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.2002 d.276, effective August 19, 2002.
See: 33 N.J.R. 2754(a), 34 N.J.R. 3024(a).

Chapter Expiration Date

In accordance with N.J.S.A. 52:14B-5.1c, Chapter 65, Controlled Dangerous Substances, expires on February 15, 2008. See: 39 N.J.R. 3854(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).

Subchapter 2, Security Requirements, was amended by R.1973 d.358. See: 5 N.J.R. 373(a), 6 N.J.R. 10(b). Subchapter 8, Miscellaneous Provisions, and Subchapter 10, Controlled Dangerous Substances Schedules, became effective January 17, 1973, as R.1973 d.23. See: 5 N.J.R. 42(b).

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

Subchapter 6, Order Forms, was amended by R.1975 d.56, effective March 12, 1975. See: 7 N.J.R. 55(a), 7 N.J.R. 164(a).

Subchapter 7, Prescription Requirements for Controlled Dangerous Substances, was amended by R.1975 d.58, effective March 12, 1975. See: 7 N.J.R. 54(a), 7 N.J.R. 164(f).

Subchapter 11, Narcotic Treatment Program, 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, Narcotic Treatment Program, became effective November 18, 1975 as R.1975 d.349. See: 7 N.J.R. 263(a), 7 N.J.R. 556(b).

Subchapter 9, Administrative Functions, Practice and Procedures, was repealed by R.1976 d.376, effective November 24, 1976.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).

Subchapter 7, Prescription Requirements for Controlled Dangerous Substances, was amended by R.1978 d.391 effective November 1, 1978. See: 10 N.J.R. 427(c), 10 N.J.R. 556(b).

Subchapter 2, Security Requirements, was amended by R.1979 d.73 effective February 15, 1979. 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Subchapter 4, Quotas, was repealed by R.1979 d.74, effective February 15, 1979.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).

Subchapter 6, Order Forms, was amended by R.1979 d.75 effective February 15, 1979 d.75. See: 11 N.J.R. 13(a), 11 N.J.R. 131(a).

Subchapter 7, Prescription Requirements for Controlled Dangerous Substances, was amended by R.1979 d.76 effective February 15, 1979. See: 11 N.J.R. 14(a), 11 N.J.R. 131(b). Further amendments to Subchapter 7, Prescription Requirements for Controlled Dangerous Substances, became effective April 18, 1979 as R.1979 d.152. See: 11 N.J.R. 128(a), 11 N.J.R. 237(b).

Subchapter 1, General Provisions; Registration, Subchapter 2, Security Requirements, Subchapter 5, Records and Reports of Registrants, and Subchapter 6, Order Forms, were amended by R.1980 d.86 effective February 14, 1980. 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).

Subchapter 8, Miscellaneous Provisions, was amended by R.1981 d.238 effective July 9, 1981. See: 13 N.J.R. 131(a), 13 N.J.R. 411(b).

Subchapter 7, Prescription Requirements For Controlled Dangerous Substances, was amended by R.1981 d.452 effective November 16, 1981. See: 13 N.J.R. 130(b), 13 N.J.R. 845(a).

Subchapter 7, Prescription Requirements For Controlled Dangerous Substances, was amended by R.1982 d.124 effective April 19, 1982. See: 14 N.J.R. 195(a), 14 N.J.R. 389(b).

Subchapter 7, Prescription Requirements For Controlled Dangerous Substances, was amended by R.1983 d.193 effective June 6, 1983. See: 15 N.J.R. 125(a), 15 N.J.R. 923(d).

Pursuant to Executive Order No. 66(1978), Subchapter 7, Prescription Requirements For Controlled Dangerous Substances, expired on November 1, 1983.

Pursuant to Executive Order No. 66(1978), Subchapter 6, Order Forms, 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).

Subchapter 7, Prescription Requirements for Controlled Dangerous Substances, was adopted as new rules by R.1985 d.607 effective January 7, 1985. See: 16 N.J.R. 2327(a), 17 N.J.R. 83(b).

Pursuant to Executive Order No. 66(1978), Subchapter 1, General Provisions; Registration, Subchapter 5, Records and Reports of Registrants, and Subchapter 8, Miscellaneous Provisions, expired on February 11, 1985. Pursuant to Executive Order No. 66(1978), Subchapter 11, Narcotic Treatment Program, expired on July 17, 1985.

Subchapter 6, Order Forms, was adopted as new rules by R.1985 d.457 effective September 3, 1985. See: 17 N.J.R. 528(a), 17 N.J.R. 2135(a).

Subchapter 1, General Provisions; Registration, was adopted as new rules by R.1985 d.459 effective September 3, 1985. See: 17 N.J.R. 1508(a), 17 N.J.R. 2132(a).

Subchapter 5, Records and Reports of Registrants, was adopted as new rules by R.1985 d.606 effective December 2, 1985. See: 17 N.J.R. 524(a), 17 N.J.R. 2890(a).

Subchapter 8, Miscellaneous Provisions, was adopted as new rules by R.1986 d.65 effective March 17, 1986. See: 17 N.J.R. 2721(a), 18 N.J.R. 555(c).

Subchapter 11, Narcotic Treatment Program, was adopted as new rules by R.1986 d.330 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 rules by 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 rules by R.1996 d.342, effective July 15, 1996. See: 28 N.J.R. 2371(a), 28 N.J.R. 3653(a).

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.

Chapter 65, Controlled Dangerous Substances, expired on January 11, 2002.

Chapter 65, Controlled Dangerous Substances, was adopted as new rules by R.2002 d.276, effective August 19, 2002. See: Source and Effective Date. See, also, section annotations.

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SUBCHAPTER 11. NARCOTIC TREATMENT PROGRAM

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 of the New Jersey Department of Health and Senior Services; and

3. Hospitals and other facilities operated by any department of the United States of America.

(g) Exemption from payment of a fee for registration or renewal of registration does not relieve the person of the requirement to obtain a registration or of any other requirements or duties prescribed by law.

Amended by R.2002 d.276, effective August 19, 2002.
See: 33 N.J.R. 2754(a), 34 N.J.R. 3024(a).

8:65–1.1A Definitions

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

"Commissioner" means the Commissioner of the New Jersey Department of Health and Senior Services.

"Department" means the New Jersey Department of Health and Senior Services.

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

"Drug Enforcement Administration" means the United States Department of Justice, Drug Enforcement Administration.

"Executive Officer" means the administrator of the Drug Control Unit who may be contacted at (973) 504–6545.

New Rule, R.2002 d.276, effective August 19, 2002.
See: 33 N.J.R. 2754(a), 34 N.J.R. 3024(a).

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

(b) Every person who distributes or proposes to distribute a controlled dangerous substance or substances, unless specifically exempted by statute or specifically waived by the Commissioner, shall obtain a registration and shall obtain a renewal of the registration within 30 days of the effective of 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, shall obtain a registration and shall obtain a renewal of the registration every year thereafter.

(d) Every person who conducts research or proposes to conduct research with a controlled dangerous substance or substances, unless specifically exempted by statute or specifically waived by the Commissioner, shall obtain a registration and shall obtain a renewal of the registration every year thereafter.

(e) A person desiring to obtain a registration or a renewal of registration as provided in (a) through (d) above shall prepare and file an application in accordance with the procedure set forth in N.J.A.C. 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, shall apply for a registration and shall obtain a renewal of registration every year thereafter.

1. Applications for registration to use sodium pentobarbital for animal euthanasia may be obtained from the Drug Control Unit. Upon receipt of said application by this Unit, the security, safeguards, recordkeeping requirement and personnel training requirements shall be inspected and/or reviewed, and upon satisfactory compliance with the statute and regulations, a registration certificate shall be issued to the applicant.

(h) Every person or duly authorized agent required to register pursuant to (g) above shall be required to provide evidence of a current general liability insurance policy. A certified individual shall be deemed to be acting in behalf of and at the direction of the duly authorized agent.

(i) Every person or duly authorized agent required to register pursuant to (g) above shall be limited to the use of sodium pentobarbital only. Registration granted under (g) above shall not entitle a registrant to buy, possess and/or dispense controlled dangerous substances other than that specified in the registration.

(j) Every individual, as directed by the registered duly authorized agent to use sodium pentobarbital in animal euthanasia, shall be required to be trained in, and demonstrate proficiency with, the use of sodium pentobarbital in animal euthanasia, to the satisfaction of a New Jersey licensed veterinarian. Said New Jersey licensed veterinarian shall, in writing and filed with the registered incorporated humane society or licensed animal care facility, so certify the training and demonstrated proficiency of the individual in the use of sodium pentobarbital in animal euthanasia.

(k) Every person or duly authorized agent required to register pursuant to (g) above shall prepare written procedures and protocol, approved by a New Jersey licensed veterinarian, for the administration of sodium pentobarbital in animal euthanasia. Such written procedure and protocol must be on file at the licensed premise and readily available for review by a Drug Control Unit representative.

(*l*) A person or duly authorized agent registered as a dispenser for the purposes of purchasing and dispensing sodium pentobarbital for the purpose of animal euthanasia shall be limited to registration in Schedule II (sodium pentobarbital) and may possess or have under his control such amounts as are reasonably necessary to administer euthanasia on the premises of the registered location.

Amended by R.2002 d.276, effective August 19, 2002.
See: 33 N.J.R. 2754(a), 34 N.J.R. 3024(a).
Rewrote the section.

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 substances included in Schedules II through V shall make a separate application and be issued a separate registration to conduct such research. Such practitioner shall, in addition to the general requirements of these regulations, furnish the Drug Control Unit with a copy or photocopy of his Federal registration or Federal authorization to conduct research with such substances and a copy of the research protocol.

(e) A practitioner registered to dispense controlled dangerous substances may conduct research with nonnarcotic substances in Schedules II through V which are included in his registration without applying for a separate registration to conduct research.

(f) A practitioner not registered to dispense may be registered to conduct research only for the purpose of making a laboratory analysis of substances to determine the presence of controlled dangerous substances. Such registrant may not possess or have under his control any controlled dangerous substance except such amounts as are reasonably necessary to make such analysis on the premises of the registered location.

(g) A person registered to manufacture controlled dangerous substances may distribute those substances which he is authorized to manufacture without obtaining a separate registration, provided that distribution is from the registered location. A person desiring to distribute controlled dangerous substances other than those he is registered to manufacture or from a different location shall obtain a separate registration as a distributor.

