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 Chapter 35, except Subchapter 8, Hearing Aid Dispensers, was repealed and new rules of the Board of Medical Examiners, Subchapters 1 through 6, were adopted as R.1983 d.314, effective August 1, 1983.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 As a part of R.1994 d.522, Subchapter 7, Chiropractic Practice, was repealed, effective October 17, 1994.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.

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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(2) To a representative of the Board of Medical Examiners, the Attorney General or the Division of Consumer Affairs as soon as practicable and no later than 10 days after notice; and

(3) To a patient as authorized by this rule within 30 days of request (or promptly in the event of emergency); and

viii. A licensee wishing to continue a system of computerized patient records, which system does not meet the requirements of (b)3i through vii above, shall promptly initiate arrangements for modification of the system which must be completed by October 19, 1993. In the interim, the licensee shall assure that, on the date of the first treatment of each patient treated subsequent to October 19, 1992, the computer entry for that first visit shall be accompanied by a hard copy printout of the entire computer-recorded treatment record. The printout shall be dated and initialled by the attending licensee. Thereafter, a hard copy shall be prepared for each subsequent visit, continuing to the date of the changeover of computer program, with each page initialled by the treating licensee. The initial printout and the subsequent hard copies shall be retained as a permanent part of the patient record.

(c) Licensees shall provide access to professional treatment records to a patient or an authorized representative in accordance with the following:

1. No later than 30 days from receipt of a request from a patient or an authorized representative, the licensee shall provide a copy of the professional treatment record, and/or billing records as may be requested. The record shall include all pertinent objective data including test results and x-ray results, as applicable, and subjective information.

2. Unless otherwise required by law, a licensee may elect to provide a summary of the record in lieu of providing a photocopy of the actual record, so long as that summary adequately reflects the patient's history and treatment. A licensee may charge a reasonable fee for the preparation of a summary which has been provided in lieu of the actual record, which shall not exceed the cost allowed by (c)4 below for that specific record.

3. If, in the exercise of professional judgment, a licensee has reason to believe that the patient may be harmed by release of the subjective information contained in the professional treatment record or a summary thereof, the licensee may refuse to provide such information. That record or the summary, with an accompanying notice setting forth the reasons for the original refusal, shall nevertheless be provided upon request of and directly to:

i. The patient's attorney;

ii. Another licensed health care professional; or

iii. The patient's health insurance carrier.

4. Licensees may require a record request to be in writing and may charge a fee for the reproduction of records, which shall be no greater than $1.00 per page or $100.00 for the entire record, whichever is less. (If the record requested is less than 10 pages, the licensee may charge up to $10.00 to cover postage and the miscellaneous costs associated with retrieval of the record.) If the licensee is electing to provide a summary in lieu of the actual record, the charge for the summary shall not exceed the cost that would be charged for the actual record.

5. If the patient or a subsequent treating health care professional is unable to read the treatment record, either because it is illegible or prepared in a language other than English, the licensee shall provide a transcription at no cost to the patient.

6. The licensee shall not refuse to provide a professional treatment record on the grounds that the patient owes the licensee an unpaid balance if the record is needed by another health care professional for the purpose of rendering care.

(d) Licensees shall maintain the confidentiality of professional treatment records, except that:

1. The licensee shall release patient records as directed by a subpoena issued by the Board of Medical Examiners or the Office of the Attorney General, or by a demand for statement in writing under oath, pursuant to N.J.S.A. 45:1–18. Such records shall be originals, unless otherwise specified, and shall be unedited, with full patient names. To the extent that the record is illegible, the licensee, upon request, shall provide a typed transcription of the record. If the record is in a language other than English, the licensee shall also provide a translation. All x-ray films and reports maintained by the licensee, including those prepared by other health care professionals, shall also be provided.

2. The licensee shall release information as required by law or regulation, such as the reporting of communicable diseases or gunshot wounds or suspected child abuse, etc., or when the patient's treatment is the subject of peer review.

3. The licensee, in the exercise of professional judgment and in the best interests of the patient (even absent the patient's request), may release pertinent information about the patient's treatment to another licensed health care professional who is providing or has been asked to provide treatment to the patient, or whose expertise may assist the licensee in his or her rendition of professional services.

