"Intractable pain" means pain which has been shown to be refractory or resistant to management with standard methods of treatment or for which insufficient relief has been found after reasonable efforts.

"Narcotic" means an analgesic drug which chemically and pharmacologically acts as an opioid.

"Non-prescription substance" means an over-the-counter preparation, a vitamin or food supplement, or any compounded combination of any of these preparations and supplements or a transdermal patch or strip for which no prescription is required pursuant to law.

"Practitioner" means any licensee subject to the regulatory authority of the Board authorized to prescribe or dispense drugs, including physicians, podiatrists and, to the extent permitted by law and rule, registered residents, resident permit holders, physician assistants and certified nurse midwives.

"Prescribing" means the act of directing that a patient take a drug included in prescription legend through either a written or verbal order.

"Terminal illness" means a diagnosed medical condition with a prognosis of less than one year.

Petition for Rulemaking.
See: 30 N.J.R. 1643(a), 31 N.J.R. 2658(b).
Amended by R.2000 d.400, effective October 2, 2000.
See: 31 N.J.R. 2454(a), 32 N.J.R. 3576(a).
In definition of "Drug", substituted "medicine" for "medication"; and inserted definition for "Non-prescription substance".

13:35-7.1A Examination of patient's condition required prior to dispensing drugs or issuing a prescription; exceptions

(a) Except as provided in (b) below, a practitioner shall not dispense drugs or issue prescriptions to an individual, pursuant to the requirements of this subchapter, without first having conducted an examination, which shall be appropriately documented in the patient record. As part of the patient examination, the practitioner shall:

1. Perform an appropriate history and physical examination;

2. Make a diagnosis based upon the examination and all diagnostic and laboratory tests consistent with good medical care;

3. Formulate a therapeutic plan and discuss such plan, along with the basis for the plan and the risks and benefits of various treatment options, with the patient; and

4. Ensure the availability of the physician or coverage for the patient for appropriate follow-up care.

(b) Notwithstanding (a) above, an examination of the patient's condition shall not be required prior to the dispensing of drugs or the issuance of a prescription under the following circumstances:

1. In admission orders for a newly hospitalized patient;

2. For a patient of another physician for whom the practitioner is taking calls;

3. For continuation medications on a short term basis for a new patient prior to the patient's first appointment;

4. For an established patient who, based on sound medical practice, the physician believes does not require a new examination before issuing a new prescription;

5. For a patient examined by a healthcare professional who is in collaborative practice with the practitioner; and

6. When treatment is provided by a practitioner for an emergency medical condition.

(c) For purposes of this section, the term "emergency medical condition" as used in (b) above means:

1. A medical condition manifesting itself by acute symptoms of sufficient severity, including severe pain, such that the absence of immediate medical attention could reasonably be expected to result in:

i. Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;

ii. Serious impairment to bodily functions; or

iii. Serious dysfunction of any bodily organ or part.

New Rule, R.2003 d.372, effective September 15, 2003.
See: 34 N.J.R. 3059(a), 35 N.J.R. 4287(a).

13:35-7.2 Requirements for issuing written prescriptions for medicines

(a) A practitioner, acting within the scope of lawful practice and after an examination or evaluation of the patient's condition, may issue a written prescription for a drug to a patient, guardian or authorized representative in the form authorized by this section. The practitioner shall assure that appropriate follow-up is provided and that the effects of the drug are properly evaluated and integrated into the treatment plan for the patient.

(b) (Reserved)

(c) Written prescriptions shall be issued only on New Jersey Prescription Blanks (NJPB), secured from an approved vendor and subject to the required security mandates of the prescription blank program.

