(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".

13:45H-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. 13:45H-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).

13:45H-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.

13:45H-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.

13:45H-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 CFR 1305.13 except that:

1. Order forms or electronic orders 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 or as specified in the electronic order 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).
Amended by R.2008 d.58, effective March 17, 2008.
See: 39 N.J.R. 3854(a), 40 N.J.R. 1680(a).
In the introductory paragraph of (b), substituted "CFR 1305.13" for "C.F.R. 1305.09"; in (b)1, inserted "or electronic orders"; and in (b)2, inserted "as specified in the electronic order" and a comma following "outside".

SUBCHAPTER 7. PRESCRIPTION REQUIREMENTS FOR CONTROLLED DANGEROUS SUBSTANCES

13:45H-7.1 Scope

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

13:45H-7.2 Definitions

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

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

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

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

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

"Pharmacist" means any pharmacist licensed by the State of New Jersey to dispense controlled substances and shall include any other person (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.).

13:45H-7.3 Persons entitled to issue prescriptions

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

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

2. Either registered or exempted from registration pursuant to 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".

13:45H-7.4 Purpose of issue of prescription

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

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

(c) A prescription may not be used for the dispensing of narcotic drugs listed in any schedule for "detoxification" or "maintenance treatment" as defined in N.J.A.C. 13:45H-11.1.

Cross References

Additional requirements, see N.J.A.C. 13:45H-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).

13:45H-7.5 Manner of issuance of prescriptions

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the full name, address, proper academic degree or other definitive identification of the professional practice for which he or she is licensed and registration number of the practitioner. All prescriptions for controlled substances, regardless of schedules, shall be presented to the pharmacist for filling

within 30 days after the date when issued. 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.

Cross References

Oral prescriptions, see N.J.A.C. 13:45H-7.13.

13:45H-7.6 Persons entitled to fill prescriptions

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

13:45H-7.7 Administering or dispensing of narcotic drugs

(a) The administering or dispensing directly (but not prescribing) of narcotic drugs listed in any schedule to a narcotic drug dependent person for "detoxification treatment" or "maintenance treatment" as defined in N.J.A.C. 13:45H-11.1 shall be deemed to be within the meaning of the term "in the course of professional practice or research"; provided that the practitioner is separately registered with the Drug Control Unit as required by N.J.A.C. 13:45H-11.2 and then thereafter complies with the regulatory standards imposed relative to treatment qualifications, security, records and unsupervised use of drugs pursuant to the Act.

(b) Nothing in this section shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three days and may not be renewed or extended.

(c) This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts.

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 "provided" for "Provided" and "Drug Control Unit" for "Department of Health".

Case Notes

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

13:45H-7.8 Requirements of prescriptions; schedule II

(a) A pharmacist may dispense directly a controlled substance listed in schedule II, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the prescribing individual practitioner, except as provided in (d) below.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in schedule II in the course of his professional practice without a prescription, subject to N.J.A.C. 13:45H-7.6.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user.

(d) In the case of an emergency situation, as defined by the Secretary in the Code of Federal Regulations, Title 21, part

290.10, a pharmacist may dispense a controlled substance listed in schedule II upon receiving oral authorization of a prescribing individual practitioner, provided that:

1. The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period not to exceed 72 hours (dispensing beyond the emergency period must be pursuant to a written prescription signed by the prescribing individual practitioner);

2. The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in N.J.A.C. 13:45H-7.4, except for the signature of the prescribing individual practitioner;

3. If the prescribing individual practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory and/or other good faith efforts to insure his identity; and

4. Within 72 hours after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed (not to exceed the amount for a 72 hour period) to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of N.J.A.C. 13:45H-7.4, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 72-hour period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacist shall notify the Drug Control Unit and the nearest office of the DEA in his district if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense with a written prescription of a prescribing individual practitioner.

(e) A practitioner shall not prescribe or dispense a schedule II controlled substance to an individual patient in excess of the limits set forth at N.J.A.C. 13:35-7.6, except that prescriptions for patients in a Long Term Care Facility (LTCF) may be in amounts as set forth in N.J.A.C. 13:45H-7.10(d).

Amended by R.1999 d.71, effective March 1, 1999.
See: 30 N.J.R. 1364(a), 31 N.J.R. 678(a).
In (e), substituted "the limits set forth at N.J.A.C. 13:35-7.6" for "120 dosage forms or a 30 days' supply, whichever is the lesser amount" following "excess of".
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)4, substituted "Drug Control Unit" for "Department of Health".

13:45H-7.9 Refilling prescriptions; schedule II

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

13:45H-7.10 Partial filling of prescriptions; schedule II

(a) The partial filling of a prescription for a controlled substance listed in schedule II is permissible, if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription).

(b) The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall so notify the prescribing individual practitioner.

(c) No further quantity may be supplied beyond 72 hours without a new prescription.

(d) Prescriptions for schedule II controlled substances written for patients in a Long Term Care Facilities (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist shall contact the practitioner prior to partially filling the prescription. Both the pharmacist and practitioner shall assure that a controlled substance is for a terminally ill patient. The pharmacist shall record on the prescription whether the patient is "terminally ill" or an "LTCF" patient. A prescription that is partially filled and does not contain the notation that the patient is "terminally ill" or a patient in a "LTCF" shall be deemed to have been filled in violation of N.J.S.A. 24:21. For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed and the identification of the dispensing pharmacist. Prior to any subsequent partial filling, the pharmacist shall determine that the additional partial filling is necessary. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions, for patients in a LTCF, or patients with a medical diagnosis documenting a terminal illness, shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of the medication.

(e) Information pertaining to current Schedule II prescriptions for patients in a LTCF or for patients with a medical diagnosis documenting a terminal illness may be maintained in a computerized system if this system has the capability to permit: