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NEW JERSEY ADMINISTRATIVE CODE  
TITLE 13  
LAW AND PUBLIC SAFETY  
CHAPTER 45H  
CONTROLLED DANGEROUS SUBSTANCES

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**SUBCHAPTER 1.  
GENERAL PROVISIONS; REGISTRATION**

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**13:45H-1.1 REGISTRATION FEES**

- a) Manufacturers of controlled dangerous substances shall pay an annual fee of \$200.00 at the time of application for registration or for renewal of registration.
- b) Distributors and reverse distributors of controlled dangerous substances shall pay an annual fee of \$100.00 at the time of application for registration or for renewal of registration.
- c) Dispensers of controlled dangerous substances or practitioners registered to conduct research with controlled dangerous substances shall pay an annual fee of \$20.00 at the time of application for registration or for renewal of registration.
- d) Incorporated humane societies or licensed animal control facilities registered to purchase and administer sodium pentobarbital for the purpose of animal euthanasia shall pay an annual fee of \$20.00 for registration or renewal of registration as a Dispenser in the category of hospital/clinic.
- e) A separate fee shall be paid for each separate place of business or professional practice for which registration is required.
- f) The following persons shall be exempt from payment of a fee for registration or renewal of registration:
  - 1) Any hospital, clinic, institution, or other facility operated by any department of the State of New Jersey;
  - 2) Any other agency, excluding individual State employees, for which the State of New Jersey would be responsible for payment of the fee, provided that such exemption is approved by the Director of the Division of Consumer Affairs in the Department of Law and Public Safety; and
  - 3) Hospitals and other facilities operated by any department of the United States of America.
- g) Exemption from payment of a fee for registration or renewal of registration does not relieve the person of the requirement to obtain a registration or of any other requirements or duties prescribed by law.

**13:45H-1.1A DEFINITIONS**

The following words and terms, when used in this chapter, shall have the following meanings unless, the context clearly indicates otherwise:

“Controlled dangerous substance” or “controlled substance” means a controlled dangerous substance as defined in N.J.S.A. 24:21-2.

“Days” means calendar days.

“Director” means the Director of the Division of Consumer Affairs in the Department of Law and Public Safety.

“Division” means the Division of Consumer Affairs in the Department of Law and Public Safety.

“Drug Control Unit” means the administrative unit within the Department of Law and Public Safety, Division of Consumer Affairs located at PO Box 45045, Newark, NJ 07101.

“Drug Enforcement Administration” or “DEA” means the United States Department of Justice, Drug Enforcement Administration.

“Executive Officer” means the administrator of the Drug Control Unit who may be contacted at (973) 504-6351.

“Reverse distributor” means a person who receives controlled dangerous substances acquired from another person registered under this chapter for the purpose of:

- 1) Returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer’s agent; or
- 2) Where necessary, processing such substances or arranging for processing such substances for disposal.

**13:45H-1.2 REGISTRATION REQUIREMENTS**

a) Every person who manufactures or proposes to manufacture a controlled dangerous substance or substances, unless specifically exempted by statute or specifically waived by the



Director, shall obtain a registration and shall obtain a renewal of the registration every year thereafter.

- b) Every person who distributes or proposes to distribute a controlled dangerous substance or substances, or who acts or proposes to act as a reverse distributor of a controlled dangerous substance or substances, unless specifically exempted by statute or specifically waived by the Director, shall obtain a registration and shall obtain a renewal of the registration every year thereafter.
- c) Every person who dispenses (including prescribing, administering, compounding, or delivering) or proposes to dispense a controlled dangerous substance or substances, unless specifically exempted by statute or specifically waived by the Director, shall obtain a registration and shall obtain a renewal of the registration every year thereafter.
- d) Every person who conducts research or proposes to conduct research with a controlled dangerous substance or substances, unless specifically exempted by statute or specifically waived by the Director, shall obtain a registration and shall obtain a renewal of the registration every year thereafter.
- e) A person desiring to obtain a registration or a renewal of registration as provided in (a) through (d) above shall prepare and file an application in accordance with the procedure set forth in N.J.A.C. 13:45H-1.4, accompanied by the annual registration fee as set forth in N.J.A.C. 13:45H-1.1.
- f) A separate application shall be made and a separate registration obtained for each place of business or professional practice, where the applicant manufactures, distributes, acts as a reverse distributor or dispenses controlled dangerous substances. A separate application shall be made and a separate registration obtained for each separate and distinct business entity, affiliated corporation, or subsidiary corporation that engages in such activities, but a single entity doing business at one location under more than one business name or trade name may obtain a single registration provided that all such business names or trade names are stated in the application.
- g) Every person or duly authorized agent who dispenses or proposes to dispense sodium pentobarbital for purposes of animal euthanasia, unless specifically exempted by statute or specifically waived by the Director, shall apply for a registration and shall obtain a renewal of registration every year thereafter.
  - 1) Applications for registration to use sodium pentobarbital for animal euthanasia may be obtained from the Drug Control Unit. Upon receipt of said application by this Unit, the security, safeguards, recordkeeping requirement and personnel training requirements

shall be inspected and/or reviewed, and upon satisfactory compliance with the statute and regulations, a registration certificate shall be issued to the applicant.

- h) Every person or duly authorized agent required to register pursuant to (g) above shall be required to provide evidence of a current general liability insurance policy. A certified individual shall be deemed to be acting in behalf of and at the direction of the duly authorized agent.
- i) Every person or duly authorized agent required to register pursuant to (g) above shall be limited to the use of sodium pentobarbital only. Registration granted under (g) above shall not entitle a registrant to buy, possess and/or dispense controlled dangerous substances other than that specified in the registration.
- j) Every individual, as directed by the registered duly authorized agent to use sodium pentobarbital in animal euthanasia, shall be required to be trained in, and demonstrate proficiency with, the use of sodium pentobarbital in animal euthanasia, to the satisfaction of a New Jersey licensed veterinarian. Said New Jersey licensed veterinarian shall, in writing and filed with the registered incorporated humane society or licensed animal care facility, so certify the training and demonstrated proficiency of the individual in the use of sodium pentobarbital in animal euthanasia.
- k) Every person or duly authorized agent required to register pursuant to (g) above shall prepare written procedures and protocol, approved by a New Jersey licensed veterinarian, for the administration of sodium pentobarbital in animal euthanasia. Such written procedure and protocol must be on file at the licensed premise and readily available for review by a Drug Control Unit representative.
- l) A person or duly authorized agent registered as a dispenser for the purposes of purchasing and dispensing sodium pentobarbital for the purpose of animal euthanasia shall be limited to registration in Schedule II (sodium pentobarbital) and may possess or have under his control such amounts as are reasonably necessary to administer euthanasia on the premises of the registered location.
- m) Every person or duly authorized agent required to register pursuant to this section shall provide the Drug Control Unit with its Drug Enforcement Administration registration number within 60 days of registration.

### **13:45H-1.3 ACTIVITIES REQUIRING REGISTRATION**

- a) Registration under N.J.A.C. 13:45H-1.2(a) or (b) shall be issued to authorize the registrant to manufacture, distribute or act as a reverse distributor of, respectively, specific controlled dangerous substances included in Schedule I or Schedule II, or to authorize the registrant to

manufacture, distribute or act as a reverse distributor of, respectively, the controlled dangerous substances included in Schedules III, IV, or V. Any registrant authorized to manufacture, distribute or act as a reverse distributor of substances included in Schedules III, IV, or V may manufacture, distribute or act as a reverse distributor of, respectively, any controlled dangerous substance listed in the Schedule or Schedules for which he is registered.

- b) A person desiring to obtain a registration under N.J.A.C. 13:45H-1.2(a) or (b) shall specify the controlled dangerous substances or the Schedules for which he wishes to obtain a registration in his application and may manufacture, distribute or act as a reverse distributor of, only those controlled dangerous substances authorized in his registration.
- c) Registration under N.J.A.C. 13:45H-1.2(c) shall be issued to authorize the registrant to dispense controlled dangerous substances in Schedules II, III, IV, or V by Schedules. Any person desiring to obtain a registration to dispense shall specify the Schedules for which he wishes to be registered in his application and may dispense only those controlled dangerous substances in the Schedules included in his registration.
- d) Every practitioner registered to dispense controlled dangerous substances who desires to conduct research with substances included in Schedule I or with substances included in Schedules II through V shall make a separate application and be issued a separate registration to conduct such research. Such practitioner shall, in addition to the general requirements of these regulations, furnish the Drug Control Unit with a copy or photocopy of his Federal registration or Federal authorization to conduct research with such substances and a copy of the research protocol.
- e) A practitioner registered to dispense controlled dangerous substances may conduct research with nonnarcotic substances in Schedules II through V which are included in his registration without applying for a separate registration to conduct research.
- f) A practitioner not registered to dispense may be registered to conduct research only for the purpose of making a laboratory analysis of substances to determine the presence of controlled dangerous substances. Such registrant may not possess or have under his control any controlled dangerous substance except such amounts as are reasonably necessary to make such analysis on the premises of the registered location.
- g) A person registered to manufacture controlled dangerous substances may distribute those substances which he is authorized to manufacture without obtaining a separate registration, provided that distribution is from the registered location. A person desiring to distribute controlled dangerous substances other than those he is registered to manufacture or from a different location shall obtain a separate registration as a distributor.

- h) For purposes of registration, the following activities by a registrant shall not be deemed to require an additional registration for a separate location:
- 1) An office used by a registered manufacturer, distributor or reverse distributor or his agents or employees to solicit or make sales of controlled dangerous substances, provided that no such substances are contained in or distributed from such office.
  - 2) An office used by a registered dispenser where controlled dangerous substances are prescribed, provided that no such substances are administered, delivered, or otherwise dispensed, and no such substances are contained in such office.
- i) A person or duly authorized agent registered as a dispenser for the purchasing and dispensing of sodium pentobarbital for the purpose of animal euthanasia shall be limited to registration in Schedule II (sodium pentobarbital) and may possess or have under his or her control such amounts as are reasonably necessary to administer euthanasia on the premises of the registered location.

#### **13:45H-1.4 REGISTRATION APPLICATION**

- a) All applications for registration shall be made on forms provided by the Executive Officer and shall be filed with the Drug Control Unit at PO Box 45045, Newark, NJ 07101.
- b) Applications shall contain all information called for on the forms provided, except where such information is not applicable in which case this fact shall be stated.
- c) The Director may require an applicant to submit documents and statements pertinent to the application or may require the applicant to amend the application to make it more definite and certain.
- d) Each application and each additional document or statement required by the Director shall be signed by the applicant, if an individual; by a general partner of the applicant, if a partnership; or by an officer of the applicant, if a corporation or other entity.
- e) Any application may be amended or withdrawn by the applicant as a matter of right prior to the date of service of any order to show cause pursuant to N.J.S.A. 24:21-12. An application may be amended or withdrawn by the applicant after the date of service of such an order to show cause only upon written consent of the Director.
- f) A duplicate copy of each application and of each additional document or statement required pursuant to (c) above shall be kept by the applicant at the location to be registered.

