

Case Notes

Psychiatrist's engaging in sexual relations with patient warrants suspension of medical license. In the Matter of the Suspension or Revocation of the License of Tricarico, 96 N.J.A.R.2d (BDS) 18.

Florida's revocation of physician's license for sexual misconduct supports New Jersey's license revocation. In the Matter of Vatakencherry, 96 N.J.A.R.2d (BDS) 1.

13:35-6.4 Delegation of administration of subcutaneous and intramuscular injections to certified medical assistants

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

1. "Physician" means a doctor of medicine (M.D.), a doctor of osteopathic medicine (D.O.), or a doctor of podiatric medicine.

2. "Certified medical assistant" means a graduate of a post-secondary medical assisting education program accredited by CAHEA (The Committee on Allied Health Education and Accreditation of the American Medical Association), or its successor; ABHES (Accrediting Bureau of Health Education Schools), or its successor; or any accrediting agency recognized by the U.S. Department of Education. The educational program shall include, at a minimum, 600 clock hours of instruction and shall encompass training in the administration of intramuscular and subcutaneous injections and instruction and demonstration in: pertinent anatomy and physiology appropriate to injection procedures; choice of equipment; proper technique including sterile technique; hazards and complications; and emergency procedures. The medical assistant must also maintain current certification from the Certifying Board of the American Association of Medical Assistants (AAMA), or registration from the American Medical Technologists (AMT), or any other recognized certifying body approved by the Board.

(b) A physician may direct a certified medical assistant employed in the medical practice in which the physician practices medicine, to administer to the physician's patients an intramuscular or subcutaneous injection in the limited circumstances set forth in this section, without being in violation of the pertinent professional practice act implemented by the Board, to the extent such conduct is permissible under any other pertinent law or rule administered by the Board or any other State agency.

(c) A physician may direct the administration of an injection by a certified medical assistant only where the following conditions are satisfied:

1. The physician has determined and documented that the certified medical assistant has the qualifications set forth in (a)2 above and has attained a satisfactory level of comprehension and experience in the administration of intramuscular and subcutaneous injection techniques.

2. The physician shall examine the patient to ascertain the nature of the trauma, disease or condition of the patient; to determine the appropriate treatment of the patient including administration of an injection; to assess the risks of such injection for a given patient and the diagnosed injury, disease or condition; and to determine that the anticipated benefits are likely to outweigh those risks.

3. The physician shall determine all components of the precise treatment to be given, including the type of injection to be utilized, dosage, method and area of administration, and any other factors peculiar to the risks, such as avoidance of administration sites on certain parts of the body. The physician shall assure that this information shall be written on the patient's record and made available at all times to the medical assistant carrying out the treatment instructions, who shall also be identified by name and credentials in the patient record on each occasion that an injection is administered.

4. The physician shall remain on the premises at all times that treatment orders for injections are being carried out by the assistant and shall be within reasonable proximity to the treatment room and available to observe, assess and take any necessary action regarding effectiveness, adverse reaction or any emergency.

5. The certified medical assistant shall wear a clearly visible identification badge indicating his or her name and credentials.

(d) The physician shall not direct the administration by a certified medical assistant of an injection which includes any of the following: any substance related to allergenic testing or treatment, local anesthetics, controlled dangerous substances, experimental drugs including any drug not having approval of the Food and Drug Administration (FDA), or any substance used as an antineoplastic chemotherapeutic agent with the exception of corticosteroids.

Amended by R.1989 d.532, effective October 16, 1989.

See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).

In (a)3, inserted "purchasing or" preceding "prescribing".

Repealed by R.1992 d.75, effective February 18, 1992 (operative April 15, 1992).

See: 23 N.J.R. 161(a), 23 N.J.R. 1063(a), 24 N.J.R. 626(a).

Section was "Prohibition of kickbacks, rebates or receiving a payment for services not rendered."

New Rule, R.1997 d.226, effective June 2, 1997.

See: 28 N.J.R. 2317(a), 28 N.J.R. 3512(a), 29 N.J.R. 2564(a).

Amended by R.1998 d.560, effective December 7, 1998.

See: 29 N.J.R. 4740(a), 30 N.J.R. 4247(b).

In (c), deleted former 4 and recodified former 5 and 6 as 4 and 5; and added (d).

13:35-6.5 Preparation of patient records, computerized records, access to or release of information; confidentiality, transfer or disposal of records

(a) The following terms shall have the following meanings unless the context in which they appear indicates otherwise:

“Authorized representative” means, but is not necessarily limited to, a person who has been designated by the patient or a court to exercise rights under this section. An authorized representative may be the patient’s attorney or an employee of an insurance carrier with whom the patient has a contract which provides that the carrier be given access to records to assess a claim for monetary benefits or reimbursement. If the patient is a minor, a parent or guardian who has custody (whether sole or joint) will be deemed to be an authorized representative, except where the condition being treated relates to pregnancy, sexually transmitted disease or substance abuse.

“Examinee” means a person who is the subject of professional examination where the purpose of that examination is unrelated to treatment and where a report of the examination is to be supplied to a third party.

“Licensee” means any person licensed or authorized to engage in a health care profession regulated by the Board of Medical Examiners.

“Patient” means any person who is the recipient of a professional service rendered by a licensee for purposes of treatment or a consultation relating to treatment.

