

CHAPTER 65

CONTROLLED DANGEROUS SUBSTANCES

Authority

N.J.S.A. 24:21-1 et seq., specifically 24:21-3 and 24:21-9.

Source and Effective Date

R.1996 d.342, effective July 15, 1996.
See: 28 N.J.R. 2371(a), 28 N.J.R. 3563(a).

Chapter Expiration Date

In accordance with N.J.S.A. 52:14B-5.1c, Chapter 65, Controlled Dangerous Substances, expires on January 11, 2002. See: 33 N.J.R. 2754(a).

Chapter Historical Note

Chapter 65, Controlled Dangerous Substances, became effective January 17, 1973 as R.1973 d.24. See: 4 N.J.R. 303(b), 5 N.J.R. 42(c).

1973 Revisions: Amendments to Subchapter 2 became effective December 18, 1973 as R.1973 d.358. See: 5 N.J.R. 373(a), 6 N.J.R. 10(b). Subchapter 8 and Subchapter 10, Controlled Dangerous Substances Schedules, became effective January 17, 1973, as R.1973 d.23. See: 5 N.J.R. 42(b).

1974 Revisions: Amendments to Subchapter 2 became effective April 24, 1974 as R.1974 d.130. See: 6 N.J.R. 107(b), 6 N.J.R. 184(b). Further amendments to Subchapter 2 became effective September 20, 1974 as R.1974 d.261. See: 6 N.J.R. 309(b), 6 N.J.R. 397(c).

1975 Revisions: Subchapter 6 was amended by R.1975 d.56, effective March 12, 1975. See: 7 N.J.R. 55(a), 7 N.J.R. 164(a). Amendments to Subchapter 7 became effective March 12, 1975 as R.1975 d.58. See: 7 N.J.R. 54(a), 7 N.J.R. 164(f). Subchapter 11 became effective March 12, 1975 as R.1975 d.59. See: 7 N.J.R. 50(c), 7 N.J.R. 164(c). Further amendments to Subchapter 7 became effective November 18, 1975 as R.1975 d.349. See: 7 N.J.R. 265(a), 7 N.J.R. 556(a).

1976 Revisions: Subchapter 9, Administrative Functions, Practice and Procedures, was repealed by R.1976 d.376, effective November 24, 1976. See: 8 N.J.R. 512(a), 9 N.J.R. 17(b).

1978 Revisions: Amendments to Subchapter 7 became effective November 1, 1978 as R.1978 d.391. See: 10 N.J.R. 427(c), 10 N.J.R. 536(c).

1979 Revisions: Amendments to Subchapter 2 became effective February 15, 1979 as R.1979 d.73. See: 11 N.J.R. 12(b), 11 N.J.R. 130(e). Subchapter 4, Quotas, was repealed by R.1979 d.74, effective February 15, 1979. See: 11 N.J.R. 12(c), 11 N.J.R. 130(f). Amendments to Subchapter 6 became effective February 15, 1979 as R.1979 d.75. See: 11 N.J.R. 13(a), 11 N.J.R. 131(a). Amendments to Subchapter 7 became effective February 15, 1979 as R.1979 d.76. See: 11 N.J.R. 14(a), 11 N.J.R. 131(b). Further amendments to Subchapter 7 became effective April 18, 1979 as R.1979 d.152. See: 11 N.J.R. 128(a), 11 N.J.R. 237(b).

1980 Revisions: Amendments to Subchapters 1, 2, 5 and 6 became effective February 14, 1980 as R.1980 d.86. See: 12 N.J.R. 13(a), 12 N.J.R. 117(b). An exempt emergency Rule amending Subchapter 11 became effective July 18, 1980 as R.1980 d.328. See: 12 N.J.R. 468(c). Further amendments to Subchapter 5 became effective as an exempt emergency rule August 7, 1980 as R.1980 d.360. See: 12 N.J.R. 517(a).

1981 Revisions: Amendments to Subchapter 8 became effective July 9, 1981, as R.1981 d.238. See: 13 N.J.R. 131(a), 13 N.J.R. 411(b). Amendments to Subchapter 7 became effective November 16, 1981 as R.1981 d.452. See: 13 N.J.R. 130(b), 13 N.J.R. 845(a).

1982 Revisions: Amendments to Subchapter 7 became effective April 19, 1982 as R.1982 d.124. See: 14 N.J.R. 195(a), 14 N.J.R. 389(b).

1983 Revisions: Amendments to Subchapter 7 became effective June 6, 1983 as R.1983 d.193. See: 15 N.J.R. 125(a), 15 N.J.R. 923(d). Pursuant to Executive Order No. 66(1978), Subchapter 7 expired on November 1, 1983.

Pursuant to Executive Order No. 66(1978), Subchapter 6 expired on February 15, 1984. Pursuant to Executive Order No. 66(1978), Subchapter 2, Security Requirements, was readopted as R.1984 d.529, effective October 31, 1984, with amendments effective November 19, 1984. See: 16 N.J.R. 1311(a), 16 N.J.R. 3203(a).

1985 Revisions: A new Subchapter 7, Prescription Requirements for Controlled Dangerous Substances, became effective January 7, 1985 as R.1984 d.607. See: 16 N.J.R. 2327(a), 17 N.J.R. 83(b).

Pursuant to Executive Order No. 66(1978), Subchapters 1, 5 and 8 expired on February 11, 1985. Pursuant to Executive Order No. 66(1978), Subchapter 11 expired on July 17, 1985. A new Subchapter 6, Order Forms, became effective September 3, 1985 as R.1985 d.457. See: 17 N.J.R. 528(a), 17 N.J.R. 2135(a). A new Subchapter 1, General Provisions; Registration, became effective September 3, 1985 as R.1985 d.459. See: 17 N.J.R. 1508(a), 17 N.J.R. 2132(a). A new Subchapter 5, Records and Reports of Registrants, became effective December 2, 1985 as R.1985 d.606. See: 17 N.J.R. 524(a), 17 N.J.R. 2890(a).

1986 Revisions: Subchapter 8, Miscellaneous Provisions, became effective March 17, 1986 as R.1986 d.65. See: 17 N.J.R. 2721(a), 18 N.J.R. 555(c). A new Subchapter 11, Narcotic Treatment Program, became effective August 4, 1986 as R.1986 d.330. See: 18 N.J.R. 924(b), 18 N.J.R. 1592(b).

Pursuant to Executive Order No. 66(1978), Chapter 65, Controlled Dangerous Substances, expired on December 2, 1990. The expired rules were adopted as new, as R.1991 d.292, effective June 17, 1991. See: 22 N.J.R. 3190(a), 23 N.J.R. 1943(a).

Pursuant to Executive Order No. 66(1978), Chapter 65, Controlled Dangerous Substances, expired on June 17, 1996. The expired rules were adopted as new, as R.1996 d.342, effective July 15, 1996. See: Source and Effective Date. See, also, section annotations.

Annual Publication of Controlled Dangerous Substances List: 16 N.J.R. 3063(a), 18 N.J.R. 2463(a), 20 N.J.R. 108(d), 28 N.J.R. 3675(a).

Additions or deletions of drugs to the schedules in Subchapter 10 are exempt from the public notice and comment requirements of the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and are made by Public Notice of the Commissioner's Order in the New Jersey Register.

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SUBCHAPTER 1. GENERAL PROVISIONS; REGISTRATION

8:65-1.1 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 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 commissioner;
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.

8:65-1.2 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 Commissioner of Health, shall obtain a registration within 30 days of the effective date of these regulations, 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, unless specifically exempted by statute or specifically waived by the Commissioner of Health, shall obtain a registration within 30 days of the adoption of these regulations, and shall obtain a renewal of the registration within 30 days of the effective date of these regulations, 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 Commissioner of Health, shall obtain a registration within 30 days of the effective date of these regulations, 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 Commissioner of Health, shall obtain a registration within 30 days of the effective date of these regulations, 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. 8:65-1.4, accompanied by the annual registration fee as set forth in N.J.A.C. 8:65-1.1.

(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 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 Commissioner of Health, shall apply for a registration within 30 days of the effective date of the regulations 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 Program, Division of Narcotic and Drug Abuse Control, New Jersey State Department of Health, CN 362, Trenton, New Jersey 08625. Upon receipt of said application by this Department, 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 Department 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.

Case Notes

Surgeon's license revoked; unauthorized prescriptions for controlled dangerous substances, failure to maintain medical records, and prescribing medications in manner deviating from accepted professional standards. In Matter of Suspension or Revocation of License of Makarenko. 92 N.J.A.R.2d (BDS) 1.

8:65-1.3 Activities requiring registration

(a) Registration under N.J.A.C. 8:65-1.2(a) or (b) shall be issued to authorize the registrant to manufacture or distribute respectively specific controlled dangerous substances included in Schedule I or Schedule II, or to authorize the registrant to manufacture or distribute respectively the controlled dangerous substances included in Schedules III, IV, or V. Any registrant authorized to manufacture or distribute substances included in Schedules III, IV, or V may manufacture or distribute 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. 8:65-1.2(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 or distribute only those controlled dangerous substances authorized in his registration.

(c) Registration under N.J.A.C. 8:65-1.2(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 narcotic 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 Commissioner of Health with a copy or photocopy of his Federal registration or Federal authorization to conduct research with such substances and, where required by Federal regulations, 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 will not be deemed to require an additional registration for a separate location:

1. An office used by a registered manufacturer or 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 N (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.

