

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 dispensed 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

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  
Biphedamine

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.

6. Is incapable of discharging the functions assigned by the supervising physician;

7. Has exhibited any behavior or engaged in any conduct reasonably demonstrating a mental impairment or substance abuse; or

8. Has engaged in activities or performed tasks without physician direction and supervision, beyond the scope of those permitted herein or beyond the abilities, experience or training of the physician assistant or the supervising physician.

(h) The director of an approved program shall give notice to the Board and immediately revoke or suspend the privilege of any supervising physician participating in the program if the director has information indicating that the physician, in the course of performing responsibilities as a supervisor:

1. Has engaged in the use or employment of dishonesty, fraud, deception, misrepresentation, false promise or false pretense;

2. Has engaged in gross negligence, gross malpractice or gross incompetence or repeated acts of malpractice, negligence or incompetence;

3. Has been convicted of a crime or has pleaded guilty, non vult, or nolo contendere to a crime or any other offense which relates adversely to the physician assistant's delegated activities;

4. Has had his or her license or authority to practice revoked, suspended, rescinded or limited by any other state, agency or authority;

5. Is incapable of discharging the functions as a supervising physician;

6. Has exhibited any behavior or engaged in any conduct reasonably demonstrating a mental impairment or substance abuse; or

7. Has allowed or permitted a physician assistant to engage in tasks without physician direction and supervision, beyond the scope of those permitted under this rule or beyond the abilities, experience or training of the physician assistant or the supervising physician.

(i) The director shall not reinstate any revoked participant without the approval of the Board.

(j) Any physician who delegates tasks to a person not in accordance with the requirements set forth in this rule or who allows a physician assistant to perform tasks in violation of (d) above shall be deemed to have engaged in professional misconduct in violation of N.J.S.A. 45:1-21(e).

(k) This section shall be operative May 12, 1991. Two years following that operative date, the Board shall determine after study and consultation with such experts as it

may deem warranted whether the program established pursuant to this rule should be continued, altered or expanded.

New Rule, R.1991 d.56, effective February 4, 1991 (operative May 12, 1991).  
See: 22 N.J.R. 2135(b), 23 N.J.R. 311(a).

### 13:35-6.16 Professional practice structure

(a) A licensee of the Board of Medical Examiners shall engage in professional practice in this State only when in possession of a current biennial registration issued by the Board.

1. The term "professional practice" is deemed to include the offering by a Medical Board licensee of opinions on matters of professional practice (including testimony and professional review organization service), whether or not the offeror has provided direct patient care, where the holding of a professional board license is a significant component or foundation for the offering of the professional opinion.

2. The name of the professional practice entity shall be composed of the actual last names of one or more of the owning licensees, partners or shareholders or composed of a phrase or words reasonably descriptive of the type of professional practice.

(b) The practice shall be conducted in a business form consistent with the principles set forth in this rule and, where so noted, only in accordance with the designated special conditions pertaining to that form. There shall be policies and procedures with respect to professionally licensed personnel. These topics shall include, but not be limited to, the following:

1. Responsibility of a licensed practitioner for review and approval of hiring professional staff and timely demand for and verification of current licensing credentials and any other educational credentials required by law or pertinent agency rule (for example, recertifications, continuing professional education, cardiopulmonary resuscitation, etc.);

2. Medical policies at the office or place where services shall be rendered;

3. Cleanliness of premises;

4. Maintenance, registration and inspection of professional equipment as necessary;

5. Standards for recordkeeping as to patient medical records, billing records, and such other records as may be required by law or rule including Controlled Dangerous Substance inventories, as applicable;

6. Security, including drug storage, prescription pad control, confidentiality of patient records;

7. Periodic audit of patient records and of professional services to assure quality professional care on the premises;

8. Responsibility for the professional propriety of billing and of advertising or other representations including disclosure of financial interest in health care services offered to the public; and

9. Preparation and maintenance of a written list of current fees for standard services, which list shall be available to patients on request.

(c) The licensee shall post a conspicuous notice in the waiting room stating: "INFORMATION ON PROFESSIONAL FEES IS AVAILABLE TO YOU ON REQUEST."