**13:45H-1.5 ACTION UPON APPLICATION**

- a) After an application for registration has been filed, the Drug Control Unit shall make such inspection of the place of business or professional practice described in the application and such investigation of the applicant as may be necessary to determine that the applicant meets the requirements of the applicable statutes and regulations.
- b) (Reserved)
- c) Any application for renewal of a registration issued pursuant to the New Jersey Controlled Dangerous Substances Act and this chapter may in the discretion of the Director be granted and a renewal of registration issued prior to the making of an inspection or investigation by the Director or his or her authorized agent or representative.
- d) The issuance of a registration pursuant to (c) above shall not be deemed to vest any right to continue the registration or to obtain a renewal thereof, if upon subsequent inspection or investigation, the Director determines that the registrant does not meet the requirements of the applicable statutes or rules.
- e) The registration certificate issued pursuant to this chapter shall be displayed conspicuously in the registered location.

**13:45H-1.6 ASSIGNMENT OR TRANSFER OF REGISTRATION**

- a) No registration nor any right granted thereunder shall be assigned or otherwise transferred to any person not named as the registrant therein nor to any place of business or professional practice not stated therein, except as provided by statute or regulations.
- b) A registrant who changes his place of business or professional practice from the location which is stated in the registration to a new location within the State of New Jersey, without any change in the ownership of the business or professional practice, may obtain an endorsement validating his registration for the remainder of the registration period at the new location by notifying the Director in writing, which notice shall set forth the name and registration number of the registrant, the address of the registered location, the address of the new location, and the effective date of the change of location.
- c) A registration shall terminate and become void if and when the registrant dies, ceases legal existence, or discontinues business or professional practice in the State of New Jersey. A registrant who ceases legal existence or discontinues business or professional practice shall notify the Director in writing and surrender his current registration. In the event that the business or professional practice will be continued or resumed after a change in ownership a new application for registration shall be made pursuant to N.J.A.C. 13:45H-1.1 and 1.2 of this Chapter.

- d) For purposes of this section it shall be deemed to be a change of ownership of a business or professional practice in the case of a partnership, and in the case of a corporation if there is a change in the president or chief executive officer of the corporation, or in the ownership of ten per cent or more of the outstanding shares in the corporation.

### **13:45H-1.7 CHANGES IN SCHEDULE**

Consistent with the provisions set forth in N.J.S.A. 24:21-3, regulations promulgated pursuant to the United States Comprehensive Drug Abuse Prevention and Control Act of 1970, which designate, reschedule or delete a substance as a controlled substance under Federal Law, shall be deemed to be effective under the New Jersey Controlled Dangerous Substance Act (N.J.S.A. 24:21-1 et seq.) 30 days after their effective date of the Federal regulation, unless the Director, within that 30 day period, shall object to inclusion, rescheduling or deletion, which objection shall thereafter be published in the New Jersey Register.

### **13:45H-1.8 DUPLICATE REGISTRATION**

Any registrant requesting a duplicate of a certificate of registration shall apply to the Drug Control Unit in writing and pay a fee of \$5.00 for such duplicate.

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## **SUBCHAPTER 2. SECURITY REQUIREMENTS**

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### **13:45H-2.1 SECURITY REQUIREMENTS GENERALLY**

- a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances. In order to determine whether a registrant has provided effective controls against diversion, the Division shall use the security requirements set forth in N.J.A.C. 13:45H-2.2, 2.3 and 2.5 as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in N.J.A.C. 13:45H-2.2, 2.3 and 2.5 may be used in lieu of the materials and construction described in those sections.
- b) Substantial compliance with the standards set forth in N.J.A.C. 13:45H-2.2 through 2.6 may be deemed sufficient by the Division after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Division may consider any of the following factors as the Division may deem relevant to the need for strict compliance with security requirements:

- 1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, co-operative buying, and so forth);
- 2) The type and form of controlled substances handled (e.g., bulk liquids or dosage units, usable powders or non-usable powders);
- 3) The quantity of controlled substances handled;
- 4) The location of the premises and the relationship such location bears on security needs;
- 5) The type of building construction comprising the facility and the general characteristics of the building or buildings;
- 6) The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used;
- 7) The type of closures on vaults, safes, and secure enclosures;
- 8) The adequacy of key control systems and/or combination lock control systems;
- 9) The adequacy of electric detection and alarm systems, if any, including use of supervised transmittal lines and standby power sources;
- 10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any;
- 11) The adequacy of supervision over employees having access to manufacturing and storage areas;
- 12) The procedures for handling business guests, visitors, maintenance personnel, and nonemployee service personnel;
- 13) The availability of local police protection or of the registrant's or applicant's security personnel, and;
- 14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations.

- c) When physical security controls become inadequate as a result of a controlled substance being transferred to a different schedule or as a result of a significant increase in the quantity of controlled substances in the possession of the registrant during normal business operations, the physical security controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in N.J.A.C. 13:45H-2.2 through 2.6 when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or a result of a controlled substance being removed from control, or as a result of a significant decrease in the quantity of controlled substances in the possession of the registrant during normal business operations.
- d) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in N.J.A.C. 13:45H-2.2 through 2.6 may submit any plans, blueprints, sketches or other materials regarding the proposed security system to the Drug Control Unit.

### **13:45H-2.2 PHYSICAL SECURITY CONTROLS FOR NONPRACTITIONERS: STORAGE AREAS**

- a) Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedule I or II shall be stored in one of the following secure storage areas;
- 1) Where small quantities permit, a safe or steel cabinet:
    - i. Which safe or steel cabinet shall have the following specifications or the equivalent; 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;
    - ii. Which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and
    - iii. Which safe or steel cabinet, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system, which upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Division may approve.
  - 2) A vault constructed before, or under construction on, September 1, 1971 which is of substantial construction with a steel door, combination of key lock, and an alarm system;  
or



- 3) A vault constructed after September 1, 1971:
  - i. The walls, floors and ceilings of which vault are constructed of at least eight inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with 1/2 inch steel rods tied six inches on center, or the structural equivalent to such reinforced walls, floors and ceilings;
  - ii. The door and frame unit of which vault shall conform to the following specifications or the equivalent; 30 man-minutes against surreptitious entry, ten man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;
  - iii. Which vault, if operations require it to remain open for frequent access, is equipped with a "day-gate" which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;
  - iv. The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Division may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;
  - v. The door of which vault is equipped with contact switches; and
  - vi. Which vault has one of the following; complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Division.
- b) Raw materials, bulk materials awaiting further processing, and finished products which are controlled substances listed in Schedules III, IV, and V shall be stored in one of the following secure storage areas:
  - 1) Where small quantities permit, a safe which complies with the requirements set forth in (a)1 above;
  - 2) A vault which complies with the requirements set forth in either (a)2 or 3 above; or
  - 3) A building or areas located within a building, which building or area:

- i. Has walls or perimeter fences of sufficient height and construction to provide security from burglary;
  - ii. Has substantial doors which may be securely locked during non-working hours by a multiple position combination or key lock;
  - iii. Is equipped with an alarm which, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Division may approve; and
  - iv. In which all controlled substances are segregated from all other merchandise and kept under constant surveillance during normal business hours.
- c) Where several types or classes of controlled substances are handled separately by the registrant or applicant for different purposes (that is, returned goods, or goods in process), the controlled substances may be stored separately, provided that each storage area complies with the requirements set forth in this Section.
- d) The controlled substances storage areas shall be accessible only to an absolute minimum number of specifically authorized employees. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests or visitors to be present in or pass through controlled substances storage areas, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.
- e) A registrant or authorized agent may request an exception from the provisions of this subchapter from the Division, when, due to the bulk volume of the controlled substance, achieving the required level of security may appear to be economically unreasonable or technically infeasible. Upon receipt of a request, the Division will assess the physical arrangements of the present or proposed security system. Based on considerations of public health and safety, the Division may accept a lesser level of security. A final decision of the Division, and the reasons therefore, shall be entered upon the records of the Division and sent to the registrant or authorized agent.

### **13:45H-2.3 PHYSICAL SECURITY CONTROLS FOR NONPRACTITIONERS; MANUFACTURING AREAS**

- a) All manufacturing activities (including processing, packaging and labeling) involving controlled substances listed in any schedule shall be conducted in accordance with the following:

- 1) All in-process substances shall be returned to the controlled substances storage area at the termination of the process. If the process is not terminated 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 such substances shall be securely locked, with adequate security for the area or building. If the security requires an alarm, such alarm, upon unauthorized entry, shall transmit a signal directly to a central station protection company, or local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant.
- 2) Manufacturing activities with controlled substances shall be conducted in an area or areas of clearly defined limited access which is under surveillance by an employee or employees designated in writing as responsible for the area "limited access" may be provided, in the absence of physical dividers such as walls or partitions, by traffic control lines or restricted space designation. The employee designated as responsible for the area may be engaged in the particular manufacturing operation being conducted, provided, that he is able to provide continuous surveillance of the area in order that unauthorized persons may not enter or leave the area without his knowledge.
- 3) During the production of controlled substances, the manufacturing areas shall be accessible to only those employees required for efficient operation. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests or visitors to be present in or pass through manufacturing areas during production of controlled substances, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.

#### **13:45H-2.4 OTHER SECURITY CONTROLS FOR NONPRACTITIONERS**

- a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry with the Drug Control Unit to determine that the person is registered to possess the controlled substance.
- b) The registrant shall design and operate a system to disclose suspicious orders of controlled substances. The registrant shall inform the Drug Control Unit of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.
- c) The registrant shall notify the Drug Control Unit of any theft or loss of any controlled substances upon discovery of such theft or loss. The supplier shall be responsible for reporting in-transit losses of controlled substances by the common or contract carrier selected pursuant to (e) below upon discovery of such theft or loss. The registrant shall also complete DDC-52 form regarding such theft or loss. Thefts must be reported whether or not

the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them.

- d) The registrant shall not distribute any controlled substance listed in Schedules II through V as a complimentary sample to any potential or current customer without the prior written request of the customer, to be used only for satisfying the legitimate medical needs of patients of the customer, and only in reasonable quantities. Such request must contain the name, address and registration number of the customer and the name and quantity of the specific controlled substance desired. The request shall be preserved by the registrant with other records of distribution of controlled substances. In addition, the requirements of N.J.A.C. 13:45H-6 shall be complied with for any distribution of a controlled substance listed in Schedule II. For purposes of this paragraph, the term "customer" includes a registrant to whom a complimentary sample of a substance is given in order to encourage the prescribing or recommending of the substance by the registrant.
- e) When shipping controlled substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When storing controlled substances in a public warehouse, a registrant is responsible for selecting a warehouseman which will provide adequate security to guard against storage losses; wherever possible, the registrant shall store controlled substances in a public warehouse which complies with the requirements set forth in N.J.A.C. 13:45H-2.2. In addition, the registrant shall employ precautions (for example assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in-transit losses.
- f) When distributing controlled substances through agents (for example, detailmen), a registrant is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.
- g) Before the initial distribution of carfentanil, etorphine hydrochloride, and/or diprenorphine to any person, the registrant must verify that the person is authorized to handle the substance(s) by contacting the Drug Enforcement Administration.

