

# **Part 80 - Rules and Regulations on Controlled Substances**

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Public Health Law, Sections 338, 3300, 3305, 3307, 3308, 3309, 3381, 3701(1), (6), art. 33

## **GENERAL PROVISIONS**

### **Section 80.1 - Definitions**

#### **GENERAL PROVISIONS**

Section 80.1 Definitions. Except where different meanings are expressly specified, the terms used in this Part shall have the meanings set forth in Public Health Law, section 3302.

(a) Authorized practitioner and practitioner means practitioner as such term is defined in the Public Health Law (section 3302(28)), and shall include certified nurse practitioners and licensed midwives certified by the Education Department to prescribe and administer drugs. The term shall also include registered physician's assistants certified by the Education Department.

(b) GSA means the United States General Services Administration.

(c) Department means the Department of Health of the State of New York.

(d) Commissioner means the Commissioner of Health of the State of New York.

(e) Bureau of Narcotic Enforcement means the Bureau of Narcotic Enforcement of the Department of Health of the State of New York.

(f) Drug Enforcement Administration registration number means such number assigned by the Drug Enforcement Administration, United State Department of Justice, or its successor agency, to a practitioner, authorized practitioner, or any person authorized to manufacture, distribute, sell, dispense or administer controlled substances.

(g) Automated dispensing system means a system approved by the Department that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of controlled substances, and which collects, controls, and maintains all transaction information.

(h) Digital signature means a record created when a file is algorithmically transformed into a fixed length digest that is then encrypted using an asymmetric cryptographic private key associated with a digital certificate. The combination of the encryption and algorithm transformation ensure that the signer's identity and the integrity of the file can be confirmed.

(i) Electronic signature means the creation of an electronic identifier (i.e. an electronic sound, symbol, or process, attached to or logically associated with an electronic record and executed or adopted by a person with the intent to sign the record) in accordance with regulations of the commissioner and the commissioner of education.

(j) Written prescription, for the purposes of this Part, and issued in New York State, shall mean an official New York State prescription form.

(k) Compliance with the requirements of this Part does not alter the responsibilities of the practitioner, pharmacist or pharmacy to comply with any applicable federal law or regulation.

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## **Section 80.2 - Exemptions**

### 80.2 Exemptions.

(a) Pursuant to section 3305 of the Public Health Law, the provisions of this Part restricting the possession of controlled substances shall not apply to:

(1) common carriers or warehousemen while engaged in lawfully transporting or storing such substances or to any employee of the same acting within the scope of his employment;

(2) public officers or their employees in the lawful performance of their official duties requiring possession of controlled substances;

(3) temporary incidental possession by employees or agents of persons lawfully entitled to possession or by persons whose possession is for the purpose of aiding public officers in performing their official duties;

(4) a person in the employ of the United States government, its territories, districts or insular governments by reason of his official duties;

(5) a master of a ship or a person in charge of any aircraft upon which a physician is not regularly employed; or

(6) a duly authorized agent of an incorporated society for the prevention of cruelty to animals or a municipal animal control facility for the limited purpose of purchasing, possessing and dispensing sodium pentobarbital to registered and certified personnel, to euthanize animals and ketamine hydrochloride to anesthetize animals prior to euthanasia.

(b) The provisions of article 33 with respect to the payment of fees and costs shall not apply to the State of New York or any political subdivision thereof or any agency or instrumentality of either.

(c) The following exemptions are granted to the possession and use of schedule III or IV substances as part of an industrial process or manufacture of substances other than drugs: None.

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### **Section 80.3 - Exceptions, reclassification and exemptions of scheduled controlled substances**

80.3 Exceptions, reclassification and exemptions of scheduled controlled substances. (a) Exemptions.

(1) Those nonnarcotic substances listed in section 1308.22 of title 21 of the Code of Federal Regulations, currently and as thereafter amended, are excepted from the application of sections 3306 and 3319 of the Public Health Law.

(2) Those drugs, which are restricted by law to dispensing on prescription, listed in section 1308.32 of title 21 of the Code of Federal Regulations, currently and as thereafter amended, are excepted from the application of sections 3306 and 3319 of the Public Health Law.

(3) Those chemical preparations and mixtures listed in section 1308.24 of title 21 of the Code of Federal Regulations, currently and as thereafter amended, are excepted from the application of sections 3306 and 3319 of the Public Health Law.

(4) The following compounds, mixtures or preparations containing a narcotic antagonist substance having no potential for abuse, and being excepted or exempted from control under the Federal Controlled Substances Act (21 USC 801 et seq.) are excepted from the application of sections 3306 and 3319 of the Public Health Law:

(i) naloxone and its salts; and

(ii) naltrexone and its salts.

(b) Reclassifications. The following drugs listed in schedule II(c) of section 3306 of the Public Health Law are hereby reclassified as schedule III substances.

TRADE NAME OR OTHER DESIGNATION	COMPOSITION	MANUFACTURER OR SUPPLIER
Mediatric-tablets, capsules and liquid	<p>Tablet and capsule:  Conjugated estrogens-equine (Premarin (R)), 0.25 mg.;  Methyltestosterone, 2.5 mg.;  Ascorbic Acid (Vit. C) 100 mg. (for capsules, provided as ascorbic acid, 70 mg. and as Sodium ascorbate, 30 mg.);  Cyanocobalamin, 2.5 mcg.;  Thiamine mononitrate, 10.0 mg.;  Riboflavin, 5.0 mg.;  Niacin-amide, 50.0 mg.;  Pyridoxine HCl, 3.0 mg.;  Calc. panto thenate, 20.0 mg.;  Ferrous sulfate exsic., 30.0 mg.;  Methamphetamine HCl, 1.0 mg. Liquid: Premarin (R)(Conjugated estrogens, (U.S.P.), 0.25 mg.;  Methyltestosterone, 2.5 mg.;  Thiamine HCl, 5.0 mg.;  Cyanocobalamin, 1.5 mcg.;  Methamphetamine HCl, 10 mg.;  Alcohol, 15%.</p>	Ayerst
Phelantin-Kapseals	<p>Phenobarbital (1/2gr) 30 mg.;  Dilantin (Diphenylhydantoin)(1-1/2gr) 100 mg.;  Methamphetamine Hydrochloride 2.5 mg.</p>	Parke-Davis

(c) Exemptions. The following compounds, mixtures or preparations containing an anabolic steroid listed in subdivision (h) of Schedule II of Section 3306 of the Public Health Law have ingredients included therein in such combinations, quantity, proportion or concentration as to reduce substantially the potential for abuse and, therefore, are exempted from the requirements of Public Health Law Article 33:

TRADE NAME	COMPOSITION	MANUFACTURER OF SUPPLIER
Estratest	Esterified estrogens (1.25mg); Methyl- testosterone (2.5mg)	Solvay Pharmaceuticals Marietta, GA
Estratest HS	Esterified estrogens (0.625mg); Methyl- testosterone (1.25mg)	Solvay Pharmaceuticals Marietta, GA
Premarin with Methyltestosterone	Conjugated estrogens (0.625 mg); Methyl-testosterone (5.0mg)	Wyeth-Ayerst Laboratories Philadelphia, PA
Premarin with Methyltestosterone	Conjugated estrogens (1.25mg); Methyl-testosterone (10mg)	Wyeth-Ayerst Laboratories Philadelphia, PA

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Public Health Law, Section 3307

#### **Section 80.4 - Habit-forming drugs**

80.4 Habit-forming drugs. The following chemical derivatives of barbituric acid, a substance named in section 502(d) of the Federal Food, Drug and Cosmetic Act, are hereby designated as habit-forming:

CHART - PARENT SUBSTANCE--BARBITURIC ACID (refer to pages 228.2f1 H 4-30-74 through 228.2g H 4-30-77)

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## **Section 80.5 - Licenses**

80.5 Licenses. (a) Licenses for controlled substances privileges shall be issued by the department in the following classifications:

### *Class Issued to:*

Manufacturers and distributors

1 Manufacturer

1a Manufacturer out-of-State

2 Distributor

2a Distributor out-of-State

### *Institutional dispenser*

3 Institutional dispenser

3a Institutional dispenser, limited

### *Research and instructional*

4 Researcher--II to V

4a Researcher--Special industrial II to V

5 Instructional activities--II to V

6 Treatment programs, methadone

6a Treatment programs, methadone and other substances

6b Hospital pharmacies--detoxification, temporary treatment

7 Research and instructional activities--I

8 Analytical laboratories

### *Importers and exporters*

## 9 Importer

### 9a Importer broker

## 10 Exporter

### 10a Exporter broker

## *Registered Community Pharmacy*

### 11 Registered Community Pharmacy--Automated dispensing system

(1) A person licensed to manufacture or import any controlled substance shall be authorized to distribute that substance, but no other substance which he is not licensed to manufacture or import;

(2) A person licensed to manufacture any controlled substance listed in schedules II through V shall be authorized to conduct chemical analysis and preclinical research (including quality control analysis) with narcotic and non-narcotic controlled substances listed in those schedules in which he is authorized to manufacture;

(3) A person licensed to conduct research with a controlled substance listed in schedule I shall be authorized to manufacture such class if, and to the extent that, such manufacture is set forth in the research protocol filed with the application for license and to distribute such class to other persons licensed or authorized to conduct research with such class or licensed or authorized to conduct chemical analysis with controlled substances;

(4) A person licensed or authorized to conduct chemical analysis with controlled substances shall be authorized to manufacture and import such substances for analytical or instructional purposes, to distribute such substances to other persons licensed or authorized to conduct chemical analysis or instructional activities or research with such substances and to persons exempted from license pursuant to section 3305 of Public Health Law, to export such substances to persons in other countries performing chemical analysis or enforcing laws relating to controlled substances or drugs in those countries, and to conduct instructional activities with controlled substances; and

(5) A person licensed or authorized to conduct research with controlled substances listed in schedules II through V shall be authorized to conduct chemical analysis with controlled substances listed in those schedules in which he is authorized to conduct research to manufacture such substances if, and to the extent that, such manufacture is set forth in a statement filed with the application for license, and to distribute such substances to other persons licensed or authorized to conduct chemical analysis, instructional activities, or research with, such substances and to persons exempted from licensing under section 3305 of the Public Health Law, and to conduct instructional activities with controlled substances;

(6) A person licensed to dispense controlled substances listed in schedules II through V shall be authorized to conduct research and to conduct instructional activities with those substances.

(7) A single license to engage in any group of independent activities may include one or more controlled substances listed in the schedules authorized in that group of independent activities.

(8) A separate license is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed or dispensed by a person.

(9) The following locations shall be deemed not to be places where controlled substances are manufactured, distributed or dispensed:

(i) a warehouse where controlled substances are stored by or on behalf of a licensed person, unless such substances are distributed directly from such warehouse other than the licensed location from which the substances were delivered or to persons not required to be licensed in accordance with section 3305 of the Public Health Law;

(ii) an office used by agents of a licensee where sales of controlled substances are solicited, made or supervised, but which neither contains such substances nor serves as a distribution point for filling sales orders; and

(iii) an office used by a practitioner (who is registered at another location) where controlled substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled substances are maintained.

(b) Holders of licenses shall register with the appropriate Federal agency or agencies in the comparable controlled substances schedule and license class provided for under Federal regulations.

(c) A controlled substances license shall be permanently displayed in the place to which it applies.

(d) No controlled substances license shall be considered valid and in good standing unless the indicated activity is conducted at the address stated therein and by the person in whose name the license has been issued and unless the license has been renewed as required.

(e) A controlled substances license shall be promptly returned to the department upon revocation or suspension, or when the activity for which the applicant is licensed has been discontinued.

(f) A registered community pharmacy licensed in class 11 and maintaining a separate registration with the Drug Enforcement Administration may install and operate automated dispensing systems in a Residential Health Care Facility ("RHCF") which is licensed or approved by the Department.

(g) A registered community pharmacy operating an automated dispensing system as provided in paragraph (f) of this section shall provide to such system only those controlled substances obtained under the Drug Enforcement Administration registration of the registered community



pharmacy and not the Drug Enforcement Administration registration of the automated dispensing system.

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## **Section 80.6 - Safeguarding controlled substances**

80.6 Safeguarding controlled substances.

(a) Controlled substances shall at all times be properly safeguarded and securely kept at the address on file with the Drug Enforcement Administration and which is used in the ordering of the controlled substances, where they will be available for inspection by properly authorized officers, agents and employees of the New York State Department of Health, Bureau of Narcotic Enforcement.

(b) Access to controlled substances stocks shall be limited to the minimum number of employees actually required to efficiently handle the manufacture, distribution, custody, dispensing, administration or other handling of such substances.

(c) The administrative head of a licensee hospital, laboratory, dispensary, nursing home and health-related facility and the supervisor of a manufacturer or distributor is responsible for the proper safeguarding and handling of controlled substances within the hospital or other facility. An administrative head or supervisor is not relieved of his responsibility to detect and correct any diversion or mishandling of controlled substances by a delegation of responsibility.

(d) Persons operating pharmacies and supervising pharmacists of such pharmacies are responsible for the proper safeguarding and handling of controlled substances within the pharmacy. Persons operating pharmacies and supervising pharmacists are not relieved of their responsibility to detect and correct any diversion or mishandling of controlled substances by a delegation of responsibility.

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## **MANUFACTURERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS**

### **Section 80.10 - Unlicensed activity**

MANUFACTURERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS

80.10 Unlicensed activity. (a) Except as provided for in section 80.5 of this Part, no person shall act as a manufacturer, distributor, importer or exporter of controlled substances in this State without first having obtained a license from the department.

(b) Holders of licenses in such categories shall register with the appropriate Federal agency or agencies in the comparable controlled substances schedules and license class provided for under Federal regulations.

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### **Section 80.11 - Additional requirements for manufacturers and distributors**

80.11 Additional requirements for manufacturers and distributors. In addition to the requirements set forth in article 33 of the Public Health Law, holders of licenses shall comply with the following requirements:

(a) A class 1 manufacturer who produces a final product that by its composition or combination with other ingredients is intended for human or animal consumption and presents a potential for abuse, must employ a full-time pharmacist and the licensed controlled substance activity must be under the personal supervision of a pharmacist or a chemist. The supervisor shall not be at the same time a supervisor of any other class 1 or class 2 establishment licensed by the New York State Department of Health. A chemist is a person who meets the following requirements:

(1) possess a bachelor of science or a bachelor of arts degree in chemistry, pharmacology or equivalent specialization and have had not less than four years of experience in the manufacture of drug products;

(2) be a citizen of the United States or an alien lawfully admitted for permanent residence in the United States;

(3) be of the age of 21 years or older;

(4) be of good moral character and, if the person has been convicted of one or more criminal offenses, he or she must be found eligible after a balancing of the factors set out in Article 23-A of Correction Law. In accordance with that Article, no person shall be deemed not to be a chemist on account of having been previously convicted of one or more criminal offense unless (i) there is a direct relationship between one or more of the previous criminal offenses and the duties required of the position or (ii) deeming the person a chemist would involve an unreasonable risk to property or the safety or welfare of a specific individual or the general public. In addressing these questions, the Department shall evaluate all factors listed under New York State Correction Law Section 753; and

(5) not be, and not have been, a habitual user of narcotics or any other habit-forming drugs.

(b) A class 1 manufacturer who produces a final product that by its composition or combination with other ingredients is not intended for human or animal consumption and does not present a potential for abuse, must employ either a full-time pharmacist or a full-time chemist and the licensed activity in which he or she is engaged must be under the supervision of either a pharmacist, or a chemist, as defined in subdivision (a) of this section. The supervisor shall not be at the same time a supervisor of any other class 1 or class 2 establishment licensed by the New York State Department of Health.

(c) An applicant for licensure who is a registered outsourcing facility pursuant to Title 8 of the Education Law and who compounds controlled substances not pursuant to a patient specific prescription shall be deemed as conducting manufacturing activities of controlled substances. Manufacturing activities shall be conducted under the personal supervision of a licensed pharmacist. An applicant for licensure who is a registered wholesaler pursuant to Title 8 of the Education Law who bottles or rebottles, packs or repacks, labels or relabels, controlled substances shall be deemed as conducting class 1 manufacturing activities of controlled substances and subject to the requirements of subdivision (a) of this section. An applicant for licensure who is a registered wholesaler pursuant to Title 8 of the Education Law who does not bottle or rebottle, pack or repack, label or relabel, controlled substances may obtain a class 2 distributor license, provided that the licensed activity in which he or she is engaged is conducted under the personal supervision of a pharmacist or a person approved by the department. The supervisor shall not be at the same time a supervisor of any other establishment registered by the New York State Board of Pharmacy. A person not a pharmacist shall meet the following requirements:

- (1) possess a high school diploma, or the equivalent thereof;
- (2) be a citizen of the United States or an alien lawfully admitted for permanent residence in the United States;
- (3) be of the age of 21 years or over;
- (4) be of good moral character and if the person has been convicted of one or more criminal offenses, he or she must be found eligible after a balancing of the factors set out in Article 23-A of Correction Law. In accordance with that Article, no distributor license shall be denied by reason of the applicable employee having been previously convicted of one or more criminal offenses unless (i) there is a direct relationship between one or more of the previous criminal offenses and the duties required of the license or (ii) licensing the applicant would involve an unreasonable risk to property or the safety or welfare of a specific individual or the general public. In determining these questions, the agency will look at all factors listed under New York State Correction Law Section 753;
- (5) not be, and not have been, an habitual user of narcotics or other habit-forming drugs; and
- (6) have had not less than eight years of experience in the wholesaling of controlled substances, or such other experience determined by the department to be the equivalent thereof.

(d) Persons conducting manufacturing activities of controlled substances within the State of New York shall obtain a class 1 license from the department.

(e) Persons conducting manufacturing activities of controlled substances outside of the State of New York and doing business within the State of New York shall obtain a class 1a license from the department. A class 1a license applicant shall meet the following requirements:

(1) the out-of-state manufacturer possesses a valid New York State Board of Pharmacy registration or exemption; and

(2) the out-of-state manufacturer possesses a valid U.S. Drug Enforcement Administration registration; and

(3) based on the application, the commissioner is satisfied that the out-of-state manufacturer will be able to maintain effective control against diversion of controlled substances.

(f) Persons conducting distributing activities of controlled substances within the State of New York shall obtain a class 2 license from the department, except that;

(1) Except in an adult care facility subject to provisions of Title 18 NYCRR Parts 487, 488 and 490, a pharmacy may distribute a controlled substance to a practitioner in a Class 3a institutional dispenser limited solely for stocking in sealed emergency medication kits. Such distribution shall be pursuant only to a written request by the Class 3a facility indicating the name and address of the facility, the name and address of the pharmacy, the date of the request, the type and quantity of the drug requested and the signature of the authorized person making the request. With each distribution, the pharmacy shall provide the Class 3a facility with an itemized list indicating the name and address of the pharmacy, the name and address of the Class 3a facility, the date of the distribution, the type and quantity of the drug distributed, and the signature of the pharmacist.

(g) Out-of-State persons conducting distributing activities of controlled substance to persons within the State of New York shall obtain a class 2a license from the department. A class 2a license applicant shall meet the following requirements:

(1) the out-of-state distributor possesses a valid New York State Board of Pharmacy registration or exemption; and

(2) the out-of-state distributor possesses a valid U.S. Drug Enforcement Administration registration; and

(3) based on the application, the commissioner is satisfied that the out-of-state distributor will be able to maintain effective control against diversion of controlled substances.

(h) All persons authorized to manufacture or distribute controlled substances shall accept returns of such controlled substances manufactured or distributed by them, and either destroy them or provide for the return, disposition, and disposal of such controlled substances in a manner approved by the Department pursuant to section 80.51(c)(2).

(i) An individual who is designated as the supervisor of controlled substance activity pursuant to subdivisions (a), (b) or (c) of this section shall be responsible for the following non-delegable tasks:

(1) maintaining all required records relating to the purchase and distribution of all controlled substances manufactured or repacked at that facility;

(2) providing for the proper storage of controlled substances in order to prevent loss or theft;

(3) assuring security and limiting access to all areas holding controlled substances;

(4) insuring against all unauthorized sales or distribution of controlled substances to establishments or professionals not authorized to receive such items;

(5) issuing verbal and written notice to each of his or her subordinates concerning the applicable state and federal laws, regulations and rules to ensure full compliance;

(6) for manufacturers, assuring that all Good Manufacturing Procedures as outlined by the FDA are followed; and

(7) for manufacturers engaged in compounding of controlled substances, assuring that all controlled substances are compounded under the personal supervision of a licensed pharmacist.

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## **Section 80.12 - Additional requirements for importers and exporters**

80.12 Additional requirements for importers and exporters.

(a) (1) All persons acting as importers of controlled substances shall first obtain a class 9 license from the department and thereafter, a registration from the Drug Enforcement Administration, United States Department of Justice, or its successor agency.

(2) Persons conducting activities as importer broker of controlled substances within New York State where there is no physical possession of controlled substances are required to obtain a class 9a license from the department and wherever necessary, proper license from the appropriate Federal agency.

(b) (1) All persons exporting controlled substances shall first obtain a class 10 license from the department and thereafter, a registration from the Drug Enforcement Administration, United States Department of Justice, or its successor agency.

(2) Persons conducting activities as exporter broker of controlled substances within New York State where there is no physical possession of controlled substances are required to obtain a class 10a license from the department and wherever necessary, proper license from the appropriate Federal agency.

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### **Section 80.13 - Minimum security standards for nonpractitioner handling; schedule I and II controlled substances**

80.13 Minimum security standards for nonpractitioner handling; schedule I and II controlled substances. Schedule I and II raw materials, bulk materials awaiting further processing, and finished products shall be stored in one of the following secure storage areas:

(a) Where small quantities permit, in a safe of GSA Class 5 rated or equivalent, if the safe weighs less than 750 pounds it shall be bolted or cemented to the floor or wall in such a way that it cannot readily be removed. The safe shall, where required by the commissioner, be equipped with tamper-proof closed circuit alarm system approved by Underwriter's Laboratories, which when unauthorized entry is attempted, transmits a signal directly to a central protection company, a local police agency which has a legal duty to respond or a 24-hour control station operated by the registrant.

(b) A vault constructed or under construction before April 1, 1973 and approved by the commissioner which is of substantial construction with a steel door, combination or key lock and an alarm system.

(c) A vault constructed on or after April 1, 1973 which meets the following specifications or their equivalent as determined by the commissioner:

(1) Walls, floors and ceilings constructed of at least eight inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with one-half inch steel rods tied six inches on center, or the structural equivalent to such reinforced walls, floors and ceilings.

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

(3) The vault, if operations require it to remain open for frequent access shall be equipped with a "day gate" or the equivalent, which is self closing and self-locking. 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 or perimeter of the vault shall be equipped with a tamper-proof closed circuit alarm approved by Underwriter's Laboratories which, when unauthorized entry is attempted, transmits a signal directly to a central station protection company, a local police agency which has a legal duty 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 shall be equipped with a contact switch.

(6) The vault shall have one of the following:

(i) complete electrical lacing of the walls, floor and ceiling;

(ii) sensitive ultrasonic equipment within the vault;

(iii) sensitive sound accumulator system; or

(iv) such other device designated to detect illegal entry as may be approved by the department.

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#### **Section 80.14 - Minimum security standards for nonpractitioner handling; schedule III, IV and V controlled substances**

80.14 Minimum security standards for nonpractitioner handling; schedule III, IV and V controlled substances. (a) Minimum security standards for storage of schedule III, IV and V controlled substances shall include the following requirements:

(1) The controlled substance shall be separated from all other merchandise except that controlled substances may be stored with other pharmaceuticals in a separate room or storage area within a building if there is limited access to the room or storage area.

(2) During working hours the controlled substances shall be kept under constant surveillance by a supervisor or specific individual who has the responsibility for this duty; and

(3) An alarm system installed on the outer perimeter of the building or on the safe, cabinet, vault, or inside storage area, which shall be equipped to transmit, upon unauthorized entry, a signal to a central station protection company, a local police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant.

(b) Storing the controlled substances in the following manner shall be deemed compliance with this section:

(1) where small quantities permit, in a safe of GSA Class 5 rating or its equivalent, which complies with requirements of this Part for storing' schedule I and II substances;

(2) in a vault which complies with the security requirements of this Part for storage of schedule I and II substances; or

(3) in a building or area located within a building which has walls or perimeter fences of sufficient height and construction to provide security from burglary and has substantial doors which shall be securely locked during non-working hours by a multiple position combination or key lock.

