CHAPTER 35

BOARD OF MEDICAL EXAMINERS

Authority

N.J.S.A. 26:6A-1 et seq., specifically 26:6A-4; 45:1-15.1 and 45:9-2.

Source and Effective Date

R.2005 d.120, effective March 17, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).

Chapter Expiration Date

Pursuant to Executive Order No. 1(2010), the chapter expiration date is extended from March 17, 2010 until the completion of the review of administrative regulations and rules by the Red Tape Review Group, and until such time as the extended regulation or rule is readopted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. See: 42 N.J.R. 1310(a).

Chapter Historical Note

Chapter 35, Board of Medical Examiners, was adopted 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Chapter 35, Board of Medical Examiners, was repealed and Chapter 35, Board of Medical Examiners, was adopted as new rules by R.1983 d.314, effective August 1, 1983.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 September 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Examiners, was readopted as R.1994 d.522, effective September 19, 1994, and Subchapter 7, Chiropractic Practice, was repealed by R.1994 d.522, effective October 17, 1994.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: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).

Subchapter 12, Electrologists Advisory Committee; Licensure of Electrologists and Electrology Instructors; Electrology Standards of Practice, was adopted as R.2004 d.279, effective July 19, 2004. See: 35 N.J.R. 3263(a), 36 N.J.R. 3401(a).

Subchapter 13, Perfusionists, Advisory Committee, was adopted as R.2005 d.88, effective March 7, 2005. See: 36 N.J.R. 1721(a), 37 N.J.R. 782(a).

Chapter 35, Board of Medical Examiners, was readopted as R.2005 d.120, effective March 17, 2005. See: Source and Effective Date. See, also, section annotations.

Subchapter 6A, Declarations of Death Upon the Basis of Neurological Criteria, was repealed and Subchapter 6A, Declarations of Death Upon the Basis of Neurological Criteria, was adopted as new rules by R.2007 d.120, effective May 7, 2007. See: 38 N.J.R. 2021(a), 39 N.J.R. 1751(a).

Subchapter 1, Medical Schools, Colleges, Externships, Clerkships And Post-Graduate Work, was renamed Medical Schools, Colleges, Externships and Clerkships; and Subchapter 3, Licensing Examinations and Endorsements, Limited Exemptions from Licensure Requirements, was renamed Licensing Examinations and Endorsements, Limited Exemptions from Licensure Requirements; Post-Graduate Training by R.2008 d.100, effective April 21, 2008. See: 39 N.J.R. 3876(a), 40 N.J.R. 2115(a).

Law Review and Journal Commentaries

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

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SUBCHAPTER 1. MEDICAL SCHOOLS, COLLEGES, EXTERNSHIPS AND CLERKSHIPS

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".

Case Notes

Regulations relied upon by the State, such as N.J.A.C. 8:39-11.2, to establish a standard of care were never part of the Board of Medical Examiners regulations, and were never administered by the Board of Medical Examiners; in view of this, the physician licensee's failure to comply with these regulations did not constitute professional misconduct in violation of N.J.S.A. 45:1-21(e) and/or repeated acts of negligence in violation of N.J.S.A. 45:1-21(d). In re Suspension or Revocation of License of Anama, OAL Dkt. No. BDS 2628-02, 2007 N.J. AGEN LEXIS 394, Initial Decision (June 11, 2007).

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 (Reserved)

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.
Recodified to N.J.A.C. 13:35-3.15 by R.2008 d.100, effective April 21, 2008.
See: 39 N.J.R. 3876(a), 40 N.J.R. 2115(a).
Section was "Postgraduate training".

Case Notes

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

13:35–1.4 Military service in lieu of M.D. or D.O. internship or postgraduate training

The Board may grant a license to practice medicine and surgery to any person who shall furnish proof, satisfactory to the Board, that such person has fulfilled all of the formal requirements established by law, and who has served at least two years in active military service in the United States Army, Air Force, Navy, Marine Corps, Coast Guard or the U.S. Public Health Service as a commissioned officer and physician and surgeon in a medical facility which the Board determines constitutes the substantial equivalent of the approved internship or residency training program required by law; provided, however, that such military service actively occurred subsequent to graduation from an approved medical school.

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 N.J.S.A. deleted and replaced with word "law".

13:35–1.5 Registration and permit requirements for graduate medical education programs in medicine or podiatry

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

"Applicant" means a graduate of a medical or podiatric school, unlicensed in this State, seeking authorization to engage in the practice of medicine or podiatry as a resident in a graduate medical education program. A registration applicant is seeking authorization to participate in the first year of a graduate medical education program. A permit applicant is seeking authorization to participate in his or her second year (or beyond) of a graduate medical education program.

"Director" means a physician holding a plenary license to practice medicine and surgery in New Jersey who is responsible for the conduct of a graduate medical education program at a hospital licensed in this State and whose responsibilities shall include generally overseeing the selection, training and evaluation of residents. With respect to graduate medical education programs in podiatry, the director shall be a podiatric physician licensed to practice podiatry in New Jersey.

"Graduate Medical Education Program" means an education program, whether denominated as an internship, residency, or fellowship, which is accredited by the Accreditation Council on Graduate Medicine Education (ACGME) or by the American Osteopathic Association (AOA) in which the graduates of medical schools participate for a limited period of time under the supervision of plenary licensed physicians. With respect to podiatry, "Graduate Medical Education Program in Podiatry" means an education program, whether denominated as an internship, residency, or fellowship, which is accredited by the Council on Podiatric Medical Education of the American Podiatric Medicine Association (APMA) in which the graduates of podiatric schools participate for a limited period of time under the supervision of a licensed podiatric physician.

"Master list" means a list prepared by the director setting forth the name of each person seeking to practice medicine or podiatry in that graduate medical education program in New Jersey, designating the date of birth and medical or podiatric schools attended.

"Permit" means a document issued by the New Jersey State Board of Medical Examiners authorizing the holder to engage in the practice of medicine or podiatry in the second year of a graduate medical education program (or beyond) in medicine or podiatry in this State, subject to the limitations set forth in this rule.

"Permit holder" means a person authorized to engage in the practice of medicine or podiatry, as appropriate, while in the second year or beyond of a graduate medical education program in medicine or podiatry in the State of New Jersey, subject to the limitations set forth in this rule.

"Registered resident" means an applicant granted authorization to engage in the practice of medicine or podiatry in the State of New Jersey in the first year of a graduate medical education program, subject to the limitations set forth in this rule.

"Registration" means authorization to engage in the practice of medicine or podiatry in this State in the first year of a graduate medical education program subject to the limitations set forth in this rule.

"Resident" means a participant in training in a graduate medical education program in medicine or in podiatry at a licensed hospital in this State. For purposes of this rule, persons serving in internships and fellowships shall be deemed residents.

(b) No unlicensed person shall engage in the practice of medicine or podiatry in the first year of a graduate medical education program unless and until he or she is registered with the Board. No unlicensed person shall engage in the practice of medicine or podiatry in the second year of graduate medical education or beyond unless or until he or she has been issued a permit by the Board.

(c) A registration applicant shall certify that he or she:

1. Has attained the preliminary educational prerequisites for licensure, including:

i. Completion of at least 60 undergraduate level credits, at a college or university attained prior to medical or podiatric school. With respect to medical residents, the credits shall include at least one course each in biology, chemistry and physics.

ii. With respect to medical residents, graduation from a medical school which, during each year of attendance, was either accredited by the Liaison Committee on Medical Education (LCME) or the American Osteopathic Association (AOA) or listed in the World Directory of Medical Schools and that the didactic training was completed in the jurisdiction where the school is authorized to confer a medical degree. If the applicant has attended more than one medical school, he or she shall certify that each school attended was accredited or listed in the World Directory of Medical Schools during the same time he or she was matriculated.

iii. With respect to podiatry residents, graduation from a college of podiatric medicine accredited by the Council on Podiatric Medical Education (CPME) of the American Podiatric Medicine Association (APMA). If the applicant has attended more than one college of podiatric medicine, he or she shall certify that each school attended was accredited or listed.

iv. Attendance at medical or podiatric school for at least 32 months prior to graduation.

v. With respect to medical students, where clinical clerkships have been completed away from the site of a medical school not approved by the LCME or AOA, satisfactory completion of clinical clerkships of at least four weeks duration each in internal medicine, surgery, obstetrics and gynecology, pediatrics and psychiatry at hospitals which maintained at the time of the clerkship a graduate medical education program in that field accredited by the LCME or the AOA;

2. Has never:

i. Been the subject of an administrative disciplinary proceeding by any state professional licensing agency;

ii. Been convicted of a criminal offense of any grade or admitted to a pre-trial diversionary program;

iii. Been denied licensure eligibility to sit for an examination or eligibility to participate in a postgraduate training program in this or any other state;

iv. Had privileges at a hospital terminated or curtailed for cause;

v. Been asked to resign from a graduate medical education program or hospital staff;

vi. Had privileges to prescribe controlled dangerous substances curtailed or limited by any regulatory authority; and

vii. Had privileges to participate in any state or Federal medical assistance program (Medicare, Medicaid) curtailed or limited by any regulatory authority;

3. Is not, at the time that the certification is executed, the subject of an administrative disciplinary proceeding by any state professional licensing agency, or other Federal or state regulatory authority (such as the U.S. Drug Enforcement Agency, Medicare or Medicaid), or the subject of any criminal proceeding (under arrest, indictment or accusation);

4. Is not physically or mentally incapacitated to a degree which would impair his or her ability to practice medicine or podiatry, as applicable, and is not at the time of application habituated to alcohol or a user of any controlled dangerous substance except upon good faith prescription of a physician; and

5. Has obtained ECFMG or Fifth Pathway certification, if he or she is a graduate of a foreign medical school.

(d) The Director shall obtain a registration form from each registration applicant and shall retain those forms, which may be subject to review by the Board. The Director shall certify that he or she has personally reviewed the registration form of each registration applicant who has accepted an offer of employment to ascertain that the registration applicant has certified that he or she has attained the prerequisites set forth in (c) above and that the Director is unaware of any information which would contradict any of the representations contained in that registration application form. If the Director shall have reason to question the veracity or reliability of those representations, he or she shall direct the registration applicant to supply the supporting documentation. The Director shall prepare a master list which contains the names of all registration applicants and the names and addresses of the institutions from which the applicants graduated and shall submit the master list to the Board, along with his or her certification, no later than one month before the registration applicants are to begin participating in the graduate medical education program.

(e) The Board shall review the Director's certification, and shall issue to the Director a list of residents registered to engage in the practice of medicine or podiatry in the first year of the graduate medical education program conducted by that hospital. The Board shall provide to the Director a permit application for dissemination to each registered resident.

(f) A registration applicant unable to certify that he or she has attained the prerequisites set forth at (c) above shall state on the registration application form the reason that he or she is unable to so certify. The Director seeking to offer employment to a registration applicant unable to certify that he or she has attained all the prerequisites, may seek from the Board a waiver which would enable the applicant to participate in the first year of a graduate medical education program. The Board, in its discretion, may grant or withhold such waiver for good cause. However, in no event may the applicant begin participating until the waiver for good cause request has been granted and the individual's name included on the list of registered residents or temporary authorization has been granted pursuant to (g) below.