### **13:45H-2.5 PHYSICAL SECURITY CONTROLS FOR PRACTITIONERS**

- a) Controlled substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.
- b) Controlled substances listed in Schedules II, III, IV and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies may disperse such substances throughout the stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

- c) This section shall also apply to non-practitioners authorized to conduct research or chemical analysis under another registration. The registrant shall not employ as an agent or employee who has access to controlled substances any person who has had an application for registration denied, or has had his registration revoked, at any time.
- d) The registrant shall notify the Drug Control Unit of the theft or loss of any controlled substances upon discovery of such loss or theft. The registrant shall also complete DDC-52 form regarding such loss or theft.
- e) Carfentanil, etorphine hydrochloride and diprenorphine shall be stored in a safe or steel cabinet equivalent to a U.S. Government Class V security container.
- f) This section shall apply to those persons or duly authorized agents registered for the purposes of purchasing and dispensing sodium pentobarbital for animal euthanasia. Safeguards and security to the sodium pentobarbital shall be in compliance with N.J.A.C. 13:45H-2.1.
- g) A person or duly authorized agent registered to use sodium pentobarbital for purposes of animal euthanasia shall maintain records and inventories and shall file the reports required by this subchapter.

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### **SUBCHAPTER 3. LABELING AND PACKAGING REQUIREMENTS**

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#### **13:45H-3.1 SCOPE**

Requirements governing the labeling and packaging of controlled substances pursuant to Sections 305 and 1008(d) of the Act (21 U.S.C. 825 and 958(d)) are set forth generally by those Sections and specifically by the Sections of this part.

#### **13:45H-3.2 DEFINITIONS**

- a) The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

“Commercial container” means any bottle, jar, tube, ampule or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term “commercial container” does not include any package liner, package insert or other material

kept with or within a commercial container, nor any carton, crate, drum or other package in which commercial containers are stored or used for shipment of controlled substances.

“Label” means any display of written, printed or graphic matter placed upon the commercial container of any controlled substance by any manufacturer of such substance.

“Labeling” means all labels and other written, printed or graphic matter upon any controlled substance or any of its commercial containers or wrappers, or accompanying such controlled substance.

“Manufacture” means the producing, preparation, propagation, compounding or processing of a drug or other substance or the packaging or repackaging of such substance, or the labeling or relabeling of the commercial container of such substance, but does not include the activities of a practitioner who, as an incident to his administration or dispensing such substance in the course of his professional practice, prepares, compounds, packages or labels such substance. The term “manufacture” means a person who manufactures a drug or other substance, whether under a registration or as a manufacturer or under authority of registration as a research or chemical analyst.

b) Any term not defined in this section shall have the definition set forth in Section 102 of the Act (21 U.S.C. 802) or 21 CFR Part 1300.

**13:45H-3.3 SYMBOL REQUIRED; EXCEPTIONS**

a) Each commercial container of a controlled substance (except for a controlled substance excepted by the Division pursuant to N.J.S.A. 24:21-8d) shall have printed on the label the symbol designating the schedule in which such controlled substance is listed. Each such commercial container, if it otherwise has no label, must bear a label complying with the requirement of this part.

b) Each manufacturer shall print upon the labeling of each controlled substance distributed by him the symbol designating the schedule in which such controlled substance is listed.

c) The following symbols shall designate the schedule corresponding thereto:

Schedule

Symbol

- |                 |               |
|-----------------|---------------|
| 1) Schedule I   | I or C-I;     |
| 2) Schedule II  | II or C-II;   |
| 3) Schedule III | III or C-III; |
| 4) Schedule IV  | IV or C-IV;   |
| 5) Schedule V   | V or C-V;     |
- 6) The word "Schedule" need not be used. No distinction need be made between narcotic and nonnarcotic substances.
- d) The symbol is not required on a carton or wrapper in which a commercial container is held if the symbol is easily legible through such carton or wrapper.
- e) The symbol is not required on a commercial container too small or otherwise unable to accommodate a label, if the symbol is printed on the box or package from which the commercial container is removed upon dispensing to an ultimate user.
- f) The symbol is not required on a commercial container containing, or on the labeling of, a controlled substance being utilized in clinical research involving blind studies.

#### **13:45H-3.4 LOCATION AND SIZE OF SYMBOL ON LABEL**

- a) The symbol shall be prominently located on the right upper corner of the principal panel of the label of the commercial container and/or the panel of the commercial container normally displayed to dispensers of any controlled substance listed in Schedules I through V. The symbol must be at least two times as large as the largest type otherwise printed on the label.
- b) In lieu of locating the symbol in the corner of the label, as prescribed in (a) above, the symbol may be overprinted on the label, in which case the symbol must be printed at least one-half the height of the label and in a contrasting color providing clear visibility against the background color of the label.
- c) In all cases the symbol shall be clear and large enough to afford easy identification of the schedule of the controlled substance upon inspection without removal from the dispenser's shelf.

#### **13:45H-3.5 LOCATION AND SIZE OF SYMBOL ON LABELING**

- a) The symbol shall be prominently located on all labeling other than labels covered by N.J.A.C. 13:45H-3.4.

- b) In all cases the symbol shall be clear and large enough to afford prompt identification of the controlled substance upon inspection of the labeling.

### **13:45H-3.6 EFFECTIVE DATES OF LABELING REQUIREMENTS**

- a) All labels on commercial containers of, and all labeling of, a controlled substance which is listed in any schedule on May 1, 1971, and which is packaged after December 1, 1971, shall comply with the requirements of N.J.A.C. 13:45H-3.3.
- b) All labels on commercial containers of, and all labeling of, a controlled substance which either is listed in any schedule on May 1, 1971, and thereafter transferred to another schedule or is added to any schedule after May 1, 1971, and which is packaged more than 180 days following the date on which the transfer or addition becomes effective, shall comply with the requirements of N.J.A.C. 13:45H-3.3.
- c) The Division may, in the case of any controlled substance, require compliance with the requirements of N.J.A.C. 13:45H-3.3 within a period of time shorter than required by this section if he finds that public health or safety necessitate an earlier effective date.
- d) Until compliance is required under this section, the label on commercial container containing, and the labeling of, any controlled substance shall comply with any requirements under Federal and State law as to labels of such containers and as to labeling of such substances existing prior to the effective date prescribed in this section.

### **13:45H-3.7 SEALING OF CONTROLLED SUBSTANCES**

On each bottle, multiple dose vial, or other commercial container of any controlled substance listed in Schedule I or II or of any narcotic controlled substance listed in Schedule III or IV, there shall be securely affixed to the stopper, cap, lid covering or wrapper of such container a seal to disclose upon inspection any tampering or opening of the container.

### **13:45H-3.8 LABELING AND PACKAGING REQUIREMENTS FOR IMPORTED AND EXPORTED SUBSTANCES**

- a) The symbol requirements of N.J.A.C. 13:45H-3.3 through 3.6 apply to every commercial container containing, and to all labeling of, controlled substances imported into the jurisdiction of and/or the customs territory of the United States, as defined to be the several states, the District of Columbia and Puerto Rico.
- b) The symbol requirements of N.J.A.C. 13:45H-3.3 through 3.6 do not apply to any commercial containers containing, or any labeling of, a controlled substance intended for export from the



jurisdiction of the United States, as defined to be the several states, the District of Columbia and Puerto Rico.

- c) The sealing requirements of N.J.A.C. 13:45H-3.7 apply to every bottle, multiple dose vial, or other commercial container of any controlled substance listed in Schedule III or IV, imported into, exported from, or intended for export from, the jurisdiction of and/or the customs territory of the United States, as defined to be the several states, the District of Columbia, and Puerto Rico.

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#### **SUBCHAPTER 4. (RESERVED)**

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#### **SUBCHAPTER 5. RECORDS AND REPORTS OF REGISTRANTS**

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##### **13:45H-5.1 SCOPE**

Inventory and other records and reports required under Section 307 or Section 1008(d) of the Act (21 U.S.C. 827 and 958(d)) shall be in accordance with, and contain the information required by, those Sections and by the Sections of this part.

##### **13:45H-5.2 DEFINITIONS**

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

“Act” means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

“Commercial container” means any bottle, jar, tube, ampule, or other receptacle in which a substance is held for distribution or dispensing to an ultimate user, and in addition, any box or package in which the receptacle is held for distribution or dispensing to an ultimate user. The term “commercial container” does not include any package liner, package insert or other material kept with or within a commercial container, nor any carton, crate, drum, or other package in which commercial containers are stored or are used for shipment of controlled substances.

“Dispenser” means an individual practitioner, institutional practitioner, pharmacy or pharmacist who dispenses a controlled substance.

“Individual practitioner” means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

“Institutional practitioner” means a hospital or other person (other than an individual) licensed, registered, or otherwise permitted by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

“Name” means the official name, common or usual name, chemical name, or brand name of a substance.

“Pharmacist” means any pharmacist licensed by a State to dispense controlled substances, and shall include any other person (e.g., pharmacist intern) authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State.

“Readily retrievable” means that certain records are kept by automatic data processing systems or other electronic or mechanized record keeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

Any term not defined in this section shall have the definition set forth in Sections 102 and 1001 of the Act (21 U.S.C. 802 and 951) and in N.J.S.A. 24:21-1 et seq.

### **13:45H-5.3 PERSONS REQUIRED TO KEEP RECORDS AND FILE REPORTS**

- a) Each registrant shall maintain the records and inventories and shall file the reports required by this part, except as exempted by this section. Any registrant who is authorized to conduct other activities without being registered to conduct those activities, either pursuant to N.J.S.A. 24:21-10 or pursuant to N.J.A.C. 13:45H-8.5 or 21 CFR 1301.22(b), 1307.11, or 1307.13, or Part 1317, shall maintain the records and inventories and shall file the reports required by this part for persons registered or authorized to conduct such activities (for example, when a registered manufacturer conducts chemical analysis, he or she shall

maintain the records and inventories required of chemical analysts). All records of each activity may be maintained in one consolidated record system.

- b) A registered individual practitioner is not required to keep records with respect to narcotic controlled substances listed in Schedules II through V, which he or she prescribes in the lawful course of his or her professional practice; he or she shall keep records, however, with respect to such substances that he or she administers and dispenses.
- c) A registered individual practitioner is required to keep records with respect to nonnarcotic controlled substances listed in Schedules II through V, which he or she dispenses or administers.
- d) A registered person using any controlled substance in research conducted in conformity with an exemption granted under Section 505(i) or 512(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i) or 360b(j)) at a registered establishment which maintains records in accordance with either of these sections is not required to keep records if he notifies the Bureau of the name, address, and registration number of the establishment maintaining such records.
- e) A registered person using any controlled substance in preclinical research or in teaching at a registered establishment which maintains records with respect to such substances is not required to keep records if he notifies the Drug Enforcement Administration and the Drug Control Unit of the name, address, and registration number of the establishment maintaining such records.
- f) Notice required by (d) and (e) above shall be given at the time the person applies for registration or reregistration and shall be made in the form of an attachment to the application, which shall be filed with the application.

#### **13:45H-5.4 MAINTENANCE OF RECORDS AND INVENTORIES**

- a) Every inventory and other record required to be kept under this subchapter shall be kept by the registrant and be available, for at least two years from the date of such inventory of records or pursuant to recordkeeping provisions of the State professional licensing board governing the registrant, whichever is longer, for inspecting and copying by authorized employees of the Drug Enforcement Administration and the Drug Control Unit, except that financial and shipping records (such as invoices and packing slips but not executed order forms subject to 21 CFR 1305.17) may be kept at a central location rather than at the registered location in accordance with 21 CFR 1304.04, which is incorporated herein by reference.