4. The licensee, in the exercise of professional judgment, who has a good faith belief that the patient because of a mental or physical condition may pose an imminent danger to himself or herself or to others, may release pertinent information to a law enforcement agency or other health care professional in order to minimize the threat of danger.

(e) Where the patient has requested the release of a professional treatment record or a portion thereof to a specified individual or entity, in order to protect the confidentiality of the records, the licensee shall:

1. Secure and maintain a current written authorization, bearing the signature of the patient or an authorized representative;

2. Assure that the scope of the release is consistent with the request; and

3. Forward the records to the attention of the specific individual identified or mark the material "Confidential."

(f) Where a third party or entity has requested examination, or an evaluation of an examinee, the licensee rendering those services shall prepare appropriate records and maintain their confidentiality, except to the extent provided by this section. The licensee's report to the third party relating to the examinee shall be made part of the record. The licensee shall:

1. Assure that the scope of the report is consistent with the request, to avoid the unnecessary disclosure of diagnoses or personal information which is not pertinent;

2. Forward the report to the individual entity making the request, in accordance with the terms of the examinee's authorization; if no specific individual is identified, the report should be marked "Confidential"; and

3. Not provide the examinee with the report of an examination requested by a third party or entity unless the third party or entity consents to its release, except that should the examination disclose abnormalities or conditions not known to the examinee, the licensee shall advise the examinee to consult another health care professional for treatment.

(g) (Reserved)

(h) If a licensee ceases to engage in practice or it is anticipated that he or she will remain out of practice for more than three months, the licensee or designee shall:

1. Establish a procedure by which patients can obtain treatment records or acquiesce in the transfer of those records to another licensee or health care professional who is assuming the responsibilities of that practice;

2. Publish a notice of the cessation and the established procedure for the retrieval of records in a newspaper of general circulation in the geographic location of the licensee's practice, at least once each month for the first three months after the cessation; and

3. Make reasonable efforts to directly notify any patient treated during the six months preceding the cessation, providing information concerning the established procedure for retrieval of records.

Repeal and New Rule, R.1990 d.176, effective March 19, 1990.
See: 21 N.J.R. 3253(a), 22 N.J.R. 978(a).
Amended by R.1992 d.429, effective October 19, 1992.
See: 24 N.J.R. 50(a), 24 N.J.R. 3729(d).
Revised (b).
Amended by R.1994 d.119, effective April 4, 1994.
See: 25 N.J.R. 4862(a), 26 N.J.R. 1522(a).

Case Notes

Verification may be required before personal injury protection benefits are paid. State Farm Mut. Auto. Ins. Co. v. Dalton, 234 N.J.Super. 128, 560 A.2d 683 (A.D.1989) certification denied 117 N.J. 664, 569 A.2d 1356, certiorari denied 110 S.Ct. 1131, 493 U.S. 1078, 107 L.Ed.2d 1037.

Reprimand by Board for failure to prepare patient record noted; transcript of Board proceeding not records within the meaning of the Right to Know Law, but are public records under common law; injury action's plaintiff's right to examine and inspect records superior to Board's interest in confidentiality (citing former N.J.A.C. 13:13–6.12). Beck v. Bluestein, 194 N.J.Super. 247, 476 A.2d 842 (App.Div.1984).

Revocation of license; psychiatrist who engaged in sexual contact with patients. In the Matter of the Suspension or Revocation of the License of Schermer, 94 N.J.A.R.2d (BDS) 33.

Performing numerous cardiac procedures without sufficient medical justification, failing to maintain accurate patient records, along with other acts of negligence, malpractice and incompetence, warranted license revocation; penalty and costs also assessed. In Matter of Suspension or Revocation of License of Rodriguera, 93 N.J.A.R.2d (BDS) 33.

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.

13:35–6.6 Requirements for issuing prescriptions for and dispensing all medications; special requirements for prescribing or dispensing controlled drugs

(a) Physicians who possess a plenary license to practice medicine and surgery and podiatrists who issue prescriptions for medication shall advise all patients by adequate notice,

such as but not limited to, a sign or pamphlet in the waiting room of the practitioner's office, that a request of the practitioner may be made by the patient to substitute a generic drug for any prescribed medication.