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#### **Section 80.15 - Multiple storage area; schedule I-V controlled substances**

80.15 Multiple storage area; schedule I-V controlled substances. Where necessary for licensees (nonpractitioner category) to handle several classes of controlled substances separately, for example, damaged goods, returned goods and goods in process, the controlled substances may be stored apart from the main stock of controlled substances, provided that each storage area complies with the security requirements set forth in this Part.

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#### **Section 80.16 - Accessibility to storage areas; schedule I-V controlled substances**

80.16 Accessibility to storage areas; schedule I-V controlled substances. (a) In order to minimize the possibility of internal diversion the licensee shall limit access to the storage areas for controlled substances to a minimum number of employees with a security pass system if the size, type or other factors indicate a need, as determined by the department.

(b) Where it is necessary for employee maintenance or nonemployee maintenance personnel, business guests or other visitors to have access to or pass through the controlled substances storage area the licensee shall authorize in writing an employee to provide adequate observation during the time these otherwise unauthorized persons are in the storage area.



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### **Section 80.17 - Security standards; agents of nonpractitioners**

80.17 Security standards; agents of nonpractitioners. When controlled substances are distributed by nonpractitioners through agents (i.e. detailmen), the licensee is responsible for providing and requiring adequate security to guard against theft or diversion while the substances are being stored or handled by the agent.

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### **Section 80.18 - Security standards; public warehouse and common or contract carriers**

80.18 Security standards; public warehouse and common or contract carriers.

(a) Licensees who store controlled substances in a public warehouse are responsible for utilizing a warehouse that will provide adequate security against theft or diversion. The licensee and not the warehouse is responsible for the security of the controlled substances. The department shall determine if the overall security is adequate. The licensee shall notify the department in writing within 30 days of any change in the warehouse inspected and approved by the department.

(b) The licensees are also responsible for utilizing a common or contract carrier that will provide adequate security of the controlled substances while they are in transit. If the licensee has substantial quantities of controlled substances lost or stolen in transit when utilizing the facilities of a particular common or contract carrier, steps shall be taken to obtain another carrier or means of transportation for shipping controlled substances. Precautions such as securely wrapping and sealing packages containing controlled substances or utilizing unmarked or coded boxes or shipping containers are required for guarding against losses in storage or in transit.

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### **Section 80.19 - Security controls for nonpractitioners; manufacturing areas**

80.19 Security controls for nonpractitioners; manufacturing areas. All manufacturing activities, including processing, packaging, and labeling, involving controlled substances listed in any schedule shall conform to the following security controls:

(a) All substances in process of manufacture shall be returned to the controlled substances storage area at the termination of the process. If the process is not completed at the end of a workday, except where a continuous process or other normal manufacturing operation should not be interrupted, the processing area or tanks, vessels, bins, or bulk containers containing

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

(b) Manufacturing activities with controlled substances shall be conducted in an area or areas with limited access and shall be kept under surveillance by an employee or employees designated in writing by the licensee to be responsible for the area. The designated employee or employees shall be able to provide continuous surveillance of the area in order that unauthorized persons may not enter or leave the area without his knowledge. Limited access may be accomplished by use of physical dividers such as walls or partitions, by traffic control lines or by restricted space designations.

(c) During the production of controlled substances, the manufacturing area shall be accessible only to those employees necessary for efficient operation. If it is necessary for maintenance personnel, visitors or others to be present or pass through the manufacturing areas during production, the licensee shall have an employee designated in writing as being responsible for providing surveillance of the area.

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#### **Section 80.20 - Theft or loss**

##### **80.20 Theft or loss.**

The licensee shall promptly notify the department of any theft or loss of any controlled substance. Such theft or loss shall be reported on forms furnished by the department. Thefts shall be reported whether or not the controlled substances are subsequently recovered, the responsible parties identified or action taken against them.

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#### **Section 80.21 - Good faith inquiry**

##### **80.21 Good faith inquiry.**

The licensee shall make a good faith inquiry either to the department or the Drug Enforcement Administration, United States Department of Justice to determine that a person is licensed to possess a controlled substance before distributing any such controlled substance to a person who the licensee does not know to be licensed to possess the controlled substance.

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Wednesday, November 26, 2008  
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## **Section 80.22 - Suspicious orders**

### **80.22 Suspicious orders.**

The licensee shall establish and operate a system to disclose to the licensee suspicious orders for controlled substances and inform the department of such suspicious orders. Suspicious orders shall include, but not be limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

Doc Status:  
Complete

## **Section 80.23 - Records and reports**

### **80.23 Records and reports.**

(a) Manufacturer records. Manufacturers shall keep records of all controlled substances manufactured, received, disposed of or distributed by them, which shall include date of manufacture, type and quantity of drug manufactured.

(1) Records of drugs received shall indicate date of receipt, type and quantity of drug received, and name and address of supplier of such drug.

(2) Records of drugs disposed of or distributed shall indicate date of disposal or distribution, name and address of the person receiving such drugs and type and quantity of such drugs.

(b) Distributors, importers and exporters records. Distributors, importers and exporters shall keep records of all controlled substances received, disposed of or distributed by them.

(1) Records of drugs received shall indicate the date of receipt, type and quantity of drug received, and the name and address of supplier of such drug.

(2) Record of drugs disposed of or distributed shall indicate the name and address of persons receiving such drugs and the type and quantity of such drugs.

(c) Purchase requests. Manufacturers or distributors may sell schedule III, IV and V controlled substances to authorized practitioners, pharmacies, institutional dispensers or other authorized persons on a written request submitted by the purchaser on his professional or business stationery or on a written order submitted by a representative of the vendor. All such purchase requests

shall indicate the name and address of the vendor, the name and address of the vendee, Drug Enforcement Administration registration number, date of the order, type and quantity of drug ordered. Schedule I and II drugs shall be ordered on an official Federal order form only.

(d) Invoice required. The manufacturer or distributor shall furnish the vendee with each shipment of controlled substances an invoice in duplicate, or separate itemized list of all such drugs sold, which shall include the name and address of the vendor, the name and address of the vendee, date of shipment or delivery, type and quantity of drug sold.

(e) Record maintenance. Manufacturers and distributors shall maintain all required records of controlled substances in a separate file or in such a manner as will make them readily available for inspection by authorized representatives of the Bureau of Narcotic Enforcement, New York State Department of Health.

(f) Reports. Manufacturers and distributors shall report to the Department, in a manner approved by the Department, information from the sale of controlled substances. Such information shall be filed electronically with the Bureau of Narcotic Enforcement, utilizing a transmission format acceptable to the Department. The information filed with the Department shall include, but not be limited to:

(i) the manufacturer's or distributor's name, address, phone number, DEA registration number and controlled substance license number issued by the Department;

(ii) the name, address and DEA registration number of the entity to whom the controlled substance was sold;

(iii) the date of the sale of the controlled substance;

(iv) the name and National Drug Code (NDC) of the controlled substance sold; and

(v) the number of containers and the strength and metric quantity of controlled substance in each container of controlled substance sold.

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Wednesday, February 25, 2009

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## **Section 80.24 - Identification of controlled substances**

### **80.24 Identification of controlled substances.**

(a) No controlled substances may be manufactured or delivered within this State in solid or capsule form unless it has clearly marked or printed upon each capsule or solid the national drug code number or other identifying symbol assigned to the manufacturer or distributor and the drug manufactured or distributed, or other set or sets of identifying symbols or coding as approved by

the commissioner. The commissioner may except from the requirement of this subdivision controlled substances manufactured in such form as to render any imprinting thereon unreasonably difficult or impossible.

(b) Each manufacturer or distributor of controlled substances shall furnish the department with a list of all controlled substances manufactured or delivered by them within the State and the national drug code number or other symbol assigned to each such substance.

(c) No controlled substance contained within a bottle, vial, carton or other container or package for delivery to an ultimate consumer, shall be manufactured or distributed within this State unless such container or package has clearly and permanently marked or imprinted upon it:

(1) the national drug code identification number assigned to the manufacturer or distributor, or other identification number approved by the commissioner, and

(2) the national drug code number or other identification number approved by the commissioner and designated for such substance.

(d) The commissioner does hereby direct each such manufacturer or distributor to adopt the national drug code number or other identification number approved by the commissioner and assigned to each controlled substance manufactured or distributed by such licensee for the purpose of meeting the requirements of article 33, Public Health Law.

Doc Status:  
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## **Section 80.25 - Distribution of free samples**

80.25 Distribution of free samples.

(a) It shall be unlawful to distribute free samples of controlled substances except by licensees licensed under this Part to persons licensed by the department for research, instructional activities or chemical analysis.

(b) No such distribution shall be made without giving prior notice to the department regarding the proposed manner of distribution and the names of those persons to whom such distribution will be made. A record of all such distributions shall be made.

Doc Status:  
Complete

## **RESEARCH, INSTRUCTIONAL ACTIVITIES AND CHEMICAL ANALYSIS**

### **Section 80.35 - Unlicensed activity**

#### **RESEARCH, INSTRUCTIONAL ACTIVITIES AND CHEMICAL ANALYSIS**

80.35 Unlicensed activity. (a) No person shall conduct research, instructional activities or chemical analysis of controlled substances in this State without first having obtained a license from the department.

(b) Licensees. Licensees shall register with the appropriate Federal agency or agencies in the comparable controlled substance schedule provided for under Federal regulations.

Doc Status:  
Complete

### **Section 80.36 - Additional requirements, research, instructional activities and chemical analysis**

80.36 Additional requirements, research, instructional activities and chemical analysis.

(a) Persons engaged in research of controlled substances in schedules II to V shall first obtain a Class 4 license from the department and thereafter a registration from the Drug Enforcement Administration, United States Department of Justice, or its successor agency.

(b) Persons engaged in industrial or commercial processes requiring the use of controlled, substances in schedules II to V shall first obtain a Class 4a license from the department and thereafter a registration from the Drug Enforcement Administration, United States Department of Justice, or its successor agency.

(c) Persons engaged in instructional activities requiring the use of controlled substances in schedules II to V shall first obtain a license from the department in Class 5 and thereafter, a registration from the Drug Enforcement Administration, United States Department of Justice, or its successor agency.

(d) Persons conducting research with controlled substances in schedule I shall apply to the department for such research license in Class 7 and file with the department three copies of a research protocol describing the research project.

(1) The research protocol shall contain all pertinent information including the objective, material, security, procedures (such as species and number of animals, daily dose regimen and route of administration) and investigators, if any.

(2) If the commissioner finds that the applicant is qualified and competent, and has furnished a satisfactory protocol, the department shall license such applicant unless he finds that the application should be denied by reason of false statements in the application, conviction of a felony relating to controlled substances suspension, revocation or denial of the applicant's Federal license or registration, failure to provide adequate safeguards against diversion of the controlled substances from legitimate medical or scientific use or other good and sufficient reason.

(e) A person licensed to conduct research with controlled substances listed in schedule I may conduct research with only such substances in schedule I for which he has filed and had approved a research protocol.

(f) All persons conducting research and instructional activities with controlled substances listed in schedule I shall first obtain a Class 7 license from the department and thereafter, a registration from the Drug Enforcement Administration, United States Department of Justice, or its successor agency.

(g) All persons conducting analytical laboratories involving controlled substances shall first obtain a Class 8 license from the department and thereafter, a registration from the Drug Enforcement Administration, United States Department of Justice, or its successor agency.

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## **Section 80.37 - Records; researchers**

### **80.37 Records; researchers.**

(a) Researchers, licensed and authorized to possess and use controlled substances, shall keep a record of all such substances received and used by them.

(1) A record of all such controlled substances received shall include date of receipt, name and address of vendor, type and quantity of drug received. A duplicate invoice or separate itemized list furnished by the vendor will be sufficient to meet this record requirement providing it contains all the information required and is maintained in a separate file.

(2) A record of all controlled substances used shall include the name of the person authorized to control and use such drugs, the date, type and quantity of drug and signature of the user.

(b) In addition, such records shall contain the following information for each controlled substance:

(1) Name of substance.

(2) Each finished form (such as 10 mg. tablet, or 10 mg. concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container.

(3) The number of commercial containers of such finished form received from other persons, including the date of and number of containers in each receipt, and the name, address, and registration number of the person from whom the containers were received.

(4) The amount of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, and the written or typewritten name or initials of the individual who dispensed or administered the substance.

(5) The number of units or volume of the finished form and/or commercial containers disposed of in any other manner by the researcher, including the date and manner of disposal.

Doc Status:  
Complete

### **Section 80.38 - Records; instructional activities**

80.38 Records; instructional activities.

Persons authorized to possess and use controlled substances for instructional activities shall keep a record of all controlled substances received and used by them.

(a) The record shall include date of receipt, name and address of vendor, type and quantity of drug received. A duplicate invoice or separate itemized list furnished by the vendor for schedule III, IV and V controlled substances will be sufficient to meet this record requirement providing it contains all the information required and is maintained in a separate file. Duplicate copies of Federal order forms for schedule I and II substances shall also be maintained.

(b) A record of controlled substances used shall include the name of the person authorized to control and use such drugs, the date, type and quantity of drug and signature of the user.



Doc Status:  
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### **Section 80.39 - Records; analytical laboratories**

#### 80.39 Records; analytical laboratories.

Analytical laboratories authorized to possess and use controlled substances shall keep a record of all controlled substances received and used by them.

(a) The record of controlled substances received shall include date of receipt, name and address of vendor, type and quantity of drug received. A duplicate invoice or separate itemized list furnished by the vendor will be sufficient to meet this record requirement providing it contains all the information required and is maintained in a separate file. In addition, duplicate copies of Federal order forms for schedule II controlled substances shall be retained.

(b) A record of controlled substances used shall include the name of the person authorized to control and use such drugs, the date, type and quantity of drug used and signature of the user.

Doc Status:  
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### **INSTITUTIONAL DISPENSERS**

#### **Section 80.45 - Unlicensed activity**

#### INSTITUTIONAL DISPENSERS

#### 80.45 Unlicensed activity.

(a) No person shall act as an institutional dispenser or institutional dispenser limited of controlled substances in this State without first having obtained a license from the department.

(b) Licensees shall register with the appropriate Federal agency or agencies in the comparable controlled substance schedule provided for under Federal regulations.

Doc Status:  
Complete

### **Section 80.46 - Institutional dispensers; additional requirements**

80.46 Institutional dispensers; additional requirements. (a) Hospitals, veterinary hospitals, mental hospitals, or similar facilities qualified for controlled substances privileges shall first obtain a

Class 3 license from the department and thereafter, a registration from the Drug Enforcement Administration, United States Department of Justice, or its successor agency.

(b) Nursing homes and other facilities having the services of a physician, registered nurses and a licensed and registered pharmacist may qualify for a Class 3 license for controlled substances privileges. Such facilities shall first obtain a Class 3 license from the department and thereafter, a registration from the Drug Enforcement Administration, United States Department of Justice, or its successor agency.

(c) Institutional dispensers licensed by the department in class 3 may purchase stocks of controlled substances only from authorized distributors or manufacturers licensed by the department.

(d) Institutional dispenser stocks of controlled substances obtained pursuant to a class 3 license are for inpatient and outpatient use through a registered pharmacy dispenser.

(e) Bulk stocks of controlled substances may be distributed within the institution to wards, floor stocks, operating rooms and emergency rooms and carried as substocks of the hospital.

(1) With each substock of a schedule II controlled substance, an administration sheet or other record as the commissioner may approve shall be furnished.

(2) The administration sheet shall list the type of controlled substance, doses and number of doses furnished to the substock and shall indicate:

(i) date and hour of administration;

(ii) name of patient;

(iii) name of prescribing practitioner;

(iv) quantity administered;

(v) balance on hand after each administration; and

(vi) signature of administering nurse.

(f) Administration of all controlled substances shall be authorized only by written order of an authorized practitioner except that:

(1) In an emergency situation, as defined in this subdivision, a practitioner may have a controlled substance administered by oral order provided that immediately thereafter such order is reduced to writing and that a notation be made of the emergency condition which required the administration of the drug. Such oral order shall be signed by the practitioner within 48 hours.

(2) Emergency means that the immediate administration of the drug is necessary for proper treatment, that no alternative treatment is available and it is not possible for the practitioner to provide a written order before the administration of such drug.

(3) As required orders (P.R.N., pro re nata) for controlled substances are not valid beyond 72 hours and must be rewritten at least every 72 hours.

(4) Routine orders or an order in which there is no specific order written by a specific physician or other authorized practitioner are not permissible.

(5) Standing orders or specific controlled substances orders for individual patients to be administered at specified times shall not be valid after seven days and for continuing validity shall be rewritten at least every seven days, except that for a stabilized patient with convulsive disorders or chronic spasticity or minimal brain dysfunction in an institutional setting, and for patients in residential health care facilities, or in prisons, which possess class three controlled substances licenses, such orders shall be valid for 30 days but shall be rewritten at least every 30 days.

(6) Written controlled substances orders for hospitalized patients may, if permissible under the bylaws, rules and regulations of the hospital, be signed by a physician's assistant for patients under the care of the physician or physicians to whom the registered physician's assistant is assigned for supervision, subject to compliance by the registered physician's assistant with any of the foregoing conditions set forth in this section that are applicable to his/her supervising physicians. In every case, such written orders shall be countersigned by the supervising physician within 24 hours if deemed necessary and appropriate by the supervising physician or the hospital. Countersignature by the supervising physician is not required before execution of the order.

(7) Doses of controlled substances shall be withdrawn from the container immediately before administration is to be made to the patient.

(g) Institutional dispensers operating an outpatient department pharmacy shall also obtain a registration from the Drug Enforcement Administration, United States Department of Justice, or its successor agency.

(1) Such pharmacy shall be registered by the New York State Board of Pharmacy and under the supervision of a licensed and registered pharmacist.

(2) Controlled substances dispensed through outpatient department pharmacy to patients or employees of the institutional dispenser shall be dispensed only pursuant to prescriptions issued by an authorized practitioner.

(h) Independent out-of-hospital health facilities, such as clinics, may qualify to obtain official New York State institutional prescription forms required for prescribing schedule II controlled substances under the New York State Controlled Substances Act by complying with the following:

(1) Obtain an operating certificate from the New York State Department of Health as required under the New York State Hospital Code (Chapter V of this Title) or license by the New York State Department of Mental Hygiene.

(2) Obtain a registration as a clinic from the Drug Enforcement Administration (schedules II, III, IV and V), United States Department of Justice, or its successor agency.

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### **Section 80.47 - Institutional dispenser, limited**

80.47 Institutional dispenser, limited.

(a) Nursing homes, convalescent homes, health-related facilities, adult care facilities subject to the provisions of Title 18 NYCRR Parts 487, 488 and 490, 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.

(b) 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 controlled substances in emergency medical kits may be administered to patients as provided in Section 80.49(d) of this Part; however, controlled substances in emergency medication kits may not be administered to patients in an adult care facility subject to the provisions of Title 18 NYCRR Parts 487, 488 and 490.

(c) 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.

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### **Section 80.48 - Records and reports of institutional dispensers**

80.48 Records and reports of institutional dispensers.

(a) Hospitals and other facilities licensed and authorized by the department to purchase, possess and use controlled substances shall keep the following records:

(1) 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.

(2) 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.

(3) A record of authorized requisitions for such drugs for distribution to substations or wards. Such records shall show receipt at substation or ward by the signature of a person authorized to control such substation or ward; and

(i) with each substock of schedule II controlled substances, an administration sheet shall be furnished.

(ii) the administration sheet shall list the type of controlled substances, dose and number of doses furnished to the substock; and

(a) date and hour of administration;

(b) name of patient;

(c) name of prescribing physician or practitioner;

(d) quantity of administration;

(e) balance on hand after each administration; and

(f) signature of administering nurse.

(4) 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.

(b) Records of controlled substances received shall include date of receipt, name and address of vendor, type and quantity of such drugs received. A duplicate invoice or separate itemized list

furnished by the vendor will be sufficient to satisfy this record requirement provided it includes all required information and is maintained in a separate file. In addition, duplicate copies of Federal order forms for schedule II controlled substances must be retained.

(c) Records of controlled substances administered shall include date of administration, name of patient, prescriber's signature, signature of person administering, type and quantity of drug and such other information as may be required by regulation or provisions of article 33 of the Public Health Law.

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Complete

### **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 pharmacy prescription number of the prescription containing the controlled substance, for patients under their care.

(c) A separate record shall be maintained of the administration of prescribed 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.

(d) In an emergency situation, a controlled substance from a sealed emergency medication kit may be administered to a patient by an order of an authorized practitioner. An oral order for such controlled substance shall be immediately reduced to writing and a notation made of the condition which required the administration of the drug. Such oral order shall be signed by the practitioner within 48 hours.

(1) For purposes of this subdivision, emergency means that the immediate administration of the drug is necessary and that no alternative treatment is available.

(2) A separate record shall be maintained of the administration of controlled substances from an emergency medication kit. Such record shall indicate the date and hour of administration, name and quantity of controlled substances, name of the practitioner ordering the administration of the controlled substance, patient's name, signature of the person administering and the balance of the controlled substances in the emergency medication kit after such administration.

(3) The institutional dispenser limited shall notify the pharmacy furnishing controlled substances for the emergency medication kit within 24 hours of each time the emergency kit is unsealed, opened, or shows evidence of tampering.

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**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 Enforcement 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 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) Except as provided in paragraph (1) of this subdivision, 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.

(1) Except for adult care facilities subject to the provisions of Title 18 NYCRR Parts 487, 488 and 490, institutional dispensers limited may possess limited supplies of controlled substances in sealed emergency medication kits for use as provided in section 80.49(d) of this Part. Each kit may contain up to a 24-hour supply of a maximum of ten different controlled substances in unit dose packaging, no more than three of which may be in an injectable form. Each kit shall be secured in a stationary, double-locked system or other secure method approved by the Department.

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

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## **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 Narcotic Enforcement 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:

(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 Narcotic Enforcement 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; or

(6) transfer such controlled substances into an authorized collection receptacle, located at the residential health care facility and maintained by a properly licensed and registered pharmacy, no longer than three business days after discontinuation.

(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.

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Complete

### **Section 80.52 - Returns to supplier**

80.52 Returns to supplier. Any person holding a Federal registration number who is in possession of a controlled substance listed in any schedule may, without being licensed as a distributor, return that substance to either the distributor from whom he obtained it or to the manufacturer of the substance provided that:

(a) In the case of a Schedule II controlled substance, an order form is used as provided under Federal regulations.

(b) In the case of a Schedule III, IV or V controlled substance, a written record is maintained which indicated the:

(1) date of transaction;

(2) name, form and quantity of the substance;

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

(4) name, address and registry number of the supplier or manufacturer.

Doc Status:

Complete

## **PRESCRIBING AND DISPENSING CONTROLLED SUBSTANCES**

### **Section 80.60 - Ordering**

#### **PRESCRIBING AND DISPENSING CONTROLLED SUBSTANCES**

80.60 Ordering. No practitioner shall obtain Schedule II controlled substances except by means of his or her official Federal written order forms. Schedules II, III, IV and V controlled substances shall be obtained from manufacturers or distributors licensed under article 33 of the Public Health Law and this Part.

Effective Date:

Wednesday, November 26, 2008

Doc Status:

Complete

### **Section 80.61 - Personal use**

80.61 Personal use. A person authorized by law to obtain controlled substances for professional use shall not use such drugs for the treatment of his own addiction, or habitual use.

Doc Status:  
Complete

### **Section 80.62 - Use of controlled substances in treatment**

80.62 Use of controlled substances in treatment.

(a) Physicians and other authorized practitioners in the course of their professional practice, may dispense, administer or prescribe controlled substances for legitimate medical purposes or treatment, other than treatment for addiction to controlled substances, when the practitioner regulates the dosage and prescribes or administers a quantity of such drugs no greater than that ordinarily recognized by members of his profession as sufficient for proper treatment in a given case.

(b) Such practitioners shall maintain a written patient record of administration, dispensing and prescription of all controlled substances. The patient record shall contain sufficient information to justify the diagnosis and warrant the treatment. The record shall contain at least the following information: patient identification data; chief complaint; present illness; physical examination as indicated; diagnosis; other data which support the diagnosis or treatment; and the regimen including the amount, strength, and directions for use of the controlled substance. This subdivision shall not be construed to require a record distinct from the medical record of the patient.