- b) Each registered manufacturer, distributor, reverse distributor, importer, and exporter shall maintain inventories and records and controlled substances as follows:
- 1) Inventories and records of controlled substances listed in schedules I and II shall be maintained separately from all of the records of the registrant; and
  - 2) Inventories and records of controlled substances listed in schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant.
- c) Each registered individual practitioner required to keep records and institutional practitioner shall maintain inventories and records of controlled substances in the manner prescribed in (b) above.
- d) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:
- 1) Inventories and records of all controlled substances listed in schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file; and
  - 2) Inventories and records of controlled substances listed in schedules III, IV, and V shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy, and prescriptions for such substances shall be maintained either in separate prescription file for controlled substances listed in schedules III, IV, and V only or in such form that they are readily retrievable from other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than one-inch high and filed either in the prescription file for controlled substances listed in schedules I and 11 or in the usual consecutively numbered prescription file for non-controlled substances.
- e) A person or duly authorized agent registered to use sodium pentobarbital for purposes of animal euthanasia and required to keep records shall maintain inventories and records of controlled substances in the manner prescribed in (b) above.

### **13:45H-5.5 GENERAL REQUIREMENTS FOR INVENTORIES**

- a) Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken. Controlled substances shall be deemed to be "on

hand” if they are in the possession of or under the control of the registrant, including substances returned by a customer, substances ordered by a customer but not yet invoiced, substances stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples.

- b) A separate inventory shall be made by a registrant for each registered location. In the event controlled substances in the possession or under the control of the registrant at a location for which he is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. Each inventory for a registered location shall be kept at the registered location.
- c) A separate inventory shall be made by a registrant for each independent activity for which he is registered, except as provided in N.J.A.C. 13:45H-5.12.
- d) A registrant may take an inventory on a date that is within four days of the registrant’s biennial inventory date pursuant to N.J.A.C. 13:45H-5.7 if, as part of the registrant’s CDS registration renewal, the registrant provides the Drug Control Unit with the date the inventory was taken. A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate on the inventory records whether the inventory is taken as of the opening or as of the close of business and the date the inventory was taken.
- e) An inventory must be maintained in a written, typewritten or printed form. An inventory taken by use of an oral recording device must be promptly transcribed.

### **13:45H-5.6 INITIAL INVENTORY DATE**

Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he or she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with 21 CFR 1304.11(b), which is incorporated herein by reference.

### **13:45H-5.7 BIENNIAL INVENTORY DATE**

Every two years following the date on which the initial inventory is taken by a registrant pursuant to N.J.A.C. 13:45H-5.6, the registrant shall take a new inventory of all stocks of controlled substances on hand. The biennial inventory may be taken on the day of the year on which the initial inventory was taken or on the registrant’s regular general physical inventory date, if any, which is nearest to and does not vary by more than six months from the biennial

date that would otherwise apply. If the registrant elects to take the biennial inventory on his regular general physical inventory date or another fixed date, he shall notify the Drug Enforcement Administration and the Drug Control Unit of this election and of the date on which the biennial inventory will be taken.

### **13:45H-5.8 INVENTORY DATE FOR NEWLY-CONTROLLED SUBSTANCES**

On the effective date of a rule by the Drug Enforcement Administration Administrator pursuant to 308.48, 308.49 or 308.50 of the Act or the Division pursuant to N.J.S.A. 24:21-3 adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter such substances shall be included in each inventory made by the registrant pursuant to N.J.A.C. 13:45H-5.7.

### **13:45H-5.9 INVENTORIES OF MANUFACTURERS, DISTRIBUTORS, DISPENSERS, RESEARCHERS, REVERSE DISTRIBUTORS, IMPORTERS, EXPORTERS, AND CHEMICAL ANALYSTS**

Each person registered or authorized under 21 CFR 1301.13(e), 1307.11, or 1307.13 or N.J.A.C. 13:45H-1.3 to manufacture, distribute, reverse distribute, dispense, import, export, or conduct research or chemical analysis with controlled substances and required to keep records pursuant to N.J.A.C. 13:45H-5.3 shall include in the inventory the information required in 21 CFR 1304.11(e), which is incorporated herein by reference.

### **13:45H-5.10 GENERAL REQUIREMENTS FOR CONTINUING RECORDS**

- a) Every registrant required to keep records pursuant to N.J.A.C. 13:45H-5.3 shall maintain on a current basis a complete and accurate record of each substance manufactured, imported, received, sold, delivered, exported, or otherwise disposed of by him or her, except that no registrant shall be required to maintain a perpetual inventory.
- b) Separate records shall be maintained by a registrant for each registered location except as provided in N.J.A.C. 13:45H-5.4(a). In the event controlled substances are in the possession or under the control of a registrant at a location for which he is not registered, the substance shall be included in the records of the registered location to which they are subject to control or to which the person possessing the substance is responsible.
- c) Separate records shall be maintained by a registrant for each independent activity for which he is registered, except as provided in N.J.A.C. 13:45H-5.18 and 5.19.

- d) In recording dates of receipt, importation, distribution, exportation, or other transfers, the date on which the controlled substances are actually received, imported, distributed, exported, or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (e.g., invoices or packing slips).
- e) In addition to any other recordkeeping requirements, any registrant that destroys a controlled substance pursuant to 21 CFR 1317.95(d), or causes the destruction of a controlled substance pursuant to 21 CFR 1317.95(c), shall maintain a record of destruction in accordance with 21 CFR 1304.21(e), which is incorporated herein by reference.

### **13:45H-5.11 RECORDS FOR MANUFACTURERS, DISTRIBUTORS, DISPENSERS, RESEARCHERS, IMPORTERS, EXPORTERS, AND REVERSE DISTRIBUTORS**

Each person registered or authorized under 21 CFR 1301.13(e), 1307.11, or 1307.13 or N.J.A.C. 13:45H-1.3 to manufacture, distribute, reverse distribute, dispense, import, export, or conduct research with controlled substances shall maintain records with the information listed in 21 CFR 1304.22, which is incorporated herein by reference.

### **13:45H-5.12 RECORDS FOR CHEMICAL ANALYSTS**

Each person registered or authorized by 21 CFR 1301.13(e) or N.J.A.C. 13:45H-1.3 to conduct chemical analysis with controlled substances shall maintain records in accordance with 21 CFR 1304.23, which is incorporated herein by reference.

### **13:45H-5.13 GENERAL REQUIREMENTS FOR REPORTING: MANUFACTURERS, IMPORTERS, EXPORTERS, DISTRIBUTORS, AND REVERSE DISTRIBUTORS**

Every registered manufacturer, registered importer, registered exporter, registered distributor, and reverse distributor, except any officer or agency of the Veteran's Administration or who or which is exempted from registration pursuant to 21 U.S.C. § 822(c) and N.J.A.C. 13:45H-1.3 shall file reports in accordance with 21 CFR 1304.33, which is incorporated herein by reference.

### **13:45H-5.14 REPORTS FROM MANUFACTURERS IMPORTING NARCOTIC RAW MATERIAL**

Every manufacturer which imports or manufactures from narcotic raw material (opium, poppy straw, and concentrate of poppy straw) shall submit information pursuant to 21 CFR 1304.31, which is incorporated herein by reference.

**13:45H-5.15 REPORTS OF MANUFACTURERS IMPORTING COCA LEAVES**

Every manufacturer importing or manufacturing from raw coca leaves shall submit information pursuant to 21 CFR 1304.32, which is incorporated herein by reference.

**13:45H-5.16 INVENTORY AND RECORD REQUIREMENTS FOR REGISTERED USERS OF SODIUM PENTOBARBITAL**

a) A person or duly authorized agent registered to use sodium pentobarbital for purposes of animal euthanasia and required to keep records shall maintain a quarterly inventory (last day of March, June, September, and December) on forms provided by the Drug Control Unit in the manner prescribed in N.J.A.C. 13:45H-5.9. A copy of such inventory shall be received in the Drug Control Unit within seven days after such required report is completed.

b) Each person or duly authorized agent registered to use sodium pentobarbital for purposes of animal euthanasia shall make, keep, and maintain records of the use of sodium pentobarbital on forms provided by the Drug Control Unit.

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**SUBCHAPTER 6.  
ORDERS FOR SCHEDULE I AND II CONTROLLED SUBSTANCES**

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**13:45H-6.1 GENERAL REQUIREMENTS**

Procedures governing the issuance, use, and preservation of orders for Schedules I and II controlled substances are set forth generally by section 308 of the Act (21 U.S.C. § 828) and specifically by 21 CFR Part 1305, which is incorporated herein by reference, and this subchapter.

**13:45H-6.2 DEFINITIONS**

The following words and terms, when used in this subchapter, shall have the following meanings, unless the contents clearly indicate otherwise:

“Act” means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and the Controlled Substance Import and Export Act (84 Stat. 1285; 21 U.S.C. 951).

“D.E.A.” means the Drug Enforcement Administration.



“Digital signature” means a digital signature as defined in 21 CFR 1311.02 and which is issued by the D.E.A. or the D.E.A. certification authority.

“Electronic order” means an order signed with a digital signature and which complies with the requirements of Subpart C of 21 CFR Part 1305 (21 CFR 1305.21 through 1305.29) and Subparts A and B of 21 CFR Part 1311 (21 CFR 1311.01 through 1311.08 and 1311.10 through 1311.65), which are incorporated herein by reference as amended and supplemented.

“Purchaser” means any registered person entitled to obtain and execute order forms pursuant to 21 CFR Part 1305.

“Supplier” means any registered person entitled to fill order forms pursuant to 21 CFR Part 1305.

Any term not defined in this section shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) 301.02 and 302.02 of the Act, or N.J.S.A. 24:21-1 et seq.

### **13:45H-6.3 ORDERS FOR HUMANE SOCIETY OR LICENSED ANIMAL SHELTER**

The registered agent of a humane society or licensed animal shelter may apply for Federal purchase order forms as described in 21 CFR 1305.04 and 1305.11. Execution of the order forms shall be as specified in 21 CFR 1305.12.

### **13:45H-6.4 PRESERVATION OF ORDER FORMS**

Order forms are required to be kept available for inspection for a period of two years or pursuant to the recordkeeping provisions of the State professional licensing board governing the registrant, whichever is longer.

### **13:45H-6.5 PERSONS ENTITLED TO FILL ORDERS FOR SCHEDULE I AND SCHEDULE II CONTROLLED SUBSTANCES**

a) An order for Schedules I and II controlled substances, whether on a DEA Form 222 or an electronic order, may be filled only by a person registered with DEA as a manufacturer or distributor of controlled substances listed in Schedule I or II pursuant to section 303 of the Act (21 U.S.C. § 823) or as an importer of such substances pursuant to section 1008 of the Act (21 U.S.C. § 958), except for the following:

- 1) A person registered with DEA to dispense the substances, or to export the substances, if he or she is discontinuing business or if his or her registration is expiring without reregistration, may dispose of any Schedule I or II controlled substances in his or her possession with a DEA Form 222 or an electronic order in accordance with N.J.A.C. 13:45H-8.10;
- 2) A purchaser who has obtained any Schedule I or II controlled substance by either a DEA Form 222 or an electronic order may return the substance to the supplier of the substance with either a DEA Form 222 or an electronic order from the supplier;
- 3) A person registered to dispense Schedule II substances may distribute the substances to another dispenser with either a DEA Form 222 or an electronic order only in the circumstances described in 21 CFR 1307.11;
- 4) A person registered or authorized to conduct chemical analysis or research with controlled substances may distribute a Schedule I or II controlled substance to another person registered or authorized to conduct chemical analysis, instructional activities, or research with the substances with either a DEA Form 222 or an electronic order, if the distribution is for the purpose of furthering the chemical analysis, instructional activities, or research; and
- 5) A person registered as a compounder of narcotic substances for use at off-site locations in conjunction with a narcotic treatment program at the compounding location, who is authorized to handle Schedule II narcotics, is authorized to fill either a DEA Form 222 or an electronic order for distribution of narcotic drugs to off-site narcotic treatment programs only.