(b) Physicians and podiatrists shall provide the following on all prescriptions:

1. Prescriber's full name, address, telephone number and proper academic degree or identification of professional practice for which licensed. Identification may be in the form of a general term of plenary or limited licensure and may, in addition list a practice specialty; for example: Dr. John Doe, physician and surgeon; or Dr. Jane Smith, physician; or Dr. John Doe, surgeon; or Dr. Jane Smith, licensed to practice medicine and surgery; or Dr. John Doe, physician, practice limited to (name of specialty); or Dr. John Doe, podiatrist; or similar accurate descriptive terms;

2. Full name, age and address of patient;

3. Date of issuance of the prescription;

4. Name, strength and quantity of drug or drugs to be dispensed;

5. Adequate instruction for the patient; a direction of "p.r.n." or "as directed" alone shall be deemed an insufficient direction;

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

7. Prescriber's D.E.A. number when required for the prescribing of Controlled Dangerous Substances as scheduled under the Controlled Dangerous Substance Act of 1970. *Each prescription for a Controlled Dangerous Substance shall be written on a separate prescription blank;

8. Signature of prescriber, hand-written;

9. When pre-printed prescription blanks are not available, the full name of the prescriber must be printed or stamped in block letters under the signature of the prescriber;

10. Every prescription blank shall be imprinted with the words "substitution permissible" and "do not substitute" and shall contain space for the physician's or podiatrist's initials next to the chosen option, in addition to the space required for the signature in (b)8 above;

11. In no instance shall a physician or podiatrist utilize a prescription form which includes pre-printed information such as but not limited to, language, initials or other indications to discourage or prohibit substitution, which a prescriber may prohibit only by initialing or writing "do not substitute" on the individual prescription.

(c) With respect to any prescription issued for a Schedule II Controlled Dangerous Substance, and in addition to the requirements of N.J.A.C. 13:35–6.7 respecting prescribing of amphetamines, the following shall be observed:

1. The quantity of each drug shall be stated by word in addition to number; for example, ten (10) Percodan; or five (5) Ritalin 5 mg., etc.;

2. A practitioner shall not, at one time, prescribe or dispense to an individual patient in excess of 120 dosage forms or a 30–day supply, whichever is less.

(d) With respect to narcotic drugs listed in any schedule, a prescription shall not be used for "detoxification" or "maintenance treatment". Narcotic drugs may, however, be dispensed directly, but not prescribed, for these purposes, but only by a practitioner who is separately registered with the Attorney General of the State of New Jersey and the New Jersey Department of Health and authorized so to do.

(e) Nothing in this rule 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.

(f) Nothing in this rule is intended to limit a physician or authorized hospital staff from administering or dispensing 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.

(g) Nothing in this rule is intended to limit a physician from prescribing or dispensing narcotic drugs to person with intractable pain from which no relief or cure is possible or none has been found after reasonable efforts. When protected prescribing is utilized for the alleviation of intractable pain, practitioners shall remain alert to the availability of new or alternative types of treatment which may be less addictive than the present treatment. The practitioner should attempt periodically to either cease the medication or taper down the dosage, or try other medication or treatment modalities in a regular and vigilant effort to reduce the addiction propensity for the patient.

(h) Every physician and podiatrist shall assure that each container of medication dispensed directly to a patient is labeled in a legible manner with at least the following information:

1. Physician's or podiatrist's full name;

2. Full name of patient;

3. Date medication is dispensed;

4. Expiration date of medication;

5. Name, strength and quantity of medication dispensed;

6. Adequate instructions for the patient regarding the frequency of administration of the medication;

7. When a physician or podiatrist dispenses a pharmaceutical sample which has been packaged and labeled by the manufacturer and such sample package contains the information required by 5. and 6. above, the information listed in 1 through 3, inclusive, above need not be added;

8. When a physician or podiatrist dispenses a medication, other than a sample exempted pursuant to 7. above, in a container without sufficient space for the information required by this subsection, the container shall be placed in a large container or envelope, and the larger container or envelope shall be labeled as indicated in this subsection;

9. Each container of medication dispenses shall contain only one type of medication.

(i) In no instance shall a physician or podiatrist dispense drugs or signs a blank prescription form without complying with the above standards.