(d) A licensee, alone or with the other investing licensees, may employ a licensed health care professional as director of the professional entity to carry out those policies and procedures designated by the licensee(s). The director must be licensed to conduct all services offered at the premises. Either the director, one of the investing licensees, or another licensed health care professional authorized to render those medical services without direct supervision, must be on the premises at all times when patients or clients are receiving professional services, except as specified herein or otherwise permitted by rule of the Board. With regard to health care entities whose services are performed away from the primary office address (for example, entities providing house calls, mobile medical services, or provision and management of services relating to durable medical equipment, etc.), the director need not be present at all times, provided that patients or clients are receiving professional services from an investing or employed professional who is a licensee of a professional health care board of this State, except as may be limited by law or by another rule of this Board.

(e) A licensee may invest in a health care service as defined in N.J.A.C. 13:35-6.17(a). Said service shall be owned solely by one or more licensed health care professionals except as otherwise permitted by licensure granted by another State agency. Whether or not any or all of the owners, partners or directors all regularly practice on the premises or within the entity, each such person who is a licensee of this Board shall be responsible to the Board for requiring maintenance of all professional practice standards and control set forth in this rule, except as excused by (g) below. A licensee who has invested in a health care service in which he or she has a significant beneficial interest as defined in N.J.A.C. 13:35-6.17(a)5, to which he or she refers patients, shall assure that professional justification for the referred service is documented in the patient record maintained at that entity. Referred services include but are not limited to prescriptions for devices such as hearing aids, eyeglasses, intraocular lenses, requests for radiologic studies, etc. Referral of patients is now limited to the exceptions set forth in N.J.S.A. 45:9-22.4 as amended.

(f) Acceptable professional practice forms are as follows:

1. Solo: A practitioner may practice solo and/or may employ or otherwise remunerate other licensed practitioners to render professional services within the scope of practice of each employee's license, but which scope shall not exceed that of the employer's license. The practitioner may employ ancillary non-licensed staff in accordance with Board rules, if any, and accepted standards of practice.

2. Partnership or professional association: A practitioner may practice in a partnership or professional association, but such entity shall be composed solely of licensed health care professionals. The professional services offered by each practitioner, whether a partner or shareholder, shall be the same or in a closely allied medical or professional health care field. For the purpose of this rule, closely allied fields, pursuant to the Professional Service Corporation Act, N.J.S.A. 14A:17-1 et seq., shall be deemed to include the health care professions licensed by the State Professional Boards under the Division of Consumer Affairs, for example, chiropractic, dentistry, nursing, nurse midwifery, optometry, physical therapy, podiatry, psychology, social work, etc. If the scope of practice authorized by law for each such person differs, any document used in connection with professional practice including but not limited to professional stationery, business cards, advertisements or listings and bills, shall designate the field to which such person's practice is limited. Prescriptions shall list only those practitioners authorized by law to prescribe; shall designate the practice of each listed prescriber as required by N.J.A.C. 13:35-6.1; and shall comply with the data requirements of N.J.A.C. 13:35-6.6.

3. Associational relationship with other practitioner or professional entity: For the purpose of this rule, the term "employment" shall include an ongoing associational relationship between a licensee and professional practitioner(s) or entity on the professional practice premises for the provision of professional services, whether the licensee is denominated as an employee or independent contractor, for any form of remuneration.

i. A practitioner may be employed, as so defined, within the scope of the practitioner's licensed practice and in circumstances where quality control of the employee's professional practice can be and is lawfully supervised and evaluated by the employing practitioner. Thus, a practitioner with a plenary license shall not be employed by a practitioner with a limited scope of license, nor shall a practitioner with a limited license be employed by a practitioner with a more limited form of limited license. By way of example, a physician with a plenary license may be employed by another plenary licensed physician, but an M.D. or D.O. may not be employed by a podiatrist (D.P.M.) or chiropractor (D.C.) or midwife or certified nurse midwife (R.M., C.N.M.). A podiatrist may not employ a chiropractor. This section shall not preclude any licensee from employing licensed personnel such as nurses, x-ray technologists, physical therapists, ophthalmic dispensers and ophthalmic technicians, etc., as appropriate to the primary practice of the employer.