Amended by R.1988 d.498, effective October 17, 1988.
See: 20 N.J.R. 366(a), 20 N.J.R. 2574(b).
Added (i).

8:65-1.4 Registration application

(a) All applications for registration shall be made on forms provided by the Commissioner of Health and shall be filed with the Division of Narcotic and Drug Abuse Control, Drug Control Program, State Department of Health, CN 362, Trenton, NJ 08625.

(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 Commissioner 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 Commissioner 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 Commissioner.

(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.

8:65-1.5 Action upon application

(a) After an application for registration has been filed, the Commissioner or his authorized agent or representative 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) A person lawfully engaged in the manufacture, distribution or dispensing of any controlled dangerous substance prior to January 17, 1971, who was registered or licensed by the State to engage in such activity, may in the discretion of

the Commissioner, after making proper application for registration, be issued a registration as to such controlled dangerous substances prior to the making of an inspection or investigation by the Commissioner or his authorized agent or representative.

(c) Any application for renewal of a registration issued pursuant to the New Jersey Controlled Dangerous Substances Act and these regulations may in the discretion of the Commissioner be granted and a renewal of registration issued prior to the making of an inspection or investigation by the Commissioner or his authorized agent or representative.

(d) The issuance of a registration pursuant to paragraphs (b) or (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 Commissioner determines that the registrant does not meet the requirements of the applicable statutes or regulations.

(e) The registration certificate issued hereunder shall be displayed conspicuously in the registered location.

8:65-1.6 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 Commissioner 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 Commissioner 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. 8:65-1.1 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.

8:65-1.7 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 Commissioner, within that 30 day period, shall object to inclusion, rescheduling or deletion, which objection shall thereafter be published in the New Jersey Register.

8:65-1.8 Duplicate registration

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

SUBCHAPTER 2. SECURITY REQUIREMENTS

8:65-2.1 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 Department shall use the security requirements set forth in sections 2 through 6 of this subchapter 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 sections 2, 3, and 5 of this subchapter may be used in lieu of the materials and construction described in those sections.

(b) Substantial compliance with the standards set forth in section 2 through 6 of this subchapter may be deemed sufficient by the Department 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 Department may consider any of the following factors as 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 nonusable 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 Sections 2 through 6 of this Subchapter when the need for such controls decreases as a result of a controlled substance being transferred to a different schedule, or as 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 Sections 2 through 6 of this Subchapter may submit any plans, blueprints, sketches or other materials regarding the proposed security system to the New Jersey State Department of Health, Division of Narcotic and Drug Abuse Control, Drug Control Program, CN 362, Health John Fitch Plaza, Trenton, New Jersey 08625.

(e) Physical security controls of locations licensed under the New Jersey Uniform Narcotic Drug Act (N.J.S.A. 24:18-1 et seq.) on January 17, 1971, shall be deemed to comply substantially with the standards set forth in Sections 2, 3 and 5 of this Subchapter. Any new facilities or work or storage area constructed or utilized for controlled substances, which facilities or work or storage areas have not been previously approved by the Department, shall not necessarily be deemed to comply substantially with the standards set forth in Sections 2, 3 and 5 of this Subchapter, notwithstanding that such facilities or work or storage areas have physical security controls similar to those previously approved by the Department.

**8:65-2.2 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 Department 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 $\frac{1}{2}$ 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 Department 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 Department.

(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 subsection (a)1 of this Section;

2. A vault which complies with the requirements set forth in either subsection (a)2 or 3; 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 Department 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 Department, 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 Department will assess the physical arrangements of the present or proposed security system. Based on considerations of public health and safety, the Department may accept a lesser level of security. A final decision of the Department, and the reasons therefore, shall be entered upon the records of the Department and sent to the registrant or authorized agent.

As amended, R.1973 d.358, effective December 18, 1973.

See: 5 N.J.R. 373(a), 6 N.J.R. 10(b).

As amended, R.1984 d.529, effective November 19, 1984.

See: 16 N.J.R. 1311(a), 16 N.J.R. 3203(a).

Substituted "Department" for "Bureau"; added subsection (e).

8:65-2.3 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.

8:65-2.4 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 New Jersey State Department of Health 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 New Jersey State Department of Health, Drug Control Program, 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 New Jersey State Department of Health, Drug Control Program, of any theft or significant 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 N.J.A.C. 8:65-2.4(e) 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 Subchapter 6 of this Act 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 section 2 of this subchapter. 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.

As amended, R.1974 d.261, effective September 20, 1974.
See: 6 N.J.R. 309(b), 6 N.J.R. 397(c).

As amended, R.1979 d.70, effective February 15, 1979.
See: 11 N.J.R. 12(a), 11 N.J.R. 130(b).

As amended, R.1984 d.529, effective November 19, 1984.
See: 16 N.J.R. 1311(a), 16 N.J.R. 3203(a).

Substituted "registrant" for "person".
Amended by R.1992 d.241, effective June 15, 1992.
See: 23 N.J.R. 1911(a), 24 N.J.R. 2256(a).

Carfentanil added to (g).

8:65-2.5 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 noncontrolled substances in such a manner as to obstruct the theft or diversion of the controlled substances.

(c) This section shall also apply to nonpractitioners 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 New Jersey State Department of Health, Drug Control Program, of the theft or significant 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. 8:65-2.1.

(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.

As amended, R.1974 d.130, effective April 24, 1974.

See: 6 N.J.R. 107(b), 6 N.J.R. 184(b).

As amended, R.1979 d.73, effective February 15, 1979.

See: 11 N.J.R. 12(b), 11 N.J.R. 130(e).

As amended, R.1980 d.86, effective February 14, 1980.

See: 12 N.J.R. 13(a), 12 N.J.R. 117(b).

As amended, R.1984 d.529, effective November 19, 1984.

See: 16 N.J.R. 1311(a), 16 N.J.R. 3203(a).

Form changed from "BND form 106" to "DDC-52 form".

Amended by R.1992 d.241, effective June 15, 1992.

See: 23 N.J.R. 1911(a), 24 N.J.R. 2256(a).

Carfentanil added to (e).

Case Notes

Failure to keep Schedule II substances in securely locked cabinet. In re: Marvin Gastman, 147 N.J.Super. 101, 370 A.2d 866 (App.Div.1977).

SUBCHAPTER 3. LABELING AND PACKAGING REQUIREMENTS

8:65-3.1 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.

8:65-3.2 Definitions

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.

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 301.02 of 21 CFR.

8:65-3.3 Symbol required; exceptions

(a) Each commercial container of a controlled substance (except for a controlled substance excepted by the Department 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.

8:65-3.4 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 subsection (a) of this section, 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.

8:65-3.5 Location and size of symbol on labeling

(a) The symbol shall be prominently located on all labeling other than labels covered by section 4 of this subchapter.

(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.

8:65-3.6 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 section 3 of this subchapter.

(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 section 3 of this subchapter.

(c) The Department may, in the case of any controlled substance, require compliance with the requirements of section 3 of this subchapter 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.

8:65-3.7 Sealing of controlled substances

(a) 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.

(b) Any seal accepted for use under Federal law prior to May 1, 1971, shall be deemed acceptable for use under this section.

8:65-3.8 Labeling and packaging requirements for imported and exported substances

(a) The symbol requirements of sections 3 through 6 of this subchapter 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 sections 3 through 6 of this subchapter 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 section 7 of this subchapter 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.

SUBCHAPTER 4. (RESERVED)

SUBCHAPTER 5. RECORDS AND REPORTS OF REGISTRANTS

8:65-5.1 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.

8:65-5.2 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.

8:65-5.3 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. 8:65-8.4 to 8.8, shall maintain the records and inventories and shall file the reports required by this part for persons registered to conduct such activities (e.g., when a registered manufacturer conducts chemical analysis, he shall maintain the records and inventories required of chemical analysis).

(b) A registered individual practitioner is not required to keep records with respect to narcotic controlled substances listed in schedule II through V which he prescribes in the lawful course of his professional practice; he shall keep records, however, with respect to such substances that he 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 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 Bureau and the Department of Health of the name, address, and registration number of the establishment maintaining such records.

(f) Notice required by subsections (d) and (e) of this section 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.

Amended by R.1985 d.606, effective December 2, 1985.

See: 17 N.J.R. 524(a), 17 N.J.R. 2890(a).
Substantially amended.

8:65-5.4 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, for inspecting and copying by authorized employees of the Administration and the Department of Health, except that financial and shipping records (such as invoices and packing slips but not executed order forms subject to N.J.A.C. 8:65-6.13) may be kept at a central location, rather than at the registered location, if the registrant has notified the Administration and the Department of Health of his intentions to keep central records. Written notification must be submitted by registered or certified mail, return receipt requested to the Special Agent in Charge in the region in which the registrant is located and the State Department of Health. Unless the registrant is informed by the Special Agent in Charge or the State Department of Health that permission to keep central records is denied, the registrant may maintain central records commencing 14 days after receipt of his notification by the Special Agent in Charge and the Department of Health. Registrants who desire to continue maintaining central record keeping will make notification to the local Special Agent in Charge and the Department of Health as provided in this section. All notifications shall include the following:

1. The nature of the records to be kept centrally and the exact location where the records will be kept; the name, address, DEA registration number and type of DEA registration of the registrant whose records are being maintained centrally, and whether central records are being maintained in a manual, or computer readable form.