As amended, R.1984 d.197, effective May 21, 1984.
See: 16 N.J.R. 416(a), 16 N.J.R. 1281(a).
(h) amended concerning labeling of drugs.
Amended by R.1984 d.600, effective January 7, 1985.
See: 15 N.J.R. 2415(a), 17 N.J.R. 102(a).
(b)1 substantially amended.
Amended by R.1985 d.505, effective October 7, 1985.
See: 17 N.J.R. 1866(a), 17 N.J.R. 2442(a).
(h)4 added; (b) 4 through (h)8 recodified to (h)5 through (h)9.
Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
NOTE added.

* NOTE: A practitioner must be separately and concurrently registered with the State Department of Health and the Federal Drug Enforcement Administration.

Case Notes

Revocation of doctor's license proper; charges of illegal use or prescription for use of controlled substances. In the Matter of the Suspension or Revocation of the License of Ray, 95 N.J.A.R.2d (BDS) 24.

Physician; prescribing controlled substances; suspension. In the Matter of the Suspension or Revocation of the License of Caragine, 94 N.J.A.R.2d (BDS) 2.

13:35–6.7 Prescribing of amphetamines and sympathomimetic amine drugs

(a) No physician shall prescribe, order, dispense, administer, sell or transfer any amphetamine or sympathomimetic amine drug or compound designated as a Schedule II Controlled Dangerous Substance pursuant to the laws of New Jersey, to or for any person except:

1. For the treatment of the following conditions. A patient's records shall contain documentation to justify the prescribing including the use of appropriate testing, and with respect to those conditions which are not readily diagnosed by objective testing, documentation that appropriate consultation has been secured.

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;

vii. Senile apathetic behavior; or

2. Immediate use in a hospital for acute conditions such as depression associated with illness, medical or surgical; or

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 of Medical Examiners and approval granted before any such investigation is begun.

(b) In addition to the prohibitions set forth in (a) above, no physician shall prescribe, order, dispense, administer, sell or transfer any amphetamine or sympathomimetic amine drug or compound designated as a Schedule II Controlled Dangerous Substance pursuant to the laws of New Jersey, for use in weight management, dieting or any other anorectic purpose, or for the treatment of fatigue.

(c) Violation of any of the foregoing shall be deemed to constitute one or more of the following:

1. Distribution or dispensing of a controlled dangerous substance in an indiscriminate manner, not in good faith, or without good cause, pursuant to N.J.S.A. 45:1–13; or

2. Gross or repeated malpractice, gross neglect, or gross incompetence in the practice of medicine pursuant to N.J.S.A. 45:1–21 (c) and/or (d); or

3. Professional misconduct in the practice of medicine, pursuant to N.J.S.A. 45:1–21(e).

(d) The following list, although not exhaustive or exclusive, does include many of the generic and brand-name Schedule II drugs which fall within the above regulation:

Amphetamine
Benzedrine

Biphetamine
Desoxyn
Dexamyl
Dexedrine
Dextroamphetamine
Eskatrol
Fetamin
Methamphetamine
Methylphenidate
Obetrol
Obotan
Phenmetrazine
Preludin
Ritalin

Amended by R.1983 d.490, effective November 7, 1983.
See: 15 N.J.R. 785(a), 15 N.J.R. 1866(a).
In (c)2., added "or repeated" malpractice and added section (c) to statutory cite.
Amended by R.1991 d.597, effective December 16, 1991.
See: 23 N.J.R. 2248(a), 23 N.J.R. 3763(a).
Revised (a)1.
Amended by R.1994 d.522, effective October 17, 1994.
See: 26 N.J.R. 2526(a), 26 N.J.R. 4195(a).

Cross References

See N.J.A.C. 10:51–1.13, Pharmaceutical services requiring prior authorization.

Case Notes

Regulation proscribing physician use of amphetamines in obesity treatment valid and reasonably related to government objective of controlling controlled dangerous substance traffic (cited as N.J.A.C. 13:35–6.16). Lemmon Co. v. New Jersey State Bd. of Medical Examiners, 175 N.J.Super. 40, 417 A.2d 568 (App.Div.1980) certification denied 85 N.J. 148, 425 A.2d 299 (1980).