(b) Licensees shall prepare contemporaneous, permanent professional treatment records. Licensees shall also maintain records relating to billings made to patients and third-party carriers for professional services. All treatment records, bills and claim forms shall accurately reflect the treatment or services rendered. Treatment records shall be maintained for a period of seven years from the date of the most recent entry.

1. To the extent applicable, professional treatment records shall reflect:

- i. The dates of all treatments;
- ii. The patient complaint;
- iii. The history;
- iv. Findings on appropriate examination;
- v. Progress notes;
- vi. Any orders for tests or consultations and the results thereof;
- vii. Diagnosis or medical impression;
- viii. Treatment ordered, including specific dosages, quantities and strengths of medications including refills if prescribed, administered or dispensed, and recommended follow-up;
- ix. The identity of the treatment provider if the service is rendered in a setting in which more than one provider practices;

x. Documentation when, in the reasonable exercise of the physician’s judgment, the communication of test results is necessary and action thereon needs to be taken, but reasonable efforts made by the physician responsible for communication have been unsuccessful; and

xi. Documentation of the existence of any advance directive for health care for an adult or emancipated minor, and associated pertinent information. Documented inquiry shall be made on the routine intake history form for a new patient who is a competent adult or emancipated minor. The treating doctor shall also make and document specific inquiry of or regarding a patient in appropriate circumstances, such as when providing treatment for a significant illness, or where an emergency has occurred presenting imminent threat to life, or where surgery is anticipated with use of general anesthesia.

2. Corrections/additions to an existing record can be made, provided that each change is clearly identified as such, dated and initialed by the licensee.

3. A patient record may be prepared and maintained on a personal or other computer only when it meets the following criteria:

i. The patient record shall contain at least two forms of identification, for example, name and record number or any other specific identifying information;

ii. An entry in the patient record shall be made by the physician contemporaneously with the medical service and shall contain the date of service, date of entry, and full printed name of the treatment provider. The physician shall finalize or “sign” the entry by means of a confidential personal code (“CPC”) and include date of the “signing”;

iii. Alternatively, the physician may dictate a dated entry for later transcription. The transcription shall be dated and identified as “preliminary” until reviewed, finalized and dated by the responsible physician as provided in (b)3ii above;

iv. The system shall contain an internal permanently activated date and time recordation for all entries, and shall automatically prepare a back-up copy of the file;

v. The system shall be designed in such manner that, after “signing” by means of the CPC, the existing entry cannot be changed in any manner. Notwithstanding the permanent status of a prior entry, a new entry may be made at any time and may indicate correction to a prior entry;

vi. Where more than one licensee is authorized to make entries into the computer file of any professional treatment record, the physician responsible for the medical practice shall assure that each such person obtains a CPC and uses the file program in the same manner;

vii. A copy of each day's entry, identified as preliminary or final as applicable, shall be made available promptly:

(1) To a physician responsible for the patient's care;

(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 initialed 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 initialed 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's mental or physical condition will be adversely affected upon being made aware of the subjective information contained in the professional treatment record or a summary thereof, with an accompanying notice setting forth the reasons for the original refusal, shall nevertheless be provided upon request and directly to:

- i. The patient's attorney;
- ii. Another licensed health care professional;

iii. The patient's health insurance carrier through an employee thereof; or

iv. A governmental reimbursement program or an agent thereof, with responsibility to review utilization and/or quality of care.

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 had 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. Nothing in this paragraph, however, shall be construed to authorize the release of the content of a record containing identifying information about a person who has AIDS or an HIV infection, without patient consent, for any purpose other than those authorized by N.J.S.A. 26:5C-8. If a licensee, without the consent of the patient, seeks to release information contained in an AIDS/HIV record to a law enforcement agency or other health care professional in order to minimize the threat of danger to others, an application to the court shall be made pursuant to N.J.S.A. 26:5C-5 et seq.

(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 a copy of the treatment records or acquiesce in the transfer of those records to another licensee or health care professional who is assuming responsibilities of the practice. However, a licensee shall not charge a patient, pursuant to (c)4 above, for a copy of the records, when the records will be used for purposes of continuing treatment or care.
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).

Amended by R.1998 d.184, effective April 6, 1998.

See: 29 N.J.R. 840(b), 30 N.J.R. 1295(a).

In (a), added exception at the end of the sentence; in (c)3, substituted "patient's mental or physical condition will be adversely affected upon being made aware" for "patient may be harmed by release"; in (c)3iii, added "through an employee thereof; or" at the end of the sentence and added a new iv; in (d)4, added the last two sentences; in (h)1, inserted "a copy of the" preceding "treatment records" and added the last sentence.

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).

Use of improper procedures at abortion clinics and failure to supervise staff support suspension of doctors operating facility. In the *Matter of Miro and Steck*, 97 N.J.A.R.2d (BDS) 1.

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 (Reserved)

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).

Repealed by R.1997 d.475, effective November 3, 1997.

See: 29 N.J.R. 842(a), 29 N.J.R. 4706(a).

Section was "Requirements for issuing prescriptions for and dispensing all medications; special requirements for prescribing or dispensing controlled drugs".

13:35-6.7 (Reserved)

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).

Repealed by R.1997 d.475, effective November 3, 1997.

See: 29 N.J.R. 842(a), 29 N.J.R. 4706(a).

Section was "Prescribing of amphetamines and sympathomimetic amine drugs".

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.