

CHAPTER 35
BOARD OF MEDICAL EXAMINERS

Authority

N.J.S.A. 45:9-2.

Source and Effective Date

R.1999 d.356, effective September 20, 1999.
See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

Chapter Expiration Date

In accordance with N.J.S.A. 52:14B-5.1c, Chapter 35, Board of Medical Examiners, expires on March 19, 2005. See: 36 N.J.R. 4633(a).

Chapter Historical Note

Chapter 35, Board of Medical Examiners, was filed and became effective prior to September 1, 1969.

Chapter 35, Board of Medical Examiners, was repealed and Chapter 35, Board of Medical Examiners, was adopted as new rules by R.1983 d.314, effective August 1, 1983.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, Board of Medical Examiners, 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, Board of Medical Examiners, was readopted as R.1994 d.522, effective September 19, 1994, and Subchapter 7, Chiropractic Practice, was repealed by R.1994 d.522, effective October 17, 1994. See: 26 N.J.R. 2526(a), 26 N.J.R. 4195(a).

Subchapter 2B, Limited Licenses: Physician Assistants, was adopted as R.1994 d.538, effective November 7, 1994. See: 25 N.J.R. 5099(b), 26 N.J.R. 4411(b).

Subchapter 11, Alternate Resolution Program, was adopted as R.1995 d.339, effective June 19, 1995. See: 27 N.J.R. 1363(a), 27 N.J.R. 2412(a).

Subchapter 7, Prescription, Administration and Dispensing of Drugs, was adopted as R.1997 d.475, effective November 3, 1997. See: 29 N.J.R. 842(a), 29 N.J.R. 4706(a).

Subchapter 4A, Surgery, Special Procedures, and Anesthesia Services Performed in an Office Setting, was adopted as R.1998 d.294, effective June 15, 1998. See: 29 N.J.R. 2238(a), 30 N.J.R. 2236(b).

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

Pursuant to Executive Order No. 66(1978), Chapter 35, Board of Medical Examiners, was readopted as R.1999 d.356, effective September 20, 1999. See: Source and Effective Date. See, also, section annotations.

Law Review and Journal Commentaries

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

CHAPTER TABLE OF CONTENTS

SUBCHAPTER 1. MEDICAL SCHOOLS, COLLEGES, EXTERNSHIPS, CLERKSHIPS AND POST-GRADUATE WORK

- 13:35-1.1 Observership program
- 13:35-1.2 Fifth Pathway
- 13:35-1.3 Postgraduate training
- 13:35-1.4 Military service in lieu of M.D. or D.O. internship or postgraduate training
- 13:35-1.5 Registration and permit requirements for graduate medical education programs in medicine or podiatry

SUBCHAPTER 1A. STANDARDS FOR NEW JERSEY CLINICAL TRAINING PROGRAMS SPONSORED BY MEDICAL SCHOOLS NOT ELIGIBLE FOR EVALUATION AND NOT APPROVED BY THE L.C.M.E., THE A.O.A. OR OTHER AGENCY RECOGNIZED BY THE NEW JERSEY STATE BOARD OF MEDICAL EXAMINERS

- 13:35-1A.1 Definitions and principles of responsibility
- 13:35-1A.2 Administration of the clinical training program
- 13:35-1A.3 Faculty
- 13:35-1A.4 Education program
- 13:35-1A.5 Facilities
- 13:35-1A.6 Request for approval
- 13:35-1A.7 Public record
- 13:35-1A.8 Termination of program approval
- 13:35-1A.9 Violations
- 13:35-1A.10 Severability
- 13:35-1A.11 Clerkship program approvals: effective date; limited waiver provision; no new applications

SUBCHAPTER 2. LIMITED LICENSES: PODIATRY, DIAGNOSTIC TESTING CENTERS AND MISCELLANEOUS

- 13:35-2.1 Approved colleges of podiatry
- 13:35-2.2 Podiatry internship or postgraduate work
- 13:35-2.3 Military service in lieu of internship in podiatry
- 13:35-2.4 through 13:35-2.5 (Reserved)
- 13:35-2.6 Medical standards governing screening and diagnostic medical testing offices; determinations with respect to the validity of certain diagnostic tests
- 13:35-2.7 through 13:35-2.12 (Reserved)
- 13:35-2.13 Limited privileges and conditions of practice permitted for a graduate physician pending licensure
- 13:35-2.14 (Reserved)

SUBCHAPTER 2A. LIMITED LICENSES: MIDWIFERY

- 13:35-2A.1 Midwifery practice
- 13:35-2A.2 Definitions
- 13:35-2A.3 Midwifery Liaison Committee
- 13:35-2A.4 Application for licensure
- 13:35-2A.5 Independent practice
- 13:35-2A.6 Affiliated physicians; clinical guidelines
- 13:35-2A.7 Biennial renewal
- 13:35-2A.8 Antepartum management

- 13:35-2A.9 Management of antepartum women at increased risk
- 13:35-2A.10 Intrapartum management
- 13:35-2A.11 Management of intrapartum women at increased risk
- 13:35-2A.12 Postpartum care
- 13:35-2A.13 Well woman care
- 13:35-2A.14 Prescriptive authorization
- 13:35-2A.15 Limited ultrasound examination
- 13:35-2A.16 Colposcopies
- 13:35-2A.17 Circumcisions

SUBCHAPTER 2B. LIMITED LICENSES: PHYSICIAN ASSISTANTS

- 13:35-2B.1 Purpose and scope
- 13:35-2B.2 Definitions
- 13:35-2B.3 Practice requirements
- 13:35-2B.4 Scope of practice
- 13:35-2B.5 Eligibility for licensure
- 13:35-2B.6 Refusal to issue, suspension or revocation of license
- 13:35-2B.7 License renewal, continuing education requirement
- 13:35-2B.8 Credit-hour requirements
- 13:35-2B.9 Waiver of continuing education requirement
- 13:35-2B.10 Supervision
- 13:35-2B.11 Recordkeeping
- 13:35-2B.12 Requirements for issuing prescriptions for medications
- 13:35-2B.13 Eligibility for temporary licensure
- 13:35-2B.14 Temporary licensure; scope of practice
- 13:35-2B.15 Supervision of temporary license holder
- 13:35-2B.16 Expiration of temporary license; renewal
- 13:35-2B.17 Reinstatement of lapsed license
- 13:35-2B.18 Sexual misconduct

SUBCHAPTER 3. LICENSING EXAMINATIONS AND ENDORSEMENTS, LIMITED EXEMPTIONS FROM LICENSURE REQUIREMENTS

- 13:35-3.1 Licensure examination; physicians
- 13:35-3.2 Endorsement; physicians
- 13:35-3.3 Endorsement; podiatric physicians
- 13:35-3.4 (Reserved)
- 13:35-3.5 Endorsement; certified nurse midwives
- 13:35-3.6 Bioanalytical laboratory director license, plenary or specialty, granted to physicians
- 13:35-3.7 Limited exemption from licensure; physicians
- 13:35-3.8 Administrative processing of license application
- 13:35-3.9 Postponement of or absence from examination; transfer or refund of fee
- 13:35-3.10 Subversion or attempt to subvert the licensing examination process
- 13:35-3.11 Standards for licensure of physicians graduated from medical schools not approved by American national accrediting agencies
- 13:35-3.12 Standards for licensure of physicians with post-secondary educational deficiencies
- 13:35-3.13 Criminal history record information

SUBCHAPTER 4. SURGERY

- 13:35-4.1 Major surgery; qualified first assistant
- 13:35-4.2 Termination of pregnancy

SUBCHAPTER 4A. SURGERY, SPECIAL PROCEDURES, AND ANESTHESIA SERVICES PERFORMED IN AN OFFICE SETTING

- 13:35-4A.1 Purpose
- 13:35-4A.2 Scope
- 13:35-4A.3 Definitions
- 13:35-4A.4 Policies and procedures requirements
- 13:35-4A.5 Duty to report incidents related to surgery, special procedures or anesthesia in an office
- 13:35-4A.6 Standards for performing surgery and special procedures in an office; privileges necessary; pre-procedure counseling; patient records; recovery and discharge

- 13:35-4A.7 Standards for administering or supervising the administration of anesthesia services in an office; pre-anesthesia counseling; patient monitoring; recovery; patient record; discharge of patient
- 13:35-4A.8 Performance of general anesthesia; authorized personnel
- 13:35-4A.9 Administration of regional anesthesia; authorized personnel
- 13:35-4A.10 Administration of conscious sedation; authorized personnel
- 13:35-4A.11 Administration of minor conduction blocks; authorized personnel
- 13:35-4A.12 Alternative privileging procedure
- 13:35-4A.13 Requirements for anesthetizing locations; emergency equipment and supplies
- 13:35-4A.14 Requirements for anesthetizing locations; safety systems, monitoring devices
- 13:35-4A.15 Equipment requirements for recovery areas
- 13:35-4A.16 Maintenance requirements
- 13:35-4A.17 Compliance timetables
- 13:35-4A.18 Enforcement

SUBCHAPTER 5. EYE EXAMINATIONS; EYEGLASSES

- 13:35-5.1 Minimum eye examination; contact lenses
- 13:35-5.2 Minimum standards and tolerances of optical lenses

SUBCHAPTER 6. GENERAL RULES OF PRACTICE

- 13:35-6.1 Practice identification
- 13:35-6.2 Pronouncement of death
- 13:35-6.3 Sexual misconduct
- 13:35-6.4 Delegation of administration of subcutaneous and intramuscular injections to certified medical assistants
- 13:35-6.5 Preparation of patient records, computerized records, access to or release of information; confidentiality, transfer or disposal of records
- 13:35-6.6 Standards for joint protocols between advanced practice nurses and collaborating physicians
- 13:35-6.7 (Reserved)
- 13:35-6.8 Prescribing, administering or dispensing amygdalin (laetrile)
- 13:35-6.9 Referral for radiological services
- 13:35-6.10 Advertising and solicitation practices
- 13:35-6.11 Excessive fees
- 13:35-6.12 (Reserved)
- 13:35-6.13 Fee Schedule
- 13:35-6.14 Delegation of physical modalities to a licensed health care provider or an unlicensed physician aide
- 13:35-6.15 Continuing medical education
- 13:35-6.16 Professional practice structure
- 13:35-6.17 Professional fees and investments, prohibition of kickbacks
- 13:35-6.18 Medical malpractice coverage; letter of credit
- 13:35-6.19 Duty to report changes in status
- 13:35-6.20 Physician delegation of tasks to radiologic technologists and nuclear medicine technologists
- 13:35-6.21 Hair replacement techniques
- 13:35-6.22 Termination of licensee-patient relationship
- 13:35-6.23 Presence of chaperones

SUBCHAPTER 6A. DECLARATIONS OF DEATH UPON THE BASIS OF NEUROLOGICAL CRITERIA

- 13:35-6A.1 Purpose
- 13:35-6A.2 Definitions
- 13:35-6A.3 Requirements for physicians authorized to declare death on the basis of neurological criteria
- 13:35-6A.4 Standards for determination of brain death
- 13:35-6A.5 Criteria and testing for establishment of brain death
- 13:35-6A.6 Objective documentation
- 13:35-6A.7 Certification of death

BOARD OF MEDICAL EXAMINERS

SUBCHAPTER 7. PRESCRIPTION, ADMINISTRATION AND DISPENSING OF DRUGS

- 13:35-7.1 Definitions
- 13:35-7.1A Examination of patient's condition required prior to dispensing drugs or issuing a prescription; exceptions
- 13:35-7.2 Requirements for issuing written prescriptions for medicines
- 13:35-7.3 Verbal prescriptions (Reserved)
- 13:35-7.4 Facsimile transmitted prescriptions
- 13:35-7.4A Electronically transmitted prescriptions
- 13:35-7.5 Requirements for the dispensing of drugs and special limitations applicable to the dispensing of drugs for a fee
- 13:35-7.5A Limitations on prescribing, administering or dispensing of drugs for the treatment of obesity
- 13:35-7.6 Limitations on prescribing, administering or dispensing of controlled substances; special exceptions for management of pain
- 13:35-7.7 Prohibitions on prescribing, administering or dispensing of controlled substances for detoxification; limited exceptions
- 13:35-7.8 Prohibitions and limitations in the prescribing, administering or dispensing of amphetamines and sympathomimetic amines
- 13:35-7.9 Prohibitions and special limitations on prescribing, administering or dispensing anabolic steroids
- 13:35-7.10 Enforcement

SUBCHAPTER 8. HEARING AID DISPENSERS

- 13:35-8.1 Purpose
- 13:35-8.2 Definitions
- 13:35-8.3 Training and experience requirements
- 13:35-8.4 Training permits; issuance and practice
- 13:35-8.5 Temporary licenses; issuance
- 13:35-8.6 Temporary licenses; practice
- 13:35-8.7 Sponsors
- 13:35-8.8 Scope of practice
- 13:35-8.9 Fitting and dispensing of deep ear canal hearing aid devices
- 13:35-8.10 Supervising licensee
- 13:35-8.11 Notification to the Committee; suspension of license for failure to renew
- 13:35-8.12 Equipment
- 13:35-8.13 Hearing testing
- 13:35-8.14 Advertising and Solicitation
- 13:35-8.15 Abandonment; excessive fees
- 13:35-8.16 Itemization of services and equipment; retention of records
- 13:35-8.17 Licensing examination
- 13:35-8.18 Violation of the Rules
- 13:35-8.19 Fee schedule
- 13:35-8.20 License renewal; continuing education requirement

SUBCHAPTER 9. ACUPUNCTURE

- 13:35-9.1 Purpose and scope
- 13:35-9.2 Definitions
- 13:35-9.3 Credentials required for certification
- 13:35-9.4 Examination requirements
- 13:35-9.5 Prohibited titles
- 13:35-9.6 Fee schedule
- 13:35-9.7 Term of lawful practice; biennial registration
- 13:35-9.8 Referral; informed consent
- 13:35-9.9 Accepted equipment and devices; procedures
- 13:35-9.10 Precautionary and sterilization procedures
- 13:35-9.11 Preparation of patient records; computerized records; access to or release of information; confidentiality, transfer or disposal of records
- 13:35-9.12 Guest acupuncturist
- 13:35-9.13 Tutorial applications and design of tutorial program
- 13:35-9.14 Responsibilities of supervising acupuncturist
- 13:35-9.15 Responsibilities of the acupuncture apprentice
- 13:35-9.16 Training required of a physician or dentist

- 13:35-9.17 Continuing professional education requirements

APPENDIX A. (RESERVED)

SUBCHAPTER 10. ATHLETIC TRAINERS

- 13:35-10.1 Scope and purpose
- 13:35-10.2 Definitions
- 13:35-10.3 Application for licensure
- 13:35-10.4 Approved activities
- 13:35-10.5 Violations
- 13:35-10.6 Fees
- 13:35-10.7 (Reserved)
- 13:35-10.8 (Reserved)

SUBCHAPTER 11. ALTERNATIVE RESOLUTION PROGRAM

- 13:35-11.1 Definitions
- 13:35-11.2 Creation of Impairment Review Committee
- 13:35-11.3 Duties of an approved professional assistance program
- 13:35-11.4 Duties of the Impairment Review Committee
- 13:35-11.5 Professional assistance program: approval and discontinuance
- 13:35-11.6 Colleague referrals
- 13:35-11.7 (Reserved)

SUBCHAPTER 12. ELECTROLOGISTS ADVISORY COMMITTEE; LICENSURE OF ELECTROLOGISTS AND ELECTROLOGY INSTRUCTORS; ELECTROLOGY STANDARDS OF PRACTICE

- 13:35-12.1 Purpose and scope
- 13:35-12.2 Definitions
- 13:35-12.3 Office of the Committee
- 13:35-12.4 Notification of change of address
- 13:35-12.5 License issuance without written examination (Grandfathering)
- 13:35-12.6 Licensing requirements for electrologist
- 13:35-12.7 Licensing requirements for electrology instructor
- 13:35-12.8 Application for license: electrologist
- 13:35-12.9 Application for license: electrology instructor
- 13:35-12.10 Licensing requirements for office premises
- 13:35-12.11 Infection control standards
- 13:35-12.12 Posting of licenses and required notices
- 13:35-12.13 Examination requirements; reexamination
- 13:35-12.14 License issuance, renewal; change of license status: inactive to active; reinstatement of suspended license
- 13:35-12.15 Unlicensed practice
- 13:35-12.16 Licensure by credentials (comity license)
- 13:35-12.17 Suspension, revocation or refusal to renew license
- 13:35-12.18 Recordkeeping
- 13:35-12.19 Continuing education, programs, standards
- 13:35-12.20 Sexual misconduct
- 13:35-12.21 Advertising and solicitation practices
- 13:35-12.22 Fee schedule

SUBCHAPTER 13. PERFUSIONISTS ADVISORY COMMITTEE

- 13:35-13.1 Purpose and scope
- 13:35-13.2 Definitions
- 13:35-13.3 Office of the Committee
- 13:35-13.4 Notification of change of address and record
- 13:35-13.5 Licensure under grandfathering
- 13:35-13.6 Licensing requirements for perfusionist
- 13:35-13.7 Grace period for practicing without licensure pending application
- 13:35-13.8 Licensure by reciprocity
- 13:35-13.9 License required for designation as perfusionist
- 13:35-13.10 Temporary license; supervision
- 13:35-13.11 License renewal
- 13:35-13.12 Change of license status: inactive to active
- 13:35-13.13 Reinstatement of suspended license
- 13:35-13.14 Duty to report change in status
- 13:35-13.15 Suspension, revocation or refusal to renew license
- 13:35-13.16 Continuing education

**SUBCHAPTER 1. MEDICAL SCHOOLS,
COLLEGES, EXTERNSHIPS, CLERKSHIPS
AND POST-GRADUATE WORK**

13:35-1.1 Observership program

(a) "Observer" shall mean an undergraduate medical student of an allopathic or osteopathic school accredited either by the Liaison Committee on Medical Education or the American Osteopathic Association or a foreign medical school listed in the World Health Organization Directory and whose graduates are accepted by the New Jersey Board of Medical Examiners as eligible to sit for the licensure examination. Observerships are limited to the student's vacation period in an extra-curricular professional experience as delineated in this section.

(b) An observership program shall be limited to:

1. Observation of operative procedures;
2. The taking of histories;
3. The performance of physical examinations;
4. The performance of non-invasive procedures under the direct supervision of and in the immediate presence of the supervising licensed physician; and
5. The participation in patient rounds and other organized patient care activities of the supervising physician.

(c) At no time shall the observer be delegated any responsibility for the care of the patient, the patient's diagnosis or any aspect of the patient's treatment, including the prescription of medication for the patient. An observer shall make no entries on the patient's permanent record.

(d) The observer shall at all times of patient contact wear an identifying badge inscribed "Medical Student."

(e) Prior to commencing participation in an observership program, the student shall have obtained written permission from the Chief of Staff and the Administration of the participating hospital and shall retain such letter.

(f) Under no circumstances shall the performance of any of the duties listed in (b) above by an observer, while engaged in such a program, be construed as the practice of medicine.

(g) The time spent in an observership program shall not be considered as part of or credited toward fulfillment of any statutory academic or clinical requirements for licensure.

Amended by R.1999 d.356, effective October 18, 1999.
See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

Substituted references to observers for references to externs and substituted references to observerships for references to externships throughout; in (a), substituted "delineated in this section" for "hereafter delineated" at the end; and in (f), substituted "duties listed in (b) above" for "above duties" following "any of the".

13:35-1.2 Fifth Pathway

(a) The Board shall accept application for licensure from an applicant who does not meet the usual statutory prerequisites for educational background, in the following circumstances to be known as the Fifth Pathway:

1. The applicant has completed the entirety of the academic curriculum in residence at a medical school in a foreign country located outside of the United States, Puerto Rico or Canada or in a school-authorized clinical training program;

2. The medical school was approved throughout the applicant's period of education by the government of the country of domicile to confer the degree of Doctor of Medicine and Surgery or its equivalent, and was listed in the World Health Organization Directory;

3. The applicant has satisfactorily completed all the requirements for a matriculated student of that foreign medical school to receive a diploma, except for internship and/or social service;

4. The applicant has achieved a passing score on a screening examination acceptable to the Educational Commission on Foreign Medical Graduates (ECFMG) even though not eligible for ECFMG certification; and

5. The applicant has had his or her academic record reviewed and approved by a medical school approved by the Liaison Committee on Medical Education, which school has accepted the applicant in a one-academic-year program of supervised clinical training under its direction, and the applicant has satisfactorily completed that program as evidenced by receipt of a certificate issued by the sponsoring medical school.

(b) The applicant meeting the requirements in (a) shall thereafter be deemed by the Board to be eligible to enter a graduate training program approved by the Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA). Upon satisfactory completion of the three years of post-graduate training required by N.J.A.C. 13:35-3.11, the applicant may apply for licensure in this State.

Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).

Rule deleted and replaced with new text.

13:35-1.3 Postgraduate training

Postgraduate training shall be taken under the auspices of a hospital or hospitals accredited for such training by the Accreditation Council for Graduate Medical Education (ACGME) or by the American Osteopathic Association (AOA) or by the American Podiatric Medical Association (APMA), as applicable to the profession. The program shall further be acceptable to the Board, which shall take into account the standards adopted by the Advisory Graduate Medical Education Council (AGMEC).

Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
Rule deleted and replaced with new text.

Case Notes
Reasonable regulation of advertising. Att'y Gen. Form Op. No. 20
(1977).

(b) No hospital accredited for postgraduate training programs shall be under any obligation by virtue of these regulations to accept medical students in clinical programs, and any medical school or hospital accredited for postgraduate training programs may impose standards for admission to the clinical programs which exceed the standards set forth in this regulation.

13:35-1A.6 Request for approval

(a) At least six months prior to the anticipated start of the clinical program, two copies of a detailed outline of the entire proposed program shall be submitted to the Board on

a form provided by the Board. The application shall include the certified copies of hospital approvals described in N.J.A.C. 13:35-1A.5(a) and shall be signed by the administrative heads of both the parent medical school and the affiliate institution.

(b) The original application for Board approval as well as any request for renewal thereof shall be accompanied by an agreement signed by a school representative duly authorized to do so, consenting to financial responsibility for all reasonable costs incurred by the Board in performing the administrative review and monitoring of the program.

1. The application shall include a certified check for \$10,000 drawn on a United States bank payable to the New Jersey State Board of Examiners, which sum shall serve as a deposit for costs incurred by the Board and the Department of Higher Education for review of the program and also for subsequent inspections to assure compliance during such period as the Board has authorized the program to function. If the school's application is denied, the Board shall deliver a statement of account and shall arrange to refund to the school in United States dollars any sum received in excess of the amount due. If the application is approved, with or without conditions, and the school elects to proceed with the program as approved, the Board shall deliver a statement of account to the school from time to time, and shall arrange to refund to the school at the conclusion of Board monitoring of the program any sum received in excess of the amount due, in United States dollars. Should the statement of account at any time show a balance due and payable, the school shall promptly remit the payment due in United States dollars.

(c) An on-site inspection shall be required at the affiliate institution during the review period, and also may be required at the parent medical school, taking into account alternatives available under N.J.A.C. 13:35-1A.1(a). The parent medical school shall agree in advance to be responsible for all reasonable out-of-pocket expenses incurred by the Board and an inspection committee appointed by the Board.

(d) Following review of the program and on-site inspection visit, if any, the inspection committee shall submit a report to the Board, a copy of which shall be provided to the parent medical school and the proposed affiliate institution. The report shall evaluate program strengths and weaknesses, provide suggestions for improvement and make recommendations respecting approval.

(e) The parent medical school and/or affiliate shall have 30 days to comment in writing on the report, if desired.

(f) Following review of the report and written comments, if any, the Board shall attempt to issue notice of its decision no later than three months before the anticipated start of the program.

(g) The Board's decision may provide for any of the following:

1. Approval for a period of two years;
2. Probationary approval for a specified period, with status reporting requirements;
3. Denial of approval, with reason;
4. Revocation of prior approval, with reasons;
5. Reapproval of prior approved program following review of status report updating all the elements of prior application.

(h) Subsequent to notice of program approval and prior to the start of any clinical program in this State, the medical school shall provide the Board a list identifying each student participating in the clinical program, a listing of the facilities and locations at which all didactic education is to be received, the affiliate institution(s) to which such person is assigned, and dates for such program participation. The school shall bring such records up to date as necessary.

Amended by R.1999 d.356, effective October 18, 1999.
See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

In (c), rewrote the last sentence; in (d), substituted a reference to the inspection committee for a reference to the Department of Education in the first sentence, and rewrote the last sentence; and in (h), inserted "a listing of the facilities and locations at which all didactic education is to be received" following "program,".

13:35-1A.7 Public record

A list of currently approved schools and affiliates together with the final Board determination on the status of their programs shall be maintained at the office of the New Jersey State Board of Medical Examiners and shall be available on request.

13:35-1A.8 Termination of program approval

(a) A program approved by the Board shall be deemed to have continuing approval for the time set forth in the Board decision unless and until:

1. A notice of revocation is sent by the Board to the parent medical school which may then request hearing on the matter;

2. Any substantial change is made by the medical school relative to the site of the didactic education of the students participating in the program, or any substantial change is made by either the parent medical school or affiliate institution in the program respecting general subject matter of the program, length of course components or topics, credentials or number of faculty assigned to the instruction, number of students per program, financial security of the program, program facilities at the affiliate institution or management thereof; or

3. A notice of termination is sent to the Board by either the parent medical school or the affiliate institution.

Amended by R.1999 d.356, effective October 18, 1999.
See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

In (a)2, inserted "substantial change is made by the medical school relative to the site of the didactic education of the students participating in the program, or any" following "Any".

13:35-1A.9 Violations

Violation of the above requirements for establishing a clinical education program in this State, or maintaining or participating in an unapproved program whether as student or faculty, may be regarded as engaging in the unlicensed practice of medicine or aiding and assisting in the unlicensed practice, pursuant to the residual or other general

powers of the Medical Practice Act, N.J.S.A. 45:9-1 et seq. and also, in particular, N.J.S.A. 18A:68-12 et seq., N.J.S.A. 45:9-6, 45:9-8, 45:9-18, 45:9-22, and 45:1-21(c) and 45:1-23. Violators shall be subject to the monetary penalties and/or other disciplinary sanctions authorized by law.

13:35-1A.10 Severability

If any provisions of this rule or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect any other provisions or applications of the rule which can be given effect without the invalid provision or application, and to this end the provisions of this rule are declared to be severable.

13:35-1A.11 Clerkship program approvals: effective date; limited waiver provision; no new applications

This rule shall apply to all clinical training programs, as defined in N.J.A.C. 13:35-1A.1, taking place in New Jersey on or after January 1, 1983. However, the Board recognizes that, prior to the adoption of this rule, it has granted to a number of foreign medical schools permission to sponsor modest clinical programs which were not required to meet the explicit standards now set forth herein, and which permission reserved all rights of the Board respecting the ultimate evaluation of the adequacy of any such program. No new applications for clinical clerkship programs shall be accepted.

Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
Reference to clerkship programs added.

SUBCHAPTER 2. LIMITED LICENSES: PODIATRY, DIAGNOSTIC TESTING CENTERS AND MISCELLANEOUS

13:35-2.1 Approved colleges of podiatry

An applicant for podiatric licensure shall have graduated from a college or colleges of podiatry approved during the entire course of the applicant's training by the American Podiatric Association and approved by the Board.

Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
Deleted N.J.S.A. reference.

13:35-2.2 Podiatry internship or postgraduate work

The applicant for licensure shall have successfully completed an internship or postgraduate program fully approved by the American Podiatric Medical Association in a duly licensed clinic, hospital or institution acceptable to the Board, which shall take into account the standards adopted by the Advisory Graduate Medical Education Council (AG-MEC).

Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
Old text deleted, replaced with new text.

13:35-2.3 Military service in lieu of internship in podiatry

The Board may grant a license to practice podiatry to any person who shall furnish proof, satisfactory to the Board, that such person has fulfilled all of the formal requirements established by the Podiatric Practice Act, N.J.S.A. 45:5-1 et seq., and has served at least two years in active military service in the United States Army, Air Force, Navy, Marine Corps, Coast Guard or the United States Public Health Service as a commissioned officer and podiatrist in a medical facility which the Board determines constitutes the post-graduate training program required by law; provided, however, that such military service actively occurred subsequent to graduation from an approved school of podiatry.

Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
Reference to Podiatric Practice Act.

13:35-2.4 (Reserved)

Amended by R.1985 d.102, effective March 4, 1985.
See: 16 N.J.R. 3177(a), 17 N.J.R. 605(a).
(k) substantially amended.
Amended by R.1985 d.631, effective December 16, 1985.
See: 17 N.J.R. 2231(b), 17 N.J.R. 2991(b).
Deleted "effective date of this rule" and substituted "March 4, 1985"; deleted "August 1, 1987" and substituted "March 31, 1988."
Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
At (k), reference made to March 18, 1988 as date prior to which students are recognized.
Repealed by R.1994 d.522, effective October 17, 1994.
See: 26 N.J.R. 2526(a), 26 N.J.R. 4195(a).
Section was "Requirements for approval of college of chiropractic."

Case Notes

Emphasis on common subjects in medical and chiropractic education noted; medical doctor competent as expert in chiropractic diagnosis and use of x-rays in each area which the disciplines share in common in terms of education, training and licensure (citing former N.J.A.C. 13:35-10.0 and 13:35-10.9). Rosenberg by Rosenberg v. Cahill, 99 N.J. 318, 492 A.2d 371 (1985).

13:35-2.5 (Reserved)

Repealed by R.2001 d.43, effective February 20, 2001.
See: 32 N.J.R. 19(a), 33 N.J.R. 670(a).
Section was "Medical standards governing screening and diagnostic medical testing offices"

13:35-2.6 Medical standards governing screening and diagnostic medical testing offices; determinations with respect to the validity of certain diagnostic tests

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

"Board" means the New Jersey State Board of Medical Examiners.

“Clinically supported” means that a practitioner, prior to selecting, performing or ordering the administration of a diagnostic test, has:

1. Personally performed a physical examination, making an assessment of any current and/or historical subjective complaints, observations, objective findings, neurological indications;
2. Considered any and all previously performed test relating the patient’s medical condition and the results; and
3. Documented in the patient record positive and negative findings, observations and medical indications to justify the test.

“Diagnostic office” means a practice location, whether stationary or mobile, not licensed by the State Department of Health and Senior Services, which provides equipment and staff necessary for the offering or performance of diagnostic tests and related services to any branch of the medical profession or to the public.

“Diagnostic test” means a medical service utilizing biomechanical, neurological, neurodiagnostic, radiological, vascular or any means, other than bioanalysis, intended to assist in establishing a medical diagnosis, for the purpose of recommending a course of treatment for the tested patient to be implemented by the treating practitioner or by the consultant.