Doc Status:  
Complete

### **Section 80.63 - Prescribing**

80.63 Prescribing. (a) A prescription as defined by the Public Health Law means:

- (1) an official New York State prescription;
- (2) an electronic prescription;

(3) an oral prescription; or

(4) an out-of-state prescription, which means a prescription issued in lieu of an official prescription by a practitioner in another state who is licensed by that state to prescribe controlled substances.

(b) The use of preprinted prescriptions which indicate the controlled substance or the strength, dosage and/or quantity of the controlled substance is prohibited. Such prohibition shall not apply to printed prescriptions generated by means of a computer or an electronic medical record system, provided such printed prescriptions are generated at the time a practitioner prescribes a controlled substance for a patient.

(c)(1) Prior to prescribing for or dispensing to a patient any controlled substance listed on schedule II, III, or IV of section 3306 of the public health law, every practitioner shall consult the

prescription monitoring program registry for the purpose of reviewing that patient's controlled substance history. The patient's controlled substance history shall be obtained from the prescription monitoring program registry no more than 24 hours prior to the practitioner prescribing or dispensing any controlled substance to that patient. A practitioner shall document such consultation in the patient's medical chart or, if the practitioner does not consult the prescription monitoring program registry, the practitioner shall document in the patient's medical chart the reason such consultation was not performed. Such documentation shall include the specific exception listed in paragraph (2) of this Subdivision.

(i) When such consultation is not performed due to circumstances specified in subparagraph (2)(vii) of this Subdivision, the practitioner shall further document in the patient's medical chart the conditions, occurrences, or circumstances that caused such consultation in a timely manner to be unreasonable. Such documentation shall include a description of the barrier(s) to accessing the registry, and the efforts made by the practitioner to contact other designees.

(ii) When such consultation is not performed due to circumstances specified in subparagraph (2)(viii) of this Subdivision, the practitioner shall further document in the patient's medical chart a description of the circumstances supporting the practitioner's conclusion that consultation of the registry would adversely impact the patient's ability to obtain a prescription in a timely manner and the relationship between that delay and the patient's medical condition.

(2) The duty to consult the prescription monitoring program registry shall not apply to:

(i) veterinarians;

(ii) a practitioner dispensing pursuant to public health law section 3351(3);

(iii) a practitioner administering a controlled substance, as defined in public health law section 3302(2);

(iv) a practitioner prescribing or ordering a controlled substance pursuant to public health law section 3342(1) for a patient of an institutional dispenser as defined by public health law section 3302 for use on the premises of, or during an emergency transfer from, the institutional dispenser;

(v) a practitioner prescribing a controlled substance in the emergency department of a general hospital, provided that the quantity of controlled substance prescribed does not exceed a five-day supply if the controlled substance were used in accordance with the directions for use;

(vi) a practitioner prescribing a controlled substance to a patient under the care of a hospice, as defined by public health law section 4002;

(vii) a practitioner when:

(a) it is not reasonably possible for the practitioner to access the registry in a timely manner;

(b) no other practitioner or designee authorized to access the registry, pursuant to public health law section 3343-a, is reasonably available; and

(c) the quantity of controlled substance prescribed does not exceed a five-day supply if the controlled substance were used in accordance with the directions for use;

(viii) a practitioner acting in circumstances under which consultation of the registry would, as determined by the practitioner, result in a patient's inability to obtain a prescription in a timely manner, thereby adversely impacting the medical condition of such patient, provided that the quantity of the controlled substance does not exceed a five-day supply if the controlled substance were used in accordance with the directions for use;

(ix) a situation where the registry is not operational as determined by the department or where it cannot be accessed by the practitioner due to a temporary technological or electrical failure as defined in Section 80.64 of this Part. In the instance of a temporary technological or electrical failure, a practitioner shall, without undue delay, seek to correct any cause for the failure that is reasonably within his or her control; or

(x) a practitioner to whom the commissioner has granted a waiver from the requirement to consult the registry. A waiver may be issued by the commissioner based upon a showing by a practitioner that his or her ability to consult the registry in accordance with this section is unduly burdened by:

(a) technological limitations that are not reasonably within the control of the practitioner; or

(b) other exceptional circumstance demonstrated by the practitioner.

The practitioner's showing shall include a sworn statement of facts detailing the circumstances in support of a waiver, and should be accompanied by any and all other information which would be relevant to the commissioner's determination. As part of the application for a waiver, the practitioner shall also provide any information which would tend to negate the need for a waiver. A waiver shall be granted by the commissioner for a specified period of time, but in no event for more than one year. Subsequent waivers shall be applied for in the same manner and shall be subject to the same requirements as the original waiver. A practitioner who has been granted a waiver shall notify the department in writing within five business days upon gaining the capability to consult the prescription monitoring program registry. Without regard to the original expiration date, the waiver granted to the practitioner shall terminate within a reasonable period of time as determined by the department, allowing for the practitioner to make accommodations to begin consulting the prescription monitoring program registry.

(3) A practitioner may authorize a designee to consult the prescription monitoring program registry on his or her behalf, provided that the ultimate decision as to whether or not to prescribe or dispense a controlled substance remains with the practitioner and is reasonably informed by the relevant controlled substance history information obtained from the registry. A practitioner may only appoint a designee if:



(i) such designee is located in the state of New York when accessing the prescription monitoring program registry;

(ii) the designee is employed by the same professional practice or is under contract with such practice. For purposes of this subparagraph, professional practice shall include, but not be limited to, an institutional dispenser where the designating practitioner is employed, under contract, or otherwise has privileges or authorization to practice;

(iii) the practitioner takes reasonable steps to ensure or has actual knowledge that such designee is sufficiently competent in the use of the registry and that such designee is aware of and conforms to all relevant federal and state privacy statutes;

(iv) the practitioner remains responsible for ensuring that access to the registry by the designee is limited to authorized purposes and occurs in a manner that protects the confidentiality of the information obtained from the registry, and the practitioner remains responsible for any breach of confidentiality; and

(v) the practitioner selects and maintains all active designees authorized to access the prescription monitoring program registry in a format acceptable to the department. Upon a designee's relinquishment or termination of employment or authorization as a designee, a designating practitioner shall immediately notify the department, in a fashion deemed appropriate by the commissioner, of the revocation of the designee's authorization to access the prescription monitoring program registry on the designating practitioner's behalf.

(4) A pharmacist may consult the prescription monitoring program registry in order to review the controlled substance history of an individual for whom one or more prescriptions for controlled substances is presented to such pharmacist. A pharmacist may designate another pharmacist or a pharmacy intern as defined by section sixty-eight hundred six of the education law to consult the prescription monitoring program registry on the pharmacist's behalf, provided that:

(i) such designee is located in the state of New York when accessing the prescription monitoring program registry and is employed by the same pharmacy or is under contract with such pharmacy; and

(ii) the designating pharmacist selects and maintains all active designees authorized to access the prescription monitoring program registry in a format acceptable to the department. Upon relinquishment or termination of employment or authorization as a designee, a designating pharmacist shall immediately notify the department, in a fashion deemed appropriate by the commissioner, of the revocation of the designee's authorization to access the prescription monitoring program registry on the designating pharmacist's behalf.

(d)(1) No controlled substance prescription shall be issued prior to the examination of the patient by the practitioner except as otherwise permitted by this subdivision.

(2) Once the initial examination has been completed, the frequency and necessity for future examinations prior to prescribing, either for the same acute or chronic condition, will be made by the practitioner utilizing generally accepted medical standards, including taking into account the drug to be prescribed and the patient's condition, history and disposition toward the use of

controlled substances.

(3) In the temporary absence of the initial prescriber, an authorized practitioner may issue a controlled substance prescription for a patient as part of a continuing therapy if the practitioner:

(i) had direct access to the patient's medical records and such records warrant continued controlled substance prescribing, or (ii) had direct and adequate consultation with the initial prescriber, who assures the necessity of continued controlled substance prescribing and with which the practitioner concurs. If the patient record is not available, the practitioner shall document the activity for his or her own record and shall transmit to the initial prescriber the prescription information. The initial prescriber shall include the prescription information in the patient's record.

(4) A practitioner may prescribe a controlled substance to his or her patient after review of the patient's record if the record contains the result of an examination performed by a consulting physician or hospital and such record warrants the prescribing.

(5) If a patient develops a new condition that would warrant the issuance of a prescription for a controlled substance, a practitioner may issue such prescription prior to performing an examination if: (i) the prescribing practitioner has a previously established practitioner/patient relationship with the patient; and (ii) an emergency exists; and (iii) the prescription does not exceed a 5 day supply as determined by the directions for use. An emergency means that the immediate administration of the drug is necessary for the proper treatment of the patient and that no alternative treatment is available. If the practitioner prescribes such substance orally, the practitioner must comply with the requirements of section 80.68 and section 80.70 of this Part.

Effective Date:

Tuesday, August 27, 2013

Doc Status:

Complete

## **Section 80.64 - Who may issue**

### **80.64 Who may issue.**

(a) A prescription for a controlled substance may be issued only by a practitioner who is:

(1) authorized to prescribe controlled substances pursuant to his licensed professional practice; and

(2) either registered under the Federal Controlled Substances Act and in possession of a registration number from the Drug Enforcement Administration, United States Department of Justice, or its successor agency, or exempted from such registration as an exempt official.

(b) A practitioner issuing an electronic prescription for a controlled substance, in addition to meeting the provisions as noted in paragraph (a) of this section, shall also:

(1) use an electronic prescribing application that is consistent with federal requirements; and

(2) register the certified electronic prescribing application with the New York State Department of Health, Bureau of Narcotic Enforcement.

(c) Prescriptions excepted from any electronic prescribing requirement set forth in Article 2-a of the public health law include prescriptions:

(1) issued by veterinarians;

(2) issued in circumstances where electronic prescribing is not available due to temporary technological or electrical failure. For the purposes of this Part, temporary technological or electrical failure shall be defined as: any failure of a computer system, application, or device, or the loss of electrical power to that system, application, or device, or any other service interruption to a computer system, application, or device in such a manner that is reasonably prevents a practitioner from utilizing his or her certified electronic prescribing application to transmit an electronic prescription for a controlled substance in accordance with this section and federal requirements. In the instance of a temporary technological or electrical failure, a practitioner shall, without undue delay, seek to correct any cause for the failure that is reasonably within his or her control;

(3) issued by practitioners to whom the commissioner has granted a waiver, or a renewal thereof, from the requirement to use electronic prescribing. A waiver may be issued by the commissioner based upon a showing of a practitioner that his or her ability to issue an electronic prescription in accordance with this section is unduly burdened by:

(a) economic hardship;

(b) technological limitations that are not reasonably within the control of the practitioner; or

(c) other exceptional circumstance demonstrated by the practitioner.

The practitioner's showing shall include a sworn statement of facts detailing the circumstances in support of a waiver, and should be accompanied by any and all other information which would be relevant to the commissioner's determination. The practitioner shall also provide any information which would tend to negate the need for a waiver. A waiver shall be granted by the commissioner for a specified period of time, but in no event for more than one year. A practitioner may apply for a renewal of a previously granted waiver. Any application for the renewal of a previously granted waiver shall include an updated statement of facts detailing the continuing circumstances in support of the renewal, along with any facts reasonably known to the practitioner which tend to weigh against the granting of a renewal. Any renewal granted shall be subject to the same requirements as the original waiver.

(4) issued by a practitioner under circumstances where such practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the patient's medical condition, provided that if such prescription is for a controlled substance, the quantity of controlled substances does not exceed a five day supply if the controlled substance were used in accordance with the directions for use; or

(5) issued by a practitioner to be dispensed by a pharmacy located outside the state.

(d) A practitioner who issues a prescription pursuant to paragraph (2) of subdivision (c) of this section shall file information about the issuance of such prescription with the department as soon as practicable, but in no instance more than 72 hours following the end of the technological or electrical failure that prevented the issuance of an electronic prescription.

(e) A practitioner who issues a prescription pursuant to paragraphs (4) or (5) of subdivision (c) of this section shall file information about the issuance of such prescription with the department within 48 hours of the date of issue.

(f) A practitioner who has been granted a waiver pursuant to paragraph (3) of subdivision (c) of this section shall notify the department in writing within five business days upon gaining the capability to issue an electronic prescription. Without regard to the original expiration date, the waiver granted to the practitioner shall terminate within a reasonable period of time as determined by the department, allowing for the practitioner to make accommodations to begin issuing electronic prescriptions.

(g) Any prescription issued pursuant to paragraph (c) of this section shall be issued as an Official New York State prescription or an oral prescription in accordance with 80.63, 80.67, 80.68, 80.69 and 80.70.

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Wednesday, March 27, 2013

Doc Status:

Complete

### **Section 80.65 - Purpose of issue**

80.65 Purpose of issue. A prescription, in order to be effective in legalizing the possession of controlled substances, shall be issued for legitimate medical purposes only. The responsibility for the proper prescribing and dispensing of controlled substances shall be on the physician, dentist, podiatrist, veterinarian or other authorized practitioner, but a corresponding liability shall rest with the pharmacist who fills the prescription. An order purporting to be a prescription, issued to an addict or habitual user of controlled substances, not in the course of professional treatment but for the purpose of providing the user with narcotics or other controlled substances sufficient to keep him comfortable by maintaining his customary use, is not a prescription within the meaning of subdivision 30 of section 3302 of the Public Health Law and the person knowingly filling such an order, as well as the person issuing it, shall be subject to the penalties provided for violation of the provisions of law relating to controlled substances.

Doc Status:  
Complete

### **Section 80.66 - Schedule I substances**

80.66 Schedule I substances. No prescriptions shall be made or filled for controlled substances in schedule I.

Doc Status:  
Complete

### **Section 80.67 - Schedule II and certain other substances**

80.67 Schedule II and certain other substances.

(a) Prescriptions shall not be refilled for schedule II substances and:

Alprazolam  
Bromazepam  
Camazepam  
Chlordiazepoxide  
Clobazam  
Clonazepam  
Clorazepate  
Clotiazepam  
Cloxazolam  
Delorazepam  
Diazepam  
Estazolam  
Ethyl Loflazepate  
Fludiazepam  
Flunitrazepam  
Flurazepam  
Halazepam  
Haloxazolam  
Ketazolam  
Loprazolam  
Lorazepam  
Lormetazepam  
Medazepam  
Midazolam  
Nimetazepam  
Nitrazepam  
Nordiazepam  
Oxazepam  
Oxazolam  
Pinazepam  
Prazepam

Quazepam  
Temazepam  
Tetrazepam  
Triazolam

(b) Such prescription shall be written with ink, indelible pencil, typewriter, or by other electronic means approved by the department, and shall be signed by the practitioner. Electronic prescriptions may be created, signed, and transmitted electronically provided the practitioner

complies with all other requirements for issuing a prescription for a controlled substance in this Part and with federal requirements for electronic prescribing of controlled substances. The prescription shall contain the following:

(1) name, sex, address and age of the ultimate user for whom the substance is intended, or, if the ultimate user is an animal, the species of such animal and the name and address of the owner or person in custody of such animal;

(2) the printed name, address, Drug Enforcement Administration registration number, telephone number and handwritten signature of the prescribing practitioner. The printed name of the prescriber who has signed the prescription shall be imprinted or stamped legibly and conspicuously on the prescription, shall appear in an appropriate location on the prescription form and shall not be entered in or upon the space or line reserved for the prescriber's signature. The imprinted or stamped name shall not be a substitute for or fulfill any legal requirement otherwise mandating that the prescription be signed by the prescriber;

(3) specific directions for use, including, but not limited to the dosage and frequency of dosage and the maximum daily dosage; and

(4) the date upon which such prescription was prepared and actually signed by the prescribing practitioner. A prescription shall be dated as of, and signed on, the date it is issued.

(5) the quantity of dosage units prescribed. On an official New York State prescription, the quantity of dosage units prescribed shall be

indicated in both numerical and written word form.

(6) An electronic prescription shall contain the requirements as provided in subdivision (b)(1-5) except such prescription shall contain an electronic signature and shall be transmitted and received by electronic means. Such electronic signature shall meet the signature requirements set forth in subdivision (b)(2).

(7) A prescription generated on an electronic system and printed out or transmitted via facsimile is not an electronic prescription and shall be manually signed.

(8) a section wherein prescribers may indicate whether an individual is limited English proficient, as defined in section sixty-eight hundred twenty-nine of the education law; and if the patient is limited English proficient, a specification of the preferred language indicated by the patient. Failure to include such indication on the part of the prescriber shall not invalidate the prescription.

(c) Except as provided for in subdivision (d) of this section, no such prescription shall be made for a quantity of substances which would exceed a 30-day supply if the substance were used in accordance with the directions for use, specified on the prescription. No additional prescriptions for a controlled substance may be issued by a practitioner to an ultimate user within 30 days of the date of any prescription previously issued unless and until the ultimate user has exhausted all but a seven days' supply of that controlled substance provided by any previously issued prescription.

(d)(1) A practitioner may issue a prescription for up to a three month supply of a controlled substance, including chorionic gonadotropin, or up to a six month supply of an anabolic steroid if

used in accordance with the directions for use, provided that the prescription has been issued for the treatment of:

- (i) panic disorders, designated as code A;
- (ii) attention deficit disorder, designated as code B;
- (iii) chronic debilitating neurological conditions characterized as a movement disorder or exhibiting seizure, convulsive or spasm activity, designated as code C;
- (iv) relief of pain in patients suffering from conditions or diseases known to be chronic or incurable, designated as code D;
- (v) narcolepsy, designated as code E; or
- (vi) hormone deficiency states in males, gynecologic conditions that are responsive to treatment with anabolic steroids or chorionic gonadotropin, metastatic breast cancer in women, anemia and angioedema, designated as code F.

(2) Such prescription shall specify the condition being treated on the face of the prescription. The practitioner issuing such prescription shall either:

- (i) specify the name of such condition on the face of the prescription; or
- (ii) specify a code on the prescription to denote the condition for which the prescription has been issued, in accordance with codes designated in paragraph (d)(1) of this section.

(3) Either the name of the condition or one of the designated codes shall fulfill the requirement in:

- (i) section 3332(3) of the Public Health Law for the specific condition to be given on the face of the prescription; and
- (ii) section 3333(1) of the Public Health Law for the statement that the controlled substance has been prescribed to treat one of the conditions that have been enumerated by the regulations of the commissioner as warranting the prescribing of greater than a 30 days' supply of a controlled substance.

(e) Such official New York State prescription or out-of-state written prescription for a patient enrolled in a hospice program or for a patient residing in a Residential Health Care Facility (RHCF) may be transmitted by the practitioner, or a person authorized by the practitioner, to the dispensing pharmacy by facsimile, provided;

(1) The hospice program or RHCF is licensed or approved by the Department;

(2) The dispensing pharmacy has a written agreement or contract with the hospice program or "RHCF" to dispense controlled substances to a patient of such program or facility;

(3) The practitioner shall note on the prescription that the patient is a "hospice patient" or "RHCF patient"; and

(4) Within 72 hours, the prescribing practitioner shall cause to be delivered to the pharmacist the original official New York State prescription or the original out-of-state written prescription. If the pharmacist fails to receive such prescription, he/she shall notify the Department in writing or electronically within 7 days from the date of dispensing the substance.

(f) An official New York State prescription or an out-of-state written prescription for a Schedule II narcotic substance or for those controlled substances listed in paragraph (a) of this Section to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner, or a person authorized by the practitioner, to the dispensing pharmacy by facsimile. Within 72 hours,



the prescribing practitioner shall cause to be delivered to the pharmacist the original official New York State prescription or the original out-of-state written prescription. If the pharmacist fails to receive such prescription, he/she shall notify the Department in writing or electronically within 7 days from the date of dispensing the substance.

(g) When an official New York State prescription or an out-of-state written prescription prepared by a practitioner is incomplete, the practitioner may orally furnish the missing information to the pharmacist and authorize him or her to enter such information on the prescription. The pharmacist shall write the date he or she received the oral authorization on the prescription and shall affix his or her signature. This procedure shall not apply to unsigned or undated prescriptions or where the name and/or quantity of the controlled substance is not specified or where the name of the ultimate user is missing. The pharmacist is not required to obtain authorization from the practitioner to enter the patient's address, sex or age if the pharmacist obtains this information through a good-faith effort.

(h) A practitioner may orally authorize a pharmacist to change information on an official New York State prescription or an out-of-state written prescription. This procedure shall not apply to the practitioner's signature, date the prescription was signed by the practitioner, drug name or name of the ultimate user. The pharmacist shall write the date he or she received the oral authorization on the prescription, the reason for the change and his or her signature. The pharmacist shall also indicate the change on the prescription and initial the change.

(i) When a pharmacist fills a prescription under subdivision (g) or subdivision (h) of this section, in a manner that would require the pharmacist to make a notation on the prescription if the prescription were written, the pharmacist shall make the same notation electronically when filling an electronic prescription and retain the annotation electronically in the prescription record.

(j) When a practitioner is notified that an electronic prescription was not successfully delivered, the practitioner shall indicate on any written or oral prescription issued as a replacement of the original electronic prescription that the prescription was originally transmitted electronically, to which pharmacy the prescription was originally transmitted, and that the original transmission failed.

(k) If the content of any of the information required by this Part for a prescription is altered during the transmission of an electronic prescription, the prescription is deemed to be invalid and the pharmacy may not dispense the controlled substance.

Effective Date:  
Wednesday, March 27, 2013  
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**Section 80.68 - Emergency oral prescriptions for schedule II substances and certain other controlled substances**

80.68 Emergency oral prescriptions for schedule II substances and certain other controlled substances.

- (a) In an emergency, a practitioner may orally prescribe and a pharmacist may dispense, to an ultimate user, controlled substances in schedule II and those controlled substances listed in section 80.67 of this Part; provided, however, the pharmacist shall:
- (1) contemporaneously reduce such prescription to writing or, to the extent authorized by federal requirements, to an electronic record;
  - (2) dispense the substance in conformity with the labeling requirements applicable to the type of prescription which would be required but for the emergency; and
  - (3) make a good-faith effort to verify the identity of both the practitioner and the ultimate user.
- (b) No oral prescription shall be filled for a quantity of controlled substances which would exceed a five-day supply if the substance were used in accordance with the directions for use.
- (c) Within 72 hours after authorizing an emergency oral prescription, the prescribing practitioner shall cause to be delivered to the pharmacist a written or an electronic prescription. Such prescription shall, in addition to the information otherwise required, also have written or typed upon its face the words: "Authorization for emergency dispensing." If the pharmacist fails to receive such prescription, he shall notify the department in writing or electronically within seven days from the date of dispensing the substance.
- (d)(1) The pharmacist filling the prescription shall endorse upon the prescription the date of delivery, and his/her signature.
- (2) The endorsed prescription shall be retained by the proprietor of the pharmacy for a period of five years. The prescription information shall be filed electronically with the Bureau of Narcotic Enforcement, utilizing a transmission format acceptable to the Department, not later than 24 hours after the substance was delivered. A waiver allowing a pharmacy to make such filings within a longer period of time may be issued by the commissioner based upon a showing of economic hardship, technological limitations that are not reasonably within the control of the pharmacy; or other exceptional circumstance demonstrated by the pharmacy. Such waiver and any subsequent waiver shall be applied for in the same manner and shall be subject to the same requirements as specified in Section 80.63(c)(2)(x) of this Part and, if granted, such waiver shall not provide for a filing period longer than the 15th day of the next month following the month in which the substance was delivered. The information filed with the department shall include but not be limited to:
- (i) pharmacy prescription number;
  - (ii) pharmacy's national identification number;
  - (iii) patient name, in the case of an animal, the patient name field shall be filled with the name of the animal's

- owner;
- (iv) patient address, including street, city, state, ZIP code;
  - (v) patient date of birth;
  - (vi) patient's sex;
  - (vii) date prescription filled;
  - (viii) metric quantity;
  - (ix) national drug code number of the drug;
  - (x) number of days supply;
  - (xi) prescriber's Drug Enforcement Administration (DEA) number;
  - (xii) date prescription issued;
  - (xiii) serial number of official prescription form or an identifier designated by the department;
  - (xiv) payment method;
  - (xv) species code; and
  - (xvi) name of animal, if applicable.
- (e) Emergency means that the immediate administration of the drug is necessary for proper treatment, that no alternative treatment is available and it is not possible for the practitioner to provide a written or electronic prescription for the drug at the time.