2. If the records are kept on microfilm, computer media or in any form requiring special equipment to render the records easily readable, the registrant shall provide access to such equipment with the records. If any code system is used (other than for pricing information) a key to the code shall be provided to make the records understandable.

3. The registrant agrees to deliver all or any part of such records to the registered location within two business days upon receipt of a request from the Administration or the Department of Health for such records, and if the Administration or the Department of Health chooses to do so in lieu of requiring delivery of such records to the registered location, to allow authorized employees of the Administration or the Department of Health to inspect such records at central location upon request by such employees without a warrant of any kind; and

4. In the event that a registrant fails to comply with these conditions, the Special Agent in Charge or the Department of Health may cancel such central record keeping authorization, and all other central record keeping authorizations held by the registrant without a hearing or other procedures. In the event of a cancellation of central record keeping authorization under this subparagraph the registrant shall within the time specified by the Special Agent in Charge, of the Department of Health, comply with the requirements of this section that all records be kept at the registered location.

5. Registrants need not notify the Special Agent in Charge or the Department of Health or obtain central record keeping in order to maintain records on an in-house computer system.

(b) Each registered manufacturer, 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 subsection (b) of this section.

(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 II

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 subsection (b) of this section.

As amended, R.1980 d.86, effective February 14, 1980.

See: 12 N.J.R. 13(a), 12 N.J.R. 117(b).

As amended, R.1980 d.360, effective August 7, 1980.

See: 12 N.J.R. 517(a).

Amended by R.1985 d.606, effective December 2, 1985.

See: 17 N.J.R. 524(a), 17 N.J.R. 2890(a).

Substantially amended.

Cross References

Oral prescriptions, Schedule V, see N.J.A.C. 8:65-7.18.

Case Notes

Violation by failure to properly file controlled dangerous substance records and failure to mark records with red "C"; penalties. State Board of Pharmacy v. Yanuzzi, 4 N.J.A.R. 489 (1981).

8:65-5.5 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 section 12 of this subchapter.

(d) A registrant may take an inventory on a date that is within four days of his biennial inventory date pursuant to section 7 of this subchapter if he notifies in advance the Special Agent in Charge of the Bureau in his region and the Department of Health of the date on which he will take the inventory. 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, type-written or printed form. An inventory taken by use of an oral recording device must be promptly transcribed.

Amended by R.1985 d.606, effective December 2, 1985.

See: 17 N.J.R. 524(a), 17 N.J.R. 2890(a).

Added text in (d) "and the Department of Health."

Case Notes

Separate inventory required for each registered location; inventory dates set by date upon which person, not location, is first registered. In re: Marvin Gastman, 147 N.J.Super. 101 (App.Div.1977).

8:65-5.6 Initial inventory date

(a) Every person required to keep records who is provisionally registered on May 1, 1971, shall take an inventory of all stocks of controlled substances on hand on that date in accordance with sections 9 through 13 of this subchapter as applicable.

(b) Every person required to keep records who is registered after May 1, 1971, and who was not provisionally registered on that date, shall take an inventory of all stocks of controlled substances on hand on the date he first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with sections 9 through 13 of this subchapter, as applicable.

Case Notes

Separate inventory required for each registered location; inventory dates set by date upon which person, not location, is first registered. In re: Marvin Gastman, 147 N.J.Super. 101 (App.Div.1977).

8:65-5.7 Biennial inventory date

Every two years following the date on which the initial inventory is taken by a registrant pursuant to section 6 of this subchapter, 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 Bureau and the Department of Health of this election and of the date on which the biennial inventory will be taken.

Amended by R.1985 d.606, effective December 2, 1985.

See: 17 N.J.R. 524(a), 17 N.J.R. 2890(a).

Added "Department of Health."

Case Notes

Separate inventory required for each registered location; inventory dates set by date upon which person, not location, is first registered. In re: Marvin Gastman, 147 N.J.Super. 101 (App.Div.1977).

8:65-5.8 Inventory date for newly-controlled substances

On the effective date of a rule by the Administrator pursuant to 308.48, 308.49 or 308.50 of the Act or the Department of Health 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 section 7 of this subchapter.

Amended by R.1985 d.606, effective December 2, 1985.

See: 17 N.J.R. 524(a), 17 N.J.R. 2890(a).

Substituted "Administrator" for "Director" and added "Department of Health".

8:65-5.9 Inventories of manufacturers

(a) Each person registered or authorized (by 301.22(b) of the Act) or N.J.A.C. 8:65-1.3(a) to manufacture controlled substances shall include the following information to his inventory:

1. For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or noncontrolled substances in the finished form:

- i. The name of the substance; and

- ii. The total quantity of the substance to the nearest metric unit weight consistent with unit size (except that for inventories made in 1971, avoirdupois weights may be utilized where metric weights are not readily available).

2. For each controlled substance in the process of manufacture on the inventory date:

- i. The name of the substance;

- ii. The quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number;

- iii. The physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g., ten-milligram tablet or ten-milligram concentration per fluid ounce or milliliter) and the number or volume thereof; and

3. For each controlled substance in finished form:

- i. The name of the substance;

- ii. Each finished form of the substance (e.g., ten-milligram tablet or ten-milligram concentration per fluid ounce or milliliter);
 - iii. The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or three-milliliter vial); and
 - iv. The number of commercial containers of each such finished form (e.g., four 100-tablet bottles or six three-milliliter vials).
4. For each controlled substance not included in paragraphs (1), (2) or (3) of this subsection (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compounds):

- i. The name of the substance;
- ii. The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and
- iii. The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

Amended by R.1985 d.606, effective December 2, 1985.
See: 17 N.J.R. 524(a), 17 N.J.R. 2890(a).

Changed authorization from 8:65-8.5 or 8.8 to 1.3(a).

8:65-5.10 Inventories of distributors

Each person registered or authorized (by 301.22(b) of the Act) or N.J.A.C. 8:65-1.3(a) to distribute controlled substances shall include in his inventory the same information of manufacturers pursuant to N.J.A.C. 8:65-5.9(a)3 and 4.

Amended by R.1985 d.606, effective December 2, 1985.
See: 17 N.J.R. 524(a), 17 N.J.R. 2890(a).

Changed authorization from 8:65-8.4-8.7 to 1.3(a).

8:65-5.11 Inventories of dispensers and researchers

(a) Each person registered or authorized (by 301.22(b) of the Act) or N.J.A.C. 8:65-1.3(d) to dispense or conduct research with controlled substances and required to keep records pursuant to N.J.A.C. 8:65-5.3, shall include in his inventory the same information required of manufacturers pursuant to N.J.A.C. 8:65-5.9(a)3 and 4. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser shall do as follows:

1. If the substance is listed in schedule I or II, he shall make a count or measure of the contents; and
2. If the substance is listed in schedule III, IV, or V, he shall make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he must make an exact count of the contents.

(b) 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, December) on forms provided by this Department in the manner prescribed in subsection (a) of this section. A copy of such inventory shall be received in the Department within seven days after such required report is completed.

As amended, R.1980 d.86, effective February 14, 1980.
See: 12 N.J.R. 13(a), 12 N.J.R. 117(b).
Amended by R.1985 d.606, effective December 2, 1985.
See: 17 N.J.R. 524(a), 17 N.J.R. 2890(a).
Added "or N.J.A.C. 8:65-1.3(d)."

8:65-5.12 Inventories of importers and exporters

(a) Each person registered or authorized (by 301-22(b) of this Chapter) to import or export controlled substances shall include in his inventory the same information required of manufacturers pursuant to N.J.A.C. 8:65-5.9(a)1, 3 and 4.

(b) Each such person who is also registered as a manufacturer or as a distributor shall include in his inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).

8:65-5.13 Inventories for chemical analysts

(a) Each person registered or authorized (by 301.22(b) of the Act) and N.J.A.C. 8:65-1.3 to conduct chemical analysis with controlled substances shall include in his inventory the same information required of manufacturers pursuant to N.J.A.C. 8:65-5.9(a)1, 3 and 4, as to substances which have been manufactured, imported or received by such person.

(b) If less than one kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in schedule I), or less than 20 grams of a hallucinogenic substance listed in schedule I (other than lysergic acid diethylamide), or less than 0.5 gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory.

(c) Laboratories of the Bureau may possess up to 150 grams of any hallucinogenic substance in schedule I without regard to a need for an inventory of those substances.

(d) No inventory is required of known or suspected controlled substances received as evidentiary materials for analysis.

Amended by R.1985 d.606, effective December 2, 1985.
See: 17 N.J.R. 524(a), 17 N.J.R. 2890(a).
Added "and N.J.A.C. 8:65-1.3."

8:65-5.14 General requirements for continuing records

(a) On and after May 1, 1971, every registrant required to keep records pursuant to Section 3 of this Subchapter 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, 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 Section 4(a) of this Subchapter. 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 Sections 18 and 19 of this Subchapter.

(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).