“Emergency care” means all medically necessary treatment of a traumatic injury or a medical condition manifesting itself by acute symptoms of sufficient severity such that absence of immediate attention could reasonably be expected to result in: death; serious impairment of bodily functions; or serious dysfunction of a bodily organ or part. “Emergency care” includes all medically necessary care immediately following a traumatic injury including, but not limited to, immediate pre-hospitalization care, transportation to a hospital or trauma center, emergency department care, surgery, critical and acute care and extends during the period of initial hospitalization until the patient is discharged from acute care by the attending physician.

“Normal” or “normally” means the usual, routine, customary or common experience and conclusion, which may in unusual circumstances differ from the actual judgment or course of treatment. The unusual circumstances shall be based on clinically supported findings of a practitioner. The use of these terms is intended to indicate some flexibility and avoid rigidity in the application of these rules and to recognize the good faith educated judgment of a practitioner.

“Physician” means a medical or osteopathic physician holding a plenary license issued by the New Jersey State Board of Medical Examiners.

“Practitioner” means a physician, podiatric physician, physician assistant or certified nurse midwife licensed by or registered with the New Jersey State Board of Medical Examiners.

“Screening office” means a practice location, whether stationary or mobile, not licensed by the State Department of Health and Senior Services, which provides equipment and staff necessary for the offering or performance of screening tests and related services to any branch of the medical profession or to the public, either upon referral or by walk-in.

“Screening test” means a medical service utilizing biomechanical, neurological, neurodiagnostic, radiological, vascular or any means, other than bioanalysis, performed in the absence of apparent immediate need for medical treatment for the purpose of providing medically useful information in circumstances where the anticipated benefits of the testing for an appropriate category of individual care are reasonably believed to outweigh the assessed risks, resulting in a health care evaluation, analysis or assessment; but does not include screenings such as, but not limited to, hypertension or glaucoma screenings, offered at no cost to examinees by community-sponsored public health services, hospitals or nonprofit professional or civic organizations, providing some means is established to give follow-up advice and referrals.

(b) A practitioner who identifies a need for a patient to undergo a diagnostic test:

1. Is authorized, if consistent with the practitioner’s scope of practice, to perform the diagnostic test, for which a specific CPT code is assigned and for which a fee shall be charged, upon the attainment of education and supervised training in the pertinent test;
2. May directly request a specific diagnostic test, for which a specific CPT code is assigned and for which a fee shall be charged, when clinically supported, provided that referring practitioner:
 - i. Is capable of recognizing scientifically supportable and practical indications for the test;
 - ii. Has knowledge in the proper administration of the test;
 - iii. Possesses skill at proper interpretation of the test; and
 - iv. Has obtained training in how to integrate the test results into management of the patient’s condition; or
3. May refer the patient to a practitioner who is deemed to meet the criteria identified at (b)2i through iv above.

(c) A practitioner qualified pursuant to (b) above to perform a diagnostic test may charge the patient or bill a third party payor for that test, except that:

1. No practitioner shall bill for any diagnostic tests which fail to yield data of sufficient clinical value in the development, evaluation or implementation of a plan of treatment, including the following:

- i. Spinal diagnostic ultrasonography/ultrasound imaging of the spine;
- ii. Iridology;
- iii. Reflexology;
- iv. Surrogate arm mentoring;
- v. Brain mapping, when not done in conjunction with appropriate neurodiagnostic testing;
- vi. Surface EMG;
- vii. Mandibular tracking and stimulation;
- viii. Videofluoroscopy; and
- ix. Computer supported range of motion tests.

2. The practitioner may bill for any of the following diagnostic tests which can yield data of sufficient clinical value in the development evaluation or implementation of a plan of treatment, when clinically supported, subject to the limitations relating to timing, frequency and manner as follows:

- i. Thermography when used to evaluate pain associated with reflex sympathetic dystrophy ("RSD"), in a controlled setting by a physician experienced in such use and properly trained.
- ii. Needle electromyography (needle EMG) when used in the evaluation and diagnosis of neuropathies and radicular syndrome where clinically supported findings reveal a loss of sensation, numbness or tingling. A needle EMG is not indicated in the evaluation of TMJD and is contraindicated in the presence of infection on the skin or cellulitis. This test should not normally be performed within 14 days of a traumatic injury and should not be repeated where initial results are negative. Only one followup exam is normally appropriate.
- iii. Somasensory evoked potential (SSEP), visual evoked potential (VEP), brain audio evoked potential (BAEP), or brain evoked potential (BEP), nerve conduction velocity (NCV) and H-reflex Study when used to evaluate neuropathies and/or signs of atrophy, but not within 21 days following the traumatic injury.
- iv. Electroencephalogram (EEG) when used to evaluate head injuries, where there are clinically supported findings of an altered level of sensorium and/or a suspicion of seizure disorder. This test, if indicated by clinically supported findings, can be administered immediately following a traumatic injury. Repeat testing is not normally conducted more than four times per year.

v. Magnetic resonance imaging (MRI) when used in accordance with the guidelines contained in the American College of Radiology, Appropriateness Criteria to evaluate injuries in numerous parts of the body, particularly the assessment of nerve root compression and/or motor loss. MRI is not normally performed within five days of a traumatic injury. However, clinically supported indications of neurological gross motor deficits, incontinence or acute nerve root compression with neurologic symptoms may justify MRI testing during the acute phase immediately post injury.

vi. Computer assisted tomographic studies (CT or CAT scan) when used to evaluate injuries in numerous aspects of the body. With the exception of suspected brain injuries, CAT scan is not normally administered immediately post injury, but may become appropriate within five days of the trauma. Repeat CAT scans should not be undertaken unless there is clinically supported indications of an adverse change in the patient's condition.

vii. Sonograms/ultrasound when used in the acute phase to evaluate the abdomen and pelvis for intra-abdominal bleeding. These tests are not normally used to assess joints (knee and elbow) because other tests are more appropriate. Where MRI is performed, sonograms/ultrasound are not necessary. These tests should not be used to evaluate TMJD. However, echocardiogram is appropriate in the evaluation of possible cardiac injuries when clinically supported.

3. Notwithstanding the limitations set forth at (c)1 and 2 above, a practitioner may perform an enumerated diagnostic test, for which there shall be no charge to the patient or third party payor, after assuring that written informed consent has been obtained.

4. Notwithstanding the limitations set forth at (c)1 and 2 above, a practitioner may perform and charge for diagnostic tests necessary to provide emergency care.

(d) Any diagnostic or screening office offering diagnostic or screening tests for a fee shall:

1. Be solely owned and under the responsibility of one or more physicians (or practitioners, in the case of an office offering only tests within the scope of that practitioner's practice);
2. Ensure that all test results are interpreted by a practitioner licensed by the Board and acting within the scope of licensed practice, documented in a written report and maintained in accordance with the requirements of N.J.A.C. 13:35-6.5; and
3. Designate a physician owner or employee (or practitioner owner or employee, in the case of an office offering only tests within the scope of that practitioner's practice) to be responsible for the management of the office and the specific obligations set forth in this section.

(e) Any practitioner designated to be responsible for the management of a diagnostic or screening office not licensed by the Department of Health and Senior Services (DOHSS) shall:

1. Establish and make available to personnel written policies and procedures concerning the following:
 - i. The specific tests which may be performed in the office;
 - ii. The standards for equipment operation;
 - iii. The procedures to be followed in obtaining informed consent;
 - iv. The standards with regard to record documentation;
 - v. The procedures relating to follow-up reporting to examinees, patients, and/or referring practitioners, as applicable; and
 - vi. Minimum safety precautions;
2. Delineate or approve billing procedures;
3. Ensure that any equipment which emits radiation shall conform to the applicable sections of N.J.A.C. 7:28 and maintain documentation with respect to those requirements at the office;
4. Verify, through a documented review of credentials, upon hiring and on at least an annual basis, that:
 - i. All personnel, other than physicians, operating testing equipment which emits radiation are licensed by the New Jersey Radiologic Technology Board of Examiners as shall be required by the Department of Environmental Protection in accordance with N.J.S.A. 26:2D-1 et seq. and N.J.A.C. 7:28-19;
 - ii. All personnel, other than physicians, operating magnetic resonance imaging equipment are licensed as may be required by the Department of Environmental Protection (DEP), or demonstrate technical training to perform MRIs and are not otherwise precluded by any requirements of the DEP; and
 - iii. All personnel, other than physicians, operating ultrasound equipment are certified by the American Registry of Diagnostic Medical Sonographers or by the American Registry of Radiologic Technologists, or demonstrate technical training to perform ultrasounds and are not otherwise precluded by any requirements of the Department of Environmental Protection;
5. Implement on an ongoing basis a quality assurance program as required by (f) below; and
6. Ensure that, when entering into a contract for the provision of diagnostic or screening test to be provided by a mobile entity for or on the premises of any licensed health care facility, notice is given by the health care facility to the Department of Health and Senior Services

of the name of the testing entity and the identity of the practitioner(s) designated to be responsible for the provision of the diagnostic or screening tests.

(f) Every diagnostic or screening office shall have a quality assurance program which:

1. On at least a quarterly basis, requires the following:
 - i. An evaluation of personnel skills and performance;
 - ii. An assessment of the supervision being provided to employees; and
 - iii. A review of test performance techniques, accuracy and data recordation; and
2. On at least an annual basis, requires the following:
 - i. An audit of billing records for accuracy; and
 - ii. Documented regular inspections of equipment.

(g) In addition to the obligations set forth in (e) and (f) above, any practitioner designated to be responsible for the management of a screening office shall:

1. Ensure that all bills accurately describe screening tests performed and do not misrepresent tests to be diagnostic;
2. Establish a written protocol identifying professionally recognized criteria to be evaluated in accepting eligible examinees for each type of screening test and providing a procedure for excluding examinees who do not meet the criteria. For example, for bone densitometry, mammography, and other screening tests, the protocol shall include specific criteria relating to age, family history, personal medical history, and permissible frequency of testing and shall specify contraindications and foreseeable risks;
3. Designate in writing those employees who have been assigned responsibility for the implementation of the protocol and quality control review, reflecting the type of credentials held;
4. Develop informed consent forms or other mechanisms to provide information to examinees;
5. Devise a system by which screening office records are maintained in accordance with the basic information standards set forth in N.J.A.C. 13:35-6.5; and
6. Upon the request of the Board, prepare statistical reports reflecting the total number of screening examinees, and the total number of abnormality reports issued and the advisory letter required by (h) below.

(h) In addition to the obligations set forth in (e) through (g) above, any practitioner designated to be responsible for the management of a screening office at which mammography is offered shall:

1. Ensure that mammography screening tests are performed only under the supervision of a physician who meets the requirements as mandated by the Mammography Quality Standards Act (MQSA), 42 U.S.C. §§ 263(b) et seq., and that such tests are interpreted only by a physician who meets the MQSA requirements. The supervising and interpreting physician(s) shall maintain proof on the premises of having attained such credentials;

2. Establish a written protocol in compliance with the requirements of the Mammography Quality Standards Act, 42 U.S.C. §§ 263(b) et seq., and 21 CFR 900.1 et seq., which shall include:

i. Guidance with respect to appropriate positioning preparatory to the test;

ii. Methods for providing instruction in breast self-examination, which may include written materials;

iii. Advice regarding referrals concerning follow-up care with respect to any person who presents as a self-referral for "screening" but who also mentions awareness of symptoms which may be indicative of abnormality, including, but not limited to, nipple discharge, pain or suspicion of a lump. A person who mentions awareness of such symptoms shall be specifically advised to seek follow-up care; and

iv. Procedures for providing in lay language both verbal and written advice at the time of testing, and on the testing report, that a screening mammography is not a comprehensive examination nor sufficient to detect all abnormalities and that examinees should seek a complex examination from a physician; and

3. Retain baseline mammography images and periodic images for seven years from the date of issuance of the last test interpretation report, except that the physician shall, upon request, release the original of any image, provided that signed documentation thereof is retained in the examinee's file and an interpretation report is retained.

(i) In addition to the obligations set forth in (e) and (h) above, at any screening office which operates without a practitioner on the premises, the practitioner designated to be responsible for the management of a screening office shall also:

1. Specify certain screening tests that may be performed when the responsible physician is not physically present;

2. Designate another licensed health care professional, such as a registered professional nurse or a radiologic technologist, to perform tasks consistent with the test procedure and the delegated person's scope of licensed practice; and

3. Identify tasks of a non-medical nature that may be delegated to non-licensed employees under the supervision of a licensed employee, where not inconsistent with applicable laws or rules, and consistent with accepted standards of practice pertinent to that screening test.

(j) A practitioner designated to be responsible for the management of a screening office not licensed by the Department of Health and Senior Services (DOHSS) shall ensure that reports with respect to screening tests which yield abnormal results are prepared in writing, include clear direction as to necessary follow-up, and are issued within three business days from the date of receipt of the report by the testing entity.

1. With respect to those patients who have identified a referring or treating practitioner, the reports are to be sent to the identified practitioner and upon request, sent also to the examinee or other authorized person, to the extent authorized by N.J.A.C. 13:35-6.5. A report delayed pending receipt of additional material shall be issued as soon as possible after the report is complete;

2. With respect to any abnormality warranting follow-up care, the referring practitioner shall be contacted in writing, and, if immediate follow-up care is clinically indicated, shall additionally be contacted promptly by other means (which may be a verbal communication contemporaneously documented in the examinee record) to insure notification to the examinee;

3. When an abnormality has been discovered, and no referring or treating practitioner is identified by the examinee, the written notice of abnormality which shall be provided to the examinee shall contain a clear advisory concerning the need to seek follow-up medical consultation as well as appropriate referral information;

4. In the circumstances set forth in (j)3 above, efforts shall be made additionally to personally contact the examinee by telephone to confirm that the examinee was made aware of the need to follow up, which efforts shall be documented in the examinee record. When efforts to contact the examinee have been unsuccessful over a period not to exceed 10 days, a letter shall be forwarded to the examinee's address of record by certified mail, return receipt requested, with a copy maintained in the chart, advising of the abnormality and the need for follow-up and referral; and

5. If the examinee with a discovered abnormality cannot be reached as required by (j)4 above, but the examinee has listed the name and address of a treating practitioner, efforts shall be made to contact the treating practitioner listed. The treating practitioner shall be requested to make reasonable efforts to notify an examinee, last seen by that practitioner within the last 12 months, about the report.

(k) Any practitioner performing a diagnostic test in any location, whether or not licensed by the Department of Health and Senior Services shall retain raw data or graphs arising out of a diagnostic test administration and shall prepare and retain a comprehensive report, on professional letterhead bearing the practitioner's full name and title or degree ("Dr." alone is insufficient) and office name, address and telephone number. The report shall include at least the following:

1. The date on which the test was performed;
2. The location at which the test was performed;
3. A summary of the pertinent medical/psychological history;
4. An identification of the specific test(s) performed;
5. An identification of any unlicensed individual performing the test unless reflected in the patient record or in a logbook maintained by the supervising practitioner, who shall be identified as the supervisor;
6. The length of time of all electrodiagnostic tests (including EMG and NCV) and invasive procedures, unless reflected in the patient record or in a logbook maintained by the supervising practitioner, who shall be identified as the supervisor;
7. A description of the pertinent findings, diagnosis or impression and any recommendations;
8. Cross-references to any other tests performed on the same patient pertinent to the patient's presenting medical condition or injuries, if not addressed in a consolidated report; and
9. The date on which the report was prepared.

(l) Pursuant to (b)2 above, a practitioner in any location, whether or not licensed by the DOHSS, may directly request that another practitioner (such as a radiologist, neurologist, physiatrist, psychiatrist, or other licensed practitioner) perform diagnostic tests, which request shall, except when relating to emergency care, be in writing or by a personal communication documented in the patient record, for which the patient shall not be separately charged, setting forth:

1. The patient's reported symptoms and objective signs, if any, pertinent to the problem;
2. A brief history of the reported medical condition; and
3. An indication of prior testing relating to the medical condition and results thereof.

(m) Any practitioner, in any location, whether or not licensed by DOHSS, accepting a referral for the performance of a diagnostic test, except with respect to emergency care, shall:

1. Require that the referral be preceded by verbal communication or delivery of the written request (which may be faxed) as set forth in (l) above;
2. Retain a copy of the referring request or document the personal communication in the patient record;
3. Institute a procedure to assure that sufficient clinical data has been provided to justify the requested test;
4. Personally consult with the referring practitioner in advance of performing the test, if additional information is needed to determine if the diagnostic test requested is the most appropriate test to elicit the clinical information sought;
5. Perform a focused clinical examination if, in the practitioner's discretion, such examination is necessary;
6. Verify the indications for and appropriateness of diagnostic testing, if the referral has been made by a practitioner with a limited license to a plenary licensee;
7. Prepare a report containing the information set forth in section (k) above; and
8. Assure that explanation has been provided to the patient and, where there is significant risk or likelihood of side effects, obtain informed consent.

(n) Any practitioner designated to be responsible for the management of a diagnostic office which operates without the full-time presence of an appropriately licensed and trained physician shall ensure that:

1. All invasive tests, including transesophageal echocardiography and needle electromyography, are personally performed and interpreted by a physician;
2. Direct personal supervision by the physician, whereby the physician is immediately available, is provided for all diagnostic tests requiring anesthesia or contrast as set forth in N.J.A.C. 13:35-4A and, in particular, N.J.A.C. 13:35-4A.8 through 4A.11;
3. Direct physician presence, supervision and interpretation is provided for all diagnostic tests which, although not invasive, require a sequential analysis with respect to the extent of medically necessary testing, for example, nerve conduction studies, somatosensory evoked potentials, and similar studies;
4. Direct supervision by a knowledgeable physician present in the office suite, immediately available to furnish assistance, is provided for cardiovascular stress tests;
5. Direct supervision is provided for diagnostic tests delegated to a trained radiologic technologist (LRT(R)). Such tests include but are not necessarily limited to MRI with contrast and CT with contrast. Except in a documented emergency, such studies shall not be scheduled or performed in the absence of the physician. Studies utilizing contrast material shall be performed only as permitted by N.J.A.C. 13:35-6.20;

6. Standing orders shall be issued in the event that a physician is unable to be present to direct the performance of the test. The standing orders shall pertain to the methods to be used in the performance of the test, the timing and manner of issuance of the physician's oral and written report, and timely notification to the patient or referring physician of results or the need to repeat the test.

i. The standing orders shall be specific in nature and disseminated to those responsible for implementation, indicating certain tasks that may be delegated to another licensed health care practitioner, such as a registered professional nurse or radiologic technologist, consistent with the applicable scope of practice; and

7. Physician availability (by telephone or in person) be provided for the following diagnostic tests:

- i. Plain film radiology;
- ii. CT or MRI studies without contrast, and without sedation; and
- iii. Electrocardiograms.

(o) A practitioner performing a diagnostic test in all locations, whether or not licensed by the DOHSS, shall promptly issue the results of the test, by preliminary verbal report when necessary and no later than three business days from the date of receipt of the report by the testing entity, to the referring practitioner and upon request to the patient or other authorized person, to the extent authorized by N.J.A.C. 13:35-6.5. An interpretation delayed pending receipt of additional material shall be issued as soon as possible thereafter. All abnormalities shall be clearly identified for the attention of a physician or other treating practitioner.

(p) Bills for diagnostic or screening tests submitted for payment to either the patient or a third party payor shall reflect:

1. The name of provider and licensure status;
2. The office address of the billing practitioner;
3. The location where the test was performed, if different from the billing practitioner's office addresses;
4. The date on which the test was performed; and
5. No charge for any test:
 - i. Designated pursuant to (c) above to be without apparent clinical value and thus lacking validity;
 - ii. Performed at a stage or frequency or in a manner not consistent with the limitations set forth in (c) above; or

iii. Where the result is professionally incomplete as to the intended view or study or non-diagnostic due to inadequate equipment or technique, except that when the reason for the deficiency relates to an unanticipated physical condition of the patient which precludes completion of the intended examination, such study shall not be deemed professionally incomplete for billing purposes.

(q) A practitioner responsible for the management of a diagnostic or screening office may arrange to utilize or lease testing equipment owned by another person or entity or, if permissible as to a given test, to utilize or engage unlicensed technicians who are not employed by the practitioner, and subject to professional supervision, provided that the practitioner shall:

1. Be responsible for ascertaining and documenting, identifying the indications for and the medical necessity of the diagnostic or screening test;
2. Understand the purpose and use of the equipment including benefits, risks and contraindications for the patient;
3. Recognize proper calibration and other functioning of the equipment used;
4. Be capable of properly using the equipment in the performance of the diagnostic testing;
5. Be competent to interpret the resulting data;
6. Ensure that no technician or other unlicensed person conducts an intake inquiry through direct questioning or by the use of a "checklist" of sample signs and symptoms to elicit information from the patient as the sole historical or other basis for the performance of a diagnostic test which shall be determined by the practitioner pursuant to (q)1 above;
7. Not provide the lessor with a "certificate of medical necessity" or any document which implies authority to issue a bill for services to anyone other than the leasing practitioner;
8. Not allow the lessor entity or its technician prior or subsequent access to any portion of a patient or examinee record regarding treatment or billing or financial information;
9. Not allow the technician to conduct a clinical interview of the patient or to make any decisions regarding which tests are to be performed or their sequence or the method of performance of the test;
10. Not be a party to a contract, whether written or verbal, with the lessor of the equipment, its technicians or any other agent, whereby the lessor or agent would recommend or provide a consultant practitioner to read or overread and interpret the test data;
11. (Reserved);

12. Be fully responsible for the reasonableness of the fee charged.

(r) Consistent with N.J.A.C. 13:35-6.17(c), a consulting practitioner shall not request or receive, offer or pay, directly or indirectly, any form of remuneration from the practitioner/professional office for accepting a referral of a patient.

1. A referring practitioner shall not request or receive, offer or pay, directly or indirectly, any form of remuneration from the consulting practitioner for providing a referral.

2. A practitioner shall not request or receive any form of remuneration from the company providing testing equipment or technicians to that practitioner or to his or her office, whether in the form of a shared fee, or for "rent" (whether on premises or off-premises) or for "administrative services" or under any other description.

3. A referring or consulting practitioner shall not be deemed an independent contractor to anyone associated with the testing of a specific patient; thus, the bill, if any, for any component of the testing shall be submitted solely in the name of the referring or consulting practitioner, as applicable.

(s) A practitioner who transmits diagnostic test data/records for interpretation by a consultant who is not a licensee of the Board shall assure that advance written consent for such interpretation service by such consultant has been obtained from the patient/third party payor.

New Rule, R.1999 d.70, effective March 1, 1999.

See: 30 N.J.R. 3751(a), 31 N.J.R. 659(a).

Amended by R.2001 d.43, effective February 20, 2001.

See: 32 N.J.R. 19(a), 33 N.J.R. 670(a).

In (a), added "Diagnostic office", "Screening office", and "Screening test"; added (d) through (s).

Administrative correction.

See: 33 N.J.R. 1203(a).

13:35-2.7 (Reserved)

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

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

Deleted qualification of 2 years Obstetrical clinical experience.

Repealed by R.1992 d.332, effective September 8, 1992.

See: 23 N.J.R. 3682(a), 24 N.J.R. 3094(a).

Section was "Qualifications".

13:35-2.8 (Reserved)

Repealed by R.1992 d.332, effective September 8, 1992.

See: 23 N.J.R. 3682(a), 24 N.J.R. 3094(a).

Section was "Minimum conditions of practice".

13:35-2.9 (Reserved)

Repealed by R.1992 d.332, effective September 8, 1992.

See: 23 N.J.R. 3682(a), 24 N.J.R. 3094(a).

Section was "Minimum standards for C.N.M. and lay midwife practice during prenatal stages".

13:35-2.10 (Reserved)

Repealed by R.1992 d.332, effective September 8, 1992.

See: 23 N.J.R. 3682(a), 24 N.J.R. 3094(a).

Section was "Management by a physician C.N.M. team for high-risk patients".

13:35-2.11 (Reserved)

Repealed by R.1992 d.332, effective September 8, 1992.

See: 23 N.J.R. 3682(a), 24 N.J.R. 3094(a).

Section was "Intrapartum management".

13:35-2.12 (Reserved)

Repealed by R.1992 d.332, effective September 8, 1992.

See: 23 N.J.R. 3682(a), 24 N.J.R. 3094(a).

Section was "Postpartum and other care".

13:35-2.13 Limited privileges and conditions of practice permitted for a graduate physician pending licensure

(a) Persons who are graduates of medical schools recognized by the Board may commence a period of supervised post-graduate training in a licensed hospital with an Accreditation Council on Graduate Medical Education (ACGME) or American Osteopathic Association (AOA) approved residency training program in this State immediately upon graduation. A training period commencing prior to the start of a formal ACGME or AOA approved post-graduate year term shall not exceed six months and shall be documented in the hospital record.

(b) Persons who are graduates of foreign medical schools recognized by the Board but who are not yet deemed eligible for licensure in this State because of the requirements of N.J.S.A. 45:9-8 and N.J.A.C. 13:35-3.11 may sit for the USMLE Step 3 upon completion of one year of approved post-graduate training and satisfaction of all other requirements of N.J.S.A. 45:9-1 et seq. and N.J.A.C. 13:35-3.1.

R.1984 d.138, effective April 16, 1984.

See: 16 N.J.R. 216(a), 16 N.J.R. 920(a).

Amended by R.1994 d.522, effective October 17, 1994.

See: 26 N.J.R. 2526(a), 26 N.J.R. 4195(a).

13:35-2.14 (Reserved)

R.1984 d.245, effective June 18, 1984.

See: 16 N.J.R. 685(a), 16 N.J.R. 1612(a).

Repealed by R.1992 d.332, effective September 8, 1992.

See: 23 N.J.R. 3682(a), 24 N.J.R. 3094(a).

Old section "Reserved" recodified to 13:35-2A.10. Section was "Limited privileges and conditions of practice permitted for a graduate nurse midwife pending results of certifying examination and licensure".

SUBCHAPTER 2A. LIMITED LICENSES: MIDWIFERY

13:35-2A.1 Midwifery practice

(a) The rules in this subchapter are intended to protect the health and safety of the public through licensure of midwives, pursuant to N.J.S.A. 45:10-1 et seq.

(b) This subchapter prescribes standards for midwifery licensure and for the renewal, suspension or revocation of that licensure.

Repeal and New Rule, R.2003 d.210, effective May 19, 2003.
See: 34 N.J.R. 3433(a), 35 N.J.R. 2227(a).
Section was "Certified Nurse Midwife practice".

13:35-2A.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meaning, unless the context clearly indicates otherwise:

"Affiliated physician" means a person who holds a plenary license to practice medicine and surgery in New Jersey, issued by the Board, who adheres to clinical guidelines with a licensed midwife.

"Board" means the New Jersey State Board of Medical Examiners.

"Certified midwife (CM)" means a person who is not a registered nurse and who holds certification from the American College of Nurse Midwives Certification Council (ACC) or its successors.

"Certified nurse midwife (CNM)" means a person who is a registered nurse and who holds certification from the American College of Nurse Midwives (ACNM) or the ACC or their successors.

"Certified professional midwife (CPM)" means a person who holds certification from the North American Registry of Midwives (NARM) or its successor.

"Clinical guidelines" means a written agreement, signed by both the licensee and the affiliated physician, which sets forth patterns of care and which provides for consultation, collaboration, management and referral as indicated by the health status of a woman receiving care from a licensee.

"Committee" means the Midwife Liaison Committee of the New Jersey State Board of Medical Examiners.

"Licensee" means any person who holds a license from the Board to practice as a midwife.

Repeal and New Rule, R.2003 d.210, effective May 19, 2003.
See: 34 N.J.R. 3433(a), 35 N.J.R. 2227(a).
Section was "Qualifications".

13:35-2A.3 Midwifery Liaison Committee

(a) The Midwifery Liaison Committee shall consist of eight members who shall serve as consultants to the Board and who shall be appointed by the Board. The Committee shall include at least one certified nurse midwife, at least one certified professional midwife, at least one certified midwife, and two other midwives, all of whom shall hold licensure from the Board. The Committee shall also include one certified nurse midwife who is a member of the Board and two physicians, one of whom shall be a member of the Board of Medical Examiners and one of whom shall be Board-certified by either the American Board of Obstetrics and Gynecology, the American Osteopathic Board of Obstetrics and Gynecology or any other certification organization with comparable standards.

(b) The Board shall appoint each member for a term of three years. Committee members may be reappointed.

(c) Functions of the Committee shall include the following:

1. Advising and assisting the Board in the evaluation of applicants for midwifery licensure and certified nurse midwife applicants for prescriptive authorization;
2. Investigating complaints against licensees and unlawful conduct by licensees;
3. Approving professional education programs; and
4. Advising and assisting the Board in drafting and reviewing rules to govern midwifery practice.

New Rule, R.2003 d.210, effective May 19, 2003.
See: 34 N.J.R. 3433(a), 35 N.J.R. 2227(a).

Former N.J.A.C. 13:35-2A.3, Minimum conditions of practice, recodified to N.J.A.C. 13:35-2A.6.

13:35-2A.4 Application for licensure

(a) An applicant for licensure as a midwife shall submit to the Committee:

1. A completed application for licensure requesting information regarding the applicant's address, telephone number, date of birth and social security number;
2. Proof that the applicant is 18 years old or older;
3. An official transcript from a midwifery program, accredited by the American College of Nurse Midwives (ACNM) or the Midwifery Education Accreditation Council (MEAC), or their successors;
4. A notarized copy of Certification from either ACNM, ACC, NARM, or their successors;
5. The applicant's curriculum vitae;
6. Three photographs of the applicant, signed, dated and notarized; and
7. The application fee pursuant to N.J.A.C. 13:35-6.13(a)6i.

(b) Once the applicant has been approved, he or she shall submit the initial license fee pursuant to N.J.A.C. 13:35-6.13(a)6iv.

Repeal and New Rule, R.2003 d.210, effective May 19, 2003.
See: 34 N.J.R. 3433(a), 35 N.J.R. 2227(a).
Section was "Normal antepartum management".

13:35-2A.5 Independent practice

(a) Certified nurse midwife and certified midwife practice shall include the provision of maternity care and well woman care within a health care system which provides for consultation, referral and collaboration, and:

1. For licensees without prescriptive authority, administering or dispensing those medications listed in the clinical guidelines; or

2. For licensees with prescriptive authority pursuant to N.J.A.C. 13:35-2A.14, prescribing, ordering, administering or dispensing medications.

(b) Certified nurse midwives and certified midwives shall conduct their practice pursuant to standards set forth by the ACNM in Standards for the Practice of Nurse Midwifery (1993), as amended and supplemented, available from the American College of Nurse-Midwives, 818 Connecticut Ave., Suite 900, Washington, DC 20006, which is incorporated herein by reference as part of this rule.