Effective Date:

Tuesday, August 27, 2013

Doc Status:

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### **Section 80.69 - Schedule III, IV and V substances**

80.69 Schedule III, IV and V substances.

(a) In addition to the requirements set forth in sections 80.67 and 80.70 of this Part, substances in schedule III, IV or V shall be prescribed by a practitioner on an official New York State prescription or, subject to the following, an electronic prescription, in good faith, and in the course of his/her professional practice. Electronic prescriptions may be created, signed and transmitted electronically provided the practitioner complies with all other requirements for issuing controlled substance prescriptions in this Part, and with federal requirements for electronic prescribing of controlled substances. A prescription generated on an electronic system that is printed out or transmitted via facsimile is not considered an electronic prescription and shall be manually signed.

(b) The prescription shall contain the following:

- (1) name, address and age of the ultimate user for whom the substance is intended, or, if the ultimate user is an animal, the species of such animal and the name and address of the owner or person in custody of such animal;
- (2) the printed name, address, Drug Enforcement Administration registration number, telephone number and handwritten signature or, in the case of an electronic prescription, the electronic signature of the prescribing practitioner. The printed name of the prescriber who has signed the prescription shall be imprinted or stamped legibly and conspicuously on the prescription, shall appear in an appropriate location on the prescription form and shall not be entered in or upon the

space or line reserved for the prescriber's signature. The imprinted or stamped name shall not be a substitute for or fulfill any legal requirement otherwise mandating that the prescription be signed by the prescriber;

(3) specific directions for use, including but not limited to the dosage and frequency of dosage and the maximum daily dosage;

(4) the date upon which such prescription was actually signed by the prescribing practitioner. A prescription shall be dated as of, and signed on, the date when issued; and

(5) the quantity of dosage units prescribed and the number of times that the prescription may be refilled. On an official New York State prescription, the quantity of dosage units and the number of times that the prescription may be refilled shall be indicated in both numerical and written word form.

(6) An electronic prescription shall contain the requirements as provided in subdivision (b)(1-5) except such prescription shall contain an electronic signature and shall be transmitted and received by electronic means. Such electronic signature shall meet the signature requirements set forth in subdivision (b)(2).

(7) a section wherein prescribers may indicate whether an individual is limited English proficient, as defined in section sixty-eight hundred twenty-nine of the education law; and if the patient is limited English proficient, a specification of the preferred language indicated by the patient. Failure to include such indication on the part of the prescriber shall not invalidate the prescription.

(c) Except as provided in subdivision (d) of this section, no such prescription shall be made for a quantity of substances which would exceed a 30-day supply if the substance were used in accordance with the directions for use, as specified on the prescription. No additional prescriptions for a controlled substance may be issued by a practitioner to an ultimate user within 30 days of the date of any prescription previously issued unless and until the ultimate user has exhausted all but a seven days' supply of that controlled substance provided by any previously issued prescription.

(d)(1) A practitioner may issue a prescription for up to a three month supply of a controlled substance if used in accordance with the directions for use, provided that the prescription has been issued for the treatment of:

(i) panic disorders, designated as code A;

(ii) attention deficit disorder, designated as code B;

(iii) chronic debilitating neurological conditions characterized as a movement disorder or exhibiting seizure, convulsive or spasm activity, designated as code C;

(iv) relief of pain in patients suffering from conditions or diseases known to be chronic or incurable, designated as code D;

(v) narcolepsy, designated as code E; or

(vi) hormone deficiency states in males, gynecologic conditions that are responsive to treatment with anabolic steroids or chorionic gonadotropin, metastatic breast cancer in women, anemia and angioedema, designated as code F.

(2) Such prescription shall specify the condition being treated on the face of the prescription. The practitioner issuing such prescription shall either:

(i) specify the name of such condition on the face of the prescription; or

(ii) specify a code on the prescription to denote the condition for which the prescription has been issued, in accordance with codes issued by the department.

(3) Either the name of the condition or one of the designated codes shall fulfill the requirement in:

(i) section 3332(3) of the Public Health Law for the specific condition to be given on the face of the prescription; and

(ii) section 3333(1) of the Public Health Law for the statement that the controlled substance has been prescribed to treat one of the conditions that have been enumerated by the regulations of the commissioner as warranting the prescribing of greater than a 30 days' supply of a controlled substance.

(e) Such official New York State prescription or out-of-state written prescription for a patient enrolled in a hospice program or for a patient residing in a Residential Health Care Facility (RHCF) may be transmitted by the practitioner, or a person authorized by the practitioner, to the dispensing pharmacy by facsimile, provided;

(1) The hospice program or RHCF is licensed or approved by the Department;

(2) The dispensing pharmacy has a written agreement or contract with the hospice program or "RHCF" to dispense controlled substances to a patient of such program or facility;

(3) The practitioner shall note on the prescription that the patient is a "hospice patient" or "RHCF patient"; and

(4) Within 72 hours, the prescribing practitioner shall cause to be delivered to the pharmacist the original official New York State prescription or the original out-of-state written prescription. If the pharmacist fails to receive such prescription, he/she shall notify the Department in writing or electronically within 7 days from the date of dispensing the substance.

(f) An official New York State prescription or out-of-state written prescription for a Schedule III, IV, or V controlled substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner, or a person authorized by the practitioner, to the dispensing pharmacy by facsimile. Within 72 hours, the prescribing practitioner shall cause to be delivered to the pharmacist the original official New York State prescription or the original out-of-state written prescription. If the pharmacist fails to receive such prescription, he/she shall notify the Department in writing or electronically within 7 days from the date of dispensing the substance.

(g) An official New York State prescription, an out-of-state written prescription, or an electronic prescription for a Schedule III, IV, or V controlled substance, other than such substances as listed in section 80.67 of this Part, may be refilled, but not more than the number of times specifically authorized by the prescriber upon the prescription; provided, however, no such authorization shall be effective for longer than six months from the date the prescription is signed and that not more than five refills are made. When the initial prescription is issued for a quantity of substance

in excess of a 30-day supply under the authority of subdivision (c) of this section, the prescription may only be refilled once.

(h) Unless an earlier refilling is authorized by the prescriber, no prescription shall be refilled earlier than seven days prior to the date the previously dispensed supply would be exhausted if used in conformity with the directions for use.

(i) On refills the dispensing pharmacist shall indicate on the prescription the amount dispensed, the date dispensed, and the signature of the dispensing pharmacist. When refills are recorded in an electronic recordkeeping system:

(1) the pharmacist shall ensure that the computer application used for such recordkeeping shall:

(i) provide online retrieval of original prescription information; and

(ii) provide online retrieval of the current refill history for Schedule III, IV and V controlled substance prescriptions.

(2) each time an official New York State prescription or an out-of-state written prescription for a Schedule III, IV or V controlled substance is refilled, the dispensing pharmacist shall document that the refill information entered into the computer has been reviewed and is correct by manually signing:

(i) a hard-copy printout of each day's controlled substance prescription refill data, or;

(ii) a bound log book containing a statement that the refill information entered into the computer that day has been reviewed and is correct as shown.

(3) When a prescription is received electronically, the prescription and all required annotations shall be retained electronically.

(4) The pharmacy shall employ a procedure to be used for documentation of refills of Schedule III, IV and V controlled substance prescriptions in the event of system downtime. The procedure shall ensure that refills are authorized by the original prescription and that the maximum number of refills authorized has not been exceeded.

(j) Prescriptions which indicate pharmacy prescription numbers only of prior controlled substances prescriptions are not valid and shall not be refilled.

(k) Upon expiration of the authorization of the prescription to be refilled or the six-month limitation of the prescription, the practitioner shall execute a new prescription if he desires the medication to be continued.

(l) When a prescription prepared by a practitioner is incomplete, the practitioner may orally furnish the missing information to the pharmacist and authorize him or her to enter the missing information on the prescription. The pharmacist shall write the date he or she received the oral authorization on the prescription and shall affix his or her signature. This procedure shall not apply to unsigned or undated prescriptions or where the name and/or quantity of the controlled substances is not specified or where the name of the ultimate user is missing. The pharmacist is

not required to obtain authorization from the practitioner to enter the patient's address, sex or age if the pharmacist obtains the information through a good-faith effort.

(m) ) A practitioner may orally authorize a pharmacist to change information on a controlled substance prescription. This procedure shall not apply to the practitioner's signature, date the prescription was signed by the practitioner, drug name or name of the ultimate user. The pharmacist shall write the date he or she received the oral authorization on the prescription, reason for the change and his or her signature. The pharmacist shall also indicate the change on the prescription and initial the change.

(n) When a pharmacist fills a prescription in a manner that would require, under subdivision (l) or subdivision (m) of this section, the pharmacist to make a notation on the prescription if the prescription were written, the pharmacist shall make the same notation electronically when filling an electronic prescription and retain the annotation electronically in the prescription record.

(o) When a practitioner is notified that an electronic prescription was not successfully delivered, the practitioner shall ensure that any written or oral prescription issued as a replacement of the original electronic prescription indicates that the prescription was originally transmitted electronically, shall indicate which pharmacy the prescription was originally transmitted to, and that the transmission failed.

(p) If the content of any of the information required by this Part for a controlled substance prescription is altered during the transmission of an electronic prescription, the prescription is deemed to be invalid and the pharmacy may not dispense the controlled substance.

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Wednesday, March 27, 2013

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### **Section 80.70 - Oral prescriptions for schedule III, IV and V substances**

80.70 Oral prescriptions for schedule III, IV and V substances.

(a) Except as provided in sections 80.67 and 80.68 of this Part, a practitioner may orally prescribe and a pharmacist may dispense, to an ultimate user, controlled substances in schedule III, IV or V; provided, however, the pharmacist shall:

(1) contemporaneously reduce such prescriptions to written memoranda, or to the extent authorized by federal requirements, to an electronic record, indicating the name and address of the prescriber and the practitioner's Drug Enforcement Administration registration number, name and address of ultimate user, date on which the controlled substance was ordered, name and quantity of controlled substances prescribed, directions for use and the fact that it is a telephone order. The memoranda for such oral prescriptions shall be filed in the schedule III, IV and V prescription file, or in the case of an electronic record, shall be filed electronically. The

pharmacist filling such oral orders shall indicate on the memoranda the date filled, the signature of the pharmacist filling the prescription and the pharmacy prescription number under which it is recorded in the pharmacy prescription file;

(2) dispense the substance in conformity with the labeling requirements applicable to a written prescription; and

(3) make a good faith effort to verify the identity of both the practitioner and the ultimate user.

(b) No oral prescription shall be filled for a quantity of controlled substances which would exceed a five-day supply, or with respect to schedule IV substances a 30-day supply or 100 dosage units whichever is less, if the substances were used in accordance with the directions for use; provided, however, that this provision shall not apply to any schedule IV controlled substance limited to a five day supply by section 80.68 of this Part.

(c) Within 72 hours after authorizing such an oral prescription, the prescribing practitioner shall cause to be delivered to the pharmacist a written, or an electronic prescription. The electronic prescription, in addition to the information otherwise required, shall also have upon it the words: "Follow-up prescription to oral order." If the pharmacist fails to receive such prescription, he shall record on the memorandum for said oral prescription this notation: "Follow-up prescription not received", the name of the pharmacist and the date of the recording.

(d) Follow-up prescriptions from prescribers for schedule III, IV and V controlled substances shall be attached to or otherwise stored with the corresponding oral orders, and shall be filed in the schedule III, IV and V controlled substances file.

(e) The pharmacist receiving such follow-up prescriptions shall endorse on such prescription his or her signature, the date of filling, the number of the prescription under which it is recorded in the pharmacy prescription file and the fact that such prescription is a follow-up to the prior oral order. In addition, he or she shall place on the follow-up prescription the date of receipt, the pharmacy prescription number and the date the oral order was filled, as follows: "Follow-up prescription to oral order, pharmacy prescription number ....., oral order filled on ..... , follow-up prescription received....." In the case of electronic prescriptions and where the pharmacy maintains such records electronically, such information may be created and maintained by the pharmacy in electronic form.

(f) The prescription information shall be filed with the department in accordance with section 80.73(f) of this Part.



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## **Section 80.71 - Practitioners; dispensing controlled substances**

80.71 Practitioner; dispensing controlled substances.

(a) Practitioners, in good faith and in the course of their professional practice only, and as limited in this Part may dispense controlled substances.

(b) Except as provided in subdivision (c) of this section, the quantity of substances dispensed may not exceed a 30-day supply if the substances were used in accordance with the directions for use. No additional dispensing of a controlled substance may be made by a practitioner to an ultimate user within 30 days of the date of the previous dispensing unless and until the ultimate user has exhausted all but a seven days' supply of that controlled substance previously dispensed.

(c)(1) A practitioner may dispense up to a three month supply of a controlled substance, including chorionic gonadotropin, or up to a six month supply of an anabolic steroid if used in accordance with the directions for use, provided that such supply has been dispensed for the treatment of a condition specified in section 80.67(d) and 80.69(d) of this Part.

(d) No controlled substance shall be dispensed unless it is enclosed within a suitable and durable container upon which is indelibly typed, printed or otherwise legibly written upon an orange label affixed to such container, in a manner which would inhibit its removal, the following:

(1) name and address of the ultimate user for whom the substance is intended, or, if intended for use upon an animal, the species of such animal and the name and address of the owner or person having custody of such animal;

(2) name, address and telephone number of the dispensing practitioner;

(3) specific directions for use, including but not limited to the dosage and frequency of dosage, and the maximum daily dosage;

(4) the legend, prominently marked or printed in either boldface or upper case lettering: "CONTROLLED SUBSTANCE, DANGEROUS UNLESS USED AS DIRECTED";

(5) the date of dispensing; and

(6) either the name of the substance or such code number assigned by the department for the particular substance pursuant to section 80.24 of this Part.

(e) The practitioner shall submit dispensing information, for all controlled substances dispensed, electronically to the department utilizing a transmission format acceptable to the department, not

later than 24 hours after the substance was delivered. A waiver allowing a practitioner to make such filings within a longer period of time may be issued by the commissioner based upon a showing of economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner. Such waiver and any subsequent waiver shall be applied for in the same manner and shall be subject to the same requirements as specified in Section 80.63(c)(2)(x) of this Part and, if granted, such waiver shall not provide for a filing period longer than the 15th day of the next month following the month in which the substance was delivered. The information filed with the department shall include but not be limited to:

- (1) dispenser identifier;
- (2) patient name, in the case of an animal, the patient name field shall be filled with the name of the animal's owner;
- (3) patient address, including street, city, state, ZIP code;
- (4) patient date of birth;
- (5) patient's sex;
- (6) date controlled substance dispensed;
- (7) metric quantity;
- (8) national drug code number of the drug;
- (9) number of days supply;
- (10) prescriber's Drug Enforcement Administration (DEA) number;
- (11) payment method;
- (12) species code; and
- (13) name of animal, if applicable.

When applicable, the practitioner shall file a zero report with the department as specified in Section 80.73(f)(2)(i) of this Part, or a practitioner may apply for a waiver of the requirement to file a zero report as specific in Section 80.73(f)(2)(ii) of this Part.

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## **Section 80.72 - Issuance of official New York State prescription forms**

80.72 Issuance of official New York State prescription forms.

(a) A practitioner shall register with the department to be issued official New York State prescription forms. The registration application shall include, but not be limited to, the requesting practitioner's name, specialty, primary address and other practice site address(s), number of prescriptions requested, the Federal registration number or exemption certificate, the State professional practice license number, and shall be signed by the requesting practitioner.

(b) A practitioner's registration shall be without fee and subject to approval by the department. Such registration shall be valid for a period of two years.

(c) A practitioner registered to be issued official prescription forms shall order such forms in the manner required by the department.

(1) The number of prescriptions requested by practitioners shall be subject to approval by the department and shall be issued free of charge in the manner and quantity approved by the department.

(2) The address of the practitioner to which the forms shall be sent shall be the address of a registered practitioner's Federal Drug Enforcement Administration (DEA) registration.

(3) The commissioner may specify that such forms or series of forms shall be valid for a limited period of time and may be cancelled by the commissioner by giving notice to the practitioner.

(d) The commissioner may revoke, cancel or withhold official New York State prescription forms for prescribing controlled substances upon a finding of willful failure to comply with the Public Health Law or this Title. Notice of such finding shall specify that a formal hearing pursuant to the provisions of the Public Health Law may be granted, provided such person shall request the hearing within five days after receipt of the notice.

(e) Official New York State prescription forms of practitioners who are deceased or who no longer prescribe controlled substances shall be returned to the Bureau of Narcotic Enforcement, NYS Department of Health, Corning Tower, The Governor Nelson A. Rockefeller Empire State Plaza, Albany, NY 12237, or an authorized narcotic enforcement representative of the department, by the practitioner or, if the practitioner is deceased, by the next of kin of the practitioner or, if the next of kin is unable to obtain the prescription forms, by a representative of the estate of the practitioner.

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**Section 80.73 - Pharmacists; dispensing schedule II substances and certain other controlled substances**

80.73 Pharmacists; dispensing schedule II substances and certain other controlled substances.

(a) A licensed, registered pharmacist, or a pharmacy intern acting in conformity with the provisions of section 6806 of the Education Law and regulations thereunder in a registered pharmacy, may, in good faith and in the course of his/her professional practice, sell and dispense to an ultimate user schedule II controlled substances or those schedule III or schedule IV controlled substances listed in section 80.67(a) of this Part, provided they are dispensed pursuant to an official New York State prescription, an out-of-state prescription or an electronic prescription delivered within 30 days of the date such prescription was signed by the authorized practitioner or an oral prescription where permitted.

(b) No such substance shall be dispensed or sold unless it is enclosed within a suitable and durable container to which is affixed, in such a manner which would inhibit its removal, an orange label upon which is indelibly typed, printed or otherwise legibly written:

- (1) the name and address of the ultimate user for whom the substance is intended, or, if intended for use upon an animal, the species of such animal and the name and address of the owner or person having custody of such animal;
- (2) the name, address and telephone number of the pharmacy from which such substance is dispensed;
- (3) specific directions for use as stated on the prescription;
- (4) the name of the prescribing practitioner;
- (5) the legend, prominently marked or printed in either boldface or upper case lettering: "CONTROLLED SUBSTANCE, DANGEROUS UNLESS USED AS DIRECTED";
- (6) the number of the prescription under which it is recorded in the pharmacy prescription file;
- (7) the date of filling; and
- (8) the name of the controlled substance or such code number assigned by the department for the particular substance pursuant to section 80.24 of this Part.

(c) A licensed, registered pharmacist in a registered pharmacy may, in good faith and in the course of his/her professional practice, sell and dispense, to an ultimate user, controlled substances upon the delivery to such pharmacist, within 30 days of the date such prescription was issued by an authorized practitioner, an official New York State prescription or an out-of-state written prescription transmitted by facsimile in accordance with subdivision (e) or subdivision (f) of section 80.67 of this Part.

(d) The pharmacist filling the prescription shall endorse upon the prescription his/her signature, the date of filling, and the number of the prescription under which it is recorded in the pharmacy prescription file.

(e) A pharmacy shall make a good faith effort to verify the identity of any person accepting delivery of a dispensed prescription for a controlled substance by requiring such person, if unknown to the pharmacy, to present appropriate identification.

(f)(1) The endorsed prescription shall be retained by the proprietor of the pharmacy for a period of five years. The prescription information shall be filed electronically with the Bureau of Narcotic Enforcement, utilizing a transmission format acceptable to the department, not later than 24 hours after the substance was delivered. A waiver allowing a pharmacy to make such filings within a longer period of time may be issued by the commissioner based upon a showing of economic hardship, technological limitations that are not reasonably within the control of the pharmacy, or other exceptional circumstance demonstrated by the pharmacy. Such waiver and any subsequent waiver shall be applied for in the same manner and shall be subject to the same requirements as specified in Section 80.63(c)(2)(x) of this Part and, if granted, such waiver shall not provide for a filing period longer than the 15th day of the next month following the month in which the substance was delivered. Pharmacies delivering prescriptions by mail or licensed express delivery services shall file the prescription information with the Bureau of Narcotic Enforcement, utilizing a transmission format acceptable to the department, not later than 72 hours after the substance was shipped from the pharmacy. The information filed with the department shall include but not be limited to:

- (i) pharmacy prescription number;
- (ii) pharmacy's national identification number;
- (iii) patient name, in the case of an animal, the patient name field shall be filled with the name of the animal's owner;
- (iv) patient address, including street, city, state, ZIP code;
- (v) patient date of birth;
- (vi) patient's sex;
- (vii) date prescription filled;
- (viii) metric quantity;
- (ix) national drug code number of the drug;
- (x) number of days supply;
- (xi) prescriber's Drug Enforcement Administration number;
- (xii) date prescription issued;
- (xiii) serial number of official prescription form, or an identifier designated by the department;
- (xiv) payment method;
- (xv) number of refills authorized;
- (xvi) refill number;
- (xvii) species code; and
- (xviii) name of animal, if applicable.

(2) (i) When applicable, pharmacies and dispensing practitioners shall file a zero report with the Bureau of Narcotic Enforcement in a format acceptable to the department. For the purposes of this Part, a zero report shall be a report that no controlled substances were dispensed by a pharmacy or dispensing practitioner during the relevant period of time. A zero report shall be submitted no later than 14 days following the most recent previously reported dispensing of a

controlled substance, the submission of a prior zero report, or the termination of a waiver of the requirement to file a zero report.

(ii) A waiver of the requirement to file a zero report may be issued by the commissioner based upon a showing that a pharmacy or practitioner does not dispense controlled substances within the state of New York. The request for a waiver shall include a sworn statement of facts detailing the circumstances in support of a waiver, and should be accompanied by any and all other information which would be relevant to the commissioner's determination, as well as any information which would tend to negate the need for a waiver. A waiver granted by the commissioner shall be for a specified period of time, but in no event for more than two years. Subsequent waivers shall be applied for in the same manner and shall be subject to the same requirements set forth above. A pharmacy or practitioner who has been granted a waiver shall notify the department in writing within five business days of any change in circumstances that would result in the possible dispensing of a controlled substance. The waiver granted to the pharmacy or practitioner shall be terminated effective the date of notification, and the pharmacy or practitioner shall comply with all reporting requirements of this Part until or unless a subsequent waiver is granted.

(g) Emergency oral prescriptions for schedule II controlled substances or those schedule III or schedule IV controlled substances listed in section 80.67(a) of this Part may be dispensed by a pharmacist to an ultimate user in an emergency situation, provided the pharmacist shall:

(1) contemporaneously reduce such prescriptions to written memoranda or, to the extent authorized by federal requirements, to an electronic record and shall indicate on such memoranda the name and address of the prescriber and his/her Drug Enforcement Administration registration number, name and address of the ultimate user, date on which it is ordered, name and quantity of drugs prescribed, directions for use and the fact that it is a telephone order. The memoranda or electronic record for such emergency oral prescription shall be filed in the same manner as is otherwise required for such prescription. The pharmacist filling such oral orders shall indicate on the face of such telephone order his/her signature, the date filled and the number of the prescription under which it is recorded in the pharmacy prescription file;

(2) dispense the substance in conformity with labeling requirements applicable to the type of prescription which would be required but for the emergency; and

(3) make a good-faith effort to verify the identity of both the practitioner and the ultimate user.

(4) No emergency oral prescription shall be filled for a quantity of controlled substances which would exceed a five-day supply if the substance were used in accordance with the directions for use.

(5) Within 72 hours after authorizing an emergency oral prescription, the prescribing practitioner shall cause to be delivered to the pharmacist a written or an electronic prescription. Such prescription shall, in addition to the information otherwise required, also have written or typed upon its face the words: "Authorization for emergency dispensing". If the pharmacist fails to receive such prescription, he/she shall notify the department in writing or electronically within seven days from the date of dispensing the substance.

(h) Within 72 hours after transmitting a prescription to a pharmacist by facsimile in accordance with subdivision (e) or (f) of section 80.67 of this Part, the prescribing practitioner shall cause to be delivered to the pharmacist the original official New York State prescription or an original

out-of-state written prescription. Such original prescription shall be attached to any prescription transmitted by facsimile. If the pharmacist fails to receive such prescription, he/she shall notify the Department in writing or electronically within 7 days from the date of dispensing the substance.