(h) For purposes of registration, the following activities by a registrant 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).
Amended by R.2002 d.276, effective August 19, 2002.
See: 33 N.J.R. 2754(a), 34 N.J.R. 3024(a).
In (d), deleted "narcotic" preceding "substances" in the first sentence; substituted "Drug Control Unit" for "Commissioner of Health" in the second sentence; and deleted ", where required by Federal regulations," in the last sentence.

8:65–1.4 Registration application

(a) All applications for registration shall be made on forms provided by the Executive Officer and shall be filed with the Drug Control Unit at PO Box 45045, Newark, NJ 07101.

(b) Applications shall contain all information called for on the forms provided, except where such information is not applicable in which case this fact shall be stated.

(c) The 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.

Amended by R.2002 d.276, effective August 19, 2002.
See: 33 N.J.R. 2754(a), 34 N.J.R. 3024(a).
Rewrote (a).

8:65–1.5 Action upon application

(a) After an application for registration has been filed, the Drug Control Unit shall make such inspection of the place of business or professional practice described in the application and such investigation of the applicant as may be necessary to determine that the applicant meets the requirements of the applicable statutes and regulations.

(b) 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.

Amended by R.2002 d.276, effective August 19, 2002.
See: 33 N.J.R. 2754(a), 34 N.J.R. 3024(a).
In (a), substituted "the Drug Control Unit" for "the Commissioner or his authorized agent or representative".

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 Drug Control Unit in writing and pay a fee of $5.00 for such duplicate.

Amended by R.2002 d.276, effective August 19, 2002.
See: 33 N.J.R. 2754(a), 34 N.J.R. 3024(a).
Substituted "Drug Control Unit" for "Department".

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;

8:65–5.4 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 Drug Enforcement Administration and the Drug Control Unit, except that financial and shipping records (such as invoices and packing slips but not executed order forms subject to 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 Drug Enforcement Administration and the Drug Control Unit 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 Drug Control Unit. Unless the registrant is informed by the Special Agent in Charge or the Drug Control Unit 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 Drug Control Unit. Registrants who desire to continue maintaining central recordkeeping will make notification to the local Special Agent in Charge and the Drug Control Unit 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 Drug Enforcement Administration or the Drug Control Unit for such records, and if the Drug Enforcement Administration or the Drug Control Unit chooses to do so in lieu of requiring delivery of such records to the registered location, to allow authorized employees of the Drug Enforcement Administration or the Drug Control Unit 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 Drug Control Unit may cancel such central recordkeeping authorization, and all other central recordkeeping authorizations held by the registrant without a hearing or other procedures. In the event of a cancellation of central recordkeeping authorization under this paragraph the registrant shall within the time specified by the Special Agent in Charge, or the Drug Control Unit, 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 Drug Control Unit or obtain central recordkeeping 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.
Amended by R.2002 d.276, effective August 19, 2002.
See: 33 N.J.R. 2754(a), 34 N.J.R. 3024(a).
In (a), inserted "Drug Enforcement" preceding "Administration" in the introductory paragraph and 3, substituted "paragraph" for "subparagraph" and "or" for "of" in 4, and substituted "Drug Control Unit" for "Department of Health" and "State Department of Health" throughout.

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 N.J.A.C. 8:65–5.7 if he notifies in advance the Special Agent in Charge of the Drug Enforcement Administration in his region and the Drug Control Unit 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, typewritten 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."
Amended by R.2002 d.276, effective August 19, 2002.
See: 33 N.J.R. 2754(a), 34 N.J.R. 3024(a).
In (d), substituted "N.J.A.C. 8:65–5.7" for "section 7 of this subchapter", substituted "Drug Enforcement Administration" for "Bureau", and substituted "Drug Control Unit" for "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 N.J.A.C. 8:65–5.6, the registrant shall take a new inventory of all stocks of controlled substances on hand. The biennial inventory may be taken on the day of the year on which the initial inventory was taken or on the registrant's regular general physical inventory date, if any, which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply. If the registrant elects to take the biennial inventory on his regular general physical inventory date or another fixed date, he shall notify the Drug Enforcement Administration and the Drug Control Unit of this election and of the date on which the biennial inventory will be taken.

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."
Amended by R.2002 d.276, effective August 19, 2002.
See: 33 N.J.R. 2754(a), 34 N.J.R. 3024(a).

Substituted "N.J.A.C. 8:65–5.6," for "section 6 of this subchapter", substituted "Drug Enforcement Administration" for "Bureau", and substituted "Drug Control Unit" for "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 Drug Enforcement Administration Administrator pursuant to 308.48, 308.49 or 308.50 of the Act or the Department pursuant to N.J.S.A. 24:21–3 adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter such substances shall be included in each inventory made by the registrant pursuant to N.J.A.C. 8:65–5.7.

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".
Amended by R.2002 d.276, effective August 19, 2002.
See: 33 N.J.R. 2754(a), 34 N.J.R. 3024(a).
Inserted "Drug Enforcement Administration" before "Administrator", deleted "Health" after "Department", and substituted "N.J.A.C. 8:65–5.7" for "section 7 of this subchapter".

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 tem-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 the Drug Control Unit in the manner prescribed in (a) above. A copy of such inventory shall be received in the Drug Control Unit 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)."
Amended by R.2002 d.276, effective August 19, 2002.
See: 33 N.J.R. 2754(a), 34 N.J.R. 3024(a).
In (b), substituted "the Drug Control Unit" for "this Department" and substituted "(a) above" for "subsection (a) of this section" in the first sentence and "Drug Control Unit" for "Department" in the second sentence.

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 Drug Enforcement Administration 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."
Amended by R.2002 d.276, effective August 19,2002.
See: 33 N.J.R. 2754(a), 34 N.J.R. 3024(a).
In (c), substituted "Drug Enforcement Administration" for "Bureau".

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 expiration; 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 Drug Control Unit.

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)".
Amended by R.2002 d.276, effective August 19, 2002.
See: 33 N.J.R. 2754(a), 34 N.J.R. 3024(a).
In (b), substituted "Drug Control Unit" for "Department".

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.

(b) All narcotic controlled substances listed in schedules I, II, and III received by a manufacturer or importer, shall be recorded on D.E.A. Form 333 in order and at the time of receipt. Where record on D.E.A. Form 333 cannot, for any good and sufficient reason, be made immediately, the manufacturer or importer shall have available for inspection such invoices, delivery or duplicate sales slips, or other papers or records as may be required to evidence any unrecorded purchase or receipt.

(c) All dispositions of narcotic controlled substances listed in schedules I, II, and III by a manufacturer or importer, including exporters, distributors, and losses shall be recorded on D.E.A. Form 333.

1. A separate sheet, properly headed in the space provided, shall be used for each different type of transaction. On each sheet, separate entries shall be used to report dispositions of each substance and of each different type and size of container or unit involved. All losses reported shall be fully explained.

2. The details of all exports and all domestic distribution of narcotic controlled substances shall be reported in full on D.E.A. Form 333, except that the details of distribution of narcotic controlled substances listed in schedule III sold to dispensers shall be included in summarized entries on D.E.A. Form 333.

3. For all such distributions not reported on detail, the manufacturer shall have available for inspection original sales orders, delivery slips, or other papers or records sufficient to fully evidence and explain the dispositions.

(d) All narcotic controlled substances listed in schedules I, II and III used in the production of other drugs or preparations, with the exception of transactions involving original manufacture from raw opium or coca leaves, shall be entered on D.E.A. Form 333 in the order and at the time they are placed into the process of manufacture. All narcotic controlled substances listed in schedules I, II, and III and preparations produced therefrom shall be entered on the same form, at the time of production, which entry shall be clearly identified with the entry of substances used in their production.

1. Where record of "Used for Production" or "Production" cannot be made immediately, the manufacturer shall have available such batch tags, production orders, or other papers as may be required to evidence any unrecorded quantity used or produced.

2. Any loss in manufacture, and any recoverable wastes salvaged from the manufacturer shall be reported. All wastes shall be returned to raw stock and included in the report of raw materials on hand at the end of the month.

3. Any narcotic controlled substance listed in schedules I, II, and III actively in process of manufacture at the end of the month shall be so reported. Where substances are placed in process during one quarter and a portion of the production is removed from process as finished goods during the same quarter, the portion thus removed from process shall be reported "Produced" and the remainder reported as "In process" at the close of the period.

4. Narcotic controlled substances listed in schedules I, II, and III placed in process for the manufacture or narcotic controlled substances listed in schedule V shall be reported on a separate D.E.A. Form 333, on which the kind and quantity of narcotic used and the name of the substance to be produced therefrom shall be stated.

(e) All narcotic controlled substances listed in schedules I, II, and III, either bulk finished goods or goods already packaged, which are used during the quarter for packaging or repackaging into commercial containers shall be reported as credit entries in the D.E.A. Form 333, and in each instance clearly identified with the entry of the substance used in such packaging. A separate entry shall be made for each different size of commercial container produced, but all entries representing a single packaging lot shall be grouped together.

1. The number of commercial containers of a given size produced, the size of the commercial container (indicating the number of pills, tablets, ounces, and so forth), the narcotic controlled substance contained in each unit in the commercial container, the total narcotic controlled substance content of each container, and the aggregate narcotic controlled substance content of all commercial containers, represented by the entry shall be indicated.

2. The recoverable wastes salvaged from the packaging operation and the losses in packaging shall be shown as credit entries on the form. All recoverable wastes reported during the quarter shall be returned to raw stock and further accounted for as raw materials.

3. Any goods actively in process of packaging at the close of the quarter shall be so reported. Where substances are placed in process of packaging during one quarter and a portion thereof are removed as commercial containers, produced during the same quarter, the portion thus removed shall be reported as commercial containers produced and the remainder reported as in process at the end of the quarter.

(f) Each manufacturer and importer shall submit as a part of his fourth quarterly report (D.E.A. Form 333) an inventory (D.E.A. Form 333) of narcotic controlled substances listed in schedules I, II, and III which are in possession on December 31 of each year. The substances shall be classified as follows:

1. Raw materials;

2. Goods in process;

3. Finished bulk stock;

4. Finished goods in marketable commercial containers;

5. Miscellaneous stock.

Amended by R.1985 d.606, effective December 2, 1985.
See: 17 N.J.R. 524(a), 17 N.J.R. 2890(a).
Substituted "D.E.A." for "BDN" and changed Form "234" to "333".