(c) Certified professional midwife practice shall include the provision of maternity care within a health care system which provides for consultation, referral and collaboration with a licensed physician and the administration or dispensing of those medications listed in the clinical guidelines.

(d) Certified professional midwives shall conduct their practice pursuant to standards set forth by the NARM in the Midwifery Model of Care (2000), as amended and supplemented, available from North American Registry of Midwives, 5257 Rosestone Drive, Lilburn, GA 30047, which is incorporated herein by reference as part of this rule.

Repeal and New Rule, R.2003 d.210, effective May 19, 2003.
See: 34 N.J.R. 3433(a), 35 N.J.R. 2227(a).

Section was "Normal intrapartum management".

13:35-2A.6 Affiliated physicians; clinical guidelines

(a) Prior to beginning practice as a midwife, a licensee shall enter into an affiliation with a physician who is licensed in New Jersey and who:

1. Holds hospital privileges in operative obstetrics/gynecology;

2. Has a binding agreement with a physician who holds operative privileges in operative obstetrics/gynecology; or

3. Holds hospital privileges in gynecology, if a licensee limits his or her practice to non-obstetrical.

(b) The licensee shall establish written clinical guidelines with the affiliated physician which outlines the licensee's scope of practice.

(c) The clinical guidelines shall set forth:

1. An outline of routine care;

2. Procedures the licensee will perform or provide;

3. Procedures to follow if one of the risk factors from N.J.A.C. 13:35-2A.9 and 2A.11 are encountered;

4. The circumstances under which consultation, collaborative management, referral and transfer of care of

women between the licensee and the affiliated physician are to take place, and the manner by which each is to occur;

5. If the licensee is a certified nurse midwife with prescriptive authority pursuant to N.J.A.C. 13:35-2A.12, a formulary listing the categories of drugs, which may include controlled dangerous substances, the certified nurse midwife may order, prescribe, administer or dispense;

6. If the licensee does not hold prescriptive authority pursuant to N.J.A.C. 13:35-2A.14, a list of all medications the licensee may dispense or administer pursuant to the directions of the affiliated physician;

7. A mechanism for determining the availability of the affiliated physician, or a substitute physician, for consultation and emergency assistance or medical management when needed; and

8. The manner by which emergency care for newborns will be provided.

(d) Prior to beginning practice, a licensee shall file with the Board a notice identifying the affiliated physician, the physician's telephone number and business address and the effective date of the clinical guidelines. In the event of any change of affiliated physician, the licensee shall notify the Board in writing within 30 days of the change.

(e) Clinical guidelines shall be made available to the Board upon request.

(f) The clinical guidelines shall include provisions for periodic conferences with the affiliated physician for review of patient records and for quality improvements.

(g) A licensee who practices without establishing clinical guidelines with an affiliated physician commits professional misconduct as proscribed by N.J.S.A. 45:1-21(e).

Recodified from N.J.A.C. 13:35-2A.3 and amended by R.2003 d.210, effective May 19, 2003.

See: 34 N.J.R. 3433(a), 35 N.J.R. 2227(a).

Rewrote the section. Former N.J.A.C. 13:35-2A.6, Postpartum and well-woman health care, repealed.

13:35-2A.7 Biennial renewal

(a) A license shall be renewed every two years.

(b) When renewing a license, the licensee shall submit to the Board:

1. A completed renewal form; and

2. The biennial registration fee pursuant to N.J.A.C. 13:35-6.13(a)6v.

New Rule, R.2003 d.210, effective May 19, 2003.

See: 34 N.J.R. 3433(a), 35 N.J.R. 2227(a).

Former N.J.A.C. 13:35-2A.7, Management of antepartum women at risk, recodified to N.J.A.C. 13:35-2.9.

13:35-2A.8 Antepartum management

(a) A licensee's scope of practice during antepartum stages includes:

1. Ordering medical, therapeutic and diagnostic measures in accordance with clinical guidelines; and
2. Identifying women with medical, obstetrical or gynecological risk factors outlined in N.J.A.C. 13:35-2A.9.

Repeal and New Rule, R.2003 d.210, effective May 19, 2003.

See: 34 N.J.R. 3433(a), 35 N.J.R. 2227(a).

Section was "Care of intarpartum women at risk".

13:35-2A.9 Management of antepartum women at increased risk

(a) A licensee may participate in the management of antepartum patients at increased risk under the following conditions:

1. The affiliated physician and licensee shall have agreed to include the woman at increased risk in the caseload;
2. The affiliated physician and licensee shall have established and documented a management plan for all women identified as at increased risk, which shall delineate the role of both the affiliated physician and the licensee in the care of the woman. The management plan shall set forth the following:
 - i. Frequency of physician visits;
 - ii. Timing of indicated diagnostic and evaluative procedures;
 - iii. Specific parameters for consultation; and
 - iv. A proposed plan for the birth, including the type, place and provider.
3. The management plan shall be reviewed periodically by the licensee and the affiliated physician and revised when necessary.

(b) The following are risk factors that require management as outlined in (a) above:

1. Maternal health status:
 - i. Acute and/or chronic hypertension;
 - ii. Congenital or acquired heart disease;
 - iii. Anti-phospholipid syndrome;
 - iv. HIV positive or AIDS;
 - v. Chronic renal disease;
 - vi. Seizure disorder requiring medications;
 - vii. Chronic anemia and/or hemoglobinopathy;
 - viii. Diabetes mellitus;
 - ix. Drug addiction;

- x. Psychosis;
- xi. Asthmatic on daily oral medication;
- xii. Any connective tissue disorder;
- xiii. Multiple sclerosis;
- xiv. History of cerebrovascular accident; or
- xv. History of cancer.

2. Maternal reproductive health history:

- i. Incompetent cervix;
- ii. Two or more second or third trimester fetal losses;
- iii. Preterm labor and/or delivery;
- iv. Parity of six or more;
- v. Previous cesarean delivery;
- vi. Surgery involving the uterine wall;
- vii. Previous placental abruption;
- viii. Previous postpartum blood transfusion;
- ix. Previous cervical surgeries including Loop Electrosurgical Excision Procedures (LEEP), cone biopsies or three or more surgical cervical dilations; or
- x. Intra-uterine growth restriction and/or delivery of an infant weighing less than 2,500 grams at 36 weeks or more.

3. Current maternal obstetrical status:

- i. Obstructive uterine myomata;
- ii. Polyhydramnios or oligohydramnios;
- iii. Isoimmunization;
- iv. Multiple gestation;
- v. Intrauterine growth restriction;
- vi. Current evidence of fetal chromosome disorder confirmed by amniocentesis and/or congenital anomaly;
- vii. Gestational diabetes;
- viii. Maternal age less than 14 years or more than 40 years;
- ix. PAP smear indicating dysplasia;
- x. Placenta previa;
- xi. Medicated pre-term labor; or
- xii. Preeclampsia.

Recodified from N.J.A.C. 13:35-2A.7 and amended by R.2003 d.210, effective May 19, 2003.

See: 34 N.J.R. 3433(a), 35 N.J.R. 2227(a).

Rewrote the section. Former N.J.A.C. 13:35-2A.9, Certified Nurse Midwife Liaison Committee, repealed.

- v. Amniotic fluid evaluation; and
 - vi. Biophysical profile parameters;
7. Components of gynecological ultrasound examination:
- i. Identification of uterine position;
 - ii. Evaluation of uterine size;
 - iii. Assessment of number, size and location of early gestational sac(s) and presence and length of embryonic pole(s); and
 - iv. Recognition of early fetal cardiac activity; and
8. Formulation of a plan of care based on assessments made, including the need for consultation, referral and follow-up.

(d) A licensee who intends to perform limited ultrasound examinations pursuant to (a) above shall amend the clinical guidelines to include circumstances when the licensee may perform limited ultrasound examinations.

New Rule, R.2003 d.210, effective May 19, 2003.
See: 34 N.J.R. 3433(a), 35 N.J.R. 2227(a).

13:35-2A.16 Colposcopies

(a) A CNM or CM who has completed a course as required by (b) below and clinical experience required by (c) below may perform colposcopies for the purposes of evaluating and diagnosing abnormal cervical findings.

(b) A CNM or CM who wishes to perform colposcopies shall complete a 20-hour colposcopy course, given by a college or university accredited by an accrediting association recognized by the U.S. Department of Education or given by an organization recognized by either the American Society of Colposcopy and Cervical Pathology, the American College of Obstetrics and Gynecology, the American College of Nurse-Midwives or the National Association of Nurse Practitioners in Reproductive Health.

(c) A CNM or CM who intends to perform colposcopies independently shall first complete 50 colposcopies under the supervision of a CNM or CM who has met the requirements of this section or an individual who has received education and training substantially similar to that required by this section.

(d) A CNM or CM who has successfully completed a colposcopy course shall maintain a certificate from the sponsor of the colposcopy course indicating that the CNM or CM has completed the course.

(e) A CNM or CM who intends to perform colposcopy pursuant to (a) above shall amend the clinical guidelines to include circumstances when the midwife may perform colposcopy.

New Rule, R.2003 d.210, effective May 19, 2003.

See: 34 N.J.R. 3433(a), 35 N.J.R. 2227(a).

13:35-2A.17 Circumcisions

(a) A licensee who has completed a course as required by (b) below and clinical experience as outlined in (c) below may perform circumcisions.

(b) A licensee who intends to perform circumcisions shall complete a course given by a licensed physician or licensed midwife who has privileges to perform circumcisions in a licensed health care facility. The circumcision course shall include:

1. The theory of circumcisions, including the procedure's benefits and risks, and alternatives to the procedure;
2. Providing informed consent to the parents;
3. Indications and contraindications for circumcision; and
4. Potential complications.

(c) Prior to performing any circumcisions independently as permitted by this section, the licensee shall observe five circumcisions and perform 20 circumcisions under the direct supervision of a licensed physician or a midwife qualified to perform independently pursuant to this section. For purposes of this subsection, "direct supervision" means the presence of, and observation of the procedure by, a licensed physician, or midwife qualified to perform circumcisions, in the location where the circumcision is being performed.

(d) A licensee who intends to perform circumcisions pursuant to (a), (b) and (c) above shall maintain, as part of the licensee's records, documentation which indicates that the licensee has met the education requirements of (b) and (c) above.

(e) A licensee who intends to perform circumcisions pursuant to (a), (b) and (c) above shall amend the clinical guidelines to include circumstances when the licensee may perform circumcisions.

New Rule, R.2003 d.210, effective May 19, 2003.
See: 34 N.J.R. 3433(a), 35 N.J.R. 2227(a).

SUBCHAPTER 2B. LIMITED LICENSES: PHYSICIAN ASSISTANTS

13:35-2B.1 Purpose and scope

(a) The rules in this subchapter implement the provisions of the Physician Assistant Licensing Act, P.L. 1991, c.378, as amended by P.L. 1992, c.102.

(b) This subchapter shall apply to all physician assistants licensed pursuant to the provisions of this subchapter and to

anyone within the jurisdiction of the Physician Assistant Advisory Committee.

13:35-2B.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings unless the context clearly indicated otherwise:

“Board” means the State Board of Medical Examiners.

“Committee” means the Physician Assistant Advisory Committee.

“Direct supervision” means supervision by a plenary licensed physician which shall meet all of the conditions established in N.J.A.C. 13:35-2B.10(b) or N.J.A.C. 13:35-2B.15, as applicable.

“Director” means the Director of the Division of Consumer Affairs.

“Licensee” means a physician assistant licensed pursuant to this subchapter.

“Licensed personnel” means health care practitioners licensed in the State of New Jersey to perform specific duties in the health care field.

“Physician” means a person who holds a current, valid license to practice medicine and surgery in this State.

“Physician assistant” means a person who holds a current, valid license to practice as a physician assistant in this State.

“Physician designee” means a plenary licensed physician who is assigned by the supervising physician in case of his or her temporary absence and whose scope of practice encompasses the duties assigned to a physician assistant.

“Supervising physician” means a plenary licensed physician in good standing who, pursuant to N.J.S.A. 45:9-27.18, engages in the direct supervision of physician assistants whose duties shall be encompassed by the supervising physician’s scope of practice.

Amended by R.1995 d.423, effective August 7, 1995.
See: 27 N.J.R. 1526(a), 27 N.J.R. 2959(a).

13:35-2B.3 Practice requirements

(a) A licensee may engage in clinical practice in any medical care setting provided that:

1. The licensee is under the direct supervision of a physician pursuant to the provisions of N.J.A.C. 13:35-2B.10;
2. The licensee limits his or her practice to those procedures authorized pursuant to N.J.A.C. 13:35-2B.4;
3. Upon initial involvement in a patient’s course of care or treatment, the licensee or the supervising physician advises the patient that authorized procedures are to be performed by the physician assistant;

4. The licensee conspicuously wears an identification tag using the term "physician assistant" whenever acting in that capacity; and

5. The licensee complies with the recordkeeping requirements set forth in N.J.A.C. 13:35-2B.11.

(b) The licensee shall file with the Board a notice of employment for each place of employment, on forms provided by the Committee, within 10 days after the date on which employment commences. Furthermore, the licensee shall report to the Board any change in employment or supervisor within 10 days of the change.

13:35-2B.4 Scope of practice

(a) A licensee who has complied with the provisions of N.J.A.C. 13:35-2B.3 may perform the following procedures on a discretionary and routine basis:

1. Approaching a patient to elicit a detailed and accurate history, perform an appropriate physical examination, identify problems, record information and interpret and present information to the supervising physician, determine and implement therapeutic plans jointly with the supervising physician and compile and record pertinent narrative case summaries;

2. Suturing and follow up care of wounds including removing sutures and clips and changing dressings, except for facial wounds, traumatic wounds requiring suturing in layers and infected wounds;

3. Providing patient counseling services and patient education consistent with directions of the supervising physician;

4. Assisting a physician in an inpatient setting by conducting patient rounds, recording patient progress notes, determining and implementing therapeutic plans jointly with the supervising physician and compiling and recording pertinent narrative case summaries;

5. Assisting a physician in the delivery of services to patients requiring continuing care in a private home, nursing home, extended care facility, private office practice or other setting, including the review and monitoring of treatment and therapy plans;

6. Facilitating the referral of patients to, and promoting their awareness of, health care facilities and other appropriate agencies and resources in the community;

7. Collecting fluids for diagnostic purposes, including, but not limited to, blood, urine, sputum and exudates;

8. Placing and utilizing access catheters and tubes for diagnostic, therapeutic or interventional purposes, including, but not limited to, intravenous, arterial, nasogastric and urinary;

9. Performing minor surgical procedures such as simple excisions, incision and drainage, debridement and packing of wounds;

10. Applying and removing medical and surgical appliances and devices such as splints, casts, immobilizers, traction, monitors and infusion pumps;

11. Management of emergency and life threatening conditions;

12. Performing low-risk obstetrical deliveries in a licensed hospital with the supervising physician or physician designee on premises and available to respond immediately; and

13. Subject to review by the Board, such other written procedures established by the employer, provided the procedures are within the training and experience of both the supervising physician and the physician assistant.

(b) A licensee who has complied with the provisions of N.J.A.C. 13:35-2B.3 may perform the following procedures, provided the procedures are within the training and experience of both the supervising physician and the physician assistant, only when the supervising physician directs the licensee to perform the procedures or orders or prescribes the procedures, or the procedures are specified in a written protocol approved by the Board.

1. Performing non-invasive laboratory procedures and related studies or assisting licensed personnel in the performance of invasive laboratory procedures and related studies;

2. Giving injections, administering medications and ordering diagnostic studies;

3. Suturing and caring for facial wounds, traumatic wounds requiring suturing in layers and infected wounds;

4. Ordering medications and prescribing other than controlled dangerous substances and writing orders to implement therapeutic plans identified pursuant to (a)4 above.

5. In the operating room, assisting a supervising surgeon as a first assistant or as a second assistant when deemed necessary by the supervising surgeon and when a qualified assistant physician is not required by N.J.A.C. 13:35-4.1;

6. Performing other procedures for diagnostic, therapeutic or interventional purposes such as, but not limited to, introduction of contrast material for radiologic studies, use of endoscopic instruments and aspiration of fluid from joints and body cavities, collection of cerebrospinal fluid, biopsy of tissues, placement of central venous catheters or chest tubes, and endotracheal intubation.

i. The supervising physician or physician designee shall be available on premises for those procedures requiring intravenous or intra-arterial injection of contrast material, endoscopic biopsy of tissue, and elective endotracheal intubation.

ii. The supervising physician shall maintain documentation, or ensure that documentation is maintained,

evidencing that the physician assistant has the training, experience and proficiency to perform such procedures; and

7. Subject to review and approval by the Board, such other written procedures established by the employer, provided the procedures are within the training and experience of both the supervising physician and the physician assistant.

Amended by R.1996 d.126, effective March 4, 1996.

See: 27 N.J.R. 1956(a), 28 N.J.R. 1390(a).

In (a) added low-risk obstetrical deliveries and in (b) added other procedures for diagnostic, therapeutic or interventional purposes.

Amended by R.1999 d.356, effective October 18, 1999.

See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

In (b)4, deleted "In an inpatient setting," at the beginning.

13:35-2B.5 Eligibility for licensure

(a) An applicant for licensure shall submit to the Board, with the completed application form and the required fee, evidence that the applicant:

1. Is at least 18 years of age;
2. Is of good moral character, evidence of which shall require the applicant for licensure to respond to such inquiry as the Board deems appropriate regarding past and present fitness to practice, and issues pertinent thereto;
3. Has successfully completed an education program for physician assistants which is approved by the Committee on Allied Health Education and Accreditation, or its successor; and
4. Has passed the examination administered by the National Commission on Certification of Physician Assistants (NCCPA), except as set forth in (b) below.

(b) An applicant who submits satisfactory proof that he or she holds a current license, certification or registration to practice as a physician assistant in a state which has standards substantially equivalent to those of this State shall be deemed to satisfy the examination requirement set forth in (a)4 above.

13:35-2B.6 Refusal to issue, suspension or revocation of license

(a) The Board may refuse to issue or may suspend or revoke any license issued by the Board for any of the reasons set forth in N.J.S.A. 45:1-21.

(b) Prior to any license suspension or revocation, the licensee shall be afforded the opportunity for a hearing pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

13:35-2B.7 License renewal, continuing education requirement

(a) The Board shall not issue a biennial license renewal unless the applicant submits, with the renewal application, proof that he or she completed courses of continuing professional education of the types and number of credits specified in N.J.A.C. 13:35-2B.8.

(b) Falsification of any information submitted with the renewal application may result in an appearance before the Board or a duly appointed Committee thereof and, after due notice to the licensee and the opportunity for a hearing pursuant to the Administrative Procedure Act and the Uniform Administrative Procedure Rules, penalties and/or suspension or revocation of the license.

(c) The Board will, from time to time, conduct inquiries among licensees on a random basis to determine compliance with continuing education requirements.

13:35-2B.8 Credit-hour requirements

(a) Each applicant for a biennial license renewal shall be required to complete, during the preceding biennial period, a minimum of 40 continuing education credit hours in category I courses approved by the American Medical Association, the American Academy of Physician Assistants, the American Academy of Family Physicians, the American Osteopathic Association or the Accreditation Council on Continuing Medical Education. The Board reserves the right to review and approve continuing education courses offered by entities other than those set forth above.

(b) Fifteen credits may be carried over into a succeeding biennial period only if earned during the last six months of the preceding biennial period.

13:35-2B.9 Waiver of continuing education requirement

(a) The Board may, in its discretion, temporarily waive continuing education requirements on an individual basis for reasons of hardship, such as illness or disability, or other good cause.

(b) Any licensee seeking a waiver of the continuing education requirements must apply to the Board in writing and set forth with specificity the reasons for requesting the waiver. The licensee shall also provide the Board with such additional information as it may reasonably request in support of the application.

13:35-2B.10 Supervision

(a) A physician assistant shall engage in practice only under the direct supervision of a physician.

(b) The physician assistant shall not render care unless the following conditions are met:

1. In an inpatient setting, the supervising physician or physician-designee is continuously or intermittently present on-site with constant availability through electronic communications for consultation or recall;

2. In an outpatient setting, the supervising physician or physician-designee is constantly available through electronic communications for consultation or recall;

3. The supervising physician regularly reviews the practice of the physician assistant;

4. The supervising physician personally reviews all charts and patient records and countersigns all medical orders as follows:

i. In an inpatient setting, within 24 hours of the physician assistant's entry of the order in the patient record; and

ii. In an outpatient setting, within a maximum of seven days of the physician assistant's entry of the order in the patient record, except that in the case of any medical order prescribing or administering medication, a physician shall review and countersign the order within 48 hours of its entry by the physician assistant; and

5. The following supervisory ratios are met:

i. In a private practice which is not hospital based or institutionally affiliated, no more than two physician assistants to one physician at any one time;

ii. In all other settings, no more than four physician assistants to one physician at any one time.

(c) Upon application to the Board, the Board may alter the supervisory ratios set forth in (b) above.

(d) A supervising physician who is a department head may assign physician assistants under his or her supervision to attending and staff physicians, who shall be responsible for the practice of the physician assistant during the assignment. In all other settings in which a physician assistant is employed, the supervising physician of record shall be considered to be the person responsible for the practice of the physician assistant.

Amended by R.2000 d.349, effective August 21, 2000.

See: 31 N.J.R. 2132(a), 32 N.J.R. 3174(a).

In (b)4ii, inserted an exception.

13:35-2B.11 Recordkeeping

(a) Licensees shall make contemporaneous, permanent entries into professional treatment records which shall accurately reflect the treatment or services rendered. To the extent applicable, professional treatment records shall reflect:

1. The dates and times of all treatments;

2. The patient complaint;

3. The history;

4. Findings on appropriate examination;

5. Progress notes;

6. Any orders for tests or consultations and the results thereof;

7. Diagnosis or medical impression; and

8. Treatment ordered. If medications are ordered, the patient record shall include:

i. Specific dosages, quantities and strengths of medications;

ii. A statement indicating whether the medication order is written pursuant to protocol or specific physician direction. Acceptable abbreviations are "prt" for protocol and "spd" for specific physician direction;

iii. The physician assistant's full name, printed or stamped, and the license number; and

iv. The supervising physician's full name, printed or stamped.

(b) If the information required pursuant to (a)8iii and iv appears at least once in the patient record, it need not be repeated each time a medication order is entered in the patient record.

(c) The physician assistant shall sign each entry in the patient record and record the designation "PA-C" following his or her signature.

(d) To the extent a physician assistant is charged with independent responsibility for the provision of information used to prepare bills and claims forms, such information shall accurately reflect the treatment or services rendered.

13:35-2B.12 Requirements for issuing prescriptions for medications

(a) A physician assistant may issue prescriptions only in accordance with the following conditions:

1. A physician assistant shall not issue prescriptions for controlled dangerous substances.

2. A physician assistant shall provide the following on all prescription blanks:

i. The physician assistant's full name, professional identification ("PA-C"), license number, address and telephone number. This information shall be printed or stamped on all prescription blanks;

ii. The supervising physician's full name, printed or stamped;

iii. A statement indicating whether the prescription is written pursuant to protocol or specific physician direction. Acceptable abbreviations are "prt" for protocol and "spd" for specific physician direction;

- iv. The full name, age and address of the patient;
- v. The date of issuance of prescription;
- vi. The name, strength and quantity of drug or drugs to be dispensed and route of administration;
- vii. Adequate instruction for the patient. A direction of "p.r.n." or "as directed" alone shall be deemed an insufficient direction;
- viii. The number of refills permitted or time limit for refills, or both;
- ix. The signature of the prescriber, hand-written; and
- x. Every prescription blank shall be imprinted with the words "substitution permissible" and "do not substitute" and shall contain space for the physician assistant's initials next to the chosen option, in addition to the space required for the signature in (a)3ix above.

Amended by R.1999 d.356, effective October 18, 1999.

See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

In (a), deleted a former 1, and recodified former 2 and 3 as 1 and 2.

13:35-2B.13 Eligibility for temporary licensure

(a) An individual who has filed an application for licensure and is waiting to take the next scheduled examination administered by the National Commission on Certification of Physician Assistants (NCCPA) or awaiting the results of the examination may apply to the Board for a temporary license to be employed under the direct supervision of a physician, as defined in N.J.A.C. 13:35-2B.2 and 2B.15.

(b) An applicant for temporary licensure shall submit to the Board, with the completed application form, the documents required pursuant to N.J.A.C. 13:35-2B.5, the required fee, and evidence that the applicant has filed an application for the NCCPA examination.

New Rule, R.1995 d.423, effective August 7, 1995.

See: 27 N.J.R. 1526(a), 27 N.J.R. 2959(a).

13:35-2B.14 Temporary licensure; scope of practice

(a) A temporary license holder who has complied with the practice requirements set forth in N.J.A.C. 13:35-2B.3 may perform all of the procedures within the scope of practice of a physician assistant, as set forth in N.J.A.C. 13:35-2B.4(a) and (b) and subject to the limitations therein, except that a temporary license holder shall not issue prescriptions.

(b) A temporary license holder shall engage in practice only under the direct supervision of a physician pursuant to the provisions of N.J.A.C. 13:35-2B.15.

New Rule, R.1995 d.423, effective August 7, 1995.

See: 27 N.J.R. 1526(a), 27 N.J.R. 2959(a).

13:35-2B.15 Supervision of temporary license holder

(a) A temporary license holder shall not render care unless the following conditions are met:

1. In any setting, the supervising physician or physician designee or a licensed physician assistant with privileges in the same discipline:

- i. Is continuously present on-site; and
- ii. Countersigns, immediately after its entry in the chart, any order for medication written by the temporary license holder.

2. The supervising physician or physician designee:

i. Personally reviews all charts and patient records within 24 hours of the temporary license holder's entry in the chart and record; and

ii. Countersigns any order for medication written by the temporary licensee and countersigned by a licensed physician assistant.

New Rule, R.1995 d.423, effective August 7, 1995.

See: 27 N.J.R. 1526(a), 27 N.J.R. 2959(a).

13:35-2B.16 Expiration of temporary license; renewal

(a) A temporary license shall expire 30 days after the temporary license holder has received notification of successful completion of the examination or immediately upon the applicant's receipt of notification of failure to pass the examination.

(b) An applicant who fails an examination shall cease and desist from the performance of his or her duties.

(c) Except in extenuating circumstances such as the applicant's critical illness or incapacitation, a temporary license may not be renewed. An applicant seeking to renew based upon extenuating circumstances shall be required to present to the Board satisfactory documentation of the basis for the renewal request.

New Rule, R.1995 d.423, effective August 7, 1995.

See: 27 N.J.R. 1526(a), 27 N.J.R. 2959(a).

13:35-2B.17 Reinstatement of lapsed license

(a) An individual whose license has lapsed for nonpayment of a biennial renewal fee shall be reinstated by the Board, provided the applicant otherwise qualifies for licensure pursuant to N.J.S.A. 45:9-27.10 et seq., and submits one of the following to the Board:

- 1. A certification or licensure in good standing from any other state or jurisdiction in which the applicant has practiced as a physician assistant during the period of lapsed licensure in this State;

2. An affidavit by the applicant stating that he or she has practiced as a physician assistant in a state or jurisdiction which does not require certification or licensure, during the period of lapsed licensure in this State;

3. An affidavit by the applicant stating that he or she has practiced as a physician assistant in an exempt setting, during the period of lapsed licensure in this State; or

4. An affidavit by the applicant stating that he or she has not practiced as a physician assistant, in this or any other jurisdiction during the period of lapsed licensure in this State.

(b) An applicant shall submit written verification, on a form provided by the Board, from all of the applicant's employers. Said verification shall document dates of employment from the date the license lapsed to the date of application for reinstatement.

(c) An applicant who has been practicing as a physician assistant during the period of lapsed licensure in any manner described in (a)1 through 3 above shall submit proof that he or she has completed a minimum of 40 Board-approved continuing education credit hours in the two-year period immediately prior to application for reinstatement.

(d) An applicant who has not practiced as a physician assistant during the period of lapsed licensure shall meet the following continuing educational requirements as a condition of reinstatement:

1. An individual whose license has lapsed for a period of two years or less shall complete 40 hours of Board-approved continuing education within the two-year period preceding reinstatement;

2. An individual whose license has lapsed for a period of more than two and less than five years shall complete 60 hours of Board-approved continuing education within the three-year period immediately preceding reinstatement; and

3. An individual whose license has lapsed for a period of five or more years shall complete 80 hours of Board-approved continuing education within the four-year period immediately preceding reinstatement.

(e) An applicant who has maintained National Commission on Certification of Physician Assistants (NCCPA) certification since the date of lapsed licensure shall be deemed to have met the continuing education requirements of (c) and (d) above and shall submit current NCCPA certification to demonstrate maintenance of professional standards.

(f) Prior to reinstatement, an applicant shall pay a reinstatement fee pursuant to N.J.A.C. 13:35–6.13.

(g) An individual who practices as a physician assistant or an individual who holds himself or herself out as a physician assistant in New Jersey without a license or during a period

of lapsed licensure in this State shall be subject to the penalties prescribed by N.J.S.A. 45:9–22 for practicing without a license.

New Rule, R.2000 d.397, effective October 2, 2000.
See: 31 N.J.R. 2449(a), 32 N.J.R. 3573(a).

13:35–2B.18 Sexual misconduct

(a) The purpose of this section is to identify for physician assistants licensed by the State Board of Medical Examiners conduct which shall be deemed sexual misconduct.

(b) As used in this section, the following terms have the following meanings unless the context clearly indicates otherwise:

“Patient” means any person who is the recipient of a professional service rendered by a physician assistant relating to treatment.

“Patient-physician assistant relationship” means a relationship between a physician assistant and a patient wherein the licensee owes a continuing duty to the patient to render physician assistant services consistent with his or her training and experience.

“Sexual contact” means the knowing touching of a person's body directly or through clothing, where the circumstances surrounding the touching would be construed by a reasonable person to be motivated by the licensee's own prurient interest or for sexual arousal or gratification. “Sexual contact” includes, but is not limited to, the imposition of a part of the licensee's body upon a part of the patient's body, sexual penetration, or the insertion or imposition of any object or any part of a licensee or patient's body into or near the genital, anal or other opening of the other person's body.

“Sexual harassment” means solicitation of any sexual act, physical advances, or verbal or non-verbal conduct that is sexual in nature, and which occurs in connection with a licensee's activities or role as a provider of physician assistant services, and that either: is unwelcome, is offensive to a reasonable person, or creates a hostile workplace environment, and the licensee knows, should know, or is told this; or is sufficiently severe or intense to be abusive to a reasonable person in that context. “Sexual harassment” may consist of a single extreme or severe act or of multiple acts and may include conduct of a licensee with a patient, co-worker, employee, student or supervisee whether or not such individual is in a subordinate position to the licensee. “Sexual harassment” may also include conduct of a nonsexual nature if it is based on the sex of an individual.