4. Shareholder or employee of a general business corporation: A licensee may offer health care services as an employee of a general business corporation in this State only in one or more of the following settings. Any such setting shall have a designated medical director licensed in this State who is regularly on the premises and who (alone or with other persons authorized by the State Department of Health, if applicable) is responsible for licensure credentialing and provision of medical services.

i. The corporation is licensed by the New Jersey Department of Health as a health maintenance organization, hospital, long or short-term care facility, ambulatory care facility or other type of health care facility or health care provider such as a diagnostic imaging facility. The above may include a licensed facility which is a component part of a for-profit corporation employing or otherwise remunerating licensed physicians.

ii. The corporation is not in the business of offering treatment services but maintains a medical clinic for the purpose of providing first aid to customers or employees and/or for monitoring the health environment of employees. The provisions of N.J.A.C. 13:35-6.5 regarding preparation, maintenance and release of treatment and health monitoring records shall apply to persons receiving care or evaluation in this setting.

iii. The corporation is a non-profit corporation sponsored by a union, social or religious or fraternal-type organization providing health care services to members only.

iv. The corporation is an accredited educational institution which maintains a medical clinic for health care service to students and faculty.

v. The corporation is licensed by the State Department of Insurance as an insurance carrier offering

coverage for medical treatment and the licensee is employed to perform quality assurance services for the insurance carrier.

5. A licensee may also have an equity or employment interest in a professional practice (including a professional service corporation) which is a limited partner to a general business corporation which, in turn, has a contractual agreement with the professional service entity, in the following circumstances only. The general business corporation may contract to provide the professional practice with services exclusively of a non-professional nature such as but not limited to routine office management, hiring of non-professional staff, provision of office space and/or equipment and servicing thereof, and billing services. The licensee shall nevertheless be responsible, at all times except as excused by (g) below, to assure that an appropriate licensed health care professional determines and carries out all services and medical care policies set forth in (b) and (c) above, including retention of sole discretion regarding establishment of patient fees and modification or waiver thereof in an individual case. The licensee shall assure, as a condition of such contractual arrangement, that the general business corporation makes no representations to the public of offering, under its own corporate name, health care services which require licensure.

(g) A licensee employed or having a significant beneficial interest in any of the practice forms listed in (f) above shall terminate such employment or sever professional affiliation upon acquiring personal knowledge that the entity regularly fails to provide or observe the quality control/assurance mechanisms listed in (b) and (c) above and refuses, upon request, to implement such mechanisms. A licensee terminating employment or affiliation with a general business corporation as described in (f)4 above for reasons required by this section shall so notify the Board.

(h) In addition to the practice forms set forth above, a licensee may participate in organized managed health care plans including, but not limited to, those involving wholly or partially pre-paid medical services. By way of example, this includes plans commonly described as health maintenance organizations, preferred provider organizations, competitive medical plans, individual practice associations, or other similar designations. Such plans typically cover certain types of health care services but only when the services are rendered by licensees who are provider-members of the plan; or the patient has been referred to a specialist or admitted to a hospital by a provider-member and has secured the advance approval of the plan administration. Such plans usually permit coverage for referrals in situations of emergency or other special conditions. A licensee may participate in any such plan which complies with the following professional requirements:

1. The licensee retains authority at all times to exercise professional judgment within accepted standards of practice regarding care, skill and diligence in examinations, diagnosis and treatment of each patient.

2. The licensee retains authority at all times to inform the patient of appropriate referrals to any other health care providers:

i. Whether or not those persons are provider-members of the plan; and

ii. Whether or not the plan covers the cost of service by such non-member providers to the patient.

3. Plan patients are informed that they may be personally responsible for the cost of treatment by a provider who is not a member-provider within the plan, or for treatment not having the approval of the plan administration.

4. Provisions for remuneration to the licensee shall not be inconsistent with the principles listed in N.J.A.C. 13:35-6.17(f).

(i) The following pertain to laboratory service:

1. A Board-licensed physician having a financial interest in a laboratory for the performance of bioanalytical tests may prescribe and/or perform such tests on the physician's primary medical office premises solely for the patients of the prescribing licensee. The licensee is responsible for establishing and maintaining a protocol for quality and cost control and for compliance with the provisions of the Clinical Laboratory Improvement Act, N.J.S.A. 45:9-42.26 et seq. Billing shall be done only in the name of the practitioner's medical office and in compliance with N.J.S.A. 45:1-10.