(i) Such prescriptions shall be endorsed, retained and filed in the same manner as is otherwise required for such prescriptions. The follow-up prescriptions shall be attached to, or otherwise associated with, the corresponding memoranda of oral orders or to prescriptions transmitted by facsimile. The information required in section 80.68(d)(2) shall be filed electronically with the New York State Department of Health, not later than 24 hours after the substance was delivered. The pharmacy must submit this information electronically to the department utilizing a transmission format acceptable to the department. A waiver allowing a pharmacy to make such filings within a longer period of time may be issued by the commissioner based upon a showing of economic hardship, technological limitations that are not reasonably within the control of the pharmacy, or other exceptional circumstance demonstrated by the pharmacy. Such waiver and any subsequent waiver shall be applied for in the same manner and shall be subject to the same requirements as specified in Section 80.63(c)(2)(x) of this Part and, if granted, such waiver shall not provide for a filing period longer than the 15th day of the next month following the month in which the substance was delivered.

(j) A pharmacist may partially fill a prescription for a schedule II controlled substance or those schedule III or schedule IV controlled substances listed in section 80.67(a) of this Part provided that:

(1) the pharmacist does not have a sufficient quantity to fill a prescription and he/she makes a notation of the quantity supplied on the prescription. The remaining portion of the prescription may be filled with 72 hours of the first partial filling. However, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing practitioner. No further quantity may be supplied beyond 72 hours without a new prescription; or

(2) the patient is a resident in a Residential Health Care Facility ("RHCF") which is licensed or approved by the department; or

(3) the patient has been diagnosed as being terminally ill.

(4) when such prescription is partially filled in accordance with paragraphs (2) or (3) of this subdivision, the pharmacist shall:

(i) record on the prescription whether the patient is "terminally ill" or is a "RHCF patient"; and

(ii) record on the prescription the date of the partial filling, quantity dispensed, quantity remaining and the signature of the dispensing pharmacist.

(5) The prescription shall be valid for a period not to exceed 30 days from the date the prescription was issued by the practitioner unless terminated sooner upon notification from the practitioner of the discontinuance of medication. All partial fillings filled under subdivision (1) of this section must occur within 30 days from the date the prescription was issued, except that

partial fillings of prescriptions issued for more than a 30 day supply for patients residing in a residential healthcare facility or for patients enrolled in a hospice program that is licensed or approved by the Department must occur within 60 days from the date the prescription was issued.

(6) The date of filling on the prescription shall be the date when the prescription has been filled to completion or the date when the pharmacy is notified by the practitioner that the prescription has been discontinued.

(k) When an official New York State prescription or an out-of-state written prescription prepared by a practitioner is incomplete, the practitioner may orally furnish the missing information to the pharmacist and authorize him or her to enter such information on the prescription. The pharmacist shall write the date he or she received the oral authorization on the prescription and shall affix his or her signature. This procedure shall not apply to unsigned or undated prescriptions or where the name and/or quantity of the controlled substance is not specified or where the name of the ultimate user is missing. The pharmacist is not required to obtain authorization from the practitioner to enter the patient's address, sex or age if the pharmacist obtains this information through a good-faith effort.

(l) A practitioner may orally authorize a pharmacist to change information on an official New York State prescription or an out-of-state written prescription. This procedure shall not apply to the practitioner's signature, date the prescription was signed by the practitioner, drug name or name of the ultimate user. The pharmacist shall write the date he or she received the oral authorization on the prescription, reason for the change and his or her signature. The pharmacist shall also indicate the change on the prescription and initial the change.

(m) ) When a pharmacist fills a prescription in a manner that would require, under subdivision (k) or subdivision (l) of this section, the pharmacist to make a notation on the prescription if the prescription were written, the pharmacist shall make the same notation electronically when filling an electronic prescription and retain the annotation electronically in the prescription record.

(n) When a pharmacist receives a written or an oral prescription for a schedule II controlled substance or those schedule III or schedule IV controlled substances listed in section 80.67(a) of this Part that indicates that it was originally transmitted electronically to the pharmacy, the pharmacist shall conduct a reasonable search of the pharmacy records to ensure that the electronic version was not received and the prescription dispensed. If both prescriptions were received, the pharmacist shall mark one as void.

(o) When a pharmacist receives a written or an oral prescription for a schedule II controlled substance or those schedule III or schedule IV controlled substances listed in section 80.67(a) of this Part that indicates that it was originally transmitted electronically to a separate pharmacy, the pharmacist shall confer with the separate pharmacy to determine if the separate pharmacy received that prescription and if the separate pharmacy dispensed upon that electronic prescription. If the separate pharmacy that received the original electronic prescription had not dispensed the prescription, that pharmacy shall mark the electronic version as void or cancelled.



If the pharmacy that received the original electronic prescription dispensed the prescription, the pharmacy receiving the written or oral version shall not dispense the prescription and shall mark it as void.

(p) A pharmacist shall use a pharmacy computer application that meets federal security requirements to process electronic controlled substance prescriptions and shall register such pharmacy computer application with the New York State Department of Health, Bureau of Narcotic Enforcement.

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### **Section 80.74 - Pharmacists; dispensing schedule III, IV and V controlled substances**

80.74 Pharmacists; dispensing schedule III, IV and V controlled substances.

(a) Except as provided in sections 80.67 and 80.73 of this Part, a licensed, registered pharmacist, or a pharmacy intern acting in conformity with the provisions of section 6808 of the Education Law, and regulations thereunder, in a registered pharmacy may, in good faith and in the course of his professional practice, dispense to an ultimate user, controlled substances in schedule III, IV or V provided they are dispensed pursuant to a prescription presented within 30 days of the date such prescription was signed by an authorized practitioner.

(b) Such substances may be dispensed only if packaged and labeled in conformity with provisions set forth in section 80.73(b) of this Part.

(c) A licensed, registered pharmacist in a registered pharmacy may, in good faith and in the course of his/her professional practice, sell and dispense, to an ultimate user, controlled substances for which a prescription is required upon the delivery to such pharmacist, within 30 days of the date such prescription, or official New York State prescription, or an out-of-state written prescription if sent by facsimile in accordance with subdivision (e) or subdivision (f) of section 80.69 of this Part was issued by an authorized practitioner.

(d) Within 72 hours after transmitting a prescription to a pharmacist by facsimile in accordance with subdivision (e) or (f) of section 80.69 of this Part, the prescribing practitioner shall cause to be delivered to the pharmacist the original official New York State prescription or the original out-of-state written prescription. Such original prescription shall be attached to the prescription transmitted by facsimile. If the pharmacist fails to receive such original prescription, he/she shall notify the Department in writing within 7 days from the date of dispensing the substance.

(e) The pharmacist filling the prescription shall endorse on such prescription his/her signature, the date of filling, and the number of the prescription under which it is recorded in the pharmacy prescription file. Such endorsed prescription shall be retained by the proprietor of the pharmacy

for a period of five years. Prescription information from the filling of such prescription shall be filed with the department in accordance with section 80.73(f) of this Part.

(f) A pharmacy shall make a good faith effort to verify the identity of any person accepting delivery of a dispensed prescription for a controlled substance by requiring such person, if unknown to the pharmacy, to present appropriate identification.

(g) When a prescription prepared by a practitioner is incomplete, the practitioner may orally furnish the missing information to the pharmacist and authorize him to enter the missing information on the prescription. The pharmacist shall write the date he or she received the oral authorization on the prescription and shall affix his or her signature. This procedure shall not apply to unsigned or undated prescriptions or where the name and/or quantity of the controlled substance is not specified or where the name of the ultimate user is missing. The pharmacist is not required to obtain authorization from the practitioner to enter the patient's address, sex or age if the pharmacist obtains this information through a good-faith effort.

(h) A practitioner may orally authorize a pharmacist to change information on a controlled substance prescription. This procedure shall not apply to the practitioner's signature, date the prescription was signed by the practitioner, drug name or name of the ultimate user. The pharmacist shall write the date he or she received the oral authorization on the prescription, reason for the change and his or her signature. The pharmacist shall also indicate the change on the face of the prescription and initial the change.

(i) When a pharmacist fills a prescription in a manner that would require, under subdivision (g) or subdivision (h) of this section, the pharmacist to make a notation on the prescription if the prescription were written, the pharmacist shall make the same notation electronically when filling an electronic prescription and retain the annotation electronically in the prescription record.

(j) Except as provided in sections 80.67 and 80.73 of this Part, a pharmacist may partially fill a prescription for a controlled substance provided that:

(1) each partial filling is recorded in the same manner as a refill;

(2) the total quantity dispensed does not exceed the total quantity prescribed for a 30 day period.

(k) When a pharmacist receives a prescription for a schedule III, IV or V controlled substance that indicates that it was originally transmitted electronically to the pharmacy, the pharmacist shall check the records to ensure that the electronic version was not received and the prescription dispensed. If both prescriptions were received, the pharmacist shall mark one as void.

(l) When a pharmacist receives a prescription for a schedule III, IV or V controlled substance that indicates that it was originally transmitted electronically to another pharmacy, the pharmacist shall check with an employee at that pharmacy to determine whether the prescription was received and dispensed. If the pharmacy that received the original electronic prescription had not dispensed the prescription, that pharmacy shall mark the electronic version as void or cancelled. If the pharmacy that received the original electronic prescription dispensed the

prescription, the pharmacy with the written version shall not dispense the prescription and shall mark the prescription as void.

(m) A pharmacist shall use a pharmacy computer application that meets federal security requirements to process electronic controlled substance prescriptions, and shall register such pharmacy computer application with the New York State Department of Health, Bureau of Narcotic Enforcement.

Effective Date:

Wednesday, March 27, 2013

Doc Status:

Complete

### **Section 80.75 - Institutional dispensers**

80.75 Institutional dispensers.

(a) Institutional dispensers licensed by the department may cause controlled substances to be administered or dispensed for use on the premises only pursuant to a written order by a practitioner for such medication. A prescription is not required for inpatient use. In an emergency situation in which a physician determines that it is necessary to transfer a critically ill patient from one hospital to an alternative medical facility, an institutional dispenser may cause a single dose of a controlled substance to be dispensed to the medical attendant accompanying the patient if the duration of the transfer may reasonably be expected to exceed three hours.

(b) An institutional dispenser may dispense controlled substances for use off its premises only pursuant to a prescription issued by a practitioner. All such prescriptions for outpatient use shall be filled only in a hospital pharmacy or other registered pharmacy. However, a practitioner in the emergency room of a hospital without a full-time pharmacy and when the services of a registered pharmacy are not available may dispense controlled substances to a patient in an emergency situation. For the purposes of this subdivision, an emergency means that the immediate dispensing of the controlled substance is necessary and no alternative treatment is available. The practitioner may dispense no more than a 24-hour supply in accordance with directions for use and must conform with the applicable labeling requirements of section 80.71 of this Part.

(c) Official New York State prescription forms are available for use by institutional dispensers. Institutional dispensers shall register with the department to be issued official prescriptions.

(1) The registration application for an institutional dispenser shall include but not be limited to the requesting institution's name, primary or other practice site address(s), the Federal registration number or exemption certificate, where applicable, a State agency license number, if applicable, and shall be signed by a person authorized by the institution to request such forms.

(2) An institutional dispenser's registration shall be without fee and subject to approval by the department. Such registration shall be valid for a period of two years.

(3) An institutional dispenser registered to be issued official prescription forms shall order such forms in the manner required by the Department. The number of prescriptions requested by the institution shall be subject to approval by the Department and shall be issued free of charge in the manner and quantity approved by the Department.

(4) Official prescription forms shall be sent to the institutional dispenser's primary address. Primary address is the address of a registered institution's Federal Drug Enforcement Administration (DEA) registration or, if such facility is not required to be registered with DEA, an address designated as the primary address in the facility's registration with the department.

(d) Staff practitioners are required to use such forms to prescribe controlled substances for outpatient use, indicating the practitioner's Drug Enforcement Administration registration number on the form. Staff practitioners may create, sign and transmit electronic prescriptions for controlled substances for outpatient use provided the practitioner complies with all other requirements for issuing controlled substance prescriptions in this Part and with federal requirements for electronic prescribing of controlled substances. A prescription generated on an electronic system that is printed out or transmitted via facsimile is not considered an electronic prescription and shall be manually signed.

(e) Interns or residents are required to use the Drug Enforcement Administration registration number of the institution and the code number assigned by the institution for such purpose. Any practitioner who is an intern, resident or foreign physician may dispense and prescribe controlled substances under the registration of the hospital or other institution which is registered and by whom the physician is employed provided that:

(1) the dispensing or prescribing is in the usual course of his professional practice;

(2) the practitioner is authorized or permitted to do so by the laws of New York State;

(3) the hospital or institution has determined that the practitioner is permitted to dispense or prescribe drugs in New York State;

(4) the practitioner acts only within the scope of his employment in the hospital or institution;  
and

(5) the hospital or institution authorizes the intern, resident, or foreign physician to dispense or prescribe under its registration number and assigns a specific code number for each practitioner so authorized.

(f) It is the responsibility of the dispensing institution to obtain all official prescriptions for outpatient use and to assign such prescriptions to staff practitioners and interns and to insure the security of all such official prescriptions. Institutions obtaining official New York State prescriptions shall establish a system of control and security which will include the following:

(1) A record of all such prescriptions received.

- (2) A record of all such prescriptions assigned to staff practitioners.
- (3) A system requiring that such prescriptions be kept under lock and key when not in use.
- (4) A system whereby official prescriptions are surrendered to the institution if the practitioner to whom they were assigned terminates his affiliation with the institution.
- (5) A system whereby the Bureau of Narcotic Enforcement, New York State Department of Health, is notified immediately of the loss, destruction or theft of any such official prescriptions assigned to the institution.
- (6) A system whereby the institution has a sufficient number of official prescriptions in reserve for use by the institution.
- (g) Staff practitioners, interns, residents, or foreign physicians who are authorized to dispense or prescribe controlled substances in a hospital or other institution and use the institution's official New York State prescription forms, other hospital or institutional forms, or the institution's electronic prescribing application must conform to the requirements of sections 80.67, 80.69 and 80.71 of this Part.

Effective Date:

Wednesday, March 27, 2013

Doc Status:

Complete

### **Section 80.76 - Dispensing; prohibition**

80.76 Dispensing; prohibition. Controlled substances shall not be prescribed for, administered or dispensed to addicts or habitual users of controlled substances except as provided by the Public Health Law or this Part.

Doc Status:

Complete

### **Section 80.77 - Practitioners; control and reporting of official New York State prescription forms and electronic prescribing credentials**

80.77 Practitioners; control and reporting of official New York State prescription forms and electronic prescribing credentials.

- (a) Adequate safeguards and security measures shall be undertaken by practitioners holding official New York State prescription forms to assure against the loss, destruction, theft or unauthorized use of the forms. Practitioners shall maintain a record of the disposition of all forms, including but not limited to use as a prescription, cancellation, return, loss, destruction, unauthorized use and nonreceipt. The forms may be used only by the practitioner to whom they are issued and are not transferable.

(b) Practitioners shall immediately notify the department, upon forms supplied by the department, of the loss, destruction, theft or unauthorized use of any official New York State prescription forms issued to them, as well as the failure to receive official New York State prescription forms within a reasonable time after ordering them from the department.

(c) Practitioners shall retain sole possession and safeguard credentials used to sign electronic prescriptions for controlled substances and shall not share such credentials with any other person. The practitioner shall not allow any other person to use such credentials to sign prescriptions for controlled substances.

(d) Practitioners shall immediately notify the Bureau of Narcotic Enforcement that his or her credentials used to sign electronic prescriptions for controlled substances have been lost, stolen or compromised.

(e) Practitioners shall immediately notify the Bureau of Narcotic Enforcement upon discovery that one or more prescriptions issued under that practitioner's DEA registration were prescriptions the practitioner had not signed or were not consistent with the prescription the practitioner signed.

Effective Date:

Wednesday, March 27, 2013

Doc Status:

Complete

### **Section 80.78 - Pharmacists; dispensing out-of-state prescriptions; schedule II, III, IV and V controlled substances**

80.78 Pharmacists; dispensing out-of-state prescriptions; schedule II, III, IV and V controlled substances.

(a) A licensed, registered pharmacist, or a pharmacy intern acting in conformity with the provisions of section 6808 of the Education Law, and regulations thereunder, in a registered pharmacy may, in good faith and in the course of his/her professional practice, dispense to an ultimate user, controlled substances in schedule II, III, IV and V upon delivery to such pharmacist of an out-of-state prescription within 30 days of the date such prescription was signed by an authorized practitioner.

(b) Such prescription shall have been written with ink, indelible pencil, typewriter, or by other electronic means approved by the department, and shall be signed by the practitioner. Electronic prescriptions may be created, signed and transmitted electronically, provided the practitioner complies with all other requirements for issuing controlled substance prescriptions in this Part and with federal requirements for electronic prescribing of controlled substances. A prescription generated on an electronic system that is printed out or transmitted via facsimile is not considered an electronic prescription and shall be manually signed. The prescription shall contain the following:

- (1) name, sex, address and age of the ultimate user for whom the substance is intended, or, if the ultimate user is an animal, the species of such animal and the name and address of the owner or person in custody of such animal;
- (2) the printed name, address, Drug Enforcement Administration registration number, telephone number and the handwritten signature or, in the case of an electronic prescription, the electronic signature of the prescribing practitioner;
- (3) specific directions for use, including, but not limited to, the dosage and frequency of dosage;
- (4) the date upon which such prescription was prepared and actually signed by the prescribing practitioner. The prescription shall have been dated as of, and signed on, the date it is issued; and
- (5) the quantity of dosage units prescribed.
- (6) An electronic prescription shall contain the requirements as provided in subdivision (b)(1-5) except such prescription shall contain an electronic signature and shall be transmitted and received by electronic means. Such electronic signature shall meet the signature requirements set forth in subdivision (b)(2).
- (c) Out-of-state prescriptions shall be dispensed in conformity with provisions set forth in this Part for official prescriptions and electronic prescriptions. Prescription information from all out-of-state prescriptions for a controlled substance shall be filed with the department in accordance with section 80.73(f) of this Part.
- (d) Pharmacies shall file out-of-state prescriptions for a controlled substance in the same manner as otherwise required by this Part.

Effective Date:  
Wednesday, March 27, 2013  
Doc Status:  
Complete

## **DISPENSING TO ADDICTS AND HABITUAL USERS, AND TREATMENT PROGRAMS**

Effective Date:  
Wednesday, November 22, 2017

### **Section 80.84 - Practitioners and pharmacies; prescribing, administering and dispensing for the treatment of narcotic addiction**

80.84 Practitioners and pharmacies; prescribing, administering and dispensing for the treatment of narcotic addiction.

Pursuant to the provisions of the federal Drug Addiction Treatment Act of 2000 (DATA 2000) (106 P.L. 310, Div. B, Title XXXV, Section 3502(a)), an authorized practitioner may prescribe, administer or dispense an approved controlled substance, and a licensed registered pharmacist may dispense an approved controlled substance, to a patient participating in an authorized controlled substance maintenance program approved pursuant to Article 32 of the Mental Hygiene Law for the treatment of narcotic addiction.

(a) An approved controlled substance shall mean the following controlled substance which has been approved by the Food and Drug Administration (FDA), or its successor agency, and the New York State Department of Health for the treatment of narcotic addiction:

(1) buprenorphine

(b) An authorized practitioner is a practitioner specifically registered with the Drug Enforcement Administration to prescribe, administer or dispense an approved controlled substance for the treatment of narcotic addiction, and approved for such purpose pursuant to the provisions of Article 32 of the Mental Hygiene Law.

(1) The total number of such patients of an authorized practitioner at any one time shall not exceed the limit established by DATA 2000 and the Department of Health and Human Services (HHS) Substance Abuse and Mental Health Services Administration (SAMHSA), or its successor agency.

(2) An authorized practitioner prescribing an approved controlled substance for the treatment of narcotic addiction, in addition to preparing and signing an official New York State prescription or an electronic prescription in accordance with Section 3332 of the Public Health Law and Section 80.69 of this Part, shall also include his/her unique DEA identification number on the prescription.

(3) An authorized practitioner may dispense an approved controlled substance for the treatment of narcotic addiction in accordance with Section 3331 of the Public Health Law and Section 80.71 of this Part.

(c) A pharmacist may dispense an approved controlled substance for the treatment of narcotic addiction pursuant to a prescription issued by an authorized practitioner. Such dispensing shall be in accordance with Section 3333 of the Public Health Law and Section 80.74 of this Part.



Effective Date:  
Wednesday, November 22, 2017  
Doc Status:  
Complete  
Statutory Authority:  
Public Health Law, Section 3308(2)

## **Section 80.85 - Administration of controlled substances to addicts and habitual users**

### **DISPENSING TO ADDICTS AND HABITUAL USERS, AND TREATMENT PROGRAMS**

80.85 Administration of controlled substances to addicts and habitual users. (a) The administration of controlled substances to narcotic addicts or habitual users of controlled substances is prohibited except as provided for in this Part.

(b) Controlled substances may be administered to narcotic addicts or habitual users of controlled substances upon the order of a person authorized by law to practice medicine or osteopathy in this State and who possesses a Federal registration by the Drug Enforcement Administration, United States Department of Justice, authorizing him to use controlled substances in connection with his professional practice as follows:

(1) for bona fide patients suffering from disease known to be incurable, such as cancer, advanced tuberculosis, and other diseases well recognized as coming within this class;

(2) for addicts who are aged and infirm, or severely ill and it is determined that withdrawal of controlled substances would be dangerous to life, provided that:

(i) such determination has been confirmed by adequate consultation;

(ii) complete records of treatment, administration or dispensing of controlled substances including patient's name, date and type and quantity of controlled substance administered or dispensed are kept;

(iii) adequate safeguards have been taken against diversion of the controlled substances from the intended use; and

(iv) the patient is carefully supervised;

(3) to relieve acute withdrawal symptoms, except that:

(i) only the amount of controlled substances essential for relief of such acute symptoms shall be administered; and

(ii) administration shall be in an institutional or other setting reasonably certain to provide a drug-free environment;

(4) for detoxification of an addict participating in an authorized treatment program approved pursuant to article 23 of the Mental Hygiene Law; and

(5) for treatment of addicts participating in an authorized methadone or other controlled substances maintenance program approved pursuant to article 23 of the Mental Hygiene Law.

(c) In properly verified cases of severe illness, infirmity, or physical disability, a licensed physician, registered nurse, licensed practical nurse, or registered pharmacist may deliver medication to the patient.

Doc Status:  
Complete

## **Section 80.86 - Records and reports of treatment programs**

80.86 Records and reports of treatment programs.

(a) All persons approved pursuant to article 32 of the Mental Hygiene Law to operate a chemical dependence program, other than authorized physicians and pharmacists as defined in Section 80.84 of this Part who are registered with the department to prescribe, administer or dispense approved controlled substances for the treatment of narcotic addiction, and who possess a Federal registration by the Drug Enforcement Administration, United States Department of Justice to purchase, possess and use controlled substances shall keep the following records:

(1) records of controlled substances received by approved persons including date of receipt, name and address of distributor, type and quantity of such drugs received and the signature of the individual receiving the controlled substance. A duplicate invoice or separate itemized list furnished by the distributor will be sufficient to satisfy this record requirement provided it includes all required information and is maintained in a separate file. In addition, duplicate copies of Federal order forms for schedule II controlled substances must be retained; and

(2) records of controlled substances administered or dispensed including date of administration or dispensing, name of patient, signature of person administering or dispensing, type and quantity of drug and such other information as may be required by this Part.

(b) By the 10th day of each month, a person other than an authorized physician as defined in Section 80.84(b) of this Part, approved to conduct a maintenance program pursuant to article 32 of the Mental Hygiene Law shall file with the department a report summarizing its controlled substances activity in the preceding month. Such a report shall be on forms provided by the department and shall include:

(1) an inventory of the quantity of controlled substances on hand at the commencement and at the conclusion of such month's activity;

(2) the date of the inventory;

- (3) the signature of the persons performing the inventory;
  - (4) the total quantity of controlled substances received, the distributor from whom each order was received, and the form and dosage unit in which such substance was received;
  - (5) a separate listing of the total quantity of controlled substances prescribed, dispensed and administered during such month;
  - (6) total quantity of methadone surrendered to the department for destruction;
  - (7) total number of patients treated during the month; and
  - (8) each incident or alleged incident involving the theft, loss or possible diversion of controlled substances.
- (c) Each incident or alleged incident involving the theft, loss or possible diversion of controlled substances shall also be reported to the department immediately.