“Spouse” means either the husband or wife of the licensee or an individual involved in a long-term committed relationship with the licensee.

(c) A licensee shall not engage in sexual contact with a patient with whom he or she has a patient-physician assistant relationship. The patient-physician assistant relationship is ongoing for purposes of this section, unless:

1. Physician assistant services are actively terminated by way of written notice to the patient and is documented in the patient record; or
2. The last physician assistant services were rendered more than one year ago.

(d) A licensee shall not seek or solicit sexual contact with a patient with whom he or she has a patient-physician assistant relationship and shall not seek or solicit sexual contact with any person in exchange for professional services.

(e) A licensee shall not engage in any discussion of an intimate sexual nature with a patient, unless that discussion is related to legitimate patient needs. Such discussion shall not include disclosure by the licensee of his or her own sexual relationships.

(f) A licensee shall provide privacy and examination conditions which prevent the exposure of the unclothed body of the patient unless necessary to the professional services rendered.

(g) A licensee shall not engage in sexual harassment whether in a professional setting such as an office, hospital, residence or health care facility, or outside of the professional setting.

(h) A licensee shall not engage in any other activity, such as, but not limited to, voyeurism or exposure of the genitalia of the licensee, which would lead a reasonable person to believe that the activity serves the licensee's personal prurient interest or is for the sexual arousal, the sexual gratification or the sexual abuse of the licensee or patient.

(i) Violation of any of the prohibitions or directives set forth in (c) through (h) above shall be deemed to constitute gross or repeated malpractice pursuant to N.J.S.A. 45:1-21(c) or (d) or professional misconduct pursuant to N.J.S.A. 45:1-21(e).

(j) Nothing in this section shall be construed to prevent a licensee from rendering physician assistant services to a spouse, as defined in (b) above, providing that the rendering of such physician assistant services is consistent with accepted standards of physician assistants and that the performance of physician assistant services is not utilized to exploit the patient spouse for the sexual arousal or sexual gratification of the licensee.

(k) It shall not be a defense to any action under this section that:

1. The patient solicited or consented to sexual contact with the licensee; or
2. The licensee is in love with or held affection for the patient.

New Rule, R.2000 d.456, effective November 20, 2000.
See: 31 N.J.R. 3040(a), 32 N.J.R. 4122(a).

SUBCHAPTER 3. LICENSING EXAMINATIONS AND ENDORSEMENTS, LIMITED EXEMPTIONS FROM LICENSURE REQUIREMENTS

13:35-3.1 Licensing examination; physicians

(a) Effective December 1994, the standard medical and surgical licensing examination in the State of New Jersey shall be the United States Medical Licensing Examination (USMLE), Step 3. The licensing examination administered by the National Osteopathic Board of Examiners shall also be recognized as an alternative standard licensing examination for graduation of American Osteopathic Association-approved Osteopathic Medical Schools.

(b) Prior to January 1995, the Federation Licensing Examination (FLEX) shall serve as one of the two standard medical and surgical licensing examinations in the State of New Jersey.

(c) A candidate for examination who has met all other requirements of law for medical licensure shall be admitted to USMLE, Step 3, upon appropriate demonstration to the Board of successful completion of one of the following examination sequences. Completion of the examination sequence includes attainment of a passing score on each portion of the sequence. (The passing score for each portion of the examination sequence will be the score that was deemed passing by the Board at the time the examination was administered.)

1. USMLE Step 1 or National Board Part I and USMLE Step 2 or National Board Part II; or
2. FLEX Component I.

(d) The entire examination sequence shall be passed within a seven-year period. The seven-year period begins when the first portion of the examination is passed. No passing credit shall be carried beyond the seven-year period. Candidates shall be required to repeat the entire USMLE sequence if the entire examination is not passed within seven years of the initial date of passage.

(e) No candidate shall be permitted more than five attempts to pass Step 3 of USMLE without demonstration of additional education, experience or training acceptable to the Board.

Amended by R.1985 d.224, effective May 6, 1985.

See: 17 N.J.R. 561(a), 17 N.J.R. 1131(c).

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).

Added alternate method for taking FLEX exam; deleted (e).

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.1999 d.356, effective October 18, 1999.

See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

In (a), added a second sentence.

Case Notes

Physician loses license for gross negligence by performing risky hysteroscopic examinations. In the Matter of Brookman, 97 N.J.A.R.2d (BDS) 43.

Conjecture and supposition insufficient evidence to support finding podiatrist assisted suspended podiatrist in unlawful practice. In the Matter of DeTolla, 97 N.J.A.R.2d (BDS) 37.

There was no violation of law warranting suspension or revocation of surgeon's license. In the Matter of the Suspension or Revocation of the License of Termanini, 93 N.J.A.R.2d (BDS) 85.

13:35-3.2 Endorsement; physicians

(a) The Board shall grant without examination a license to practice medicine and surgery to any person who shall furnish proof that he or she can fulfill the requirements of law relating to applicants for admission by examination and who:

1. Has presented certification of either the National Board of Medical Examiners or Osteopathic Examiners that the applicant has attained diplomate status from either of those organizations;
2. Has been licensed in another state upon successful passage of a non-FLEX written plenary examination tak-

en in English prior to December 31, 1972, and submits proof of active and reputable practice of medicine and surgery for 10 or more years;

3. Has been licensed in another state upon successful passage of a non-FLEX written plenary examination and presents proof of certification as a diplomate of any specialty board recognized by the American Board of Medical Specialties or the American Osteopathic Association;

4. Has taken the FLEX exam prior to January 1981, and attained a FLEX weighted average of 74.5 or better;

5. Has taken the FLEX exam between January 1981 and June 1985, and attained a weighted score of 75 or better;

6. Has taken the FLEX exam between June 1985 and December 1994 and attained a FLEX weighted average of 75 or better in each of the two components;

7. Has presented certification from either the National Board of Medical Examiners or Osteopathic Examiners that the applicant has successfully passed the first two parts of the examination administered by those entities, as well as proof of the attainment of a score of 75 or better on Component II of the FLEX or passing scores on Step 3 of the USMLE; or

8. Has taken the full USMLE examination sequence in a manner consistent with New Jersey standards, as set forth in N.J.A.C. 13:35-3.1.

Amended by R.1985 d.224, effective May 6, 1985.

See: 17 N.J.R. 561(a), 17 N.J.R. 1131(c).

Added text: "in an examination . . . a five year period."

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).

13:35-3.3 Endorsement; podiatric physicians

The Board shall grant without examination a license to practice podiatry to any person who shall furnish proof of satisfaction of the requirements of law relating to applicants for admission by examination and who shall further furnish proof of certification by the National Board of Podiatric Medical Examiners certifying that the applicant has attained a passing score in said examination.

As amended, R.1983 d.510, effective November 7, 1983.

See: 15 N.J.R. 784(a), 15 N.J.R. 1865(e).

Added (c).

Amended by R.1985 d.224, effective May 6, 1985.

See: 17 N.J.R. 561(a), 17 N.J.R. 1131(c).

Added text to (a) 4. "prior to June 1985, . . . 75 or better."

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 and added reference to taking test "in English".

Amended by R.1994 d.522, effective October 17, 1994.

See: 26 N.J.R. 2526(a), 26 N.J.R. 4195(a).

13:35-3.4 (Reserved)

Amended by R.1985 d.224, effective May 6, 1985.

See: 17 N.J.R. 561(a), 17 N.J.R. 1131(c).

Added text "Component II".

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.
 Repealed by R.1994 d.522, effective October 17, 1994.
 See: 26 N.J.R. 2526(a), 26 N.J.R. 4195(a).

Section was "Examination in FLEX Component II after proof of passing the first two parts of the National Boards of Medical or Osteopathic Examiners".

13:35-3.5 Endorsement; certified nurse midwives

The Board shall grant a license to practice midwifery so long as authorized by law and registration to practice as a certified nurse midwife to such person who shall furnish proof of satisfaction of the requirements of law and N.J.A.C. 13:35-2.6 relating to applicants for admission by examination, and furthermore provide with the application certification by the American College of Nurse-Midwives, or other evidence to the Board's satisfaction, that the person has been licensed to practice midwifery and has been certified as a nurse-midwife in a sister state where such license was granted by examination with a grade average of 75 percent or over.

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.

13:35-3.6 Bioanalytical laboratory director license, plenary or specialty, granted to physicians

(a) The Board shall grant to any person licensed in this State to practice medicine and surgery a plenary license to direct and supervise a registered bioanalytical laboratory, without examination, provided that:

1. Such person is certified in clinical pathology by a specialty board approved by the A.M.A. or the A.O.A.; or
2. Such person, is certified in anatomical pathology or is Board-eligible, and can demonstrate to the satisfaction of the Board, following a personal appearance, appropriate training, including completion of a residency program in pathology in a laboratory or laboratories acceptable to the Board, and not less than three full years of post graduate general bioanalytical laboratory experience in a laboratory or laboratories acceptable to the Board.

(b) The Board shall grant to any person licensed in the State to practice medicine and surgery, a specialty license in one or more of the following fields: toxicological chemistry, microbiology, cytogenetics, biochemical genetics, clinical chemistry, and such other specialties as may be hereafter authorized by law, without examination, provided that such person is certified by a national accrediting board in one of the above specialties, which board requires a doctorate degree plus experience, such as the American Board of Pathology, the American Osteopathic Board of Pathology, the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis and the American Society of Cytogenetics, or any other national accrediting board recognized by the Board of Medical Examiners. The specialty license shall authorize the licensee to perform and supervise only those tests which are within the scope of the specific specialty license issued by the Board.

(c) Nothing herein shall be construed to waive registration and fees required by the Bioanalytical Laboratory Director Licensing Act, as amended.

(d) It shall be deemed to be professional misconduct for a bioanalytical laboratory director to accept a request for examination of material from the human body unless the request originates from a licensed plenary physician, dentist, podiatrist, chiropractor or any other health care professional authorized by Board rule, public health officer or agency or local board of health. The reports of the scientific data obtained shall be submitted in writing bearing the original, rubber stamp or electronic signature of a licensed laboratory director and shall be addressed to individuals who originate a request pursuant to this subsection.

Amended by R.1987 d.368, effective September 8, 1987.
 See: 19 N.J.R. 1179(a), 19 N.J.R. 1647(a).

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).

At (a)2, added requirement of completion of residency program in pathology in a laboratory.

Amended by R.1991 d.565, effective November 18, 1991.
 See: 23 N.J.R. 23(a), 23 N.J.R. 3520(b).
 Added (d).

13:35-3.7 Limited exemption from licensure; physicians

(a) "Exempt physician" means a person holding the academic degree of M.D. or D.O., currently employed or pending employment on a salary basis at a State or county institution on its medical staff or as a member of the teaching or scientific staff of a State agency, who has patient care responsibility and who does not conduct any type of private medical practice.

(b) "Exemption" means the exercise of discretion granted to the State Board of Medical Examiners of New Jersey pursuant to law to permit a physician unlicensed in the State of New Jersey to engage in the limited practice of medicine and surgery under the conditions set forth in said statute without being in violation of the Medical Practice Act, N.J.S.A. 45:9-1 et seq.

(c) Any physician employed or to be employed under an exemption from licensure must:

1. Satisfy all statutory and regulatory requirements preceding examination required by law;
2. Take and pass the earliest USMLE Step 3 examination given subsequent to the physician's start of employment;
3. Make application for licensure within 10 days after notification of successfully passing USMLE or cease employment.

(d) Following the physician's start of employment, the exemption will automatically terminate either on the date of the earliest USMLE Step 3 not taken or on the date the physician is notified of failure on the earliest USMLE Step 3 taken, whichever is later.

1. Proof of successful completion of the full term of a fellowship program accredited by the Accreditation Council on Graduate Medical Education or the American Osteopathic Association acceptable to the Board; or

2. Satisfactory completion of at least three years' clinical training gained through either a residency program or programs that satisfy three years of a nationally prescribed course of training in one discipline pursuant to Accreditation Council on Graduate Medical Education or American Osteopathic Association accreditation standards for a particular specialty.

(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).
Amended by R.2000 d.398, effective October 2, 2000.
See: 31 N.J.R. 2451(a), 32 N.J.R. 3574(a).
Rewrote (c).

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

Subchapter Historical Note

Petition for Rulemaking. See: 31 N.J.R. 2276(a), 32 N.J.R. 609(a), 32 N.J.R. 1260(a).

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 the 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 on the premises of the health care facility;

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 and Senior Services, a duly qualified registered nurse first assistant (RNFA) or a duly qualified physician assistant may so act. A duly qualified certified nurse midwife (CNM) may also act as a qualified first assistant in the performance of cesarean sections. For purposes of this subsection, a licensed CNM shall be deemed to be "duly qualified" provided that the CNM has taken and passed a 30-hour didactic training course that includes anatomy, physiology, surgical technique (including wound closure), and direct observation of cesarean sections. Following the completion of the course, a CNM shall serve and be supervised as a second assistant on 10 cesarean sections and complete a supervised preceptorship as a first assistant in 20 cesarean sections.

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

(e) Licensees shall comply with the rules as promulgated by the medical staff at the health care facility and shall cooperate to assure compliance with the rules of the Board as well as any rules of the Department of Health and Senior Services which licenses the facility.

(f) In all instances in which a registered nurse first assistant, a physician assistant, or duly qualified certified nurse midwife (CNM) 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).

Amended by R.1999 d.356, effective October 18, 1999.

See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

In (a)1, substituted "on the premises of the health care facility" for "in the operating suite" at the end; and rewrote (e).

Amended by R.2000 d.66, effective February 22, 2000.

See: 31 N.J.R. 252(a), 32 N.J.R. 710(a).

In (c), added the second through fourth sentences; and in (d) and (f), inserted references to duly qualified certified nurse midwives.

Cross References

Physician assistant, assisting surgery, see N.J.A.C. 13:35-2B.1 et seq.

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.

(e) Where the probable death has occurred outside a licensed hospital and the attending or recovering physician is known but cannot be reached after exercise of reasonable diligence, or no attending physician is known, then any physician, professional nurse or paramedic in accordance with N.J.A.C. 8:41-7.5 may proceed to the scene and make the determination and pronouncement of death. A written record shall be prepared as set forth in (d) above. Following pronouncement of death, the information shall be promptly communicated to the physician for preparation of the death certificate and a copy of the report provided as soon as practicable. If no attending physician is known or if an attending physician is not available to sign in a reasonable period of time, the death shall be immediately reported to the County Medical Examiner.

(f) In cases of death within the jurisdiction of the County Medical Examiner, the examiner shall without inordinate delay require the proper and established means for the determination and pronouncement of death, and shall arrange for the removal of the body and completion of the death certificate.

(g) A certificate of death shall be prepared and completed by a physician within a reasonable period of time, not to exceed 24 hours after the pronouncement of death. The factual data set forth in the certificate shall be based, to the greatest extent possible, upon the personal knowledge of the physician preparing the certificate. The physician shall provide an immediate cause of death as well as such contributing causes as the physician can best determine from the medical history obtained from other health care professionals, family or friends of the decedent, from observation of the condition of the body when pronounced and the circumstances known concerning the death. If the physician lacks sufficient information to provide an immediate cause of death, he or she may indicate an underlying potentially fatal medical condition which in the professional judgment of the physician may, or is likely to, have caused death.

(h) Nothing contained in this section shall be deemed to impose an obligation upon any person not licensed by the Board of Medical Examiners to pronounce death.

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.412, effective August 7, 1995.
See: 27 N.J.R. 1745(a), 27 N.J.R. 2960(a).

13:35-6.3 Sexual misconduct

(a) By this section, the Board of Medical Examiners is identifying for its licensees conduct which it shall deem to be violative of law. Specialized concerns with respect to those licensees who provide psychiatric or psychotherapeutic services are also identified.

(b) As used in this section, the following terms have the following meanings unless the context indicates otherwise:

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

2. "Patient" means any person who is the recipient of a professional service rendered by a licensee for purposes of diagnosis, treatment or a consultation relating to treatment. "Patient" for purposes of this section also means a person who is the subject of professional examination even if the purpose of that examination is unrelated to treatment.

3. "Patient-physician relationship" means an association between a physician and patient wherein the physician owes a continuing duty to the patient to be available to render professional services consistent with his or her training and experience. The performance of any professional medical service including, but not limited to, the issuance of a prescription or authorization of a refill of a prescription is deemed to be a professional service and evidence of a patient-physician relationship.

4. "Sexual contact" means the knowing touching of a person's body directly or through clothing, where the circumstances surrounding the touching would be construed by a reasonable person to be motivated by the licensee's own prurient interest or for sexual arousal or gratification. "Sexual contact" includes, but is not limited to, the imposition of a part of the licensee's body upon a part of the patient's body, sexual penetration, or the insertion or imposition of any object or any part of a licensee or patient's body into or near the genital, anal or other opening of the other person's body.

5. "Sexual harassment" means solicitation of any sexual act, physical advances, or verbal or non-verbal conduct that is sexual in nature, and which occurs in connection with a licensee's activities or role as a provider of medical services, and that either: is unwelcome, offensive to a reasonable person, or creates a hostile workplace environment, and the licensee knows, should know or is told this; or is sufficiently severe or intense to be abusive to a reasonable person in that context. "Sexual harassment" may consist of a single extreme or severe act or of multiple acts and may include, but is not limited to, conduct of a licensee with a patient, co-worker, employee, student or supervisee whether or not such individual is in a subordinate position to the licensee.

6. "Spouse" means either the husband or wife of the licensee or an individual in a long-term committed relationship with the licensee.

(c) A licensee shall not engage in sexual contact with a patient with whom he or she has a patient-physician relationship. The patient-physician relationship is considered ongoing for purposes of this section in all contexts other than the provision of psychiatric or psychotherapeutic services, unless: actively terminated, by way of written notice to the patient and documentation in the patient record; or

the last professional service was rendered more than one year ago.

1. In the context of the provision of psychiatric or psychotherapeutic services, the patient-physician relationship shall be considered ongoing for purposes of this section unless the last professional service was rendered more than two years ago; provided, however, the patient-physician relationship shall be considered ongoing for an indefinite period of time if the patient, by reason of emotional or cognitive disorder, is vulnerable to the exploitative influence of the licensee.

(d) A licensee shall not seek or solicit sexual contact with a patient with whom he or she has a patient-physician relationship and shall not seek or solicit sexual contact with any person in exchange for professional services.

(e) A licensee shall not engage in any discussion of an intimate sexual nature with a patient, unless that discussion is related to legitimate patient needs. Such discussion shall not include disclosure by the licensee of his or her own intimate sexual relationships.

(f) A licensee shall provide privacy and examination conditions which prevent the exposure of the unclothed body of the patient unless necessary to the professional services rendered.

(g) A licensee shall not promote, permit or condone sexual contact between group members in therapy groups.

(h) A licensee shall not engage in sexual harassment, whether in a professional setting (including, but not limited to, an office, hospital or health care facility) or elsewhere.

(i) A licensee shall not engage in any other activity (such as, but not limited to, voyeurism or exposure of the genitalia of the licensee) which would lead a reasonable person to believe that the activity serves the licensee's personal prurient interests or is for the sexual arousal, the sexual gratification or the sexual abuse of the licensee or patient.

(j) Violation of any of the prohibitions or directives set forth at (c) through (i) above shall be deemed to constitute gross or repeated malpractice pursuant to N.J.S.A. 45:1-21(c) or (d) or professional misconduct pursuant to N.J.S.A. 45:1-21(e).

(k) Nothing in this section shall be construed to prevent a licensee from rendering medical examination or treatment to a spouse, providing that the rendering of such service is consistent with accepted standards of medical care and that the performance of medical services is not utilized to exploit the patient for the sexual arousal or sexual gratification of the licensee.

(l) It shall not be a defense to any action under this section that:

1. The patient solicited or consented to sexual contact with the licensee; or
2. The licensee was in love with or had affection for the patient.

APPENDIX

POLICY STATEMENT REGARDING SEXUAL ACTIVITY BETWEEN PHYSICIANS AND PATIENTS AND IN THE PRACTICE OF MEDICINE

It is beyond dispute that sexual contact with patients is in conflict with the very essence of the practice of medicine. Despite that fact, the Board of Medical Examiners continues to receive complaints of sexual activity involving physicians and other licensees with patients. While the Board is promulgating a regulation to specifically notify licensees of conduct which it deems to be violative of law and will subject them to disciplinary action, this statement is meant as an advisory to licensees to guide professional behavior and further expand upon the Board's reasoning in promulgating such a regulation.

A. Background. It is well established that sexual activity between physicians and patients is almost always harmful to the patient and is prohibited. Whether harkening back to the proscription of the Hippocratic oath,¹ or referring to more recent pronouncements such as the Code of Medical Ethics of the Council of Ethical and Judicial Affairs of the American Medical Association which term sexual activities between physicians and patients harmful,² commentators have uniformly condemned such activities by physicians.

(i) **Rationale for the Policy.** A patient must have absolute confidence and trust in his or her physician. Insertion of sexual activity into the professional relationship destroys such trust because the personal interest of the physician is in conflict with the interest of the patient.

(ii) **Inequality of Power Between Physician and Patient.** Physicians are in a unique position as to the physical and emotional vulnerability of patients. Physicians are expected to examine patients undressed who expose not only their bodies but the most intimate details of their personal lives.

(iii) **Physician in Position of Authority.** Patients seek assistance and guidance from physicians. The doctor/patient relationship is not one of equality, the patient being vulnerable to abuses of power.

(iv) **Negative Psychological Consequences for Patient.** Commentators and researchers have concluded that sexual activity between physicians and patients is almost always damaging to the patient.

(v) **Public Trust in the Profession.** In order to maintain the community perception of the integrity of the medical profession, personal boundaries must be maintained.

(vi) **Sexual or Romantic Relationships with Former Patients.** Sexual activity with a former patient may also be inappropriate if the patient has been unduly influenced by the prior professional relationship or if the physician utilizes trust, knowledge, or emotions derived from the previous professional relationship. The clearest example of this phenomenon is known as “transference” between a patient and psychotherapist, which may last for many years following the conclusion of therapy.

B. Recommendations and Guidelines for Conduct.

(i) **Licensee Responsibility**—The physician or other licensee is always responsible to ensure that the boundaries of the professional relationship are maintained. Licensees should therefore avoid verbal or physical behavior which might be interpreted as inviting a romantic or sexual relationship. Even if the patient encourages such behavior, it is the licensee’s responsibility to maintain a professional manner.

(ii) **Maintaining Boundaries in Psychotherapeutic Relationships**—A licensee bears an even greater responsibility to establish and maintain boundaries between physician and patient in psychotherapeutic relationships. In furtherance of that obligation, a licensee should ensure that to the greatest extent possible, treatment should take place during the licensee’s usual working hours in a professional setting, unless the specific therapy mandates otherwise (i.e. home visits for the housebound, in vivo desensitization as part of behavioral therapy). A licensee should not engage in economic dealings with psychotherapy patients.

(iii) **Explanation of Procedures, Tests and Need for Examinations**—This will ensure that patients do not misunderstand the appropriateness of the exposure of their bodies or the touching that occurs.

(iv) **Patient Privacy**—Examination conditions should ensure that patients are not embarrassed. To that end, licensees should provide privacy while a patient is removing or replacing undergarments and should provide examination gowns or draping cloths which limit exposure of the patient to the field of clinical interest.

(v) **Chaperon**— Pursuant to N.J.A.C. 13:35-6.23, a licensee shall provide notice to a patient, or any other person who is to be examined, of the right to have a chaperon present during breast and pelvic examinations of females and during genitalia and rectal examinations of both males and females. In all other instances, consistent with promoting patient privacy, licensees should inform patients of the option of having a chaperon present during examination and should provide a chaperon when requested by a patient.

(vi) **Avoidance of Discussion of Personal Matters**—While it is appropriate for a licensee to discuss for example his or her training and qualifications with patients, in furtherance of the maintenance of appropriate

boundaries, licensees should avoid any discussion of their own intimate personal problems or disclosure of details of their sexual lives.

¹ “. . . I will come for the benefit of the sick, remaining free . . . of all mischief and in particular of sexual relations with both female and male persons . . .”.

² “sexual or romantic interactions between physicians and patients detract from the goals of the physician patient relationship, may exploit the vulnerability of the patient, may obscure the physician’s objective judgment concerning the patient’s health care, and ultimately may be detrimental to the patient’s well being . . . at a minimum, a physician’s ethical duties include terminating the physician patient relationship before initiating a dating, romantic or sexual relationship with a patient . . . sexual or romantic relationships with former patients are unethical if the physician uses or exploits trust, knowledge, emotions or influence derived from the previous professional relationship.”

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.1990 d.291, effective June 4, 1990.

See: 22 N.J.R. 905(a), 22 N.J.R. 1738(a).

Included podiatric physicians as those who can countersign orders and prescriptions written by a podiatric trainee.

Repealed by R.1994 d.522, effective October 17, 1994.

See: 26 N.J.R. 2526(a), 26 N.J.R. 4195(a).

Section was “Countersigning of order and prescriptions of unlicensed physicians.”

New Rule, R.1996 d.242, effective May 20, 1996.

See: 28 N.J.R. 65(a), 28 N.J.R. 2560(a).

Amended by R.2004 d.135, effective April 5, 2004.

See: 35 N.J.R. 3262(a), 36 N.J.R. 1814(a).

In the appendix, rewrote B(v).

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.

Sexually abusing patients while conducting gynecological examinations warranted revocation of license and imposition of fine. In Matter of Suspension or Revocation of License of Chunmuang, 93 N.J.A.R.2d (BDS) 27.

No proof of alleged sexual molestation by doctor. In Matter of Suspension and Revocation of License of Prada, 93 N.J.A.R.2d (BDS) 1.

Podiatrist’s improper touching of female patients and relative of one patient constituted professional misconduct; license revoked and civil penalties imposed. In Matter of Suspension or Revocation of License of Schulman, 92 N.J.A.R.2d (BDS) 16.

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), the National Center for Competency Testing (NCCT), 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).

Amended by R.1999 d.356, effective October 18, 1999.

See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

In (a)2, inserted a reference to the National Center for Competency Testing.

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.

Petition for Rulemaking.

See: 36 N.J.R. 4333(a).

Case Notes

Any error in trial court's failure to charge jury concerning duty specialist physician had to communicate his findings of stress test he performed on patient to patient's primary care physician, was harmless in medical malpractice action brought by executrix of patient's estate against specialist after patient died within two weeks after having undergone stress test; no dispute existed that specialist advised patient of his preliminary findings, told him that they were essentially normal, and sent a written report to primary physician, but alleged negligence at issue went to specialist's evaluation of patient's condition. *Sinclair v. Roth*. N.J.Super.A.D., 2002.

Physician's disclosure of patient's medical records to patient's husband's attorney in response to subpoena that did not include patient's authorization to disclose, or a notice of physician's deposition, and which patient and her attorney were not copied on, supported a cause of action against physician, in lawsuit against physician alleging breach of confidentiality, violation of physician-patient privilege, medical malpractice, intentional infliction of emotional distress, and negligent infliction of emotional distress. *Crescenzo v. Crane*, 350 N.J.Super. 531.

To the extent that a contract purports to insulate the examining physician from liability for breaching the duty to communicate abnormalities found in a pre-employment exam, it violates public policy of

New Jersey in addition to common law notions. *Reed v. Bojarski*, 166 N.J. 89 (2001).

Board of Medical Examiners neither abused its statutory authority nor mistakenly exercised its discretion when it refused to expunge or otherwise modify consent order disciplining a doctor for failing to keep adequate patient medical records; consent order was legally entered into with doctor's consent, and the Board had authority to file order and fine doctor accordingly. In *re D'Aconti*, 316 N.J.Super. 1, 719 A.2d 652 (N.J.Super.A.D. 1998).

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 Standards for joint protocols between advanced practice nurses and collaborating physicians

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

"Collaboration" means the ongoing process by which an advanced practice nurse and a physician engage in practice, consistent with agreed upon parameters of their respective practices.

"Device" means an article, other than medication, for use in the diagnosis, cure, mitigation, treatment or prevention of disease, injury, pain or deformity or physical or emotional condition or health problem in humans or intended to affect the structure or function of the human body.

"Joint protocol" means an agreement or contract between an advanced practice nurse and a collaborating physician which conforms to the standards established by the Director of the Division of Consumer Affairs pursuant to this rule.

"Medication" means any substance for which a prescription is required which is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease, injury, pain or deformity or physical or emotional condition or health problem in humans or intended to affect the structure or function of the human body.

(b) Advance practice nurses who seek to prescribe or order medications or devices and the collaborating physician(s) with whom they are in collaboration shall develop a joint protocol, which shall be:

1. In writing;
2. Signed by both the advanced practice nurse and the physician, with an acknowledgment that any inappropriate professional behavior or violation of the protocol on the part of either the physician or the advanced practice nurse will be reported to his or her respective licensing board;
3. Maintained on the premises of every office in which the advanced practice nurse practices;
4. Updated on an ongoing basis to reflect changes in the practice, office personnel, skills of the advanced practice nurse, frequency of record review, and reference materials containing practice guidelines or accepted standards of practice; and
5. Reviewed at least on an annual basis.

(c) The content of a joint protocol under (b) above shall address:

1. The nature of the practice, the patient population (for example, pediatric patients) and settings (for example, inpatient, nursing home, patient residences or other alternative care environments);
2. Any particular circumstances for which, prior to prescribing, a specific examination is to be performed or a definitive diagnosis made;
3. The recordkeeping methodology to be used in the practice (for example, the protocol might indicate that records should contain subjective complaints, objective findings, an assessment and a plan of treatment);
4. A list of categories of medications appropriate to the practice;
5. A delineation of specific medications and the specific number of refills, to be prescribed pursuant to the direction of the physician;

6. Specific requirements with respect to the recordation, in the patient record and/or in separate logs, of medications prescribed or dispensed, dosages, frequency, duration, instructions for use and authorizations for re-fills;

7. Any medical conditions or findings within the nature of the practice which should require direct consultation prior to the prescribing or ordering of medications or devices;

8. The frequency and methodology to be employed to ensure periodic review of patient records;

9. Identification of the means by which the advanced practice nurse and collaborating physician can be in direct communication, as well as a description of arrangements which will assure that the collaborating physician or peer coverage is accessible and available;

10. Procedures for the use of medications in emergency situations; and

11. Identification of reference materials containing practice guidelines or accepted standards of practice.

(d) Failure to establish and implement joint protocols consistent with the standards set forth in this section and any violation of the joint protocol by an advanced practice nurse or physician may be deemed professional misconduct or other grounds for disciplinary sanction within the meaning of N.J.S.A. 45:1-21 by his or her respective licensing board.