8:65-5.15 Records of manufacturers

(a) Each person registered or authorized (by 301.22(b) or 307.15 of the Act) and N.J.A.C. 8:65-1.3(a) to manufacture controlled substances shall maintain records with the following information:

1. For each controlled substance in bulk form to be used in, or capable of use in, or being used in, the manufacture of the same or other controlled or noncontrolled substances in finished form,

i. The name of the substance;

ii. The quantity manufactured in bulk form by the registrant, including the date, quantity and batch or other identifying number of each batch manufactured;

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 manufacture by him, including the date, quantity, and import permit or declaration number for each importation;

v. The quantity used to manufacture the same substance in finished form, including:

(1) The date and batch or other identifying number of manufacture;

(2) The quantity used in the manufacture;

(3) The finished form (such as, ten-milligram tablets or ten-milligram concentration per fluid ounce or milliliter);

(4) The number of units of finished form manufactured;

(5) The quantity used in quality control;

(6) The quantity lost during manufacturing and the cause therefor, if known;

(7) The total quantity of the substance 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 manufacturing 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 Section;

vii. The quantity distributed in bulk form to other persons, including the date and quantity of each distribution and the name, address, and registration number of each person 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;

ix. The quantity distributed in any other manner by the registrant (such as, by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity distributed or disposed of.

2. For each controlled substance in finished form,

i. The name of the substance;

ii. Each finished form (such as, 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 (such as, 100-tablet bottle or three-milliliter vial);

iii. The number of containers of each such commercial finished form manufactured from bulk form by the registrant, including the information required pursuant to paragraph 1v of subsection (a) 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 the 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 permit or declaration number for, each importation;

vi. The number of units and/or commercial containers manufactured 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 manufacture;

(2) The operation performed (such as, repackaging or relabeling);

(3) The number of units of finished form used in the manufacture, the number manufactured and the number lost during manufacture, with the causes for such losses, if known; and

(4) Such other information as is necessary to account for all controlled substances used in the manufacturing process;

vii. The number of commercial containers distributed to other persons, including the date of an number of containers in each distribution, and the name, address, and registration number of the person to whom the containers were distributed;

viii. 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 for each exportation; and

ix. The number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (such as, by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity in finished form distributed or disposed of.

Amended by R.1985 d.606, effective December 2, 1985.
See: 17 N.J.R. 524(a), 17 N.J.R. 2890(a).
Added "8:65-1.3(a)".

8:65-5.16 Records for distributors

(a) Each person registered or authorized (by 301.22(b) or 307.11-307.14 of the Act) and N.J.A.C. 8:65-1.3(a) to distribute controlled substances shall maintain records with the following information for each controlled substance:

1. The name of the substance;
2. Each finished form (such as, 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 (such as, 100-tablet bottle or three-milliliter vial);

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

4. The number of commercial containers or each such finished form imported directly by the person (under a registration or authorization to import), including the date of, the number of commercial containers in, and the import permit or declaration number for, each importation;

5. The number of commercial containers of each such finished form distributed to other persons, including the date of and number of containers in each distribution and the name, address, and registration number of the person to whom the containers were distributed;

6. The number of commercial containers of each such finished form exported directly by the person (under a registration or authorization to export), including the date of, the number of commercial containers in, and the export permit or declaration number for, each exportation; and

7. The number of units or volume of finished forms and/or commercial containers distributed or disposed of in any other manner by the person (e.g., by distribution as complimentary samples or by destruction) including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity of the substance in finished form distributed or disposed.

Amended by R.1985 d.606, effective December 2, 1985.
See: 17 N.J.R. 524(a), 17 N.J.R. 2890(a).
Added "and N.J.A.C. 8:65-1.3(a)".

8:65-5.17 Records for dispensers and researchers

(a) Each person registered or authorized (by 301.22(b) of the Act) and N.J.A.C. 8:65-1.3(e) to dispense or conduct research with controlled substances and required to keep records pursuant to Section 3 of this subchapter shall maintain records with the following information for each controlled substance:

1. The name of the substance;
2. Each finished form (e.g., 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 (e.g., 100-tablet bottle or three-milliliter vial);
3. The number of commercial containers of each such finished form received from other persons, including the date and number of containers in each receipt and the

name, address, and registration number of the person from whom the containers were received;

4. The number of units or volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser; and

5. The number of units or volume of such finished forms and/or commercial containers disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity of the substance in finished form disposed.

(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 Department.

As amended, R.1980 d.86, effective February 14, 1980.
See: 12 N.J.R. 13(a), 12 N.J.R. 117(b).
Amended by R.1985 d.606, effective December 2, 1985.
See: 17 N.J.R. 524(a), 17 N.J.R. 2890(a).
Added "and N.J.A.C. 8:65-1.3(c)".

8:65-5.18 Records for importers

(a) Each person registered or authorized (by 301.22(b) of the Act) to import controlled substances shall maintain records with the following information for each controlled substance:

1. The name of the substance;
2. The quantity (or number of units or volume in finished form) imported, including the date, quantity (or number of units or volume), and import permit or declaration number for each importation;
3. The quantity (or number of units or volume in finished form) distributed to other persons, including the date, quantity (or number of units or volume) of each distribution and the name, address, and registration number of each person to whom a distribution was made; and
4. The quantity disposed of in any other manner by the registrant (except quantities used in manufacturing by an importer under a registration as a manufacturer, which quantities are to be recorded pursuant to N.J.A.C. 8:65-5.15(a)4 or (b)5, including the date and manner of disposal and the quantity disposed.

8:65-5.19 Records for exporters

(a) Each person registered or authorized (by 301.22(b) of the Act) to export controlled substances shall maintain records with the following information for each controlled substance:

1. The name of the substance;
2. The quantity (or number of units or volume in finished form) received from other persons, including the date and quantity (or number of units or volume) of each receipt and the name, address, and registration number of each person from whom the substance was received;

3. The quantity (or number of units or volume), and the export permit or declaration number for each exportation, but excluding all quantities (and numbers of units and volumes) manufactured by an exporter under a registration as a manufacturer, which quantities (and numbers of units and volumes) are to be recorded pursuant to N.J.A.C. 8:65-5.15(a)1viii or 2viii; and

4. The quantity disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity disposed.

8:65-5.20 Records for chemical analysts

(a) Each person registered or authorized (by 301.22(b) of the Act) to conduct chemical analysis with controlled substances shall maintain records with the following information (to the extent known and reasonably ascertainable by him) for each controlled substance:

1. The name of the substance;
2. The form or forms in which the substance is received, imported, or manufactured by the registrant (e.g., powder, granulation, tablet, capsule, or solution) and the concentration of the substance in such form (e.g., C.P., U.S.P., N.F., ten-milligram tablet or ten-milligram concentration per milliliter);

3. The total number of the forms received, imported or manufactured (e.g., 100 tablets, thirty one-milliliter vials, or ten grams of powder), including the date and quantity of each receipt, importation, or manufacture and the name, address, and registration number, if any, of the person from whom the substance was received;

4. The quantity distributed, exported, or destroyed in any manner by the registrant (except quantities used in chemical analysis or other laboratory work), including the date and manner of distribution, exportation, or destruction, and the name, address, and registration number, if any, of each person to whom the substance was distributed or exported.

(b) Records of controlled substances used in chemical analysis or other laboratory work are not required.

(c) Records relating to known, or suspected, controlled substances received as evidentiary material for analysis are not required under paragraph (a) of this Section.

8:65-5.21 Reports from manufacturers and importers

(a) Each registered manufacturer and registered importer shall submit a quarterly report (D.E.A. Form 333) accounting for all stocks of narcotic controlled substances listed in schedules I, II and III on hand at the beginning and end of the quarter, and for all receipts (D.E.A. Form 333), dispositions (D.E.A. Form 333), manufacturing (D.E.A. Form 333) and packaging (D.E.A. Form 333), of such substances on the appropriate Federal forms. The returns shall be obtained from and submitted to the Distribution Audit Branch, Department of Justice, Drug Enforcement Administration, Washington, D.C. 20537, on or before the 15th day of the month succeeding the period for which it is submitted.

(e) Each order form shall be signed and dated by a person authorized to sign a requisition for order forms on behalf of the purchaser pursuant to N.J.A.C. 8:65-6.5(c). The name of the purchaser, if different from the individual signing the order form, shall also be inserted in the signature space. Unexecuted order forms may be kept and may be executed at a location other than the registered location printed on the form, provided that all executed forms are delivered promptly to the registered location.

(f) The registered agent of a Humane Society or licensed animal shelter may apply for Federal purchase order forms as described in N.J.A.C. 8:65-6.4 and 8:65-6.5. Execution of the order forms shall be as specified in (a) through (e) **above**.

Amended by R.1988 d.498, effective October 17, 1988.
See: 20 N.J.R. 366(a), 20 N.J.R. 2574(b).

Added (f).

Amended by R.1992 d.241, effective June 15, 1992.
See: 23 N.J.R. 1911(a), 24 N.J.R. 2256(a).

Order forms for carfentanil, etorphine hydrochloride and diprenorphine to list only those substances.

Cross References

Preservation of order forms, see N.J.A.C. 8:65-6.13.

8:65-6.7 Power of attorney

(a) Any purchaser may authorize one or more individuals, whether or not located at the registered location of the purchaser, to obtain and execute order forms on his behalf by filing a power of attorney with records of the registrant.

(b) The power of attorney shall be signed by the same person who signed the most recent application for registration or reregistration and shall contain the signature of the individual being authorized to obtain and execute order forms, which individual shall affirm his signature.