(d) A practitioner shall include the following information on each written prescription:

1. The prescribing practitioner's full name, address, telephone number, license number, and proper academic degree or identification of professional practice for which licensed;

2. The full name, age and address of the patient;

3. The date of issuance;

4. The name, strength and quantity of the drug prescribed;

5. Words, in addition to numbers, to indicate the drug quantity authorized if the prescription is for a Schedule II controlled substance, for example: ten (10) Percodan; or five (5) Ritalin 5 mg;

6. The number of refills permitted or time limit for refills, or both;

7. The handwritten original signature of the prescribing practitioner;

8. An explicit indication, by initials placed next to "do not substitute" (see (e) below), if it is the prescribing practitioner's intention that a specified brand name drug be dispensed;

9. The prescribing practitioner's D.E.A. number, if the drug is a controlled substance; and

10. Adequate instruction for the patient as to frequency; a direction of "p.r.n." or "if needed" alone may be used if appropriate.

(e) A prescribing practitioner shall advise each patient by adequate notice, for example, by a sign or pamphlet in the waiting room of the office, that the patient may request the practitioner to substitute a generic drug for any brand name drug prescribed.

(f) Each practitioner shall use only written prescription blanks which shall be imprinted with the words "substitution permissible" and "do not substitute," with a space for the prescribing practitioner's initials next to the chosen option, and which shall not include preprinted information designed to discourage or prohibit substitution.

(g) When using health care facility or multi-prescriber prescription blanks, the full name and license number of the prescribing practitioner shall be legibly printed at the top of the prescription or the identity of the prescriber shall be designated by a checkmark or other legible means.

(h) Each prescription for a controlled substance shall be written on a separate NJPB.

1. An NJPB that contains prescriptions for two or more controlled substances shall be invalid.

2. An NJPB that contains a prescription for only one controlled substance and contains other prescription(s) other than another controlled substance shall be valid.

Amended by R.2000 d.400, effective October 2, 2000.
See: 31 N.J.R. 2454(a), 32 N.J.R. 3576(a).
Inserted a new (c), and recodified former (c) as (d); in the new (d), inserted ", license number," following "telephone number" in 1; recodified former (d) through (f) as (e) and (g); rewrote the new (g); and added (h).
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
In (h), added 1 and 2.

Case Notes

Charges of misconduct against physician who prescribed medication to his girlfriend were dismissed due to his familiarity with her medical history and her sophisticated knowledge of such medication. In the Matter of the Suspension or Revocation of the License of Kunish, 96 N.J.A.R.2d (BDS) 9.

13:35-7.3 Verbal prescriptions (Reserved)

13:35-7.4 Facsimile transmitted prescriptions

(a) A practitioner, acting within his or her scope of lawful practice and after an examination of the patient's condition, consistent with the requirements of N.J.A.C. 13:35-7.1A, may transmit, or have an authorized agent transmit, a facsimile prescription to a pharmacy which has been approved by a patient, a patient's guardian, or a patient's authorized representative, consistent with the requirements of this section. For purposes of this section, "facsimile prescription" means a prescription issued by the practitioner which is transmitted by a device which sends an exact image to the receiver.

(b) A practitioner shall comply with all requirements set forth in this subchapter, and shall ensure that all information required to be included on a written prescription pursuant to N.J.A.C. 13:35-7.2(d) is provided on each facsimile prescription, except that an NJPB shall not be required for the prescription.

(c) The transmission of a facsimile prescription shall contain the following:

1. The identification number of the facsimile machine which is used to transmit the prescription to the pharmacy;

2. The time and date of the transmission of the prescription;

3. The name, address, telephone number and facsimile number of the pharmacy to which the prescription is being transmitted; and

4. If an authorized agent transmits the facsimile prescription, the full name and title of the transmitting agent.

(d) A practitioner shall provide verbal verification of the facsimile prescription upon request of the pharmacy when the pharmacist has a question regarding the authenticity, accuracy or appropriateness of the prescription. A practitioner's authorized agent may provide verbal verification of the facsimile prescription to the pharmacy when the pharmacist has a question regarding the authenticity or legibility of the prescription.