2. A Board-licensed physician having a financial interest in a laboratory offering services only to patients of the owning licensee(s) but conducted at a site other than the office premises of the owners shall assure that such laboratory has a director and that the laboratory is licensed under the New Jersey Clinical Laboratory Improvement Act. The physician shall assure compliance with N.J.S.A. 45:1-10 and with N.J.S.A. 45:9-22.4 as amended, and the name of the laboratory shall be accompanied at all times by the name(s) of the owning licensee(s) except as authorized for media advertising pursuant to N.J.A.C. 13:35-6.10(l). Petition may be made for exemption on billing forms for good cause shown. Patient referral may be made only by a licensee holding such financial interest prior to July 31, 1991.

3. A Board licensee having a financial interest in a laboratory which accepts referrals from physicians who are not owners/investors shall assure that such laboratory is licensed under the New Jersey Clinical Laboratory Improvement Act and is directed by a bioanalytical laboratory director licensed pursuant to N.J.S.A. 45:9-42 et seq. who shall establish and maintain quality and cost control. The physician shall assure compliance with N.J.S.A. 45:1-10 and with N.J.S.A. 45:9-22.4, as amended, and the name of the laboratory shall be accompanied at all times by the name(s) of the owning licensee(s), except as authorized for media advertising pursuant to N.J.A.C. 13:35-6.10(l). Petition may be made for exemption on billing forms for good cause shown. Patient referral may be made only by a licensee holding such financial interest prior to July 31, 1991.

(j) The following pertain to physical therapy:

1. A physician may perform and/or prescribe physical therapy to be administered in the physician's office. Billing shall be done only in the name used by the physician's office. A bill for services of a physician's employees, which were rendered by licensed professionals authorized

to provide services without medical supervision, shall identify the provider of service by name and degree.

2. A physician having a financial interest in a physical therapy entity at a location other than the physician's office, whether conducted under the physician's name or under another name, shall establish quality control/assurance provisions as required by (b) and (c) above. The physician shall assure compliance with service provider identification in (j)1 above, and with N.J.S.A. 45:9-22.4, as amended, and the name of the entity shall be accompanied at all times by the name(s) of the owning licensee(s) except as authorized for media advertising pursuant to N.J.A.C. 13:35-6.10(l). Petition may be made for exemption on billing forms for good cause shown. Patient referral may be made only by a licensee holding such financial interest prior to July 31, 1991.

(k) The following pertain to radiology:

1. A physician may prescribe and/or perform radiologic services on the physician's office premises. Billing shall be done only in the name of the prescriber or office. Where reading of film is done by an outside consultant, see N.J.A.C. 13:35-6.17(c)3.

2. A physician having a financial interest in a radiologic service facility at a location other than the physician's fixed office premises, whether conducted under the physician's name or under another name, shall establish quality control/assurance provisions as required by (b) and (c) above. The physician shall assure compliance with N.J.S.A. 45:9-22.4, as amended, and the name of the facility shall be accompanied at all times by the name(s) of the licensee(s) except as authorized for media advertising by N.J.A.C. 13:35-6.10(l). Petition may be made for exemption on billing forms for good cause shown. Patient referral may be made only by a licensee holding such financial interest prior to July 31, 1991, or by a licensee having a financial interest in a facility offering radiation therapy pursuant to an oncological protocol.

(l) The following pertain to ophthalmology:

1. A physician may prescribe eyeglasses or external contact lenses and may offer to sell the devices. Billing shall be done only in the name of the physician or office. A bill for services of a physician's employees, which were rendered by licensed professionals authorized to provide services without medical supervision, shall identify the provider of service by name and degree.

2. A physician having a financial interest in a service entity for the selling of eyewear at a location other than the physician's office, conducted under the physician's name or another name, shall establish quality control/assurance provisions as required by (b) and (c) above. The physician shall assure compliance with service provider identification in (l)1 above, and with N.J.S.A. 45:9-22.4, as amended, and the name of the entity shall be accompanied at all times by the name(s) of the owning licensee(s) except as authorized for media advertising pursuant to N.J.A.C. 13:35-6.10(l). Patient referral may be made only by a licensee holding such financial interest prior to July 31, 1991.