(c) Any power of attorney may be revoked at any time by filing a notice of revocation, signed by the person who signed the power of attorney.

(d) It shall be necessary to submit a new power of attorney upon the registration of a purchaser only if the application for reregistration was signed by a person different from the person who signed the existing power of attorney.

8:65-6.8 Persons entitled to fill order forms

(a) An order form may be filled only by a person registered as a manufacturer or distributor of controlled substances listed in schedules I or II under section 303 of the Act (21 U.S.C. 823) or as an importer of such substances under section 1008 of the Act (21 U.S.C. 958), except for the following:

1. A person registered to dispense such substances under section 303 of the Act, or to export such substances under section 1008 of the Act, if he is discontinuing

business or if his registration is expiring without reregistration may dispose of any controlled substances listed in schedule I or II in his possession pursuant to order forms in accordance with N.J.A.C. 8:65-8.7;

2. A person who has obtained any controlled substance in schedule I or II by order form may return such substance, or portion thereof, to the person from whom he obtained the substance or the manufacturer of the substance pursuant to the order form of the latter person; and

3. A person registered to dispense such substances may distribute such substances to another dispenser pursuant to, and only in the circumstances described in, N.J.A.C. 8:65-8.4;

4. 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 order forms for distribution of narcotic drugs to off-site narcotic treatment programs only.

8:65-6.9 Procedure for filling order forms

(a) The purchaser shall submit copy 1 and copy 2 of the order form to the supplier, and retain copy 3 in his own files.

(b) The supplier shall fill the order, if possible and if he desires to do so, and record on copies 1 and 2 the number of commercial or bulk containers furnished on each item and the date on which such containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the order form. No order form shall be valid more than 60 days after its execution by the purchaser, except as specified in (f) below.

(c) The controlled substances shall only be shipped to the purchaser and at the location printed by the D.E.A. on the order form, except as specified in (f) below.

(d) The supplier shall retain copy 1 of the order form for his own files and forward copy 2 to the Regional Director of the D.E.A. in the region in which the supplier is located. Copy 2 shall be forwarded at the close of the month during which the order is filled; if an order is filled by partial shipments, copy shall be forwarded at the close of the month during which the final shipment is made or during which the 60-day validity period expires.

(e) The purchaser shall record on copy 3 of the order form the number of commercial or bulk containers furnished on each item and the dates on which such containers are received by the purchaser.

(f) Order forms submitted by registered procurement officers of the Defense Personnel Support Center of Defense

Supply Agency for delivery to armed services established within the United States may be shipped to locations other than the location printed on the order form, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

Case Notes

Failure to record substance amounts and dates received contributes violation directly impugning reliability and integrity with respect to controlled dangerous substances; penalty. In re: Marvin Gastman, 147 N.J.Super. 101 (App.Div.1977).

8:65-6.10 Procedure for endorsing order forms

(a) An order form made out to any supplier who cannot fill all or a part of the order within the time limitation set forth in N.J.A.C. 8:65-6.9 may be endorsed to another supplier for filling. The endorsement shall be made only by the supplier to whom the order form was first made, shall state (in the spaces provided on the reverse sides of copies 1 and 2 of the order form) the name and address of the second supplier, and shall be signed by a person authorized to obtain and execute order forms on behalf of the first supplier. The first supplier may not fill any part of an order on an endorsed form. The second supplier shall fill the order, if possible and if he desires to do so, in accordance with N.J.A.C. 8:65-6.9(b), (c) and (d), including shipping all substances directly to the purchaser.

(b) Distribution made on endorsed order forms shall be reported by the second supplier in the same manner as all other distributions except that where the name of the supplier is requested on the reporting form, the second supplier shall record the name, address and registration number of the first supplier.

8:65-6.11 Unaccepted and defective order forms

(a) No order form shall be filled if it:

1. Is not complete, legible, or properly prepared, executed or endorsed; or
2. Shows any alteration, erasure, or change of any description.

(b) If an order form cannot be filled for any reason under this Section, the supplier shall return copies 1 and 2 to the purchaser with a statement as to the reason (e.g., illegible or altered). A supplier may for any reason refuse to accept any order and if a supplier refuses to accept the order, a statement that the order is not accepted shall be sufficient for purposes of this paragraph.

(c) When received by the purchaser, copies 1 and 2 of the order form and the statement shall be attached to copy 3 and retained in the files of the purchaser in accordance with N.J.A.C. 8:65-6.13. A defective order form may not be corrected; it must be replaced by a new order form in order for the order to be filled.

8:65-6.12 Lost and stolen order forms

(a) If a purchaser ascertains that an unfilled order form has been lost, he shall execute another in triplicate and a statement containing the serial number and date of the lost form, and stating that the goods covered by the first order form were not received through loss of that order form. Copy 3 of the second form and a copy of the statement shall be retained with copy 3 of the order form first executed. A copy of the statement shall be attached to copies 1 and 2 of the second order form sent to the supplier. If the first order form is subsequently received by the supplier to whom it was directed, the supplier shall mark upon the face thereof "Not accepted" and return copies 1 and 2 to the purchaser, who shall attach it to copy 3 and the statement.

(b) Whenever any used or unused forms are stolen from or lost (otherwise than in the course of transmission) by any purchaser or supplier, he shall immediately upon discovery of such theft or loss, report the same to the Registration Branch, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, D.C. 20005, and the Drug Control Program, New Jersey Department of Health, CN 362, Trenton, NJ 08625 stating the serial number of each form stolen or lost. If the theft or loss includes any original order forms received from purchasers and the supplier is unable to state the serial numbers of such order forms, he shall report the date or approximate date of receipt thereof and the names and addresses of the purchasers.

(c) If an entire group of order forms is lost or stolen, and the purchaser is unable to state the serial numbers of the order forms contained therein, he shall report, in lieu of the numbers of the forms contained in such group, the date or approximate date of issuance thereof. If any unused order form reported stolen or lost is subsequently recovered or found, the registration branch of the bureau and the Department of Health shall immediately be notified.

8:65-6.13 Preservation of order forms

(a) The purchaser shall retain copy 3 of each order form which has been filled. He shall also retain in his files all copies of each unaccepted or defective order form and each statement attached thereto.

(b) The supplier shall retain copy 1 of each order form which he has filled.

(c) Order forms must be maintained separately from all other records of the registrant. Order forms are required to be kept available for inspection for a period of two years. If a purchaser has several registered locations, he must retain copy 3 of the executed order forms and any attached statements or other related documents (not including unexecuted order forms which may be kept elsewhere pursuant to N.J.A.C. 8:65-6.6(e)) at the registered location printed on the order form.

Cross References

Oral prescriptions, see N.J.A.C. 8:65-7.13.

8:65-7.6 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.

8:65-7.7 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. 8:65-11.1 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 Department of Health as required by N.J.A.C. 8:65-11.2 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.

Case Notes

Administrative regulation relating to administering or dispensing of narcotic drugs does not apply to laboratory managers who administered nitroglycerin to heart patient. 296 N.J.Super. 298, 686 A.2d 1212 (A.D. 1997).

8:65-7.8 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 subsection (d) of this section.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in schedule II in the course of his professional practice without a prescription, subject to N.J.A.C. 8:65-7.6.

(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 in the Code of Federal Regulations, Title 21, part 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. 8:65-7.4, 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 72 hours 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. 8:65-7.4, 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 72-hour 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 Department of Health and the nearest office of the DEA in his district if the prescribing individual practitioner fails to deliver a written prescription to him; 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) 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. 8:65-7.10(d).

Amended by R.1999 d.71, effective March 1, 1999.

See: 30 N.J.R. 1364(a), 31 N.J.R. 678(a).

In (e), substituted "the limits set forth at N.J.A.C. 13:35-7.6" for "120 dosage forms or a 30 days' supply, whichever is the lesser amount" following "excess of".

8:65-7.9 Refilling prescriptions; schedule II

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

8:65-7.10 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 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 Facilities (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 a "LTCF" shall be deemed to have been filled in violation of N.J.S.A. 24:21. 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 a 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 a 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. 8:65-7.14(e)1 through 5 for schedule III and IV prescription refill information.

Amended by R.1992 d.205, effective May 4, 1992.

See: 23 N.J.R. 3618(a), 24 N.J.R. 1795(a).

Partial prescriptions for LTCF or terminally-ill patient permitted.

8:65-7.11 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; and
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.

8:65-7.12 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. 8:65-5.17.

8:65-7.13 Requirements of prescriptions; schedule III and IV

(a) A pharmacist may dispense directly a controlled substance listed in schedule III or IV 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.

(b) A pharmacist may dispense directly a controlled substance listed in schedule III or IV, 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. 8:65-7.5(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 or IV in the course of his professional practice without a prescription, subject to section 6 of this subchapter.

(d) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in schedule III or IV pursuant to an oral prescription made by a prescribing individual practitioner, or pursuant to an order for medication made by an individual user, subject to section 7 of this subchapter.

8:65-7.14 Refilling of prescriptions; schedules III and IV

(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) Each refilling of a prescription shall be entered on the back of the prescription (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.

(c) If the pharmacist merely initials and dates the back of the prescription he shall be deemed to have dispensed a refill for the full face amount of the prescription.

(d) 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 section 13 of this subchapter which shall be a new and separate prescription.

