored with Schedule II Controlled Substances in compliance with security measures as required per Section 21a-262-9 (a) or separately from other drugs and/or substances in a separate secure locked nonportable immobile substantially constructed cabinet or container. Access to such cabinet or container shall be limited to a minimum number of personnel essential for efficient operation.

(d) Schedule III, IV, 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.

(e) The same security requirements shall apply for controlled substances obtained pursuant to individual patient(s) prescriptions as for stock controlled substances as outlined under this section 21a-262-9 inclusive. Controlled substances obtained pursuant to such individual patient(s) prescriptions shall not be used for any other patient(s) and when no longer required for the intended specific individual patient, shall be securely kept and safeguarded until properly disposed of.

(f) In cases involving Unit Dose or experimental, trial, new, or innovative drug distribution procedures, the Commissioner of Consumer Protection may approve of other controlled substance(s) security safeguards for a specific time period, in lieu of any required by section 21a-262-1 through section 21a-262-10 inclusive, on an individual basis after evaluating each such drug distribution procedure. Such approval may be extended indefinitely by said Commissioner upon such successful completion of the trial period. If approval is not given by said Commissioner prior

to the implementation of any such drug distribution procedure, controlled substance security requirements as outlined in section 21a-262-1 through section 21a-262-10 inclusive shall apply.

(g) Where unwanted partial or individual doses of Controlled Substances are discarded by nursing personnel, a record of each such destruction must be made indicating the date and time of each such destruction; the name, form, strength, and quantity of Controlled Substance destroyed; the signature of the nurse destroying the Controlled Substance, and the signature of another nurse who witnesses such destruction. In other than hospital locations, an authorized person may witness such destruction.

(h) In cases involving distribution of an individual patient's controlled substance medication by means of the use of mobile medication carts within chronic and convalescent nursing homes, and rest homes with nursing supervision, the following security safeguards shall be approved in lieu of any required by section 21a-262-9 (a) and (c); except that compliance with this subsection shall not be required of a facility using a mobile medication cart system previously approved for use in that facility by the commissioner of consumer protection. Compliance with this subsection by facilities with previously approved systems shall be in lieu of the requirements of such previously approved systems.

(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 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, and

(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. All medication and injection equipment shall be stored within the locked cart. Locking devices shall be maintained in good working order;

(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;

(6) Requirements of section 21a-262-9 (b) concerning audits of controlled substance stocks shall be extended to include schedule III, IV, and V controlled substance stock in addition to schedule II controlled substance stock;

(7) Record keeping entries of controlled substances administered shall be made at the time of administration;

(8) The director of nursing or his/her nursing supervisor designee shall conduct unannounced documented audits of all controlled substance stocks on all units at least twice a month; and

(9) All controlled substance medications shall be inventoried when received and immediately placed into the controlled substance drawer or compartment within the mobile cart. Quantities of patients' controlled substance medications 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.

(i) In cases involving distribution of an individual patient's controlled substance medication by means of the use of mobile medication carts within chronic and convalescent nursing homes, and rest homes with nursing supervision, other security safeguards in lieu of any required by section 21a-262-9 (h) may be approved by the commissioner of consumer protection on an individual basis after evaluating the drug distribution procedure of the applicant for approval pursuant to this subsection.

(Effective July 27, 1984)

Sec. 21a-262-10. Industrial health facilities, educational institution infirmaries, clinics, summer camps, and other institutions or establishments providing health care services including those which are group, private, state, and/or municipally operated

(a) Schedule II and III Controlled Substance Stock, if No. 15 controlled substance units or less shall be stored separate from other drugs and substances in a separate secure substantially constructed locked metal or wood cabinet.

Schedule II and III Controlled Substance Stock if in excess of No. 15 controlled substance units shall be stored in an approved safe.

(b) Schedule IV and V Controlled Substance Stock shall be stored in a separate secure locked location or with Schedule II and III Controlled Substances in compliance with security measures as required per section 21a-262-10 (a).

(c) Controlled Substances for Stock use shall be purchased or obtained by the medical director or physician in charge from a wholesaler or manufacturer of drugs, and shall be handled only by an authorized physician, Connecticut licensed pharmacist, or Connecticut licensed nurse. Controlled substances shall be the property of the medical director or physician in charge who shall be responsible for security requirements and record keeping procedures.

(d) The same security requirements shall apply for controlled substances obtained pursuant to patient(s) prescriptions as for stock controlled substances. Controlled substances obtained pursuant to such individual patient(s) prescriptions shall not be used for any other patient(s) and when no longer required for the intended specific individual patient shall be securely kept and safeguarded until properly disposed of.

(Effective July 27, 1984)