New Rule, R.2000 d.274, effective July 3, 2000 (operative September 1, 2000).

See: 31 N.J.R. 1459(a), 32 N.J.R. 2448(a).

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 charge 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.

iii. Copies of all laboratory and follow-up examinations; and

iv. Periodical clinical measurements of tumor activity.

4. Date or procurement of amygdalin (laetrile), quantity, cost, name and address of manufacturer and supplier, batch number and expiration date when administered or dispensed by a physician.

5. Records are to be readily available without prior notice for inspection by the appropriate official agency, including, but not limited to the New Jersey Board of Medical Examiners and the New Jersey State Department of Health.

6. Copies of records shall be forwarded to State Department of Health at quarterly intervals.

(e) Solicitation is prohibited. Such prohibited activity shall include, but is not limited to, the dissemination of information concerning amygdalin (laetrile) which may be found by the Board of Medical Examiners as:

1. False, fraudulent, deceptive, misleading or flamboyant;
2. Using testimonials;
3. Guaranteeing that satisfaction or cure will result from the use of amygdalin (laetrile);
4. Making claims of professional superiority;
5. Stating fees for professional services which are false, deceptive and/or misleading.

(f) A licensed physician may, in the regular course of medical practice and pursuant to a justifiable medical basis, prescribe, administer, or dispense amygdalin (laetrile) in accordance with the Act concerning Laetrile (Chapter 318, P.L. 1977) and these rules and regulations.

As amended, R.1984 d.67, effective March 19, 1984.
See: 15 N.J.R. 2029(b), 16 N.J.R. 552(a).
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.

13:35-6.9 Referral for radiological services

(a) "Physician" shall mean a physician possessing a plenary license to practice medicine and surgery and practitioners legally licensed to practice chiropractic or podiatry.

(b) A physician possessing a plenary license to practice medicine and surgery who provides diagnostic radiological services for other physicians possessing a plenary license to practice medicine and surgery shall, upon the request of a chiropractic or podiatric physician, provide diagnostic radiological services to such chiropractic or podiatric physician without discrimination on the basis of classification of license, provided the diagnostic radiological services requested pertain to skeletal areas of the body.

(c) Denial of professional diagnostic radiological services, as set forth herein, shall constitute purposeful and intentional discrimination and shall subject the licensee to appropriate disciplinary action by the Board of Medical Examiners.

Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
Added reference to podiatric services.

Case Notes

Rule valid as within statutory power and duties of Board to regulate practice of medicine, surgery and chiropractic and to secure patients the expert diagnostic radiological services referred to therein (cited as N.J.A.C. 13:35-6.18). *Brodie v. New Jersey Bd. of Medical Examiners*, 177 N.J.Super. 523, 427 A.2d 104 (App.Div.1981) certification denied 87 N.J. 386, 434 A.2d 1068 (1981).

13:35-6.10 Advertising and solicitation practices

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

1. The term "advertisement" shall mean any attempt directly or indirectly by publication, dissemination, or circulation in print or electronic media which directly or indirectly induces or attempts to induce any person or entity to purchase or enter into an agreement to purchase services, treatment, or goods related thereto from a Board licensee.

2. "Board licensee" shall mean any individual holding a license issued by the State Board of Medical Examiners.

3. The term "routine professional service" shall refer to a service which a board licensee or professional association routinely performs.

4. The term "print media" shall include newspapers, magazines, periodicals, professional journals, telephone directories, circulars, handbills, flyers, billboards, signs, matchcovers and other similar items, documents or comparable publications, the content of which is disseminated by means of the printed word.

5. The term "electronic media" shall include radio, television, and Internet.

6. The term "range of fees" shall refer to any expressly stated upper and lower limit on the fees charged for services or goods offered by a Board licensee.

7. The term "graphic representation" shall mean the use of drawings, animations, clinical photographs, dramatizations, music or lyrics.

(b) A Board licensee may provide information to the public by advertising in print or electronic media.

(c) A Board licensee who engages in the use of advertising which contains any of the following shall be deemed to be engaged in professional misconduct:

1. Any statement, claim or format including, but not limited to, a graphic representation, which is false, fraudulent, misleading or deceptive;

2. Any misrepresentation of a material fact;

3. The suppression, omission or concealment of any material fact under circumstances which a Board licensee knows or should know that the omission is improper or prohibits a prospective patient from making a full and informed judgment on the basis of the information set forth in the advertisement;

4. Any claim that the service performed or the materials used are superior to that which is ordinarily performed or used in the profession;

5. Any promotion of a professional service which the Board licensee knows or should know is beyond the licensee's ability to perform;

6. A technique or communication which appears to intimidate, exert undue pressure or to unduly influence a prospective patient or consumer;

7. Any personal testimonial attesting to the quality or competence of a service or treatment by a licensee involving medical or technical assessments which are beyond the patient's competency to assess, or any testimonial not in compliance with (n) below;

8. The communication of any fact, data or information which may personally identify a patient without that patient's signed written permission obtained in advance;

9. An offer to pay, give or accept a fee or other consideration to or from a third party for the referral of a patient;

10. Any print, language or format which directly or indirectly obscures a material fact;

11. Any guarantee of results from any procedure is prohibited;

12. Any violations of (d) through (n) below.

(d) The licensing board may require a licensee to substantiate the truthfulness of any assertion or representation set forth in an advertisement. Failure of a Board licensee to provide factual substantiation to support a representation or assertion shall be deemed professional misconduct.

(e) A Board licensee shall not engage either directly or through the use of any agent, employee or representative in in-person solicitation with a prospective patient or consumer. This subsection shall not prohibit a licensee from offering services through materials provided to a community service organization which makes known the availability of all professional services desiring to be listed; nor shall it prohibit the offering of services by a Board licensee to any bona fide representative of prospective patients including, but not limited to, employers, labor union representatives, or insurance carriers.

(f) Advertising making reference to or setting forth a fee shall be limited to that which contains a fixed or a stated range of fees for specifically described routine professional services or goods offered by licensees.

1. A Board licensee who advertises fees shall disclose all relevant and material variables and considerations which are ordinarily included in such a service so that the fee will be clearly understood by prospective patients or consumers.

2. In the absence of such disclosure referred to in (f)1 above, the stated fees shall be presumed to include everything ordinarily required for such a service. No additional charges shall be made for an advertised service unless the advertisement includes a specific delineation of additional services contemplated in the fee to be charged therefor.

(g) The requirements for advertising free or discounted services are as follows:

1. An advertisement offering a fee reduction shall state the reduced fee or range of fees and the physician's usual fee or range of fees for each service for which a reduction is advertised. The reference fee required in this subsection shall have been the usual fee charged for the advertised service for a period of not less than 90 days prior to the advertised reduction.

2. All offers of free services or discounts shall include a statement of the specific charges for all associated or reasonably anticipated services which are not included in the offer of free or discounted services. If the discount or free service does not apply to all services to be rendered, the advertisement shall specify any associated

or reasonably anticipated services which are not included (for example, free eye screening for senior citizens does not include charges for refraction, eyeglasses and contact lens fitting).

3. The licensee shall maintain a list of the patient names and dates of service for all patients for whom he or she has provided free or discounted services. The list may be maintained as part of the physician's appointment book as long as the patient receiving free or discounted services is identifiable. The list shall be maintained for seven years from the date of last entry except in the case of massive screening programs performed off-site (out of the office) as a community service, and which are sponsored by a governmental or non-profit organization.

4. Any person offering free or discounted medical services shall file copies of any such advertisement with the Board within 30 days of initial publication. The Board's acceptance for filing of such an advertisement shall not be deemed approval of the advertisement's content.

5. Any offer of free or discounted diagnostic services shall include the providing of results to the patient or a designated licensee or duly authorized representative within 30 days of a written request by the patient or duly authorized representative.

6. A patient record shall be maintained for all discounted or free services for seven years from the date of last entry except in the case of massive screening programs done off-site (out of the office) as a community service, and which are sponsored by a governmental or non-profit organization.

7. The patient record maintained shall be made available upon patient request to the same extent as under the Board's patient record rule (N.J.A.C. 13:35-6.5), and the patient shall be advised at the time the service is rendered that the record will be available to him or her.

8. Except for those services specifically excluded in the advertisement offering free services, the physician shall not charge for any service whatsoever rendered during a period of 72 hours from the time the free service was rendered.

(h) The name and nature of professional practice of every licensee practicing independently or as an employee of another licensee or of a professional service corporation shall appear on professional stationery and shall be conspicuously displayed and kept at the entrance of the place where the licensed practice is conducted. The name of every licensee employed by an ambulatory health care facility licensed by the New Jersey Department of Health shall be posted at the entrance to the treatment area and the licensee providing professional services shall be identified on the bill and insurance claim form.

(i) The responsibility for the form and content of any advertisement offering services or goods by a Board licensee shall be jointly and severally that of each Board licensee who is a principal, partner or officer of the firm or entity identified in the advertisement.

(j) The time period during which an advertised fee will remain in effect shall be set forth on the face of the advertisement. In the absence of such disclosure, the effective period shall be deemed to be 30 days from the date of the advertisement's final publication.

(k) A video or audio tape of every advertisement communicated by electronic media shall be retained by the Board licensee and shall be made available for review upon request by the Board or its designee. A copy of any advertisement appearing in the print media shall also be retained by the licensee and made available for review. The tapes and print media copies required to be retained by this subsection, shall be kept for a period of three years from the date of the last authorized publication or dissemination of the advertisement.

(l) All Board licensee advertisements and public representations intended to be displayed or circulated away from the office premises, including telephone directory advertisements, may, if desired, list the professional service corporation or trade name under which the practice is conducted but shall disclose the nature of the practice, and the name and address or telephone number of at least one of the principal practitioners. This requirement does not apply to licensees employed by an ambulatory health care facility licensed by the New Jersey State Department of Health.

(m) Any licensee advertising Board certification in a specialty shall possess certification by a certifying agency. A list of certifying agencies recognized by the American Board of Medical Specialties, the American Osteopathic Association, and/or the American Podiatric Medicine Association shall be maintained by the Board.

(n) The requirements for testimonial advertisements are as follows:

1. All testimonials involving a specific or identifiable procedure shall truthfully reflect the actual experience of the patient and shall include the following conspicuously displayed statements:

i. "This procedure may not be suitable for every patient. All patients must be evaluated by a physician as to the appropriateness of performing the procedure".

ii. "The above testimonial represents the individual's response and reaction to the procedure; however, no medical procedure is risk-free. Associated potential risks and complications should be discussed with the physician rendering this procedure".

2. Where an advertiser directly or indirectly provides compensation to a testimonial giver, the fact of such compensation shall be conspicuously disclosed in a legible and readable manner in any advertisement in the following language: "COMPENSATION HAS BEEN PROVIDED FOR THIS TESTIMONIAL."

3. A physician who advertises through the use of testimonials shall maintain documentation relating to such testimonials for a period of three years from the date of the last use of the testimonial. Such documentation shall include, but not be limited to, the name, address and telephone number of the individual in the advertisement, the type and amount or value of compensation and a signed, notarized statement and release verifying the truthfulness of the information contained in the testimonial and indicating that person's willingness to have his or her testimonial used in the advertisement obtained prior to the time the testimonial is advertised.

4. Any guarantee of results from any procedure is prohibited.

(o) Nothing contained in this section shall be construed to prohibit the licensing board from adopting additional rules concerning advertising by Board licensees. To the extent that any conflict or inconsistency may arise between the provisions of this section and any subsequently adopted rule dealing more specifically with the same subject matter as set forth, such subsequent adopted rule shall control.

R.1984 d.139, effective April 16, 1984.

See: 16 N.J.R. 32(a), 16 N.J.R. 921(a).

A rule entitled "Advertising and Solicitation" formerly at this cite was repealed and replaced.

Amended, R.1984 d.372, effective August 20, 1984.

See: 16 N.J.R. 1026(b), 16 N.J.R. 2286(a).

Subsection (m) new.

Amended by R.1986 d.467, effective December 1, 1986.

See: 18 N.J.R. 1788(d), 18 N.J.R. 2390(a).

Text added to (h) and (l).

Amended by R.1989 d.325, effective June 19, 1989.

See: 21 N.J.R. 696(a), 21 N.J.R. 1710(b).

In (a): deleted "Definitions" and added new 7 regarding graphic representation. Revised language throughout to modify an existing prohibition on use of testimonials, discounts and offering of free services.

Added new (c)11 and 12, deleting old (c)11.

Added new (g)1-8 and new (m) and (n), recodifying old "n" as new "o".

Amended by R.1994 d.329, effective July 5, 1994.

See: 26 N.J.R. 1219(b), 26 N.J.R. 2795(c).

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.1999 d.356, effective October 18, 1999.

See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

In (a)5, added a reference to the Internet.

Case Notes

Abstention; action by podiatrist association challenging constitutionality of regulation restricting medical professionals' advertising of board certification. *American Institute of Foot Medicine v. New Jersey State Bd. of Medical Examiners*, D.N.J.1992, 807 F.Supp. 1170.

Former N.J.A.C. 13:35-4.1 and 13:35-6.13 requiring degree designations on licenses and regulating advertising, respectively, held invalid as

outside Board's authority under the Medical Practices Act. *Eatough v. Bd. of Medical Examiners*, 191 N.J.Super. 166, 465 A.2d 934 (App.Div. 1983).

13:35-6.11 Excessive fees

(a) The Board of Medical Examiners shall review information and complaints concerning allegations of excessive fees charged by licensees of the Board and may establish Excessive Fee Review Committees to perform various aspects of the review function. This regulation is not intended to impinge upon the strong public policy in favor of a competitive, free enterprise economy embodied in the anti-trust laws of the United States and of this State. Excessive Fee Review Committees shall consider comparable fees charged by licensees not under inquiry only to the minimum extent necessary to render a determination as to whether a fee is excessive.

(b) A licensee of the Board of Medical Examiners shall not charge an excessive fee for services. A fee is excessive when, after a review of the facts, a licensee of ordinary prudence would be left with a definite and firm conviction that the fee is so high as to be manifestly unconscionable or overreaching under the circumstances.

(c) Factors which may be considered in determining whether a fee is excessive include, but are not limited to, the following:

1. The time and effort required;
2. The novelty and difficulty of the procedure or treatment;
3. The skill required to perform the procedure or treatment properly;
4. Any requirements or conditions imposed by the patient or by the circumstances;
5. The nature and length of the professional relationship with the patient;
6. The experience, reputation and ability of the licensee performing the services;
7. The nature and circumstances under which services are provided. Unless services are provided during an emergency or other circumstances where opportunity, custom and practice will preclude discussion prior to the rendition of such services, the licensee shall, in advance of providing services, specify or discuss and agree with the patient, the fee or basis for determination of the fee to be charged.

(d) Charging an excessive fee in violation of (b) above shall constitute professional misconduct subjecting the licensee to disciplinary action by the Board of Medical Examiners.

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

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

(c)4 deleted, 5-8 recodified to 4-7.

Deleted (a)2 [Chiropractic (license)]; redesignated existing (a)3 through 11 as (a)2 through 10.

Changed fees in (a)1 through 8.

Amended by R.1993 d.91, effective February 16, 1993.

See: 24 N.J.R. 4011(a), 25 N.J.R. 708(a).

Revised (a)1 through 4.

Amended by R.1993 d.92, effective February 16, 1993.

See: 24 N.J.R. 4334(a), 25 N.J.R. 709(a).

Added new (a)10; redesignated old (a)10 to (a)11.

Amended by R.1993 d.260, effective June 7, 1993.

See: 25 N.J.R. 1058(a), 25 N.J.R. 2487(a).

Amended by R.1993 d.299, effective June 21, 1993.

See: 24 N.J.R. 4013(a), 25 N.J.R. 2689(c).

Amended by R.1994 d.170, effective April 4, 1994.

See: 25 N.J.R. 4583(a), 26 N.J.R. 1520(a).

Administrative Correction.

See: 26 N.J.R. 2589(b).

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.330, effective June 19, 1995.

See: 27 N.J.R. 640(a) (see also, 27 N.J.R. 1746(a)), 27 N.J.R. 2410(a).

Increased some of the fees.

Amended by R.1995 d.423, effective August 7, 1995.

See: 27 N.J.R. 1526(a), 27 N.J.R. 2959(a).

Added Physician Assistant temporary license fee at (a)8.ii.

Administrative correction.

See: 33 N.J.R. 1411(a).

Case Notes

Degree designation on license. *Eatough v. Albano*, 673 F.2d 671 (1982) certiorari denied 102 S.Ct. 2931, 457 U.S. 1119, 73 L.Ed.2d 1331, see: dissenting opinion.

Preliminary injunction against rule. *Davis v. Board of Medical Examiners*, 497 F. Supp. 525 (1980).

13:35-6.14 Delegation of physical modalities to a licensed health care provider or an unlicensed physician aide

(a) "Physician," for the purpose of this section, shall mean a doctor of medicine (M.D.), a doctor of osteopathic medicine (D.O.) or a doctor of podiatric medicine (D.P.M.).

1. "Licensed health care provider," for the purpose of this section, shall mean an individual holding a current, valid license in this State as a physical therapist, registered nurse, licensed practical nurse, physician assistant, chiropractor or athletic trainer.

(b) A physician may direct his or her unlicensed employee to administer to the doctor's patients certain physical modalities 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 a licensed health care provider with training and experience to administer to the physician's patients physical modalities including ultraviolet (B and C bands) and electromagnetic rays including, but not limited to, deep heating agents, microwave diathermy, shotwave diathermy, ultrasound, and those modalities listed in (d) below. The physician shall retain responsibility for examining the patient, determining the appropriate modalities,

assessing training and experience, as well as providing the appropriate level of supervision consistent with practice standards, applicable to the specific licensed health care provider.

(d) A physician may direct an unlicensed aide to administer the following physical modalities: hot packs, cold packs, paraffin baths, contrast baths, and whirlpool baths. The aide shall not be permitted to perform any rehabilitative exercise programs. No other modalities including T.E.N.S. or traction shall be performed by the unlicensed physician's aide.

(e) A physician may direct the administration of an appropriate physical modality by an unlicensed assistant only where the following conditions are satisfied:

1. The doctor shall examine the patient to ascertain the nature of the trauma or disease; to determine whether the application of a physical modality will encourage the alleviation of pain and promotion of healing; to assess the risks of the modality for a given patient and the diagnosed injury or disease and to decide that the anticipated benefits are likely to outweigh those risks.

2. The doctor shall determine all the components of the precise treatment to be given at the present therapy session, including the type of modality to be used, extent of area to which it shall be applied, the length of treatment, and any other factors peculiar to the risks of that modality such as strict avoidance of certain parts of the body. This information shall be written on the patient's chart and made available at all times to the assistant carrying out the instructions. The doctor shall assure that the aide administering the treatment is identified in the patient chart on each such occasion.

3. The doctor shall ascertain a satisfactory level of education, competence and comprehension of the particular assistant, who shall be at least 18 years of age, to whom instruction has been given by the doctor as to modalities used in that office. The doctor shall prepare and maintain a written document certifying as to the instructions given to each assistant, and both doctor and assistant shall sign it.

4. The doctor shall see the patient prior to any subsequent scheduled application of the modality to ascertain that continued treatment is appropriate and that no contraindications to treatment have become apparent.

5. The doctor shall remain on the premises at all times that treatment orders are being carried out by the assistant and shall be within reasonable proximity to the treatment room and available in the event of emergency.

(f) A physician shall have due regard for the specialized training and experience of registered physical therapists, and of physiatrists and orthopedists. Injuries or diseases requiring prolonged treatment, if not administered personally by the doctor, shall normally be referred to a licensed physical

therapist, to a physiatrist, orthopedist or other appropriate health care provider.

(g) A bill rendered for the limited consultation set forth in (d)4 above shall not exceed a sum which reasonably reflects the actual level of service, supervision and responsibility personally rendered by the doctor, and consistent with the factors listed in the rule prohibiting excessive fees, N.J.A.C. 13:35-6.11(b) and (c).

(h) On a health insurance claim form pertaining to such service and requiring certification by the doctor, the doctor shall specify the modality applied and shall not generically identify physical therapy.

New Rule, R.1985 d.159, effective April 1, 1985.

See: 16 N.J.R. 2065(a), 17 N.J.R. 836(a).

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

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

Requirements added that aides be identified on the patient Chart and that the aides be at least 18 years of age.

Amended by R.1994 d.522, effective October 17, 1994.

See: 26 N.J.R. 2526(a), 26 N.J.R. 4195(a).

Case Notes

Rule was not ultra vires as to the Board of Medical Examiners on theory that authority rested solely with the Board of Physical Therapists. Matter of Promulgation of N.J.A.C. 13:35-6.14, 205 N.J.Super. 492, 501 A.2d 547 (App.Div.1985).

13:35-6.15 Continuing medical education

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

“Category I” and “Category II” mean the categories of medical education courses recognized by the American Medical Association as credited toward the Physician Recognition Award, and those categories of medical education courses recognized by the American Osteopathic Association or the American Podiatric Medical Association.

“Licensee” means a physician or podiatrist licensed and subject to regulation by the Board of Medical Examiners (the “Board”).

(b) Except as provided in (b)1 and 2 and (c) below, a licensee applying for a biennial license renewal shall complete, in each biennial renewal period commencing with the biennial renewal period beginning on July 1, 2003, 100 continuing medical education credits in Category I or Category II courses, of which at least 40 of such credits shall be in Category I.

1. A licensee shall be required to complete 50 continuing medical education credits for the biennial renewal period beginning on July 1, 2003, if this section becomes effective on or before July 1, 2004, of which at least 20 credits shall be in Category I courses.

i. A licensee who completes credits in excess of the 50 continuing medical education credits required pursuant to (b)1 above may apply no more than 25 of the excess credits to the continuing medical education requirements for the following biennial period only.

2. A licensee shall be exempt from the continuing medical education requirements for the biennial renewal period beginning on July 1, 2003, if this section becomes effective after July 1, 2004.

(c) An applicant for initial licensure who has completed an accredited graduate medical education program within 12 months prior to licensure shall be exempt from the continuing medical education requirements of this section for the initial biennial period of licensure. Notwithstanding such exemption from the continuing medical education requirements, the applicant, once licensed by the Board, shall complete, within 24 months of becoming licensed, an orientation course which is presented or approved by the Board.

(d) A licensee shall certify on the application for biennial licensure renewal that he or she has completed the required number of continuing medical education credits. The Board may conduct random audits to determine licensee compliance with the continuing medical education requirements of this section.

(e) A licensee who completes credits in excess of the 100 continuing medical education credits required pursuant to this section may apply no more than 25 of the excess credits to the continuing medical education requirements for the following biennial period only.

(f) Licensees holding an inactive or retired license shall be exempt from continuing medical education requirements, except that any licensee holding an inactive or retired license, or whose license is suspended or revoked, who applies to resume practice shall provide proof of having attained 50 credits of continuing medical education for each year out of practice in New Jersey. At least 50 credits shall have been obtained in the year preceding the application to resume practice. At the time of application to resume practice, the licensee shall provide proof of the completed continuing medical education during the period while out of practice in New Jersey. The Board may accept such continuing medical education credits or require additional credits as a condition to return to practice.

(g) The Board may delineate specific topics of medical education which the Board deems necessary to address a particular issue or problem. Notification of the specific topic(s) shall be through the Board newsletter, the Division of Consumer Affairs website or by direct communication to licensees.

(h) To report continuing medical education credits, a licensee shall:

(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).

Law Review and Journal Commentaries

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

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

13:35-6.18 Medical malpractice coverage; letter of credit

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

"Covered" means ongoing maintenance of insurance in the sum of \$1 million per occurrence and \$3 million per policy year, with extended reporting endorsement coverage for claims made ("tail coverage") issued by a carrier authorized to write medical malpractice policies.

"Letter of credit" means a non-assignable, non-transferable, unexpired, continuous irrevocable obligation issued by a bank or saving association authorized to do business in this State, payable to the physician or podiatrist as the beneficiary within 30 days after a demand for payment and the presentation of a final judgment or settlement in a medical malpractice action.

"Maintaining a professional practice with responsibility for patient care" means the furnishing of professional services to patients in New Jersey, including, but not limited to, the testing for, or diagnosis of, or the offering or furnishing of treatment, preventative medical care or consultation relating to human disease or dysfunction or physical condition, including the prescribing, administering or dispensing of products, devices or drugs at a place, such as an office (even if located in a home), hospital or clinic, or through a business entity, such as a laboratory or mobile van service.

"Not available" means that a physician or podiatrist is unable to purchase medical malpractice insurance coverage from a carrier authorized to write medical malpractice insurance, including through programs relating to high risk retention groups. "Not available" for purposes of this section does not mean "not affordable."

(b) All physicians and podiatrists licensed to practice in this State who maintain a professional practice and have responsibility for patient care shall be covered by medical malpractice insurance or, if medical malpractice insurance is not available, shall secure and maintain a letter of credit at least in the sum of \$500,000 or more.

(c) For purposes of this section, physicians or podiatrists when practicing as employees of the Federal, State or county government or physicians practicing pursuant to an exemption from the prohibitions of the Medical Practice Act set forth at N.J.S.A. 45:9-21 will not be deemed to be maintaining a professional practice.

(d) Physicians and podiatrists who are not covered by medical malpractice insurance shall present to the Board a true copy of the letter of credit required pursuant to (b) above and shall notify the Board, within seven days, whenever:

1. A demand for payment on the letter has been made;
2. The continuing viability of the letter has been affected, for whatever reason; or
3. There has been a change in status affecting whether the physician or podiatrist is or continues to be exempt from the requirement.

(e) Violations of (b) and (d) above shall be deemed professional misconduct within the meaning of N.J.S.A. 45:1-21(e).

New Rule, R.1993 d.604, effective December 6, 1993.

See: 24 N.J.R. 4012(a), 25 N.J.R. 5487(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, dispensing or administering anabolic steroids".

New Rule, R.1999 d.117, effective April 5, 1999.

See: 30 N.J.R. 4318(a), 31 N.J.R. 881(a).

Petition for Rulemaking.

See: 35 N.J.R. 3418(a), 3967(c).

Petition for Rulemaking.

See: 36 N.J.R. 588(a).

Public Notice: Conference for Solicitation of Informal Public Input on Medical Malpractice Coverage Requirements.

See: 36 N.J.R. 1134(a).

Petition for Rulemaking.

See: 36 N.J.R. 4180(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.

“Illegal use of controlled dangerous substances” means the use of controlled dangerous substances obtained illegally (for example, heroin or cocaine) as well as the use of controlled dangerous substances which are not obtained pursuant to a valid prescription or not taken in accordance with the directions of a licensed health care practitioner.

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

“Licensing authority” means any professional or occupational licensing board charged with granting, suspending or revoking licensure or certification privileges.

“Medical condition” includes physiological, mental or psychological conditions or disorders, such as, but not limited to, orthopedic, visual, speech, or hearing impairments, cerebral palsy, epilepsy, muscular dystrophy, multiple sclerosis,

cancer, heart disease, diabetes, mental retardation, emotional or mental illness, specific learning disabilities, HIV disease, tuberculosis, drug addiction and alcoholism.

“Practice location” means the actual physical site of the office and business address from which the licensee provides professional services and where relevant books and records are or should be maintained.

“Practice name” means the title under which a group practice of five or more practitioners is conducted.

“Practitioner” means physician or podiatrist licensed by the Board.

(b) A licensee shall provide notice to the Board in writing, on such forms as the Board may require and within 21 days, of any changes, additions or deletions pertaining to the following information last provided by the licensee on the biennial license renewal form:

1. The name and address of all practice locations;
2. The name of all practitioners directly associated with the practice, or the practice name if five or more practitioners are offering professional services through the same practice entity;
3. The name and address of each licensed health care facility and health maintenance organization with which the licensee has an affiliation, except that with respect to health maintenance organization affiliations, the licensee shall be relieved of this reporting obligation if the entities with which the licensee has an affiliation have agreed to provide the Board with a list of participating providers on a quarterly basis;
4. The name and address of the licensee’s medical malpractice insurer, if any; and
5. The name and address of any health care service entity in which the licensee or any member of his or her immediate family has acquired a financial interest, the date on which that interest was acquired and whether the licensee refers patients to that service.

(c) A licensee shall provide notice to the Board in writing of any changes in circumstances which would alter the response last provided by the licensee to questions on the biennial renewal form eliciting information pertaining to pending or finalized actions, including those predicated on a no contest or nolo contendere plea or other consensual or voluntary agreement, or a surrender or resignation of license or of privileges or a consent to limitations on practice which occurred in the face of an investigation or of pending action. Reporting of the following actions is required:

1. Actions by criminal authorities for violations of law or regulation;
2. Actions by a health care facility or health maintenance organization grounded, in whole or in part, upon patient care concerns which actions condition, curtail, limit, suspend or revoke privileges;
3. Disciplinary actions by state licensing authorities;

4. Actions by the Department of Health;
5. Actions by the Drug Enforcement Administration or any state drug enforcement agency;
6. Actions by Medicaid, Medicare, CHAMPUS, or other governmental insurance program;
7. Actions by professional review organizations or utilization review organizations; or
8. Actions by a medical malpractice insurance carrier declining coverage or a continuation of coverage, assessing a surcharge based on claims experience, imposing new limitations or restrictions on practice, or requiring remedial education or office monitoring.

(d) A licensee, who is not already known to the Board’s Impairment Review Committee through participation in the Alternative Resolution Program, shall provide notice to the Board in writing of any changes in circumstances which would alter the response last provided by the licensee to questions on the biennial renewal form pertaining to medical conditions and use of chemical substances which in any way impair or limit the licensee’s ability to practice with reasonable skill and safety. Licensees shall provide notice to the Board of any hospitalization, in-patient treatment or participation in supervised rehabilitation programs relating to these medical conditions. Licensees shall notify the Board of any leave of absence taken from a health care facility or health maintenance organization for reasons related to these medical conditions. (Parental leaves need not be reported.) Any notices received by the Board pursuant to this subsection shall be retained by the Board in a confidential manner and shall not be deemed to be public records within the meaning of N.J.S.A. 47:1A-1 et seq.

(e) To the extent that a required disclosure may relate to the illegal use of controlled dangerous substances or other criminal activity which may give a licensee reasonable cause to believe he or she is exposed to the possibility of criminal prosecution, the licensee may assert, on the form provided by the Board, the Fifth Amendment privilege against self-incrimination. Any claim of Fifth Amendment privilege must be made in good faith, and does not relieve the licensee from making disclosures not implicating criminal liability. The Board may make follow-up inquiries and the licensee may later be directed by the Attorney General to make a disclosure of information previously withheld on the basis of the Fifth Amendment, provided that the Attorney General first grants immunity afforded by statutory law. N.J.S.A. 45:1-20.