Effective Date:

Wednesday, September 1, 2004

Doc Status:

Complete

## **REPORTS AND RECORDS**

### **Section 80.100 - General requirements**

#### **REPORTS AND RECORDS**

##### **80.100 General requirements.**

- (a) Records of all transactions concerning controlled substances required to be kept by manufacturers, distributors, importers, exporters, institutional dispensers, persons conducting research, instructional, analytical or maintenance treatment programs, pharmacies and practitioners shall be kept for a period of five years from the date of transaction.
- (b) Records, orders and prescriptions required by this Part or article 33 of the Public Health Law, shall be readily available and promptly produced for inspection and copying upon request by authorized representatives of the Bureau of Narcotic Enforcement, New York State Department of Health.
- (c) Records, orders and prescriptions required by this Part or provisions of article 33 of the Public Health Law shall be maintained at the premises where the licensed activity is conducted. Records, orders and prescriptions required by this Part or provisions of article 33 of the Public Health Law that are maintained electronically shall be made available to the department upon

request, in a hardcopy format that is readily understandable, at the premises where the licensed activity is conducted.

(d) Records, orders and prescriptions required to be maintained by this Part or article 33 of the Public Health Law and which may be required as evidence of a violation in connection with an investigation by this department shall be released to authorized representatives of the Bureau of Narcotic Enforcement, New York State Department of Health, upon request and upon the furnishing of a receipt therefor.

Effective Date:  
Wednesday, March 27, 2013  
Doc Status:  
Complete

#### **Section 80.101 - Manufacturers, distributors, importers and exporters**

80.101 Manufacturers, distributors, importers and exporters. Manufacturers, distributors, importers and exporters of controlled substances shall keep records required by article 33 of the Public Health Law, and as otherwise provided by this Part and in particular section 80.23.

Doc Status:  
Complete

#### **Section 80.102 - Research, instructional activities and chemical analysis**

80.102 Research, instructional activities and chemical analysis. Persons conducting research, instructional activities or chemical analysis of controlled substances shall keep records required by article 33 of the Public Health Law, and as otherwise provided by this Part and in particular section 80.36.

Doc Status:  
Complete

#### **Section 80.103 - Institutional dispensers**

80.103 Institutional dispensers. Persons acting as institutional dispensers of controlled substances shall keep records required by article 33 of the Public Health Law, and as otherwise provided by this Part and in particular section 80.48.

Doc Status:  
Complete

### **Section 80.104 - Treatment programs**

80.104 Treatment program. Persons conducting treatment programs pursuant to article 23 of the Mental Hygiene Law shall keep records required by section 3352 of the Public Health Law and submit a monthly methadone usage report on a form furnished by the department.

Doc Status:  
Complete

### **Section 80.105 - Practitioners**

80.105 Practitioners. Every physician, dentist, podiatrist, veterinarian, or other authorized practitioner shall keep a record of all controlled substances purchased by him and a record of all such drugs dispensed or administered by him out of his own stock of such drugs.

(a) Records of controlled substances purchased shall include date of delivery, type and quantity of drugs and the name and address of the supplier of the drug. A duplicate invoice or separate itemized list furnished by the vendor will be sufficient to satisfy this record requirement for schedule III, IV, and V controlled substances provided it includes all required information and is retained in a separate file. In addition, duplicate copies of Federal order forms for schedule I and II controlled substances shall be retained.

(b) Records of disposition of controlled substances shall include date of dispensing or administering of such drug, name and address of patient, and type and quantity of drug.

Doc Status:  
Complete

### **Section 80.106 - Pharmacies**

80.106 Pharmacies.

(a) Pharmacies shall keep records of all controlled substances received and delivered or disposed of by them.

(1) The records of controlled substances received by pharmacies shall include date of receipt, name and address of vendor, and kind and quantity of such drug received. A duplicate invoice or separate itemized list furnished by the vendor will be sufficient to satisfy this record requirement for schedule III, IV, and V controlled substances provided it includes all required information and is maintained in a separate file. Duplicate copies of Federal order forms for schedule II controlled substances shall be retained.

(2) The records of all controlled substances delivered or disposed of shall consist of the prescriptions filled for such drugs. The prescription shall indicate the name and address of the prescriber, Drug Enforcement Administration registration number, signature of the prescriber, name and address of the patient, date of issue, date of dispensing by pharmacist, serial number, type and quantity of drug and such other information as may be required by this Part or provisions of article 33 of the Public Health Law.

(b)(1) Schedule II controlled substances prescriptions shall be maintained together in a separate file.

(2) Schedule III, IV and V controlled substances prescriptions shall be maintained together in a separate file.

(c) If a prescription for a Schedule II, III, IV or V controlled substance is created, signed, transmitted and received electronically, all records related to that prescription shall be retained electronically. These records shall be readily retrievable from all other records, and shall be easily readable or easily rendered into a format that a person can read.

(d) If a pharmacy ceases to use an application service provider, the pharmacy shall ensure that the application service provider transfer any records subject to this Part to the pharmacy in a format that can be displayed, read, and printed, and in a manner readily accessible to, and readable by, representatives of the department.

(e) Pharmacies shall keep a separate record of all controlled substances distributed to an automated dispensing system and returned to the pharmacy from such system.

(f) Pharmacies shall keep a separate record for an automated dispensing system for all records required by this Part.

Effective Date:

Wednesday, March 27, 2013

Doc Status:

Complete

### **Section 80.107 - Confidentiality**

80.107 Confidentiality. No person who has knowledge by virtue of his office of the identity of a particular patient or research subject, a manufacturing process, a trade secret or a formula shall disclose such knowledge, or any report or record thereof, except:

(a) to another person who by virtue of his office as an employee of the department is entitled to obtain such information;

(b) pursuant to judicial subpoena or court order in a criminal investigation or proceedings;

(c) to an agency department of government, or official board authorized to regulate, license or otherwise supervise a person who is authorized by article 33 of the Public Health Law to deal in controlled substances, or in the course of any investigation or proceeding by or before such agency, department or board; or

(d) to the prescription monitoring program registry and to authorized users of such registry as set forth in Public Health Law section 3371(2);

(e) to a practitioner to inform him or her that a person under his or her treatment with a controlled substance also may be under treatment with a controlled substance by another practitioner for the purposes of Public Health Law section 3371(2), and to facilitate the department's review of individual challenges to the accuracy of controlled substance histories pursuant to Public Health Law section 3343-a(6);

(f) to a pharmacist to provide information regarding prescriptions for controlled substances presented to the pharmacist for the purposes of Public Health Law section 3371(2) and to facilitate the department's review of individual challenges to the accuracy of controlled substance histories pursuant to Public Health Law section 3343-a(6);

(g) to the deputy attorney general for Medicaid fraud control, or his or her designee, in furtherance of an investigation of fraud, waste or abuse of the Medicaid program, pursuant to an agreement with the department;

(h) to a local health department for the purpose of conducting public health research or education:

(1) pursuant to an agreement with the commissioner;

(2) when the release of such information is deemed appropriate by the commissioner;

(3) for use in accordance with measures required by the commissioner to ensure that the security and confidentiality of the data is protected; and

(4) provided that disclosure is restricted to individuals within the local health department who are engaged in the research or education;

(i) to a medical examiner or coroner who is an officer of or employed by a state or local government, pursuant to his or her official duties;

(j) to an individual for the purpose of providing such individual with his or her own controlled substance history or, in appropriate circumstances, in the case of a patient who lacks capacity to make health care decisions, a person who has legal authority to make such decisions for the patient and who would have legal access to the patient's health care records, if requested from the department pursuant to Public Health Law section 3343-a(6) or from a treating practitioner pursuant to Public Health Law section 3371(2)(a)(iv); and

(k) to appropriate law enforcement agencies, as reasonably appears to be necessary, for the purposes of providing relevant information about suspected criminal activity, including controlled substances prescribed or dispensed, where the department has reason to believe that a crime related to the diversion of controlled substances has been committed.

Effective Date:

Tuesday, August 27, 2013

Doc Status:

Complete

### **Section 80.108 - Practitioner patient reporting**

80.108 Practitioner patient reporting. It shall be the duty of every attending practitioner and every consulting practitioner to report promptly to the commissioner the name and address and such other data as may be required by the commissioner with respect to any person under treatment if he finds that such person is an addict or a habitual user of any narcotic drug. Such report shall be kept confidential and may be utilized only for statistical, epidemiological, or research purposes, except that those reports which originate in the course of a criminal proceeding other than section 210 of the Mental Hygiene Law shall be subject only to the confidentiality requirements of section 3371 of the Public Health Law.

Doc Status:

Complete

### **Section 80.109 - Confidential communications**

80.109 Confidential communications. For the purpose of duties arising out of article 33 of the Public Health Law and provisions of this Part, no communication made to a practitioner shall be deemed confidential within the meaning of the Civil Practice Law and Rules relating to confidential communications between such practitioner and patient.

Doc Status:

Complete

### **Section 80.110 - Notification by licensee**

80.110 Notification by licensee. Persons licensed or certified pursuant to article 33 of the Public Health Law and persons authorized to possess controlled substances in connection with his authorized activities shall promptly notify the department of:

(a) each incident or alleged incident of theft, loss or possible diversion of controlled substances manufactured, ordered, distributed or possessed by such person; a form of this purpose furnished by the department shall be filed with the Bureau of Narcotic Enforcement, New York State Department of Health.



(b) any charge or proceeding brought in any court or before any governmental agency, State or Federal, in which it is alleged that the licensee, its employees, subsidiaries, managing officers, or directors has failed to comply with the provisions of the Federal Controlled Substances Act or the laws of any State relating to controlled substances.

Effective Date:

Wednesday, November 26, 2008

Doc Status:

Complete

### **Section 80.111 - Inventory; required substances**

80.111 Inventory; required substances. Controlled substances listed in section 3306 of the Public Health Law are designated as inventory required substances and a biennial inventory shall be prepared and maintained in accordance with the provisions of section 80.112 of this Part.

Doc Status:

Complete

### **Section 80.112 - Inventory; procedure for filing**

80.112 Inventory; procedure for filing.

(a) All manufacturers, distributors, importers, and exporters licensed to deal in controlled substances; all institutional dispensers and persons conducting research, instructional activities, maintenance treatment programs and analytical laboratories certified for controlled substance privileges; and all physicians, dentists, podiatrists, veterinarians and other practitioners, and all pharmacies possessing, having under their control, selling, prescribing, administering, dispensing or compounding any controlled substances in New York State shall as of May 1, 1975 and every two years thereafter, prepare and maintain an inventory of all controlled substances specified by the State Commissioner of Health by regulation as substances requiring inventory. A separate entry shall be made with respect to each kind of substance or preparation, and each kind or size of package. Each entry shall show the name, quantity and content of controlled substance and the size of the individual package, the number of packages and the total content of all packages covered by the entry on hand as of the date of the inventory. Maintaining for inspection a biennial inventory of controlled substances prepared and maintained in compliance with federal statute and regulations shall be deemed compliance with this section.

(b) A copy of the inventory shall be retained on file with other controlled substances records, and shall be kept available for inspection for at least five years.

Doc Status:  
Complete

## **OFFENSES, VIOLATIONS AND ENFORCEMENT**

### **Section 80.120 - Powers of commissioner**

#### **OFFENSES, VIOLATIONS AND ENFORCEMENT**

80.120 Powers of commissioner. The commissioner, and any representative authorized by him, shall have the power to administer oaths, compel the attendance of witnesses and the production of books, papers and records and to take proof and testimony concerning all matters within the jurisdiction of the department.

Doc Status:  
Complete

### **Section 80.121 - Rules and regulations**

80.121 Rules and regulations.

Rules, regulations and determinations, when made and promulgated by the commissioner, shall be the rules and regulations and determinations of the department, and, until modified or rescinded, shall have the force and effect of law.

Doc Status:  
Complete

### **Section 80.122 - Enforcement**

80.122 Enforcement.

It shall be the duty of the department to enforce all of the provisions of article 33 of the Public Health Law and all of the rules, regulations and determinations made thereunder.

Doc Status:  
Complete

### **Section 80.123 - Access to records**

80.123 Access to records.

The department and its representatives shall have access at all times to all orders, prescriptions or records required to be kept under article 33 of the Public Health Law and this Part.

Doc Status:  
Complete

### **Section 80.125 - Fraud and deceit**

#### **80.125 Fraud and deceit.**

(a) No person shall:

(1) obtain or attempt to obtain a controlled substance prescription or a controlled substance, or procure or attempt to procure the administration of a controlled substance:

(i) by fraud, deceit, misrepresentation or subterfuge;

(ii) by the use of a forged or altered prescription or written order;

(iii) by the concealment of a material fact; or

(iv) by the use of a false name or the giving of a false address;

(2) willfully make a false statement in any prescription, order, report or record required by this Article;

(3) falsely assume the title of, or represent himself to be, a manufacturer, wholesaler, pharmacy, pharmacist, intern, nurse, physician, dentist, veterinarian or other authorized person, for the purpose of obtaining a controlled substance;

(4) make or utter any false or forged prescription or false or forged written order;

(5) affix any false or forged label to a package or receptacle containing controlled substances; or

(6) willfully transmit an electronic prescription using an application or application provider that the practitioner knows does not comply with federal requirements or is otherwise non-compliant.

(b) Possession of a false or forged controlled substance prescription by any person other than a pharmacist in the pursuance of his profession shall be presumptive evidence of his intent to use the same for the purpose of illegally obtaining a controlled substance.

(c) Any person who, in the course of treatment, is supplied with controlled substances or a prescription therefor by one physician and who, without disclosing the fact, is supplied during such treatment with controlled substances or a prescription therefor by another physician shall be

guilty of a violation of this Part.

Effective Date:

Wednesday, March 27, 2013

Doc Status:

Complete

## **TOXIC VAPORS, HYPODERMIC SYRINGES AND NEEDLES**

### **Section 80.130 - Toxic solvents**

#### **TOXIC VAPORS, HYPODERMIC SYRINGES AND NEEDLES**

##### **80.130 Toxic solvents.**

(a) All glue, cement or other adhesives containing one or more of the following chemical compounds are designated as glue substances containing a solvent having the property of releasing toxic vapors or fumes: acetone, cellulose acetate, benzene, butyl alcohol, ethyl alcohol, ethylene dichloride, ethylene trichloride, isopropyl alcohol, methyl alcohol, methyl ethyl ketone, pentachlorophenol, petroleum ether, and toluene, or such other similar material as the commissioner shall by regulation prescribe.

(b) No person shall sell or offer to sell, to any person, any tube or container of glue containing a solvent having the property of releasing toxic vapors or fumes:

(1) if he has knowledge that the product sold or offered for sale will be used in violation of article 33 of the Public Health Law;

(2) unless there has been added to such glue a sufficient quantity of an additive approved by the commissioner which shall act as a deterrent to inhalation and not be harmful or toxic to the human body. This provision shall not apply to glue manufactured and sold for industrial use.

(i) Industrial use shall mean glue packaged in a container of more than four ounces by volume.

(ii) Approval as an additive, which shall act as a deterrent to inhalation of allyl isothiocyanate (oil of mustard) when added at a level of not less than 0.25 nor more than 0.35 per centum by weight of total product is withdrawn for any glue manufactured 180 days after the effective date of this Part; a request for approval of any other such additive shall be made to the Bureau of Narcotic Enforcement of the department.

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Doc Status:

Complete

## **Section 80.131 - Prescription, sale and possession of hypodermic syringes and hypodermic needles**

80.131 Prescription, sale and possession of hypodermic syringes and hypodermic needles.

(a) For purposes of this section, "prescription" shall have the same meaning as provided in section 3302 of the public health law, as supplemented by the meaning provided in section 3381 of the public health law. It shall be unlawful for any person to sell or furnish, to any other person or persons, or to possess, a hypodermic syringe, hypodermic needle, or a hypodermic syringe or hypodermic needle pre-filled with a non-controlled substance, except:

- (1) pursuant to a prescription; or
- (2) such sale, furnishing or possession has been authorized by the commissioner; or
- (3) pursuant to Section 80.137 of this Part.

(b) Subject to the provisions of this section, a practitioner may orally prescribe or authorize a refill, and an employee of the prescribing practitioner, or a health care professional in a Residential Health Care Facility (RHCF) who is licensed by the state education department pursuant to the education law, may orally communicate a prescription or refill for, one or more hypodermic syringes or hypodermic needles. Subject to the provisions this section, a pharmacist may dispense, to an ultimate user, such hypodermic syringes or hypodermic needles; provided, however, the pharmacist shall:

- (1) contemporaneously reduce such oral prescription to a written or electronic memorandum indicating the name, address and telephone number of the prescriber, the name, address, and age of the ultimate user, date on which the hypodermic syringe or hypodermic needle was ordered, quantity prescribed, directions for use, the name and strength of the drug, if applicable, number of refills authorized, the signature or readily identifiable initials of the pharmacist accepting the oral memorandum and documenting the fact that it is a telephone order;
- (2) indicate on the memoranda the date filled and the number of the prescription under which it is recorded in the pharmacy prescription file, and sign or electronically sign the memorandum; and
- (3) make a good faith effort to verify the identity of the practitioner and the practitioner's employee or RHCF professional, if applicable, and the ultimate user, if not known to the pharmacist.

(c) A prescription for one or more hypodermic syringes or hypodermic needles shall include:

- (1) the name, address and age of the ultimate user;
- (2) the name, address, telephone number and signature or electronic signature of the practitioner;

(3) the date on which it was issued; and

(4) the name, and strength of the drug, if applicable, the directions for use, the quantity of the hypodermic syringes or hypodermic needles prescribed, and the number of authorized refills.

(d) Any pharmacist selling or furnishing a hypodermic syringe or hypodermic needle pursuant to a prescription shall record upon the prescription, his or her signature or, as applicable, electronic signature, and the date of the sale or furnishing of the hypodermic syringe or hypodermic needle. Prescriptions and oral prescription memorandums shall be retained on file for a period of five years and be readily accessible for inspection by any public officer or employee engaged in the enforcement of this section. A prescription may be refilled not more than the number of times specifically authorized by the prescriber upon the prescription; provided, however, no such authorization shall be effective for a period longer than two years from the date the prescription is signed.

(e) A pharmacist receiving an oral authorization for the refill of a prescription for one or more hypodermic syringes or hypodermic needles shall enter on the original prescription or electronic record maintained on an electronic data processing system, the date, time, and name of the authorizing practitioner and the name of the practitioner's employee or RHCF professional, if applicable, and shall sign or electronically sign such record.

(f) Pharmacists at registered pharmacies may, at the express request and approval of a patient or a person authorized to act on behalf of the patient, and subject to the requirements of 8 NYCRR Section 63.6(8), transfer information relating to a prescription for one or more hypodermic syringes or hypodermic needles, including a prescription for one or more hypodermic syringes or hypodermic needles pre-filled with a non-controlled substance, or accept a transfer of such information from another registered pharmacy or a pharmacy authorized to do business in another jurisdiction for the exclusive purpose of providing one authorized refill per transfer.

(g) Any prescription for one or more hypodermic syringes or hypodermic needles prefilled with a controlled substance shall be issued and dispensed according to the requirements as set forth in 80.67, 80.68, 80.69, 80.70, 80.73 and 80.74 of this Part.

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Wednesday, October 9, 2013

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### **Section 80.132 - Hypodermic syringes and needles; designation of persons or classes of persons**

80.132 Hypodermic syringes and needles; designation of persons or classes of persons.

(a) The following persons or classes of persons may obtain hypodermic syringes and hypodermic needles without prescription for use within the scope of their professions or activities:

- (1) physicians;
- (2) dentists;
- (3) veterinarians;
- (4) undertakers;
- (5) nurses;
- (6) podiatrists;
- (7) registered pharmacists;
- (8) hospitals;
- (9) sanitariums;
- (10) clinical laboratories;
- (11) medical institutions;
- (12) manufacturers or dealers in medical, pharmaceutical, surgical or dental supplies or their agents;
- (13) resident physicians or interns of hospitals, sanitariums or other medical institutions;
- (14) a duly authorized agent of an incorporated society for the prevention of cruelty to animals or a municipal animal control facility for the limited purpose of purchasing, possessing and dispensing (i) sodium pentobarbital to registered and certified personnel to euthanize animals and (ii) ketamine hydrochloride to registered and certified personnel to anesthetize animals prior to euthanasia;
- (15) persons engaged in an agricultural activity, provided that the manufacturer, distributor or supplier of the hypodermic syringe or hypodermic needle or of any product pre-packaged in a hypodermic syringe has an established needle and syringe return program in compliance with any applicable law;
  - (i) for purposes of this section, agricultural activity shall mean the production of food for human consumption and fiber through crops, livestock and livestock products.
- (16) an advanced life support agency; and
- (17) persons certified by the New York State Department of Environmental Conservation as wildlife rehabilitators. Wildlife rehabilitators are responsible for the proper safeguarding and

handling of hypodermic syringes and needles and must comply with section 80.133(h)-(j) of this Part. All needles and syringes shall be stored in compliance with section 80.133(g) of this Part;

(18) licensed respiratory therapists and licensed respiratory therapy technicians;

(19) certified home health agencies, licensed home care services agencies and long term home health care programs approved under Article 36 of the Public Health Law; and

(20) certified hospices licensed under Article 40 of the Public Health Law.

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### **Section 80.133 - Hypodermic syringes and needles; certificate of need**

80.133 Hypodermic syringes and needles; certificate of need.

(a) The following are authorized to possess hypodermic syringes and hypodermic needles, provided they file with the commissioner a certificate of need and obtain a written authorization from the commissioner to possess and use such hypodermic syringes and needles:

(1) educational institutions, which also must comply with section 811 of the Education Law and file a separate certificate of need with the Commissioner of Education; and

(2) persons engaged in commercial, industrial or agricultural activities.

(b) The certificate of need shall set forth the names of individuals authorized by the educational institution or commercial or industrial firms to have custody of the hypodermic syringes and needles to be used in connection with their activities and the names of individuals designated as responsible for supervision of the use of such hypodermic syringes and needles.

(c) Any administrative officer of the institution or firm filing a certificate of need may be designated as responsible for the custody of hypodermic syringes and needles used on their premises. It shall be the duty of the designated custodial administrative officer to provide for safeguards and maintenance of records of receipt and disposition of all hypodermic syringes and needles acquired or possessed by the institution or firm.

(d) The head of any department, laboratory or division of an educational institution or commercial, agricultural or industrial firm filing a certificate of need may be designated as the person responsible for supervising the use of hypodermic syringes and needles used within the institution or firm. It shall be the responsibility of such designated person to supervise the use of hypodermic syringes and needles by students or other members of such institutions or firms and to keep and maintain records of all hypodermic syringes and needles used under his supervision.



(e) Any change in designated custodial or supervisory personnel shall be reported within 30 days to the department.

(f) Location of use. The location of authorized use of hypodermic syringes and needles includes any classroom, laboratory, lecture hall, department or division, designated by the institution or the firm in its certificate of need on file with the department. Any change in designated location of use shall be reported within 30 days to the department.

(g) Storage. (1) Hypodermic syringes and needles shall be stored in a locked secure place. In no instance shall spring or combination dial locks be employed.

(2) Reserve or main stock shall be kept in double cabinets under locked protection of suitable locks and keys. Both cabinets, inner and outer, shall be stationary.

(3) Hypodermic syringes and needles not in reserve, not in main stocks, and not in use, shall be kept under suitable locked protection.

(h) Records. (1) A record of all purchases of hypodermic syringes and needles shall be maintained.

(2) Main storage records shall include a running inventory of all hypodermic syringes and needles indicating type, size and number of each item purchased, distribution made, balance on hand, and date of receipt or disposition.

(3) An annual physical inventory shall be taken each June 30th and entered in the running inventory record.

(4) A record of all hypodermic syringes and needles destroyed shall be kept, indicating the type, size, and number of each item destroyed, the date of destruction, and the person by whom destroyed. The records shall be kept for a period of two years from the date of the transaction. Every such record shall list hypodermic syringes and needles lost or stolen, indicating kind and number and the date of discovery of such loss or theft. A report of such loss or theft, and other pertinent related facts, shall be made immediately upon discovery to the department.

(i) Disposal of hypodermic syringes and needles.

(1) All hypodermic syringes and needles which are no longer usable or required shall be disposed of in a manner consistent with universal precautions so as to be rendered inoperable.

(2) Procedures for disposal may include but are not limited to placement of such syringes, needles and disposable units in a leak-proof, puncture resistant container prior to disposal.

(i) Inspection. All records and stocks of hypodermic syringes and needles maintained by educational institutions or commercial or industrial firms shall be readily available and promptly produced for inspection by authorized representatives of the State Commissioner of Health.