(e) As an alternative to the procedures provided by subsection (a) through (d), an automated data processing system may be used for the storage and retrieval of refill

information for prescription orders for controlled substances in Schedule III and IV, subject to the following conditions:

1. Any such proposed computerized system must provide on-line retrieval (via CRT display or hard-copy printout) of original prescription order information for those prescription orders which 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 and address of the practitioner, and the name, strength, dosage form, quantity of the controlled substance prescribed (or 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 CRT 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 is not 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 or IV 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 would sign a check or legal document (e.g., J.H. Smith, or John H. Smith). This document shall be maintained at that pharmacy for a period of two 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 48 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 two 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 record-keeping location must be capable of sending the printout to the pharmacy within 48 hours and if a representative of the Department of Health request a copy of such printout from the user pharmacy, it must, if requested to do so by the representative of the Department of Health verify the printout transmittal capability of its system by documentation (e.g., postmark).

5. In the event that a pharmacy which employs such a computerized system experiences system down-time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of schedule III and IV 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.

(f) When filing refill information for original prescription orders for schedule III or IV controlled substances, a pharmacy may use only one of the two systems described in this section.

(g) Any registrant who intends to use a system provided by (e) through (f) above must first apply for a Permit to Maintain Central Records as required by the Department of Health.

(h) The transfer of original prescription information for a controlled dangerous substance listed in schedule III or IV for the purpose of refill dispensing is permissible between pharmacies on a one time basis 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;

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;

iii. Record the date of the transfer and the name of the pharmacist transferring the information.

2. The pharmacist receiving the transferred prescription information shall reduce to writing the following:

i. Write the word "TRANSFER" on the face the prescription;

ii. Provide all information required to be on a prescription pursuant to N.J.S.A. 24:21-17 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 of last refill;

(5) Pharmacy's name, address and DEA registration number and original number from which the prescription information was transferred;

(6) Name of transferor pharmacist.

3. Both the original and transferred prescription must be maintained for a period of two years from the date of the last refill.

4. Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferral.

5. The procedure allowing the transfer of prescription information for refill purposes is permissible only if allowable under existing State or other applicable law.

8:65-7.15 Partial filling of prescriptions; schedules III and IV

(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.

8:65-7.16 Labeling of substances; schedules III and IV

(a) The partial filling of a prescription for a controlled substance listed in schedule III or IV 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 subsection (a) of this section do not apply when a controlled substance listed in schedule I or IV is prescribed for administration to an ultimate user who is institutionalized: provided, that:

8:65-8.5 Manufacture and distribution of narcotic solutions and compounds by a pharmacist

As an incident to a distribution under N.J.A.C. 8:65-8.4 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.

8:65-8.6 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 obtained it or to the manufacturer of the substance, provided that a written record is maintained which indicates the date of the transaction, the name, form and quantity of the substance, the name, address, and registration number, if any, of the person making the distribution, and 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. 8:65-6 and be maintained as the written record of the transaction. Any person not required to register pursuant to Section 302(c) or 1007(b)1 of the Act or N.J.A.C. 8:65-1.3 shall be exempt from maintaining the records required by this section.

8:65-8.7 Distribution upon discontinuance or transfer of business

(a) Any registrant desiring to discontinue or transfer business activities altogether or with respect to controlled substances shall return his Federal Certificate of Registration, and any unexecuted order forms in his possession to the Drug Control Program, New Jersey State Department of Health, CN 362, Trenton, NJ 08625 as well as the State Certificate of Registration for cancellation. Any controlled substances in his possession may be disposed of in accordance with Section 307.21 of the Act or N.J.A.C. 8:65-8.10 or by transfer to another registrant. If the registrant desires to transfer the substances to another registrant, he shall take an inventory, together with his name, address, and registration number, and the name, address, and registration number of the proposed transferee and send them to the Special Agent in Charge of the District Office of the Drug Enforcement Administration in the region in which he is doing business at least 15 days in advance of the date of the proposed transfer. If the Special Agent in Charge does not notify the registrant that the transfer should be postponed or cancelled, the registrant may transfer the substances to the named transferee without being registered as a distributor. All controlled substances listed in schedule I or II must be transferred pursuant to an order form in accordance with Part 305 of the Act or N.J.A.C. 8:65-6. Schedule III, IV and V substances will be transferred in accordance to the

inventory prepared by the registrant and submitted to the Special Agent in Charge. If the Special Agent in Charge denies the registrant authority to make the proposed transfer, the registrant shall either dispose of the substances in accordance with N.J.A.C. 8:65-8.10 or transfer the substances to another registrant in accordance with this section and/or instructions of the Special Agent in Charge.

(b) In the case of registrants required to make reports pursuant to Part 304 of the Act, a report marked "Final" will be prepared and submitted by the transferor registrant showing the disposition of all the controlled substances for which a report is required; no additional reports will be required from him, provided that no further transactions involving controlled substances are consummated by him. The initial report of the transferee registrant shall account for transactions beginning with the day next succeeding the date of discontinuance or transfer of business by the transferor registrant, and the substances transferred to him shall be reported as receipts in his initial report.

(c) A registrant shall notify the Drug Control Program, New Jersey State Department of Health, CN 362, Trenton, NJ in writing no less than 15 days prior to the discontinuance or transfer of business activities with respect to controlled substances as set forth in (a) above, unless the Program waives requirements in individual instances. 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.

8:65-8.8 Distribution to ocean vessels or aircraft

(a) Any registrant lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to a medical officer, master or first officer, of any ocean vessel engaged in international trade or in trade between points of the United States and any merchant vessel belonging to the United States Government; or to any aircraft operated by a carrier under a certificate of permit issued pursuant to the Federal Aviation Act of 1958 (49 U.S.C. 1301) provided that:

1. The medical officer shall be:
 - i. Licensed in a state as a physician;
 - ii. Employed by the owner or operator of the vessel, aircraft or other entity; and
 - iii. Registered under the Act at either of the following locations:
 - (1) The principal office of the owner or operator of the vessel, aircraft or other entity; or
 - (2) At any other location provided that the name, address, registration number and expiration date as they appear on the Certificate of Registration for this location are maintained for inspection at said principal office in a readily retrievable manner.

2. A registered medical officer may serve as medical officer for more than one vessel, aircraft, or other entity under a single registration, unless he serves as medical officer for more than one owner or operator, in which case he shall either maintain a separate registration at the location of the principal office of each such owner or operator or utilize one or more registrations pursuant to 1iii(2) above.

3. If no medical officer is employed by the owner or operator of a vessel or aircraft, or in the event the medical officer is not accessible and the acquisition of controlled substance is required, the master or first officer of the vessel, or aircraft, who shall not be registered, may purchase controlled substances from a registered manufacturer or distributor or from an authorized pharmacy through the following procedure:

- i. The master or first officer of the vessel or aircraft must personally appear at the vendor's place of business, present proper identification, (for example, Seaman's photographic identification card) and a written requisition for the controlled substances;
- ii. The written requisition must be on the vessel or aircraft's official stationery or purchase order and must include the name and address of the vendor, the name of the controlled substance (dosage form, strength and number or volume per container) number of containers ordered, the name of the vessel, the vessel's official number and country of registry, the owner or operator of the vessel, the port at which the vessel is located, the controlled substances and the date of the requisition;
- iii. The vendor may, after verifying the identification of the vessel's officer requisitioning the controlled substances, deliver the controlled substances to that officer. The transaction shall be documented, in triplicate, on a record of sale in a format similar to that outlined in this subsection. The vessel's requisition shall be attached to copy 1 of the record of sale and filed with the controlled substances records of the vendor. Copy 2 of the record of sale shall be furnished to the officer of the vessel and retained aboard the vessel. Copy 3 of the record of sale shall be forwarded to the nearest DEA Division office within 15 days after the end of the month in which the sale is made;

iv. The vendor's record of sale should be similar to, and must contain all the information required in the following format:

Sale of Controlled Substances to Vessels

(Name of Registrant) _____

(Address of Registrant) _____

(DEA Registration Number) _____

Line No.	Number of Packages	Size of Packages	Name	Pkg. Dist.	Date
1.	_____	_____	_____	_____	_____
2.	_____	_____	_____	_____	_____
3.	_____	_____	_____	_____	_____

Line numbers may be continued according to the needs of the vendor.

Number of lines completed _____

Name of the vessel _____

Vessel's official number _____

Vessel's country of registry _____

Owner or operator of vessel _____

Name and title of vessel's officer who presented requisition _____

Signature of vessel's officer who presented the requisition _____

4. Any registered pharmacy which wishes to distribute controlled substances pursuant to this section shall be authorized to do so, provided that:

- i. The registered pharmacy notifies the nearest Division officer of the Drug Enforcement Administration of its intentions to distribute controlled substances prior to the initiation of such activity. This notification shall be by registered mail and shall contain the name, address and registration number of the pharmacy as well as the date upon which such activity will commence; and
- ii. Such activity is authorized by state law; and
- iii. The total number of dosage units of controlled substances meet the requirements of N.J.A.C. 8:65-8.4.