(f) For each change, addition or deletion in the foregoing information, the licensee shall further indicate the effective date of the change, addition or deletion and provide an explanation therefor.

(g) Failure by a licensee to provide the Board with notice of any information required pursuant to this section within 21 days of the change or the event necessitating the filing of the notice may be deemed professional misconduct within the meaning of N.J.S.A. 45:1-21(e).

New Rule, R.1996 d.243, effective May 20, 1996.
See: 27 N.J.R. 1746(b), 28 N.J.R. 2563(a).

13:35-6.20 Physician delegation of tasks to radiologic technologists and nuclear medicine technologists

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

“Authorized medical user” shall mean a licensed physician who is identified as an authorized user on a New Jersey Department of Environmental Protection radioactive materials license that authorizes the medical use of naturally occurring or accelerator-produced radioactive materials, or on a Nuclear Regulatory Commission license that authorizes the medical use of byproduct radioactive materials.

“Diagnostic x-ray technologist license” shall mean a license for general diagnostic radiology (LRT(R)).

“Direct physician supervision” shall mean instruction, direction and guidance by a physician who is personally aware of the procedure intended for a given patient; who is present in the facility and is readily available to physically attend to the patient; and who has assured that emergency equipment shall be available for immediate use by a licensed physician trained to use that equipment. All tasks which this section permits a physician to delegate may be performed in a licensed hospital or in a licensed outpatient facility or in the physician’s private office, unless otherwise specified.

“Licensed nuclear medicine technologist” or “LNMT” shall mean an individual holding a license issued directly by the Department of Environmental Protection.

“Limited technologist license” shall mean a license in chest x-ray (LRT(C)), dental x-ray (LRT(D)), podiatric x-ray (LRT(P)), orthopedic x-ray (LRT(O)) or urologic x-ray (LRT(U)) issued by the New Jersey Radiologic Technology Board of Examiners.

“Medical resident” shall mean a graduate physician who is authorized to practice medicine and surgery by means of a valid permit issued by the Board of Medical Examiners to a person authorized to engage in the practice of medicine and surgery while in the second year or beyond of a graduate medical education program pursuant to N.J.A.C. 13:35-1.5.

“Physician,” unless otherwise specified, shall mean an individual holding a plenary license to practice medicine and surgery issued by the State Board of Medical Examiners.

“Technologist” shall mean an individual who holds a current license in a specific category of radiologic practice from the New Jersey Radiologic Technology Board of Examiners or the Department of Environmental Protection, as applicable.

(b) A physician may direct a technologist holding the license for general diagnostic radiology (LRT(R)) from the New Jersey Radiologic Technology Board of Examiners to perform the tasks set forth in (c) below provided that:

1. The physician (or another plenary-licensed physician in the office or, in a licensed health care facility, the head of the pertinent Department) has personally certified and documented the radiologic technologist’s training and competency to perform the task. The documents shall be preserved in the personnel record and retained for at least the duration of such technologist’s employment by or for that physician or facility;
2. A physician or a medical resident is on the premises and immediately available to physically attend to the patient;
3. The physician is responsible for the choice and ordering of all pharmaceuticals and contrast materials and for the determination of dosage and route of administration; and
4. For pediatric patients, the physician shall have experience in the performance of the pertinent procedures with such patients.

(c) A physician may direct a technologist, in the circumstances set forth in (b) above, to perform the following tasks:

1. Establish a peripheral intravenous line;
2. Administer contrast material into a peripheral intravenous line or into a pre-existing central intravenous line;
3. Administer contrast material through the use of a power injector;
4. Administer contrast materials into pre-existing urinary catheters, whether indwelling or otherwise;
5. Administer contrast materials into pre-existing nasogastric tubes or other gastric or intestinal feeding tubes;
6. Administer intravenous flush solutions such as saline or heparin; and
7. Administer glucagon and such other pharmaceuticals as shall be approved by the Board.

1. Notify the patient, in writing, that the licensee shall no longer provide care to the patient as of a date certain. The notification required by this paragraph shall be made no less than 30 days prior to the date on which care is to be terminated, and shall be made by certified mail, return receipt requested, sent to the patient's last known address;

2. Provide all necessary emergency care or services, including the provision of necessary prescriptions, until the date on which services are terminated. The provision of any such emergency care or services shall not be deemed to manifest any intention to reestablish a licensee-patient relationship; and

3. Comply with all requirements set forth in N.J.A.C. 13:35-6.5 for access to and transfer of patient records.

(d) Notwithstanding (c) above, a licensee shall not terminate a licensee-patient relationship in the following circumstances:

1. Where to do so would be for any discriminatory purpose and/or would violate any laws or rules prohibiting discrimination; or

2. Where the licensee knows, or reasonably should know, that no other licensee is currently able to provide the type of care or services that the licensee is providing to the patient.

(e) A licensee need not comply with the requirements set forth in (c)1 above if:

1. The licensee-patient relationship has been terminated by the patient as evidenced by conduct manifesting a deliberate intention to terminate the relationship; or

2. The reason for the termination of an ongoing licensee-patient relationship is because the licensee has discontinued providing services to a particular managed care provider or health maintenance organization, in which the patient is enrolled and such managed care provider or HMO has discharged its notice obligation pursuant to N.J.S.A. 26:2S-5a(1).

(f) When requested by the patient, the licensee shall make reasonable efforts to assist the patient in obtaining medical services from another licensee qualified to meet the patient's medical needs. These efforts may include, but are not limited to, providing referrals to the patient.

New Rule, R.2000 d.399, effective October 2, 2000.
See: 31 N.J.R. 2452(a), 32 N.J.R. 3574(b).

13:35-6.23 Presence of chaperones

(a) In all office settings, a licensee shall provide notice to a patient, or any other person who is to be examined, of the right to have a chaperone present:

1. During breast and pelvic examinations of females; and
2. During genitalia and rectal examinations of both males and females.

(b) The notice required by (a) above shall either be provided in written form to the patient or by conspicuously posting a notice in a manner in which patients or any other person who is to be examined are made aware of the right to request a chaperone and to decline care if a chaperone acceptable to the patient is not available. In circumstances where the posting or the provision to the patient of the written notice would not convey the right to have a chaperone present, the licensee shall use another means to ensure that the patient or person to be examined understands his or her right to have a chaperone present.

(c) A licensee shall not be obligated to provide further care for the immediate medical problem presented if the licensee is unable to provide a requested chaperone acceptable to the patient.

(d) A licensee shall not be obligated to provide further care for the immediate medical problem presented if the patient refuses to have a chaperone present and it is the licensee's desire to have a chaperone present during the examination.

(e) If care is not to be provided to a patient under the circumstances described in (c) or (d) above, the licensee shall, consistent with the principles of informed consent, discuss with the patient the risks of not receiving further care.

New Rule, R.2004 d.135, effective April 5, 2004.
See: 35 N.J.R. 3262(a), 36 N.J.R. 1814(a).

SUBCHAPTER 6A. DECLARATIONS OF DEATH UPON THE BASIS OF NEUROLOGICAL CRITERIA

13:35-6A.1 Purpose

(a) The rules in this subchapter are established pursuant to N.J.S.A. 26:6A-1 et seq. (P.L. 1991, c.90), the New Jersey Declaration of Death Act, and set forth:

13:35-6A.7 Certification of death

The attending physician and the corroborating physician shall both document within the patient record the results of all tests performed during their examinations, and shall both sign the chart. After the two clinical examinations and appropriate confirmatory tests have been completed and documented on the patient's chart, and if both examiners have been able to make all requisite determinations, then brain death may be declared. The two physicians who performed the clinical examinations shall both certify death in the patient's chart and the attending physician shall certify death on the death certificate.

**SUBCHAPTER 7. PRESCRIPTION,
ADMINISTRATION AND DISPENSING OF
DRUGS**

13:35-7.1 Definitions

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

“Actual acquisition cost” means the cost actually incurred by the practitioner in acquiring a drug from a supplier and shall not include any amounts charged by any entity in which the practitioner has a direct or indirect financial or other beneficial interest.

“Administer” means the physical, in-person provision of a drug by way of injection, vaccine, allergenic extract or nebulized preparation or the provision of multiple dose vials of injectable medications.

“Amphetamine or sympathomimetic amine” means a drug which, chemically and pharmacologically, acts as a central nervous system stimulant.

“Anabolic steroid” means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogen, progestin and corticosteroids), which promotes muscle growth, as well as any salt, ester, or isomer of such substance which acts in a similar manner in the human body.

“Controlled substance” means a drug classified in any of the schedules (I through V) of the Controlled Dangerous Substances Act, N.J.S.A. 24:21-5 to 24:21-8.1, recognized to have a potential for abuse or to lead to physical or psychological dependence.

“Dispensing” means the distribution of drugs intended by the physician for the personal use of the patient. “Dispensing” as used in this subchapter does not include the in-office administration of injections, vaccines, allergenic extracts or

nebulized preparations or the provision of multiple dose vials of injectable medication.

“Drug” means any article recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement to those sources, including, but not limited to, a controlled substance, a prescription legend drug, an over-the-counter preparation, a vitamin or food supplement, or any compounded combination of any of the above or a transdermal patch or strip, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or medical condition in humans or intended to affect the structure or function of the human body. The term, as used in this subchapter, is synonymous with “medicine” as used in N.J.S.A. 45:9-22.11. “Drug,” as used in this subchapter, does not mean a device or durable medical equipment.

“Intractable pain” means pain which has been shown to be refractory or resistant to management with standard methods of treatment or for which insufficient relief has been found after reasonable efforts.

“Narcotic” means an analgesic drug which chemically and pharmacologically acts as an opioid.

“Non-prescription substance” means an over-the-counter preparation, a vitamin or food supplement, or any compounded combination of any of these preparations and supplements or a transdermal patch or strip for which no prescription is required pursuant to law.

“Practitioner” means any licensee subject to the regulatory authority of the Board authorized to prescribe or dispense drugs, including physicians, podiatrists and, to the extent permitted by law and rule, registered residents, resident permit holders, physician assistants and certified nurse midwives.

“Prescribing” means the act of directing that a patient take a drug included in prescription legend through either a written or verbal order.

“Terminal illness” means a diagnosed medical condition with a prognosis of less than one year.

Petition for Rulemaking.

See: 30 N.J.R. 1643(a), 31 N.J.R. 2658(b).

Amended by R.2000 d.400, effective October 2, 2000.

See: 31 N.J.R. 2454(a), 32 N.J.R. 3576(a).

In definition of “Drug”, substituted “medicine” for “medication”; inserted definition for “Non-prescription substance”.

**13:35-7.1A Examination of patient's condition required
prior to dispensing drugs or issuing a
prescription; exceptions**

(a) Except as provided in (b) below, a practitioner shall not dispense drugs or issue prescriptions to an individual, pursuant to the requirements of this subchapter, without first having conducted an examination, which shall be appro-

priately documented in the patient record. As part of the patient examination, the practitioner shall:

1. Perform an appropriate history and physical examination;
2. Make a diagnosis based upon the examination and all diagnostic and laboratory tests consistent with good medical care;
3. Formulate a therapeutic plan and discuss such plan, along with the basis for the plan and the risks and benefits of various treatment options, with the patient; and
4. Ensure the availability of the physician or coverage for the patient for appropriate follow-up care.

(b) Notwithstanding (a) above, an examination of the patient's condition shall not be required prior to the dispensing of drugs or the issuance of a prescription under the following circumstances:

1. In admission orders for a newly hospitalized patient;
2. For a patient of another physician for whom the practitioner is taking calls;
3. For continuation medications on a short term basis for a new patient prior to the patient's first appointment;
4. For an established patient who, based on sound medical practice, the physician believes does not require a new examination before issuing a new prescription;
5. For a patient examined by a healthcare professional who is in collaborative practice with the practitioner; and
6. When treatment is provided by a practitioner for an emergency medical condition.

(c) For purposes of this section, the term "emergency medical condition" as used in (b) above means:

1. A medical condition manifesting itself by acute symptoms of sufficient severity, including severe pain, such that the absence of immediate medical attention could reasonably be expected to result in:
 - i. Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;
 - ii. Serious impairment to bodily functions; or
 - iii. Serious dysfunction of any bodily organ or part.

New Rule, R.2003 d.372, effective September 15, 2003.
See: 34 N.J.R. 3059(a), 35 N.J.R. 4287(a).

13:35-7.2 Requirements for issuing written prescriptions for medicines

(a) A practitioner, acting within the scope of lawful practice and after an examination or evaluation of the patient's condition, may issue a written prescription for a drug to a patient, guardian or authorized representative in the form authorized by this section. The practitioner shall assure that appropriate follow-up is provided and that the effects of the drug are properly evaluated and integrated into the treatment plan for the patient.

(b) (Reserved)

(c) Written prescriptions shall be issued only on New Jersey Prescription Blanks (NJPB), secured from an approved vendor and subject to the required security mandates of the prescription blank program.

(d) A practitioner shall include the following information on each written prescription:

1. The prescribing practitioner's full name, address, telephone number, license number, and proper academic degree or identification of professional practice for which licensed;
2. The full name, age and address of the patient;
3. The date of issuance;
4. The name, strength and quantity of the drug prescribed;
5. Words, in addition to numbers, to indicate the drug quantity authorized if the prescription is for a Schedule II controlled substance, for example: ten (10) Percodan; or five (5) Ritalin 5 mg;
6. The number of refills permitted or time limit for refills, or both;
7. The handwritten original signature of the prescribing practitioner;
8. An explicit indication, by initials placed next to "do not substitute" (see (e) below), if it is the prescribing practitioner's intention that a specified brand name drug be dispensed;
9. The prescribing practitioner's D.E.A. number, if the drug is a controlled substance; and
10. Adequate instruction for the patient as to frequency; a direction of "p.r.n." or "if needed" alone may be used if appropriate.

(e) A prescribing practitioner shall advise each patient by adequate notice, for example, by a sign or pamphlet in the waiting room of the office, that the patient may request the practitioner to substitute a generic drug for any brand name drug prescribed.

(f) Each practitioner shall use only written prescription blanks which shall be imprinted with the words "substitution permissible" and "do not substitute," with a space for the prescribing practitioner's initials next to the chosen option, and which shall not include preprinted information designed to discourage or prohibit substitution.

(g) When using health care facility or multi-prescriber prescription blanks, the full name and license number of the prescribing practitioner shall be legibly printed at the top of the prescription or the identity of the prescriber shall be designated by a checkmark or other legible means.

(h) Each prescription for a controlled substance shall be written on a separate NJPB.

Amended by R.2000 d.400, effective October 2, 2000.
See: 31 N.J.R. 2454(a), 32 N.J.R. 3576(a).

Inserted a new (c), and recodified former (c) as (d); in the new (d), inserted ", license number." following "telephone number" in 1; recodified former (d) through (f) as (e) and (g); rewrote the new (g); and added (h).

Case Notes

Charges of misconduct against physician who prescribed medication to his girlfriend were dismissed due to his familiarity with her medical history and her sophisticated knowledge of such medication. In the Matter of the Suspension or Revocation of the License of Kunish, 96 N.J.A.R.2d (BDS) 9.

13:35-7.3 Verbal prescriptions (Reserved)

13:35-7.4 Facsimile transmitted prescriptions

(a) A practitioner, acting within his or her scope of lawful practice and after an examination of the patient's condition, consistent with the requirements of N.J.A.C. 13:35-7.1A, may transmit, or have an authorized agent transmit, a facsimile prescription to a pharmacy which has been approved by a patient, a patient's guardian, or a patient's authorized representative, consistent with the requirements of this section. For purposes of this section, "facsimile prescription" means a prescription issued by the practitioner which is transmitted by a device which sends an exact image to the receiver.

(b) A practitioner shall comply with all requirements set forth in this subchapter, and shall ensure that all information required to be included on a written prescription pursuant to N.J.A.C. 13:35-7.2(d) is provided on each facsimile prescription, except that an NJPB shall not be required for the prescription.

(c) The transmission of a facsimile prescription shall contain the following:

1. The identification number of the facsimile machine which is used to transmit the prescription to the pharmacy;
2. The time and date of the transmission of the prescription;

3. The name, address, telephone number and facsimile number of the pharmacy to which the prescription is being transmitted; and

4. If an authorized agent transmits the facsimile prescription, the full name and title of the transmitting agent.

(d) A practitioner shall provide verbal verification of the facsimile prescription upon request of the pharmacy when the pharmacist has a question regarding the authenticity, accuracy or appropriateness of the prescription. A practitioner's authorized agent may provide verbal verification of the facsimile prescription to the pharmacy when the pharmacist has a question regarding the authenticity or legibility of the prescription.

(e) A practitioner or his or her authorized agent may transmit a facsimile prescription to a pharmacy for a Schedule II controlled substance, provided that the patient is given the original signed NJPB which is presented to the pharmacist prior to the dispensing of the controlled substance, except as provided in (e)1, 2 and 3 below:

1. A prescription for a Schedule II narcotic substance prescribed for pain management to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription.

2. A prescription for a Schedule II substance prescribed for pain management for a resident of a long term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription.

3. A prescription for a Schedule II narcotic substance prescribed for pain management for a patient receiving services from a hospice certified by Medicare under Title XVIII or licensed by the State may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent shall note on the facsimile prescription that the patient is a hospice patient. The facsimile shall serve as the original written prescription.

(f) A practitioner or his or her authorized agent may transmit a facsimile prescription to a pharmacy for a Schedule III, IV, or V controlled substance consistent with the requirements of this section. The facsimile shall serve as the original written prescription.

(g) If a facsimile prescription is provided for a Schedule II substance prescribed for pain management to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, or for a resident of a long term care facility, or for a patient receiving services from a hospice certified by

Medicare under Title XVIII or licensed by the State, or for a Schedule III, IV or V controlled substance, the practitioner shall not provide the patient, the patient's guardian, or the patient's authorized representative with the original written prescription.

(h) A practitioner shall not enter into any agreement with a pharmacy that requires facsimile prescriptions be transmitted to that particular pharmacy or in any way denies a patient the right to have his or her prescription transmitted by facsimile to a pharmacy of the patient's choice.

New Rule, R.2003 d.372, effective September 15, 2003.
See: 34 N.J.R. 3059(a), 35 N.J.R. 4287(a).

13:35-7.4A Electronically transmitted prescriptions

(a) A practitioner, acting within his or her scope of lawful practice and after an examination of the patient's condition, as defined in N.J.A.C. 13:75-7.1, may transmit, or have an authorized agent transmit, an electronic prescription to a pharmacy which has been approved by a patient, a patient's guardian, or a patient's authorized representative, consistent with the requirements of this section. For purposes of this section, "electronic prescription" means a prescription which is transmitted by a computer device in a secure manner, including computer to computer and computer to facsimile transmissions.

(b) A practitioner shall comply with all requirements set forth in this subchapter, and shall ensure that all information required to be included on a written prescription pursuant to N.J.A.C. 13:35-7.2(d) is provided in each electronic prescription, except that a handwritten original signature and an NJPB shall not be required for the prescription.

(c) A practitioner's electronic signature, or other secure method of validation, shall be provided with the electronic prescription unless the prescription is transmitted by an authorized agent as provided in (e) below.

(d) To maintain confidentiality of electronic prescriptions, the practitioner shall ensure that the electronic system used to transmit the electronic prescription has adequate security and system safeguards designed to prevent and detect unauthorized access, modification or manipulation of such records, and shall include, at a minimum, electronic encryption.

(e) A practitioner may authorize an agent to electronically transmit a prescription provided that the full name and title of the transmitting agent is included on the transmission, and provided that the practitioner's authorized agent does not sign the electronic prescription.

(f) A practitioner shall provide verbal verification of an electronic prescription upon request of the pharmacy when the pharmacist has a question regarding the authenticity, accuracy or appropriateness of the prescription. A practitioner's authorized agent may provide verbal verification of the electronic prescription to the pharmacy when the pharmacist has a question regarding the authenticity or legibility of the prescription.

(g) A practitioner or the practitioner's authorized agent may transmit an electronic prescription to a pharmacy for a Schedule II controlled substance, provided that the original signed prescription is presented to the pharmacist prior to the dispensing of the controlled substance. If permitted by Federal law, and in accordance with Federal requirements, the electronic prescription shall serve as the original signed prescription and the practitioner shall not provide the patient, the patient's guardian, or the patient's authorized representative with a signed, written prescription.

(h) A practitioner or his or her authorized agent may transmit an electronic prescription to a pharmacy for a Schedule III, IV, or V controlled substance, provided that the original signed prescription for presentation at the pharmacy, an oral prescription, or a facsimile prescription is provided. If permitted by Federal law, and in accordance with Federal requirements, the electronic prescription shall serve as the original signed prescription and the practitioner shall not provide the patient, the patient's guardian, or the patient's authorized representative with a signed, written prescription.

(i) A practitioner shall not enter into any agreement with a pharmacy which requires that electronic prescriptions be transmitted to a particular pharmacy or in any way denies a patient the right to have his or her prescription transmitted electronically to a pharmacy of the patient's choice.

New Rule, R.2003 d.372, effective September 15, 2003.
See: 34 N.J.R. 3059(a), 35 N.J.R. 4287(a).

13:35-7.5 Requirements for the dispensing of drugs and special limitations applicable to the dispensing of drugs for a fee

(a) A practitioner, acting within the scope of lawful practice and after an examination or evaluation of the patient's condition, may dispense a drug directly to a patient, guardian or authorized representative under the circumstances and limitations set forth in this section. The practitioner shall assure that appropriate follow-up is provided and that the effects of the drug are properly evaluated and integrated into the treatment plan for the patient.

(b) A practitioner who dispenses drugs in the office shall maintain those drugs in an area kept in an orderly and sanitary manner, and in accordance with standard pharmaceutical practice and manufacturer recommendations concerning storage conditions, including refrigeration, where necessary. A practitioner shall not maintain in inventory any drugs which are outdated, misbranded, deteriorated, adulterated, recalled, unlabeled, damaged, discontinued or which were previously dispensed to a patient. A practitioner shall be responsible for the disposal of such drugs in a manner which will not pose a health hazard and in accordance with all local, State and Federal requirements.

(c) All drugs dispensed shall be recorded in the applicable patient record.

(d) All drugs dispensed, with the exception of samples of drugs which are not controlled substances and which are packaged and labeled by the manufacturer, shall be record-

ed in a permanent, contemporaneous dispensing log which shall contain, at a minimum, the following:

1. Shall review, at a minimum of every three months, the course of treatment, any new information about the etiology of the pain and the patient's progress toward treatment objectives;

2. Shall remain alert to problems associated with physical and psychological dependence; and

3. Shall periodically make reasonable efforts, unless clinically contraindicated, to either stop the use of the controlled substance, decrease the dosage, try other drugs such as nonsteroidal anti-inflammatories, or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence.

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

1. Shall assess the appropriateness of continued treatment with controlled substances or undertake a trial of other drugs or treatment modalities; and

2. Shall consider referring the patient for independent evaluation or treatment in order to achieve treatment objectives.

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

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

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

Amended by R.2003 d.263, effective July 7, 2003.
See: 34 N.J.R. 3441(a), 35 N.J.R. 2935(a).
Rewrote (c).

13:35-7.7 Prohibitions on prescribing, administering or dispensing of controlled substances for detoxification; limited exceptions

(a) A practitioner shall not issue a prescription for a narcotic drug or for a depressant drug listed in any schedule

which drug is intended for the purpose of "detoxification" or "maintenance treatment."

(b) Unless registered with the New Jersey Department of Health and Senior Services to conduct a narcotic treatment program pursuant to N.J.S.A. 24:21-10 and N.J.A.C. 8:65-11.2, a practitioner shall not dispense or administer a narcotic drug or a depressant drug listed in any schedule which drug is intended for the purpose of "detoxification" or "maintenance treatment," except:

1. To relieve acute withdrawal symptoms, provided that:

i. Such treatment shall not exceed 72 hours;

ii. No more than one day's supply of the drug is provided to the patient at a time; and

iii. Arrangements are made for referring the patient to an addiction specialist or a drug treatment program for treatment; or

2. As an adjunct to other medical or surgical treatment for conditions other than addiction in a licensed health care facility.

Amended by R.2000 d.400, effective October 2, 2000.
See: 31 N.J.R. 2454(a), 32 N.J.R. 3576(a).

In (a), and (b), inserted references to depressant drugs.

13:35-7.8 Prohibitions and limitations in the prescribing, administering or dispensing of amphetamines and sympathomimetic amines

(a) A practitioner shall not prescribe, order, dispense, administer, sell or transfer any amphetamine or sympathomimetic amine designated as a Schedule II controlled substance for use in weight management, dieting or any other anorectic purpose, or for the treatment of fatigue.

(b) A practitioner may prescribe, dispense or administer amphetamine or sympathomimetic amine drugs or compounds designated as Schedule II controlled substances, only as follows:

1. For the treatment of the following conditions:

i. Narcolepsy established by recognized diagnostic criteria;

ii. Idiopathic Central Nervous System Hypersomnia established by recognized diagnostic criteria;

iii. Attention Deficit Disorder established by recognized diagnostic criteria;

iv. Drug-induced brain dysfunction;

v. Epilepsy;

vi. Depression shown to be refractory to other therapeutic modalities; and

vii. Senile apathetic behavior;

2. For immediate use in a hospital for acute conditions such as depression associated with illness or surgery;

3. For the differential diagnostic psychiatric evaluation of depression; or

4. For the clinical investigation of the effects of such drugs or compounds in which case, in addition to other requirements of applicable law, prior application therefor shall have been made to the Board and approval granted before any such investigation is begun.

(c) A practitioner who prescribes, dispenses or administers amphetamines or sympathomimetic amines shall prepare and maintain patient medical records which accurately reflect the utilization of any drug subject to this section, the specific diagnosis, the information upon which the diagnosis is based, including testing and consultations, and the treatment objectives for which the drug is being prescribed.

(d) The following list, although not exhaustive or exclusive, includes many of the generic and brand-name Schedule II drugs which are subject to this section:

Adderall
Amphetamine
Desoxyn
Dexedrine
Dextroamphetamine
Methamphetamine

Methylphenidate
Ritalin

13:35–7.9 Prohibitions and special limitations on prescribing, administering or dispensing anabolic steroids

(a) Unless an accepted medical necessity exists, a practitioner shall not prescribe, order, dispense, administer, sell or transfer any anabolic steroid or human growth hormone, for the purpose of hormonal manipulation intended to increase muscle mass, strength or weight. Body building, muscle enhancement, or increasing muscle bulk or strength through the use of anabolic steroid or human growth hormone by a person in good health for the intended purpose of improving performance in any form of exercise, sport or game is not a valid medical purpose.

(b) A practitioner shall prepare and maintain patient medical records which accurately reflect the utilization of any substance or drug subject to this section, which records must indicate the diagnosis, the information upon which the diagnosis is based, and the purpose for which the substance or drug has been prescribed.

(c) The following list, although not exhaustive or exclusive, includes many of the generic and brand-name anabolic steroids and human growth hormones subject to this section:

Bolenone
Chlorotestosterone
(4-chlorotestosterone)
Chorionic gonadotropin
Closebol
Dehydrochlormethyltestosterone
Dihydrotestosterone
(4-dihydrotestosterone)
Ethylestrenol
Fluoxymesterone
Mesterolone
Methandienone
Methandriol
Methandrostenolone
Methenolone
Methyltestosterone
Mibolerone
Nandrolone
Norethandrolone
Oxandrolone
Oxymesterone
Oxymetholone
Somatrem
Somatotropin
Stanolone
Stanozolol
Testolactone
Testosterone
Trebolone

13:35–7.10 Enforcement

(a) A violation of N.J.A.C. 13:35–7.1 through 7.9 may be deemed to constitute one or more of the following:

1. Distribution or dispensing of a controlled substance in an indiscriminate manner, or not in good faith, or without good cause, as prohibited by N.J.S.A. 45:1–13;
2. Gross or repeated malpractice, neglect, or incompetence in the practice of medicine, as prohibited by N.J.S.A. 45:1–21(c) and (d);
3. Professional misconduct, as prohibited by 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, as prohibited by N.J.S.A. 45:1–21(h); and
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.

(b) A practitioner who is in possession of information which reasonably indicates that another practitioner has prescribed, dispensed or administered any drug or drugs in a manner which jeopardizes the public health, safety or welfare or for purposes deemed to be unlawful pursuant to this subchapter shall report such information to the Board pursuant to N.J.S.A. 45:9–19.5.

SUBCHAPTER 8. HEARING AID DISPENSERS

13:35–8.1 Purpose

The rules in this subchapter are established pursuant to N.J.S.A. 45:9A–7 and govern the licensing and the practice of hearing aid dispensing in the State of New Jersey.

13:35–8.2 Definitions

The following words and terms when used in this subchapter shall have the following meaning unless the context clearly indicates otherwise.

“Act” means the New Jersey Hearing Aid Dispensers Act, N.J.S.A. 45:9A–1 et seq. as amended and/or supplemented.

“Advertisement” means any attempt, directly or indirectly, by publication, display, dissemination or circulation, in print or electronic media, which induces or attempts to induce any person to purchase or enter into an agreement to purchase a hearing aid, services and/or merchandise from a licensee.

“Board” means the State Board of Medical Examiners.

“Committee” means the Hearing Aid Dispensers Examining Committee.

“Hearing aid” means a hearing aid as defined by N.J.S.A. 45:9A-2(c) and includes the earmold system.

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

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

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

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

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

13:35-8.3 Training and experience requirements

(a) An applicant for licensure as a hearing aid dispenser shall submit one of the following to the Committee:

1. Proof of completion of a minimum of six months continuous or interrupted training within a 24-month period ending with the deadline for making application to take the next examination;
2. Proof of successful completion of a county college course in hearing aid selection and fitting approved by the Committee and/or the Commission on Higher Education; or
3. Proof of successful completion of a master’s degree in audiology from an American Speech Language Hearing Association accredited college or university after January 1, 1993.

(b) An individual, including a New Jersey licensed audiologist, who has met training and experience requirements set forth in (a) above shall not dispense a hearing aid as defined by N.J.A.C. 13:35-8.7 until he or she passes the written and practical examination administered by the Committee, unless the individual is under supervision as the holder of a training permit or a temporary license.

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

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

1. 40 hours of training with an audiometer;
2. 160 hours of hearing aid dispensing procedures, including the taking of earmold impressions, the alteration of earmolds and hearing aids, and application and fitting techniques;
3. Reading all the books and articles relating to hearing aid dispensing specified in a list formulated by the Committee.

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

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

Petition for Rulemaking.

See: 30 N.J.R. 2528(a).

Amended by R.1998 d.372, effective July 20, 1998.

See: 30 N.J.R. 1191(a), 30 N.J.R. 2633(a).