(g) In the event that a registration applicant has been unable to submit the required certification in a timely manner, the Director may grant that applicant temporary authorization to participate in the first year of a graduate medical education program, which will allow him or her no more than 30 days to complete the application process, provided that notice of such a grant is provided to the Board within five working days.

(h) A registered resident may engage in the practice of medicine or podiatry provided that such practice shall be confined to a hospital affiliated with the graduate medical education program and outpatient facilities integrated into the curriculum of the program, under the supervision of licensed plenary physicians or licensed podiatric physicians, as appropriate. All prescriptions and orders issued by registered residents in the inpatient setting shall be countersigned by either a licensed physician or a licensed podiatric physician, as applicable; or a permit holder at the minimum upon the patient's discharge, or sooner if the Director so requires. All prescriptions issued by registered residents in the outpatient setting which are to be filled in a pharmacy outside a licensed health care facility shall be signed by either a licensed physician or licensed podiatric physician, as appropriate.

(i) The Board may refuse to register a registration applicant if he or she has not certified that the prerequisites set forth in (c) above have been satisfied or if the Board is in possession of any information contradicting the representation made in the registration application form. The Board shall give the Director and the registration applicant notice of its refusal, allowing the submission of documentary evidence in rebuttal. Upon a showing of good cause the applicant will be granted an appearance before a committee of the Board.

(j) In addition to any practice declared to be a basis for sanction, pursuant to P.L. 1978, c.73 (N.J.S.A. 45:1-14 et seq.), the practices listed below, upon proof, shall also provide a basis for the withdrawal of the authorization to engage in the practice of medicine or podiatry as a registered resident. Upon receipt of the notice of proposed withdrawal, the registered resident may request a hearing, which shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq.

1. Termination or withdrawal from the graduate medical education program.

2. Failure to advise the Board of a termination or withdrawal from a graduate medical education program.

3. Engaging in any act or practice beyond the scope of those authorized pursuant to (h) above.

(k) Upon a duly verified application of the Attorney General, alleging a violation of any act or regulation administered by the Board, which palpably demonstrates that the resident's continued practice would constitute a clear and imminent danger to the public health, safety and welfare, upon notice, the Board may enter an order temporarily suspending the resident's authority to engage in the practice of medicine or podiatry pending a plenary hearing on the charge.

(*l*) A permit applicant shall submit to the Director a permit application form certifying that he or she has attained the prerequisites set forth in (c) above, and, in addition, shall forward to the appropriate individuals requests for the production of the documentation listed below. The documentation sought by the permit applicant shall be sent directly to the director by the certifying individual. The permit applicant shall also submit to the director a check or money order in the sum of $50.00 made payable to the New Jersey State Board of Medical Examiners.

1. Registrar's certification of attendance or college transcript from each college attended;

2. Registrar's certification of attendance or school transcript from each medical or podiatric school attended;

3. With respect to medical residents, ECFMG or Fifth Pathway certification, if applicable;

4. Certification of successful performance during the first year of a graduate medical education program to date.

(m) The Director shall obtain from the permit applicant the application form and the $50.00 fee and shall also receive and retain certified documentation, set forth in (*l*) above. No later than four months before the date on which the applicant is scheduled to begin participating in the second year of a graduate medical education program (or beyond), the Director shall submit to the Board a complete application packet for each person to whom an offer of employment has been extended. The packet shall include:

1. Permit application, completed by the applicant.

2. Registrar's certification for each college attended or college transcript for each college attended.

3. Registrar's certification for each medical or podiatric school attended, or medical or podiatric school transcript for each medical or podiatric school attended and the jurisdiction in which the didactic training was conducted.

4. With respect to medical residents, ECFMG or Fifth Pathway certification, if applicable.

5. Certification of successful performance during the first year of graduate medical education to date.

6. Permit fee of $50.00 in the form of check or money order made payable to the New Jersey State Board of Medical Examiners.

(n) The Director shall certify that he or she has offered a position to the applicant and has personally reviewed the permit application form and all supporting documentation and is unaware of any information which would contradict any of the representations in that application form or in any of the supporting certifications. If the Director shall have reason to question the veracity or reliability of those representations, he or she shall direct the permit applicant to supply the supporting documentation.

(*o*) Upon receipt of the permit application packet, the Board shall review each permit packet and if it is satisfied that the permit applicant has the necessary prerequisites, it shall issue to the applicant a permit authorizing that person to engage in either the practice of medicine or the practice of

podiatry, as appropriate, in the second year (or beyond) of a graduate medical education program.

(p) A permit applicant unable to certify that he or she has attained the prerequisites set forth at (c) above shall state on the permit application form the reason that he or she is unable to so certify. In addition, if he or she is unable to produce the supporting documentation set forth at (m) above, an explanation must be provided. A permit applicant who has been unable to certify that he or she has attained all the prerequisites, or unable to produce the required supporting documentation, may seek from the Board a waiver which would enable the person to be issued a permit. The Board, in its discretion, may grant or withhold such waiver for good cause shown. However, in no event may the permit applicant begin to participate in the second year (or beyond) of a graduate medical education program until the program waiver request has been granted and the permit issued or a temporary permit issued.

(q) In the event that a permit applicant has been unable to submit the required certification or supporting documentation in a timely manner, the Director may grant the permit applicant a temporary permit, which will allow him or her to participate in the graduate medical education program for no more than 60 days, to allow for the completion of the application process provided that notice of such a grant is provided to the Board within five working days.

(r) A permit holder may engage in the practice of medicine or podiatry provided that such practice shall be within the context of an accredited graduate medical education program conducted at a hospital licensed by the Department of Health and Senior Services (DHSS). A permit holder may engage in practice outside the context of a graduate medical education program for additional remuneration only if that practice is approved, in writing, by the residency program director of the graduate medical education program in which the permit holder is participating and the practice is supervised by a plenary licensee who shall:

1. Either remain on the premises of the health care facility or be available through electronic communication if that practice is at or through a health care facility licensed by the DHSS; or

2. Remain on the premises if that practice is outside of a health care facility licensed by the DHSS.

(s) The residency program director shall:

1. Require each permit holder to complete and submit a verification of supervision/employment form prior to approving practice outside of the approved graduate medical education program. A verification of supervision/employment form is required for each place of employment a permit holder practices outside the context of a graduate residency training program. The form shall include, but not be limited to, the following information:

i. Name of the permit holder;

ii. Field of practice;

iii. New Jersey physician license number of the supervising physician;

iv. Type of facility;

v. Telephone number; and

vi. Street address of the facility; and

2. Retain the verification of supervision/employment forms for seven years, which may be subject to review by the Board.

(t) The supervising physician shall:

1. Complete an affidavit accepting responsibility for reading and implementing the Board's statutes, N.J.S.A. 45:9-1 et seq., and rules, N.J.A.C. 13:35, that pertain to employment of permit holders outside the context of their approved graduate medical education programs; and

2. Provide evidence to the program director that arrangements have been made for professional liability coverage of the permit holder that is consistent with the rules of the Board, specifically N.J.A.C. 13:35-6.18.

(u) Prescriptions and orders may be issued by permit holders in the inpatient setting without countersignature. All prescriptions issued by permit holders in the outpatient setting, which are to be filled in a pharmacy outside a licensed health care facility shall be signed by a licensed physician or licensed podiatric physician, as appropriate.

(v) The Board may refuse to issue a permit to a permit applicant if he or she has not certified that the prerequisites set forth in (c) above have been satisfied, if the supporting documentation set forth in (*l*) above has not been produced or if the Board is in possession of any information contradicting the representations made in the permit application form or supporting documentation. The Board shall give the Director and the applicant notice of its refusal, allowing the submission of documentary evidence in rebuttal. Upon a showing of good cause the applicant will be granted an appearance before a committee of the Board.

(w) In addition to any practice declared to be a basis for sanction, pursuant to P.L. 1978, c.73 (N.J.S.A. 45:1-14 et seq.), the practices listed below, upon proof, shall also provide basis for the termination or suspension of a permit. Upon receipt of the notice of proposed termination or suspension the permit holder may request a hearing which shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq.

1. Termination or withdrawal from a graduate medical education program.

2. Failure to advise the Board of a termination or withdrawal from a graduate medical education program.

3. Engaging in any act or practice beyond the scope of those authorized pursuant to (r) above.

(x) A permit shall be valid for the duration of the graduate medical education program in which the permit holder is participating. If the permit holder seeks to change programs, he or she must submit a transfer application form. All transfer applications must be accompanied by a certification from the Director of the graduate medical education program in which the applicant has been or is currently participating, attesting to successful performance in the program.

(y) Each hospital offering a program(s) in medicine shall designate one physician who would qualify as a Director to fulfill the responsibilities set forth in this rule. Each hospital offering a podiatry program shall designate one podiatric physician who would qualify as a Director of a podiatry program to fulfill the responsibilities set forth in this rule. The Director may delegate to individual program directors these responsibilities, so long as the Director retains ultimate responsibility for the conduct of the program, except that the Director may not delegate the authority to issue temporary authorizations. In addition to the responsibilities placed upon any Director by this rule, he or she shall:

1. Implement procedures to assure that all prescriptions and orders issued by residents are countersigned or signed in accordance with the requirements of this rule.

2. Provide broad oversight of the activities of all program participants.

3. Report to the Board any conduct by a resident which, if proven, would represent cause for the withdrawal of registration or the suspension of a permit.

4. Report to the Board if any resident is granted a leave of absence for any reason, relating to a medical or psychiatric illness or to medical competency or conduct which would represent cause for the withdrawal of the authority to practice, providing an explanation.

(z) The authorization granted to an unlicensed person to participate in the first year of a graduate medical education program shall not be construed to imply that that person will be deemed eligible for the issuance of a permit or a license. The issuance of a permit similarly should not be construed to imply that the permit holder will be deemed eligible for licensure.

New Rule, R.1988 d.203, effective May 2, 1988.
See: 19 N.J.R. 2243(a), 20 N.J.R. 986(a).
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), inserted a reference to words in the introductory paragraph, and inserted a reference to medicine in "Resident"; rewrote (c); in (d), rewrote the last sentence; in (l), substituted a reference to the Director for a reference to the Board in the introductory paragraph; and in (m)3, added "and the jurisdiction in which the didactic training was conducted" at the end.
Amended by R.2004 d.398, effective October 18, 2004.
See: 36 N.J.R. 2582(a), 36 N.J.R. 4827(a).
In (c)1ii, inserted "and that the didactic training was completed in the jurisdiction where the school is authorized to confer a medical degree" at the end of the first sentence and deleted the same at the end of the second sentence.
Amended by R.2008 d.100, effective April 21, 2008.
See: 39 N.J.R. 3876(a), 40 N.J.R. 2115(a).
Rewrote the introductory paragraph of (r); added (r)1 and (r)2; added new (s) and (t); recodified the last two sentences of the introductory paragraph of (r) as new (u) and deleted former (u); in (u), inserted a comma following the second occurrence of "setting"; recodified former (s) and (t) as (v) and (w); deleted former (y); and recodified former (v) through (x) as (x) through (z).