### **13:45H-6.6 LOST AND STOLEN ORDER FORMS**

- a) If a purchaser ascertains that an unfilled order form has been lost, the purchaser shall comply with the provisions of 21 CFR 1305.16, which is incorporated herein by reference, and (b) and (c) below.
- b) Whenever any used or unused forms are stolen or lost (other than in the course of transmission) by any purchaser or supplier, the purchaser or supplier shall comply with the provisions of 21 CFR 1305.16 and immediately upon discovery of the theft or loss, report the theft or loss to the Drug Control Unit.

c) If any unused order form reported stolen or lost is subsequently recovered or found, the Drug Control Unit shall be notified immediately.

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## **SUBCHAPTER 7. PRESCRIPTION REQUIREMENTS FOR CONTROLLED DANGEROUS SUBSTANCES**

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### **13:45H-7.1 SCOPE**

Rules governing the issuance, filling and filing of prescriptions are set forth specifically by the sections of this subchapter.

### **13:45H-7.2 DEFINITIONS**

The following words and terms when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

“Act” means the New Jersey Controlled Substances Act (N.J.S.A. 24:21-1 et seq.).

“Federal Act” means the Controlled Substances Act (Title 21, United States Code 801: 84 Stat. 1242).

“Individual practitioner” means a physician, dentist, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States, the jurisdiction in which he practices, or in New Jersey, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

“Institutional Practitioner” means a hospital or other person (other than an individual) licensed, registered, or otherwise permitted, by the United States, the jurisdiction in which it practices, or in New Jersey, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

“Pharmacist” means any pharmacist licensed by the State of New Jersey to dispense controlled substances and shall include any other person (for example, a pharmacist intern

authorized by the State to dispense controlled substances under the supervision of a pharmacist licensed by the State).

“Prescription” means an order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).

“Register” and “registered” refer to registration required and permitted by Section 10 of the New Jersey Controlled Dangerous Substances Act (N.J.S.A. 24:21-10).

Any term not defined in this section shall have the definition set forth in the New Jersey Controlled Dangerous Substances Act (N.J.S.A. 24:21-1 et seq.).

### **13:45H-7.3 PERSONS ENTITLED TO ISSUE PRESCRIPTIONS**

- a) A prescription for a controlled substance may be issued only by an individual practitioner who is:
  - 1) Authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession; and
  - 2) Either registered or exempted from registration pursuant to 21 CFR 1301.22(c) or 1301.23.
- b) A prescription issued by an individual practitioner shall be communicated to a pharmacist by the individual practitioner.

### **13:45H-7.4 PURPOSE OF ISSUE OF PRESCRIPTION**

- a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of Law relating to controlled substances.

- b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.
- c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule for "detoxification" or "maintenance treatment" as defined in N.J.A.C. 13:45H-11.1, unless the prescription is for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with 21 CFR 1301.28.

### **13:45H-7.5 MANNER OF ISSUANCE OF PRESCRIPTIONS**

- a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the full name, address, proper academic degree or other definitive identification of the professional practice for which he or she is licensed, and registration number of the practitioner. All prescriptions for controlled substances, regardless of schedules, shall be presented to the pharmacist for filling within 30 days after the date when issued, except as provided in (a)1 below. A practitioner may sign a prescription in the same manner as he or she would sign a check or legal document (for example, J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written in ink or indelible pencil or typewriter or printed on a computer printer and shall be manually signed by the practitioner. A computer-generated prescription that is printed out or faxed by the practitioner must be manually signed. The prescription may be prepared by a secretary or agent of the practitioner for the signature of the practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law or rules. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by this section.
  - 1) When up to three separate prescriptions for a total of up to a 90-day supply of a Schedule II controlled substance are issued to a patient by a physician pursuant to N.J.S.A. 45:9-22.19 (P.L. 2009, c. 165), a pharmacist shall fill such prescriptions.
    - i. All three prescriptions may be accepted at one time and held pending filling as indicated below:
      - (1) The first prescription shall be filled no later than 30 days after the date of issuance; and
      - (2) The second and third prescriptions shall be filled no later than 30 days after the date indicated on the prescription as the earliest date on which the prescription may be filled.

- ii. Prescriptions presented individually shall be filled as indicated below:
    - (1) The first prescription shall be filled no later than 30 days after the date of issuance;
    - (2) The second and third prescriptions shall be presented to the pharmacy and filled no later than 30 days after the date indicated on the prescription as the earliest date on which the prescription may be filled.
  - iii. A patient shall not be provided with more than a 30-day supply of a Schedule II medication at one time.
- b) An intern, resident, or foreign-trained physician, or physician on the staff of a Veterans' Administration facility, exempted from registration under 21 CFR 1301.22(c) shall include on all prescriptions issued by him or her the registration number of the hospital or other institution and the special internal code number assigned to him or her by the hospital or other institution as provided in 21 CFR 1301.22(c), in lieu of the registration number of the practitioner required by this section. Each written prescription shall have the name of the physician stamped, typed, or hand-printed on it, as well as the signature of the physician.
- c) An official exempted from registration under 21 CFR 1301.23(a) shall include on all prescriptions issued by him or her, his or her branch of service or agency (for example, "U.S. Army" or "Public Health Service") and his or her service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is his or her Social Security identification number. Each prescription shall have the name of the officer stamped, or hand-printed on it, as well as the signature of the officer.
- d) A prescription for a Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for "detoxification treatment" or "maintenance treatment" as defined in N.J.A.C. 13:45H-11.1 must include the identification number issued by the Administrator under 21 CFR 1301.28(d) or a written notice stating that the practitioner is acting under the good faith exception under 21 CFR 1301.28(e).

### **13:45H-7.6 PERSONS ENTITLED TO FILL PRESCRIPTIONS**

A prescription for controlled substances may only be filled by a pharmacist acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy or registered institutional practitioner.

**13:45H-7.7 ADMINISTERING OR DISPENSING OF NARCOTIC DRUGS**

- a) The administering or dispensing directly (but not prescribing) of narcotic drugs listed in any schedule to a narcotic drug dependent person for “detoxification treatment” or “maintenance treatment” as defined in N.J.A.C. 13:45H-11.1 shall be deemed to be within the meaning of the term “in the course of professional practice or research”; provided that the practitioner is separately registered with the Drug Control Unit as required by N.J.A.C. 13:45H-11.2 and then thereafter complies with the regulatory standards imposed relative to treatment qualifications, security, records and unsupervised use of drugs pursuant to the Act.
- b) Nothing in this section shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one day’s medication may be administered to the person or for the person’s use at one time. Such emergency treatment may be carried out for not more than three days and may not be renewed or extended.
- c) This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

**13:45H-7.8 REQUIREMENTS OF PRESCRIPTIONS; SCHEDULE II**

- a) A pharmacist may dispense directly a controlled substance listed in Schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the prescribing individual practitioner, except as provided in (d) and (e) below.
- b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule II in the course of his or her professional practice without a prescription, subject to N.J.A.C. 13:45H-7.6.
- c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.
- d) In the case of an emergency situation, as defined by the Secretary of the Federal Department of Health and Human Services in 21 CFR 290.10, a pharmacist may dispense a

controlled substance listed in Schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

- 1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period not to exceed 72 hours (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner);
  - 2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in N.J.A.C. 13:45H-7.5(a), except for the signature of the prescribing individual practitioner;
  - 3) If the prescribing individual practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory and/or other good faith efforts to insure his identity; and
  - 4) Within seven days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed (not to exceed the amount for a 72-hour period) to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of N.J.A.C. 13:45H-7.4, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the seven-day period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription, which had earlier been reduced to writing. The pharmacist shall notify the Drug Control Unit and the nearest office of the DEA in his or her district if the prescribing individual practitioner fails to deliver a written prescription to him or her; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense with a written prescription of a prescribing individual practitioner.
- e) If permitted by Federal law, and in accordance with Federal requirements, an electronic prescription shall serve as the original signed prescription.
- f) A practitioner shall not prescribe or dispense a Schedule II controlled substance to an individual patient in excess of the limits set forth at N.J.A.C. 13:35-7.6, except that prescriptions for patients in a long-term care facility (LTCF) may be in amounts as set forth in N.J.A.C. 13:45H-7.10(d).



- g) A practitioner may transmit a facsimile prescription for a Schedule II controlled substance in accordance with N.J.A.C. 13:35-7.4.

### **13:45H-7.9 REFILLING PRESCRIPTIONS; SCHEDULE II**

The refilling of a prescription for a controlled substance listed in Schedule II is prohibited.

### **13:45H-7.10 PARTIAL FILLING OF PRESCRIPTIONS; SCHEDULE II**

- a) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he or she makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription).
- b) The remaining portion of the prescription may be filled within 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 individual practitioner.
- c) No further quantity may be supplied beyond 72 hours without a new prescription.
- d) Prescriptions for Schedule II controlled substances written for patients in a long-term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the practitioner prior to partially filling the prescription. Both the pharmacist and practitioner shall assure that a controlled substance is for a terminally ill patient. The pharmacist shall record on the prescription whether the patient is terminally ill or an LTCF patient. A prescription that is partially filled and does not contain the notation that the patient is terminally ill or a patient in an LTCF shall be deemed to have been filled in violation of N.J.S.A. 24:21-1 et seq. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. Prior to any subsequent partial filling, the pharmacist shall determine that the additional partial filling is necessary. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions, for patients in an LTCF, or patients with a medical diagnosis documenting a terminal illness, shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of the medication.
- e) Information pertaining to current Schedule II prescriptions for patients in an LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if this system has the capability to permit:

- 1) Output (display or printout) of the original prescription number, date of issue, identification of prescribing individual practitioner, identification of patient, address of the LTCF or address of the hospital or residence of the patient, identification of medication authorized (to include dosage form, strength and quantity), listing of partial fillings that have been dispensed under each prescription and the information required in (d) above;
- 2) Immediate (real time) updating of the prescription record each time a partial filling of the prescription is conducted.
- 3) Retrieval of partially filled Schedule II prescription information in accordance with procedures specified in N.J.A.C. 13:45H-7.14(f)1 through 5 for Schedules III, IV, and V prescription refill information.

### **13:45H-7.11 LABELING OF SUBSTANCES; SCHEDULE II**

- a) The pharmacist filling a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a label, conforming to the provisions set forth in N.J.S.A. 24:21-17.
- b) The requirements of (a) above do not apply where a controlled substance listed in Schedule II is prescribed for administration to an ultimate user who is institutionalized: provided, that:
  - 1) Not more than a seven-day supply of the controlled substance listed in Schedule II is dispensed at one time;
  - 2) The controlled substance listed in Schedule II is not in the possession of the ultimate user prior to the administration;
  - 3) The institution maintains appropriate safeguards and records regarding the proper administration, control, dispensing, and storage of the controlled substance listed in Schedule II; and
  - 4) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

### **13:45H-7.12 FILING OF PRESCRIPTIONS; SCHEDULE II**

All written prescriptions and written records of emergency oral prescriptions shall be kept in accordance with requirements of N.J.A.C. 13:45H-5.4.