(m) The provisions of this rule shall be operative on April 15, 1992, except that the requirements of managed health care plans in (h) above, and requirements of a director of laboratory in (i)2 and 3 above shall be operative April 15, 1993. Licensees who have been providing professional services in a business format which does not comply with the present codification of Board interpretation of permissible practice formats shall complete a transfer to an acceptable format as soon as possible but no later than October 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).

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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).

### 13:35-6.17 Professional fees and investments, prohibition of kickbacks

(a) For the purposes of this rule, the following words and terms shall have the following meanings:

1. "Health care service" means a business entity which provides on an in-patient or out-patient basis: testing for or 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 includes, but is not limited to, a bioanalytical laboratory, pharmacy, home health care agency, home infusion therapy company, rehabilitation facility, nursing home, hospital, or a facility which provides radiologic or other diagnostic imaging services, physical therapy, ambulatory surgery, or ophthalmic services.

2. "Financial interest" means a monetary interest of any amount held by a practitioner personally or through immediate family, as defined herein, in a health care service to which the practitioner's patients are referred. It includes the offer or receipt, directly or indirectly, by the practitioner or immediate family of anything of more than negligible value as a result of a patient's purchase of a prescribed service, goods or device from the person or entity providing this. Except as set forth in (a)2i through vii below, "financial interest" includes a licensee's financial interest in a contractual arrangement with a licensed health care facility (such as a hospital, nursing home or clinic, etc.), whereby the licensee agrees to provide health care services on referral, for example, cardiac or radiologic diagnostic testing, to patients including those receiving Emergency Room care or inpatients or outpatients of the health care facility. "Financial interest" does not include the following:

- i. A straight salary or an annual retainer which is not related to the volume of patients treated;
- ii. A contractual arrangement with a licensed health care facility or health care service to provide non-

clinical services such as quality assurance review, peer review, administrative or supervisory services, duties (other than hands-on care) of a department chair or medical director, or similar services;

iii. A contractual arrangement with a licensed health care facility to provide health care services to patients who are medically indigent, under which the facility pays the licensee reasonable fees for services rendered. For purposes of this rule, "medically indigent" patient means any patient meeting the requirements for indigency established by the State Medicaid program, by the Federal government for purposes of meeting Hill-Burton obligations, by the State Department of Health for purposes of reimbursing hospitals for uncompensated care, or by any other governmental program for purposes of providing health care to indigent individuals;

iv. A contractual arrangement (including a faculty practice plan) with a licensed health care facility to provide health care services to patients of the facility, under which the licensee agrees to accept payments from third party payors (plus any deductible or coinsurance amounts) as payment in full for such services; in the absence of a third party payment mechanism, the licensee shall have agreed to provide such services at no charge or the facility shall have agreed to pay the licensee reasonable fees for services rendered;

v. A contractual arrangement with a licensed health care facility to provide health care services to patients of the facility, under which the contract establishes the maximum fees which can be charged for the services or the facility approves the licensee's fees in advance, and the services to be provided are part of the facility's normal utilization review process;

vi. A contractual arrangement with a licensed health care facility in connection with a residency or externship program conducted by the facility in affiliation with a medical school accredited by the American Council on Graduate Medical Education, the American Osteopathic Association or the American Podiatric Medicine Association under which the facility pays the licensee (either directly or through a professional corporation or nonprofit corporation or other appropriate entity) for administration, teaching, supervision and/or hands-on care, and under which the facility or licensee (directly or indirectly) bills patients and third party payors for hands-on care; or

vii. A contractual arrangement (either individually or through an individual practice association, competitive medical plan, or similar organization) with a licensed health care facility to provide health care services to the facility's employees and/or beneficiaries of the facility's health plan, and/or to provide services to eligible individuals pursuant to an agreement between the facility and a health maintenance organization, other managed health care organization, insurance company, union welfare plan, employers or other similar organizations.

