CHAPTER 35

BOARD OF MEDICAL EXAMINERS

Authority

N.J.S.A. 45:9–2.

Source and Effective Date

R.1994 d.522, effective September 19, 1994.
See: 26 N.J.R. 2526(a), 26 N.J.R. 4195(a).

Executive Order No. 66(1978) Expiration Date

Chapter 35, Board of Medical Examiners, expires on September 19, 1999.

Chapter Historical Note

Chapter 35, Board of Medical Examiners, was filed and became effective prior to September 1, 1969. Chapter 35, except Subchapter 8, Hearing Aid Dispensers, was repealed and new rules of the Board of Medical Examiners, Subchapters 1 through 6, were adopted as R.1983 d.314, effective August 1, 1983. See: 15 N.J.R. 503(a), 15 N.J.R. 1255(a). Subchapter 7, Chiropractic Practice, was adopted as R.1984 d.533, effective November 19, 1984. See: 16 N.J.R. 686(a), 16 N.J.R. 3208(a).

Pursuant to Executive Order No. 66(1978), Chapter 35 was readopted as R.1989 d.532, effective September 21, 1989. See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a). Subchapter 6A, Declarations of Death upon the Basis of Neurological Criteria, was adopted as R.1992 d.309, effective August 3, 1992. See: 23 N.J.R. 3635(a), 24 N.J.R. 2731(c). Subchapter 2A, Limited Licenses: Certified Nurse Midwifery, was adopted as R.1992 d.332, effective Subchapter 8, 1992. See: 23 N.J.R. 3632(a), 24 N.J.R. 3094(a). Subchapter 9, Acupuncture, was adopted as R.1993 d.299, effective June 21, 1993. See: 24 N.J.R. 4013(a), 25 N.J.R. 2689(c). Subchapter 10, Athletic Trainers, was adopted as R.1993 d.546, effective November 1, 1993. See: 25 N.J.R. 265(a), 25 N.J.R. 4935(a), 26 N.J.R. 483(a).

Pursuant to Executive Order No. 66(1978), Chapter 35 was readopted as R.1994 d.522. See: Source and Effective Date. As a part of R.1994 d.522, Subchapter 7, Chiropractic Practice, was repealed, effective October 17, 1994. See: 26 N.J.R. 2526(a), 26 N.J.R. 4195(a). Subchapter 11, Alternate Resolution Program, became effective June 19, 1995. See: 27 N.J.R. 640(a), 27 N.J.R. 2410(a). See, also, section annotations.

Public Notice: Petition for rulemaking. See: 30 N.J.R. 740(c).

Law Review and Journal Commentaries

How New Jersey Regulates Doctors. Theodosia Tamborlane, 132 N.J.L.J. No. 15, S24 (1992).

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SUBCHAPTER 7. PRESCRIPTION, ADMINISTRATION AND DISPENSING OF DRUGS

Authority

N.J.S.A. 45:9–2 and 45:9–22.11.

Source and Effective Date

R.1997 d.475, effective November 3, 1997.
See: 29 N.J.R. 842(a), 29 N.J.R. 4706(a).

13:35–7.1 Definitions

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

"Actual acquisition cost" means the cost actually incurred by the practitioner in acquiring a drug from a supplier and shall not include any amounts charged by any entity in which the practitioner has a direct or indirect financial or other beneficial interest.

"Administer" means the physical, in-person provision of a drug by way of injection, vaccine, allergenic extract or nebulized preparation or the provision of multiple dose vials of injectable medications.

"Amphetamine or sympathomimetic amine" means a drug which, chemically and pharmacologically, acts as a central nervous system stimulant.

"Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogen, progestin and corticosteroids), which promotes muscle growth, as well as any salt, ester, or isomer of such substance which acts in a similar manner in the human body.

"Controlled substance" means a drug classified in any of the schedules (I through V) of the Controlled Dangerous Substances Act, N.J.S.A. 24:21–5 to 24:21–8.1, recognized to have a potential for abuse or to lead to physical or psychological dependence.

"Dispensing" means the distribution of drugs intended by the physician for the personal use of the patient. "Dispensing" as used in this subchapter does not include the in-office administration of injections, vaccines, allergenic extracts or nebulized preparations or the provision of multiple dose vials of injectable medication.

"Drug" means any article recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement to those sources, including, but not limited to, a controlled substance, a prescription legend drug, an over-the-counter preparation, a vitamin or food supplement, or any compounded combination of any of the above or transdermal patch or strip, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or medical condition in humans or intended to affect the structure or function of the human body. The term, as used in this subchapter, is synonymous with "medication" as used in N.J.S.A. 45:9–22.11. "Drug," as used in this subchapter, does not mean a device or durable medical equipment.

"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.

"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.

13:35–7.2 Requirements for issuing written prescriptions for drugs

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

1. The prescribing practitioner's full name, address, telephone 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.

(d) 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.

(e) 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.

(f) When preprinted prescription blanks are not available, the full name of the prescribing practitioner must be legibly printed or stamped under the original signature.

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 Electronically transmitted prescriptions (Reserved)

13:35–7.5 Requirements for the dispensing of drugs and special limitations applicable to the dispensing of drugs for a fee

(a) A practitioner, acting within the scope of lawful practice and after an examination or evaluation of the patient's condition, may dispense a drug directly to a patient, guardian or authorized representative under the circumstances and limitations set forth in 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) A practitioner who dispenses drugs in the office shall maintain those drugs in an area kept in an orderly and sanitary manner, and in accordance with standard pharmaceutical practice and manufacturer recommendations concerning storage conditions, including refrigeration, where necessary. A practitioner shall not maintain in inventory any drugs which are outdated, misbranded, deteriorated, adulterated, recalled, unlabeled, damaged, discontinued or which were previously dispensed to a patient. A practitioner shall be responsible for the disposal of such drugs in a manner which will not pose a health hazard and in accordance with all local, State and Federal requirements.

(c) All drugs dispensed shall be recorded in the applicable patient record.

(d) All drugs dispensed, with the exception of samples of drugs which are not controlled substances and which are packaged and labeled by the manufacturer, shall be recorded in a permanent, contemporaneous dispensing log which shall contain, at a minimum, the following:

1. The full name of the patient;

2. The complete name of each drug dispensed;

3. The strength and quantity of the drug dispensed;

4. Instructions as to the frequency of use;

5. The date of dispensing; and

6. The identity of the dispensing practitioner, if more than one practitioner dispenses in the office.

(e) Each different drug dispensed, in whatever dosage form, shall be placed in a separate container with a safety closure cap, unless the patient requests otherwise or the drug is a pharmaceutical sample which has been packaged and labeled by the manufacturer.

(f) Each drug dispensed, including pharmaceutical samples, shall bear a legible label which includes the following:

1. The complete name of the drug dispensed;

2. The strength and quantity of the drug dispensed;

3. Instructions as to the frequency of use;

4. Special precautions, as appropriate; and

5. The expiration date of the drug.

(g) With respect to any drug which is not packaged by the manufacturer as a sample, the label shall also include the following:

1. The full name of the patient;

2. A list of the ingredients if the drug was compounded, not manufactured;

3. The date of dispensing; and

4. The identity of the dispensing practitioner.