8:65-8.9 Incidental manufacture of controlled substances

Any registered manufacturer who, incidentally but necessarily, manufactures a controlled substance as a result of the manufacturer of a controlled substance or basic class of controlled substance for which he is registered and has been issued an individual manufacturing quota pursuant to Part 303 of the Act (if such substance or class is listed in schedule I or II) shall be exempt from the requirement of registration pursuant to Part 301 of the Act 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 Part 303 of the Act, if such substances are disposed of in accordance with Part 307.21 of the Act.

8:65-8.10 Procedure for disposing of controlled substances

(a) Any person in possession of any controlled substance and desiring or required to dispose of such substance may request the Special Agent in Charge, U.S. Department of Justice, Drug Enforcement Administration, 970 Broad St., Newark, N.J. 07102 for authority and instructions to dispose of such substance. The person may also contact the Drug Control Program, New Jersey State Department of Health for such authority and instruction. The request shall be made in the following manner:

1. If the person is a registrant required to make reports pursuant to Part 304 of the Act, he shall list the controlled substances or substance which he desires to dispose of on the "b" subpart of the report normally filed by him, and submit three copies of that report to the Special Agent in Charge, U.S. Department of Justice, Drug Enforcement Administration, 970 Broad St., Suite 806, Newark, N.J. 07102.

2. If the person is a registrant not required to make reports pursuant to Part 304 of the Act, he shall list the controlled substance or substances which he wishes to dispose of on DEA-41 form or Form DDC-51 of the Drug Control Program, New Jersey State Department of Health, CN 362, Trenton, NJ 08625. If he elects to use the DEA-41 form, he must submit three copies of that form to the Special Agent in Charge, U.S. Department of Justice, Drug Enforcement Administration, 970 Broad St., Newark, N.J. 07102. If the person elects to use the DDC-51 form, he must submit three copies of that form to the Drug Control Program, New Jersey State Department of Health, CN 362, Trenton, N.J. 08625 or may telephone that agency.

3. If the person is not a registrant he shall submit to the Special Agent in Charge a letter stating:

- i. The name and address of the person;
- ii. The name and quantity of each controlled substance to be disposed of;
- iii. How the applicant obtained the substance, if known; and
- iv. The name, address and registration number, if known, of the person who possessed the controlled substance prior to the applicant, if known.

(b) The Special Agent in Charge or the Drug Control Program shall authorize and instruct the applicant to dispose of the controlled substances in one of the following manners:

1. By transfer to the District Office of the Special Agent in Charge;
2. By transfer to a person registered under the act and authorized to possess such substance or substances;

3. By destruction in the presence of an agent of the District Office of the Special Agent in Charge or an agent of the Drug Control Program; or

4. By such other means as the Special Agent in Charge or the Drug Control Program may determine to assure that the substance or substances does not become available to unauthorized persons.

(c) This section shall not be construed as affecting or altering in any way the disposal of controlled substances through procedures provided in laws and regulations adopted by any state.

8:65-8.11 Disposal of controlled substances by the District Office

(a) Any controlled substance delivered to the District Office of the Special Agent in Charge, U.S. Department of Justice, Drug Enforcement Administration under 307.21 or forfeited pursuant to section 511 of the Act (21 U.S.C. 881) may be delivered to any department, bureau, or other agency of the United States or of any State upon proper application addressed to the Administrator, U.S. Department of Justice, Drug Enforcement Administration, Washington, D.C. 20537.

(b) The application shall show the name, address, and official title of the person or agency to whom the controlled drugs are to be delivered, including the name and quantity of the substances desired and the purpose for which intended.

(c) The delivery of such controlled drugs shall be ordered by the Special Agent in Charge, if in his opinion, there exists a medical or scientific need therefor.

8:65-8.12 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.

8:65-8.13 Humane societies and animal care facilities

(a) Incorporated humane societies or licensed animal care facilities authorized to purchase, possess and to dispense Sodium Pentobarbital for animal euthanasia pursuant to N.J.S.A. 24:21-11(f) shall:

1. Be authorized to dispense 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. Be authorized to dispense a standard compounded formula of Sodium Pentobarbital for animal euthanasia established by the Department as follows:

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

U.S.P. Pentobarbital Sodium (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)2 above, the strength of this mixture will provide 460 mgs of Pentobarbital Sodium 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.
- 6.
- 7.
- 8.
- 9.

1. Name and address, city and State of registrant;
2. Name of preparation: "Pentobarbital Sodium 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.

New rule, R.1988 d.498, effective October 17, 1988. See: 20 N.J.R. 366(a), 20 N.J.R. 2574(b).

1. Stimulants: Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (listed by generic/established or chemical name with CDS code):

Cathine	1230
Diethylpropion	1608
Fencamfamin	1760
Fenfluramine	1670
Fenproporex	1575
Mazindol	1650
Mefenorex	1580
Phentermine	1640
Pemoline (including organometallic complexes and chelates thereof)	1530

2. Depressants: Unless specifically specified excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation (listed by generic/established or chemical name with CDS code):

Alphazolam	2862
Barbital	2145
Bromazepam	2748
Camazepam	2749
Chloral betaine	2460
Chloral hydrate	2465
Chlordiazepoxide (except Librax and Menrium)	2744
Clobazam	2751
Clonazepam	2737
Clorazepate	2768
Clotiazepam	2752
Cloxazolam	2753
Delorazepam	2754
Diazepam	2765
Estazolam	2756
Ethchlorvynol	2540
Ethinamate	2545
Ethyl loflazepate	2758
Fludiazepam	2759
Flunitrazepam	2763
Flurazepam	2767
Halazepam	2762
Haloxazolam	2771
Ketazolam	2772
Loprazolam	2773
Lorazepam	2885
Lormetazepam	2774
Mebutamate	2800
Medazepam	2836
Meprobamate	2820
Methohexital	2264

Methylphenobarbital (methobarbital)	2250
Midazolam	2884
Nimetazepam	2837
Nitrazepam	2834
Nordiazepam	2838
Oxazepam	2835
Oxzapolam	2839
Paraldehyde	2585
Petrichloral	2591
Phenobarbital	2285
Pimazepam	2883
Prazepam	2764
Quazepam	2881
Temazepam	2925
Tetrazepam	2886
Triazolam	2887

3. Other substances: Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts (listed by generic/established or chemical name with CDS code):

Pentazocine	9709
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4. Narcotic drugs: Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

i. Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit, CDS Code 9167.

ii. Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane), CDS Code 9278.

As amended, R.1974 d.2, effective January 2, 1974.

See: 6 N.J.R. 63(a).

Diethylpropion controlled (Fed. Reg. V.38, 18013, July 6, 1973).

Phentermine controlled (Fed. Reg. V.38, 18013, July 6, 1973).

Fenfluramine controlled (Fed. Reg. V.38, 15719, June 15, 1973).

As amended, R.1975 d.209, effective July 23, 1975.

See: 7 N.J.R. 363(a).

Pemoline controlled (Fed. Reg. V.40, 4150, January 1, 1975).

Chlordiazepoxide controlled (Fed. Reg. V.40, 23998, July 2, 1975).

Clonazepam controlled (Fed. Reg. V.40, 23998, July 2, 1975).

Clorazepate controlled (Fed. Reg. V.40, 23998, July 2, 1975).

Diazepam controlled (Fed. Reg. V.40, 23998, July 2, 1975).

Flurazepam controlled (Fed. Reg. V.40, 23998, July 2, 1975).

Mebutamate controlled (Fed. Reg. V.40, 4418, January 30, 1975).

Oxazepam controlled (Fed. Reg. V.40, 23998, July 2, 1975).

As amended, R.1977 d.101, effective March 29, 1977.

See: 9 N.J.R. 79(a), 9 N.J.R. 172(d).

Prazepam controlled (Fed. Reg. V.41, 55176, December 17, 1976).

As amended, R.1977 d.151, effective April 28, 1977.

See: 9 N.J.R. 119(b), 9 N.J.R. 268(a).

Dextropropoxyphene controlled (Fed. Reg. V.42, 9636, March 14, 1977).

As amended, R.1978 d.33, effective January 24, 1978.

See: 9 N.J.R. 562(b), 10 N.J.R. 62(b).

Lorazepam controlled (Fed. Reg. V.42, 545747, October 8, 1977).

As amended, R.1978 d.426, effective December 12, 1978.

See: 10 N.J.R. 482(b), 11 N.J.R. 16(a).

Paragraph 4 subsection (b) adopted.

