CHAPTER 35

BOARD OF MEDICAL EXAMINERS

Authority

N.J.S.A. 45:9–2.

Source and Effective Date

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

Executive Order No. 66(1978) Expiration Date

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

Chapter Historical Note

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 Chapter 35, except Subchapter 8, Hearing Aid Dispensers, was repealed and new rules of the Board of Medical Examiners, Subchapters 1 through 6, were adopted as R.1983 d.314, effective August 1, 1983.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

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

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 As a part of R.1994 d.522, Subchapter 7, Chiropractic Practice, was repealed, effective October 17, 1994.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

Petition for Rulemaking. See: 30 N.J.R. 740(c), 1642(a).

Law Review and Journal Commentaries

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

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(d) The Board in its discretion may waive any or all of the required subjects if the credentials presented include proof of a score of 80 on each part of the Federation Licensing Examination or the Uniform State Medical Licensing Examination.

(e) If the Board identifies substantive deficiencies, and none of the credentials identified at (b), (c) or (d) above have been presented, the applicant may be provided leave to secure such credentials and the Board, upon request, may provide guidance to applicants seeking to remediate deficiencies.

New Rule, R.1994 d.539, effective November 7, 1994.
See: 26 N.J.R. 2742(b), 26 N.J.R. 4418(a).

13:35–3.13 Criminal history record information

The Board shall require a criminal history record check by the Division of State Police of all applicants for initial licensure to practice medicine and surgery in this State. Such criminal history record checks shall be obtained, processed and maintained in accordance with the procedures established by the Division of State Police pursuant to P.L. 1994, c.60 (N.J.S.A. 53:1–20.5 et seq.) and N.J.A.C. 13:59. Such criminal history records shall be disseminated in strict accordance with the limitations established by the Division of State Police pursuant to N.J.A.C. 13:59–1.6 and are not public records within the meaning of the Right to Know Law, P.L. 1963, c.73 (N.J.S.A. 47:1A–1 et seq.). Fees for criminal history record checks shall be paid by applicants for licensure in conformity with P.L. 1994, c.60 (N.J.S.A. 53:1–7) and N.J.A.C. 13:59–1.3 and 1.4. In addition to its use in evaluating an application for initial licensure, the Board may obtain criminal history record information from the Division of State Police for any other purpose authorized by statute or regulation.

New Rule, R.1995 d.554, effective October 16, 1995.
See: 27 N.J.R. 1743(a), 27 N.J.R. 3964(a).

SUBCHAPTER 4. SURGERY

13:35–4.1 Major surgery; qualified first assistant

(a) A major surgical procedure is one with a substantial hazard to the life, health or welfare of a patient. By way of example, but not limitation, a major surgical procedure includes:

1. A procedure in which an opening is made into any of the three major body cavities (abdomen, chest or head), exclusive of endoscopic approaches which explore existing channels and involve no transverse of a body wall (for example, bronchoscopy, colonoscopy) or are exclusively diagnostic (for example, laparoscopy, colposcopy). With respect to non-diagnostic endoscopic procedures requiring the transverse of a body wall, a duly qualified first assistant shall be immediately available in the operating suite;

2. A procedure performing a major amputation;

3. A procedure performed where the locality, the condition, the difficulty or the length of time required to operate would constitute a direct hazard to the life of the patient.

(b) A major surgical procedure shall be performed by a duly qualified surgeon with a duly qualified assisting physician who may be a duly qualified resident in or rotating through a training program approved by the Accreditation Council on Graduate Medical Education or the American Osteopathic Association.

(c) In addition to those individuals listed in (b) above who may act as qualified first assistants, in a health care facility licensed by the Department of Health, a duly qualified registered nurse first assistant (RNFA) or a duly qualified physician assistant may so act.

(d) A duly qualified surgeon, duly qualified assistant physician, duly qualified resident, duly qualified registered nurse first assistant or duly qualified physician assistant shall be determined by the hospital credentials committee in conjunction with the chairman or chief of the appropriate committee in conjunction with the chairman or chief of the appropriate department or division consistent with the requirements of law or applicable rule.

(e) It shall be the responsibility of each medical staff to promulgate appropriate rules to fully and carefully implement the requirements of (b), (c), and (d) above by determining which procedures shall be considered major surgery in accordance with (a) above, and determining the credentials of each individual qualified to act as first assistant for any given major surgical procedure. The medical staff and hospital board of trustees shall assure compliance by the individual first assistants with this rule of the Board and the rules of the hospital or other facility licensed by the Department of Health.