(e) A practitioner or his or her authorized agent may transmit a facsimile prescription to a pharmacy for a Schedule II controlled substance, provided that the patient is given the original signed NJPB which is presented to the pharmacist prior to the dispensing of the controlled substance, except as provided in (e)1, 2 and 3 below:

5. Treatments and drugs prescribed or provided, as in (a) above;

6. Any agreements with the patient; and

7. Periodic reviews conducted.

Amended by R.2003 d.263, effective July 7, 2003.
See: 34 N.J.R. 3441(a), 35 N.J.R. 2935(a).
Rewrote (c).
Amended by R.2011 d.155, effective June 6, 2011.
See: 42 N.J.R. 1310(a), 43 N.J.R. 1359(b).
In (c)1, deleted "and" from the end; in (c)2, substituted "; and" for a period at the end; and added (c)3.

13:35-7.7 Prohibitions on prescribing, administering or dispensing of controlled substances for detoxification; limited exceptions

(a) A practitioner shall not issue a prescription for a narcotic drug or for a depressant drug listed in any schedule which drug is intended for the purpose of "detoxification" or "maintenance treatment."

(b) Unless registered with the Division of Consumer Affairs to conduct a narcotic treatment program pursuant to N.J.S.A. 24:21-10 and N.J.A.C. 13:45H-11.2, a practitioner shall not dispense or administer a narcotic drug or a depressant drug listed in any schedule which drug is intended for the purpose of "detoxification" or "maintenance treatment," except:

1. To relieve acute withdrawal symptoms, provided that:

i. Such treatment shall not exceed 72 hours;

ii. No more than one day's supply of the drug is provided to the patient at a time; and

iii. Arrangements are made for referring the patient to an addiction specialist or a drug treatment program for treatment; or

2. As an adjunct to other medical or surgical treatment for conditions other than addiction in a licensed health care facility.

Amended by R.2000 d.400, effective October 2, 2000.
See: 31 N.J.R. 2454(a), 32 N.J.R. 3576(a).
In (a), and (b), inserted references to depressant drugs.
Administrative change.
See: 43 N.J.R. 1204(b).

13:35-7.8 Prohibitions and limitations in the prescribing, administering or dispensing of amphetamines and sympathomimetic amines

(a) A practitioner shall not prescribe, order, dispense, administer, sell or transfer any amphetamine or sympathomimetic amine designated as a Schedule II controlled substance for use in weight management, dieting or any other anorectic purpose, or for the treatment of fatigue.

(b) A practitioner may prescribe, dispense or administer amphetamine or sympathomimetic amine drugs or compounds designated as Schedule II controlled substances, only as follows:

1. For the treatment of the following conditions:

i. Narcolepsy established by recognized diagnostic criteria;

ii. Idiopathic Central Nervous System Hypersomnia established by recognized diagnostic criteria;

iii. Attention Deficit Disorder established by recognized diagnostic criteria;

iv. Drug-induced brain dysfunction;

v. Epilepsy;

vi. Depression shown to be refractory to other therapeutic modalities; and

vii. Senile apathetic behavior;

2. For immediate use in a hospital for acute conditions such as depression associated with illness or surgery;

3. For the differential diagnostic psychiatric evaluation of depression; or

4. For the clinical investigation of the effects of such drugs or compounds in which case, in addition to other requirements of applicable law, prior application therefor shall have been made to the Board and approval granted before any such investigation is begun.

(c) A practitioner who prescribes, dispenses or administers amphetamines or sympathomimetic amines shall prepare and maintain patient medical records which accurately reflect the utilization of any drug subject to this section, the specific diagnosis, the information upon which the diagnosis is based, including testing and consultations, and the treatment objectives for which the drug is being prescribed.