3. "Immediate family" means the practitioner's spouse and children, the practitioner's siblings and parents, the practitioner's spouse's siblings and parents, and the spouses of the practitioner's children.

4. "Practitioner" means a physician, podiatrist, bioanalytical laboratory director or specialty laboratory director, acupuncturist, midwife, certified nurse midwife, physician assistant and all other categories of licensee now or henceforth under the jurisdiction of the State Board of Medical Examiners.

5. "Significant beneficial interest" means any financial interest including an equity or ownership interest in a practice or in a commercial entity holding itself out as offering health care service as defined in (a)1 above. This interest does not, however, include ownership of a building or component thereof wherein the space is leased, in writing, to a person or entity at the prevailing rate under a straight lease agreement (that is, a fixed fee for a fixed term), or any interest held in publicly traded securities.

6. "Grandfathered" means a personal attribute and status of an individual licensee derived from a significant beneficial interest in a health care service, held on or before July 30, 1991, which renders him or her exempt from the referral prohibitions set forth in N.J.S.A. 45:9-22.5. Those practitioners employed by or professionally affiliated with a grandfathered practitioner do not share the "grandfathered" status.

(b) A practitioner shall not refer a patient or direct an employee of the practitioner to refer a patient to a health care service in which the practitioner or the practitioner's immediate family, or the practitioner in combination with the practitioner's immediate family, has a significant beneficial interest, unless the practitioner held the interest prior to July 31, 1991 and discloses that interest to the patient as required herein or as otherwise permitted in this rule. Such a practitioner shall be deemed to be grandfathered. If a licensee professionally affiliated with a grandfathered practitioner obtains a significant beneficial interest in the same health care service in which the grandfathered practitioner holds an interest, on or after July 31, 1991, that practitioner shall not refer patients to that service. A licensee professionally affiliated with a grandfathered practitioner who does not hold an interest in that health care service may refer patients to that service so long as all of the disclosure requirements set forth below are met. Disclosure shall be made by the practitioner in ways appropriate to the professional circumstances including conspicuous posting of a written disclosure form prepared as set forth below, at least 8½ by 11 inches in size, in the practitioner's waiting room in all office locations. The patient shall also be provided with a personal copy of the notice. The notice format shall be as follows:

Public law/rule of the State of New Jersey/Board of Medical Examiners mandates that a physician, podiatrist and all other licensees of the Board of Medical Examiners inform patients of any significant financial interest held in a health care service.

Accordingly, take notice that practitioners in this office do have a financial interest in the following health care service(s) to which patients are referred:

(LIST APPLICABLE HEALTH CARE SERVICES)

You may, of course, seek treatment at a health care service provider of your own choice. A listing of alternative health care service providers can be found in the classified section of your telephone directory under the appropriate heading.

1. In any inquiry regarding the applicability of the financial disclosure provisions of this rule, including the holding of a significant beneficial interest or exemption therefrom, the Board may require a Board licensee to submit financial and familial information sufficient to determine the financial interest in an investment.

2. With regard to durable medical equipment, a physician having a significant beneficial interest as defined in (a) above, who prescribes and refers a patient to a source for said product, shall provide the personal notice copy to a patient in any setting, including the practitioner's office and prior to the time of patient discharge from a hospital, nursing home or free standing health care facility (for example, urgent care offices or ambulatory surgery centers).

3. Neither the prohibition on referral, nor disclosure requirements of this rule apply in the case of a practitioner providing health care services pursuant to a prepaid capitate contract with the Division of Medical Assistance and Health Services in the Department of Human Services.

4. The restrictions on referral of patients established in this subsection shall not apply to:

- i. A health care service that is provided at the practitioner's medical office for which the patient is billed directly by and in the practitioner's name; or
- ii. Radiation therapy pursuant to an oncological protocol, or lithotripsy or renal dialysis treatment, provided that there is disclosure of the financial interest.