13:35–6.8 Prescribing, administering or dispensing amygdalin (laetrile)

(a) The prescription or administration of amygdalin (laetrile) is a medical procedure which may only be performed by a physician licensed to practice medicine and surgery in the State of New Jersey, or a physician duly licensed to practice medicine and surgery in another state provided the practitioner does not open an office or place for the practice of his profession in this State.

(b) A licensed physician may prescribe, administer or dispense amygdalin (laetrile) to such physician's patient, consistent with the following standards and providing that the patient has signed the "written information request . . . for medical treatment" as set forth herein:

1. Generally:

i. As an adjunct to recognized, customary, or accepted modes of therapy; or

ii. Utilized exclusively in the treatment of any malignancy, disease, illness or physical condition; and

iii. If and when the physician has received a confirmed diagnosis of said malignancy, disease, illness or physical condition;

2. In the course of medically justifiable dietary supplement therapy;

3. As a prophylactic medication.

(c) The informed request for prescription of laetrile for medical treatment must utilize the wording appearing on a form which is available on request from the Board.

1. The form shall be prepared in quadruplicate and distributed as follows:

i. Original copy to State Department of Health;

ii. Copy to be retained by the physician;

iii. Copy to patient or person who signed form for the patient;

iv. Copy to pharmacist.

2. When amygdalin (laetrile) is utilized in the treatment of a malignancy, the diagnosis of malignancy shall be documented by a positive tissue diagnosis rendered by a qualified pathologist which shall include the size, location and type of malignancy. In the absence of tissue for diagnosis, the treating physician shall be required to obtain consultative and/or professional reports to support a positive diagnosis of a malignancy.

3. The alternative medically recognized and accepted form of therapy offered by a physician shall be thoroughly discussed with the patient and documented in writing.

(d) Complete and accurate records shall be maintained and made available to include:

1. Copy of signed informed request.

2. History of previous therapy to be included where indicated.

i. Surgery;

ii. Radiation;

iii. Chemotherapy.

3. Complete record of dates of office visits, examination and evaluation of patient with detailed progress notes.

i. Complications and/or untoward reactions from amygdalin (laetrile) shall be reported immediately to the State Department of Health.

ii. Fee for service: The patient record shall include fee charged per visit which fee shall not be greater than the physician's usual and customary fee for an office visit. When fee includes administering or dispensing amygdalin (laetrile), the change is to be itemized and recorded. When a physician administers or dispenses amygdalin (laetrile), the fee to the patient shall not exceed the cost to the physician of such substance and shall be so itemized in the charge or billing.

(j) A licensee having a significant beneficial interest, as defined in (a) above, in a health care service including a professional service corporation or a general business corporation (see N.J.A.C. 13:35–6.16(f)) shall notify the Board of such interest no later than February 18, 1993. Notice is not required for a practice conducted under the practitioner's own name.

(k) This rule shall be operative April 15, 1992.

New Rule, R.1992 d.75, effective February 18, 1992 (operative April 15, 1992, except as noted).
See: 23 N.J.R. 161(a), 23 N.J.R. 1063(a), 24 N.J.R. 626(a).
Public Notice: Stay of operative date of (e) until July 15, 1992.
See: 24 N.J.R. 1905(a).
Public Notice: Stay of operative date of portion of (a)2 until August 12, 1992.
See: 24 N.J.R. 2460(a).
Public Notice: Delayed operative date of (e) until August 15, 1992.
See: 24 N.J.R. 3443(b).
Administrative Correction to (a)5.
See: 24 N.J.R. 4409(a).
Amended by R.1995 d.8, effective January 3, 1995.
See: 25 N.J.R. 5441(a), 27 N.J.R. 120(a).

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Examiners' Board Hits Physician Referrals. 133 N.J.L.J. No. 4, 11 (1993).

Rules Changes Target Medical Group Practices. Theodosia A. Tamborlane, 136 N.J.L.J. No. 11, 10 (1994).