**13:45H-7.13 REQUIREMENTS OF PRESCRIPTIONS; SCHEDULES III, IV, AND V**

- a) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V which is a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, pursuant to a written prescription of a duly registered individual practitioner or a facsimile prescription as set forth in N.J.A.C. 13:39-7.10.
- b) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V. which is a prescription drug as determined under the Federal Food, Drug and Cosmetic Act, pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist containing all information required in N.J.A.C. 13:45H-7.5(a) except for the signature of the prescribing individual practitioner.
- c) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule III, IV, or V in the course of his or her professional practice without a prescription, subject to N.J.A.C. 13:45H-7.7.
- d) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule III, IV, or V pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in N.J.A.C. 13:45H-7.5(a) except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner, subject to N.J.A.C. 13:45H-7.7.

**13:45H-7.14 REFILLING OF PRESCRIPTIONS; SCHEDULES III, IV AND V**

- a) No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six months after the date on which such prescription was issued and no such prescription authorized to be refilled may be refilled more than five times.
- b) A prescription for a controlled substance listed in Schedule V may be refilled only as expressly authorized by the prescribing individual practitioner on the prescription. If no such authorization is given, the prescription may not be refilled.
- c) Each refilling of a prescription shall be entered on the back of the prescription or on the electronic prescription record (or on another appropriate uniformly maintained, readily retrievable record, such as medication records), which indicates by the number of the prescription the following information:
  - 1) The name and dosage of the controlled substance;
  - 2) The date of each refilling;

- 3) The quantity dispensed;
  - 4) The identity or initials of the dispensing pharmacist in each refilling; and
  - 5) The total number of refills for that prescription, initialed, and dated by the pharmacist as of the date of dispensing, and shall state the amount dispensed.
- d) If the pharmacist merely initials and dates the back of the prescription or annotates the electronic prescription record he or she shall be deemed to have dispensed a refill for the full face amount of the prescription.
- e) Additional quantities of controlled substances listed in Schedule III or IV may only be authorized by a prescribing practitioner through issuance of a new prescription as provided in N.J.A.C. 13:45H-7.13, which shall be a new and separate prescription.
- f) As an alternative to the procedures provided by (a) through (e) above, an automated data processing system may be used for the storage and retrieval of refill information for prescription orders for controlled substances in Schedules III, IV, and V subject to the following conditions:
- 1) Any such proposed computerized system must provide on-line retrieval (via computer monitor display or hard-copy printout) of original prescription order information for those prescription orders that are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number, date of issuance of the original prescription order by the practitioner, date of first filing, full name and address of the patient, name, address, and DEA registration number of the practitioner, and the name, strength, dosage form, quantity of the controlled substance prescribed (and the quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.
  - 2) Any such proposed computerized system must also provide on-line retrieval (via computer monitor display or hard-copy printout) of the current refill history for Schedule III or IV controlled substance prescription orders (those authorized for refill during the past six months). This refill history shall include, but not be limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription order.
  - 3) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedule III, IV, or V controlled substance is correct must be provided by the individual pharmacist who makes use of such a system. If such a system provides a hard-copy printout of each day's controlled

substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated is correct and then sign this document in the same manner as he or she would sign a check or legal document (for example, J.H. Smith, or John H. Smith). This document shall be maintained at that pharmacy for a period of five years from the dispensing date. This printout of the day's controlled substance prescription order refill data must be provided to each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed. It must be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. Such a book or file must be maintained at the pharmacy employing such a system for a period of five years after the date of dispensing the appropriately authorized refill.

- 4) Any such computerized system shall have the capability of producing a printout of any refill data which the user pharmacy is responsible for maintaining under the Act, and its implementing regulations. For example, this would include a refill-by-refill audit trail for any specific strength and dosage form of any controlled substance (by either brand or generic name or both). Such a printout must indicate name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name and identification code of the dispensing pharmacist, and the number of the original prescription order. In any computerized system employed by a user pharmacy, the central recordkeeping location must be capable of sending the printout to the pharmacy within 48 hours and if a representative of the Drug Control Unit request a copy of such printout from the user pharmacy, it must, if requested to do so by the representative of the Drug Control Unit verify the printout transmittal capability of its system by documentation (for example, postmark).
  - 5) In the event that a pharmacy that employs such a computerized system experiences system down-time, the pharmacy must have an auxiliary procedure that will be used for documentation of refills of Schedules III, IV, and V controlled substance prescription orders. This auxiliary procedure must insure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line data entry as soon as the computer system is available for use again.
- g) When filing refill information for original prescription orders for Schedule III, IV, or V controlled substances, a pharmacy may use only one of the two systems described in this section.

**13:45H-7.15 PARTIAL FILLING OF PRESCRIPTIONS; SCHEDULES III, IV, AND V**

- a) The partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible, provided that:
- 1) Each partial filling is recorded in the same manner as a refilling;
  - 2) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed; and
  - 3) No dispensing occurs after six months after the date on which the prescription was issued.

**13:45H-7.16 LABELING OF SUBSTANCES; SCHEDULES III, IV, AND V**

- a) The pharmacist filling a prescription for a controlled substance listed in Schedule III, IV, or V shall affix to the package a label conforming to the provisions set forth in N.J.S.A. 24:21-17.
- b) The requirements of (a) above do not apply when a controlled substance listed in Schedule III, IV, or V is prescribed for administration to an ultimate user who is institutionalized: provided, that:
- 1) Not more than a 34-day supply or 100 dosage units, whichever is less, of the controlled substance listed in Schedule III, IV, or V is dispensed at one time;
  - 2) The controlled substance listed in Schedule III, IV, or V is not in the possession of the ultimate user prior to administration;
  - 3) The institution maintains appropriate safeguards and records the proper administration, control, dispensing and storage of the controlled substance listed in Schedule III, IV, or V; and
  - 4) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product, and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

**13:45H-7.17 FILING PRESCRIPTIONS; SCHEDULES III, IV, AND V**

All prescriptions for controlled substances listed in Schedules III, IV, and V shall be kept in accordance with N.J.A.C. 13:45H-5.4.

**13:45H-7.18 TRANSFER BETWEEN PHARMACIES OF PRESCRIPTION INFORMATION FOR SCHEDULES III, IV, AND V CONTROLLED SUBSTANCES FOR REFILL PURPOSES**

- a) The transfer of original prescription information for a controlled dangerous substance listed in Schedule III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis. However, pharmacies electronically sharing a real time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.
- b) Transfers are subject to the following requirements:
- 1) The transfer is communicated directly between two licensed pharmacists and the transferring pharmacist records the following information:
    - i. Write the word "VOID" on the face of the invalidated prescription; for electronic prescriptions, information that the prescription has been transferred must be added to the prescription record;
    - ii. Record on the reverse of the invalidated prescription the name, address, and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information; for electronic prescriptions, such information must be added to the prescription record; and
    - iii. Record the date of the transfer and the name of the pharmacist transferring the information.
  - 2) For paper prescriptions and prescriptions received orally and reduced to writing by the pharmacist pursuant to N.J.A.C. 13:45H-7.8 or 7.13, the pharmacist receiving the transferred prescription information shall reduce to writing the following:
    - i. Write the word "TRANSFER" on the face of the prescription; and
    - ii. Provide all information required to be on a prescription pursuant to N.J.A.C. 13:45H-7.5(a), except for the signature of the prescribing individual practitioner, and include:
      - (1) Date of issuance of original prescription;
      - (2) Original number of refills authorized on original prescription;

- (3) Date of original dispensing;
  - (4) Number of valid refills remaining and date(s) and locations of previous refill(s);
  - (5) Pharmacy's name, address, DEA registration number, and prescription number from which the prescription information was transferred; and
  - (6) Name of transferor pharmacist; and
- 3) For electronic prescriptions being transferred electronically:
- i. The transferring pharmacist must provide the receiving pharmacist with the following information in addition to the original electronic prescription data:
    - (1) The date of the original dispensing;
    - (2) The number of refills remaining and the date(s) and locations of previous refills;
    - (3) The transferring pharmacy's name, address, DEA registration number, and the prescription number for each dispensing;
    - (4) The name of the pharmacist transferring the prescription; and
    - (5) The name, address, DEA registration number, and prescription number from the pharmacy that originally filled the prescription, if different; and
  - ii. The pharmacist receiving the transferred electronic prescription shall create an electronic record for the prescription that includes the receiving pharmacist's name and all of the information transferred with the prescription under (b)3i above.
- c) Both the original and transferred prescription must be maintained for a period of five years from the date of the last refill.
- d) Pharmacies electronically accessing the same prescription record shall satisfy all information requirements of a manual mode for prescription transferal.

### **13:45H-7.19 DISPENSING WITHOUT PRESCRIPTION**

- a) A controlled substance listed in schedule V, and a controlled substance listed in schedule II, III, or IV which is not a prescription drug as determined under the Federal Food, Drug, and



Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

- 1) Such dispensing is made only by a pharmacist (as defined in N.J.A.C. 13:45H-7.1), and not by a non-pharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery, may be completed by a non-pharmacist);
  - 2) Not more than 240 cc. (eight ounces) of any such controlled substance containing opium, nor more than 120 cc. (four ounces) of any other such controlled substance nor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any given 48-hour period;
  - 3) The purchaser is at least 18 years of age;
  - 4) The pharmacist requires every purchaser of a controlled substance under this Section not known to him to furnish suitable identification (including proof of age where appropriate);
  - 5) A bound record book for dispensing of controlled substances under this Section is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the recordkeeping requirement of N.J.A.C. 13:45H-5.4); and
- b) A prescription is not required for distribution or dispensing of the substance pursuant to another Federal, State or local law.

### **13:45H-7.20 ELECTRONIC PRESCRIPTIONS**

An individual practitioner may issue, and a pharmacist may accept for dispensing, an electronic prescription for a controlled substance, consistent with the requirements of this chapter and Federal law. For purposes of this section, "electronic prescription" means a prescription that is transmitted by a computer device in a secure manner, including computer to computer and computer to facsimile transmissions.

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## **SUBCHAPTER 8. MISCELLANEOUS PROVISIONS**

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### **13:45H-8.1 DEFINITIONS**

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

“Act” means the Controlled Substances Act (84 Stat. 1242; 21 U.S.C. 801) and/or the Controlled Substances Import and Export Act (84 Stat. 1285; 21 U.S.C. 951). Any term not defined in this Section shall have the definition set forth in Sections 102 and 1001 of the Act (21 U.S.C. 802 and 951) and in 301.02.

### **13:45H-8.2 APPLICATION OF STATE LAW AND OTHER FEDERAL LAW**

Nothing in Parts 301 through 308, 311, 312, 316 of Federal Regulations shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he desires to do such act nor shall compliance with such Parts be construed as compliance with other Federal or State laws unless expressly provided in such other laws.

### **13-45H-8.3 EXCEPTIONS TO REGULATIONS**

- a) Any person may apply for an exception to the application of any provision of Parts 301 through 308, 311, 312 of Federal Regulations by filing a written request stating the reasons for such exception.
- b) Requests shall be filed with the Administrator, Drug Enforcement Administration, U.S. Department of Justice, Washington, D.C. 20537.
- c) The Administrator may grant an exception in his discretion, but in no case shall he be required to grant an exception to any person which is not otherwise required by law or the regulations cited in this section.