(f) In all instances in which a registered nurse first assistant or a physician assistant may act as first assistant pursuant to (c) above, the operating surgeon shall have discretion to determine whether to utilize such an individual as a first assistant, despite the fact that they are permitted to so act pursuant to this rule.

(g) In the event of incapacity or unavailability of the operating surgeon during a major surgical procedure, the functions of a first assistant who is not a physician shall be limited to maintaining the status of the patient while a substitute operating surgeon is summoned, except in matters of dire emergency. "Dire emergency" shall include only those circumstances posing a significant risk of imminent death or serious bodily injury to the patient, such as uncontrolled bleeding.

Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
Deleted reference to specific statute.
Amended by R.1994 d.522, effective October 17, 1994.
See: 26 N.J.R. 2526(a), 26 N.J.R. 4195(a).
Amended by R.1995 d.503, effective September 5, 1995.
See: 27 N.J.R. 1744(a), 27 N.J.R. 3365(a).

Cross References

Physician assistant, assisting surgery, see N.J.A.C. 13:35–6.15.

Case Notes

Validity of rule (dissenting opinion). Eatough v. Albano, 673 F.2d 671 (1982) certiorari denied 102 S.Ct. 2931, 457 U.S. 1119, 73 L.Ed.2d 1331.

License revocation for violation of Medical Practice Act upheld; no denial of due process; Board could only impose monetary penalty for each statutory provision violated; additional penalties for multiple violations of each provision improper where physicians had no prior convictions for such offenses. In re Suspension of License of Wolfe, 160 N.J.Super. 114, 388 A.2d 1316 (App.Div.1978) certification denied 78 N.J. 406, 396 A.2d 592 (1978).

Former N.J.A.C. 13:35–7.1 governing the conduct of major surgery upheld as not inconsistent with the Medical Practice Act and as neither arbitrary, capricious, unreasonable nor vague. Garden State Community Hospital v. State Bd. of Medical Examiners, 147 N.J.Super. 592, 371 A.2d 794 (App.Div.1977) certification denied 74 N.J. 283, 377 A.2d 688 (1977).

13:35–4.2 Termination of pregnancy

(a) This rule is intended to regulate the quality of medical care offered by licensed physicians for the protection of the public, and is not intended to affect rules of the Department of Health establishing institutional requirements. To the extent that rules of the two agencies may overlap, the Medical Board recognizes and relies upon the regulatory procedures of the Department of Health in establishing minimum acceptable standards for non-physician personnel, equipment and resources, the adequacy of the physical plant of the facility in which surgical procedures shall be performed, and the facility's interrelationship with an adequate network of health care-related resources such as ambulance service, etc.

(b) The termination of a pregnancy at any stage of gestation is a procedure which may be performed only by a physician licensed to practice medicine and surgery in the State of New Jersey.

(c) Provisions of this rule referring to stage of pregnancy shall be in terms of weeks from start of last menstrual period or "weeks LMP." For example, the stage of pregnancy at 12 weeks' gestational size, as determined by a physician, is the equivalent of 14 weeks from the first day of the last menstrual period (LMP).

(d) After 14 weeks LMP, any termination procedure other than dilatation and evacuation (D & E) shall be performed only in a licensed hospital.

(e) Fifteen weeks through 18 weeks LMP: After 14 weeks LMP and through 18 weeks LMP, a D & E procedure may be performed either in a licensed hospital or in a licensed ambulatory care facility (referred to herein as LACF) authorized to perform surgical procedures by the Department of Health. The physician may perform the procedure in an LACF which shall have a Medical Director who shall chair a Credentials Committee. The Committee shall grant to operating physicians practice privileges relating to the complexity of the procedure and commensurate with an assessment of the training, experience and skills of each physician for the health, safety and welfare of the public. A list of the privileges of each physician shall contain the effective date of each privilege conferred, shall be reviewed at least biennially, and shall be preserved in the files of the LACF.

(f) Nineteen weeks through 20 weeks LMP: A physician planning to perform a D & E procedure after 18 weeks LMP and through 20 weeks LMP in an LACF shall first file with the Board a certification signed by the Medical Director that the physician meets the eligibility standards set forth in (f)1 through 7 below and shall comply with its requirements.

1. The physician is certified or eligible for certification by the American Board of Obstetrics-Gynecology or the American Osteopathic Board of Obstetrics-Gynecology, and the physician satisfactorily completes at least 15 hours of Continuing Medical Education each year in obstetrics-gynecology.

2. The physician has admitting and surgical privileges at a nearby licensed hospital which has an operating room, blood bank, and an intensive care unit. The hospital shall be accessible within 20 minutes driving time during the usual hours of operation of the clinic.