13:35–6.18 Prescribing, dispensing or administering anabolic steroids

(a) As used within this section, the following terms have the following meanings unless the content indicates otherwise:

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

Bolenone
Chlorotestosterone
(4–chlortestosterone)
Chorionic gonadotropin
Clostebol
Danazol
Dehydrochlormethyltestosterone
Dihydrotestosterone
(4–dihydrotesterone)
Drostanolone
Ethylestrenol
Fluoxymesterone
Formebulone (formebolone)
Mesterolone
Methandienone
Methandranone
Methandriol
Methandrosterone
Methenolone
Methyltestosterone
Mibolerone
Nandrolone
Norethandrolone
Oxandrolone
Oxymesterone
Oxymetholone
Stanolone
Stanozolol
Testolactone
Testosterone
Trenbolone

2. "Human growth hormone" ("hGH") means any polypeptide hormone of recombinant DNA origin and includes the following substances:

Somatrem
Somatropin

3. "Licensee" means a physician, registered resident or resident permit holder, podiatrist or certified nurse midwife subject to regulation by the New Jersey Board of Medical Examiners.

(b) No licensee shall 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 without an accepted medical necessity to do so, or for the intended purpose of improving performance in any form of exercise, sport or game. 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 is not a valid medical purpose.

(c) Licensees shall complete and maintain patient medical records which accurately reflect the utilization of any substance or drug included in this rule, which records must indicate the diagnosis, any additional information upon which the diagnosis is based and the purpose for which the substance or drug is being used.

(d) Violation of any of the requirements of (b) through (d) above may be deemed to constitute one or more of the following:

1. Distribution or dispensing of a controlled dangerous substance in an indiscriminate manner, not in good faith, or without good cause, pursuant to N.J.S.A. 45:1–13;

2. Gross malpractice, gross neglect, or gross incompetence in the practice of the licensed profession pursuant to N.J.S.A. 45:1–21(c);

3. Professional misconduct in the practice of the licensed profession pursuant to 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, pursuant to N.J.S.A. 45:1–21(h); or

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. 45:9–19.5.

(e) Licensees who are in possession of information which reasonably indicates that another licensee has prescribed, dispensed or administered an anabolic steroid for the purpose of hormonal manipulation that is apparently intended to increase muscle mass, strength or weight without a medical necessity to do so or for apparent purpose of improving performance in any form of exercise, sport or game shall be obligated to report such information to the Board pursuant to N.J.S.A. 45:9–19.5.

New Rule, R.1993 d.604, effective December 6, 1993.
See: 24 N.J.R. 4012(a), 25 N.J.R. 5487(a).

13:35–6.19 Duty to report changes in status

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

"Ability to practice" means and is construed to include all of the following:

1. The cognitive capacity to make appropriate clinical diagnoses and exercise reasoned medical judgments and to learn and keep abreast of medical developments;

2. The ability to communicate those judgments and medical information to patients and other health care providers, with or without the use of aids or devices, such as voice amplifiers; and

3. The physical capability to perform medical tasks such as physical examination and surgical procedures, with or without the use of aids or devices, such as corrective lenses or hearing aids.

"Affiliation" means a professional relationship, including an employment relationship, a position as an independent contractor or the grant of privileges by a health care facility or health maintenance organization in this State or any other jurisdiction.

"Alternative Resolution Program" refers to the program established pursuant to N.J.A.C. 13:35–11 by which licensees suffering from medical conditions or chemical dependency may confidentially enter into a rehabilitation and monitoring program, under the sponsorship of an approved professional assistance program, subject to the periodic submission of coded status reports and continuing confidential review by the Board's Impairment Review Committee. To be deemed a participant in the Alternative Resolution Program, the licensee must be accepted by the Impairment Review Committee and assigned a code number.

"Biennial renewal form" means the form provided to a licensee by the Board, which must be completed in order to renew and keep current a license to practice in this State.

"Chemical substances" is to be construed to include alcohol, drugs or medications, including those taken pursuant to a valid prescription for legitimate medical purposes and in accordance with the prescriber's direction, as well as those used illegally.

"Conviction" means a judgment of conviction entered following plea agreement or trial on an arrest, indictment, accusation or bill of particulars in a state or Federal criminal proceeding, or the resolution of such charges, whether by a plea of no contest or nolo contendere or by pre-trial diversion program.

"Directly associated" means a professional relationship including an employment relationship, partnership arrangement or a shareholder status in a professional service corporation or general business corporation. "Directly associated" does not include any relationship established pursuant to preferred provider agreements, IPA's or other provider panels.