8:65–5.22 Reports of distributors and exporters

(a) Every registered distributor except any officer or agency of the Veteran's Administration or who or which is exempted from registration pursuant to 301.25 of the Act and N.J.A.C. 8:65–1.3 and registered exporter shall submit a monthly report on D.E.A. Form 333 and its supplement accounting for all transactions involving narcotic controlled substances listed in schedules I and II, including all receipts (D.E.A. 333) and dispositions (D.E.A. Form 333). The report shall be submitted to the Distribution Audit Branch, Department of Justice, Drug Enforcement Administration, Washington, DC 25037, on or before the 15th day of the month succeeding that for which the return is submitted.

(b) All narcotic controlled substances listed in schedules I and II received by a distributor or exporter shall be recorded on D.E.A. Form 333 in order and at the time of receipt. Where a record of D.E.A. Form 333, such form cannot, for any good and sufficient reason, be made immediately, the distributor or exporter shall have available for inspection such invoices, delivery or duplicate sales slips, or other papers or records as may be required to evidence any unrecorded purchase or receipt.

(c) All dispositions of narcotic controlled substances listed in schedules I and II, including distributions, exports, losses shall be reported on D.E.A. Form 333. A separate sheet, properly headed in the space provided, shall be used for each different type of transaction. On each sheet, separate entries shall be made of dispositions of each substance and of each different type and size of container or unit involved. All losses reported shall be fully explained.

(d) Each distributor and exporter shall submit, as part of his December 31 month report on D.E.A. Form 333 and its supplements, any inventory on D.E.A. Form 333 of the narcotic controlled substances listed in schedules I and II which are in his possession on December 31 of each year. A separate entry shall be made for each narcotic substance as follows:

1. The name, quantity, and narcotic content of the drug or preparation;

2. The size of each commercial container; and

3. The number of commercial containers.

(e) The distributor and exporter shall report on D.E.A. Form 333 complete summary of transactions for the month.

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.

8:65–5.23 Reports from manufacturers importing opium

(a) Every manufacturer importing crude opium shall submit, in addition to the report on D.E.A. Form 333 and its supplements, D.E.A. Form 247 and its supplements 247a and 247b, accounting for the importation and the production in bulk of finished marketable products, standardized in accordance with the U.S. Pharmacopeia, National Formulary, U.S. Pharmacopoeia/National Formulary, or other recognized medical standards. Subsequent manufacture from such products, including bottling or packaging operations shall be accounted for in the quarterly returns on D.E.A. Form 333 and its supplements, D.E.A. Form 247 and its supplements and shall be submitted to the Distribution Audit Branch, Department of Justice, Drug Enforcement Administration, Washington, DC 20537 on or before the 15th day of the month immediately following the period for which it is submitted.

(b) The report of manufacture from crude opium shall consist of summaries (D.E.A. Forms 247 and 247a) with supporting detail sheets (D.E.A. Form 247b) accounting for original manufacture from crude opium, production from morphine for further manufacture and production from manufacturing opium, and also accounting for stocks of crude opium, manufacturing opium, morphine for further manufacture and other crude alkaloids.

(c) The detail sheets (D.E.A. Form 247b) supporting the summary of original manufacture from crude opium shall show separately the crude opium used for the manufacture of opium tinctures and extracts, crude opium used for the extraction of alkaloids, crude opium used for the manufacturing of controlled substances, listed in schedule V, and crude opium used for the production of manufacturing opium; and shall show separately the medicinal opium, alkaloids and salts, opium tinctures and extracts, controlled substances listed in schedule V, and manufacturing opium produced.

(d) Importation of opium shall be reported in summarized entries in the debit summary of quarterly report (D.E.A. Form 333) and shall be immediately reported by similar summarized entries in the credit summary of the quarterly report (D.E.A. Form 333) as transferred to importing manufacturing report. Such importations shall be further reported in summary (D.E.A. Form 247) and supporting detail sheets (D.E.A. Form 247b). Products manufactured therefrom shall be reported as produced in accordance with (b) and (c) above, and, with the exception of manufacturing opium, morphine for further manufacture, and other crude or unfinished alkaloids, shall be transferred to the quarterly report (D.E.A. Form 333) required when reported produced.

(e) Upon importation of crude opium, samples will be selected and assays made by the importing manufacturer in the manner and according to the method specified in the U.S. Pharmacopoeia. These assays shall be accounted for in terms of its anhydrous morphine alkaloid content. Where final assay data is not determined at the time of rendering report, the report shall be made on the basis of the best data available, subject to adjustment, and the necessary adjusting entries shall be made on the next report.

4. The quantity of exhausted or spent leaves and the quantity of each residue removed from process, and the total alkaloid contained in each, stated in ounces and grains;

5. The weight of the used filter cloth or other absorbent material removed, after saturations; and

6. The quantity, in gallons, of finished extract produced.

(e) The report of substances destroyed, shall provide in appropriate columns the following data as to each lot destroyed:

1. The lot numbers;

2. The quantity of spent leaves, residues, and saturated materials destroyed, stated separately for each; and

3. The name of the Government officer witnessing the destruction.

(f) The summary shall include a complete accounting for all transactions in raw leaves, leaves in process, and residues removed from production processes.

1. The summary of raw coca leaves shall include:

i. The quantity of special coca leaves on hand at the beginning of the quarter;

ii. The quantity of special coca leaves imported during the quarter;

iii. The quantity of special coca leaves entered into the process of manufacture during the quarter;

iv. The quantity of special coca leaves on hand at the end of the quarter; and

v. Any other transaction during the quarter which increased or decreased the quantity of raw coca leaves on hand.

2. The summary of coca leaves in process shall include:

i. The quantity of special coca leaves in process at the beginning of the quarter;

ii. The quantity of such leaves placed in the process during the quarter;

iii. The quantity of such leaves represented by lots completed during the quarter;

iv. The quantity of such leaves represented by lots in process at the end of the quarter; and

v. Any other transaction during the quarter which increased or decreased the quantity of leaves in process.

3. The summary of residues removed from production processes shall provide in appropriate columns, separately as to spent leaves, each residue and saturated material, the following information:

i. The quantity of each, on hand at the beginning of the quarter, awaiting destruction;

ii. The quantity of each removed from process during the quarter;

iii. The quantity of each destroyed during the quarter;

iv. The quantity of each on hand at the end of the quarter; and

v. Any other transaction during the quarter affecting the quantity of such residues on hand.

Amended by R.1985 d.606, effective December 2, 1985.
See: 17 N.J.R. 524(a), 17 N.J.R. 2890(a).
Changed "BND" to "D.E.A.".

SUBCHAPTER 6. ORDER FORMS

8:65–6.1 Scope

This subchapter sets forth the Federally mandated requirements governing the issuance, use, and preservation of order forms pursuant to the Controlled Substances Act (21 U.S.C. 828, section 308).

8:65–6.2 Definitions

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

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

"D.E.A." means the Drug Enforcement Administration.

"Purchaser" means any registered person entitled to obtain and execute order forms pursuant to N.J.A.C. 8:65–6.4 and 6.

"Supplier" means any registered person entitled to fill order forms pursuant to N.J.A.C. 8:65–6.8.

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

8:65–6.3 Distribution requiring order forms

(a) An order form (DEA Form 222c) is required for each distribution of a controlled substance listed in schedule I or II, except for the following:

1. The exportation of such substances from the United States in conformity with the Act;

2. The delivery of such substances to or by a common or contract carrier for carriage in the law and usual course of its business, or to or by a warehouseman for storage in the lawful and usual course of its business (but excluding such carriage or storage by the owner of the substance in connection with the distribution of a third person);

3. The procurement of a sample of such substances by an exempt law enforcement official pursuant to 316.04(d) of the Act, provided that the receipt required by that section is used and is preserved in the manner prescribed in this part for order forms;

4. The procurement of such substances by a civil defense or disaster relief organization, pursuant to 301.27 of the Act, provided that the civil defense emergency order form required by that section is used and is preserved with other records of the registrant; and

5. The purchase of such substances by the master of a vessel pursuant to 310.28(a)(3) of the Act; provided, that the special order form provided by the U.S. Public Health Service required by that section is used and preserved in the manner prescribed in this order form.

8:65–6.4 Persons entitled to obtain and execute order forms

(a) Order forms may be obtained only by persons who are registered under section 303 of the Act (21 U.S.C. 823) to handle controlled substances listed in schedules I and II, and by persons who are registered under section 1008 of the Act (21 U.S.C. 958) to export such substances. Persons not registered to handle controlled substances listed in, schedules I or II and persons registered only to import controlled substances listed in any schedule are not entitled to obtain order forms.

(b) An order form may be executed only on behalf of the registrant named thereon and only if his registration as to the substances being purchased has not expired or been revoked or suspended.

8:65–6.5 Procedure for obtaining order forms

(a) Order forms are issued in groups of 21 forms, each form containing an original, duplicate, and triplicate copy (respectively, copy 1, copy 2 and copy 3). A limit of 21 forms will be furnished on any requisition, unless additional quantities are specifically requested and a reasonable need for such additional quantity is shown.

(b) Any person applying for a registration which would entitle him to obtain order forms may requisition such forms by so indicating on the application form; order forms will be supplied upon the registration of the applicant. Any person holding a registration entitling him to obtain order forms may requisition such forms for the first time on DEA Form 222d, which may be obtained from the Registration Branch of the Administration. All requisitions shall be submitted to the Registration Branch, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, D.C. 20005.

(c) Each requisition shall show the name, address, and registration number of the registrant and the quantity of forms desired. Each requisition shall be signed and dated by the same person who signed the most recent application for registration or for reregistration, or by any person authorized to obtain and execute order forms by a power of attorney pursuant to N.J.A.C. 8:65–6.7.

(d) Order forms will be serially numbered and issued with the name, address, and registration number of the registrant, the authorized activity and schedules of the registrant. This information cannot be altered or changed by the registrant; any errors must be corrected by the Registration Branch of the Administration by returning the forms with notification of the error.

8:65–6.6 Procedure for executing order forms

(a) Order forms shall be prepared and executed by the purchaser simultaneously in triplicate by means of interleaved carbon sheets which are part of the DEA Form 222c. Order forms shall be prepared by use of a typewriter, pen, or indelible pencil.

(b) Only one item shall be entered on each numbered line. There are 10 lines on each order form. If one order form is not sufficient to include all items in an order, additional forms shall be used. Order forms for carfentanil, etorphine hydrochloride and diprenorphine shall list only these substances. The total number of items ordered shall be noted on that form in the space provided.