(c) The following pertain to miscellaneous monetary arrangements:

1. A licensee shall not, directly or indirectly, give to or receive from any licensed or unlicensed source a gift of more than nominal (negligible) value, or any fee, commission, rebate or bonus or other compensation however denominated, which a reasonable person would recognize as having been given or received in appreciation for or to promote conduct by a licensee including: purchasing a medical product, ordering or promoting the sale or lease of a device or appliance or other prescribed item, prescribing any type of item or product for patient use, or making or receiving a referral to or from another for professional services. For example, a licensee who refers a patient to a health care service (such as a cardiac rehabilitation service or a provider of durable medical equipment or a provider of testing services) shall not accept from nor give to the health care service a fee directly or indirectly in connection with the referral, whether denominated as a referral or prescription fee or consulting or supervision fee or space leasing in which to render the services (other than as permitted in (h) below), or by any other name, whether or not the licensee has a financial interest as defined in (a) above.

i. The charging of a "facility fee," as described in (h)1 below, is forbidden, except by a registered Medicare provider of surgical services who is billing pursuant to criteria for such fee established by rules of the United States Department of Health and Human Services.

ii. This section shall be construed broadly to effectuate its remedial intent. It shall not, however, prohibit a flat-fee payment by a licensee for regular advertising services (including placement on a commercially-sponsored "referral list" of licensed health care providers). It shall not prohibit receipt of reasonable payment for bona fide participation as a speaker at a professional workshop or seminar nor attendance by non-faculty licensees at a continuing medical education program whereby in conformance with the guidelines of the American Council on Continuing Medical Education or the American Podiatric Medical Association commercial sources have been utilized in calculating the registration fees to be charged to all participants. It shall not prohibit receipt of normal, commercially reasonable discounts for volume purchases from vendors, nor prohibit compensation for the sale of medical equipment by a licensee of the Board, in the disclosed capacity of a salesman, to another licensed health care professional. It shall not prohibit a licensee's participation by permit in an FDA-approved research project.

2. A laboratory director licensee may bill either the patient or the prescribing physician who submits the specimen, as permitted by N.J.S.A. 45:1-10.

3. All other categories of licensees who bill for professional services shall submit the bill directly or via a named designee entity to the patient or patient representative if

for treatment services, or to the recipient of the professional services in a non-patient capacity, as applicable.

4. A bill for services of members of a professional service corporation, or services of a physician's employees which have been rendered by licensed professionals authorized to provide services without medical supervision, shall identify the provider of service by name and degree, as well as the name of the service entity (if different).

5. A licensee may bill for only the actual cost of prescribed professional/technical services (including, for example, laboratory services, radiologic and EKG consultation, fabrication of eyeglasses, orthotics, etc.) ordered by or through the licensee, with the patient's consent, provided that the name and address of the provider of the professional/technical services and the cost as billed to the licensee, are disclosed to the patient. A licensee may contract with and provide professional/technical services to the prescribing licensee, supplying the information necessary for incorporation in the bill prepared by the prescribing licensee to the patient.

(d) A licensee shall not charge for "free samples" or other similar items obtained by the licensee from any source.

(e) Acting within the scope of lawful practice, a licensee may offer to and provide to a patient medications, including a prescription drug or an over-the-counter preparation or vitamin or food supplement, but only in accordance with the requirements of P.L. 1991, c.187, sec. 46 (N.J.S.A. 45:9-22.11) and N.J.A.C. 13:35-6.6. A licensee may also offer to and provide to a patient medical goods and devices under certain circumstances, as set forth in this rule and defined as follows: medical goods and devices include, but are not limited to, such items as hearing aids, eyeglasses, contact lenses, prosthetic devices, orthotics, etc.

1. A Board licensee shall derive his or her net professional income from the rendering of professional service. The practitioner may recoup the net discounted cost of providing those goods and devices which are ancillary to the primary professional service, plus an administrative cost not to exceed 10 percent of the cost of the item. The licensee shall not charge for these items a fee intended to generate a profit.

i. A discount is a reduction in the amount a seller charges for a good or service to the licensee who has bought (either directly or through a wholesaler or a group purchasing organization) based on an arms-length transaction.

ii. For the purpose of this rule, the practitioner need not calculate or disclose the value of a rebate check, credit or coupon directly redeemable from the seller to the extent that such reductions in price are attributable to the original good or service that was purchased or furnished, and is to be utilized only as credit toward future purchase from the same vendor;

the price of the later goods/services will reflect that discount.

iii. A practitioner shall not accept from the seller discounts which include rebates of cash, coupons other than as defined above, or other kinds of free goods or services.