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

(a) For the purpose of this subchapter, the term medical school or parent medical school shall mean a medical school approved by its country of domicile and listed in a current World Health Organization Directory, but which medical school is not currently eligible for evaluation and not approved by the Liaison Committee on Medical Education, the American Osteopathic Association or other group or agency recognized by the New Jersey State Board of Medical Examiners.

1. The term affiliate institution shall mean a licensed hospital in the State of New Jersey approved by the Accreditation Council on Graduate Medical Education, the American Osteopathic Association, or any other equivalent group or agency recognized by the New Jersey State Board of Medical Examiners, for the purpose of conducting therein one or more postgraduate training programs in specific medical specialties.

(b) A medical school offering or conducting a clinical training program in the State of New Jersey shall secure the prior approval of such program by the New Jersey State Board of Medical Examiners. Following receipt of approval for a specific program, the medical school (referred to hereinafter sometimes as the parent medical school) shall be responsible for the education, clinical training program and faculty performance at the affiliate institution in the State of New Jersey. The affiliate institution must have a current accredited postgraduate training program in the subject matter of the clinical training proposed for the program.

(c) The clinical programs as well as adequate supervision of the students assigned to such programs shall be planned and evaluated by the parent medical school and administered in close cooperation with representatives of the affiliate institution. Supervision shall include periodic onsite inspection

by a member of the parent medical school's central administration.

13:35-1A.2 Administration of the clinical training program

(a) A director of the clinical medical education program at and acceptable to the affiliate hospital shall be appointed by and be responsible to the administrative head of the parent medical school. The affiliate institution must demonstrate to the Board's satisfaction that the Director possesses the academic credentials and experience sufficient to assure competent performance of the program director's function. The position of program director shall be half-time or more, proportionate to the number of students approved by the Board and sufficient to assure comprehensive planning and supervision of the program.

(b) The clinical program of the affiliate institution with respect to instruction and faculty assignments shall be coordinated with the overall educational program of the parent medical school.

(c) The parent medical school shall file with the New Jersey State Board of Medical Examiners a certified copy of the written agreement between the parent and affiliate institution(s) establishing responsibility for the planning, financing, conduct and monitoring of the clinical program at the affiliate(s).

(d) Financial provision shall be made by the parent medical school to assure completion of each semester program at the affiliate hospital.

13:35-1A.3 Faculty

(a) The affiliate institution must demonstrate to the Board's satisfaction that all clinical faculty possess academic credentials and experience sufficient to assure competent performance of the instructional assignment.

(b) The program director shall be responsible for filing with the Board a syllabus for each course of instruction.

13:35-1A.4 Education program

(a) Student eligibility for participation in the program shall be subject to the following:

1. The parent medical school shall establish academic eligibility criteria for student participation in the clinical training program. The criteria shall include minimum academic performance as demonstrated by maintenance of no less than a passing grade for all academic course work preceding entry into the clinical program, as shown on a certified copy of the transcript submitted directly by the medical school to the director of the clinical program at the affiliate institution.

2. In addition, the academic eligibility requirement for those students participating in clinical training programs equivalent to the final two semesters or fourth year of a United States medical school curriculum shall include proof that each student has successfully completed clinical training equivalent to the fifth and sixth semesters or third year of a United States medical school curriculum through a program approved for this purpose by the parent medical school. If conducted in New Jersey, such prior clinical training is limited to those fifth and sixth semester programs approved by the State Board of Medical Examiners. Such record of prior clinical training shall include a certificate issued by the director of the clinical program to each student, noting the dates and describing the type and length of each service and the date issued. The record of prior clinical training shall also include proof of the program's supervision by the parent medical school and proof that the teaching hospital has been approved by the ACGME, the AOA or another equivalent organization recognized by the New Jersey State Board of Medical Examiners for the conduct of one or more post-graduate training programs in specific medical specialties. If the teaching hospital in which the prior clinical training took place is outside the geographical jurisdiction of the above said accrediting organizations, the record of prior clinical training must include proof that the hospital and training program have been approved by the parent medical school.

3. Preparedness of each student applying for the clinical training program shall in addition be demonstrated by achievement of either of the following:

i. A passing grade on Part I of the National Board of Medical Examiners Examination; or

ii. A passing grade on USMLE—Step 1.

4. Students who have satisfied (a)1, 2 and 3 above and who are permanent residents of the State of New Jersey shall be given preference in placement in New Jersey affiliate institutions, insofar as is practicable.

(b) Educational criteria for the program follows:

1. The clinical training program shall be limited to students entering a level of education equivalent to the final four semesters or the equivalent of the third and fourth years of clinical experience in a United States medical school curriculum.

2. The parent medical school shall be approved by the State Board of Medical Examiners for the purpose of placing students in New Jersey hospitals for clinical training. The Board shall conduct an academic review of the parent medical school in conjunction with expert authorities of higher education as recognized by the Board. The didactic elements of the medical education shall have been completed in the country of domicile authorized to confer the degree or certificate.

3. The student-faculty ratio of the program at each affiliate institution shall bear a reasonable relationship to

the availability of service of the program director, the budget proposed, faculty and facilities available, all subject to final approval of the Board.

4. A certificate shall be issued by the director of the clinical training program to each enrolled student recording the dates, type and length of each service and an evaluation of the student's accomplishment, and the date the certificate was issued.

As amended, R.1983 d.549, effective December 5, 1983.
See: 15 N.J.R. 1444(a), 15 N.J.R. 2044(a).
In (a)2, added "equivalent to the final two semesters or fourth year of a U.S. medical school curriculum" and "approved by the parent medical school. If conducted in N.J. such training is limited to those fifth and sixth semester programs approved by the Board of Medical Examiners". In (b)1., changed final "two" to "four" semesters and "final year" to "third and fourth years".
Amended by R.1985 d.564, effective November 4, 1985.
See: 17 N.J.R. 2010(a), 17 N.J.R. 2670(a).
(a) substantially amended.
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 (b)2.

13:35-1A.5 Facilities

(a) For the purpose of clinical training, the parent medical school shall propose an affiliate institution which must be a licensed hospital approved by the Accreditation Council on Graduate Medical Education, the American Osteopathic Association or other group acceptable to the Board for post-graduate training in subject area(s) of the proposed clinical training program, or which institution is part of such a program through affiliation(s) approved by the above bodies. The affiliate shall provide to the Board a certified copy of the approval(s).

(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 (AGMEC).

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 postgraduate 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."

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; and

5. Implement on an ongoing basis a quality assurance program as required by (f) below.

(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 protocol shall also include:

i. Guidance to the performer of the test 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 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 and where immediate clinical follow-up is warranted, 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. (However, raw data, graphs and reports, for example, but not limited to, radiographic images, which have been prepared as part of the patient record for a licensed health care facility such as a hospital or nursing home, may be entrusted by the preparing/interpreting practitioner to the secured custody of the licensed health care facility as part of the facility's permanent records.) 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 immediate follow-up care is indicated and no later than three business days in any event 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, other than bioanalytical specimens to a clinical laboratory under the jurisdiction of the Department of Health and Senior Services pursuant to N.J.S.A. 45:9-42.27 et seq., 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. Utilization of the provisions in this subsection shall be consistent with the requirements of (n) above. This subsection is intended to be available for special, occasional or emergent consultations only. A consultant or consultant entity rendering medical services interpreting diagnostic test data/records, whether in or out of this State, by means of any media, for 10 or more patients under treatment in New Jersey on an annual basis is deemed to be rendering medical services in this State and requires licensure by the Board. However, the exchange of information, which may include patient specific information, between a licensee and a physician licensed in another state, a possession of the United States or the District of Columbia shall not be deemed to be rendering medical services.

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).
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
Rewrote the section.

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 Purpose and scope

(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".
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).

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 document, 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.

"Midwife" means a person licensed by the Board as a certified midwife (CM), certified nurse midwife (CNM) or certified professional midwife (CPM).

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".
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
Added "Midwife".
Amended by R.2010 d.110, effective June 21, 2010.
See: 41 N.J.R. 2203(a), 42 N.J.R. 1213(b).
In definition "Clinical guidelines", substituted "document" for "written agreement, signed by both the licensee and the affiliated physician".

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 ACNM, ACC 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.

(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.

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".
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
In (a)7 and (b), amended the N.J.A.C. references.
Amended by R.2010 d.099, effective June 21, 2010.
See: 41 N.J.R. 2204(a), 42 N.J.R. 1214(a).
In (a)3, substituted "ACNM, ACC" for "American College of Nurse Midwives (ACNM)".

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, 8403 Colesville Rd., Suite 1550, Silver Spring, MD 20910, 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".
Amended by R.2010 d.110, effective June 21, 2010.
See: 41 N.J.R. 2203(a), 42 N.J.R. 1213(b).
In (b), substituted "8403 Colesville Rd., Suite 1550, Silver Spring, MD 20910" for "818 Connecticut Ave., Suite 900, Washington, DC 20006".

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 is 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) A licensee shall provide clinical guidelines and the identity of his or her affiliated physician(s) to the Board upon request.

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

(f) 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.
Amended by R.2010 d.110, effective June 21, 2010.
See: 41 N.J.R. 2203(a), 42 N.J.R. 1213(b).
In (c)3, substituted "is" for "are"; deleted former (d); recodified former (e) through (g) as (d) through (f); and in (d), substituted "A licensee shall provide clinical" for "Clinical" and "and the identity of his or her affiliated physician(s)" for "shall be made available".

13:35-2A.7 Licensure; biennial license renewal; license suspension; reinstatement of suspended license; inactive status; return from inactive status

(a) All licenses issued by the Board shall be issued for a two-year biennial licensure period. A licensee who seeks renewal of the license shall submit a completed renewal application and the renewal fee as set forth in N.J.A.C. 13:35-6.13 prior to the expiration date of the license.

(b) The Board shall send a notice of renewal to each licensee at the address registered with the Board at least 60 days prior to the expiration of the license. If the notice to renew is not sent at least 60 days prior to the expiration date, no monetary penalties or fines shall apply to the holder for failure to renew.

(c) If a licensee does not renew the license prior to its expiration date, the licensee may renew the license within 30 days of its expiration by submitting a renewal application, a renewal fee and a late fee, as set forth in N.J.A.C. 13:35-6.13. During this 30-day period, the license shall be valid, and the licensee shall not be deemed to be practicing without a license.

(d) A license that is not renewed within 30 days of its expiration shall be automatically suspended. An individual who continues to practice with a suspended license shall be deemed to be engaged in unlicensed practice and shall be subject to the penalties prescribed by N.J.S.A. 45:9-22 for practicing without a license.

(e) A licensee whose license has been automatically suspended for five years or less for failure to renew pursuant to (d) above may be reinstated by the Board upon completion of the following:

1. Payment of the reinstatement fee and all past delinquent biennial renewal fees pursuant to N.J.A.C. 13:35-6.13; and

2. Submission of an affidavit of employment listing each job held during the period of suspended license which includes the name, address, and telephone number of each employer.

