

Notice - This is an unofficial copy of NYCRR Title 10.



Effective Date:

Title: Section **80.47** - Institutional dispensers, limited

80.47 Institutional dispenser, limited. Nursing homes, convalescent homes, health-related facilities, homes for the aged, dispensaries or clinics not qualifying as institutional dispensers in license class 3 shall apply for an institutional dispenser, limited license. Such institutional dispensers qualifying for controlled substances privileges shall obtain a class 3a license from the department. An institutional dispenser licensed in class 3a may administer controlled substances to patients only pursuant to a prescription issued by an authorized physician or other authorized practitioner and filled by a registered pharmacy; except that an institutional dispenser, limited, licensed in class 3a, which is operated as an integral and physical part of a facility licensed as a class 3 institutional dispenser may be provided with bulk stocks of controlled substances obtained pursuant to such class 3 institutional dispenser license. Records of distribution and administration of such bulk stocks of controlled substances shall be kept as provided in section 80.48(a) of this Part.

Effective Date:

Title: Section **80.49** - Records and reports of institutional dispensers, limited

80.49 Records and reports of institutional dispensers limited. (a) All nursing homes, convalescent homes, health-related facilities, homes for the aged and other facilities licensed and authorized by the department as institutional dispensers limited and authorized to possess and distribute controlled substances prescribed for individual patients in their care shall keep a record of all such drugs received in custody and dispensed to patients.

(b) A separate daily running record shall be kept of all prescribed controlled substances received, indicating the date, name and quantity of prescribed controlled substances, name of the prescriber, name of the patient, name of the pharmacy and the serial number of the prescription containing the controlled substance, for patients under their care.

(c) A separate record shall be maintained of the administration of controlled substances indicating the date and hour of administration, name and quantity of controlled substances, name of the prescriber, patient's name, signature of person administering and the balance of the controlled substances on hand after such administration.

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Title: Section **80.50** - Minimum security standards for institutional dispensers, institutional dispensers limited, treatment programs, license holders engaging in research, instructional activities and chemical analysis

80.50 Minimum security standards for institutional dispensers, institutional dispensers limited, treatment programs, license holders engaging in research, instructional activities and chemical analysis.

(a) Reserve or main stocks of controlled substances shall be securely kept as follows:

(1) Schedule I and II controlled substances shall be kept in one of the following secure storage areas:

(i) A GSA class 5 rated steel cabinet or equivalent safe approved by the Bureau of Narcotic Control of the Department of Health. Any cabinet or safe weighing less than 750 pounds shall be bolted or cemented to the floor or wall in such a way that it cannot be removed. The door of the cabinet or safe shall contain a multiple position combination lock, a relocking device or the equivalent, and steel plate having a thickness of at least one-half inch.

(ii) A vault, constructed of substantial masonry and having a multiple position combination lock, a relocking device or the equivalent, and a door having a thickness of steel plate of at least one-half inch. For new construction, floor, walls and ceiling shall not be less than eight inches of reinforced concrete, but less may be accepted where there are compensating extra safeguards.

(2) Schedule III, IV and V controlled substances shall be stored in a securely locked cabinet of substantial construction.

(b) Working stocks of controlled substances of a registered pharmacy may be dispersed throughout the stocks of noncontrolled substances in such a manner as to obstruct theft or diversion provided the conditions of section 80.6 of this Part are met and the pharmacy is locked when not in operation. If not dispersed, controlled substances in Schedules II, III and IV shall be kept in a stationary, securely locked cabinet of substantial construction.

(c) Working stocks of controlled substances for institutional dispensers without a registered pharmacy, treatment programs, license holders engaging in research, instructional activities, and chemical analysis shall be securely kept as follows:

(1) Schedule I, II, III and IV controlled substances shall be kept in stationary, locked double cabinets. Both cabinets, inner and outer, shall have key-locked doors with separate keys; spring locks or combination dial locks are not acceptable. For new construction, cabinets shall be made of steel or other approved metal.

(2) Schedule V controlled substances shall be stored in a stationary, securely locked cabinet of substantial construction.

(3) Limited supplies of controlled substances for use in emergency situations may be stocked in sealed emergency medication kits.

(d) Patient care units of institutional dispensers or institutional dispensers limited shall safeguard substances as follows:

(1) Controlled substances kept as floor stocks on patient care units for general patient use and quantities

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prescribed or ordered for a specific patient which would exceed a 72-hour supply shall be stored as specified in subdivision (c) of this section.

(2) Controlled substances prescribed or ordered for a specific patient in quantities which would not exceed a 72-hour supply may be stored with the patient's other medications at the patient care unit, provided that they are kept in a securely locked medication cart or other storage unit approved by the department.

(3) Medication carts. Schedule II controlled substances may not be stocked in medication carts.

(i) Medication carts may be utilized to stock Schedule III, IV and V controlled substances as provided in paragraph (2) of this subdivision, provided they are equipped with the following:

(a) double-keyed locks;

(b) when not in use, anchored to a floor or wall device or maintained in another secure location;

(c) locked drawer system; and

(d) independent locking device.

(ii) Access to medication carts shall be limited to an identified individual at all times. Such carts are to be used only in conjunction with a pharmacy-maintained patient profile summary.

(4) Records. The following records shall be maintained of controlled substances stocked, dispensed or administered in medication carts:

(i) An order, signed by a person authorized to prescribe under the provisions of this Part, specifying the controlled substances medication for an indicated person or animal.

(ii) A separate record, at the main point of supply for controlled substances, showing the type and strength of each drug, in the form of a running inventory indicating the dates and amounts of such drugs compounded by them or received from other persons and their distribution or use.