(c) An item shall consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance; a separate item shall be made for each commercial or bulk container of different finished or bulk form, quantity or substance. For each item the form shall show the name of the article ordered, the finished or bulk form of the article (e.g., ten milligram tablet, ten-milligram concentration per fluid ounce or milliliter, or United States Pharmacopeia), the number of units or volume in each commercial or bulk container (e.g., 100–tablet bottle of three-milliliter vial) or the quantity or volume of each bulk container (e.g., 10 kilograms), the number of commercial or bulk containers ordered, and the name and quantity per unit of the controlled substance or substances contained in the article if not in pure form. The catalog number of the article may be included at the discretion of the purchaser.

(d) The name and address of the supplier from whom the controlled substances are being ordered shall be entered on the form. Only one supplier may be listed on any one form.

(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 diprenophine 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 impuning 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, PO Box 28083, Central Station, Washington, D.C. 20005, and the Drug Control Unit 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 Drug Enforcement Administration and the Drug Control Unit shall immediately be notified.

Amended by R.2002 d.276, effective August 19,2002.
See: 33 N.J.R. 2754(a). 34 N.J.R. 3024(a).
In (b), substituted "Unit" for "Program, New Jersey Department of Health, CN 362, Trenton, NJ 08625"; in (c), substituted "Drug Enforcement Administration" for "bureau" and substituted "Drug Control Unit" for "Department of Health".

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.

(d) The supplier of carfentanil, etorphine hydrochloride and diprenorphine shall maintain order forms for these substances separately from all other forms and records required to be maintained by the registrant.

Amended by R.1992 d.241, effective June 15, 1992.
See: 23 N.J.R. 1911(a), 24 N.J.R. 2256(a).
Text added at (d) to require separate order forms.

Case Notes

Failure to maintain forms for two years. In re: Marvin Gastman, 147 N.J.Super. 101 (App.Div.1977).

8:65–6.14 Return of unused order forms

If the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes his name or address as shown on his registration) or is suspended or revoked pursuant to 301.45 or 301.46 of the Act as to all controlled substances listed in schedules I and II for which he is registered, he shall return all unused order forms for such substance to the nearest office of the Administration.

8:65–6.15 Cancellation and voiding of order forms

(a) A purchaser may cancel part or all of an order on an order form by notifying the supplier in writing of such cancellation. The supplier shall indicate the cancellation on copies 1 and 2 of the order form by drawing a line through the cancelled items and printing "canceled" in the space provided for number of items shipped.

(b) A supplier may void part or all of an order on an order form by notifying the purchaser in writing of such voiding. The supplier shall indicate the voiding in the manner prescribed for cancellation in (a) above.

(c) No cancellation or voiding permitted by this section shall affect in any way contract rights of either the purchaser or the supplier.

8:65–6.16 Special procedure for filling certain order forms

(a) The purchaser of carfentanil, etorphine hydrochloride or diprenorphine shall submit copy 1 and 3 of the order form to the supplier and retain copy 3 in his or her own files.

(b) The supplier, upon determining that the purchaser is a veterinarian engaged in zoo and exotic animal practice, wildlife management programs and/or research and authorized by the D.E.A. to handle these substances, shall fill the order in accordance with the procedures set forth in 21 C.F.R. 1305.09 except that:

1. Order forms for carfentanil, etorphine hydrochloride and diprenorphine shall only contain these substances in reasonable quantities; and

2. The substances shall only be shipped to the purchaser at the location printed by the D.E.A. upon such order forms under secure conditions using substantial packaging material with no markings on the outside which would indicate the content.

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 (a) and (b).

SUBCHAPTER 7. PRESCRIPTION REQUIREMENTS FOR CONTROLLED DANGEROUS SUBSTANCES

8:65–7.1 Scope

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

8:65–7.2 Definitions

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

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

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

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

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

"Pharmacist" means any pharmacist licensed by the State of New Jersey to dispense controlled substances and shall include any other person (e.g., a pharmacist intern authorized by the State to dispense controlled substances under the provision of a pharmacist licensed by the State).

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

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

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

8:65–7.3 Persons entitled to issue prescriptions

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

1. Authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession; and

2. Either registered or exempted from registration pursuant to the Code of Federal Regulations, Title 21, part 1301.24(c) or 1301.25.

(b) A prescription issued by an individual practitioner shall be communicated to a pharmacist by the individual practitioner.

Amended by R.1985 d.461, effective September 3, 1985.
See: 17 N.J.R. 876(a), 17 N.J.R. 2138(a).
Text changed in (b) from "may" to "shall".

8:65–7.4 Purpose of issue of prescription

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

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be used for the dispensing of narcotic drugs listed in any schedule for "detoxification" or "maintenance treatment" as defined in N.J.A.C. 8:65–11.1.

Cross References

Additional requirements, see N.J.A.C. 8:65–7.8.

Case Notes

Statutory requirement of "good faith in course of professional practice only" for issuance of controlled dangerous substances prescription not unconstitutional for vagueness. State v. Vaccaro, 142 N.J.Super. 167 (App.Div.1976), cert. den. 71 N.J. 518 (1976).

8:65–7.5 Manner of issuance of prescriptions

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the full name, address, proper academic degree or other definitive identification of the professional practice for which he or she is licensed and registration number of the practitioner. All prescriptions for controlled substances, regardless of schedules, shall be presented to the pharmacist for filling within 30 days after the date when issued. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (for example, J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written in ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescription may be prepared by a secretary or agent of the practitioner for the signature of the practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law or rules. A corresponding liability rests upon the pharmacist who fills a prescription not prepared in the form prescribed by these rules.

(b) An intern, resident, or foreign-trained physician, or physician on the staff of a Veteran's Administration facility, exempted from registration under the Code of Federal Regulations, Title 21, part 1301.24(c) shall include on all prescriptions issued by him the registration number of the hospital or other institution and the special internal code number assigned to him by the hospital or other institution as provided in the Code of Federal Regulations, Title 21, part 1301.24(c), in lieu of the registration number of the practitioner required by this section. Each written prescription shall have the name of the physician stamped, typed, or handprinted on it, as well as the signature of the physician.

(c) An official exempted from registration under the Code of Federal Regulations, Title 21, part 1301.25 shall include on all prescriptions issued by him, his branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and his service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is his Social Security identification number. Each prescription shall have the name of the officer stamped, or handprinted on it, as well as the signature of the officer.

Amended by R.1992 d.205, effective May 4, 1992.
See: 23 N.J.R. 3618(a), 24 N.J.R. 1795(a).
Drug name, strength, dosage, form, quantity, directions and degree or identification of the prescriber to be included in each prescription.

1. Not more than a 34–day supply or 100 dosage units, whichever is less, of the controlled substance listed in schedule III or IV is dispensed at one time;

2. The controlled substance listed in schedule III or IV is not in the possession of the ultimate user prior to administration;

3. The institution maintains appropriate safeguards and records the proper administration, control, dispensing and storage of the controlled substance listed in schedule III or IV; 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.

8:65–7.17 Filing prescriptions; schedules III and IV

All prescriptions for controlled substances listed in schedules III and IV shall be kept in accordance with N.J A.C. 8:65–5.17.

8:65–7.18 Requirement of prescriptions; schedule V

(a) A pharmacist may dispense directly a controlled substance listed in schedule V pursuant to a prescription as required for controlled substances listed in N.J.A.C. 8:65–7.13 schedules III and IV. A prescription for a controlled substance listed in schedule V may be refilled only as expressly authorized by the prescribing individual practitioner on the prescription; if no such authorization is given, the prescription may not be refilled. A pharmacist dispensing such substance pursuant to a prescription shall label the substance in accordance with N.J.A.C. 8:65–7.16 and file the prescription in accordance with N.J.A.C. 8:65–7.17.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in schedule V in the course of his professional practice without a prescription, subject to N.J.A.C. 8:65–7.7.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in schedule V only pursuant to a written prescription signed by the prescribing individual practitioner or 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. 8:65–5.4(b) except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner, which is dispensed for immediate administration to the ultimate user, subject to N.J.A.C. 8:65–7.7.

(d) The transfer of original prescription information for a controlled dangerous substance listed in schedule V 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.

8:65–7.19 Dispensing without prescription

(a) A controlled substance listed in schedule V, and a controlled substance listed in schedule II, III, or IV which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

1. Such dispensing is made only by a pharmacist (as defined in 8:65–7.1), and not by a nonpharmacist employ-

ee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his professional and legal responsibilities set forth in this section, the actual cash, credit transaction, or delivery, may be completed by a nonpharmacist);

2. Not more than 240 cc. (eight ounces) of any such controlled substance containing opium, nor more than 120 cc. (four ounces) of any other such controlled substance nor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any given 48–hour period;

3. The purchaser is at least 18 years of age;

4. The pharmacist requires every purchaser of a controlled substance under this Section not known to him to furnish suitable identification (including proof of age where appropriate);

5. A bound record book for dispensing of controlled substances under this Section is maintained by the pharmacist, which book shall contain the name and address of the purchaser, the name and quantity of controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the recordkeeping requirement of N.J.A.C. 8:65–5.4); and

(b) A prescription is not required for distribution or dispensing of the substance pursuant to another Federal, State or local law.

Case Notes

Indiscriminate sale of controlled dangerous substance by pharmacist in violation of regulation constitutes grossly unprofessional conduct permitting license revocation by Board; revocation absent regulation setting standards of proscribed conduct proper; monetary penalty procedurally defective. In re: Suspension of Heller, 73 N.J. 292, 374 A.2d 1191 (1977).

SUBCHAPTER 8. MISCELLANEOUS PROVISIONS

8:65–8.1 Definitions

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

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

8:65–8.2 Application of State Law and other Federal Law

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

8:65–8.3 Exceptions to regulations

(a) Any person may apply for an exception to the application of any provision of Parts 301 through 308, 311, 312 of Federal Regulations by filing a written request stating the reasons for such exception.

(b) Requests shall be filed with the Administrator, Drug Enforcement Administration, U.S. Department of Justice, Washington, D.C. 20537.

(c) The Administrator may grant an exception in his discretion, but in no case shall he be required to grant an exception to any person which is not otherwise required by law or the regulations cited in this section.

8:65–8.4 Distribution by dispenser to another practitioner

(a) A practitioner who is registered to dispense controlled substances may distribute (without being registered to distribute) a quantity of such substance to another practitioner for the purpose of general dispensing by the practitioner to his or its patients; provided, that:

1. The practitioner to whom the controlled substance is to be distributed is registered under the Act and the State Act (N.J.S.A. 24:21–10) to dispense that controlled substance;

2. The distribution of such controlled substance is recorded by the distributing practitioner in accordance with N.J.A.C. 8:65–5.17(a)5 and by the receiving practitioner in accordance with N.J.A.C. 8:65–5.17(a)3;

3. If the substance is listed in schedule I or II, an order form is used as required in N.J.A.C. 8:65–6;

4. The total number of dosage units of all controlled substances distributed by the practitioner pursuant to this section during the 12–month period in which the practitioner is registered to dispense does not exceed five percent of the total number of dosage units of all controlled substances distributed and dispensed by the practitioner during the 12–month period.