"Disciplinary order" means a disposition suspending or revoking licensure privileges or imposing civil penalties or ordering the restoration of money or ordering corrective action or medical or other professional treatment or monitoring, or censuring or reprimanding a licensee.

"Financial interest" means a monetary interest of any amount held by a practitioner personally or through immediate family, as defined at N.J.S.A. 45:9–22.4 et seq.

"Health care facility" means a facility or institution, whether public or private, engaged in providing medical services, including diagnosis or treatment of human disease, pain, injury, deformity or physical condition, including, but not limited to, a general hospital, special hospital, mental hospital, health maintenance organizations, public health center, diagnostic center, treatment center, rehabilitation center, extended care facility, skilled nursing home, nursing home, intermediate care facility, tuberculosis hospital, chronic disease hospital, maternity hospital, outpatient clinic, dispensary, home health care agency, boarding home for the sheltered care of adult persons, and bio-analytical laboratory or central services facilities serving one or more such institutions but excluding institutions that provide healing solely by prayer.

"Health care service entity" means a business entity which provides on an inpatient or outpatient basis: testing for a diagnosis or treatment of human disease or dysfunction; or dispensing of drugs or medical devices for the treatment of human disease or dysfunction. Health care service entity includes, but is not limited to, a bio-analytical laboratory, pharmacy, home health care agency, rehabilitation facility, nursing home, hospital, home infusion company, or facility which provides radiological or other diagnostic imagery services, physical therapy, ambulatory surgery, or ophthalmic services.

"Health maintenance organization" means any entity licensed by the State Department of Health which directly or through contracts with providers furnishes health care services on a prepaid basis to enrollees.

SUBCHAPTER 7. (RESERVED)

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.

"Licensee" means any person who has been duly issued a license to fit and dispense hearing aids in accordance with N.J.S.A. 45:9A–1 et seq. and this subchapter.

"Place of practice" means the actual physical location of the office and business address from which the licensee conducts his or her business and where relevant books and records are maintained.

"Sponsor" means any person holding a valid license pursuant to N.J.S.A. 45:9A–1 et seq. for two or more years who is deemed qualified by the Committee to instruct, train and supervise in the requisite skills, methods and techniques so as to insure competency in the fitting and dispensing of hearing aids and who has assumed the responsibilities for supervising and training in accordance with N.J.S.A. 45:9A–16 and the provisions of this subchapter.

"Temporary license" means a temporary license as defined by N.J.S.A. 45:9A–16(a) and the provisions of this subchapter.

"Training permit" means a temporary license as defined by N.J.S.A. 45:9A–16(b) and the provisions of this subchapter.

13:35–8.3 Training permits; issuance and practice

(a) The Committee may issue a training permit in accordance with N.J.S.A. 45:9A–16(b) and the provisions of this subchapter.

(b) The requisite training and experience referred to in N.J.S.A. 45:9A–9 and 16(b) shall be a minimum of six months continuous or interrupted training within a 24–month period ending with the deadline for making application to take the next examination. Where proof of successful completion of a course of study approved by the State Board of Education or the Department of Higher Education is presented to the Committee, the Committee may accept this training as a substitute for any portion of the training and experience requirement.

(c) No person shall commence training as a hearing aid dispenser until such time as he or she has received a training permit. The training period shall be calculated to have commenced on the date the permit is issued.

(d) Upon being issued a training permit, the trainee shall train in the same office or business location as that of his or her sponsor and in the physical presence of the sponsor. The training shall consist of the following:

1. 40 hours of training with an audiometer;

2. 160 hours of hearing aid dispensing procedures, including the taking of earmold impressions, the alteration of earmolds and hearing aids, and application and fitting techniques;

3. Reading all the books and articles relating to hearing aid dispensing specified in a list formulated by the Committee.

(e) No trainee shall be permitted to sell, fit or dispense hearing aids or to engage in the potential fitting or dispensing of hearing aids except in the same office or business location of his or her sponsor and in the physical presence of the sponsor.

(f) A trainee shall complete the training only with the sponsor designated by the Committee and only during regular business hours.