**13:45H-8.4 DISTRIBUTION BY DISPENSER TO ANOTHER PRACTITIONER OR REVERSE DISTRIBUTOR**

A practitioner who is registered to dispense controlled substances may distribute (without being registered to distribute) a quantity of such substance in accordance with 21 CFR 1307.11, which is incorporated herein by reference.

**13:45H-8.5 MANUFACTURE AND DISTRIBUTION OF NARCOTIC SOLUTIONS AND COMPOUNDS BY A PHARMACIST**

As an incident to a distribution under N.J.A.C. 13:45H-8.4 a pharmacist may manufacture (without being registered to manufacture) an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in a proportion not exceeding 20 percent of the completed solution, compound or mixture.

**13:45H-8.6 DISTRIBUTION TO SUPPLIER**

- a) Any person lawfully in possession of a controlled substance listed in any Schedule may distribute (without being registered to distribute) that substance to the person from whom he or she obtained it or to the manufacturer of the substance, or, if designated, to the manufacturer's registered agent for accepting returns, provided that a written record is maintained, which indicates the date of transaction, the name, form and quantity of the substance, the name, address, and registration number, if known, of the supplier or manufacturer.
- b) In the case of returning a controlled substance listed in Schedule I or II, an order form shall be used in the manner prescribed in Part 305 of the Act and N.J.A.C. 13:45H-6 and be maintained as the written record of the transaction. An electronic order may also be used to return a Schedule I or II controlled substance in accordance with this chapter and 21 CFR 1305.05. Any person not required to register pursuant to 21 U.S.C. §§822(c), 957(b)1 or N.J.A.C. 13:4511-1.3 shall be exempt from maintaining the records required by this section.

**13:45H-8.7 DISTRIBUTION UPON DISCONTINUANCE OR TRANSFER OF BUSINESS**

- a) Any registrant desiring to discontinue or transfer business activities altogether or with respect to controlled dangerous substances shall comply with the provisions of 21 CFR 1301.52, which is incorporated herein by reference.
- b) A registrant shall notify the Drug Control Unit in writing no less than 14 days prior to the discontinuance or transfer of business activities with respect to controlled substances as set forth in (a) above, unless the Drug Control Unit waives this time limitation in individual instances, and shall return for cancellation to the Drug Control Unit, within 10 days of the

discontinuance or transfer of business activities, the State Certification of Registration. Such notification shall include but not be limited to:

- 1) Name, address, State CDS and Federal DEA registration numbers of the registrant discontinuing or transferring his controlled substances activities;
- 2) Name, address, State CDS and Federal DEA registration numbers of the registrant, or proof of application for same, of registrant to whom the controlled substances are to be transferred;
- 3) Name, address, State CDS and Federal DEA registration numbers, or proof of application for same of the registrant receiving the records, which include prescription files, or patient orders of practitioners of the discontinued business;
- 4) Name, and address of the person or firm who will maintain records, such as invoices, purchase records and executed order forms of the discontinued or transferred business for a period of not less than two years; and
- 5) The date on which the discontinuance or transfer of the business activity will take place.

### **13:45H-8.8 DISTRIBUTION TO OCEAN VESSELS OR AIRCRAFT**

If acquired by and dispensed under the general supervision of a medical officer described in 21 CFR 1301.25(b), or the master or first officer of the vessel under the circumstances described in 21 CFR 1301.25(d), controlled substances may be held for stocking, be maintained in, and dispensed from medicine chests, first aid packets, or dispensaries on board any vessel engaged in international trade or in trade between ports of the United States and any merchant vessel belonging to the U.S. Government, or on board any aircraft operated by an air carrier under a certificate of permit issued pursuant to the Federal Aviation Act of 1958 (49 U.S.C. § 1301) as set forth in 21 CFR 1301.25, which is incorporated herein by reference.

### **13:45H-8.9 INCIDENTAL MANUFACTURE OF CONTROLLED SUBSTANCES**

Any registered manufacturer who, incidentally but necessarily, manufactures a controlled substance as a result of the manufacture of a controlled substance or basic class of controlled substance for which he or she is registered and has been issued an individual manufacturing quota pursuant to 21 CFR Part 1303 (if such substance or class is listed in Schedule I or II) shall be exempt from the requirement of registration pursuant to 21 CFR Part 1301 and, if such incidentally manufactured substance is listed in Schedule I or II, shall be exempt from the

requirement of an individual manufacturing quota pursuant to 21 CFR Part 1303, if such substances are disposed of in accordance with 21 CFR Part 1317.

### **13:45H-8.10 PROCEDURE FOR DISPOSING OF CONTROLLED SUBSTANCES**

Any person in possession of any controlled substance and desiring or required to dispose of such substance shall comply with 21 CFR Part 1317, which is incorporated herein by reference.

### **13:45H-8.11 REGISTRANT RETURN OR RECALL**

Each registrant shall comply with the return or recall provisions set forth in 21 CFR 1317.10, which is incorporated herein by reference.

### **13:45H-8.12 REVERSE DISTRIBUTOR AUTHORIZED ACTIVITIES**

Every reverse distributor shall acquire controlled substances from a registrant as set forth in 21 CFR 1317.15, which is incorporated herein by reference.

### **13:45H-8.13 NOTIFICATION FROM REGISTRANTS AUTHORIZED TO COLLECT CONTROLLED SUBSTANCES**

- a) Every registrant shall notify the Drug Control Unit within five days of the Drug Enforcement Administration authorizing the registrant to be an authorized collector of controlled substances as set forth in 21 CFR Part 1317 Subpart C.
- b) Every registrant shall notify the Drug Control Unit whenever there is any change to its status as an authorized collector within five days of such change.

### **13:45H-8.14 NATIVE AMERICAN CHURCH**

The listing of peyote as a controlled substance in schedule I does not apply to the nondrug use of peyote in bona fide religious ceremonies of the Native American Church, and members of the American Native Church so using peyote are exempt from registration. Any person who manufactures peyote for or distributes peyote to the Native American Church, however, is required to obtain registration annually and to comply with all other requirements of law.

### **13:45H-8.15 HUMANE SOCIETIES AND ANIMAL CARE FACILITIES**

- a) Authorized agents of incorporated humane societies or licensed animal care facilities registered to purchase, possess, and to dispense sodium pentobarbital for animal euthanasia pursuant to N.J.S.A. 24:21-11.f shall be authorized to dispense:

- 1) Any commercially prepared sodium pentobarbital drug product for animal euthanasia approved for interstate sale by the United States Food and Drug Administration, provided the registrant complies with the approved recommended dosage regime in the labeling;
- 2) A standard compounded formula of sodium pentobarbital for animal euthanasia established by the Division as follows:

- i. Sodium pentobarbital injection (for animal euthanasia), formula non-sterile solution:

U.S.P. Sodium Pentobarbital (Powder)	460 grams
Isopropyl Alcohol	250 mls.
Methyl Violet	1 drop
U.S.P. Water for injection	
quantity sufficient to make	1000 mls.

- ii. Using the formula in (a)2i above, the strength of this mixture will provide 460 mgs of sodium pentobarbital per milliliter.
    - iii. Lethal dose: one milliliter per 10 pounds of body weight for small animals; horses and other large animals —one milliliter per 10 pounds of body weight subject to a maximum dose of 100 milliliters.
    - iv. Package and storage: Package in tight containers with rubber stoppers and store under refrigeration. Solutions decompose on standing. Heat accelerates the decomposition.
    - v. Expiration date: five days from date of manufacture.

b) Labeling: sample labeling is as follows:

- 1.
- 2.
- 3.

4.

5.

7.

6.

8.

9.

- 1) Name and address, city and State of registrant;
  - 2) Name of preparation: "Sodium Pentobarbital Injection";
  - 3) Strength of the preparation: "460 milligrams per one milliliter";
  - 4) "Lethal dose: one milliliter per 10 pounds of body weight for small animals; horses and large animals—one milliliter per 10 pounds of body weight subject to a maximum dose of 100 milliliters";
  - 5) "Batch number.....";
  - 6) "Net contents.....";
  - 7) "Expiration date.....";
  - 8) "Keep under refrigeration.";
  - 9) "Warning: Do not use the injection if it contains a precipitate."
- c) A master formula and production record shall be made and retained on file at the formulating (compounding) site. This record shall contain:
- 1) Name, address, city and State of registrant;
  - 2) Name and strength of the product and a description of the dosage form;
  - 3) The name and weight or measure of each active ingredient including the control number of each such ingredient;
  - 4) A statement of the theoretical yield of finished product;

- 5) A statement describing the equipment and utensils used in the formulating (compounding);
  - 6) A description of the finished drug product containers and closures including a specimen or copy of each label and all other labeling signed and dated by the person or persons responsible for approval of such labeling; and
  - 7) Complete manufacturing and control instructions, procedures, special notations and precautions to be followed.
- d) Batch production records shall be prepared for each batch of drug product produced and shall include complete information relating to the production of each batch. The records shall contain:
- 1) An accurate reproduction of the appropriate master formula production record, checked for accuracy, dated and signed;
  - 2) Documentation that each significant step in the manufacture, processing, packaging or holding of the batch was accomplished, including:
    - i. Dates;
    - ii. Identity of the individual equipment used;
    - iii. Specific identification of each batch of component or materials used;
    - iv. Weights and/or measures of components used in processing;
    - v. Copy of all labeling used;
    - vi. Identification of the person performing each step in the process and identification of the person checking the weights, measures and operations;
    - vii. A statement of the theoretical yield; and
    - viii. A statement of the actual yield.



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**SUBCHAPTER 9.  
(RESERVED)**

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**SUBCHAPTER 10.  
CONTROLLED DANGEROUS SUBSTANCES SCHEDULES**

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**13:45H-10.1 SCHEDULES OF CONTROLLED DANGEROUS SUBSTANCES**

- a) The Federal controlled dangerous substance Schedules I, II, III, IV and V at 21 CFR 1308.11 through 1308.15, as amended and supplemented, promulgated by the United States Attorney General pursuant to 21 U.S.C. §§811 and 812, are incorporated herein by reference.
- b) Any reference in this chapter to controlled dangerous substance Schedules I, II, III, IV and V shall mean the Federal schedules promulgated at 21 CFR 1308.11 through 1308.15 and incorporated by reference pursuant to (a) above, unless the Director objects to the inclusion, rescheduling or deletion of a substance in accordance with the provisions of N.J.S.A. 24:21-3 and N.J.A.C. 13:45H-1.7.
- c) Any substance designated as an immediate precursor by the United States Attorney General pursuant to 21 U.S.C. §811(e), or designated a controlled dangerous substance by temporary order issued by the United States Attorney General in accordance with and subject to the provisions of 21 U.S.C. §811(d) or (h), as amended and supplemented, shall be subject to regulation under this chapter.
- d) Notwithstanding the provisions of (b) above, any substance that is an immediate precursor or that, when ingested, is metabolized or otherwise becomes a controlled dangerous substance, may be designated by the Director as a controlled dangerous substance.
- e) In accordance with (d) above, the following substances shall be designated and controlled as Schedule I controlled dangerous substances:
- 1) Gamma Butyrolactone
  - 2) 1,4 Butanediol
  - 3) 4-methylmethcathinone (Mephedrone, 4-MMC)

- 4) 3,4-methylenedioxypropylamphetamine (MDPV)
- 5) 3,4-Methylenedioxyamphetamine (Mephedrone, MDMC)
- 6) 4-Methoxyamphetamine (Mephedrone, bk-PMMA, PMMC)
- 7) 3-Fluoromethamphetamine (3-FMC)
- 8) 4-Fluoromethamphetamine (Flephedrone, 4-FMC)

**13:45H-10.2 (RESERVED)****13:45H-10.3 (RESERVED)****13:45H-10.4 (RESERVED)****13:45H-10.5 (RESERVED)****13:45H-10.6 EXCLUDED O.T.C. SUBSTANCES**

- a) The list of non-narcotic substances that, may, under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301) may be lawfully sold over the counter without a prescription, are excluded from all schedules of the New Jersey Controlled Dangerous Substance Act.
- b) A complete list of non-narcotic substances is found in 21 CFR 1308.22 (38 F.R. 8255, March 30, 1973, as amended 41 F.R. 16553, April 20, 1976; 41 F.R. 53477, Dec. 7, 1976). Copies of 21 CFR, Part 1300 to end, revised as of April 1, 1977, may be purchased from the U.S. Government Printing Office at <http://www.gpo.gov/fdsys/>.
- c) A complete listing of those non-narcotic substances subject to this subchapter may be reviewed in the office of the Drug Control Unit.