(b) If, at any time during the 12–month period which the practitioner is registered to dispense, the practitioner has reason to believe that the total number of dosage units of all controlled substances which will be distributed by him pursuant to this section will exceed five percent of the total number of dosage units of all controlled substances distributed and dispensed by him during the 12–month period, the practitioner shall obtain a registration to distribute controlled substances.

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 Unit 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 Unit 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.

Amended by R.2002 d.276, effective August 19, 2002.
See: 33 N.J.R. 2754(a), 34 N.J.R. 3024(a).
In (a), substituted "Unit" for "Program, New Jersey State Department of Health, CN 362, Trenton, NJ 08625"; in (c), substituted "Unit" for "Program, New Jersey State Department of Health, CN 362, Trenton, NJ".

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.

SUBCHAPTER 9. (RESERVED)

SUBCHAPTER 10. CONTROLLED DANGEROUS SUBSTANCES SCHEDULES

8:65–10.1 Controlled dangerous substances; Schedule I

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

1. The drug or other substance has high potential for abuse.

2. The drug or other substance has no currently accepted medical use in treatment in the United States.

3. There is lack of accepted safety for use of the drug or other substance under medical supervision.

(b) The following is Schedule I listing of the controlled dangerous substances by generic, established or chemical name and the controlled dangerous substance code number.

1. Opiates: Unless specifically excepted or unless listed in another schedule, any of the following opiates, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation (listed by generic/established or chemical name with CDS code):

Acetylmethadol (except levo-alphacetylmethadol also known as levo-alpha-acetylmethadol, levomethadyl acetate, LAAM)	9603
Allylprodine	9602
Alpha Methylfentanyl	9614
Alphacetylmethadol	9603
Alphameprodine	9604
Alphamethadol	9605
Benzethidine	9606
Betacetylmethadol	9607
Betameprodine	9608
Betamethadol	9609
Betaprodine	9611
Clonitazene	9612
Dextromeramide	9613
Diampromide	9615
Diethylthiambutene	9616
Difenoxin	9168
Dimenoxadol	9617
Dimepheptanol	9618
Dimethylthiambutene	9619
Dioxaphetylbutyrate	9621
Dipipanone	9622
Ethylmethylthiambutene	9623
Etonitazene	9624
Etoxeridine	9625
Furethidine	9626
Hydroxypethidine	9627
Ketobemidone	9628
Levomoramide	9629
Levophenacylmorphan	9631
Morpheridine	9632
Noracymethadol	9633
Norlevorphanol	9634
Normethodone	9635
Norpipanone	9636
Phenadoxone	9637
Phenampromide	9638
Phenomorphan	9647
Phenoperidine	9641
Piritramide	9642
Proheptazine	9643
Properidine	9644
Propiram	9649
Racemoramide	9645
Tilidine	9750
Trimeperidine	9646

2. Opium derivatives: Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, 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):

Acetorphine	9319
Acetyldihydrocodeine (Acetylcodone)	9051
Benzylmorphine	9052
Codeine methylbromide	9070
Codeine-N-Oxide	9053
Cyprenorphine	9054
Desomorphine	9055
Dihydromorphone	9145
Drotebanol	9335
Etorphine (Except Hydrochloride Salt)	9056
Heroin	9200
Hydromorphinol	9301
Methyldesorphine	9302
Methyldihydromorphine	9404
Morphine Methylbromide	9305
Morphine Methylsulfonate	9306
Morphine-N-Oxide	9307
Myrephine	9308
Nicocodeine	9309
Nicomorphine	9312
Normorphine	9313
Pholcodine	9314
Thebacon	9315

3. Hallucinogenic substances: Unless specifically excepted or unless listed in another schedule, any material compound, mixture, or preparation which contains any quantity of the following hallucinogenic substances or which contains any of 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 (for purposes of this paragraph only, the term "isomer" includes the optical, positions, and geometric isomers) (listed by generic/established or chemical name with CDS code):

4-bromo-2,5-dimethoxy-amphetamine (Some trade or other names: 4-bromo-2,5-dimethoxy-alpha-methylphenethylamine; 4-bromo-2,5-DMA.) 7391
2,5-dimethoxyamphetamine (Some trade or other names: 2,5-dimethoxy-alpha-methylphenethylamine; 2,5-DMA.) 7396
4-methoxyamphetamine (Some trade or other names: 4-methoxy-alpha-methylphenethylamine; paramethoxyamphetamine, PMA.) 7411
5-methoxy-3,4-methylenedioxy-amphetamine. 7401
4-methyl-2,5-dimethoxy-amphetamine (Some trade and other names: 4-methyl-2,5-dimethoxy-alpha-methylphenethylamine; "DOM"; and "STP".) 7395
3,4-methylenedioxy amphetamine. 7400
3,4,5-trimethoxy amphetamine 7390
Beta-hydroxy-3-methylfentanyl 9830
Bufoteine (Some trade and other names: 3-(beta-Dimethyl-aminoethyl-5-hydroxyindole; 3-(2-dimethylaminoethyl-5-indolol; N,N-dimethylserotonin; 5-hydroxy-N,N-dimethyltryptamine; mappine.) 7395
Diethyltryptamine (Some trade and other names: N, N-Diethyltryptamine DET.) 7395
Dimethyltryptamine (Some trade or other names: DMT.) 7435
Ibogaine (Some trade and other names: 7-Ethyl-6,6,7,8,9,10,12, 13-octahydro-2-methosy-6,9-methano-5H-pyrido (1',2':1,2 axepino 5,6-b) Indole; tabernanthe iboga.) 7260
Lysergic acid diethylamide 7315
Marihuana 7360
Mescaline 7381
4-methylaminorex 1590
Methylenedioxymethamphetamine 7405
3,4-methylenedioxy-N-ethylamphetamine 7404
Parahexyl (Some trade or other names: 3-Hexyl-1-hydroxy-7,8,9,10-tetra-hydro-6,6,9-trimethyl-6H-dibenzyo (b,d) pyran; Synhexyl.) 7374
Peyote (Meaning all parts of the plant presently classified botanically as Lophophora Williamsii Lemaire, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture or preparation of such plant, its seeds or extracts.) 7415
N-ethyl-3-piperidyl benzilate 7482
N-hydroxy-3-4-methylenedioxyamphetamine 7402
N-methyl-3-piperidyl benzilate 7484
Psilocybin 7437
Psilocyn 7438
Tetrahydrocannabinols (Synthetic equivalents of the substances contained in the plant, or in the resinous extractives cannabis, sp. and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity such as the following:
1 cis or trans tetrahydrocannabinol, and their optical isomers. 6 cis or trans tetrahydrocannabinol, and their optical isomers. 3,4 cis or trans tetrahydrocannabinol, and its optical isomers. (Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation of atomic positions are covered.) 7370
Thiphene Analog of Phencyclidine (Some trade or other names: 1-1-(2-theinyl) cyclohexyl piperidine; 2-Thienyl Analog of Phencyclidine; TPCP.) 7470
1-[1-(2-thienyl)cycloheryl] pyrolidine 7473

4. Depressants: 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 depressant effect on the central nervous system, 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):

i. Mecloqualone 2572
ii. Methaqualone 2565

5. Precursors (listed with CDS code):

N-Ethyl-1-phenylcyclohexylamine 7455
1-(1-phenylcyclohexyl) pyrrolidine 7458

6. 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:

Fenethylline 1503
n-Ethylamphetamine 1475

7. Temporary listing of substances subject to emergency scheduling. Any material, compound, mixture, or preparation which contains any quantity of the following substances:

i. 3-Methylfentanyl (N-(3-methyl-1-(2-phenylethyl)-4-iperidyl)-N-phenylpropanamide), its optical and geometric isomers, salts and salts of isomers 9613.
ii. 3, 4-Methylenedioxymethamphetamine: its optical positional and geometric isomers, salts and salts of isomers 7405.
iii. 1-methyl-4-phenyl-4-proprionoxypiperidine (MPPP), its optical isomers, salts and salts of isomers 9661
iv. 1-2(2-phenylethyl)-4-4phenyl-4-acetyloxypipidine (PEPAP), its optical isomers, salts and salts of isomers 9663.
v. acetyl-alpha-methylfentanyl (N-(1-(1-methyl-2-phenyl) ethyl-4-piperidyl)-N-phenylacetamide), its optical isomers, salts, and salts of isomers 9615;
vi. alpha-methylthiofentanyl (N-(1-(1-methyl-2-(2-thienyl) ethyl-4-piperidyl)-N-phenylpropanamide), its optical isomers, salts, and salts of isomers 9832;
vii. benzylfentanyl (N-(1-benzyl-4-piperidyl)-N-phenylpropanamide), its optical isomers, salts, and salts of isomers 9818;
viii. beta-hydroxyfentanyl (N-(1-(2-hydroxy-2-phenyl) ethyl-4-piperidyl)-N-phenylpropanamide), its isomers, salts, and salts of isomers 9830;
ix. beta-hydroxy-3-methylfentanyl (N-(3-methyl-1-(2-hydroxy-2-phenyl) ethyl-4-piperidyl)-N-phenylpropanamide), its isomers, salts, and salts of isomers 9831;

x. 3–methylthiofentanyl (N–(3–methyl–1–(2–(2–thienyl) ethyl–4–piperidyl)–N–phenylpropanamide, its isomers, salts, and salts of isomers 9833;
xi. thenylfentanyl (N–(1–(2–(2–thienyl) methyl–4–piperidyl)–N–phenylpropanamide, its isomers, salts, and salts of isomers 9834;
xii. thiofentanyl (N–(1–(2–(2–thienyl) ethyl–4–piperidyl)–N–phenylpropanamide, its isomers, salts, and salts of isomers 9835.
xiii. Paraflourofentanyl (N–(2–1–phenylethyl)–4–piperidyl)–N–(4–flourophenyl) propanamide.
xiv. Methcathinone (2–Methylamino–1–Phenylpropran–1–one; Ephedrone; Monomethylpropion; UR 1431), its salts, optical isomers and salts of its isomers. 1237.