13:35–8.4 Temporary licenses; issuance

(a) The Committee may issue a temporary license in accordance with N.J.S.A. 45:9–16(a) and the provisions of this subchapter to an applicant provided he or she has not previously held a training permit or has not previously taken the licensing examination described in N.J.S.A. 45:9A–10 and N.J.A.C. 13:35–8.15. A temporary license shall not be renewed when an applicant has failed the licensing examina-

tion, except on showing of good cause (such as illness or emergency precluding the taking of the examination).

(b) Persons from another jurisdiction who are not eligible for license by endorsement under N.J.S.A. 45:9A–13 who wish to sit for the licensing examination shall demonstrate a minimum of two years of full-time independent experience in dispensing, fitting and selling hearing aids as defined by N.J.S.A. 45:9A–2(d) and N.J.A.C. 13:35–8.7. The applicant must submit documentation and verification of said experience satisfactory to the Committee, or submit verification of current licensure to practice audiology in the State of New Jersey.

(c) Applicants may be interviewed by the Committee, at which time their education, training and experience will be examined. Where an applicant's documentation of education, training and experience appears unsatisfactory, the Committee may deny a temporary license, but may permit the applicant to sit for the next licensing examination.

13:35–8.5 Temporary licenses; practice

(a) A temporary licensee shall spend a minimum of 20 days in the office or business location of his or her sponsor within any 60–day period.

(b) A temporary licensee shall not maintain an independent office or a place of business for the purpose of dispensing hearing aids, but shall at all times operate in the sponsor's office in a manner consistent with the ability of his or her sponsor to provide responsible supervision.

(c) No temporary licensee shall complete a sale of hearing aids without the physical presence of his or her sponsor, and without obtaining the sponsor's signature on the purchase agreement.

(d) Every temporary licensee shall submit a daily written report of his or her activities to his or her sponsor which shall be retained as part of the permanent records.

(e) Upon submitting an application for a license, every temporary licensee shall submit an affidavit from his or her sponsor attesting to the supervision requirements of N.J.S.A. 45:9A–1 et seq. and this subchapter.

(f) Upon request, all records shall be made available to the Committee for its review and evaluation.

13:35–8.6 Sponsors

(a) Every trainee and temporary licensee shall be supervised and trained by a sponsor who has fulfilled the requirements of N.J.S.A. 45:9A–16 and the provisions of this subchapter.

(b) In addition, a sponsor shall:

1. Supervise at any one time no more than a total of two persons who may be temporary licensees and/or permit holders;

2. Be present in the same physical location for purposes of training and supervision;

3. Not pre-sign purchase agreements;

4. Maintain a daily log for each day of supervision and training as part of the permanent record;

5. Provide an affidavit attesting to the supervision requirements of N.J.S.A. 45:9A–1 et seq. and this subchapter; and

6. Notify the Committee within five days of any termination in the sponsorship arrangement, stating the reasons therefor.

13:35–8.7 Scope of practice

(a) The practice of fitting a hearing aid as defined by N.J.S.A. 45:9A–2(d) shall include:

1. The evaluation or measurement of the power or range of human hearing utilizing customary and appropriate instrumentation available in the field;

2. The making of an ear impression;

3. Pursuant to N.J.A.C. 13:35–8.8, the fitting and dispensing of a deep ear canal hearing aid device that requires an impression taking technique involving instruments applied to the tympanic membrane;

4. The cleaning, change of design or alteration of an earmold (including tubing);

5. The change of frequency response of any instrument;

6. The selection or adaptation of a hearing aid; and

7. The interpretation and evaluation of hearing tests and the physical examination of a person's ear, where such interpretation, evaluation or examination is used in conjunction with the dispensing of a hearing aid.

(b) The practice of dispensing a hearing aid as defined by N.J.S.A. 45:9A–2(d) shall include the sale, rental or lease of hearing aids, the evaluation of the necessity for repair of a hearing aid, and the delivery after repair.

(c) The practice of fitting and dispensing a hearing aid shall include any activity which reasonably may be expected to result in the sale of a hearing aid, including but not limited to canvassing, counselling, soliciting and screening for potential hearing aid users.

(d) The terms of this subchapter are not to be construed to include activities of a licensed audiologist under N.J.S.A. 45:3B–21 et seq., unless he or she is also engaged in the dispensing of hearing aids.