Difenoxin in combination with atropine sulfate controlled (Fed. Reg. V.43, No. 167, August 28, 1978).
 As amended, R.1979 d.150, effective April 18, 1979.
 See: 11 N.J.R. 129(b), 11 N.J.R. 236(c).
 Pentazocine controlled (Fed. Reg. V.44 No. 7, January 10, 1979).
 As amended, R.1979 d.301, effective August 6, 1979.
 See: 11 N.J.R. 440(e).
 Amended text of paragraph (b)4.
 As amended, R.1980 d.327, effective July 18, 1980.
 See: 12 N.J.R. 468(b).
 Dextropropoxyphene moved from (b)3 to (b)4 (Fed. Reg. V.45, 42264-42265, July 24, 1980).
 As amended, R.1982 d.124, effective April 19, 1982.
 See: 14 N.J.R. 195(a), 14 N.J.R. 398(b).
 (b)1: Added "Mazindol 1650";
 (b)2: Added "Halazepam 2762";
 (b)3: Added "Alphazolam 2882";
 As amended, R.1983 d.339, effective August 15, 1983.
 See: 15 N.J.R. 844(a), 15 N.J.R. 1375(a).
 Added Temazepam to (b)2.
 Amended by R.1985 d.191, effective April 15, 1985.
 See: 16 N.J.R. 2901(a), 17 N.J.R. 957(a).
 Temazepam added.
 As amended, R.1985, d.190, effective April 15, 1985.
 See: 16 N.J.R. 3390(a), 17 N.J.R. 956(a).
 Substantially amended.
 Amended by R.1986 d.374, effective September 8, 1986.
 See: 18 N.J.R. 1166(b), 18 N.J.R. 1827(a).
 Added midazolam and quazepam.
 Amended by R.1987 d.340, effective August 17, 1987.
 See: 19 N.J.R. 911(a), 19 N.J.R. 1557(c).
 Deleted (b)4i and substituted new.
 Commissioner's Order, effective January 3, 1989.
 See: 21 N.J.R. 70(c).
 Added Cathine (1230), Fencamfamin (1760), Fenproporex (1575) and Mefenorex (1580) to Schedule IV at (b)1. These drugs were published in the Federal Register on May 17, 1988 (see 53 FR 17459) pursuant to N.J.S.A. 24:21-3(c).

Case Notes

Private employer could subject employee to drug test. Hennessey v. Coastal Eagle Point Oil Co., 247 N.J.Super. 297, 589 A.2d 170 (A.D. 1991), certification granted 126 N.J. 340, 598 A.2d 897, affirmed 129 N.J. 81, 609 A.2d 11.

8:65-10.5 Controlled dangerous substances; Schedule V

(a) The following are criteria for inclusion in Schedule V of controlled dangerous substances.

1. The substance has a low potential for abuse relative to the substances listed in Schedule IV.
2. The substance has currently accepted medical use in treatment in the United States.
3. The substance has limited physical dependence or psychological dependence liability relative to the substances listed in Schedule IV.

(b) The following is the Schedule V listing of controlled dangerous substances by generic, established or chemical name and the controlled dangerous substances code numbers for Narcotic Drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, or mixture or preparation containing any of the following narcotic drugs and their salts is included in this schedule:

Buprenorphine 9064

(c) The following is the Schedule V listing of controlled dangerous substances by generic, established or chemical name and the controlled dangerous substances code numbers for Narcotic Drugs Containing Non-Narcotic Active Medicinal Ingredients. Any compound, mixture or preparation containing any of the following narcotic drugs or their salts calculated as the free anhydrous base or alkaloid in limited quantities as set forth below, which shall include one or more non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone, is included in this schedule:

1. Not more than 200 milligrams of codeine or any of its salts per 100 milliliters or per 100 grams.
2. Not more than 100 milligrams of dihydrocodeine or any of its salts per 100 milliliters or per 100 grams.
3. Not more than 100 milligrams of ethylmorphine or any of its salts per 100 milliliters or per 100 grams.
4. Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.
5. Not more than 100 milligrams of opium or any of its salts per 100 milliliters or per 100 grams.
6. Difenoxin, 0.5 mg. in combination with 0.025 mg. atropine sulfate.

(d) The following is the Schedule V listing of controlled dangerous substances by generic, established or chemical name and the controlled dangerous substances code numbers for Stimulants. Unless specifically exempted or excluded, or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including salts, isomers and salts of isomers is included in this schedule:

Pyrovalerone 1485

As amended, R.1977 d.440, effective November 4, 1977.
 See: 9 N.J.R. 465(c), 9 N.J.R. 567(a).
 Loperamide controlled (Fed. Reg. V.42, 54547, October 8, 1977).
 As amended, R.1978 d.426, effective December 12, 1978.
 See: 10 N.J.R. 482(b), 11 N.J.R. 16(a).
 Difenoxin in combination with atropine sulfate controlled (Fed. Reg. V.43, No. 167, August 28, 1978).
 As amended, R.1979 d.301, effective August 6, 1979.
 See: 11 N.J.R. 440(e).
 Amended text of paragraph (b)1.
 As amended, R.1983 d.171, effective June 6, 1983.
 See: 15 N.J.R. 126(a), 15 N.J.R. 923(a).
 Deleted Loperamide as a controlled dangerous substance.
 Amended by R.1985 d.460, effective September 3, 1985.
 See: 17 N.J.R. 1234(a), 17 N.J.R. 2138(c).
 (b)2 added. Buphenorphine added as a controlled dangerous substance.
 Amended by R.1988 d.496, effective October 11, 1988.
 See: 20 N.J.R. 1506(a), 20 N.J.R. 2575(a).
 Substantially amended.
 Commissioner's Order, effective January 3, 1989.

See: 21 N.J.R. 70(d).

Added Propylhexadrine (8161) and Pyrovalerone (1485) to Schedule V at (d). The drugs were published in the Federal Register on April 4, 1988 (see 53 FR 10869) pursuant to N.J.S.A. 24:21-3(c). Administrative Correction to spell Buprenorphine correctly.

See: 22 N.J.R. 3619(c).

Public Notice, effective March 16, 1992.

See: 24 N.J.R. 947(a).

Deletion of Propylhexadrine.

8:65-10.6 Excluded O.T.C. substances

(a) The list of non-narcotic substances which, 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 Section 1308.22 of 21 C.F.R. (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 C.F.R., Part 1300 to end, revised as of April 1, 1977, may be purchased from:

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402
Price—\$4.25 per copy

(c) A complete listing of those non-narcotic substances subject to this proposal may be reviewed in the office of Drug Control, Consumer Health Services, CN 362, Trenton, New Jersey 08625 (609-392-1180).

As Amended, R.1978 d.60, effective February 21, 1978.

See: 10 N.J.R. 11(b), 10 N.J.R. 103(d).

8:65-10.7 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 Section 1308.32 of 21 C.F.R. Copies of 21 C.F.R. Part 1300 to end, revised as of April 1, 1977, may be purchased from:

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20202
Price: \$4.25 per copy

(c) A complete listing of those excepted prescription drugs subject to this proposal may be reviewed in the Office of Drug Control, Consumer Health Services, CN 362, Trenton, NJ 08625 (609-392-1180).

As amended, R.1978 d.61, effective February 21, 1978.

See: 10 N.J.R. 11(a), 10 N.J.R. 103(e).

8:65-10.8 Exempt chemical preparations

(a) 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.

(b) A complete listing of the exempt preparations and mixtures may be reviewed at:

Office of Drug Control
Department of Health
300 Whitehead Road
CN 362
Trenton, N.J. 08625

As amended, R.1978 d.59, effective February 21, 1978.

See: 10 N.J.R. 10(d), 10 N.J.R. 103(c).

As amended, R.1979 d.244, effective June 15, 1979.

See: 11 N.J.R. 235(b), 11 N.J.R. 332(b).

As amended, R.1979 d.361, effective September 13, 1979.

See: 11 N.J.R. 375(b), 11 N.J.R. 505(b).

As amended, R.1980 d.180, effective April 23, 1980.

See: 12 N.J.R. 316(b).

As amended, R.1981 d.50, effective February 9, 1981.

See: 13 N.J.R. 132(b).

(a): "No. 191" was "No. 35"; "September 30, 1980" was "February 30, 1980".

Amended by R.1985 d.84, effective March 4, 1985.

See: 16 N.J.R. 3280(a), 17 N.J.R. 592(b).

Text changed from "Volume 45, No. 19" to "Volume 48, No. 199"; address changed.

Commissioner's Order, effective May 18, 1992.

See: 24 N.J.R. 1895(a).

Updated Federal Register reference (see 57 F.R. 5818).

SUBCHAPTER 11. NARCOTIC TREATMENT PROGRAM

8:65-11.1 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 detoxification treatment with narcotic drugs.

8:65-11.2 Registration; fees

(a) Every person who engages in a narcotic treatment program, including a compounder, shall obtain a registration within 30 days of the adoption of these regulations, 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. 8:65-5.6.

(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 subsection (d) of this Section shall be subject to the exemptions provided in N.J.A.C. 8:65-1.1.

8:65-11.3 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. 8:65-1.4.

8:65-11.4 Security requirements

(a) Applicants to conduct a narcotic treatment program shall comply with the general security requirements as provided in N.J.A.C. 8:65-2.1.

(b) In addition to the security requirements required in subsection (a) of this Section, 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 30; and with standards established by the secretary of health, education and welfare (after consultation with the administration) respecting the quantities of narcotic drugs which may be provided to persons enrolled in a narcotic treatment program for unsupervised use.

5. New Jersey State Department of Health 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.

8:65-11.5 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. 8:65-8.4 to 8.8.

(b) In addition to the record keeping requirements required in subsection (a) of this Section, 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 subsection (b) of this Section will be maintained in a dispensing log at the narcotic treatment program site and will be maintained in compliance with N.J.A.C. 8:65-5.4.

(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.

8:65-11.6 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. 8:65-8.9.

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 subparagraph 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, re-packaging 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. 8:65-8.9.

8:65-11.7 Drugs Used For Treatment of Narcotic Addicts

The FDA regulations at 21 C.F.R. 291, Drugs Used For Treatment of Narcotic Addicts, 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.

Repeal and New Rule, R.1997 d.272, effective July 7, 1997.

See: 29 N.J.R. 860(a), 29 N.J.R. 2830(a).

Section was "Use of Methadone".