

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.

(h) A practitioner shall not charge any patient a fee for a drug packaged and labeled by a manufacturer as a sample. For any drug dispensed which is not packaged by the manufacturer as a sample, a practitioner may charge a fee

to allow for a recoupment of a portion of overhead and administrative costs, which fee shall not exceed the actual acquisition cost plus an additional sum not to exceed 10 percent of the actual acquisition cost.

(i) Subject to the exception in (j) below, if a practitioner charges a fee for the drug dispensed, either directly or through a global office visit charge which is more than that practitioner's usual and customary office visit charge, the practitioner:

1. Shall not dispense that drug or a substantially equivalent drug in a quantity or in dosages greater than that which would allow the patient a seven-day supply;
2. (Reserved)
3. Shall assure that information is given to the patient regarding the alternative availability of the drug outside of the practitioner's office; and
4. Shall disclose to the patient in advance of purchase and again on the bill the actual acquisition cost of the drug.

(j) In accordance with N.J.S.A. 45:9-22.11, the requirements set forth at (i) above shall not apply to a practitioner:

1. If the office at which the dispensing occurs is situated 10 or more miles from the nearest licensed pharmacy;
2. If the drug is dispensed pursuant to an oncological or AIDS protocol;
3. If the drug dispensed is a salve, ointment or drops; or
4. If the drug is dispensed in, and directly related to, the services rendered to the patient at:
 - i. A hospital emergency room;
 - ii. A student health center at an institution of higher education; or
 - iii. A publicly subsidized community health center, family planning clinic or prenatal clinic.

13:35-7.6 Limitations on prescribing, administering or dispensing of controlled substances; special exceptions for management of pain

(a) When prescribing, dispensing or administering controlled substances, a practitioner shall ensure that a patient's medical history has been taken and physical examination accomplished, including an assessment of physical and psychological function, underlying or coexisting diseases or conditions, any history of substance abuse and the nature, frequency and severity of any pain. The medical record shall reflect:

1. A recognized medical indication for the use of the controlled substance;
2. The complete name of the controlled substance;
3. The dosage, strength and quantity of the controlled substance; and
4. The instructions as to frequency of use.

(b) With respect to Schedule II controlled substances, unless the requirements of (c) below are met, a practitioner shall not authorize a quantity calculated to exceed 120 dosage units or a 30-day supply, whichever is less.

(c) A practitioner may exceed the 120 dosage unit limitation for Schedule II controlled substances in (b) above, if the practitioner follows a treatment plan designed to achieve effective pain management which has been tailored to the needs of a patient who is suffering pain from cancer, intractable pain or terminal illness. The treatment plan shall state objectives by which treatment success is to be evaluated, such as pain relief and improved physical and psychological function, and shall indicate if any further diagnostic evaluations or other treatments are planned. The practitioner shall discuss the risks and benefits of the use of controlled substances with the patient, guardian or authorized representative.

(d) When controlled substances are continuously prescribed for management of pain for three months or more, the practitioner:

1. Shall review, at a minimum of every three months, the course of treatment, any new information about the etiology of the pain and the patient's progress toward treatment objectives;
2. Shall remain alert to problems associated with physical and psychological dependence; and
3. Shall periodically make reasonable efforts, unless clinically contraindicated, to either stop the use of the controlled substance, decrease the dosage, try other drugs such as nonsteroidal anti-inflammatories, or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence.

(e) If treatment objectives are not being met, the practitioner:

1. Shall assess the appropriateness of continued treatment with controlled substances or undertake a trial of other drugs or treatment modalities; and
2. Shall consider referring the patient for independent evaluation or treatment in order to achieve treatment objectives.

(f) A practitioner shall remain alert to the possibility that controlled substances may be misused or diverted. A practitioner managing pain in a patient with a history of substance abuse shall exercise extra care by way of monitoring, documentation and possible consultation with addiction medicine specialists, and should consider the use of an agreement between the practitioner and the patient concerning controlled substance use and consequences for misuse.

(g) The practitioner shall keep accurate and complete records including that information required by (a) above as well as:

1. The medical history and physical examination of the patient;
2. Other evaluations and consultations;
3. Treatment plan objectives;
4. Evidence of informed consent;
5. Treatments and drugs prescribed or provided, as in (a) above;
6. Any agreements with the patient; and
7. Periodic reviews conducted.

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 listed in any schedule which drug is intended for the purpose of "detoxification" or "maintenance treatment."

(b) Unless registered with the New Jersey Department of Health and Senior Services to conduct a narcotic treatment program pursuant to N.J.S.A. 24:21-10 and N.J.A.C. 8:65-11.2, a practitioner shall not dispense or administer a narcotic 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.

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.