(f) In addition to the fulfilling the requirements set forth in (e) above, a licensee whose license has been automatically suspended for more than five years who wishes to return to practice shall reapply for licensure and shall demonstrate that he or she has maintained proficiency. An applicant who fails to demonstrate to the satisfaction of the Board that he or she has maintained proficiency while suspended may be subject to an examination or other requirements as determined by the Board prior to reinstatement of his or her license.

(g) Renewal applications shall provide the licensee with the option of either active or inactive status. A licensee electing inactive status shall pay the inactive license fee set forth in N.J.A.C. 13:35-6.13 and shall not engage in practice.

(h) A licensee who elected inactive status and has been on inactive status for five years or less may be reinstated by the Board upon completion of the following:

1. Payment of the reinstatement fee; and

2. Submission of an affidavit of employment listing each job held during the period the licensee was on inactive status which includes the name, address, and telephone number of each employer.

(i) In addition to the fulfilling the requirements set forth in (h) above, a licensee who has been on inactive status for more than five years who wishes to return to practice shall reapply for licensure and shall demonstrate that he or she has maintained proficiency. An applicant who fails to demonstrate to the satisfaction of the Board that he or she has maintained proficiency while on inactive status may be subject to an examination or other requirements as determined by the Board prior to reinstatement of his or her license.

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.
Repeal and New Rule, R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
Section was "Biennial renewal".

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.

"Designated physician assistant" means a physician assistant, other than a temporary license holder, who is assigned by a supervising physician or a physician designee to supervise a temporary license holder.

"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).
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
Added "Designated physician assistant".

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 Committee a notice of employment for each full-time, part-time or per diem 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 Committee any change in employment and/or supervising physician within 10 days of the change.

Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
Rewrote (b).

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, 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 medication delivery systems;

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.
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
In (a), substituted "medication delivery systems" for "infusion pumps" in 10.

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 Accreditation Review Commission on Education for the Physician Assistant, Inc. (ARC–PA), or its successor; and

4. Has passed the examination administered by the National Commission on Certification of Physician Assis-

tants (NCCPA), or its successor, 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.

Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
In (a), rewrote 3 and inserted ", or its succession" following "Physician Assistants (NCCPA)" in 4.

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 50 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.

Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
In (a), substituted "50" for "40" following "a minimum of".

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 a period of time designated by the Committee 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.

Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
In (a), inserted "a period of time designated by the Committee for" preceding "reasons of hardship".

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 or physician designee 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 may assign physician assistants under his or her supervision to a physician designee, who shall be responsible for the practice of the physician assistant during the assignment.

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.
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
In (b), inserted "or physician designee" following "The supervising physician' in the introductory paragraph of 4; rewrote (d).
Petition for Rulemaking.
See: 42 N.J.R. 859(b), 1255(d), 2150(c).

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

6. Diagnosis or medical impression; and

7. 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.

Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
In (a), deleted former 5 and recodified former 6 through 8 as 5 through 7.

13:35-2B.12 Requirements for issuing prescriptions for medications; special requirements for issuance of CDS

(a) A physician assistant may issue prescriptions for medications only in accordance with the requirements contained in this section.

(b) A physician assistant shall provide the following on all prescription blanks:

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

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

3. 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;

4. The full name, age and address of the patient;

5. The date of issuance of the prescription;

6. The name, strength and quantity of drug or drugs to be dispensed and route of administration;

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

8. The number of refills permitted or time limit for refills, or both;

9. The signature of the prescriber, hand-written;

10. 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 required by (b)9 above; and

11. The physician assistant's Drug Enforcement Administration (DEA) registration number, if the physician assistant is authorized to issue CDS.

(c) A physician assistant may order or prescribe controlled dangerous substances (CDS) if:

1. A supervising physician has authorized a physician assistant to order or prescribe Schedule II, III, IV or V controlled dangerous substances in order to:

i. Continue or reissue an order or prescription for a controlled dangerous substance issued by the supervising physician;

ii. Adjust the dosage of an order or prescription for a controlled dangerous substance originally ordered or prescribed by the supervising physician, provided there is prior consultation with the supervising physician;

iii. Initiate an order or prescription for a controlled dangerous substance for a patient, provided there is prior consultation with the supervising physician if the order or prescription is not pursuant to iv below; or

iv. Initiate an order or prescription for a controlled dangerous substance as part of a treatment plan for a patient with a terminal illness, which for the purposes of this subparagraph means a medical condition that results in a patient's life expectancy being 12 months or less as determined by the supervising physician; and

2. The physician assistant has registered with and obtained authorization to order or prescribe controlled dangerous substances from the appropriate State and Federal agencies.

(d) Only one controlled dangerous substance shall appear on a prescription blank.

(e) 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 pursuant to N.J.S.A. 45:14-14.

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.
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
In (a), added 3.
Amended by R.2008 d.135, effective June 2, 2008.
See: 39 N.J.R. 2201(a), 40 N.J.R. 3316(a).
Section was "Requirements for issuing prescriptions for medications; memorialization of verbal orders for CDS given by physicians". In the introductory paragraph of (a), inserted "for medications" and substituted "requirements contained in this section" for "following conditions:"; added (b); recodified former (a)1 as the introductory paragraph of (c) and rewrote (c); deleted former (a)2 through (a)3; and added (d) and (e).

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. A temporary license holder may write orders for medication, treatment, or testing consistent with the provisions of N.J.A.C. 13:35-2B.15.

(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).
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
In (a), added the last sentence.

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, physician designee or a designated physician assistant:

i. Is continuously present on-site; and

ii. Countersigns, immediately after its entry in the chart, any order for medication, treatment, or testing written by the temporary license holder.

2. In the event that the countersignature in (a)1 above is that of a designated physician assistant, the supervising physician or physician designee, within the appropriate conditions set in N.J.A.C. 13:35-2B.10(b) 4, shall:

i. Personally review all charts and patient records and the temporary license holder's entry in the chart and record; and

ii. Countersign any order for medication, treatment, or testing written by the temporary licensee.

New Rule, R.1995 d.423, effective August 7, 1995.
See: 27 N.J.R. 1526(a), 27 N.J.R. 2959(a).
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
Rewrote (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.
Amended by R.1994 d.522, effective October 17, 1994.
See: 26 N.J.R. 2526(a), 26 N.J.R. 4195(a).

13:35-3.8 Administrative processing of license application

(a) In the case of candidates who are graduates of professional schools or colleges approved by the Board and whose required documents (for example, complete application form, diploma, transcript and license in foreign countries, with attested translations thereof (if not in English) by an official translator approved by the Board) are in the possession of the Board and apparently authentic, the Executive Director of the Board shall be authorized to admit such candidate to the licensing examination.

(b) Any applicant who fails to satisfy the documentary requirements set forth in (a) above may be reviewed individually 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).
Changed reference from secretary to Executive Director.

13:35-3.9 Postponement of or absence from examination; transfer or refund of fee

(a) An application for examination for any category of license may be postponed and transferred, along with the fee already paid, upon written request of the applicant, from the examination for which the applicant was scheduled, but only to the next subsequent examination. Any request for a transfer of fee must be supported by a reason accepted as valid by the Board. Request for transfer of fee and postponement of examination must be made prior to the first day of the examination.

(b) When an applicant has withdrawn from, or has failed to appear at, a scheduled examination, the Board may, at its discretion, authorize the refund of the paid examination fee. A request for refund must be made no later than 30 days after the scheduled date of the examination and must present good cause of an unusual personal nature. The Board shall review the particular circumstances of each case in determining the appropriateness of refund.

(c) No later than 90 days prior to the scheduled date of the next examination subsequent to the examination whose fee was transferred, an applicant whose request for postponement and transfer was granted pursuant to (a) above, shall submit to the Board notice of intention to take the said examination and to apply the transferred fee, along with any additional fee required by the then current fee schedule.

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

13:35-3.10 Subversion or attempt to subvert the licensing examination process

(a) The purpose of this rule is to enhance the security of licensing examination materials and to discourage certain types of conduct in the licensing examination process, whether by applicants or by current license holders subject to regulation by the Board.

(b) Any individual found by the Board to have engaged in conduct which subverts or attempts to subvert the licensing examination process may, at the discretion of the Board, have his or her scores on the licensing examination withheld and/or declared invalid, be found ineligible for licensure, be disqualified from the practice of the pertinent profession, and/or be subject to the imposition of other appropriate sanctions pursuant to N.J.S.A. 45:1-22.

(c) Conduct which subverts or attempts to subvert the licensing examination process includes, but is not limited to:

1. Conduct which violates the security of the examination materials, such as removing from the examination room any of the examination materials; reproducing or reconstructing any portion of the licensing examination; aiding by any means in the reproduction or reconstruction of any portion of the licensing examination; selling, distributing, buying, receiving or having unauthorized possession of any portion of a future, current or previously administered licensing examination.

2. Conduct which violates the standard of test administration, such as communicating with any other examinee during the administration of the licensing examination; copying answers from another examinee or permitting one's answers to be copied by another examinee during the administration of the licensing examination; having in one's possession during the administration of the licensing examination any books, notes, written or printed materials or data of any kind, other than the examination materials distributed.

3. Conduct which violates the credentialing process, such as falsifying or misrepresenting educational credentials or other information required for admission to the licensing examination; impersonating an examinee or having an impersonator take the licensing examination on one's behalf.

13:35-3.11 Standards for licensure of physicians graduated from medical schools not approved by American national accrediting agencies

(a) An applicant for a license to practice medicine and surgery in this State, who is a graduate of a medical school not eligible for and not accredited by the Liaison Committee on Medical Education (LCME) or the American Osteopathic Association (AOA), shall satisfy the conditions in this section to be deemed eligible for New Jersey licensure by examination or to be licensed by endorsement of a sister-state license.

(b) During the course of the applicant's medical training, and at the time of graduation, the medical school(s) was listed (or notified of eligibility for listing) in the World Directory of Medical Schools published by the World Health Organization, or the medical school(s) was approved and authorized by the country of domicile to confer the degree or certificate evidencing completion of a medical curriculum for the plenary practice of medicine and surgery.

(c) The applicant shall demonstrate successful completion of the full medical curriculum, didactic elements and clinical training prescribed by the medical school and by the country in which the medical school is located and within which the training took place, and successful completion of all of the educational requirements to practice medicine in that country.

(d) If the applicant is a national of the country in which the medical training was received, the applicant shall have obtained an unrestricted license or certificate of registration to practice medicine and surgery in that country.

(e) An applicant who has successfully completed the full basic science studies (or the equivalent of the first two years of an American medical school) in the foreign medical school located in the country of domicile authorized to confer the degree or certificate and has been given academic credit for successful completion of clinical training programs in United States hospitals, with residency programs approved by the American Council on Graduate Medical Education (ACGME) and the AOA in that field, shall demonstrate that the medical school was approved by the New Jersey State Board of Medical Examiners (Board) to conduct such a program in this State, or that the program was performed in a sister-state and recognized as acceptable by the Board.