Rewrote (a) and (b).

Petition for Rulemaking.

See: 30 N.J.R. 4294(b).

13:35-8.4 Training permits; issuance and practice

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

New Rule, R.1998 d.372, effective July 20, 1998.

See: 30 N.J.R. 1191(a), 30 N.J.R. 2633(a).

13:35-8.5 Temporary licenses; issuance

(a) The Committee may issue a temporary license in accordance with N.J.S.A. 45:9-16(a) and the provisions of this subchapter to an applicant provided he or she has not previously held a training permit or has not previously taken the licensing examination described in N.J.S.A. 45:9A-10 and N.J.A.C. 13:35-8.16. A temporary license shall not be renewed when an applicant has failed the licensing examination, except on showing of good cause (such as illness or emergency precluding the taking of the examination).

(b) Persons from another jurisdiction who are not eligible for license by endorsement under N.J.S.A. 45:9A-13 who wish to sit for the licensing examination shall demonstrate a minimum of two years of full-time independent experience in dispensing, fitting and selling hearing aids as defined by

N.J.S.A. 45:9A-2(d) and N.J.A.C. 13:35-8.8. The applicant must submit documentation and verification of said experience satisfactory to the Committee, or submit verification of current licensure to practice audiology in the State of New Jersey.

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

Recodified from N.J.A.C. 13:35-8.4 and amended by R.1998 d.372, effective July 20, 1998.

See: 30 N.J.R. 1191(a), 30 N.J.R. 2633(a).

Changed N.J.A.C. references throughout. Former N.J.A.C. 13:35-8.5, Temporary licenses; practice, was recodified to N.J.A.C. 13:35-8.6.

13:35-8.6 Temporary licenses; practice

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

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

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

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

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

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

Recodified from N.J.A.C. 13:35-8.5 by R.1998 d.372, effective July 20, 1998.

See: 30 N.J.R. 1191(a), 30 N.J.R. 2633(a).

Former N.J.A.C. 13:35-8.6, Sponsors, was recodified to N.J.A.C. 13:35-8.7.

13:35-8.7 Sponsors

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

(b) In addition, a sponsor shall:

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

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

3. Not pre-sign purchase agreements;

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

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

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

Recodified from N.J.A.C. 13:35-8.6 by R.1998 d.372, effective July 20, 1998.

See: 30 N.J.R. 1191(a), 30 N.J.R. 2633(a).

Former N.J.A.C. 13:35-8.7, Scope of practice, was recodified to N.J.A.C. 13:35-8.8.

13:35-8.8 Scope of practice

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

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

2. The making of an ear impression;

3. Pursuant to N.J.A.C. 13:35-8.9, the fitting and dispensing of a deep ear canal hearing aid device that requires an impression taking technique involving instruments applied to the tympanic membrane;

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

5. The change of frequency response of any instrument;

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

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

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

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

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

(e) A license to fit and dispense hearing aids does not confer upon a licensee the right to hold oneself out to the

public as an audiometrist, audiologist, otologist, otorhinolaryngologist or any such title which connotes medical or audiological competence.

Amended by R.1994 d.595, effective December 5, 1994.

See: 26 N.J.R. 1301(b), 26 N.J.R. 4780(b).

Recodified from N.J.A.C. 13:35-8.7 and amended by R.1998 d.372, effective July 20, 1998.

See: 30 N.J.R. 1191(a), 30 N.J.R. 2633(a).

In (a), changed N.J.A.C. reference in 3. Former N.J.A.C. 13:35-8.8, Fitting and dispensing of deep ear canal hearing aid devices, was recodified to N.J.A.C. 13:35-8.9.

13:35-8.9 Fitting and dispensing of deep ear canal hearing aid devices

(a) A licensee may fit and dispense a deep ear canal hearing aid device that requires an impression taking technique involving instruments applied against the tympanic membrane, provided that the licensee advises the Committee, on a form provided by the Committee, of the name and address of a Board-certified ENT physician licensed in this State who has agreed to be constantly accessible through electronic communications during the impression taking process and who is available to render immediate in-person assistance when required.

(b) The licensee shall not initiate the impression taking process unless the licensee has ensured that a physician is available as required by (a) above and that the consumer has, within seven days prior to the impression taking process, received a medical evaluation from an ENT physician licensed in the State. The physician's evaluation shall determine whether a deep ear canal hearing aid device may be safely and effectively worn by the consumer and shall be documented by written medical clearance, which the licensee shall place in the consumer's patient records.

(c) The licensee shall immediately refer any consumer who develops any complications during the impression taking or fitting process to the physician identified in (a) above or to a physician selected by the consumer.

(d) The licensee shall refer the consumer, following the impression taking process, to the physician who performed the pre-impression taking evaluation or to another plenary physician licensed in the State and shall secure a written evaluation regarding the placement of the deep ear canal hearing aid device and the consumer's continuing ability to safely and effectively wear the device.

(e) The licensee shall maintain documentation of the evaluations required pursuant to subsection (b) and (d) above consistent with the provisions of N.J.A.C. 13:35-6.5(b).

New Rule, R.1994 d.595, effective December 5, 1994.

See: 26 N.J.R. 1301(b), 26 N.J.R. 4780(b).

Recodified from N.J.A.C. 13:35-8.8 by R.1998 d.372, effective July 20, 1998.

See: 30 N.J.R. 1191(a), 30 N.J.R. 2633(a).

Former N.J.A.C. 13:35-8.9, Supervising licensee, was recodified to N.J.A.C. 13:35-8.10.

13:35-8.10 Supervising licensee

(a) Every corporation, partnership, trust, association or unincorporated business entity operating for the purpose of fitting and dispensing hearing aids shall designate a duly licensed hearing aid dispenser to act as a supervising licensee.

(b) All such businesses shall file annually with the Committee the name and license number of the designated supervising licensee.

(c) The supervising licensee shall be responsible for assuring that all records are maintained in accordance with N.J.A.C. 13:35-8.16.

Recodified from 13:35-8.8 by R.1994 d.595, effective December 5, 1994.

See: 26 N.J.R. 1301(b), 26 N.J.R. 4780(b).

Recodified from N.J.A.C. 13:35-8.9 and amended by R.1998 d.372, effective July 20, 1998.

See: 30 N.J.R. 1191(a), 30 N.J.R. 2633(a).

In (c), changed N.J.A.C. reference. Former N.J.A.C. 13:35-8.10, Notification to the Committee; suspension of license for failure to renew, was recodified to N.J.A.C. 13:35-8.11.

13:35-8.11 Notification to the Committee; suspension of license for failure to renew

(a) Every licensee shall notify the Committee of any change of residence or place of practice within seven days following such change.

(b) Every licensee, temporary licensee or trainee whose license or permit has expired or has been terminated shall return the license or permit to the Committee office within five days of such invalidation.

(c) Every licensee who does not respond to the computerized notice for renewal of his or her registration prior to the renewal deadline but who files a renewal application within 60 days after the expiration of the biennial registration period shall be assessed a late fee of \$25.00. Thereafter, licensees who seek to renew their registrations shall be assessed a reinstatement fee of \$100.00.

1. A licensee may petition for license reinstatement by making written application to the Committee.

2. The Committee may require payment for any missed registration period caused by his or her failure to renew.

3. The Committee may make reasonable inquiry to evaluate his or her qualifications for continued licensure.

(d) A licensee may retire his or her licensure by surrendering the registration for any period of time when he or she is not engaged in hearing aid dispensing. Prior to reinstatement of the license, the Committee may make reasonable inquiry to evaluate his or her qualifications for continued licensure.

Amended by R.1991 d.458, effective September 3, 1991.

See: 23 N.J.R. 1895(a), 23 N.J.R. 2651(a).

In (c), added explanation for assessment of late fee of \$25.00 and reinstatement of \$100.00. Deleted language regarding failure to respond to computerized notice of renewal. In heading, deleted "suspension of license for".

Recodified from 13:35-8.9 by R.1994 d.595, effective December 5, 1994.

See: 26 N.J.R. 1301(b), 26 N.J.R. 4780(b).

Recodified from N.J.A.C. 13:35-8.10 by R.1998 d.372, effective July 20, 1998.

See: 30 N.J.R. 1191(a), 30 N.J.R. 2633(a).

Former N.J.A.C. 13:35-8.11, Equipment, was recodified to N.J.A.C. 13:35-8.12.

13:35-8.12 Equipment

(a) The equipment necessary to dispense hearing aids in accordance with N.J.S.A. 45:9A-1 et seq. and the provisions of this subchapter shall be available for use at all place(s) of practice.

(b) All electrical equipment used in testing hearing aids including the audiometer shall be inspected as often as necessary to assure accuracy and calibrated no less often than once a year. Audiometers shall be calibrated in accordance with the American National Standard Specifications for Audiometers (ANSI S3.6-1969) and the American National Standard for an Artificial Head Bone for the Calibration of Bone Vibrations (ANSI S3.13-1972). Complete records of calibration shall be maintained as part of the licensee's permanent records.

Recodified from 13:35-8.10 by R.1994 d.595, effective December 5, 1994.

See: 26 N.J.R. 1301(b), 26 N.J.R. 4780(b).

Recodified from N.J.A.C. 13:35-8.11 by R.1998 d.372, effective July 20, 1998.

See: 30 N.J.R. 1191(a), 30 N.J.R. 2633(a).

Former N.J.A.C. 13:35-8.12, Hearing testing, was recodified to N.J.A.C. 13:35-8.13.

Petition for Rulemaking.

See: 30 N.J.R. 4294(b).

13:35-8.13 Hearing testing

(a) No hearing aid shall be sold to a person who has not first been given a hearing examination utilizing appropriate established procedures and instrumentation for the measurement of the hearing and the fitting of hearing aids, unless the dispensing consists solely of making an exact make and model replacement or spare aid of an immediately preceding hearing aid fitted within the last 12 months.

1. The appropriate hearing test which must precede any hearing aid fitting shall include at a minimum pure tone air conduction and bone conduction thresholds. In such cases, the testing shall be performed under conditions suitable to obtain valid and reliable thresholds.

2. Where indicated, SRT, MCL, TD, speech discrimination and other tests which may be necessary shall be provided by using customary and appropriate instrumentation.

(b) A significant air bone gap as referred to in N.J.S.A. 45:9A-24(f) shall be a gap of 15 db or more measured at 500 HZ, 1,000 HZ or 2,000 HZ. In the event that there is a

gap at any of these frequencies, or higher, the individual shall be referred to a medical doctor. A written waiver of the individual's right to be examined by a medical doctor may be accepted.

Recodified from 13:35-8.11 by R.1994 d.595, effective December 5, 1994.

See: 26 N.J.R. 1301(b), 26 N.J.R. 4780(b).

Petition for Rulemaking.

See: 30 N.J.R. 2528(a).

Recodified from N.J.A.C. 13:35-8.12 by R.1998 d.372, effective July 20, 1998.

See: 30 N.J.R. 1191(a), 30 N.J.R. 2633(a).

Former N.J.A.C. 13:35-8.13, Advertising and Solicitation, was recodified to N.J.A.C. 13:35-8.14.

Petition for Rulemaking.

See: 30 N.J.R. 4294(b).

13:35-8.14 Advertising and Solicitation

(a) Any licensee who engages in the use of advertising, stationery, business cards or signs which contain any of the following shall be deemed to have committed professional misconduct in violation of N.J.S.A. 45:1-21:

1. Any statement, claim or format which is false, fraudulent, misleading or deceptive;

2. Any misrepresentation of material fact;

3. Any omission or concealment of material fact, under circumstances where a licensee knows or should know that the omission is improper or is likely to hamper a customer from making a full and informed judgment on the basis of the information set forth;

4. Any claim that the service performed or the materials used are superior to that which is ordinarily performed or used in the business unless such claim can be documented as truthful and not misleading;

5. A technique or communication which appears to intimidate, exert undue pressure or undue influence on a customer;

6. The use of terms such as "prescription made" and "certified hearing aid audiologist" or "audiologist," unless the person to whom reference made is a licensed audiologist as defined by N.J.S.A. 45:3B-2(a);

7. The use of any term that connotes a medical competence that does not exist; or

8. The use of the name of a temporary licensee or trainee in an advertisement, sign, stationery or business card.

(b) The name, license number and title designation ("Hearing Aid Dispenser") of the supervising licensee shall appear on every advertisement, stationery or business card. The name and title designation of the supervising licensee shall appear on every sign.

(c) The responsibility for the form and content of every advertisement, sign, stationery or business card shall be jointly and severally that of each licensee who is a principal,

partner or officer of the firm or entity so identified as well as the supervising licensee whose name and license number is displayed therein.

(d) It shall be professional misconduct for a licensee to visit the home or office of a potential customer for the purpose of inducing a sale of a hearing aid without having obtained the express prior consent of such potential customer.

Recodified from 13:35-8.12 by R.1994 d.595, effective December 5, 1994.

See: 26 N.J.R. 1301(b), 26 N.J.R. 4780(b).

Petition for Rulemaking.

See: 30 N.J.R. 2528(a).

Recodified from N.J.A.C. 13:35-8.13 by R.1998 d.372, effective July 20, 1998.

See: 30 N.J.R. 1191(a), 30 N.J.R. 2633(a).

Former N.J.A.C. 13:35-8.14, Abandonment; excessive fees, was recodified to N.J.A.C. 13:35-8.15.

13:35-8.15 Abandonment; excessive fees

(a) It shall be professional misconduct for a licensee to unilaterally terminate without good cause as determined by the Committee, an agreement to deliver service(s) and/or equipment to a customer without first making arrangements for the orderly continuation of said services and/or equipment delivery.

(b) It shall be professional misconduct for any licensee to demand or accept excessive fees for service(s) or equipment rendered in connection with the sale or fitting of hearing aids. The excessiveness of such fee shall be determined by the Committee based on whether, after a review of the facts, a reasonable person would be left with a definite and firm conviction that the fee is so high as to be manifestly unconscionable or overreaching under the circumstances and as further described in N.J.A.C. 13:35-6.11(c).

Recodified from 13:35-8.13 by R.1994 d.595, effective December 5, 1994.

See: 26 N.J.R. 1301(b), 26 N.J.R. 4780(b).

Recodified from N.J.A.C. 13:35-8.14 by R.1998 d.372, effective July 20, 1998.

See: 30 N.J.R. 1191(a), 30 N.J.R. 2633(a).

Former N.J.A.C. 13:35-8.15, Itemization of services and equipment; retention of records, was recodified to N.J.A.C. 13:35-8.16.

13:35-8.16 Itemization of services and equipment; retention of records

(a) In addition to the written specified data and receipt requirements defined in N.J.S.A. 45:9A-23, a written itemization of the costs of all services and equipment shall be presented to a customer before dispensing a hearing aid. The itemization shall include all services and equipment including:

1. Hearing test and examination of the ear;
2. Fitting of an earmold;
3. Dispensing services;

4. Necessary cleaning, servicing and refitting for at least the first year following sale;

5. The cost of the earmold; and

6. The cost of the hearing aid.

(b) Every licensee shall prepare and retain a copy of all records including the itemization for a period of seven years following the sale.

(c) Every licensee shall obtain and maintain a medical waiver or medical clearance in accordance with applicable federal law.

(d) Every licensee shall designate his or her name or initials and license number and the date the service was rendered on all records maintained for the purpose of fitting or dispensing hearing aids.

(e) Every licensee shall make available upon the request of the Committee any and all records maintained for the purpose of fitting or dispensing hearing aids. Every customer or authorized representative of the customer shall be promptly given a copy of his or her own record as described in N.J.A.C. 13:35-6.5.

Recodified from 13:35-8.14 by R.1994 d.595, effective December 5, 1994.

See: 26 N.J.R. 1301(b), 26 N.J.R. 4780(b).

Recodified from N.J.A.C. 13:35-8.15 by R.1998 d.372, effective July 20, 1998.

See: 30 N.J.R. 1191(a), 30 N.J.R. 2633(a).

Former N.J.A.C. 13:35-8.16, Licensing examination, was recodified to N.J.A.C. 13:35-8.17.

13:35-8.17 Licensing examination

(a) The licensing examination shall consist of a written and practical examination in accordance with N.J.S.A. 45:9A-11.

(b) The written examination shall contain sections relating to theory and knowledge about fitting and dispensing hearing aids and knowledge relating to the laws and regulations governing the practice of fitting and dispensing hearing aids.

1. In order to pass the licensing examination the candidate shall attain a score of 70 percent or greater on each section.

2. Candidates who fail all or any section of the written examination shall be required to sit for the entire written examination during the next regularly scheduled examination with one exception: candidates failing only the law and regulation section may be admitted to a make-up examination for this section only.

(c) A candidate will only be permitted to take the practical examination if he or she has successfully passed the written examination. In order to pass the practical examination, a candidate shall attain a passing grade on each part of the practical examination. A candidate shall be eligible to re-take the part(s) failed for one additional examination. No passing credit shall be carried over to a third examination and the candidate failing two exam sessions shall be required to take all sections of the examination.

(d) All examinations and re-examinations will be offered only during the regularly scheduled examination session.

Recodified from 13:35-8.15 by R.1994 d.595, effective December 5, 1994.

See: 26 N.J.R. 1301(b), 26 N.J.R. 4780(b).

Recodified from N.J.A.C. 13:35-8.16 by R.1998 d.372, effective July 20, 1998.

See: 30 N.J.R. 1191(a), 30 N.J.R. 2633(a).

Former N.J.A.C. 13:35-8.17, Violation of the Rules, was recodified to N.J.A.C. 13:35-8.18.

13:35-8.18 Violation of the Rules

(a) Failure to comply with any provision of N.J.S.A. 45:9A-1 et seq., or this subchapter shall be deemed a violation of the Hearing Aid Dispensers Act and may result in disciplinary action pursuant to N.J.S.A. 45:1-21 and 45:1-22.

(b) The notice of proposed suspension or revocation shall inform the licensed individual of the right to request a hearing. The hearing shall be pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq. and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1-1 et seq.

Recodified from 13:35-8.16 by R.1994 d.595, effective December 5, 1994.

See: 26 N.J.R. 1301(b), 26 N.J.R. 4780(b).

Amended by R.1995 d.330, effective June 19, 1995.

See: 27 N.J.R. 640(a) (see also 27 N.J.R. 1746(a)), 27 N.J.R. 2410(a). Recodified from N.J.A.C. 13:35-8.17 by R.1998 d.372, effective July 20, 1998.

See: 30 N.J.R. 1191(a), 30 N.J.R. 2633(a).

Former N.J.A.C. 13:35-8.18, Fee schedule, was recodified to N.J.A.C. 13:35-8.19.

13:35-8.19 Fee schedule

(a) The fee schedule for the Hearing Aid Dispensers Examining Committee of the State Board of Medical Examiners, in the Division of Consumer Affairs of the Department of Law and Public Safety, shall be as follows:

1. Application fee: \$20.00 (non-refundable)	
2. Temporary licenses	\$50.00
3. Training permits	\$50.00
4. Examination	
i. Written	\$50.00
ii. Practical	\$25.00
5. Initial Registration Fee	
i. If paid during the first year of a biennial renewal period	\$150.00
ii. If paid during the second year of a biennial renewal period	\$75.00

6. Endorsement	
i. Review of credentials	\$30.00
ii. Endorsement fee	
During the first year of a biennial renewal period	\$110.00
During the second year of a biennial renewal period	\$55.00
7. Biennial registration renewal	\$150.00
8. Renewal or Extension of Temporary License and Training Permit	\$20.00
9. Late fee	\$25.00
10. Reinstatement, Biennial Registration	\$100.00
11. Duplicate or replacement of biennial registration certificate	\$25.00
12. Preparation of certification papers for applicants to other states	\$25.00

(b) The Committee will refund the examination fee only if the application is rejected by the Committee or withdrawn by the applicant within 14 days after the Committee's receipt of the application.

(c) An applicant who fails to sit for an examination for which payment has been submitted may, one time only, have the fee credited toward the next scheduled examination. If the applicant fails to sit for such next scheduled examination, the fee will be forfeited.

R.1977 d.7, effective January 17, 1977.

See: 8 N.J.R. 425(a), 9 N.J.R. 94(c).

Amended by R.1987 d.370, effective September 8, 1987.

See: 19 N.J.R. 1055(a), 19 N.J.R. 1649(a).

Biennial registration raised from \$50.00 to \$80.00; (a)6 and 7 added. Recodified by R.1988 d.112, effective March 7, 1988.

See: 19 N.J.R. 1949(a), 20 N.J.R. 538(a).

Recodified from 8.25.

Amended by R.1991 d.458, effective September 3, 1991.

See: 23 N.J.R. 1895(a), 23 N.J.R. 2651(a).

In (a), substantial alteration of fee schedule. Added (b) and (c).

Recodified from 13:35-8.17 by R.1994 d.595, effective December 5, 1994.

See: 26 N.J.R. 1301(b), 26 N.J.R. 4780(b).

Amended by R.1995 d.330, effective June 19, 1995.

See: 27 N.J.R. 640(a) (see also 27 N.J.R. 1746(a)), 27 N.J.R. 2410(a).

Increased some of the fees.

Recodified from N.J.A.C. 13:35-8.18 by R.1998 d.372, effective July 20, 1998.

See: 30 N.J.R. 1191(a), 30 N.J.R. 2633(a).

Former N.J.A.C. 13:35-8.19, License renewal; continuing education requirement, was recodified to N.J.A.C. 13:35-8.20.

13:35-8.20 License renewal; continuing education requirement

(a) No license renewal shall be issued by the Director unless the applicant confirms on his or her renewal application to the Hearing Aid Dispensers Examining Committee that during the two calendar years preceding application for renewal he or she participated in courses of continuing education of the type and number of credits specified in this section. Such continuing education is a mandatory requirement for license renewal. Licensees shall be solely responsible for obtaining and maintaining documentation on his or her completion of the required continuing education courses during the registration period. Such documentation shall be submitted to the Committee upon request, and will be surveyed on a random basis. The provisions of this subsec-

tion shall not apply to licensees renewing their licenses for the first time.

(b) Evidence of 20 documented course hours of continuing education shall be required of each applicant as a condition of biennial license renewal.

(c) The number of creditable course hours and course contents must be accepted and approved by the National Institute for Hearing Instruments Studies (NIHIS), the educational arm of the National Hearing Aid Society (NHAS), and the Committee except for courses completed through an accredited college or university. A course in hearing aid dispensing creditable by the institution toward three or more credits completed at an accredited college or university shall receive credit for 10 continuing education course hours.

(d) Acceptable continuing education courses shall be in any area which will update and refresh the clinical skills or knowledge of a hearing aid dispenser. Notwithstanding that the continuing education course meets the requirements, the Committee at its discretion may at any time examine and review any course claimed for credit. If, in the opinion of the Committee, such course does not clearly meet the requirements of this section, the course shall be disallowed for credit toward the required 20 continuing education credits.

(e) In the event that a candidate for license renewal shall complete in two years a number of hours in excess of the number of hours required by this section, the documented hours in excess of those required shall not be credited toward license renewal for subsequent years.

New Rule, R.1989 d.548, effective November 6, 1989.
See: 21 N.J.R. 1648(a), 21 N.J.R. 3474(a).
Recodified from 13:35-8.18 by R.1994 d.595, effective December 5, 1994.
See: 26 N.J.R. 1301(b), 26 N.J.R. 4780(b).
Recodified from N.J.A.C. 13:35-8.19 by R.1998 d.372, effective July 20, 1998.
See: 30 N.J.R. 1191(a), 30 N.J.R. 2633(a).

SUBCHAPTER 9. ACUPUNCTURE

13:35-9.1 Purpose and scope

(a) The rules of this subchapter are established pursuant to N.J.S.A. 45:2C-1 et seq. ("The Acupuncture Act") and set forth requirements for the practice of acupuncture in the State of New Jersey.

(b) These rules shall apply to all persons certified as acupuncturists by the State of New Jersey, applicants for such certification, guest acupuncturists granted temporary permission by the Board to perform acupuncture pursuant to N.J.A.C. 13:35-9.12, students participating in an approved course of study, school or tutorial program in acupuncture and persons licensed as physicians and surgeons or dentists who practice acupuncture, provided that their courses of training have included acupuncture.

Amended by R.1999 d.356, effective October 18, 1999.
See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).
Rewrote (b).

13:35-9.2 Definitions

For purposes of this subchapter, the following terms shall have the following meanings:

"Acupuncture" means the stimulation of a certain point or points on or near the surface of the body by the insertion of special needles to prevent or modify the perception of pain or to normalize physiological functions including pain control and for the treatment of certain diseases or dysfunctions of the body. "Acupuncture" includes the techniques electroacupuncture, mechanical stimulation and moxibustion.

"Acupuncture tutorial" means an acupuncture tutorial program which has been approved by the Acupuncture Examining Board and which provides applicants who successfully complete the program with the requirements to sit for the examination for certification as an acupuncturist.

"Apprentice" means a person who is registered with the Board in order to participate in an acupuncture tutorial under a supervising acupuncturist.

"Board" means the Acupuncture Examining Board established by N.J.S.A. 45:2C-1 et seq.

"Certified," "certification," and "certificate" mean Board-issued authorization that an individual possesses the qualifications to engage in the profession of acupuncture. Such terms are synonymous with licensure.

"Electroacupuncture" means the therapeutic use of weak electric currents at acupuncture loci to diagnose or to treat diseases or conditions.

"Experience" means proof that an applicant has accrued full-time independent acupuncture practice experience consisting of at least 750 patient treatment sessions annually for any three-year period prior to January 18, 1986.

"Guest acupuncturist" means an acupuncturist from another state or country who is not a certified acupuncturist in this State and is the invited guest of a professional acupuncture association, scientific acupuncture foundation, or an acupuncture training program approved by the Board.

"Mechanical stimulation" means stimulation of a certain acupuncture point or points on or near the surface of the body by means of apparatus or instrument.

"Moxibustion" means the therapeutic use of thermal stimulus at acupuncture loci by burning artemisia alone or artemisia formulations.

“Sterilize” or “sterilization” means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

“Supervising acupuncturist” or “supervisor” means a certified acupuncturist who is approved by the Board to provide an acupuncture tutorial to a trainee.

“Surface stimulation” means the application of purposeful stimuli to the surface of the body.

“Training agreement” means the written tutorial agreement between the supervisor and the trainee.

“Training plan” means the written tutorial plan that is filed with and approved by the Board.

“Training program” means and encompasses the agreement and the plan.

Amended by R.1999 d.356, effective October 18, 1999.
See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).
Rewrote the section.

13:35-9.3 Credentials required for certification

(a) At the time of application, an applicant shall provide the following credentials:

1. Proof of having attained the age of 21, in the form of a certified copy of birth record;

2. Affidavits from two persons, unrelated to the applicant, attesting to the applicant’s moral character. The signatures on any affidavits emanating from foreign jurisdictions shall be authenticated as required by (a)5i(2) below;

3. Proof of possession of a baccalaureate degree as established by (a)3i and ii below;

i. If the candidate has been awarded a baccalaureate degree from a college or university within the United States, a certified transcript shall be forwarded directly to the Board from the educational institution, which shall have been accredited by a regional accreditation agency recognized by the Commission on Recognition of Post-Secondary Accreditation or the United States Department of Education;

ii. If the candidate has been awarded a baccalaureate degree from a school located outside the United States, which is recognized by the World Health Organization or any similar credentialing organization, the applicant shall submit to the Board an original of the applicant’s transcript showing that a degree was awarded, and an evaluation of credits earned as determined by a Board-approved credential evaluation service. A list of such credential evaluation services shall be provided by the Board to an applicant upon request;

4. Applicants presenting a baccalaureate degree shall also provide evidence of graduation from a course of

study or program at a school of acupuncture accredited by the Accreditation Commission for Acupuncture and Oriental Medicine or by the Commission on Recognition of Post-Secondary Accreditation or the United States Department of Education. Evidence shall consist of a certified transcript from that school confirming that a diploma was awarded to the applicant. A list of approved acupuncture schools shall be maintained by the Board and provided to an applicant upon request.

5. As an alternative to (a)3 and 4 above, an applicant shall provide evidence of either successful completion of a tutorial program in acupuncture which meets the requirements set forth in N.J.A.C. 13:35-9.13 or experience as defined in N.J.A.C. 13:35-9.2 acquired prior to January 18, 1986.

i. Acceptable proof of experience shall include letters from past or present employers written to the Board on professional letterhead, which must be sent directly to the Board from the employer or the appropriate official at that office or institution. Such letters must clearly establish that the business existed and was offering acupuncture service during the period of time in question.

(1) When a letter from an employer, office or institution does not clearly and credibly indicate the required experience, the Board may at its discretion require that the applicant submit patient records of 750 treatment sessions or such other proof as the Board deems necessary.

(2) The signature(s) on letters of documentation emanating from foreign jurisdictions must be properly notarized and authenticated by an appropriate governmental official.

ii. If the applicant was self-employed, original patient records which clearly indicate the required 750 patient treatment sessions shall be submitted to the Board; such records shall be legible and well-organized. The Board may require records to be translated into English at the expense of the applicant; and

6. If the applicant is a physician or surgeon, the applicant shall submit, in addition to the documentation required by (a)1 and 2 above, proof that the applicant holds a current plenary license and registration to practice medicine or surgery.

(b) Any credentials required to be submitted pursuant to (a) above which are written in a language other than English shall be accompanied by an English translation prepared by a Board-approved translation service at the applicant’s expense. A list of such translation services shall be provided by the Board to an applicant upon request. Translations by any other services or persons shall not be accepted.

Amended by R.1999 d.356, effective October 18, 1999.
See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

Rewrote the section.

(3) Renewal, Annually	\$125.00
(4) Delinquency Fee	\$ 50.00
ii. Trainee:	
(1) Application Fee	\$ 25.00
(2) Initial Registration	\$ 60.00
11. Preparation of certification papers for applicants to other states:	\$ 25.00

13:35-9.4 Examination requirements

(a) An applicant shall pass the comprehensive written examination (CWE) and the clean needle technique (CNT) examination, written in English, developed by the National Certification Commission for Acupuncture and Oriental Medicine ("NCCAOM").

(b) An applicant shall pass a practical examination administered by the Board.

(c) All applicants who have received their acupuncture education at a school taught in a language other than English shall pass a test of spoken English (TSE) examination administered by the Education Testing Service (ETS). The applicant shall attain a score of 50.

Amended by R.1999 d.356, effective October 18, 1999.
See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

Rewrote the section.

13:35-9.5 Prohibited titles

(a) A person who has not met the requirements of the Acupuncture Act, N.J.S.A. 45:2C et seq., or this subchapter shall not practice as, or hold himself or herself out as, an acupuncturist.