(iii) A record of authorized requisitions for such drugs and the distribution to substations or wards should be maintained. Such records shall show delivery to substation or ward by the authorized signature of dispensing personnel. (iv) A record in the patient's chart indicating administration of the controlled substance, including the name of the administering attendant and the date and hour of administration.

(e) Institutional dispensers limited may only possess controlled substances prescribed for individual patient use, pursuant to prescriptions filled in a registered pharmacy. These controlled substances shall be safeguarded as provided in subdivision (d) of this section.

(f) Only controlled substances shall be stored within the storage facilities described in this section, except as noted in subdivisions (b) and (d)(2) of this section.

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Title: Section **80.51** - Surrender and disposal of controlled substances

80.51 Surrender and disposal of controlled substances. (a) As described in this section, the destruction of controlled substances shall mean that the substances have been rendered totally unrecoverable and beyond reclamation.

(b) Single-unit doses or partial doses remaining after the administration or attempted administration of a portion of a liquid or solid unit dose of a controlled substance may be destroyed on the premises of an institutional dispenser by a pharmacist or nurse provided that:

(1) a notation is made on the administration record sheet; and

(2) the destruction is witnessed by a second pharmacist or nurse or other responsible person designated by the administrator.

(c) A person holding a Federal registration number, or who is licensed by the Department under Article 33 of the Public Health Law, or a person with lawful temporary custody possessing controlled substances, which are undesired, deteriorated, obsolete, or for any reason no longer needed shall:

(1) return such controlled substances to the licensed distributor or manufacturer from whom the controlled substances were purchased provided, that a manufacturer or distributor is required to accept only those full packages of controlled substances still in the sealed containers but may accept partial containers if it wishes to do so; or

(2) surrender such controlled substances to such other person approved by the Bureau of Controlled Substances to receive controlled substances for destruction; or

(3) destroy the controlled substances in the presence of a witness who shall be a New York State licensed practitioner, pharmacist or nurse, provided that:

(i) the person shall request from the Department permission to destroy controlled substances at least two weeks prior to the intended destruction. Such requests must be made in writing and must include the following information:

(a) an inventory of controlled substances to be destroyed;

(b) the specific method of destruction to be employed;

(c) the date, time and location of intended destruction;

(d) the identity of at least two persons to conduct and witness the destruction. Such witnesses shall be New York State-licensed practitioners, pharmacists or nurses; and

(e) the reason for the destruction;

(ii) the Department shall determine whether or not to grant approval for the destruction by considering factors that include, but are not limited to:

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- (a) the record of compliance with Article 33 of the Public Health Law by the licensee, its employees, and the persons designated to witness the destruction;
- (b) the type, nature and schedule of the drugs proposed for destruction, including the potential for diversion of such drugs during the destruction process;
- (c) the licensee's pattern and frequency of requests for approval to destroy and of surrenders of controlled substances to the Department;
- (iii) a person may destroy controlled substances only after receiving the written approval of the Department which will include specific protocols for and methods of destruction.
- (iv) if the Department does not grant approval for the person to destroy controlled substances, the person shall surrender the controlled substances to the Department by following the requirements in subdivision (c)(4) of this section;
- (4) surrender the controlled substances to the New York State Department of Health, Bureau of Controlled Substances in the following manner:
 - (i) the person shall request a surrender date from the bureau on which to surrender the controlled substances to the bureau. Such a request shall be made on forms provided by the bureau and must include the following information:
 - (a) an inventory of all controlled substances to be surrendered;
 - (b) the identity of at least two persons who conducted the inventory of the controlled substances to be surrendered. Such persons shall be New York State licensed practitioners, pharmacists or nurses;
 - (c) the reason for the surrender of each controlled substance; and
 - (d) the proposed date of surrender and an alternative date.
 - (ii) a person may surrender controlled substances only after receiving a surrender date in writing from the bureau. The controlled substances must be shipped to the bureau no later than five days from the date the bureau has set as the surrender date. The bureau may set a date different than the date requested by the applicant.
 - (iii) all controlled substances to be surrendered to the bureau must be packaged in the following manner:
 - (a) all solid dosage forms of controlled substances must be packaged by placing each controlled substance in separate, individual, paper packaging only. The package must be properly labeled with the name of the licensee, DEA registration number and the name, strength and quantity of the controlled substance; (b) all liquids, including injectable preparations and prefilled syringes, shall be emptied into individual plastic containers. A label shall be affixed to the container with the name of the licensee, DEA registration number and the name, strength and quantity of the controlled substance. Glass containers are prohibited;
 - (c) no needles or syringes shall be surrendered to the Department for destruction; or
- (5) surrender the controlled substances to the federal Drug Enforcement Administration, or its successor agency.

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(d) Recordkeeping requirements.

(1) Any person disposing of a controlled substance by returning it to the distributor or to the manufacturer, by destroying the controlled substance in the presence of a witness, or by surrendering it to the Department, must maintain a written record containing:

(i) date of return or destruction;

(ii) name, form, quantity of the substance returned or destroyed;

(iii) name, address, registry number of the person making the return;

(iv) name, address, registry number of the supplier or manufacturer to whom the substances are returned or the name and license number of the persons performing and witnessing the destruction.

(2) Any distributor or manufacturer receiving such controlled substances shall keep a record of those controlled substances received and include:

(i) the name, address, registry number of the person making the return;

(ii) the name, form and quantity of the substance returned; and

(iii) the date the substance was received.

(3) Any person surrendering controlled substances to the Drug Enforcement Administration shall maintain records of such surrenders as may be required by that agency.

(4) Any record required to be kept under this section shall be kept for a period of five years.

(e) Persons licensed under Article 33 of the Public Health Law as manufacturers or distributors may destroy controlled substances on their premises providing that federal Drug Enforcement Administration approval is obtained and a copy of such approval is filed with the Department within 30 days of the receipt of such approval.