(f) A graduate of a foreign medical school shall demonstrate to the satisfaction of the Board that he or she holds certification issued by the Educational Commission for Foreign Medical Graduates (ECFMG) which was granted following the attainment of a passing score on an acceptable examination and verification of his or her credentials by ECFMG. The Board shall accept certification of successful completion of an approved Fifth Pathway program in lieu of issuance of the ECFMG Certificate.

(g) The applicant shall demonstrate satisfaction of all other requirements of law.

(h) The applicant shall demonstrate attainment of a passing grade on an examination approved by the Board for purposes of medical licensure in this State.

(i) An applicant who has successfully completed the full basic science studies, or the equivalent of the first two years of an American medical school, in the foreign medical school located in the country of domicile authorized to confer the degree or certificate, but who has completed clinical training in the United States in a program not specifically approved by the Board, shall demonstrate prior licensure in another state and compliance with all other provisions of this section and of law, and may then be eligible to be considered for licensure in this State by endorsement. An applicant from a program specifically disapproved by the Board or conducted outside of an available approved-program procedure shall not be eligible under this subsection.

(j) An applicant, who has graduated from a medical school on or after July 1, 1916 and before July 1, 1985 and has received a medical degree from a medical school which is not eligible for and not accredited by the LCME or the AOA, shall demonstrate to the Board, through submission of documentation, that after receiving a medical degree the applicant has successfully completed at least one year of post-graduate training in a program accredited by the ACGME, the AOA, or any other equivalent group or agency which the Board, upon review, has determined has comparable standards.

(k) An applicant, who has graduated from a medical school on or after July 1, 1985 and before July 1, 2003 and has received a medical degree from a medical school which is not eligible for and not accredited by the LCME or the AOA, shall demonstrate to the Board, through the submission of documentation, that after receiving a medical degree the applicant has successfully completed a three-year post-graduate training program accredited by the ACGME, the AOA, or any other equivalent group or agency which the Board, upon review, has determined has comparable standards.

(*l*) An applicant, who has graduated from a medical school on or after July 1, 2003 and has received a medical degree from a medical school which is not eligible for and not accredited by the LCME or the AOA shall demonstrate to the Board, through the submission of documentation, that after receiving a medical degree the applicant has completed and received academic credit for at least two years for post-graduate training in a program accredited by the ACGME, the AOA or any other equivalent group or agency which the Board, upon review, has determined has comparable standards, and has a signed contract for a third year of post-graduate training in a program accredited by the ACGME, the AOA or any other equivalent group or agency which the Board, upon review has determined has comparable standards. At least two of the three years of post-graduate training shall be:

1. In the same field; or

2. In different fields, if when considered together, the post-graduate training fields would be credited toward the criteria for certification by a single specialty board recognized by the American Board of Medical Specialties (ABMS), the AOA or any other equivalent group or agency which the Board, upon review, has determined has comparable standards.

R.1984 d.281, effective July 2, 1984 (except subsection (f) which will be operative July 1, 1985).
See: 16 N.J.R. 503(b), 16 N.J.R. 1806(a).
Amended by R.1986 d.67, effective March 17, 1986.
See: 18 N.J.R. 50(a), 18 N.J.R. 568(a).
Text added to (f) "a document indicating ... applicable) followed by".

Amended by R.1988 d.7, effective January 4, 1988.
See: 19 N.J.R. 1534(a), 20 N.J.R. 102(a).
Deleted text in (f) "followed by successful ..."; added (k).
Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(a), 21 N.J.R. 3307(a).
Deleted references to specific statutes.
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 (c), (e) and (j); and in (i), rewrote the first sentence.
Amended by R.2008 d.100, effective April 21, 2008.
See: 39 N.J.R. 3876(a), 40 N.J.R. 2115(a).
In (a), inserted "(LCME)" and "(AOA)"; in (e), inserted "(ACGME)", substituted "AOA" for "American Osteopathic Association" and inserted "(Board)"; in (h), substituted "Board" for "New Jersey Medical Board"; added new (j) and (k); recodified former (j) as (*l*); and rewrote (*l*).

13:35-3.11A Standards for licensure of physicians graduated from medical schools approved by recognized national accrediting agencies

(a) An applicant, who has graduated from a medical school on or after July 1, 1916 and before July 1, 2003 and has received a medical degree from a medical school approved by the Liaison Committee on Graduate Medical Education (LCGME) or American Osteopathic Association (AOA) or other recognized national accrediting agency, shall demonstrate to the Board, through submission of documentation, that after receiving a medical degree the applicant has successfully completed at least one year of post-graduate training in a program accredited by the American Council on Graduate Medical Education (ACGME), the AOA, or any other equivalent group or agency which the Board, upon review, has determined has comparable standards.

(b) An applicant, who has graduated from a medical school on or after July 1, 2003 and has received a medical degree from a medical school approved by the LCGME or AOA or other recognized national accrediting agency, shall demonstrate to the Board, through the submission of documentation, that after receiving a medical degree the applicant has completed and received academic credit for at least two years for post-graduate training in a program accredited by the ACGME, the AOA, or any other equivalent group or agency, which the Board, upon review, has determined has comparable standards, and has a signed contract for a third year of post-graduate training in a program accredited by the ACGME, the AOA, or any other equivalent group or agency, which the Board, upon review, has determined has comparable standards. At least two of the three years of post-graduate training shall be:

1. In the same field; or

2. In different fields, if when considered together, the post-graduate training fields would be credited toward the criteria for certification by a single specialty board recognized by the American Board of Medical Specialties (ABMS), the AOA or another certification entity which the Board, upon review, has determined has comparable standards.

New Rule, R.2008 d.100, effective April 21, 2008.
See: 39 N.J.R. 3876(a), 40 N.J.R. 2115(a).

13:35-3.12 Standards for licensure of physicians with post-secondary educational deficiencies

(a) An applicant for licensure to practice medicine and surgery in this State shall submit proof to the Board that, prior to having commenced medical school studies, he or she has successfully completed a satisfactory course of at least two years, at a college or university accredited by an agency recognized by the Board, during which period he or she shall have earned at least 60 credits, and passed at least one three-credit course in each of the following subjects: chemistry, physics and biology.

(b) The Board in its discretion may waive any or all of the pre-medical requirements set forth in (a) above if the credentials presented include proof of the following:

1. Certification by a specialty board approved by the American Board of Medical Specialties or the American Osteopathic Association;

2. Award of a Ph.D. degree in a health-related field from a college or university accredited by an agency recognized by the Board;

3. Award of an M.P.H. degree from a college or university accredited by an agency recognized by the Board; or

4. Award of a National Institute of Health Research Award.

(c) The Board in its discretion may waive up to 30 of the required credits and/or all or part of the required subjects if the credentials presented include:

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

An applicant for initial licensure in the State by the Board shall submit his or her name, address and fingerprints for purposes of a criminal history background check to be conducted by the State of New Jersey pursuant to P.L. 2002, c.104 (N.J.S.A. 45:1-28 et seq.) to determine whether criminal history record information exists which may be considered by the Board in determining whether the applicant shall be licensed in the State. 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), P.L. 2002, c.104 (N.J.S.A. 45:1-31) 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).
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
Rewrote the section.

13:35-3.14 Biennial license renewal; license suspension; reinstatement of suspended license; inactive status; return from inactive status

(a) All licenses issued by the Board shall be issued for a two-year biennial licensure period. A licensee who seeks renewal of the license shall submit a renewal application and the renewal fee set forth in N.J.A.C. 13:35-6.13 prior to the expiration date of the license.

(b) The Board shall send a notice of renewal to each licensee at the address registered with the Board at least 60 days prior to the expiration of the license. If the notice to renew is not sent at least 60 days prior to the expiration date, no monetary penalties or fines shall apply to the holder for failure to renew.

(c) If a licensee does not renew the license prior to its expiration date, the licensee may renew the license within 30 days of its expiration by submitting a renewal application, a renewal fee and a late fee, as set forth in N.J.A.C. 13:35-6.13. During this 30-day period, the license shall be valid, and the licensee shall not be deemed to be practicing without a license.

(d) A license that is not renewed within 30 days of its expiration shall be automatically suspended. An individual who continues to practice with a suspended license shall be deemed to be engaged in unlicensed practice.

(e) A licensee whose license has been automatically suspended for five years or less for failure to renew pursuant to (d) above may be reinstated by the Board upon completion of the following:

1. Payment of the reinstatement fee and all past delinquent biennial renewal fees pursuant to N.J.A.C. 13:35-6.13;

2. Completion of the continuing education units required for each biennial registration period for which the licensee was suspended, if appropriate; and

3. Submission of an affidavit of employment listing each job held during the period of suspended license which includes the name, address, and telephone number of each employer.

(f) In addition to the fulfilling the requirements set forth in (e) above, a licensee whose license has been automatically suspended for more than five years who wishes to return to have his or her license reinstated shall reapply for licensure and, in accordance with N.J.S.A. 45:5-9b or 45:9-6.1, whichever is appropriate, shall demonstrate that he or she has maintained proficiency. An applicant who fails to demonstrate to the satisfaction of the Board that he or she has maintained proficiency while suspended may be subject to an examination or other requirements as determined by the Board prior to reinstatement of his or her license.

(g) Renewal applications shall provide the licensee with the option of either active or inactive status. A licensee electing inactive status shall pay the inactive license fee set forth in N.J.A.C. 13:35-6.13 and shall not engage in practice.

(h) A licensee who elected inactive status and has been on inactive status for five years or less may be reinstated by the Board upon completion of the following:

1. Payment of the reinstatement fee;

2. The completion of the continuing education units required for each biennial registration period for which the licensee was on inactive status, if appropriate; and

3. Submission of an affidavit of employment listing each job held during the period the licensee was on inactive status which includes the name, address, and telephone number of each employer.

(i) In addition to the fulfilling the requirements set forth in (h) above, a licensee who has been on inactive status for more than five years who wishes to return to practice shall reapply for licensure and, consistent with N.J.S.A. 45:5-9b or 45:9-6.1, whichever is appropriate, shall demonstrate that he or she has maintained proficiency. An applicant who fails to demonstrate to the satisfaction of the Board that he or she has maintained proficiency while on inactive status may be subject to an examination or other requirements as determined by the Board prior to reinstatement of his or her license.

New Rule, R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).

13:35-3.15 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.

Recodified from N.J.A.C. 13:35-1.3 and amended by R.2008 d.100, effective April 21, 2008.
See: 39 N.J.R. 3876(a), 40 N.J.R. 2115(a).
Deleted the last sentence.

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, major surgical procedures include:

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

2. A procedure in which an opening is made into any of the three major body cavities (abdomen, chest or head), if the facility's credentials committee, in conjunction with the chair or chief of the relevant department or division, has delineated the procedure as one requiring a qualified first assistant.

(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), a duly qualified physician assistant or a licensed podiatric physician 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 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.
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
Rewrote (a); in (c), inserted "or a licensed podiatric physician" preceding "may so act" in the first sentence.

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.

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

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

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

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

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

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

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

i. Number of patients who received termination procedures;

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

iii. Number of patients who reported for postoperative visits;

iv. Number of patients who needed repeat procedures;

v. Number of patients who received transfusions;

vi. Number of patients suspected of perforation;

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

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

ix. Number of patients who died within 30 days.