3. The procedure shall be done in a location which is designated by the Department of Health as a licensed ambulatory care facility (LACF) authorized to perform surgical procedures as in subsection (e) above. The LACF shall be licensed by the Department of Health as an ambulatory care facility authorized to perform surgical procedures. The facility shall be in current and good standing at all times when surgical procedures are performed there. The LACF shall have a written agreement with an ambulance service assuring immediate transportation of a patient at all times when a patient has been admitted for surgery and until the patient has been discharged from the recovery room.

4. The procedure shall be done in an LACF which shall have a Medical Director and a Credentials Committee which have duly evaluated the training, experience and skill of the physician at continuous and successive levels of complexity of the D & E procedure in pregnancies advancing in stages from 18 weeks LMP through 19 weeks LMP through 20 weeks LMP, and the physician has been granted successive practice privileges consistent with management of the increased risk to the health and safety of the patient at that stage documented in the personnel file maintained for that physician. (Where the applicant physician is also the Medical Director, the physician shall submit a certificate from the Administrator or Chief of Department of a hospital or the Medical Director of an LACF where the applicant has been evaluated and credentialed in a comparable manner.) The physician new to the LACF shall have his or her operating technique evaluated initially and at least yearly by the Medical Director or his or her designee who shall possess appropriate experience with D & E procedures at least as advanced as those for which the applicant physician seeks approval. The applicant shall be evaluated during that number of procedures which shall be adequate to achieve a sufficient professional skill, and the evaluation procedure shall be documented in the personnel file maintained for that physician. The Medical Director shall agree to review the charts of all patients who suffer complications and in addition shall review charts at random, and shall calculate the complication rate of each physician.

5. The physician shall perform the procedure only on a patient who has been examined and found to be within the eligibility criteria established for advanced D & E procedures in the LACF setting.

6. The procedure shall be performed in an LACF providing adequate staff support and resources for the operative procedure as well as interim follow-up and postoperative care, and where a physician is available and readily accessible 24 hours/day to respond to any postoperative problem.

7. The physician shall cooperate with the Medical Director to maintain contemporaneous and cumulative statistical records demonstrating the utilization and safety record of each stage procedure and of each surgeon. Said records shall be available for inspection by the Board and copies shall be submitted to the Board semi-annually. These records shall include the following information and data shall be maintained in records compiled monthly, but individual patients comprising the lists shall be identified only by date and by initials and/or case number:

i. Number of patients who received termination procedures;

ii. Number of patients who received laminaria or osmotic cervical dilators who failed to return for completion of the procedure;

iii. Number of patients who reported for postoperative visits;

iv. Number of patients who needed repeat procedures;

v. Number of patients who received transfusions;

vi. Number of patients suspected of perforation;

vii. Number of patients who developed pelvic inflammatory disease within two weeks;

viii. Number of patients who were admitted to a hospital within two weeks of the procedure;

ix. Number of patients who died within 30 days.

Subparagraphs ii. through ix. above shall be summarized by number and percentage of monthly total for post–18 week procedures. The Board shall inspect such reports monthly for the first five months and at such further monthly intervals as it deems necessary.

(g) After 20 weeks: A physician may request from the Board permission to perform D & E procedures in an LACF after 20 weeks LMP. Such request shall be accompanied by proof, to the satisfaction of the Board, of superior training and experience as well as proof of support staff and facilities adequate to accommodate the increased risk to the patient of such procedure.

(h) The physician shall make suitable arrangements to insure that all tissues removed shall be properly disposed of by submission to a qualified physician for pathologic analysis or by incineration or by delivery to a person/entity licensed to make biologic and/or tissue disposals in accordance with law including rules of the Department of Health applicable to an LACF.

As amended, R.1984 d.470, effective October 15, 1984.
See: 16 N.J.R. 2064(a), 16 N.J.R. 2823(a).
Section substantially amended.
Amended by R.1985 d.530, effective October 21, 1985.
See: 17 N.J.R. 1865(a), 17 N.J.R. 2562(b).
(e) recodified to (f) and new (e) added.
New Rule, R.1986 d.25, effective February 3, 1986.
See: 17 N.J.R. 2738(a), 18 N.J.R. 286(a).
Old rule repealed and new rule added.
Amended by R.1986 d.217, effective June 16, 1986.
See: 18 N.J.R. 614(a), 18 N.J.R. 1306(b).
Substantially amended.
Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
Deleted references to specific statutes and rules.