Amended by R.1973 d.23, effective January 17, 1973.
See: 5 N.J.R. 42(b).
Tetrahydrocannabinols defined (Fed. Reg. V.36, April 28, 1975).
Amended by R.1973 d.325, effective November 20, 1973.
See: 5 N.J.R. 413(b).
Mecloqualone controlled (Fed. Reg. V.40, 28611, July 2, 1975).
Amended by R.1974 d.2, effective January 2, 1974.
See: 6 N.J.R. 63(a).
Propiram controlled (Fed. Reg. V.37, 1468, February 28, 1972).
Drotebanol controlled (Fed. Reg: V.38, 17717, August 6, 1973).
4–bromo–2,5–dimethoxy–amphetamine controlled (Fed. Reg. V.38, 26447, September 21, 1973).
2,5–dimethoxyamphetamine controlled (Fed. Reg. V.38, 26447, September 21, 1973).
4–methoxyamphetamine controlled (Fed. Reg. V.38, 26447, September 21, 1973).
Amended by R.1974 d.106, effective May 1, 1974.
See: 5 N.J.R. 413(b), 6 N.J.R. 241(b).
Mecoqualone controlled (Fed. Reg. V.40, 28611, July 2, 1975).
Amended by R.1975 d.209, effective July 23, 1975.
See: 7 N.J.R. 353(a).
Difenoxin controlled (Fed. Reg. V.40, 19813, June 1, 1975).
Etorpine HCl rescheduled from schedule I to II (Fed. Reg: V.39, 11535, April 19, 1974).
Peyote defined (Fed. Reg. V.40, April 28, 1975).
Amended by R.1977 d.441, effective November 11, 1977.
See: 9 N.J.R. 466(a), 9 N.J.R. 567(b).
Thiophene analog controlled (Fed. Reg. V.40, 28611, August 11, 1975).
Amended by R.1979 d.27, effective January 17, 1979.
See: 10 N.J.R. 534(b), 11 N.J.R. 67(c).
N–Ethyl–1–phenylcyclohexylamine controlled (Fed. Reg. V.3, 186, September 25, 1978).
1–(1–phenylcyclohexyl) pyrrolidine controlled (Fed. Reg. V.3, 186, September 25, 1978).
Amended by R.1980 d.322, effective July 17, 1980.
See: 12 N.J.R. 467(g).
Dextrorphan decontrolled (Fed. Reg. V.41, 43401–43402, October 1, 1976).
Amended by R.1981 d.50, effective February 9, 1981.
See: 13 N.J.R. 132(b).
(b)1: Added Sufentinil and Tilidine.
Amended by R.1981 d.50, effective February 9, 1981.
See: 13 N.J.R. 132(b).
(b)6 added.
Amended by R.1982 d.124, effective April 19, 1982.
See: 14 N.J.R. 195(a), 14 N.J.R. 389(b).
Amended by R.1982 d.450, effective December 20, 1982, operative January 10, 1983.
See: 14 N.J.R. 1029(b), 14 N.J.R. 1457(b).
Added methaqualone to Schedule 1.
Amended by R.1983 d.339, effective August 15, 1983.
See: 15 N.J.R. 844(a), 15 N.J.R. 1375(a).
Added Parahexyl to (b)3. and also added 6. "Stimulants"—Fenethylline and n-Ethylamphetamine.
Amended by R.1984 d.532, effective November 19, 1984.
See: 16 N.J.R. 2332(a), 16 N.J.R. 3204(a).
(b)1: Added Alfentanil.
Amended by R.1985 d.83, effective March 4, 1985.
See: 16 N.J.R. 2900(a), 17 N.J.R. 592(a).
(b)1: Deleted "Sufentanil".
Amended by R.1985 d.458, effective September 3, 1985.
See: 17 N.J.R. 1511(a), 17 N.J.R. 2138(b).
(b)7 added.
Amended by R.1985 d.669 effective January 6, 1986.
See: 17 N.J.R. 2214(a), 18 N.J.R. 87(a).
(b)7ii added.
Amended by R.1986 d.65, effective March 17, 1986.
See: 17 N.J.R. 2721(a), 18 N.J.R. 555(c).
(b)7iii and iv added.
Amended by R.1986 d.184, effective May 19, 1986.
See: 18 N.J.R. 154(b), 18 N.J.R. 1102(a).
(b)7v.–xii. added.
Amended by R.1986 d.326, effective August 4, 1986.
See: 18 N.J.R. 603(a), 18 N.J.R. 1591(b).
(b)7xii added.
Amended by R.1986 d.457, effective November 17, 1986.
See: 18 N.J.R. 1774(a), 18 N.J.R. 2327(b).
(b)3 "excepted" substituted for "expected".
Amended by R.1987 d.324, effective August 3, 1987.
See: 19 N.J.R. 841(a), 19 N.J.R. 1454(a).
Deleted Alfentanil 9737 and moved it to section 2.
Commissioner's Order, effective March 21, 1988.
See: 20 N.J.R. 1000(c).
Added 3,4–methylenedioxy–N–ethylamphetamine (7404); N–hydroxy–3,4–methylenedioxyamphetamine (7402) and 4–methylaminorex (1590) to Schedule I at (b)3. These drugs were published in the Federal Register on October 15, 1987 (see 52 FR 38225) pursuant to N.J.S.A. 24:21–3(c).
Commissioner's Order, effective March 21, 1988.
See: 20 N.J.R. 1000(d).
Added Beta–hydroxy–3–methylfentanyl (CDS–9830) to Schedule I at (b)3. This drug was published in the Federal Register on January 8, 1988 (see 53 FR 500) pursuant to N.J.S.A. 24:21–3(c).
Commissioner's Order, effective March 23, 1988.
See: 20 N.J.R. 1001(a).
Added Methylenedioxymethamphetamine (CDS–7405) to Schedule I at (b)3. This drug was published in the Federal Register on February 22, 1988 (see FR 5156) pursuant to N.J.S.A. 24:21–3(c).
Commissioner's Order, effective September 14, 1989.
See: 21 N.J.R. 3297(b).
Added 1–[1–(2–thienyl)cyclohexyl]pyrrolidine (CDS 7473) to Schedule I at (b)3, pursuant to N.J.S.A. 24:21–3(c). A final order scheduling this substance was published in the Federal Register on July 6, 1989 (see 54 FR 28414).
Commissioner's order, effective May 1, 1992.
See: 24 N.J.R. 2451(a).
Methcathinone (CDS 1237) added at (b)7xvi. A final order scheduling this substance was published in the Federal Register on May 1, 1992 (see 57 F.R. 18824).
Amended by R.1994 d.325, effective July 5, 1994.
See: 26 N.J.R. 1630(a), 26 N.J.R. 2792(b).
Acetylmethadol 9603 added.

Case Notes

School Board urinalysis drug/alcohol test policy for students unconstitutional: reasonableness test for permissible student search not met. Odenheim v. Carlstadt–East Rutherford Regional School District, 211 N.J.Super. 54 (Ch.Div.1985).

Constructive publication of addition to controlled dangerous substance schedule in New Jersey Register: lack of notice defense denied. State v. Metcalf, 168 N.J.Super. 375 (App.Div.1979), 81 N.J. 411 (1979).

8:65–10.2 Controlled dangerous substances; Schedule II

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

1. The drug or other substance has a high potential for abuse.

2. The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

3. Abuse of the drug or other substance may lead to severe psychological or physical dependence.

(b) The following is Schedule II listing the controlled dangerous substances by generic, established or chemical name and the controlled dangerous substance code number.

1. Substances, vegetable origin or chemical synthesis: Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:

i. Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, dextrophan, nalbuphine, nalmefene, maloxone and naltrexone, and their respective salts, but including the following (listed by generic/established or chemical name with CDS code):

Raw opium	9600
Opium extracts	9610
Opium fluid extracts	9620
Powdered opium	9639
Granulated opium	9640
Tincture of opium	9630
Codeine	9050
Ethylmorphine	9190
Etorphine HCL	9059
Hydrocodone	9133
Hydromorphone	9194
Metopon	9620
Morphine	9300
Oxycodone	9143
Oxymorphone	9652
Thebaine	9333

ii. Any salt, compound, derivative or preparation thereof which is chemically equivalent or identical with any of the substances referred to in subparagraph (i) of this paragraph except that these substances shall not include the isoquinoline akaloids of opium.

iii. Opium poppy and poppy straw (CDS code 9650).

iv. Coca leaves (CDS code 9040) and any salt, compounds, derivative, or preparation of coca leaves, and any salt, compounds, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine (CDS code 9041) or ecgonine (CDS code 9180).

v. Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrine alkaloids of the opium poppy) (CDS code 9670).

2. Opiates: Unless specifically excepted or unless in another schedule, any of the following opiates, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, dextorphan and levopropoxyphene excepted, (listed by generic/established or chemical name with CDS code):

Alfentanil	9737
Alphaprodine	9010
Anileridine	9020
Bezitramide	9800
Carfentanil	9743
Dihydrocodeine	9120
Diphenoxylate	9170
Fentanyl	9801
Isomethadone	9226
Levo-alphacetylmethadol (Some other names: levo-alpha-acetyl-methadol, levomethadyl acetate, LAAM)	9648
Levomethorphan	9210
Levorphanol	9220
Metazocine	9240
Methadone	9250
Methadone–Intermediate, 4–cyano–2–dimethylamino–4, 4–diphenyl butane	9254
Moramide–Intermediate, 2–methyl–3–morpholino–1, 1–diphenylpropane–carboxylic acid	9802
Pethidine	9230
Pethidine–Intermediate–A, 4–cyano–1–methyl–4–phenylpiperidine	9232
Pethidine–Intermediate–B, ethyl–4–phenylpiperidine–4–carboxylate	9233
Pethidine–Intermediate–C, 1–methyl–4–phenylpiperidine–4–carboxylic acid	9234
Phenazocine	9715
Piminodine	9730
Racemethorphan	9732
Racemorphan	9733
Sufentanil	9740

3. 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:

Amphetamine, its salts, optical isomers and salts of its optical isomers	1100
Methamphetamine, its salts, isomers and salts of its isomers	1105
Phenmetrazine and its salt	1630
Methylphenidate	1726

4. Depressants: 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 depressant effect on the central nervous system, 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):

Amobarbital	2125
Glutethimide	2550
Pentobarbital	2270
Phencyclidine	7471
Secobarbital	2315

5. Immediate precursors: Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

i. Immediate precursor to amphetamine and methamphetamine:

(1) Phenylacetone-(Some trade or other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone) (CDS code 8501).

ii. Immediate precursor to phencyclidine (PCP):

(1) 1-phenylcycloheylamine, (CDS code 7460);

(2) 1-piperidinocyclohexane-carbonitrile (PCC)6 (CDS code 8603).