(d) The following list, although not exhaustive or exclusive, includes many of the generic and brand-name Schedule II drugs which are subject to this section:

Adderall
Amphetamine
Desoxyn
Dexedrine
Dextroamphetamine
Methamphetamine
Methylphenidate
Ritalin

13:35-7.9 Prohibitions and special limitations on prescribing, administering or dispensing anabolic steroids

(a) Unless an accepted medical necessity exists, a practitioner shall not prescribe, order, dispense, administer, sell or

transfer any anabolic steroid or human growth hormone, for the purpose of hormonal manipulation intended to increase muscle mass, strength or weight. Body building, muscle enhancement, or increasing muscle bulk or strength through the use of anabolic steroid or human growth hormone by a person in good health for the intended purpose of improving performance in any form of exercise, sport or game is not a valid medical purpose.

(b) A practitioner shall prepare and maintain patient medical records which accurately reflect the utilization of any substance or drug subject to this section, which records must indicate the diagnosis, the information upon which the diagnosis is based, and the purpose for which the substance or drug has been prescribed.

(c) The following list, although not exhaustive or exclusive, includes many of the generic and brand-name anabolic steroids and human growth hormones subject to this section:

Bolenone
Chlorotestosterone
(4-chlortestosterone)
Chorionic gonadotropin
Closebol
Dehydrochlormethyltestosterone
Dihydrotestosterone
(4-dihydrotesterone)
Ethylestrenol
Fluoxymesterone
Mesterolone
Methandienone
Methandriol
Methandrostenolone
Methenolone
Methyltestosterone
Mibolerone
Nandrolone
Norethandrolone
Oxandrolone
Oxymesterone
Oxymetholone
Somatrem
Somatropin
Stanolone
Stanozolol
Testolactone
Testosterone
Trebolone

13:35-7.10 Enforcement

(a) A violation of N.J.A.C. 13:35-7.1 through 7.9 may be deemed to constitute one or more of the following:

1. Distribution or dispensing of a controlled substance in an indiscriminate manner, or not in good faith, or without good cause, as prohibited by N.J.S.A. 45:1-21(e);

2. Gross or repeated malpractice, neglect, or incompetence in the practice of medicine, as prohibited by N.J.S.A. 45:1-21(c) and (d);

3. Professional misconduct, as prohibited by N.J.S.A. 45:1-21(e);

4. A failure to comply with the provisions of an Act or regulation administered by the Board, as prohibited by N.J.S.A. 45:1-21(h); and

5. Unprofessional conduct, which would present an imminent danger to an individual patient or to the public health, safety or welfare, within the meaning of N.J.S.A. 45:1-37(a).

(b) A practitioner who is in possession of information that reasonably indicates that another practitioner has prescribed, dispensed or administered any drug or drugs in a manner that jeopardizes the public health, safety or welfare or for purposes deemed to be unlawful pursuant to this subchapter shall report such information to the Board pursuant to N.J.S.A. 45:1-37.

Amended by R.2011 d.155, effective June 6, 2011.
See: 42 N.J.R. 1310(a), 43 N.J.R. 1359(b).
In (a)1, (a)5 and (b); updated the N.J.S.A. reference; and in (b), substituted the first and third occurrences of "that" for "which".

SUBCHAPTER 8. HEARING AID DISPENSERS

13:35-8.1 Purpose

The rules in this subchapter are established pursuant to N.J.S.A. 45:9A-7 and govern the licensing and the practice of hearing aid dispensing in the State of New Jersey.

13:35-8.2 Definitions

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

"Act" means the New Jersey Hearing Aid Dispensers Act, N.J.S.A. 45:9A-1 et seq. as amended and/or supplemented.

"Advertisement" means any attempt, directly or indirectly, by publication, display, dissemination or circulation, in print or electronic media, which induces or attempts to induce any person to purchase or enter into an agreement to purchase a hearing aid, services and/or merchandise from a licensee.

"Board" means the State Board of Medical Examiners.

"Committee" means the Hearing Aid Dispensers Examining Committee.

"Hearing aid" means a hearing aid as defined by N.J.S.A. 45:9A-2(c) and includes the earmold system.