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

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

(h) The physician shall make suitable arrangements to insure that all tissues removed shall be properly disposed of by submission to a qualified physician for pathologic analysis or by incineration or by delivery to a person/entity licensed

to make biologic and/or tissue disposals in accordance with law including rules of the Department of Health applicable to an LACF.

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

Case Notes

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

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

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

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

13:35-4A.1 Purpose

These rules are designed to promote the health, safety and welfare of the members of the general public who undergo surgery (other than minor surgery), special procedures and receive anesthesia services in an office setting.

13:35-4A.2 Scope

(a) This subchapter establishes policies and procedures and staffing and equipment requirements for practitioners and physicians who perform surgery (other than minor surgery), special procedures and administer anesthesia services in an office setting.

(b) For purposes of this subchapter, the standards set forth at N.J.A.C. 13:35-4A.6 do not apply to those performing non-invasive special procedures, such as non-invasive radiologic procedures. However, the standards set forth at N.J.A.C. 13:35-4A.7, including the privileging standards set forth at (a) above, do apply to the anesthesia services provided in connection with all special procedures, whether invasive or non-invasive.

Amended by R.2002 d.404, effective December 16, 2002.
See: 33 N.J.R. 3870(a), 34 N.J.R. 4449(a).
Rewrote the section.

Case Note

Regulation promulgated by Board of Medical Examiners regarding the administration of anesthesia in physicians' offices during non-minor surgeries and procedures, which regulation required nurse anesthetists to be supervised by an anesthesiologist, was not arbitrary, capricious, or unreasonable given that anesthesiologists receive more training than nurse anesthetists, even though there was no medical research comparing mortality rates between anesthesiologists and nurses in administering anesthesia in an office setting. New Jersey State Ass'n of Nurse Anesthetists, Inc. v. New Jersey State Bd. of Medical Examiners, 859 A.2d 1239.

13:35-4A.3 Definitions

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

"Advanced cardiac life support trained" means that a licensee has successfully completed an advanced cardiac life support course offered by a recognized accrediting organization appropriate to the licensee's field of practice. For example, for those licensees treating adult patients, training in advanced cardiac life support (ACLS) is appropriate; for those treating children, training in pediatric advanced life support (PALS) or advanced pediatric life support (ALPS) is appropriate.

"Anesthesia services" means administration of any anesthetic agent with the purpose of creating conscious sedation, regional anesthesia or general anesthesia. For the purposes of this subchapter, the administration of topical or local anesthesia, minor conduction blocks, pain management or pain medication shall not be deemed to be anesthesia services.

"Anesthesiologist" means a physician who has successfully completed a residency program in anesthesiology approved by the American Council of Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA), or who currently is a diplomate of either the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology, or who was made a Fellow of the American College of Anesthesiology before 1982.

"Anesthetic agent" means any drug or combination of drugs administered with the purpose of creating conscious sedation, regional anesthesia or general anesthesia.

"Anesthetizing location" means any location in an office where anesthetic agents are administered to a patient.

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

"Certified registered nurse anesthetist" (CRNA) means a registered professional nurse who is licensed in this State and who holds current certification under a program governed or approved by the American Association of Nurse Anesthetists (AANA), and who meets the conditions for practice as a nurse anesthetist as set forth at N.J.A.C. 13:37–13.1.

"Complications" means an untoward event occurring at any time within 48 hours of any surgery, special procedure or the administration of anesthesia services which was performed in an office setting including, but not limited to, any of the following events: paralysis, nerve injury, malignant hyperthermia, seizures, myocardial infarction, renal failure, significant cardiac events, respiratory arrest, aspiration of gastric contents, cerebral vascular accident, transfusion reaction, pneumothorax, allergic reaction to anesthesia, wound infections requiring intravenous antibiotic treatment or hospitalization, unintended return to an operating room or hospitalization, death or temporary or permanent loss of function not considered to be a likely or usual outcome of the procedure.

"Conscious sedation" means the administration of a drug or drugs in order to induce that state of consciousness in a patient which allows the patient to tolerate unpleasant medical procedures without losing defensive reflexes, adequate cardio-respiratory function and the ability to respond purposefully to verbal command or to tactile stimulation if verbal response is not possible as, for example, in the case of a small child or deaf person. For the purposes of this subchapter, conscious sedation does not include an oral dose of pain medication or minimal pre-procedure tranquilization such as the administration of a pre-procedure oral dose of a benzodiazepine designed to calm the patient. Within the context of this subchapter, "conscious sedation" shall be synonymous with the term "sedation/analgesia" as used by the American Society of Anesthesiologists.

"General anesthesia" means the administration of a drug or drugs which cause loss of consciousness as the result of which the patient is unable to make meaningful responses but may still display reflex withdrawal from a painful stimulus.

"Health care personnel" means any office staff member who is licensed by a professional or health care occupational licensing board such as a professional registered nurse, licensed practical nurse or physician assistant.

"Hospital" means a hospital licensed by the state in which it is situated.

"Local anesthesia" means an agent which produces a transient and reversible loss of sensation in a circumscribed portion of the body.

"Minor conduction block" means the injection of local anesthesia to stop or prevent a painful sensation in a circumscribed area of the body (that is, local infiltration or local nerve block), or the block of a nerve by direct pressure or refrigeration. Minor conduction blocks include, but are not limited to, retrobulbar blocks, peribulbar blocks, pudendal blocks, digital blocks, metacarpal blocks and ankle blocks. "Minor conduction block" does not include regional anesthesia that affects larger areas of the body, such as brachial plexus anesthesia or spinal anesthesia.

"Minor surgery" means surgery which can safely and comfortably be performed on a patient who has received no more than the maximum manufacturer recommended dose of local or topical anesthesia, without more than minimal pre-operative medication or minimal intra-operative tranquilization and where the likelihood of complications requiring hospitalization is remote. Minor surgery specifically excludes all procedures performed utilizing anesthesia services as defined in this section. Minor surgery also specifically excludes procedures which may be performed under local anesthesia, but which involve extensive manipulation or removal of tissue such as liposuction or lipo-injection, breast augmentation or reduction, and removal of breast implants. Minor surgery includes the excision of moles, warts, cysts, lipomas, skin biopsies, the repair of simple lacerations, or other surgery limited to the skin and subcutaneous tissue. Additional examples of minor surgery include closed reduction of a fracture, the incision and drainage of abscesses, certain simple ophthalmologic surgical procedures, such as treatment of chalazions and non-invasive ophthalmologic laser procedures performed with topical anesthesia, limited endoscopies such as flexible sigmoidoscopies, anoscopies, proctoscopies, arthrocenteses, thoracenteses and paracenteses. Minor surgery shall not include any procedure identified as "major surgery" within the meaning of N.J.A.C. 13:35–4.1.

"Monitoring" means continuous visual observation of a patient and continuous observation of the patient using instruments to measure, display and record the values of certain physiologic variables such as pulse, oxygen saturation, blood pressure and respiration.

"Office" means a location at which medical, surgical or podiatric services are rendered and which contains only one operating room and which is not subject to the jurisdiction and licensure requirements of the New Jersey State Department of Health and Senior Services.

"Operating room" means that location in the office dedicated to the performance of surgery or special procedures.

"Pain management" means the administration to a patient, by any route, of pharmacologic agents or drugs which are not intended to result in a loss of consciousness, awareness or defensive reflexes, but which are intended to alleviate pain. It includes the use or application of other modalities and medical devices such as, but not limited to, heat or cold, massage, transepidermal nerve stimulation (TENS), and neurolytic techniques such as radiofrequency coagulation and cryotherapy.

"Pain medication" means, for the purpose of this subchapter, the administration to a patient, by any route, of pharmacologic agents or drugs which are not intended to result in a loss of consciousness, awareness or defensive reflexes, but which are intended to alleviate pain occurring in the absence of an invasive, operative or manipulative procedure.

"Physical status classification" means a description of a patient used in determining if an office surgery or procedure is appropriate. The American Society of Anesthesiologists enumerates classifications: I—Normal healthy patient; II—A patient with mild systemic disease; III—A patient with severe systemic disease limiting activity but not incapacitating; IV—A patient with incapacitating systemic disease that is a constant threat to life; and V—Moribund patients not expected to live 24 hours with or without operation.

"Physician" means an individual holding an M.D. or D.O. degree licensed pursuant to N.J.S.A. 45:9–1 et seq.

"Podiatrist" means an individual holding a D.P.M. degree licensed pursuant to N.J.S.A. 45:5–1 et seq.

"Practitioner" means a physician or a podiatrist.

"Privileges" means the authorization granted to a practitioner or physician by a hospital licensed in the jurisdiction in which it is located to provide specified services or alternatively by the Board pursuant to N.J.A.C. 13:35–4.12, such as surgery or the administration or the supervision of administration of one or more types of anesthetic agents or procedures.

"Recovery area" means a room or limited access area of an office dedicated to providing medical services to patients recovering from surgery or anesthesia.

"Regional anesthesia" means the administration of anesthetic agents to a patient to interrupt nerve impulses without loss of consciousness and includes epidural, caudal, spinal and brachial plexus anesthesia. Regional anesthesia does not include minor conduction blocks as defined in this section.

"Special procedure" means patient care which requires anesthesia services because it involves entering the body with instruments in a potentially painful manner, or requires the patient to be immobile, for a diagnostic or therapeutic procedure. Examples of special procedures include diagnostic or therapeutic endoscopy or bronchoscopy performed utilizing conscious sedation or general anesthesia; invasive radiologic procedures performed utilizing conscious sedation; pediatric magnetic resonance imaging performed utilizing conscious sedation; or manipulation under anesthesia (MUA). The term special procedure does not include a procedure which only requires medication to reduce anxiety such as oral benzodiazepine unless the dose given is intended to provide conscious sedation.

"Supervision" means responsibility by a credentialed physician who is immediately available to oversee the administration and monitoring of anesthesia by health care personnel authorized by this rule to render anesthesia services in an office.

"Surgery" means a manual or operative procedure, including the use of lasers, performed upon the body for the purpose of preserving health, diagnosing or treating disease, repairing injury, correcting deformity or defects, prolonging life or relieving suffering. Surgery includes, but is not limited to: incision or curettage of tissue or an organ; suture or other repair of tissue or an organ; a closed or open reduction of a fracture or extraction of tissue from the uterus.

"Topical anesthesia" means an anesthetic agent applied directly or by spray to the skin or mucous membranes, intended to produce a transient and reversible loss of sensation to a circumscribed area.

Amended by R.2002 d.404, effective December 16, 2002.
See: 33 N.J.R. 3870(a), 34 N.J.R. 4449(a).
Rewrote the section.
Administrative correction.
See: 35 N.J.R. 1936(a).