Case Notes

Preliminary injunction granted against regulation forbidding outpatient facility abortions after 18 weeks gestation or 20 weeks after last menstrual period; history of regulation; finding that plaintiffs likely to succeed in regulatory challenge due to regulation's possible result of causing women to forego their abortion rights if procedure medically acceptable on an outpatient basis is restricted to hospitals only (citing former regulation and previous codification as N.J.A.C. 13:35–7.2). Pilgrim Medical Group v. New Jersey State Bd. of Medical Examiners, 613 F.Supp. 837 (D.N.J.1985).

Former termination of pregnancy rule N.J.A.C. 13:35–7.2 upheld as properly adopted and reasonably related to maternal health; State has a compelling interest in maternal health after the first trimester of pregnancy so as to validate rules that foster that health. Livingston v. New Jersey State Bd. of Medical Examiners, 168 N.J.Super. 259, 402 A.2d 967 (App.Div.1979) certification denied 81 N.J. 406, 408 A.2d 800 (1979).

Physician's conduct in performing second trimester abortions was found not to constitute gross negligence, malpractice and incompetence; however, charges that physician's advertisements for safe, painless abortions were misleading were upheld. In the Matter of Steven Chase Brigham, 96 N.J.A.R.2d (BDS) 35.

SUBCHAPTER 5. EYE EXAMINATIONS; EYEGLASSES

13:35–5.1 Minimum eye examination; contact lenses

(a) Physicians licensed to practice medicine and surgery, when performing an eye examination for the purpose of prescribing corrective lenses, shall fully and adequately disclose to the patient the limited purpose of the eye examination. The physician shall perform, and keep a complete record of, physical examination of the patient which shall include:

1. A complete history of visual aberrations;

2. A determination of visual acuity in each eye separately;

3. A cover test, distance and near, and a determination of muscle balance or imbalance;

4. An ophthalmoscopic examination and a determination of any abnormalities of lids, cornea, pupils, lens, vitreous and fundus. A record entry of "negative" or "clear" should be made if no pathology is found.

(b) Upon observing positive findings of ocular disease or abnormality, the physician shall disclose his findings to the patient and suggest an appropriate course of action.

(c) The complete record of contact lens specifications shall be released by an ophthalmologist to another ophthalmologist, optometrist or ophthalmic dispenser licensed in New Jersey upon either the oral or written request of the patient or the professional acting on the patient's behalf.

13:35–5.2 Minimum standards and tolerances of optical lenses

(a) Every pair of lenses, spectacles, eyeglasses or appurtenances thereto, prepared for or dispensed to the intended wearers from written prescriptions of physicians duly licensed to practice their profession, or duplication, replacements, reproductions or repetitions, must conform to the following minimum standards and tolerances:

PHYSICAL QUALITY AND APPEARANCE

1. Surface imperfections

TOLERANCE: No pits, scratches (other than hairline), grayness or watermarks shall be acceptable.

2. Glass defects

TOLERANCE: No bubbles, striae and inclusions shall be acceptable.

3. Localized power errors

TOLERANCE: Waves found by visual inspection shall be passable if no deterioration in image quality is found when the localized area is examined with a standard lens measuring instrument.

4. Refractive powers

TOLERANCE: 0.0. to 6.00, + or −0.12.

6.25 to 12.00, 2 per cent of power.

Above 12.00, + or −0.25.

Maximum cylinder power variation + or −0.12.

5. Refractive power addition

TOLERANCE: + or −0.12.0.

6. Cylinder Axis

TOLERANCE: 0.12 to 0.37 + or −3 degrees.

0.50 to 1.00, + or −2 degrees.

1.12 on up, + or −1 degree.

7. Prism power and location of specified optical center

TOLERANCE: Vertical + or −0.25 prism for each lens or a total of 0.50 prism imbalance. Horizontal + or −0.25 prism for each lens or a total of 0.50 prism imbalance.

8. Segment size

TOLERANCE: + or −0.5 mm. Pair must be symmetrical upon visual inspection.

9. Segment location

TOLERANCE: As specified within + or −0.5 mm.

10. Lens size:

i. Rimless

TOLERANCE: + or −0.5 mm;

ii. Bevel, for plastic frames

TOLERANCE: + or −0.5 mm;

iii. Bevel, for metal frames

TOLERANCE: To fit standard specified frame. Lens shape must match. Edges must be smooth and straight and sharp edge must be removed.

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 not direct the administration by a certified medical assistant of an injection which includes any of the following: controlled dangerous substances, experimental drugs including any drug not having approval of the Food and Drug Administration (FDA), or any substance used as an anti-neoplastic chemotherapeutic agent with the exception of corticosteroids.

5. 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.

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

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).

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).

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.