6. Bulk chemical: Bulk dextropropoxyphene (non-dosage forms).

7. Hallucinogenic substances:

i. Dronabinol (synthetic) in sesame oil encapsulated in soft gelatin capsules in a U.S. Food and Drug Administration Approved product	7369.
ii. Some other names for Dronabinol: (6aR-trans)-6a-7, 8, 10a-tetrahydro-6, 6,9-trimethyl-3-pentyl-6H-dibenzyl (b,d) pyran-1-01, or (−)-delta-9-(trans)-tetra-hydrocannabinol.	
iii. Nabilone (another name for Nabilone: (+)-trans-3-(1, 1-dimethylheptyl)-6, 6a, 7, 8, 10a-hexahydro-1-hydroxy-6, 6-dimenthyl-9H-dibenzo(b, d)pyran-9-one).	7379

Amended by R.1973, d.23, effective January 17, 1973.
See: 5 N.J.R. 42(b).
Naloxone decontrolled (Fed. Reg: V.36, 19116, September 29, 1971; V.39, 44392, December 24, 1974).
Amphetamine rescheduled from schedule III to II (Fed. Reg. V.36, 12734, July 7, 1971).
Methamphetamine rescheduled and schedule III to II (Fed. Reg. V.36, 12734, July 7, 1971).
Phenmetrazine rescheduled III to II (Fed. Reg. V.36, 20686, October 28, 1971).
Methylphenidate rescheduled from schedule III to II (Fed. Reg. V.36, 20686, October 28, 1971).
Amended by R.1973 d.147, effective June 5, 1973.
See: 5 N.J.R. 106(b), 5 N.J.R. 222(d).
Methaqualone controlled (Fed. Reg. V.38, 27517, October 4, 1973).
Amended by R.1974 d.2, effective January 2, 1974.
See: 6 N.J.R. 63(a).
Amobarbital rescheduled from schedule III to II (Fed. Reg. V.38, 31310, November 13, 1973).
Secobarbital rescheduled from schedule III to II (Fed. Reg. V.38, 31310, November 13, 1973).
Pentobarbital rescheduled from schedule III to II (Fed. Reg. V.38, 31310, November 13, 1973).
Amended by R.1984 d.35, effective February 21, 1984.
See: 15 N.J.R. 844(a), 16 N.J.R. 369(a).
Glutethimide-2550; added.
Amended by R.1975 d.209, effective July 23, 1975.
See: 7 N.J.R. 363(a).
Naltrexone decontrolled (Fed. Reg. V.40, 10455, March 6, 1975).
Etorphine HCl rescheduled from schedule I to II (Fed. Reg. V.39, 11535, April 19, 1974).
Concentration of poppy straw defined (Fed. Reg. V.40, 6679, February 14, 1975).
Amended by R.1978 d.247, effective July 24, 1978.
See: 10 N.J.R. 238(a), 10 N.J.R. 341(b).
Phencyclidine rescheduled from III to II (Fed. Reg. V.43, 17, January 25, 1978).
Amended by R.1984 d.35, effective February 21, 1984.
See: 15 N.J.R. 844(a), 16 N.J.R. 369(a).
Glutethimide-2550; added.
Amended by R.1978 d.390, effective November 1, 1978.
See: 10 N.J.R. 427(a), 10 N.J.R. 536(b).
Amended by R.1982 d.450, effective December 20, 1982, operative January 10, 1983.
See: 14 N.J.R. 1029(b), 14 N.J.R. 1457(b).
Deleted methaqualone from Schedule II.
Phenylcyclohexylamine and piperidinocyclohexane-carbonitrile (PCC) controlled (Fed. Reg. V.43, 21324-21325, June 16, 1978).
Amended by R.1980 d.37, effective February 11, 1980.
See: 12 N.J.R. 76(a).
Adopted paragraph (b)5.
Phenylacetone controlled (Fed. Reg. V.44, 71822-71824, effective February 11, 1980).
Amended by R.1980 d.38, effective February 11, 1980.
See: 12 N.J.R. 76(b).
Adopted subparagraph ii.
Transfer phenyleyclohexylamine and piperidinocyclohexane-carbonitrile (PCC) from paragraph (b)4 to subparagraph (b)5ii.
Amended by R.1980 d.323, effective July 17, 1980.
See: 12 N.J.R. 468(a).
Apomorphine and nalbuphine (never specifically included) decontrolled (Fed. Reg. V.41, 43401-43402, October 1, 1976).
Amended by R.1981 d.50, effective February 9, 1981.
See: 13 N.J.R. 132(b).
(b)6 added.
Amended by R.1985 d.83, effective March 4, 1985.
See: 16 N.J.R. 2900(a), 17 N.J.R. 592(a).
Amended by R.1986 d.327, effective August 4, 1986.
See: 18 N.J.R. 536(a), 18 N.J.R. 1592(a).
(b)1i: added dextrophan and nalmefene.
Amended by R.1986 d.457, effective November 17, 1986.
See: 18 N.J.R. 1774(a), 18 N.J.R. 2327(b).
(b)7 added.
Amended by R.1987 d.324, effective August 3, 1987.
See: 19 N.J.R. 841(a), 19 N.J.R. 1454(a).
Moved Alfentanil from section 1.
Amended by R.1987 d.339, effective August 17, 1987.
See: 19 N.J.R. 1050(a), 19 N.J.R. 1557(a).
(b)7iii added Nabilone.
Commissioner's Order, effective January 3, 1989.
See: 21 N.J.R. 70(b).
Added Carfentanil (CDS 9743) to Schedule II at (b)2. This drug was published in the Federal Register on October 28, 1988 (see 53 FR 43684) pursuant to N.J.S.A. 24:21-3(c).
Amended by R.1994 d.325, effective July 5, 1994.
See: 26 N.J.R. 1630(a), 26 N.J.R. 2792(b).
Levo-alphacetylmethadol 9648 added.

8:65–10.3 Controlled dangerous substances; Schedule III

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

1. The drug or other substance has a potential for abuse less than the drugs or other substances in Schedules I and II.

2. The drug or other substance has a currently accepted medical use in the United States.

3. Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(b) The following is Schedule III listing the controlled dangerous substances by generic, established or chemical name and the controlled dangerous substances code numbers:

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:

i. Those compounds, mixtures, or preparation in dosage unit form containing any stimulant substances listed in Schedule II which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under 21 CFR 308.32, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances (1405).

ii. The following CDS code (listed by generic/established or chemical name with CDS code):

Benzphetamine	1228
Chlorphentermine	1645
Clortermine	1647
Phendimetrazine	1615

2. Depressants: 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 depressant effect on the central nervous system.

i. Any compound, mixture or preparation containing (listed by generic/established or chemical name with CDS code):

Amobarbital	2126
Secobarbital	2316
Pentobarbital	2271

or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule.

ii. Any suppository dosage form containing (listed by generic/established or chemical name with CDS code):

Amobarbital	2126
Secobarbital	2316
Pentobarbital	2271

or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository.

iii. Any substance which contains any quantity of a derivative of barbituric acid or any salt thereof (C.D.S. 2100).

iv. The following (listed by generic/established or chemical name with CDS code):

Chlorhexadol	2510
Lysergic acid	7300
Lysergic acid amide	7310
Methyprylon	2575
Sulfondiethylmethane	2600
Sulfonethylmethane	2605
Sulfonmethane	2610
Nalorphine	9400

v. Tiletamine and zolazepam or any salt thereof . . . 7295

(1) Some trade or other names for a tiletamine-zolazepam combination product: Telazol. Some trade or other names for tiletamine: 2-2-(2-thienyl)-cyclohexanone. Some trade or other names for zolazepam: 4-(2-fluorophenyl)- 6, 8-dihydro-1, 3, 8-trimethylpyrazolo[3,4,3] [1,4] diazepin-(1H)-one. Flupyrazapon.

3. Narcotic drugs: Unless specifically excepted or unless listed in another schedule, any material, 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:

i. Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium (CDS code 9803).

ii. Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts (CDS code 9804).

iii. Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium (CDS code 9805).

iv. Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts (CDS code 9806).

v. Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts (CDS code 9807) or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts (CDS code 9808).

vi. Not more than 500 milligrams of opium per 100 milliliters or per 100 grams, or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts (CDS code 9809).

vii. Not more than 50 milligrams of morphine per 100 milliliters per 100 grams with one or more active, nonnarcotic ingredients in recognized therapeutic amounts (CDS 9810).

4. Anabolic steroids (CDS Code 4000), with the exception of those anabolic steroid products specified in (b)5 below, as follows:

i. Boldenone;

ii. Chlorotestosterone (4–chlorotestosterone);

iii. Clostebol;

iv. Dehydrochlormethyltestosterone;

v. Dihydrotestosterone (4–dihydrotesterone);

vi. Drostanolone;

vii. Ethylestrenol;

viii. Fluoxymesterone;

ix. Formebulone (formebolone);

x. Mesterolone;

xi. Methandienone;

xii. Methandranone;

xiii. Methandriol;

xiv. Methandrostenolone;

xv. Methenolone;

xvi. Methyltestosterone;

xvii. Mibolerone;

xviii. Nandrolone;

xix. Norethandrolone;

xx. Oxandrolone;

xxi. Oxymesterone;

xxii. Oxymetholone;

xxiii. Stanolone;

xxiv. Stanozolol;

xxv. Testolactone;

xxvi. Testosterone;

xxvii. Trenbolone; and

xxviii. Any salt, ester, or isomer of a drug or substance described or listed above, if that salt, ester, or isomer promotes muscle growth.