13:35–4A.4 Policies and procedures requirements

(a) Practitioners who perform surgery (other than minor surgery) or special procedures and physicians who administer or supervise the administration or monitoring of anesthesia services in an office shall establish written policies and procedures concerning the following:

1. The specific surgical or special procedures which may be performed in the office;

2. The specific anesthesia services which may be performed in the office;

3. The responsibilities of the health care personnel providing services to patients in the office;

4. The infection control practices to be followed, including lawful disposal of hazardous waste;

5. The procedures to be followed in the event that a patient experiences a complication;

6. The procedures to be followed if the patient requires transport for emergency services, including the identity and telephone numbers of the ambulance service if one is to be utilized and the hospital to which the patient is to be transported, and the functions to be undertaken by health care personnel until a transfer of the patient is completed;

7. The procedures to be followed in the event that a surgery or special procedure needs to be terminated because of an equipment malfunction or other complication;

8. The procedures to be followed while a patient is recovering in the office;

9. The objective criteria for discharging patients; and

10. The procedures to be followed to review records, and to ensure follow-up on complications and outcomes.

(b) The written policies and procedures shall also contain the identity of the specific practitioners within the office who are responsible for ensuring that:

1. All healthcare personnel providing services to patients possess the qualifications required by this subchapter and are currently licensed, registered or certified, as applicable;

2. All equipment and instruments utilized in the performance of surgery are maintained in proper working order and in accordance with such sterilization techniques as are required for safe medical practice;

3. All equipment and safety systems utilized in the administration and monitoring of anesthesia as required by N.J.A.C. 13:35–4A.14 are maintained in proper working order;

4. All emergency equipment and supplies as required by N.J.A.C. 13:35–4A.13 are available and are not outdated; and

5. All medical records are audited on at least an annual basis to assess quality of care and complications.

(c) The written policies and procedures are to be reviewed annually and revised as needed with the person conducting the review or making the revision recording the date thereof.

(d) Written policies and procedures shall be presented to the Board upon request.

13:35–4A.5 Duty to report incidents related to surgery, special procedures or anesthesia in an office

Any incident related to surgery, special procedures or the administration of anesthesia within the office which results in a patient death, transport of the patient to the hospital for observation or treatment for a period in excess of 24 hours, or a complication or untoward event as defined in N.J.A.C. 13:35–4A.3, shall be reported to the Executive Director of the Board within seven days, in writing and on such forms as shall be required by the Board. Such reports shall be investigated by the Board and will be deemed confidential pursuant to N.J.S.A. 45:9–19.3.

13:35–4A.6 Standards for performing surgery and special procedures in an office; privileges necessary; pre-procedure counseling; patient records; recovery and discharge

(a) A practitioner who performs surgery (other than minor surgery) or special procedures in an office shall be privileged to perform that surgery or special procedure by a hospital. If a practitioner is not privileged but wishes to perform surgery or special procedures in an office, the practitioner shall apply to the Board pursuant to N.J.A.C. 13:35–4A.12 to seek Board-approved privileging.

(b) Before any practitioner may perform surgery (other than minor surgery), or special procedures, the practitioner shall have:

1. A written transfer agreement with a licensed hospital with acute care capabilities which can be reached within 20 minutes during all hours in which surgery or special procedures are performed in the office, if the hospital where the practitioner is privileged is not reachable within 20 minutes or if the practitioner is privileged by the Board; and

2. A written policy for handling emergency transport to a hospital at which the practitioner is privileged through 9–1–1 call or a written transfer agreement with a licensed ambulance service which assures immediate transport of patients experiencing complications to the hospital which the practitioner has established a transfer agreement. The written transfer agreement shall be posted in the office and all health care personnel in the office shall specifically be informed of the procedure to be followed.

(c) A practitioner who performs surgery (other than minor surgery) or special procedures in an office shall provide pre-procedure counseling and preparation as follows:

1. The practitioner shall appropriately assess, or review a referring physician's assessment of, the physical condition of the patient on whom surgery or a special procedure is to be performed. The practitioner shall refer a patient who, by reason of pre-existing medical or other conditions, are at undue risk for complications (for example, morbidly obese patients; patients with severe cardiac, pulmonary, airway or neurological problems; substance abusers) to an appropriate specialist for a pre-procedure consultation or to another treatment setting or other appropriate facility for the performance of the surgery or the special procedure. Only patients with an American Society of Anesthesiologists (ASA) physical status classification of I or II are appropriate candidates for an office surgery or special procedure for which general or regional anesthesia are to be used. Patients with an ASA physical classification of I, II or III are appropriate candidates for conscious sedation.

2. A history and physical examination shall be performed within the 14 days preceding the proposed surgery either by the practitioner performing the surgery or procedure (as appropriate to that practitioner's scope of practice) or by another physician or physician assistant under the supervision of a physician. Necessary laboratory tests, as guided by the patient's underlying medical condition, shall be conducted within seven days preceding the proposed surgery;

3. The risks and benefits of the surgery or special procedure and alternative methods or treatments shall be fully explained by the practitioner or other health care personnel, and written informed consent for the specific surgery or special procedure contemplated shall be obtained from the patient, guardian or authorized representative;

4. An appropriate fasting protocol shall be explained and provided to the patient;

5. If the history and physical are not done on the same day as the procedure, an interim assessment shall be performed by the practitioner or a physician assistant under the supervision of a physician immediately prior to the procedure, which assessment shall be documented and dated; and

6. Prior to surgery, the practitioner shall ensure that the patient removes all cosmetics, jewelry, contact lenses, dental appliances and prosthetic devices which might reasonably jeopardize patient safety.

(d) A practitioner who performs surgery (other than minor surgery) or special procedures in an office shall ensure the following during recovery and prior to discharge:

1. Immediately after the surgery or special procedure, the patient shall be evaluated by either the practitioner who performed the surgery or the physician or CRNA who administered the anesthesia;

2. At least one practitioner shall remain on the premises until the patient is discharged from the recovery area;

3. The patient shall be provided with written and verbal instructions for follow-up care and with advice concerning possible complications; and

4. The patient shall be discharged into the company of a responsible individual.

(e) A practitioner who performs surgery (other than minor surgery) or special procedures in an office shall prepare a patient record which shall include the following:

1. A pre-procedure medical history and physical, appropriate to the practitioner's scope of practice, including such data as allergies, physical and mental impairments, vital signs, drug use, mobility limitations and, as applicable, electrocardiogram results, radiologic findings, laboratory values and the identity of the examining practitioner;

2. Documentation reflecting that informed consent has been obtained;

3. A description of the surgery or special procedure performed, including pre-operative diagnosis, techniques used, names and titles of medical personnel participating, complete findings, post-operative diagnosis, and any unusual occurrence, complications or untoward events. Where similar procedures are performed at the office routinely, partially pre-printed forms may be utilized as a guide, provided that original data and conclusions applicable to the specific patient are contemporaneously entered to create a complete report;

4. A post-procedure note, entered prior to discharge from the office, which shall include at least such post-procedure data as the patient's general condition, vital signs, any treatments ordered, and all drugs prescribed, administered or dispensed including dosages, quantities and strengths;

5. The identity of healthcare personnel providing services, as evidenced by a legible signature following that staff member's notation in the patient's record; and

6. The plan for follow-up care and documentation of results of follow-up efforts.

(f) No practitioner who performs surgery (other than minor surgery) or special procedures in an office shall:

1. Prescribe, or advise a patient to take, an anesthetic agent to be administered prior to arrival at the office or outside of the anesthetizing location; or

2. Accept for the performance of surgery or a special procedure a patient to whom an anesthetic agent had been administered for that surgery or special procedure prior to arrival at the office or outside of the anesthetizing location, other than in life threatening circumstances, unless the patient is accompanied by medical personnel from an acute care facility.

Public Notice: Suspension of enforcement.
See: 30 N.J.R. 4485(b).
Amended by R.2002 d.404, effective December 16, 2002.
See: 33 N.J.R. 3870(a), 34 N.J.R. 4449(a).
Rewrote the section.

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

(a) A practitioner who administers or supervises the administration and monitoring of anesthesia services in an office shall be privileged by a hospital to provide the particular anesthesia service. If a practitioner is not privileged but wishes to administer or supervise the administration of anesthesia services, the practitioner shall apply to the Board pursuant to N.J.A.C. 13:35–4A.12 to seek Board-approved privileging.

(b) A practitioner who administers or supervises the administration and monitoring of anesthesia services in an office shall provide pre-anesthesia counseling and preparation as follows:

1. Any patient to whom anesthesia services are to be provided shall be appropriately screened by the individual administering anesthesia services. Patients who, by reason of pre-existing medical or other conditions, are at undue risk for complications (for example, morbidly obese patients; patients with severe cardiac, pulmonary, airway or neurological problems; substance abusers) shall be referred to an appropriate specialist for a pre-procedure consultation or to another treatment setting or other appropriate facility. Only patients with an ASA physical status classification of I or II are appropriate candidates for an office surgery or special procedure for which general or regional anesthesia are to be used. Patients with an ASA physical classification of I, II or III are appropriate candidates for conscious sedation.

2. A medical history shall be conducted including a review of abnormalities in any organ system; previous adverse experience with anesthesia services; any history of stridor, snoring or sleep apnea, or of advanced rheumatoid arthritis or spinal disorder; current medications being taken; drug allergies; or any history of substance abuse;

3. The risks and benefits of anesthesia and alternative methods or treatments shall be fully explained by the physician or certified registered nurse anesthetist (CRNA), and written informed consent for the anesthesia services contemplated shall be obtained from the patient, guardian or authorized representative;

4. An appropriate fasting protocol shall be explained and timely provided to the patient, guardian or authorized representative;

5. Pre-procedure laboratory test results shall be reviewed and recorded;

6. A focused physical examination shall be conducted, including auscultation of the heart and lungs, and an evaluation of the airway, particularly an assessment of anatomical abnormalities (that is, jaw, mouth, head and neck) which may increase the likelihood of an airway obstruction;

7. A plan of anesthesia shall be developed by the physician administering anesthesia services or personally reviewed by the supervising physician if the plan has been developed by other authorized personnel;

8. A patient shall be counseled prior to the procedure that the procedure will be canceled if the patient plans to drive home after the procedure and has not made arrangements to be accompanied home by an individual who accepts responsibility for the patient; and

9. Prior to the administration of anesthesia services, the physician shall ensure that the patient removes all cosmetics, jewelry, contact lenses, dental appliances and prosthetic devices which might reasonably jeopardize patient safety.