(b) Acupuncturists shall not use the designations "DOM" (doctor of Oriental medicine), "OMD" (Oriental medical doctor), or "DTCM" (Doctor of traditional Chinese medicine).

(c) Physicians, surgeons, or dentists approved for the practice of acupuncture pursuant to the Act and this subchapter shall not use the title "acupuncturist," "certified acupuncturist," or "CA."

Amended by R.1999 d.356, effective October 18, 1999.
See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

Rewrote the section.

13:35-9.6 Fee schedule

(a) The Board shall charge the following fees:

1. Application Fee	\$ 50.00
2. Examination, Oral/Practical	\$225.00
3. Examination, Written	\$350.00
4. Initial Registration Fee:	
i. If paid during the first year of a biennial renewal period:	\$230.00
ii. If paid during the second year of a biennial renewal period:	\$115.00
5. Biennial Registration	\$230.00
6. Duplicate or replacement of biennial registration certificate	\$ 25.00
7. Late Fee (biennial registration) (up to 60 days)	\$ 50.00
8. Delinquency Fee (61 days or more)	\$150.00
9. Reinstatement Fee	\$150.00
10. Tutorials:	
i. Supervisor:	
(1) Application Fee	\$ 50.00
(2) Initial Registration	\$125.00

(b) If a license lapses due to nonpayment of the biennial registration fee, it may be reinstated within five years, provided that the pertinent delinquency fee and all past due registration fees are submitted with the application.

(c) The examination fee will be refunded only if the application is rejected by the Board or withdrawn by the candidate within 14 days of receipt of the application by the Board.

(d) After the 14-day period in (c) above, an applicant who fails to sit for an examination for which payment has been submitted may, one time only, have the fee credited toward the next scheduled examination. The fee will be entirely forfeited if the applicant fails to sit for the succeeding examination.

(e) The application fee is non-refundable.

Amended by R.1995 d.330, effective June 19, 1995.
See: 27 N.J.R. 640(a) (see also 27 N.J.R. 1746(a)), 27 N.J.R. 2410(a).
Increased some of the fees.

Amended by R.1999 d.356, effective October 18, 1999.
See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

In (a), rewrote the introductory paragraph, and substituted a reference to late fees for a reference to delinquency fees in 7.

13:35-9.7 Term of lawful practice; biennial registration

(a) Licensure as an acupuncturist is not effective until the applicant receives a biennial registration certificate from the Board which signifies completion of all continuing education requirements and payment of the required fees. The certificate shall confer the right to practice acupuncture in the State of New Jersey commencing with the effective date of the certificate and ending on the expiration date of the certificate. The expiration date shall be June 30 of the next year ending with an odd number after the date of issue. The certificate shall be valid for not more than two years.

(b) It shall be an unlawful practice to engage in the practice of acupuncture prior to receipt of the biennial registration, after it has expired, or after the license certificate has been suspended or revoked by order of the Board.

(c) Registration shall be renewed biennially by the licensee on official forms supplied by the Board. Registration will be effective only upon receipt by the Board of a properly completed renewal application form and payment of the required fee as set forth in N.J.A.C. 13:35-9.6(a)5. A renewal application form submitted within 60 days after the biennial registration deadline shall be accompanied by the late fee set forth in N.J.A.C. 13:35-9.6(a) 7. A renewal application form submitted 61 days or more after the biennial registration deadline shall be accompanied by the delinquency fee set forth in N.J.A.C. 13:35-9.6(a)8.

(d) The certificate shall be posted in a conspicuous location in the office of the acupuncturist. If the acupuncturist has more than one office, he or she shall obtain from the Board duplicate certificates for each location.

(e) If the certificate to practice acupuncture in New Jersey lapses for a period of five years or more, the certificate shall be renewed by reapplying to the Board and by complying with N.J.A.C. 13:35-9.3 and 9.4.

Amended by R.1999 d.356, effective October 18, 1999.
See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).
Rewrote the section.

13:35-9.8 Referral; informed consent

(a) A certified acupuncturist may perform initial acupuncture treatment only on presentation by the patient of a referral by or diagnosis from a licensed physician. The referring or diagnosing physician shall provide to the treating acupuncturist a diagnosis and preevaluation of the patient.

(b) The acupuncturist shall fully explain to the patient the acupuncture procedures to be performed and inform the patient of the possible complications that may result from acupuncture treatment. The acupuncturist shall obtain informed written consent from the patient before beginning acupuncture treatment.

Amended by R.1999 d.356, effective October 18, 1999.
See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).
Rewrote the section.

13:35-9.9 Accepted equipment and devices; procedures

(a) Licensees may use any of the following to effect the stimulation of acupuncture points and channels: needles, moxa, cupping, thermal methods, herbal applications, magnetic stimulation, gwa-sha scraping techniques, acupatches, acuform, teishin (pressure needles), manual acutotement (defined as stimulation by an instrument that does not pierce the skin), acupressure, electroacupuncture (whether utilizing electrodes on the surface of the skin or current applied to inserted needles), laser bio-stimulation in accordance with relevant Federal law including United States Food and Drug Administration rules and regulations, and ultrasonic stimulation of acupuncture points and channels.

(b) The needles used in acupuncture shall include: solid filiform needles, dermal needles, plum blossom needles, press needles, prismatic needles and disposable lancets.

(c) The use of intra-dermal needles, staples or hypodermic needles in the practice of acupuncture is prohibited.

Amended by R.1999 d.356, effective October 18, 1999.
See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

In (b), deleted “, but not be limited to” following “include”; and in (c), inserted a reference to intra-dermal needles.

13:35-9.10 Precautionary and sterilization procedures

(a) All non-disposable needles and acupuncture equipment that comes into contact with the patient's blood or bodily fluids or penetrates the skin, and equipment used to handle or store needles or other acupuncture equipment that comes into contact with the patient's blood or bodily fluids or penetrates the skin, shall be sterilized prior to each use. Prior to sterilization, all equipment to be sterilized shall be thoroughly cleaned with a disinfectant or cleansing solution.

(b) Sterilization shall be accomplished before use by one of the following methods:

1. Steam autoclave at 250 degrees Fahrenheit (120 degrees Celsius) and 15 pounds per square inch of pressure for 30 minutes;
2. Equivalent dry heat; or
3. Ethylene oxide gas sterilization.

(c) Sterilization equipment shall be used and maintained strictly in accordance with the guidelines of the manufacturer of the equipment, and shall be monitored regularly in accordance with the manufacturer's guidelines to determine whether the equipment is functioning properly.

(d) The following methods of sterilization are prohibited: boiling acupuncture equipment, soaking acupuncture equipment in alcohol or other antiseptic solution, or glass bead sterilization.

(e) Acupuncture needles shall be placed in a rigid, puncture-proof, sealed container. The container shall be labeled as a disposal container and shall contain the following warning: “CONTAMINATED CONTENTS—USE PRECAUTIONS.” The disposal container shall be wiped with a disinfectant if blood or other bodily fluids are spilled on the outside of the container. The acupuncturist shall dispose of the container pursuant to the requirements of the Department of Environmental Protection implementing the Comprehensive Regulated Medical Waste Management Act, N.J.S.A. 13:1E-48.1 et seq., and N.J.A.C. 7:26-3A. The acupuncturist may delegate the responsibility to dispose of the container to an agent approved by the Department of Environmental Protection. A list of such approved agents shall be supplied, upon request, by the Board.

(f) If a licensee learns that a patient has a blood-borne infectious disease, the licensee shall use only disposable needles in treating the patient.

(g) The acupuncturist shall ensure that personnel responsible for performing sterilization procedures pursuant to this rule are adequately trained and supplied with a written outline of sterilization procedures. A copy of the outline shall be maintained on the premises.

Amended by R.1999 d.356, effective October 18, 1999.

See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

In (c), substituted a reference to equipment for a reference to instruments; rewrote (d) and (e); in (f), deleted "in the course of treatment of a patient," following "If", and deleted "highly" following "blood-borne"; and in (g), substituted "The acupuncturist shall" for "It shall be the responsibility of the certified acupuncturist to" at the beginning.

13:35-9.11 Preparation of patient records; computerized records; access to or release of information; confidentiality, transfer or disposal of records

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

1. "Authorized representative" means 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) shall be deemed to be an authorized representative.

2. "Patient" means any person who is the recipient of a professional service rendered by a licensee for purposes of treatment.

(b) Acupuncturists shall prepare contemporaneous, permanent professional treatment records. Acupuncturists 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. Progress notes; and
- v. Any orders for tests or consultations and the results thereof.

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

3. A patient record which is prepared and maintained on a personal or other computer shall be prepared and maintained as follows:

- 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. The entry made by the acupuncturist shall be made contemporaneously with the treatment and shall contain the date of service, date of entry, and full printed name of the treatment provider. The acupuncturist shall finalize or "sign" the entry by means of a confidential personal code ("CPC") and include date of the "signing";

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

iv. The computer 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 computer 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 acupuncturist is authorized to make entries into the computer file of any professional treatment record, the acupuncturist responsible for the acupuncture 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 to a physician responsible for the patient's care, to a representative of the Board of Acupuncture Examiners, the Attorney General or the Division of Consumer Affairs no later than 10 days after notice, or to a patient within 30 days of the request, or promptly in the event of emergency.

viii. An acupuncturist 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 shall be completed by October 18, 2000. In the interim, the acupuncturist shall assure that, on the date of the first treatment of each patient treated subsequent to October 18, 1999, 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 acupuncturist. 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 acupuncturist. The initial printout and the subsequent hard copies shall be retained as a permanent part of the patient record.

(c) Acupuncturists 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 acupuncturist 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, as applicable, and subjective information.

2. Unless otherwise required by law, an acupuncturist 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. An acupuncturist 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)3 below for that specific record.

3. Acupuncturist may require that a record request 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 licensee elects 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.

4. 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 acupuncturist shall provide a transcription at no cost to the patient.

5. The acupuncturist 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) Acupuncturists shall maintain the confidentiality of professional treatment records, except that:

1. The acupuncturist shall release patient records as directed by a subpoena issued by the Board of Acupuncture 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 acupuncturist, upon request, shall provide a typed transcription of the record. If the record is in a language other than English, the acupuncturist shall also provide a translation.

2. The acupuncturist shall release information as required by law or regulation.

3. The acupuncturist, 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 acupuncturist in his or her rendition of professional services.

(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 acupuncturist 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) If an acupuncturist ceases to engage in practice or it is anticipated that he or she will remain out of practice for more than three months, the acupuncturist 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 who is assuming responsibilities of the practice. However, an acupuncturist shall not charge a patient, pursuant to (c)3 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 acupuncturist'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.1999 d.356, effective October 18, 1999.

See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

Section was "Patient records".

13:35-9.12 Guest acupuncturist

(a) An acupuncturist from another state or country, who is not a certified acupuncturist or a physician approved for the practice of acupuncture in the State of New Jersey, and is the invited guest of a professional acupuncture association, scientific/acupuncture foundation, an acupuncture training program or acupuncture school approved by the Board, may perform acupuncture in conjunction with such professional education for up to 30 days in a calendar year upon approval by the Board, as set forth in (b) below. The guest acupuncturist shall not open an office or appoint a place to meet patients or receive calls from patients or otherwise engage in the practice of acupuncture.

(b) The sponsoring organization shall request permission from the Board, in writing, for the guest acupuncturist no later than 60 days prior to the guest acupuncturist's initial presentation in New Jersey. A resume or summary of the guest acupuncturist's credentials, written in English, shall accompany the request for approval.

Amended by R.1999 d.356, effective October 18, 1999.

See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

Rewrote (a).

13:35-9.13 Tutorial applications and design of tutorial program

(a) No person shall commence participation in a tutorial program in acupuncture in this State without prior approval of the Board.

(b) Tutorial applications shall be filed with the Board as follows:

1. Application as an acupuncture apprentice shall be filed on a form provided by the Board and accompanied by the tutorial apprentice application fee. The information to be provided on the application form shall include personal biographical and educational information and current resident status.

2. Applications for approval to supervise an acupuncture apprentice shall be filed on a form provided by the Board and accompanied by a copy of the written apprentice agreement, the tutorial supervision application fee, and any other pertinent documents required by the Board. The information to be provided on the application shall include personal biographic, educational and experiential requirements.

(c) Evidence of prior training and experience shall be submitted to the Board for its review with the applications for registration of the supervising acupuncturist and apprentice.

(d) The apprentice shall be at least 18 years of age and shall have a minimum of 120 credits at an institution of higher learning, which must be accredited by a regional accreditation agency recognized by the Commission on Recognition of Post-Secondary Accreditation or the United States Department of Education.

(e) Requirements for approval of an acupuncture tutorial program are as follows:

1. An acupuncture tutorial program shall be designed to be completed in no less than two nor more than four calendar years;

2. An acupuncture tutorial program shall be designed to provide an apprentice with a structured learning experience in all the basic skills and knowledge necessary for the independent practice of acupuncture, and shall prepare the apprentice for the Board's examination for certification;

3. Acupuncture tutorial programs may be full-time or part-time relationships; the training plan and proposed supervision shall be contained in a written agreement between the supervisor and apprentice, pursuant to (g) below;

4. An acupuncture tutorial shall provide formal clinical training with supplemental theoretical and didactic instruction which may be obtained in a post-secondary educational institution which is accredited by a regional accreditation agency recognized by the Commission on Recognition of Post-Secondary Accreditation, or the United States Department of Education;

5. The clinical training shall consist of a minimum of 1650 hours in the following areas:

- i. Practice observation;
- ii. Patient history and physical examination, including traditional Oriental medical diagnostic procedures;
- iii. Therapeutic treatment planning;
- iv. Preparation of the patient;
- v. Sterilization, use and maintenance of equipment;
- vi. Moxibustion;
- vii. Electroacupuncture;
- viii. Body and auricular acupuncture;
- ix. Treatment of emergencies, including certification in cardiopulmonary resuscitation ("CPR");
- x. Pre and post-treatment and instructions to the patient;
- xi. Contraindications and precautions; and
- xii. Optional: Shiatsu, Acupressure, TaiChi-Chuan and Qi Gong; and

6. The theoretical and didactic training shall consist of a minimum of 600 hours in the following areas:

- i. Traditional Oriental medicine;
- ii. Acupuncture anatomy and physiology;
- iii. Acupuncture techniques;
- iv. Survey of clinical medicine;
- v. History of Chinese medicine; and
- vi. Study of medical terminology and general sciences in anatomy, physiology and pathology, which training shall be obtained in a post-secondary educational setting approved by a regional accreditation agency recognized by the Commission on Recognition of Post-Secondary Accreditation, or the United States Department of Education, provided that each of the courses is for at least three academic credits.

(f) No apprentice shall be authorized to render acupuncture services to any patient unless the patient has been informed that such services will be rendered by an apprentice. The patient, on each occasion of treatment, shall be informed of the procedure to be performed by the apprentice under the supervision of the supervising acupuncturist, and shall have consented in writing prior to the initial rendering of the acupuncture procedure by the apprentice. The requirements of this subsection do not apply to those instances wherein the apprentice merely assists the supervisor in the rendering of acupuncture services.

(g) The acupuncture tutorial training program shall be set forth in a written agreement signed by the supervisor and the apprentice which shall be submitted for approval to the Board, with the application. The agreement shall include:

1. The training plan;
2. The length of training time;
3. The method of providing the theoretical and didactic training;
4. Guidelines for supervision of the acupuncture services rendered by the apprentice;
5. Tuition fees to be paid by the apprentice for participation in the program;
6. The location of the training; and
7. Any termination agreements included in the agreement between the supervisor and apprentice.

(h) An acupuncture tutorial program shall be available to all apprentices regardless of the apprentice's sex, race, religion, creed, or color and regardless of physical handicap.

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.1999 d.356, effective October 18, 1999.
See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).
Rewrote the section.

13:35-9.14 Responsibilities of supervising acupuncturist

(a) No acupuncturist shall supervise any person in an approved tutorial program in acupuncture in this State without prior approval of the Board. Board approval shall be contingent upon submission of proof satisfactory to the Board that the supervising acupuncturist is certified to practice in New Jersey and has at least seven years of experience practicing acupuncture.

(b) The supervising acupuncturist shall have the following duties and responsibilities:

1. The supervisor shall train no more than two apprentices at one time;
2. The supervisor shall at all times be responsible for and provide supervision of the work performed by the apprentice as required in this subchapter;

3. The supervisor shall assign only those patient treatments which are unlikely to endanger the health and welfare of patients receiving such services and can be safely and effectively performed by the apprentice. The acupuncture services assigned to the apprentice shall be consistent with the level of training received by the apprentice. The supervisor shall provide continuous direction and immediate supervision of the apprentice when patient services are being provided. For purposes of this paragraph, "continuous direction and immediate supervision" means that the supervisor shall be in the same facility where the apprentice is rendering services, and shall be readily available at all times to provide advice, instruction and assistance to the apprentice and the patient;

4. The supervisor shall assure that prior to performance of any procedure, a verbal explanation is given and the patient's written informed consent to the procedure and its performance by the apprentice is obtained;

5. The supervisor shall assure that the objectives of the training plan submitted to the Board are provided and met by the apprentice;

6. The supervisor shall notify the Board in writing within 10 days of the termination of any training agreement. At the time of such notification, the registration of the apprentice shall be cancelled;

7. If the apprentice plan of the acupuncture tutorial is substantially modified, the supervisor shall file with the Board a report of such modifications within 10 days;

8. The supervisor shall assure that the apprentice complies with accepted standards of practice, this subchapter, and the statutory requirements of N.J.S.A. 45:2C-5;

9. The supervisor shall file a progress report with the Board within 30 days of completion by each apprentice of each year of an approved acupuncture tutorial. The supervisor shall file a final report within 30 days of completion of the training; and

10. The supervisor shall assure that when rendering services or otherwise engaging in professional activity, the apprentice shall always identify himself or herself as an acupuncture apprentice.

Amended by R.1999 d.356, effective October 18, 1999.
See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).
Rewrote (b).

13:35-9.15 Responsibilities of the acupuncture apprentice

(a) The acupuncture apprentice shall have the following duties and responsibilities:

1. The apprentice shall not provide acupuncture services independently or without the required supervision, and shall not provide any services for which he or she is not trained or undergoing training;

2. The apprentice shall satisfactorily meet the objectives of the training plan submitted to the Board including the necessary theoretical training;

3. The apprentice shall comply with the standards of practice in these rules as well as all applicable statutory requirements;

4. The apprentice shall always identify himself or herself as an acupuncture apprentice when rendering services or otherwise engaging in professional activity;

5. The apprentice shall report to the Board any delay, interruption or termination of the acupuncture tutorial within 10 days; and

6. At the completion of the tutorial, the apprentice may file an application for examination.

Amended by R.1999 d.356, effective October 18, 1999.

See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

In (a), substituted references to apprentices for references to trainees throughout, substituted "undergoing training" for "being trained to competently perform" at the end of 1, and substituted "within 10 days" for "not reported by the supervisor" following "tutorial" in 5.

13:35-9.16 Training required of a physician or dentist

(a) No physician holding a plenary license from the New Jersey Board of Medical Examiners or dentist licensed by the New Jersey Board of Dentistry shall be prevented from practicing acupuncture provided his or her course of training has included:

1. Graduation from a school approved by the Accreditation Commission of Acupuncture and Oriental Medicine (ACAOM); or

2. Courses of training approved by the Board, as set forth in (b) below.

(b) The course of training shall be for a minimum of 300 hours, which shall include a clinical training program of at least 150 hours. Such United States or foreign training shall include:

1. Traditional Oriental medicine which includes a survey of the theory and practice of traditional diagnostic and therapeutic procedures;

2. Acupuncture anatomy and physiology which includes fundamentals of acupuncture including point location, the meridian system, special and extra loci, and auriculotherapy; and

3. Acupuncture techniques such as instruction in the use of needling techniques, moxibustion and electroacupuncture, including precautions such as sterilization of needles, contraindications and complications.

Petition for Rulemaking.

See: 25 N.J.R. 3243(a), 25 N.J.R. 4338(b).

Amended by R.1999 d.356, effective October 18, 1999.

See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

In (a), substituted a reference to the Accreditation Commission of Acupuncture and Oriental Medicine for a reference to the National Accreditation Commission of Schools and Colleges of Acupuncture and Oriental Medicine in 1, deleted a former 2, and rewrote former 3 as 2; and in (b), inserted "which includes" following "medicine" in 1, inserted "which includes" following "physiology" in 2, and inserted "such as" following "techniques" in 3.

13:35-9.17 Continuing professional education requirements

(a) The provisions of this section shall apply to all acupuncturists applying for biennial registration renewal except those seeking renewal for the first time.

(b) No registration renewal shall be issued by the Board unless the acupuncturist confirms on his or her renewal application that during the two calendar years preceding application for renewal the acupuncturist participated in courses or activities of continuing education of the type and number of credits specified in this section. Evidence of 20 documented hours of continuing education is a mandatory requirement for license renewal, except for initial renewal.

1. "Documented" means that the applicant obtains:

i. A certificate of participation;

ii. A signed document by the instructor indicating attendance; or

iii. An official transcript from an accredited local, state or national organization or learning institution, as set forth in (d) below.

2. A licensee shall obtain and maintain, for a period of three years, documentation on his or her completion of the required continuing education courses. Such documentation shall be submitted to the Board upon request, and will be surveyed from time to time.

(c) Credit for continuing professional education shall be granted as follows for each two-year period:

1. Publication in a national professional journal of an article on acupuncture: three hours per article to a maximum of six hours;

2. Attendance at seminars and conferences: one hour per contact hour;

3. Successful completion of graduate course work taken beyond that required for professional license; one hour per credit hour; and

4. Teaching courses or seminars related to the practice of acupuncture: one hour per contact hour to a maximum of six hours.

(d) Acceptable continuing professional education courses or activities shall be in any subject area which will update and refresh the clinical skills or knowledge of an acupuncturist. However, courses must be accredited by ACAOM, the New Jersey Department of Higher Education, a regional accreditation agency recognized by the Commission on Recognition of Post-Secondary Accreditation, or the United States Department of Education. Seminars and conferences must be accredited or sponsored by a local, State, or national professional organization; a local, State or Federal education or health agency; or a local, State or national medical, psychological, dental or similar professional organization.

(e) Credits taken in excess of the 20 required for biennial registration renewal shall not be carried over for use in subsequent renewal periods.

(f) The Board may, at its discretion, waive continuing education requirements on an individual basis for reasons of hardship such as illness, disability, active service in the military, or other good cause. An acupuncturist who seeks a waiver of the continuing education requirements shall provide to the Board, in writing, the specific reasons for requesting the waiver and such additional information as the Board may request in support of the waiver.

Amended by R.1999 d.356, effective October 18, 1999.

See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

Rewrote the section.

APPENDIX A

(RESERVED)

Repealed by R.1999 d.356, effective October 18, 1999.

See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

SUBCHAPTER 10. ATHLETIC TRAINERS

13:35-10.1 Scope and purpose

(a) This subchapter is promulgated by the New Jersey State Board of Medical Examiners, pursuant to N.J.S.A. 45:9-37.35 et seq., providing for the licensure and regulation of athletic trainers within the State of New Jersey.

(b) The rules contained in this subchapter shall apply to all individuals currently practicing as athletic trainers, as well as those individuals studying to become athletic trainers within this State and applicants for licensure. The rules are designed to better define the allowable activities, professional standards, and the educational requirements of athletic trainers.

Amended by R.2004 d.273, effective July 19, 2004.

See: 35 N.J.R. 2834(a), 36 N.J.R. 3400(a).

In (a), substituted "licensure" for "registration" preceding "and regulation"; in (b), inserted "and applicants for licensure" following "athletic trainers within this State".

13:35-10.2 Definitions

The following words and terms, as used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Advisory Committee" means the Athletic Training Advisory Committee established under N.J.S.A. 45:9-37.39.

"Athlete" means an individual who participates in an inter-scholastic, intercollegiate or intramural athletic activity

being conducted by an educational institution licensed in the State of New Jersey or a professional athletic activity.

"Athletic trainer" means a person who practices athletic training as an employee of a school, college, university or professional athletic team.

"Athletic training" means the practice of physical conditioning and reconditioning of athletes, the prevention of injuries incurred by athletes and at the direction of a physician licensed in the State of New Jersey, the application of physical treatment modalities to athletes as recommended by the Advisory Committee and defined in N.J.A.C. 13:35-10.4(c).

"Board" means the State Board of Medical Examiners.

"Direction of a licensed physician" means the designing and overseeing of a plan of care for the athlete by a physician licensed in the State of New Jersey (M.D., D.O., D.C., D.P.M.) within his or her permitted scope of practice as specified by N.J.S.A. 45:9-5.1, N.J.S.A. 45:9-14.5, N.J.S.A. 45:9-41.27, N.J.S.A. 45:5-7.

"Non-injured athlete" means an athlete who has not sustained an injury or who has received medical clearance from a physician licensed in the State of New Jersey for full participation after injury/illness.

"Professional athletic team" means any team, group or individual athlete paid to perform at athletic events and activities.

Amended by R.2004 d.273, effective July 19, 2004.

See: 35 N.J.R. 2834(a), 36 N.J.R. 3400(a).

Rewrote "Athletic training".

13:35-10.3 Application for licensure

(a) An applicant for athletic trainer licensure shall submit to the Board:

1. A completed application form;
2. Proof that the applicant has completed a program of education, training and experience which is approved by the National Athletic Trainers' Association Board of Certification, Inc., or its successor;
3. Proof that the applicant has passed the examination administered by the National Athletic Trainers' Association Board of Certification, Inc., or its successor, or an equivalent examination as adopted by the Board; and
4. The application fee pursuant to N.J.A.C. 13:35-10.6.

Amended by R.2004 d.273, effective July 19, 2004.

See: 35 N.J.R. 2834(a), 36 N.J.R. 3400(a).

Rewrote the section.

13:35-10.4 Approved activities

(a) A licensed athletic trainer may provide the full spectrum of pre-season, in-season and post-season conditioning programs. These programs include maintenance and reconditioning programs, as well as bandaging, wrapping, taping, padding, and splinting procedures for the prevention and management of injuries.

(b) Nothing in this subchapter shall be interpreted to prohibit licensed athletic trainers from providing first-aid.

(c) A licensed athletic trainer may, at the direction of a licensed physician, administer the following physical treatment modalities:

1. Cold;
2. Heat;
3. Light;
4. Sound;
5. Electricity;
6. Electromagnetic waves;
7. Water; and
8. Traditional mobilization techniques, rehabilitative exercise programs, traction, and massage.

(d) A licensed athletic trainer may, at the direction of a licensed physician, provide testing or neuromotor and musculoskeletal functional capability for the purposes of conditioning, reconditioning or otherwise evaluating the athlete's performance capability. However, nothing in this subchapter shall be interpreted to permit a licensed athletic trainer to conduct electromyographic testing or nerve conduction velocity studies.

(e) The licensed athletic trainer shall not diagnose an injury or illness. However, prior to implementing or while maintaining the plan of care, the licensed athletic trainer shall exercise professional judgment to determine whether any intervening circumstances have adversely affected the athlete's ability to participate in or continue to participate in the plan of care.

(f) A written record regarding the treatment of an athletic injury shall be created by the licensed athletic trainer and maintained for a period of seven years from the date of the last entry.

(g) Nothing in this subchapter shall be interpreted to prohibit licensed athletic trainers from being employed or performing activities which do not require licensure or registration provided they do not hold themselves out as athletic trainers during that employment or performance.

(h) Nothing in this section shall be interpreted to prohibit unlicensed individuals from applying bandaging, wrapping, taping, padding or splinting techniques to non-injured athletes.

Recodified from N.J.A.C. 13:35-10.6 and amended by R.2004 d.273, effective July 19, 2004.

See: 35 N.J.R. 2834(a), 36 N.J.R. 3400(a).

Rewrote the section. Former N.J.A.C. 13:35-10.4, Examinations, repealed.

13:35-10.5 Violations

Without limiting the prosecution of any practices which may be unlawful under any other state or Federal law, a violation of this subchapter shall be deemed to be a violation of the Athletic Training Licensure Act, N.J.S.A. 45:37-35 et seq., and shall be subject to the sanctions and penalties of N.J.S.A. 45:1-1 et seq.

Recodified from N.J.A.C. 13:35-10.7 and amended by R.2004 d.273, effective July 19, 2004.

See: 35 N.J.R. 2834(a), 36 N.J.R. 3400(a).

Substituted "Licensure" for "Practice" and " of N.J.S.A. 45:1-1 et seq." for "provided for thereunder".

13:35-10.6 Fees

(a) The following fees shall be charged by the Board for athletic trainer licensure:

1. Temporary licensure or authorized licensure without examination\$60.00
2. Initial Licensure Fee
 - i. If paid during the first year of a biennial renewal period\$70.00
 - ii. If paid during the second year of a biennial renewal period\$35.00
3. Biennial renewal\$70.00
4. Endorsement\$60.00
5. Late renewal fee\$50.00

Recodified from N.J.A.C. 13:35-10.8 and amended by R.2004 d.273, effective July 19, 2004.

See: 35 N.J.R. 2834(a), 36 N.J.R. 3400(a).

Rewrote the section. Former N.J.A.C. 13:35-10.6, Approved activities, recodified to N.J.A.C. 13:35-10.4.

13:35-10.7 (Reserved)

Repealed by R.2004 d.273, effective July 19, 2004.

See: 35 N.J.R. 2834(a), 36 N.J.R. 3400(a).

Former N.J.A.C. 13:35-10.7, Violations, recodified to N.J.A.C. 13:35-10.5.

13:35-10.8 (Reserved)

New Rule, R.1993 d.260, effective June 7, 1993.

See: 25 N.J.R. 1058(a), 25 N.J.R. 2487(a).

Administrative Correction.

See: 25 N.J.R. December 6, 1993.

Amended by R.1995 d.330, effective June 19, 1995.

See: 27 N.J.R. 640(a) (see also 27 N.J.R. 1746(a)), 27 N.J.R. 2410(a).

Increased some of the fees.

Repealed by R.2004 d.273, effective July 19, 2004.

See: 35 N.J.R. 2834(a), 36 N.J.R. 3400(a).

Former N.J.A.C. 13:35-10.8, Fees, recodified to N.J.A.C. 13:35-10.6.

SUBCHAPTER 11. ALTERNATIVE RESOLUTION PROGRAM

13:35-11.1 Definitions

As used in this subchapter the following words and terms have the following meanings, unless the context indicates otherwise:

“Alternative Resolution Program” or “ARP” means a program established pursuant to this subchapter for those subject to Board jurisdiction who are suffering from chemical dependencies and other impairments which shall permit

such licensees to disclose their status to an entity which would allow for confidential oversight.

“Board” means the New Jersey State Board of Medical Examiners.

“Chemical dependency” means a condition involving the continued misuse of chemical substances.

“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.