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**Section 80.134 - Authorization for the purchase, possession and dispensing of sodium pentobarbital to euthanize animals**

80.134 Authorization for the purchase, possession and dispensing of ketamine hydrochloride only to anesthetize animals for euthanasia and sodium pentobarbital to euthanize animals.

(a) Except where different meanings are specified expressly, the terms in this section shall have the following meanings:

(1) An incorporated society for the prevention of cruelty to animals (society) shall include any incorporated humane society or society for the prevention of cruelty to animals having facilities for the care and eventual disposition of animals, within the State.

(2) Municipal animal control facility (facility) shall include any pound or shelter maintained by or under contract or agreement with any county, city, town or village within the State.

(3) Solution shall mean:

(i) a premixed solution of sodium pentobarbital, manufactured only and specifically for the euthanasia of animals, which contains such other ingredients as to place such solution within schedule III of the Controlled Substances Act (article 33, Public Health Law);

(ii) schedule II sodium pentobarbital; and

(iii) ketamine hydrochloride only for the purpose of anesthetizing animals for euthanasia.

(4) An agent is a person or persons other than a licensed veterinarian appointed by the incorporated society or municipal animal control facility, and duly registered with the department, authorized to purchase, possess and dispense:

(i) ketamine hydrochloride only to anesthetize animals for euthanasia, and

(ii) sodium pentobarbital to euthanize animals.

(5) A registered individual is a person certified and registered pursuant to subdivision (f) of this section.

(b) No society, facility or its agent shall purchase, possess, dispense or cause to be administered, a controlled substance within this State without first registering with the department.

(c) A society or facility and its agents shall also register with the Federal Drug Enforcement Administration (DEA) in the controlled substance schedule provided for under this Part.

(d) Any society or facility may register an agent to purchase, possess and dispense a controlled substance, by application to the department.

(1) The department shall issue such registration unless the commissioner finds that the application should be denied by reason of false statements in the application, conviction of a felony relating to controlled substances, suspension, revocation or denial of the applicant's Federal DEA registration, failure to provide adequate safeguards against diversion of the solution, or other good and sufficient reason such as conviction for a violent felony or a felony related to theft, an administrative determination that article 33 of the Public Health Law or provisions of this Part were violated, conviction for a misdemeanor relating to controlled substances, or any conviction under the Agriculture and Markets Law relating to the treatment of animals.

(2) Such registration shall be valid for a period of three years from the date of issuance and may be suspended or revoked upon a finding by the commissioner that the society, facility, agent or certified personnel have violated the provisions of this section, or any other requirement of this Part or article 33 or any other State law or regulation relating to the proper care of animals by societies or facilities.

(3) Any society or facility registering an agent shall immediately notify the department of any change in the employment or contractual relationship with the designated agent.

(4) Such registration shall be valid only at the registered location.

(e)(1) Registered agents of societies or facilities may dispense solution for the euthanasia of animals only to registered individuals certified by the department to administer such a solution; or to a licensed and properly registered veterinarian and only for on-premises use.

(2) Solution may be dispensed for use off the premises only where the animal to be euthanized is injured or transport of such animal to the society or facility is not practical.

(f) Registration and certification of individuals to administer solution for euthanasia of animals.

(1) No person other than a licensed veterinarian shall receive a controlled substance from a duly authorized agent of a society or facility to euthanize animals unless the person is certified and registered with the department.

(2) To obtain a certification and registration from the department in order to administer a solution to euthanize animals, the applicant must:

(i) be 21 years of age or older;

(ii) hold a bachelor or associate degree in animal health sciences or related field; and

(iii) obtain a written certification from two licensed veterinarians or one licensed veterinarian and one licensed animal health technician in which the veterinarians or technicians state that they have observed the proficient use, by the applicant, of injections for the euthanasia of animals.

(3) Any person who meets the minimum qualifications stated in subparagraphs 2 (i) and (iii) of this subdivision, but who lacks the required bachelor or associate degrees, may obtain certification and registration from the department if such person has two years' experience in animal care including euthanasia of animals.

(4) The department shall issue such registration and certification unless the commissioner finds that the application should be denied by reason of false statements in the application, the applicant's conviction of a felony relating to controlled substances or for other good and sufficient reason.

(5) Such registration and certification shall be valid for a period of three years from the date of issuance and may be suspended or revoked upon a finding by the commissioner that the registered individual has violated the provisions of this Part, article 33 or any other State law or regulation relating to the proper care of animals, or is not competent to administer solution in the euthanasia of animals by injection.

(g) Renewal of registrations. Registrations issued under this section shall be renewed by the department upon receipt of a completed renewal application which includes proof of attendance at a department-sponsored or -approved course in the safe and effective use of a solution in the euthanasia of animals.

(h) Safeguarding of solution. Agents shall safeguard the solution in compliance with the standards for safeguarding controlled substances set out in section 80.6(a) and (b) of this Part.

(i) Minimum security standards for a society, facility and its agents.

(1) The solution must be stocked in a securely locked cabinet of substantial construction. The cabinet shall be stationary and made of steel or other approved metal and of sufficient size to store the stock of solution.

(2) The cabinet shall be limited to the storage of the solution, needles and syringes and solution records.

(j) Recordkeeping requirements.

(1) Agents shall keep records of all solution purchased, dispensed and administered.

(2) All purchase records, including a copy of the invoice, shall be kept in a separate file and filed by date received.

(3) A separate record of solution activities and transactions in the form of a running inventory shall be maintained and include the following:

- (i) the name of the drug (by brand name);
  - (ii) the name of the manufacturer, lot number, NDC number;
  - (iii) the strength of the drug in milligrams (mg) per milliliter (ml);
  - (iv) the total amount of drug received in milliliters;
  - (v) the name, address and DEA registration number of the supplier of the drug;
  - (vi) the date the solution was received;
  - (vii) the signature of the person receiving the solution;
  - (viii) the date of any transaction or activity, the amount of the solution dispensed at each dispensing;
  - (ix) the signature of the agent who dispensed the solution;
  - (x) the signature of the registered individual administering the solution; and
  - (xi) the remaining amount of drug on hand.
- (4) Any unused solution must be returned to the agent. The agent must record the date, the amount returned, the signatures of the agent and the registered individual returning the drug, and the amount on hand after such transaction.
- (5) A separate record shall be maintained of all losses with a brief statement describing the incident and signed by the agent and a witness.
- (6)(i) Agents shall cause the registered individual and any contracting practitioner to receive a work card or medical record sheet when dispensing the solution and such record shall be returned to the agent upon completion of each workday.
- (ii) The work card or medical report sheet shall contain information to properly identify each animal to whom the solution is administered. For each female with litter, utilize only one record or card.
- (iii) The registered individual euthanizing such animal shall document on such record the date of the administration of the drug, the amount of the drug used and the registered individual's signature.
- (7) All records pertaining to the solution shall be kept on the premises of the society or facility for a period of five years and shall be available readily and produced promptly for inspection by authorized representatives of the commissioner.

(k) Quarterly reports. Within 10 days of the end of each quarter of each year, the society or facility shall submit a report to the department signed by an officer or official and the agent and include the following:

- (1) the name, address and phone number of the society or facility;
  - (2) the agent's name, bureau registration number, DEA registration number;
  - (3) the total amount of solution received from suppliers;
  - (4) the total amount of solution dispensed to personnel;
  - (5) the total amount of solution returned from personnel;
  - (6) the total amount of solution lost for any reason;
  - (7) the total amount of solution on hand at the end of the quarter;
  - (8) an actual physical inventory count of solution on hand; and
  - (9) the total number of animals euthanized by species. (l) All agents and registered individuals are under continuing duty to report immediately to the department any loss, theft or diversion of solution from the society or facility.
- (m) ) Certification or registration by the department under this section does not authorize the use of medicated darts in a handgun.
- (n) Registered individuals may administer solution for euthanasia of animals only when in the employ of a registered society or facility and only when solution is obtained from the registered agent of such society or facility.
- (o) An agent of a society or facility may also obtain registration and certification to administer the solution as defined in paragraph (f)(2) of this section. However, the same individual may not act as both the agent dispensing and the registered individual administering in the same facility at the same time.
- (p) Agents of an incorporated society or a facility are responsible for the proper safeguarding and handling of hypodermic syringes and needles and must comply with section 80.133(h)-(j) of this Part. All needles and syringes shall be stored in compliance with subdivision (i) of this section.
- (q) The agent of a society or facility is not relieved of his responsibilities to detect or correct any diversion or mishandling of any solution by a delegation of responsibility.

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### **Section 80.135 - Authorization to conduct hypodermic syringe and needle exchange programs**

80.135 Authorization to conduct hypodermic syringe and needle exchange programs.

(a) Employees or trained volunteers of community-based not-for-profit organizations and government entities engaged in clean hypodermic syringe and needle exchange programs designed to reduce the transmission of human immunodeficiency virus may obtain, possess and furnish hypodermic syringes and hypodermic needles, without prescription, when authorized by the Commissioner in connection with the distribution or collection of hypodermic syringes and hypodermic needles for the purpose of preventing the transmission of human immunodeficiency virus in users of injectable drugs. This authorization will be granted only in accordance with a plan submitted by the not-for-profit corporation or government entity to and approved by the Commissioner, using the standards contained in this section. This authorization will be based upon the plan meeting the requirements of the regulation.

(b) The Department will review the plan submitted by the not-for-profit corporation or government entity using the following standards:

(1) The plan demonstrates the need for a hypodermic syringe and needle exchange program within the targeted community(ies);

(2) The plan demonstrates organizational capability and commitment necessary to conduct a hypodermic syringe and needle exchange program, to interact effectively with the community(ies) where a hypodermic syringe and needle exchange program is planned, and to enlist support for and to further integration of hypodermic and needle exchange services within the community(ies);

(3) The plan demonstrates an adequacy of the design and protocol for the conduct of a hypodermic syringe and needle exchange program;

(4) The plan demonstrates organizational capability to provide comprehensive harm reduction services, including HIV prevention education and counseling and direct provision of or referral to health and human services, including drug treatment;

(c) This authorization extends only to those hypodermic needles and hypodermic syringes distributed or collected pursuant to the approved plan and only as long as such employees or trained volunteers of the not-for-profit organizations or government entities are assigned to the program. The organization or entity must develop and maintain a list of employees and trained volunteers who are authorized to obtain, possess and furnish hypodermic syringes and hypodermic needles, and furnish this list to the Department. All personnel changes to this list shall be reported immediately to the Department.

(d) An approval obtained pursuant to subdivision (a) of this section shall continue until two years from the date of notification by the Commissioner of approval of the plan submitted by the not-for-profit organization or government entity or until receipt by the organization or entity of a written notice of termination of the program from the Commissioner, whichever shall first occur. The Commissioner may approve extensions of the plan for additional two year periods if the not-for-profit corporation or government entity complied with the requirements of this section during the prior two year period.

(e) Individuals participating in the approved plan may obtain and possess hypodermic syringes and hypodermic needles without prescription from individuals authorized pursuant to subdivision (a) of this section provided that:

(1) this authorization extends only to obtaining or possessing those hypodermic syringes and hypodermic needles which have been distributed or collected pursuant to the approved plan; and

(2) this authorization is effective only so long as the person is an active participant in the approved plan; and

(3) this authorization shall be automatically void with respect to any hypodermic syringe or hypodermic needle which is sold or furnished or attempted to be sold or furnished by a participant in violation of state or federal law.

(f) An approval pursuant to subdivision (a) of this section shall allow a not-for-profit organization or government entity to purchase hypodermic syringes or hypodermic needles as part of a needle exchange plan approved by the Commissioner, and designed to reduce the transmission of human immunodeficiency virus.

(g) An organization or entity authorized by the Commissioner to conduct a hypodermic syringe and needle exchange program must adhere to policies and procedures approved by the Department in connection with the conduct of a hypodermic syringe and needle exchange, which will include, but not be limited to:

(1) requirements for training for staff and volunteers;

(2) procedures to ensure staff security;

(3) policies and procedures for enlisting community support for the program, including development of a community advisory board reflective of the community in which the hypodermic syringe and needle exchange program is located;

(4) procedures and reporting requirements involving community concerns regarding the conduct of a hypodermic syringe and needle exchange program, including those involving law enforcement agencies;

(5) policies and procedures for determining eligibility of individuals for participation in a hypodermic syringe and needle exchange program;



- (6) policies and procedures to ensure comprehensive assessment and service referral for injectable drug users under the age of 18;
  - (7) procedures for enrollment of participants in a hypodermic syringe and needle exchange program and issuance of participant identification cards;
  - (8) procedures for obtaining and recording participant information;
  - (9) policies and procedures for identifying program hypodermic syringes and needles;
  - (10) policies and procedures for distribution and collection of hypodermic syringes and needles, including the number of needles that can be provided to a plan participant in a single transaction;
  - (11) procedures to ensure that hypodermic syringes and needles are secured properly and that the handling and disposal of hypodermic syringes and needles is safeguarded and in accordance with State and federal law and regulations;
  - (12) policies and procedures to terminate program participants;
  - (13) procedures for developing new sites or expanding or changing existing sites for hypodermic syringe and needle exchange programs;
  - (14) policies and procedures relating to the provision of HIV prevention education and counseling for program participants;
  - (15) policies and procedures for referring program participants to services, including developing and formalizing referral linkages;
  - (16) procedures for data collection and program reporting; and
  - (17) policies and procedures for evaluation of hypodermic syringe and needle exchange programs.
- (h) The following records of hypodermic syringes, hypodermic needles, participants and transactions shall be maintained by the organization or entity engaged in exchanging hypodermic syringes and hypodermic needles:
- (1) An inventory of hypodermic syringes and hypodermic needles, including the number purchased and distributed, and the balance on hand;
  - (2) A record of the number of hypodermic syringes and hypodermic needles distributed to each participant in each transaction;
  - (3) A record of the number of used hypodermic syringes and hypodermic needles returned by each participant in each transaction;

- (4) The number and manner of disposal of hypodermic syringes and hypodermic needles collected by the program;
- (5) A record of the number of participants provided HIV prevention education and counseling; the number and types of services directly provided or provided by referral to participants, including referral to HIV antibody testing services, health care services, including evaluation and treatment for HIV infection, sexually transmitted diseases and tuberculosis, family planning, prenatal and obstetrical care, social services and drug abuse treatment services.
- (i) An organization or entity functioning under a needle exchange plan approved under subdivision (a) of this section must ensure that hypodermic syringes and needles are secured properly and must safeguard the handling and disposal of hypodermic syringes and needles in accordance with State and federal law and regulations.
- (j) An organization or entity functioning under a needle exchange plan approved under subdivision (a) of this section must provide a quarterly report of activities to the Commissioner in a format provided by the Department which shall include, but not be limited to:
- (1) the number of program participants;
  - (2) aggregate information regarding the characteristics of program participants;
  - (3) the total number of hypodermic syringes and hypodermic needles distributed during the quarter, and the average number distributed per participant per transaction during the quarter;
  - (4) the total number of hypodermic syringes and hypodermic needles collected during the quarter, and the average number collected per participant transaction during the quarter;
  - (5) the number of participants provided HIV prevention education and counseling;
  - (6) the number and types of services directly provided or provided by referral to participants, including referral to HIV counseling and testing, health care services, including evaluation and treatment for HIV infection, sexually transmitted diseases and tuberculosis, family planning, obstetrical and prenatal care, social services and drug abuse treatment services;
  - (7) significant problems encountered and program milestones achieved; and
  - (8) other information deemed necessary by the Department to ensure that the conduct of a hypodermic syringe and needle exchange program adheres to the requirements of this regulation. The quarterly report must be submitted to the Commissioner no later than 30 days after the end of each quarter after the plan is approved.
- (k) The organization or entity functioning under an approved needle exchange plan shall provide an annual report of plan activities to the Commissioner, summarizing the information provided on a quarterly basis as contained in subdivision (j) of this section in a format provided by the Department. In addition, the report shall contain an evaluation of the organization's progress in

attaining the plan's goals. The annual report must be submitted to the Commissioner no later than 60 days after the program has been approved for a period of one year and at the same time annually thereafter.

(l) An organization or entity functioning under a needle exchange plan approved under subdivision (a) of this section may be inspected by authorized representatives of the State Commissioner of Health as necessary to ensure compliance with the requirements of this section. An organization or entity found to be in violation of these regulations will receive written notification of the violation from the Commissioner and a time period, not to exceed 30 days from the date of written notification, to correct the violation. If the organization or entity continues to be in violation of these regulations after the date required for correction, the Commissioner may terminate approval of the plan. The Commissioner may also terminate the plan immediately if s/he determines that approval of the plan is no longer in the public interest.

(m) ) Any not-for-profit organization or government entity seeking to obtain, possess and furnish hypodermic syringes and hypodermic needles, without prescription, must submit a plan to the Commissioner for approval, which must be in a format specified by the Department, and will include, but not be limited to:

- (1) the name and address of the not-for-profit organization or government entity;
- (2) the name and title of the individual authorized to represent the program in seeking approval;
- (3) information regarding organizational capability and commitment relating to the conduct of a hypodermic syringe and needle exchange program;
- (4) an assessment of the need for a hypodermic syringe and needle exchange program within the targeted community(ies);
- (5) a description of the applicant's previous and planned activities to interact with a community(ies) where a hypodermic syringe and needle exchange program is planned, to enlist support for and to further integration of the hypodermic syringe and needle exchange program within the community(ies);
- (6) a description of staffing for the proposed program, including employees or trained volunteers;
- (7) a description of training planned for employees and volunteers staffing the proposed program;
- (8) a list of employees and trained volunteers staffing the proposed program;
- (9) the design and protocols of the project, including the geographic area and the method of program operation; including procedures for determining eligibility of individuals for participation in the program; procedures to ensure comprehensive assessment and service referral to injecting drug users under the age of 18; procedures for enrollment of participants in the program, including issuance of participant identification cards; procedures for obtaining and

recording participant information; procedures for identifying program hypodermic syringes and needles; procedures to ensure staff security; procedures for distribution and collection of hypodermic syringes and needles, including the number of needles that can be provided to a participant in a single transaction.

(10) the proposed plans for the proper safeguarding and handling and disposal of hypodermic syringes and needles, including inventory control, and securing injection equipment from theft, adherence to appropriate infection control practices and appropriate disposal of used hypodermic syringes and needles;

(11) the proposed plan to provide program participants with HIV prevention education and counseling regarding drug and sexual risk behaviors and risk reduction practices, including cleaning of injection equipment, use of condoms, and distribution of bleach kits and condoms, and referral for ongoing HIV prevention education and psychosocial support.

(12) the proposed plan for direct provision or referral to HIV antibody testing services, health services, including evaluation and treatment services for HIV infection, sexually transmitted diseases and tuberculosis, family planning, prenatal and obstetrical care, social services, viral hepatitis and drug treatment services, including the plan to work with service providers and community-based organizations to establish service linkages;

(13) the proposed plan for evaluating program services and goals; and

(14) overdose prevention education that specifically includes information about methods participants should use to prevent any adverse reactions from:

(i) injecting fentanyl; and

(ii) lack of knowledge of the kinds and amounts of substances users are injecting.

(n) The Commissioner may approve programs with plans that do not include all of the elements specified in subdivision (m) of this section, provided that:

(1) the not-for-profit organization or government entity does not receive funding to operate a hypodermic syringe or needle exchange program from the Department;

(2) the not-for-profit organization or government entity provides other services to individuals at heightened risk for adverse outcomes;

(3) the plan includes at least the following elements:

(i) a description of staffing and training planned for employees and volunteers working for the proposed program.

(ii) if the plan does not have procedures for enrollment of participants in the program or issuance of participant identification cards, procedures to make it possible for clients to demonstrate that they received syringes from a legally authorized program.

(iii) policies and procedures for the proper safeguarding, handling and disposal of hypodermic syringes and needles, including inventory control, securing injection equipment from theft, adherence to appropriate infection control practices and appropriate disposal of used hypodermic syringes and needles.

(iv) policies and procedures for enlisting community support for the program, including responding to concerns from the community and law enforcement agencies.

(v) submission of quarterly reports to the Department, in a format determined by the Department; and

(4) the program is approved by any other state agency that licenses or certifies the operations of the not-for-profit organization or government entity.

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Public Health Law, Sections 3308 and 3381

### **Section 80.136 - Controlled substances for emergency medical services: purchasing, possessing, delivering, administering and safeguarding of controlled substances**

80.136 Controlled Substances for Emergency Medical Services: Purchasing, possessing, delivering, administering, and safeguarding of controlled substances.

(a) Definitions:

(1) Ambulance Service means an individual, partnership, association, corporation, municipality or any other legal entity or subdivision, thereof, engaged in providing emergency medical care and the transportation of sick, or injured persons by motor vehicle, aircraft or other form of transportation to or from facilities providing hospital services.

(2) Medical Director means a New York State licensed physician who is responsible for authorizing treatment protocols and quality assurance activities for participating advanced life support agencies within an advanced life support system. The medical director of any advanced life support system with 10 or more advanced life support agencies and/or 100 or more advanced emergency medical technicians (AEMTS) shall designate associate physicians to provide quality assurance according to a plan submitted to and approved by the Emergency Medical Services Program.

(3) Agent means a person or persons certified as an emergency medical technician-critical care or emergency medical technician-paramedic who is appointed by an advanced life support agency, approved in writing by the medical director, and registered with the Department's Bureau of Narcotic Enforcement, to purchase, possess, and deliver controlled substances for use by an advanced life support agency.

(4) Advanced Life Support First Response Service means an organization which provides advanced life support care but does not transport patients.

(5) Advanced Life Support Agency (ALS Agency) means a certified ambulance service or certified advanced life support first response service which is authorized by the medical director of an advanced life support system to provide advanced life support care.

(6) Contracting Hospital means a hospital licensed as an Institutional Dispenser Class 3 which has a written agreement with one or more ALS Agencies to provide stocks of controlled substances to such services.

(7) Advanced Life Support System means an acute medical care system organized to provide advanced life support care on site or en route to a hospital in accordance with section 3031 of the Public Health Law.

(b)(1) A hospital licensed as an Institutional Dispenser Class 3 may:

(i) enter into a written agreement with an ALS Agency to provide, sell or deliver stocks of controlled substances, to such agency for use in an advanced life support system; or

(ii) enter into a written agreement with an ALS Agency to act as agent for such agency and supply a substock of controlled substances for use in the ALS Agency's response vehicles; and

(iii) provide only those controlled substances approved by the Department and the medical director.

(2) Only those ambulance services or advanced life support services meeting the conditions of and approved under this Part may possess, deliver or administer controlled substances.

(c) An ALS Agency and/or its agent shall:

(1) purchase, possess, deliver or cause to be administered only those controlled substances approved and listed by the Department and approved by the medical director of the advanced life support system;

(2) possess a certificate issued pursuant to article 30 of the Public Health Law;

(3) possess a class 3(c) institutional dispenser limited license from the Department, except that an ALS agency, owned and operated by a hospital, is exempt from obtaining a class 3(c) institutional dispenser limited license and shall:

(i) utilize the hospital's class 3 institutional dispenser license for the delivery of controlled substances for use in any authorized response vehicle;

(ii) maintain the ALS agency's controlled substances as part of the hospital's controlled substances substock;

(iii) have the hospital act as the agent for its ambulance service;

(iv) comply with all other sections of this Part;

(4) permit only a licensed physician or a person certified pursuant to Article 30 of the Public Health Law as an advanced emergency medical technician - critical care or advanced emergency medical technician - paramedic, and authorized by the medical director of the advanced life support system to receive or administer a controlled substance.

(d)(1) Any ALS Agency may be denied approval to purchase, possess, or deliver controlled substances upon a finding by the Department that the approval should be denied or revoked by reason of false statements in the application, failure to provide adequate safeguards against diversion of the controlled substances, or other good and sufficient reason such as an administrative determination that article 30 or 33 of the Public Health Law or a provision of Part 800 of this Title or of this Part was violated.

(e) Agents.

(1) An ALS Agency shall register an agent to purchase, possess, and deliver controlled substances, by making application to the Department.

(2) The Department shall issue such registration unless the Department finds that the application should be denied by reason of false statements in the application, failure to provide adequate safeguards against diversion of the controlled substances, other good and sufficient reason such as an administrative determination that article 30 or 33 of the Public Health Law was violated, or conviction of one or more criminal offenses, as defined in section 800.3(ak), unless the applicant is found eligible after a balancing of the factors set out in Article 23-A of the Correction Law. In accordance with that Article, no application for registration shall be denied by reason of the applicant having been previously convicted of one or more criminal offenses unless (i) there is a direct relationship between one or more of the previous criminal offenses and duties required of the registration or (ii) registering the applicant would involve an unreasonable risk to property or the safety or welfare of a specific individual or the general public. In determining these questions, the department will look at all factors listed under New York State Correction Law section 753.