5. Table of Exempt Anabolic Steriod products:

Trade name	Company	NDC No.	Form	Ingredients	Quantity
Androgyn L.A.	Forest Pharmaceuticals, St. Louis, MO	0456–1005	Vial	Testosterone enanthate Estradiol valerate	90 mg/ml 4 mg/ml
Andro-Estro 90-4	Rugby Laboratories, Rockville Centre, NY	0536–1605	Vial	Testosterone enanthate Estradiol valerate	90 mg/ml 4 mg/ml
depANDROGYN	Forest Pharmaceuticals, St. Louis, MO	0456–1020	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
DEPO-T.E.	Quality Research Pharm, Carmel, IN	52765–257	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
depTESTROGEN	Martica Pharmaceuticals, Phoenix, AZ	51698–257	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Duomone	Wintec Pharmaceutical, Pacific, MO	52047–360	Vial	Testosterone enanthate Estradiol valerate	90 mg/ml 4 mg/ml
DURATESTRIN	W.E. Hauck, Alpharetta, GA	43797–016	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
DUO-SPAN II	Primedics Laboratories, Gardena, CA	0684–0102	Vial	Testosterone cypionate Esterified cypionate	50 mg/ml 2 mg/ml
Estratest	Solvay Pharmaceuticals, Marietta, GA	0032–1026	TB	Esterified estrogens Methyltestosterone	1.25 mg 2.5 mg
Estratest HS	Solvay Pharmaceuticals, Marietta, GA	0032–1023	TB	Esterified estrogens Methyltestosterone	0.625 mg 1.25 mg
PAN ESTRA TEST	Pan American Labs, Covington, LA	0525–0175	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Premann with Methyltestosterone	Ayerst Labs Inc., New York, NY	0046–0879	TB	Conjugated estrogens Methyltestosterone	1.25 mg 10.0 mg
Premann with Methyltestosterone	Ayerst Labs Inc.,New York, NY	0046–0878	TB	Conjugated estrogens Methyltestosterone	0.625 mg 5.0 mg
Synovex H Pellets in process	Syntex Animal Health, Palo Alto, CA		Drum	Testosterone propionate Estradiol benzoate	25 mg 2.5 mg
Synovex H Pellets in process granulation	Syntex Animal Health, Palo Alto, CA		Drum	Testosterone propionate Estradiol benzoate	10 parts 1 part

Trade name	Company	NDC No.	Form	Ingredients	Quantity
TEST-ESTRO Cypionates	Rugby Laboratories, Rockville Centre, NY	0536–9470	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Testagen	Clint Pharmaceuticals, Nashville, TN	55553–257	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Testosterone Cyp 50 Estradiol Cyp 2	I.D.E.-Interstate, Amityville, NY	0814–7737	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Testosterone Cypionate—Estradiol Cypionate Injection	Best Generics, No. Miami Beach, FL	54274–530	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Testosterone Cypionate—Estradiol Cypionate Injection	Goldline Labs, Ft. Lauderdale, FL	0182–3069	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Testosterone Cypionate—Estradiol Cypionate Injection	Schein Pharmaceuticals, Port Washington, NY	0364–6611	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Testosterone Cypionate—Estradiol Cypionate Injection	Steris Labs, Inc., Phoenix, AZ	0402–0257	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Testosterone Cypionate—Estradiol Cypionate Injection	The Upjohn Co., Kalamazoo, MI	0009–0253	Vial	Testosterone cypionate Estradiol cypionate	50 mg/ml 2 mg/ml
Testosterone Enanthate—Estradiol Valerate Injection	Goldline Labs, Ft. Lauderdale, FL	0182–3073	Vial	Testosterone enanthate Estradiol valerate	90 mg/ml 4 mg/ml
Testosterone Enanthate—Estradiol Valerate Injection	Schein Pharmaceuticals, Port Washington, NY	0364–6618	Vial	Testosterone enanthate Estradiol valerate	90 mg/ml 4 mg/ml
Testosterone Enanthate—Estradiol Valerate Injection	Steris Labs, Inc., Phoenix, AZ	0402–0360	Vial	Testosterone enanthate Estradiol valerate	90 mg/ml 4 mg/ml
Tilapia Sex Reversal Feed (Investigational)	Zeigler Brothers, Inc., Gardners, PA		Plastic bags	Methyltestosterone fish feed	60 mg/1 kg

As amended, R.1973 d.23, effective January 17, 1983.
See: 5 N.J.R. 42(b).
Amphetamine rescheduled from schedule III to II (Fed. Reg. V.36, 12734, July 7, 1974).
Methamphetamine rescheduled from schedule III to II (Fed. Reg. V.36, 12734, July 7, 1974).
Phenmetrazine rescheduled from schedule III to II (Fed. Reg. V.36, 20686, October 28, 1971).
Methylphenidate rescheduled from III to II (Fed. Reg. V.36, 20686, October 28, 1971).
As amended, R.1974 d.2, effective January 2, 1974.
See: 6 N.J.R. 53(a).
Amobarbital (except in suppository form or in combination with one or more active medicinal ingredients) rescheduled from schedule III to II (Fed. Reg. V.38, 31310, November 13, 1973).
Secobarbital rescheduled from schedule III to II (Fed. Reg. V.38, 31310, November 13, 1973).
Pentobarbital rescheduled from schedule III to II (Fed. Reg. V.38, 31310, November 13, 1973).
Benzphetamine controlled (Fed. Reg. V.38, 15719, June 15, 1973).
Chlorphentermine controlled (Fed. Reg. V.38, 15719, June 15, 1973).
Clortermine controlled (Fed. Reg. V.38, 15719, June 15, 1973).
Mazindol controlled (Fed. Reg. V.38, 15719, June 15, 1973).
Phendimetrazine controlled (Fed. Reg. V.38, 15719, June 15, 1973).
Amended by R.1987 d.339, effective August 17, 1987.
See: 19 N.J.R. 911(a), 19 N.J.R. 1557(a).
Changed code numbers.
Schedule II stimulates in dosage form listed on August 25, 1971 as excepted compounds under section 308.32 controlled (Fed. Reg. V.38, 15719, June 15, 1973).
As amended, R.1978 d.247, effective July 24, 1978.
See: 10 N.J.R. 238(a), 10 N.J.R. 341(b).
Phencyclidine rescheduled from schedule III to II (Fed. Reg. V.43, 17, January 25, 1978).
As amended, R.1984 d.35, effective February 21, 1984.
See: 15 N.J.R. 844(a), 16 N.J.R. 369(a).
Glutethimide—2550; deleted.
As amended, R.1979 d.301, effective August 6, 1979.
See: 11 N.J.R. 440(e).
Amended text of paragraph (b)3.
As amended, R.1982 d.124, effective April 19, 1982.
See: 14 N.J.R. 195(a), 14 N.J.R. 389(b).
(b)1ii: Deleted "mazindol 1605".
Amended by R.1987 d.337, effective August 17, 1987.
See: 19 N.J.R. 497(a), 19 N.J.R. 1557(b).
Added (b)2v Tiletamine.
Amended by R.1987 d.339, effective August 17, 1987.
See: 19 N.J.R. 911(a), 19 N.J.R. 1557(a).
Changed code numbers.
Amended by Commissioner's Order.
See: 23 N.J.R. 1943(b).
Anabolic steroids added at (b)4.
Commissioner's Order, effective June 15, 1992.
See: 24 N.J.R. 2256(b).
Spelling corrected in (b)4; salts, esters and isomers added.
Amended by R.1997 d.326, effective August 4, 1997.
See: 29 N.J.R. 2262(a), 29 N.J.R. 3450(b).

8:65–10.4 Controlled dangerous substances; schedule IV

(a) The following are criteria for inclusion in schedule IV of controlled dangerous substance.

1. The drug or other substance has a low potential for abuse relative to the drugs or other substances in Schedule III.

2. The drug or other substance has a currently accepted medical use in treatment in the United States.

3. Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule III.

(b) The following is Schedule IV listing the controlled dangerous substances by generic, established or chemical name and the controlled dangerous substances code numbers.

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

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).
Clonazepan 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 subchapter may be reviewed in the office of the Drug Control Unit.

As Amended, R.1978 d.60, effective February 21, 1978.
See: 10 N.J.R. 11(b), 10 N.J.R. 103(d).
Amended by R.2002 d.276, effective August 19, 2002.
See: 33 N.J.R. 2754(a), 34 N.J.R. 3024(a).
In (c), substituted "subchapter" for "proposal", and substituted "the Drug Control Unit" for "Drug Control, Consumer Health Services, CN 362, Trenton, NJ 08625 (609-392-1180)".

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 subchapter may be reviewed in the office of the Drug Control Unit.

As amended, R.1978 d.61, effective February 21, 1978.
See: 10 N.J.R. 11(a), 10 N.J.R. 103(e).
Amended by R.2002 d.276, effective August 19, 2002.
See: 34 N.J.R. 2754(a), 34 N.J.R. 3024(a).
In (c), substituted "subchapter" for "proposal", and substituted "the Drug Control Unit" for "Drug Control, Consumer Health Services, CN 362, Trenton, NJ 08625 (609-392-1180)".

8:65–10.8 Exempt chemical preparations

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

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).
Amended by R.2002 d.276, effective August 19, 2002.
See: 33 N.J.R. 2754(a), 34 N.J.R. 3024(a).
Deleted (b); recodified former (a) as an uncodified paragraph.

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 or detoxification treatment with narcotic drugs.

Amended by R.2002 d.276, effective August 19, 2002.
See: 34 N.J.R. 2754(a), 34 N.J.R. 3024(a).
In "Narcotic treatment program", inserted "or" between "maintenance" and "detoxification".

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

1. The acceptance of delivery of narcotic substances by a narcotic treatment program shall be made only by a licensed practitioner employed at the facility or other authorized individuals designated in writing. At the time of delivery, the licensed practitioner or other authorized individual in writing (excluding persons currently or previously dependent on narcotic drugs), shall sign for the narcotics and place his specific title (if any) on any invoice. Copies of these signed invoices shall be kept by the distributor.

2. Narcotics dispensed or administered at a narcotic treatment program will be dispensed or administered directly to the patient by either the licensed practitioner or a registered nurse under direction of the licensed practitioner, a licensed practical nurse under the direction of the licensed practitioner, or a pharmacist under the direction of the licensed practitioner.

3. Persons enrolled in a narcotic treatment program will be required to wait in an area physically separated from the narcotic storage and dispensing area.

4. All narcotic treatment programs must comply with the provisions of N.J.S.A. 26:2G–21 through 30; and with standards established by the Secretary of the Federal Department of Health and Human Services (after consultation with the Drug Enforcement Administration) respecting the quantities of narcotic drugs which may be provided to persons enrolled in a narcotic treatment program for unsupervised use.

5. The Department 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.

Amended by R.2002 d.276, effective August 19, 2002.
See: 33 N.J.R. 2754(a), 34 N.J.R. 3024(a).
In (b), substituted "(a) above" for "subsection (a) of this section" in the introductory paragraph, rewrote 4, and substituted "The Department" for "The New Jersey Department of Health" in 5.

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, repackaging or relabeling);

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

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

(5) The number of containers distributed to other programs, including the date, the number of containers in each distribution, and the name, address and registration number of the program to whom the containers were distributed;

(6) The number of commercial containers exported directly by the registrant (under a registration as an exporter), including the date, number of containers and export permit or declaration number of each exportation;

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