**13:45H-10.7 EXCEPTED PRESCRIPTION DRUGS**

- a) The list of drugs in dosage unit form, and any other drug of the quantitative composition listed for one of the listed drugs or which is the same except that it contains a lesser quantity of controlled substances, and which is restricted to dispensing by prescription, are excepted from the provisions of the New Jersey Controlled Dangerous Substances Act.
- b) A complete list of excepted prescription drugs are found in 21 CFR 1308.32. Copies of 21 CFR Part 1300, revised as of April 1, 1977, may be purchased from the U.S. Government Printing Office at <http://www.gpo.gov/fdsys/>.

- c) A complete listing of those excepted prescription drugs subject to this subchapter may be reviewed in the office of the Drug Control Unit.

### **13:45H-10.8 EXEMPT CHEMICAL PREPARATIONS**

A list of exempt preparations and mixtures as shown in 21 C.F.R. 1308.24, as amended by a final order published in the Federal Register on February 18, 1992 (see 57 F.R. 5818) which in the form and quantity listed in the application (indicated as the "date of application") are designated exempt chemical preparations and are not subject to the provisions of the New Jersey Controlled Dangerous Substances Act.

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## **SUBCHAPTER 11. NARCOTIC TREATMENT PROGRAM**

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### **13:45H-11.1 DEFINITIONS**

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Compounder" means any person engaging in maintenance or detoxification treatment who also mixes, prepares, packages or changes the dosage form of a narcotic drug listed in Schedules II, III, IV or V for use in maintenance or detoxification treatment by another narcotic treatment program.

"Detoxification treatment" means the administration or dispensing for a period not in excess of 21 days, of a narcotic drug or narcotic drugs in decreasing doses to an individual in order to alleviate adverse physiological or psychological effects incident to withdrawal from the continuous or sustained use of a narcotic drug and as a method of bringing the individual to a narcotic drug-free state within such period of time.

"Maintenance treatment" means the dispensing for a period in excess of 21 days, of a narcotic drug or narcotic drugs in the treatment of an individual for dependence upon heroin or other morphine-like drug.

"Narcotic treatment program" means a program engaged in maintenance or detoxification treatment with narcotic drugs.

**13:45H-11.2 REGISTRATION; FEES**

- a) Every person who engages in a narcotic treatment program, including a compounder, shall obtain a registration, and shall obtain a renewal of the registration each year thereafter.
- b) In conducting a narcotic treatment program using any narcotic drug listed in Schedules II, III, IV and V, employees, agents, or affiliated practitioners in programs, need not register separately.
- c) Each program site located away from the principal location and at which place narcotic drugs are stored or dispensed must be separately registered and obtain narcotic drugs by use of order forms pursuant to N.J.A.C. 13:45H-5.6.
- d) For each registration or reregistration to engage in a narcotic treatment program, including a compounder, the applicant shall pay an annual fee of \$20.00 at the time of application for registration or for renewal of registration.
- e) The payment of fees as required by (d) above shall be subject to the exemptions provided in N.J.A.C. 13:45H-1.1.

**13:45H-11.3 APPLICATION FORMS**

Application to conduct a narcotic treatment program, including a compounder, shall be made in accordance with the provisions of N.J.A.C. 13:45H-1.4.

**13:45H-11.4 SECURITY REQUIREMENTS**

- a) Applicants to conduct a narcotic treatment program shall comply with the general security requirements as provided in N.J.A.C. 13:45H-2.1.
- b) In addition to the security requirements required in (a) above, all manufacturing activities (including processing, packaging and labeling) involving controlled substances listed in any schedule and all activities of compounders shall be conducted in accordance with the following:
  - 1) The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by a licensed practitioner employed at the facility or other authorized individuals designated in writing. At the time of delivery, the licensed practitioner or other authorized individual in writing (excluding persons currently or previously dependent on narcotic drugs), shall sign for the narcotics and place his specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.

- 2) Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either the licensed practitioner or a registered nurse under direction of the licensed practitioner, a licensed practical nurse under the direction of the licensed practitioner, or a pharmacist under the direction of the licensed practitioner.
- 3) Persons enrolled in a narcotic treatment program will be required to wait in an area physically separated from the narcotic storage and dispensing area.
- 4) All narcotic treatment programs must comply with the provisions of N.J.S.A. 26:2G-21 through 30; and with standards established by the Secretary of the Federal Department of Health and Human Services (after consultation with the Drug Enforcement Administration) respecting the quantities of narcotic drugs which may be provided to persons enrolled in a narcotic treatment program for unsupervised use.
- 5) The Division may exercise discretion regarding the degree of security required in narcotic treatment programs based on such factors as the location of a program, the number of physicians, staff members and security guards. Similarly, such factors will be taken into consideration when evaluating existing security at a narcotic treatment program.

### **13:45H-11.5 PERSONS REQUIRED TO KEEP RECORDS**

- a) Applicants to conduct a narcotic treatment program shall comply with the provisions of N.J.S.A. 24:21-1 et seq. and the regulatory provisions of N.J.A.C. 13:45H-8.4 to 8.8.
- b) In addition to the record keeping requirements required in (a) above, each person registered or authorized to maintain/or detoxify controlled substance users in a narcotic treatment program shall maintain records with the following information for each controlled substance:
  - 1) Name of substance;
  - 2) Strength of substance;
  - 3) Dosage form;
  - 4) Date dispensed;
  - 5) Adequate identification of patient (consumer);
  - 6) Amount consumed;

- 7) Amount and dosage form taken home by patient;
  - 8) Dispenser's initials.
- c) The records required by (b) above will be maintained in a dispensing log at the narcotic treatment program site and will be maintained in compliance with N.J.A.C. 13:45H-5.4.
  - d) All sites which compound a bulk narcotic solution from bulk narcotic powder to liquid for on-site use must keep a separate batch record of the compounding.
  - e) Records of identity, diagnosis, prognosis, or treatment of any patients which are maintained in connection with the performance of a narcotic treatment program shall be confidential, except that such records may be disclosed for purposes and under the circumstances authorized by Part 310 and Part 1401 of 21 U.S.C.

#### **13:45H-11.6 RECORDS FOR TREATMENT PROGRAM WHICH COMPOUND NARCOTICS FOR TREATMENT PROGRAMS AND OTHER LOCATIONS**

- a) Each person registered or authorized to compound narcotic drugs for off-site use in a narcotic treatment program shall maintain records which include the following information for each narcotic drug:
  - 1) For each narcotic controlled substance in bulk form to be used in, or capable of use in, or being used in, the compounding of the same or other noncontrolled substances in finished form:
    - i. The name of the substance;
    - ii. The quantity compounded in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch compounded;
    - iii. The quantity received from other persons including the date and quantity of each receipt and the name, address and registration number of the other person from whom the substance was received;
    - iv. The quantity imported directly by the registrant (under a registration as an importer) for use in compounding by him, including the date, quantity and import permit or declaration number of each importation;
    - v. The quantity used to compound the same substance in finished form, including:

- (1) The date and batch or other identifying number of each compounding;
  - (2) The quantity used in the compound;
  - (3) The finished form (for example, ten milligram tablets or ten milligram concentration per fluid ounce or milliliter);
  - (4) The number of units of finished form compounded;
  - (5) The quantity used in quality control;
  - (6) The quantity lost during compounding and the causes therefore, if known;
  - (7) The total quantity of the substances contained in the finished form;
  - (8) The theoretical and actual yields; and
  - (9) Such other information as is necessary to account for all controlled substances used in the compounding process.
- vi. The quantity used to manufacture other controlled and non-controlled substances; including the name of each substance manufactured and the information required in subparagraph v of this paragraph;
  - vii. The quantity distributed in bulk form to other programs, including the date and quantity of each distribution and the name, address and registration number of each program to whom a distribution was made;
  - viii. The quantity exported directly by the registrant (under a registration as an exporter) including the date, quantity, and export permit or declaration number of each exportation; and
  - ix. The quantity disposed of by destruction, including the reason, date, and manner of destruction. All other destruction of narcotic controlled substances will comply with N.J.A.C. 13:45H-8.9.
- 2) For each narcotic controlled substance in finished form:
    - i. The name of the substance;

- ii. Each finished form (for example, ten-milligram tablet or ten milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (for example, 100-tablet bottle of three milliliter vial);
- iii. The number of containers of each such commercial form compounded from bulk form by the registrant, including the information required pursuant to sub-paragraph v. of paragraph 1 of this Section;
- iv. The number of units of finished forms and/or commercial containers received from other persons, including the date of and number of units and/or commercial containers in each receipt and the name, address and registration number of person from whom the units were received;
- v. The number of units of finished forms and/or commercial containers imported directly by the person (under a registration or authorization to import), including the date of, the number of units and/or commercial containers in, and the import or declaration number for, each importation;
- vi. The number of units and/or commercial containers compounded by the registrant from units in finished form received from others or imported, including:
  - (1) The date and batch or other identifying number of each compounding;
  - (2) The operation performed (for example, repackaging or relabeling);
  - (3) The number of units of finished form used in the compound, the number compounded and the number lost during compounding, with the causes for such losses, if known; and
  - (4) Such other information as is necessary to account for all substances used in the compounding process;
  - (5) The number of containers distributed to other programs, including the date, the number of containers in each distribution, and the name, address and registration number of the program to whom the containers were distributed;
  - (6) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number of each exportation;



- (7) The number of units finished forms and/or commercial containers destroyed in any manner by the registrant, including the reason, the date and manner of destruction. All other destruction of narcotic controlled substances will comply with N.J.A.C. 13:45H-8.9.

### **13:45H-11.7 TREATMENT OF NARCOTIC ADDICTS WITH OPIOID MEDICATIONS**

The United States Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT) regulations at 42 CFR Part 8, Treatment of opioid dependence with opioid medications, are incorporated herein by reference. All addiction treatment programs in New Jersey providing drugs used for treatment of narcotic addicts shall comply with these regulations and all the supplements and amendments thereto incorporated herein by reference.