(3) Such registration shall be valid for a period of two years and may be suspended or revoked upon a finding by the Department that the ALS Agency, agent, or its members have violated article 30 or 33 of the Public Health Law or any provision within Part 800 of this Title or any provision within this Part.

(4) Each ALS agency or its agent shall immediately notify the Department and the medical director of any change in the membership, employment, or contractual relationship with the designated agent or the dispensing hospital.

(5) Such registration shall be valid only for the ALS Agency and at the specified location(s) appointing the agent.

(6) An agent of an ALS Agency may deliver controlled substances, only for administration by their ALS Agency, to a licensed physician and individuals certified and authorized to administer controlled substances.

(f) ) Agents shall ensure that:

(1) Controlled substances shall be safeguarded properly and kept securely at the registered address on file with the Department;

(2) All stocks and/or substocks will be made available for inspection by authorized representatives of the Department;

(3) Access to controlled substances stocks shall be limited to the minimum number of individuals actually required to manage the administration, delivering and handling of such controlled substances efficiently;

(4) A plan is submitted to the Department for review, modification and/or approval that details the location(s) of all stocks or substocks, the safeguarding of, access to, and security standards for all controlled substances;

(5) A quality assurance plan for the administration of controlled substances is submitted to the Department; and

(6) Only a reasonable quantity of controlled substances as approved by the medical director is stored as substocks.

(g) Minimum security standards for ALS Agencies, their agents and all certified and authorized individuals:

(1) Any stock or substock of controlled substances shall be maintained in a secure manner and in compliance with this Part.

(2) Any stock or substock of controlled substances shall be stored in a locked cabinet of substantial construction at the location registered with the Department. The cabinet shall be stationary, be made of steel or other metal and be of sufficient size to store all controlled substances. This cabinet shall be limited to the storage of controlled substances, needles and syringes and associated records.



(3) Access to any stock or substock of controlled substances will be limited to the agent and require at least two locks with different keys.

(4) Any substock of controlled substances in an authorized response vehicle shall be stored as follows:

(i) When access to the patient compartment of an ambulance is kept locked at all times, controlled substances shall be secured in a locked cabinet using a key lock different than the patient compartment.

(ii) When the access to the patient compartment of an ambulance is not kept locked at all times or any other response vehicle is used, controlled substances must be secured in a locked box within a locked stationary cabinet under a two lock system using different keys.

(iii) The key(s) to access the cabinet where controlled substances are stored must be maintained under the direct control of a certified and authorized individual.

(iv) Controlled substances may be maintained in the direct possession and control of a certified and authorized individual at all times while such individual is on duty for the ALS Agency, however, at no time shall controlled substances be carried in any personal automobile.

(v) A written change of shift inventory for any substock shall be conducted when custody of controlled substances passes between certified and authorized individuals during a shift change.

(vi) Alternative forms of securing or maintaining controlled substances in authorized response vehicles are subject to the approval of the Department upon written application by the chief executive/operating officer of the ALS Agency. The application must describe the alternative methods, state reasons why the alternate method is necessary and fully describe procedures for safeguarding and controlling controlled substances and limiting access to certified and authorized individuals. (vii) Only individuals certified and authorized under this Part shall have access to controlled substances. If an agency operates at various times with different levels of personnel, all of whom are not certified and authorized, provisions shall be made to prohibit access to all controlled substances by persons who are not certified or authorized.

(h)(1) Controlled substances may only be administered pursuant to a physician's order or a protocol authorized by the medical director and approved by the Department pursuant to Article 30 of the Public Health Law and section 800.15 of this Title. A copy of the approved protocol shall be on file with the Department. Any change in such protocol shall be approved by the Department prior to being implemented.

(2) A certified and authorized individual making any administration of a controlled substance pursuant to a physician order or protocol order shall notify a medical control location to make a record of the administration as described in section 80.136(h)(3). Such notification shall be made during or immediately following the run.

(3) At any medical control location, the physician ordering or confirming the administration of a controlled substance shall make and maintain a record of such administration to include but not be limited to:

- (i) physician name and signature;
- (ii) date, time, and run identification;
- (iii) patient name;
- (iv) ALS Agency name;
- (v) AEMT number and name;
- (vi) patient's chief complaint and presenting problem;
- (vii) name of controlled substance;
- (viii) dosage and route of administration;
- (ix) quantity administered; and
- (x) receiving hospital name and record number.

(4) Each certified and authorized individual receiving an order or using a protocol to administer a controlled substance shall make a record of the administration to include but not be limited to:

- (i) ordering physician identification;
- (ii) date, time, and run identification;
- (iii) patient name;
- (iv) ALS Agency name;
- (v) AEMT number and name;
- (vi) patient's chief complaint and presenting problem;
- (vii) name of controlled substance;
- (viii) dosage and route of administration;
- (ix) quantity administered, and
- (x) receiving hospital name and record number.

The required record shall be the Department's Pre-hospital Care Report and any necessary supplement. A copy of the pre-hospital record shall become part of the patient's hospital record. Patient confidentiality shall be maintained at all times.

(5) A certified and authorized individual shall maintain an administration inventory record for all controlled substances. This record shall be returned to the agent before any controlled substances can be replenished.

(i) Recordkeeping Requirements.

(1) Agents shall keep records of all controlled substances obtained, purchased, delivered and administered.

(2) All purchase records, including date, quantity obtained and source shall be maintained in a separate file by date received.

(3) An inventory record shall be maintained and shall include the following:

(i) the name of the controlled substance;

(ii) the name of the manufacturer and lot number;

(iii) the strength of the controlled substance;

(iv) the total amount of controlled substance stock received;

(v) the name, address, and DEA registration number of the authorized person or hospital supplying the controlled substance stock;

(vi) the date the controlled substance stock was received;

(vii) the signature of the person receiving the controlled substance stock;

(viii) the date and the amount of the controlled substance delivered to a substock;

(ix) the signature of the agent who delivered the controlled substance substock;

(x) the signature of the certified and authorized individual receiving the controlled substance substock;

(xi) the vehicle identification number or location of substock; and

(xii) the remaining amount of controlled substance on hand.

(4) A separate record shall be maintained of all non-administered losses from any stock or substock with a brief statement describing the incident and signed by the certified and authorized individual and the agent.

(5) Partial doses remaining after the parental administration of a portion of an ampule or unit dose of a controlled substance may be destroyed and properly disposed of provided that:

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

(ii) the destruction is witnessed by a second certified emergency medical technician member of the ALS Agency, the agent, or other licensed health care provider.

(6) An administration record shall be kept for each substock. This record will indicate the substock location and/or the vehicle identification number, the name of each controlled substance, dose and quantities furnished to the substock and:

(i) date and hour of administration;

(ii) name of patient;

(iii) run and medical control information;

(iv) dose administered;

(v) balance on hand after each administration; and

(vi) the name and signature of the administering individual.

(j) All records pertaining to controlled substances shall be kept at the location registered with the Department by the ALS Agency for a period of five years and shall be readily available and produced promptly for inspection by authorized representatives of the Department.

(1) Within 30 days of June 30 and December 31 of each year, the ALS Agency shall submit a report for that six month period to the Department signed by the agent which report shall include the following:

(i) the name, address, and telephone number of the ALS Agency;

(ii) the Bureau of Narcotic Enforcement license number;

(iii) the agent's name;

(iv) the total amount of controlled substances received from the dispensing hospital;

(v) the total amount of controlled substances dispensed to personnel;

- (vi) the total amount of controlled substances returned from personnel;
- (vii) the total amount of controlled substances lost for any reason;
- (viii) the total amount of controlled substances on hand at the end of the period; and
- (ix) an actual physical inventory count of all controlled substances on hand.

(k) Responsibilities.

(1) All agents and members of an ALS Agency are under a continuing duty to report immediately to the Department and the medical director any loss, theft, or diversion of controlled substances.

(2) Agents and certified and authorized members of the ALS Agency are responsible for the proper safeguarding and handling of controlled substances, needles and syringes.

(3) The medical director of the advanced life support system authorizing the use and administration of controlled substances shall be accountable for the proper use and administration of the controlled substances and for maintaining a quality assurance plan and protocols approved by the Department.

(4) The chief executive/operating officer of the ALS Agency is responsible for the proper safeguarding, handling and accountability of controlled substances and for assuring that all reports and reporting procedures are carried out in accordance with this Part. The chief executive/operating officer shall not be relieved from any responsibility under this Part as a result of any delegation of responsibility.

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Public Health Law, section 3002

### **Section 80.137 - Expanded syringe access program**

Section 80.137 - Expanded syringe access program.

(a) Definitions.

(1) "Authorized provider" for the purposes of this section shall mean any of the following who have registered with the Department:

- (i) a pharmacy licensed under article one hundred thirty-seven of the education law;

- (ii) a health care facility licensed under article twenty-eight of the public health law; or
- (iii) a health care practitioner who is otherwise authorized to prescribe the use of hypodermic needles or syringes within his or her scope of practice.

(2) "Safety insert", for the purposes of this section, shall mean a document that is either developed or approved by the commissioner and shall contain, at a minimum, the following information:

- (i) information on the proper use of hypodermic syringes and needles;
- (ii) the risk of blood-borne diseases that may result from the use of hypodermic syringes and needles;
- (iii) methods for preventing the transmission or contraction of blood-borne diseases;
- (iv) proper disposal practices for hypodermic syringes and needles, including information on safe disposal and the relevant provisions of the environmental conservation law relating to the unlawful release of regulated medical waste;
- (v) the dangers of injection drug use and how to access drug treatment;
- (vi) a toll-free number for information on the human immunodeficiency virus; and
- (vii) a statement that it is legal for persons to possess syringes obtained pursuant to Article 33 of the Public Health Law.

(b) Registration.

- (1) Authorized providers must register with the Department in order to sell or furnish hypodermic needles and/or syringes without a prescription pursuant to this section.
- (2) Authorized providers must register with the Department in order to accept hypodermic needles and/or syringes for purposes of disposal. Failure of an entity to register shall not affect its obligations to accept needles and syringes originating from a private residence when such entity is already obliged to do so pursuant to Section 1389-dd of the Public Health Law.
- (3) Registration shall be limited to authorized providers in good standing and will consist of submission to the Department of a completed application in a form prescribed by the commissioner, and receipt of the acceptance from the commissioner of such registration, prior to the initiation of the selling or furnishing of hypodermic needles and syringes without a prescription and or accepting hypodermic needles and/or syringes for disposal.
- (4) The registration form must include, at a minimum, the following information:

- (i) the name, address, license number, telephone number and fax number (if available) of the authorized provider;
  - (ii) the name, address, telephone and electronic mail address, if available, of the individual designated by the authorized provider to have administrative responsibility for the provider's participation in the expanded syringe access program;
  - (iii) an attestation that the authorized provider will abide by the provisions of this section and the provisions contained in the registration form with regard to the selling or furnishing of hypodermic needles or syringes without a prescription;
  - (iv) a description of how the registrant will cooperate in the safe disposal of used hypodermic needles or syringes, or will provide such services (pharmacies and health care practitioners are not required to provide such services); and
  - (v) the signature of the individual authorized to sign the registration form on behalf of the applicant.
- (5) The registration period shall commence upon the acceptance of such registration by the commissioner and shall remain valid for a period to coincide with the maximum allowed at the time of registration under Section 3381 of the Public Health Law or until notice of termination by the Department. Authorized providers shall notify the Department of any changes in the information provided to the Department. Changes or corrections to such information shall be submitted to the Department by the completion of a revised registration form as soon as possible but no later than 30 days after such change. Should an authorized provider choose to withdraw its registration, written notification of such intent must be provided to the Department. Such withdrawal shall not be effective until receipt of such written notice is acknowledged by the Department in writing.
- (6) The name, address, and telephone number of the authorized provider may be used in the development of, or included in, a registry of authorized providers for the purpose of informing consumers of available authorized providers for the purposes of sale, furnishing, and/or disposal, as specified on the registration form.
- (c) Upon the finding of a violation of this section or when a registrant is no longer in good standing, the commissioner may suspend, for a period up to one year, an authorized provider's ability to sell or furnish hypodermic needles or syringes, or to accept hypodermic needles or syringes for disposal under this Section. Entities otherwise obliged to accept hypodermic needles or syringes for disposal pursuant to Section 1389-dd of the Public Health Law shall not be relieved from such obligation.
- (d) Requirements for authorized providers for the purpose of selling and furnishing of hypodermic needles and syringes without a prescription.
- (1) After acceptance of the registration by the commissioner, an authorized provider may obtain and possess such hypodermic syringes and needles for such purpose, provided that:

- (i) such sale or furnishing shall only be to a natural person eighteen years of age or older;
- (ii) each sale or furnishing is limited to a quantity of ten or less; and
- (iii) the sale or furnishing shall be accompanied by a safety insert as described in paragraph (a)(2) of this section. Such insert shall be attached to or included in the hypodermic syringe and/or needle packaging, or provided in brochure form, at the point of sale or furnishing.

(2) In addition, a pharmacy:

(i) shall not advertise to the public the availability for retail or furnishing of hypodermic syringes and needles without a prescription; provided, however, that in-store signage indicating that hypodermic syringes and needles may be purchased without a prescription, and which is consistent with guidance issued by the Department, shall not be considered advertising to the public; and

(ii) shall, at any location where hypodermic syringes and needles are kept for retail furnishing, store such syringes and needles in a manner that makes them available only to authorized personnel and not openly available to customers.

(e) Authorized providers that accept needles and/or syringes for purposes of disposal shall adhere to state and local public health and environmental conservation laws, rules, and regulations related to the disposal of regulated medical waste.

(f) Possession. A natural person eighteen years of age or older may obtain and possess hypodermic syringes and needles obtained pursuant to this Section.

(g) Applicability. The provisions of this section shall not apply to any sale, furnishing, or possession of hypodermic needles or syringes which is lawful under Section 3381(1)(a) or (b) of the Public Health Law.

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Public Health Law, Section 3308

## **Section 80.138 - Opioid Overdose Prevention Programs**

Section 80.138. Opioid Overdose Prevention Programs.

(a) Definitions.

(1) Opioid means an opiate as defined in section 3302 of the public health law.



(2) Opioid antagonist means a drug approved by the Food and Drug Administration, that, when administered, negates or neutralizes in whole or in part the pharmacological effects of an opioid in the body. The opioid antagonist is limited to naloxone or other medications approved by the department for this purpose.

(3) Opioid overdose prevention program means a program the purpose of which is to train individuals to prevent a fatal opioid overdose in accordance with these regulations.

(4) Opioid overdose prevention training curriculum refers to any set of instructions, consistent with guidance from the department, which provides a person encountering a suspected opioid overdose with the steps to take for preventing a fatality, including contacting emergency medical services, administering an opioid antagonist and, where appropriate, providing resuscitation.

(5) Registered provider for the purposes of this section shall mean any of the following that have the services of both a program director and a clinical director and that have registered with the department pursuant to subdivision (b) of this section:

(i) a health care facility licensed under the public health law;

(ii) a physician, physician assistant, or nurse practitioner who is authorized to prescribe the use of an opioid antagonist;

(iii) a drug treatment program licensed under the mental hygiene law;

(iv) a not-for-profit community-based organization incorporated under the not-for-profit corporation law;

(v) a local health department, public safety agency, or other local or state government agency;

(vi) an institution of higher education, recognized and approved by the regents of the university of the state of New York, which provides a course of study leading to the granting of a post-secondary degree or diploma;

(vii) a business, trade, technical or other occupational school approved as such by the regents of the university of the state of New York or accredited by a nationally recognized accrediting agency or association accepted as such by the regents of the state of New York; and

(viii) a pharmacy registered in accordance with the Article 137 of the Education Law.

(6) Program director means an individual who is identified to manage and have overall responsibility for the opioid overdose prevention program.

(7) Clinical director means a physician, physician assistant or nurse practitioner who is designated in an opioid overdose prevention program's registration for prescribing an opioid antagonist to individual or an identifiable pool of trained overdose responders and who provides oversight of the clinical aspects of the opioid overdose prevention program. This oversight

includes serving as a clinical advisor and liaison concerning medical issues related to the opioid overdose prevention program, providing consultation on training and reviewing reports of all administrations of an opioid antagonist.

(8) Affiliated prescriber means a physician, physician assistant or nurse practitioner, who, in addition to the clinical director, is designated in an opioid overdose prevention program's registration for prescribing an opioid antagonist to individual or an identifiable pool of trained overdose responders.

(9) Trained overdose responder means any individual not otherwise permitted by law to administer an opioid antagonist, who is either:

(i) an opioid antagonist recipient as defined in PHL Section 3309 who has successfully completed an opioid overdose prevention training curriculum offered by an authorized opioid overdose prevention program and has been authorized by a registered provider to possess the opioid antagonist;

(ii) a public safety officer who has completed a curriculum approved by the division of criminal justice services for purposes of intervening in opioid overdoses prior to the arrival of emergency medical services; or

(iii) a firefighter who has completed a comparable curriculum approved by the department.

(b) Registration.

(1) Registered providers may operate an opioid overdose prevention program if they obtain a certificate of approval from the department authorizing them to operate an opioid overdose prevention program and otherwise comply with the provisions of this section.

(2) Providers eligible to register to operate an opioid overdose prevention program that are in good standing may apply to the department to operate an opioid overdose prevention program on forms prescribed by the department which must include, at a minimum, the following information:

(i) the provider name, address and operating certificate or license number where appropriate;

(ii) the name, address, telephone number, fax number, e-mail address and signature of the program director;

(iii) the name, address, telephone number, fax number, e-mail address, license type, license number and signature of the clinical director;

(iv) the name, license type and license number of the affiliated prescribers, if any;

(v) the name and address of the sites at which the opioid overdose prevention program will be conducted; and

(vi) a description of the targeted population to be served and recruitment strategies to be employed by the opioid overdose prevention program.

(c) Program Operation.

(1) Each opioid overdose prevention program shall have a program director who is responsible for managing the opioid overdose prevention program and shall, either directly or through a designee, at a minimum:

(i) identify a clinical director to oversee the clinical aspects of the opioid overdose prevention program;

(ii) establish the content of the program's opioid overdose prevention training curriculum consistent with guidance from the department;

(iii) identify and train other program staff;

(iv) select and identify persons as trained overdose responders;

(v) issue certificates of completion to trained overdose responders who have successfully completed the program's opioid overdose prevention training curriculum; however, certificates of completion of curriculum under subparagraphs (ii) and (iii) of paragraph (9) of subdivision (a) of this section are not required for public safety or firefighting personnel;

(vi) establish and maintain the opioid overdose prevention program's mandated recordkeeping system;

(vii) ensure that all trained overdose responders successfully complete the program's opioid overdose prevention training curriculum;

(viii) provide liaison with local emergency medical services and emergency dispatch agencies, where appropriate;

(ix) assist the clinical director with review of reports of all overdose responses, particularly those involving administration of an opioid antagonist;

(x) report all administrations of an opioid antagonist on forms prescribed by the department; however, public safety and firefighting personnel are required to report administrations of an opioid antagonist directly, or through their department or agency, to the department; and

(xi) report the number of trained overdose responders and the number of doses of an opioid antagonist provided on a quarterly basis on forms prescribed by the department.

(2) Each opioid overdose prevention program shall have a clinical director who is responsible for clinical oversight and liaison concerning medical issues related to the opioid overdose prevention program and, at a minimum, shall:

- (i) provide clinical consultation, expertise, and oversight;
  - (ii) serve as a clinical advisor and liaison concerning medical issues related to the opioid overdose prevention program;
  - (iii) provide consultation to ensure that all trained overdose responders are properly trained;
  - (iv) adapt and approve opioid overdose prevention training curriculum content and protocols;
  - (v) review reports of all administrations of an opioid antagonist; and
  - (vi) designate individuals, either by name or by description, who are authorized to dispense or furnish an opioid antagonist to trained overdose responders and/or individuals who are responsible for ensuring orderly, controlled, shared access to an identifiable pool of trained overdose responders pursuant to a non-patient specific prescription.
- (3) The trained overdose responders shall:
- (i) complete an initial training consistent with the program's opioid overdose prevention training curriculum;
  - (ii) complete a refresher training consistent with the opioid overdose prevention training curriculum at least every two (2) years or otherwise demonstrate competence in opioid overdose recognition and response to the satisfaction of the opioid overdose prevention program director or to someone designated by the program director;
  - (iii) ensure that emergency medical service has been contacted when encountering a victim of a suspected drug overdose and advise responding emergency medical services personnel if an opioid antagonist has been used;
  - (iv) comply with protocols for response to victims of suspected drug overdose consistent with the program's opioid overdose prevention training curriculum, or, in the case of responders who are public safety or firefighting personnel, comply with policies developed by their local public safety agency or fire department; and
  - (v) report all responses to victims of suspected drug overdose to the opioid overdose prevention program director or to someone designated by the program director.
- (4) The opioid antagonist shall be provided or furnished to the trained overdose responder in accordance with all applicable laws, rules and regulations.
- (5) The opioid overdose prevention program will maintain and provide response supplies consistent with its policies and procedures; however, these supplies must include:
- (i) a mask or other barrier where rescue breathing is part of the curriculum;

(ii) an agent to prepare skin before injection where an injectable form of an opioid antagonist is used; and

(iii) instructional material required by the department, including information on how to recognize symptoms of an opioid overdose; the steps to be taken in responding to an overdose; and how to access the office of alcoholism and substance abuse services through both a toll free number and its website.

(6) The opioid overdose prevention program's record keeping system must include, at a minimum, the following elements:

(i) the names of trained overdose responders, the dates they were trained, and the dates they were furnished naloxone; however, where an opioid antagonist is furnished or dispensed by an opioid overdose prevention program pursuant to a non-patient specific prescription, the program must also maintain records on who has issued the non-patient specific prescription and which designated program staff have dispensed or furnished the opioid antagonist and/or are responsible for ensuring orderly, controlled, shared access to an identifiable pool of trained overdose responders;

(ii) program policies and procedures;

(iii) copy of the contract/agreement with the clinical director, if appropriate;

(iv) opioid antagonist administration usage reports and forms;

(v) documentation of review of administration of an opioid antagonist; and

(vi) an inventory of overdose response supplies.

(7) The opioid overdose prevention program will establish a procedure by which any administration of opioid antagonist to another individual by a trained overdose responder affiliated with an opioid overdose prevention program, shall be reported on forms prescribed by the department.

(8) Approval obtained pursuant to this section shall consist of a certificate of approval provided by the department that shall remain in effect for two years or until receipt by the authorized provider of a written notice of termination of the program from the department, whichever shall first occur. The department may renew a certificate of approval for a subsequent two-year period if the registered provider is in good standing with all applicable state and federal licensing agencies and such provider is found to have complied with the requirements of this section.

(9) Pursuant to Public Health Law section 3309(2), the purchase, acquisition, possession or use of an opioid antagonist by an opioid overdose prevention program or a trained overdose responder in accordance with this section shall not constitute the unlawful practice of a profession or other violation under title eight of the education law or article 33 of the public health law.

(10) Trained overdose responders may have shared access to, and use of, an opioid antagonist so long as the following conditions are met:

- (i) they are trained in accordance with these regulations;
- (ii) they have a common organizational or workforce bond; and
- (iii) there are policies and procedures in place within that organization or workforce that ensure orderly, controlled access to an opioid antagonist by an identifiable pool of trained overdose responders.

(11) Clinical directors and affiliated prescribers of registered providers are authorized to direct the furnishing or dispensing of an opioid antagonist to trained overdose responders pursuant to a patient-specific prescription or a non-patient specific prescription.

(12) All dispensing or furnishing of an opioid antagonist pursuant to a non-patient-specific prescription shall be to individuals who have been trained in opioid overdose recognition and response and be accompanied by documentation indicating:

- (i) that the opioid antagonist has been furnished pursuant to a non-patient specific prescription;
- (ii) the name of the prescriber;
- (iii) the opioid antagonist being prescribed;
- (iv) the date of the dispensing or furnishing; and
- (v) the name of the person (or identification of the pool under subparagraph (iii) of paragraph (10) of this subdivision) receiving the opioid antagonist.

(d) Nothing in this section shall prevent a health care practitioner from issuing a patient-specific prescription for an opioid antagonist as otherwise permitted by law.

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