2. (Reserved)

3. Where items are prescribed by a licensee, and the consumer elects to fill the prescription elsewhere, the prescriber's obligation to the patient shall include, if requested by the patient, follow-up to ascertain that the item prescribed is appropriate and/or the fit is acceptable (for example, as in the prescribing of eyeglasses or external contact lenses), and that the result of the prescribed service is properly evaluated and integrated into the treatment plan for the patient.

4. The requirement to charge no more than true cost plus 10 percent for an item prescribed and sold shall not apply to a hearing aid dispenser licensed pursuant to N.J.S.A. 45:9A-1 et seq. However, the customer receipt required by N.J.A.C. 13:35-8.14 shall clarify "cost" of earmold and of hearing aid by designating it as the "retail price" of each.

(f) As addressed in N.J.A.C. 13:35-6.16(h), a licensee may participate in and receive remuneration from organized managed health care plans including, but not limited to, those involving wholly or partially pre-paid medical service. By way of example, this includes plans commonly described as health maintenance organizations, preferred provider organizations, competitive medical plans, individual practice associations or other similar organizations.

1. A licensee is not precluded from entering into a plan agreement which provides interim remuneration to licensees by making provisional allocation of percentages of plan-member fees, whether denominated as reserves, pools, withholds, holdbacks, etc., for the purpose of funding all portions of the health care services plan.

2. A licensee may participate in a managed health care services plan which requires a purchase of shares for the purpose of providing start-up funds, provided that any profits of the plan are paid solely in accordance with the principles listed in (g) below.

(g) No licensee shall invest in an entity, including a managed health care plan, offering health care services or devices or durable medical equipment where the dividends or any other forms of remuneration are paid on any basis other than return on monetary investment. This prohibition does not preclude the issuance of shares in exchange for provision of equipment or realty or rendition of personal professional services at the entity premises, or licensing of patents in lieu of financial investment, provided that the investor's return is based on his/her capital interest.

(h) The following pertain to real estate and medical equipment arrangements:

1. A Board licensee may be an owner/investor in real estate or medical equipment utilized for the conduct of a professional health care practice, provided that rent, dividends or any other forms of remuneration are received solely on the basis of the investment or fair market value, as applicable to the circumstances.

2. A Board licensee may lease professional space from a commercial (non-professional) entity on any arrangements consistent with standard business practice in the community, provided that the arrangement does not affect the licensee's professional discretion in matters including choice of patients, professional services offered, or fees.

3. A Board licensee may lease space or medical equipment to or from another licensed health care professional to whom patients are referred, only where rent is a fixed fee set in advance and determined by the fair market value, or less, and is for a regular term and not for sporadic use of the space or equipment.

4. Any monetary arrangement other than as set forth above shall require Board approval for good cause shown.

5. A licensee who owns or practices in premises used for the performance of personal medical services including, but not limited to, ambulatory surgery services but not holding a Certificate of Need from the State Department of Health, shall not charge, or permit or condone a charge or "facility fee" separate from the fee for professional services. A facility fee may, however, be charged by a licensee who is a registered Medicare provider of surgical services, who is billing pursuant to criteria for such fee established by rules of the United States Department of Health and Human Services.

(i) A Board licensee may be an owner/investor or a lessee of medical equipment utilized in the conduct of a professional practice. Irrespective of the financial arrangements for the transaction, the lessee shall be at all times responsible to assure that an appropriate licensed health care professional determines and carries out all services and medical care policies set forth in N.J.A.C. 13:35-6.16(b) and (c), including retention of sole discretion regarding medical indications for use of the equipment, and establishment of patient fees and modification or waiver thereof in an individual case. (See also (b) above regarding mandatory disclosure to referred patients, as applicable.)

(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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### 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-chlorotestosterone)  
 Chorionic gonadotropin  
 Clostebol  
 Danazol  
 Dehydrochlormethyltestosterone  
 Dihydrotestosterone  
 (4-dihydrotestosterone)  
 Drostanolone  
 Ethylestrenol  
 Fluoxymesterone  
 Formebolone (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 medi-

cal 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.