(c) A physician who administers or supervises the administration or monitoring of any anesthesia services (general anesthesia, regional anesthesia or conscious sedation) in an office shall ensure that monitoring is provided as follows when clinically feasible for the patient:

1. Direct observation of the patient and, to the extent practicable, observation of the patient's responses to verbal commands;

2. Pulse oximetry shall be performed continuously. Any alternative method of measuring oxygen saturation may be substituted for pulse oximetry if the method has been demonstrated to have at least equivalent clinical effectiveness;

3. An electrocardiogram monitor shall be used continuously on the patient;

4. The patient's blood pressure, pulse rate, and respirations shall be measured at least every five minutes; and

5. The body temperature of a pediatric patient shall be measured continuously.

(d) In addition to the monitoring requirements in (c) above, a physician who administers or supervises the administration or monitoring of general anesthesia services in an office shall ensure that additional monitoring is provided as follows:

1. End-tidal carbon dioxide monitoring shall be performed on the patient continuously during endotracheal anesthesia;

2. An in-circuit oxygen analyzer shall be used to monitor the oxygen concentration within the breathing circuit, displaying the oxygen percent of the total inspiratory mixture;

3. A respirometer (volumeter) shall be used to measure exhaled tidal volume whenever the breathing circuit of a patient allows;

4. The body temperature of each patient shall be measured continuously; and

5. An esophageal or precordial stethoscope shall be available and utilized on the patient when indicated.

(e) A practitioner who administers or supervises the administration and monitoring of anesthesia services in an office shall establish within that office a recovery area and ensure that recovery services are provided as follows:

1. Immediately after the surgery or special procedure, the practitioner who performed the surgery or the individual who administered the anesthesia shall evaluate the patient;

2. The individual responsible for the administration or monitoring of anesthesia shall accompany the patient into the recovery area;

3. Healthcare personnel who were present with the patient at the anesthetizing location shall remain with the patient in the recovery area at least until the patient's vital signs, including blood pressure, pulse, and respiration are recorded;

4. An oral report on the patient's condition shall be given to any healthcare personnel in the recovery area not present in the anesthetizing location;

5. Whenever a patient is present in the recovery area, the recovery area shall be staffed by at least one registered professional nurse or physician assistant who is trained and experienced in advanced cardiac life support and post anesthesia care. This includes recognizing the actions and interactions of anesthetic techniques, manag-

ing of airway and ventilatory function and managing patients during altered states of consciousness, as well as cardiopulmonary resuscitation, monitoring of caridiac function, recognition of arrhythmias, and the recognition and treatment of life-threatening emergencies. For every additional two patients present in the recovery area, there shall be one additional professional registered nurse or physician assistant present, having the requisite training;

6. In addition to the healthcare personnel specified in (e)5 above, at least one other additional healthcare personnel shall remain on site in a position to render immediate assistance whenever a patient is in the recovery room; and

7. From the time of entry into the recovery area until discharge, the condition of the patient shall be regularly evaluated and the patient's vital signs checked at least every five minutes. If the patient's vital signs remain unchanged, documentation can be reflected with a straight line on the chart; any changes shall be specifically noted. Electrocardiographic monitoring and pulse oximetry monitoring shall be continued in the recovery area for each patient who has received anesthesia services.

(f) A practitioner who administers or supervises the administration and monitoring of anesthesia services may allow a patient dischargeable to home pursuant to N.J.A.C. 13:35–4A.4(a)9 and 4A.6(d) to remain in the office for a period not to exceed 23 hours in an overstay area, if the patient may benefit from additional care. The overstay area shall be staffed by at least one registered professional nurse or physician assistant for each two patients in the overstay area, the patient's vital signs shall be taken and recorded at least every four hours and a physician shall be able to reach the office within 20 minutes. Appropriate sleeping accommodations, as well as food, shall be provided for the patient.

(g) A practitioner who administers or supervises the administration and monitoring of anesthesia services in an office shall ensure the following prior to discharge:

1. That at least one practitioner shall remain on the premises until the patient is discharged to home or transferred to the special overnight stay area;

2. That the patient shall be given written and verbal instructions for follow-up care and advice concerning complications;

3. That before the patient leaves the office or is transferred to the overstay area, the physician shall evaluate the patient and shall review and sign the post-anesthesia record; and

4. That the patient shall be discharged only into the company of a responsible individual.

(h) A practitioner who administers or supervises the administration and monitoring of anesthesia services in an office shall ensure that a patient record is prepared which contains the following:

1. A pre-anesthesia note, including pre-anesthesia vital signs (blood pressure, temperature, respiration rate and pulse), and a plan of anesthesia;

2. Signed informed consent from the patient, guardian or authorized representative;

3. An intra-procedure record which includes anesthetic agents and techniques used, any changes since the inception of anesthesia in vital signs, oxygen saturation, electrocardiogram interpretation, temperature and end-tidal carbon dioxide measurements when required, as well as the volume and type of fluids administered;

4. A post-anesthesia note entered prior to the patient's discharge from the office which shall include at least such post-procedure data as the patient's vital signs and general condition, respiration, consciousness, circulation, special problems or precautions and a summary of fluids received during surgery or any complication or untoward event which occurred;

5. The identity of each healthcare personnel providing services, as evidenced by the staff member's legible signature on each entry made by that staff member in the patient record; and

6. The plan for follow-up care.

(i) No practitioner who administers or supervises the administration and monitoring of anesthesia services in an office shall:

1. Prescribe, or advise a patient to take, an anesthetic agent to be administered prior to arrival at the office or outside of the anesthetizing location; or

2. Accept for the performance of surgery or a special procedure a patient to whom an anesthetic agent had been administered for that surgery or special procedure prior to arrival at the office or outside of the anesthetizing location, other than in life threatening circumstances, unless the patient is accompanied by medical personnel from an acute care facility.

Public Notice: Suspension of enforcement.
See: 30 N.J.R. 4485(b).
Amended by R.2002 d.404, effective December 16, 2002.
See: 33 N.J.R. 3870(a), 34 N.J.R. 4449(a).
Rewrote the section.
Administrative correction.
See: 35 N.J.R. 1936(a).

13:35–4A.8 Performance of general anesthesia; authorized personnel

(a) General anesthesia shall be administered and monitored in an office only by the following individuals:

3. A precordial stethoscope or esophageal stethoscope; and

4. A peripheral nerve stimulator.

(c) In an office in which anesthesia services are to be provided to infants and children, the required emergency equipment shall be appropriately sized for a pediatric population.

13:35–4A.14 Requirements for anesthetizing locations; safety systems, monitoring devices

(a) An office in which anesthesia services are to be provided shall be equipped with the following safety systems and monitoring devices:

1. A pulse oximeter with appropriate alarms (or an equivalent method of measuring oxygen saturation);

2. A continuous electrocardiograph with paper recorder;

3. Devices for measuring blood pressure, heart rate and respiratory rate;

4. A defibrillator; and

5. An accepted method of identifying and preventing the interchangeability of gases, whenever gases are used.

(b) Any anesthesia machine or built-in anesthesia system utilized in the administration of general anesthesia in an office shall be equipped with the following:

1. An end-tidal carbon dioxide monitor (capnograph);

2. An in-circuit oxygen analyzer designed to monitor the oxygen concentration within the breathing circuit by displaying the oxygen percent of the total inspiratory mixture;

3. A respirometer (volumeter) measuring exhaled tidal volume;

4. Oxygen failure-protection devices ("fail-safe" system) which have the capacity to announce a reduction in oxygen pressure and, at lower levels of oxygen pressure, to discontinue other gases when the pressure of the supply of oxygen is reduced;

5. A vaporizer exclusion ("interlock") system, which ensures that only one vaporizer, and therefore only a single anesthetic agent, can be actuated on any anesthesia machine at one time;

6. Pressure-compensated anesthesia vaporizers, designed to administer a constant non-pulsatile output, which shall not be placed in the circuit downstream of the oxygen flush valve;

7. Flow meters and controllers, which can accurately gauge concentration of oxygen relative to the anesthetic agent being administered and prevent oxygen mixtures of less than 21 percent from being administered;

8. Alarm systems for high (disconnect), low (subatmospheric), and minimum ventilatory pressures in the breathing circuit for each patient under general anesthesia; and

9. A gas evacuation system.

(c) Anesthesia equipment used in the administration of anesthesia services for the performance of MRI shall be made of nonferrous materials to ensure the quality of the diagnostic studies. Monitoring techniques shall take into consideration the unique characteristics of the magnetic field.

(d) In an office in which anesthesia services are to be provided to infants and children, the required monitoring devices shall be appropriately sized for a pediatric population.

13:35–4A.15 Equipment requirements for recovery areas

(a) In any office in which anesthesia services are to be provided, a recovery area adjacent to, or within the operating room, shall be established. Access to the recovery area shall be limited to staff and family or significant others, as appropriate. The recovery area shall be equipped with at least the following:

1. A pulse oximeter with appropriate alarms (or an equivalent method of measuring oxygen saturation);

2. A continuous electrocardiogram monitor with paper recorder;

3. A defibrillator;

4. Drugs adequate for cardiopulmonary resuscitation;

5. Emergency equipment for intubation and extubation; and

6. Basic airway management equipment as follows:

i. A source of compressed oxygen (tank with regulator or pipeline supply with flowmeter);

ii. A source of suction, suction catheters, Yankauer-type suction;

iii. Face masks (in appropriate sizes for the patient population);

iv. A self-inflating breathing bag-valve set, oral and nasal airways and lubricant; and

v. A method by which oxygen can be administered (for example, masks, nasal cannulas).

13:35–4A.16 Maintenance requirements

(a) All equipment as required by N.J.A.C. 13:35–4A.13 through 4A.15 is subject to inspection and maintenance as follows:

1. A record shall be maintained of all service and maintenance including that performed on all anesthesia machines, ventilators and vaporizers. The record shall

include machine identification; the name of the servicing agent; the problem, if any; the work performed and the date of the work. Maintenance shall conform with maintenance requirements established by the machine manufacturer. Credentials of each servicing agent shall be approved by the machine manufacturer or shall be reasonably determined by the permit holder to be equivalent to the credentials of the manufacturer's servicing agents.

2. All anesthesia equipment shall be inspected fully at the beginning of each day of use by a physician, or a certified registered nurse anesthetist (CRNA), under the supervision of a physician, credentialed to utilize that equipment. A record of each such inspection, including the date of the inspection and the identity of the individual conducting the inspection, shall be maintained for each machine. The inspection shall conform with a checklist that is supplied by the manufacturer of the machine, or issued by the Federal Food and Drug Administration or, alternatively, reasonably developed by the physician and set forth in an appropriate written protocol.

3. Before each use, the physician or the CRNA who is to administer the anesthesia shall inspect all anesthesia equipment. Inspections shall be documented on the anesthesia record.

(b) A physician shall not permit anyone to tamper with a safety system or any monitoring device or disconnect an alarm system.

13:35–4A.17 Compliance timetables

(a) A practitioner who does not hold privileges at a hospital and, as of December 16, 2002, was offering and elects to continue offering or chooses to begin offering anesthesia services or surgery or special procedures in the office setting, shall submit an application to the Board seeking approval pursuant to the alternative privileging process set forth at N.J.A.C. 13:35–4A.12, no later than December 16, 2003. Notwithstanding any other provision in this subchapter, a practitioner who has submitted an application for alternative privileging pursuant to this subsection, may continue to offer services for which privileges have been requested until such time as the Board acts upon that application.

(b) A practitioner or physician who offers anesthesia services in an office setting shall purchase and install the equipment and safety systems, as required pursuant to this rule , no later than December 15, 1998. Alternatively, a practitioner or physician shall have written proof that by October 15, 1998, an order for such equipment has been transmitted to and received by a manufacturer or legitimate vendor of the equipment. Such proof shall include an anticipated date of delivery. All such equipment shall be properly installed in a timely fashion after delivery and shall be used in conformance with this section, no later than December 15, 1998.

(c) All other requirements of this subchapter shall be effective June 15, 1998.

Amended by R.2002 d.404, effective December 16, 2002.
See: 33 N.J.R. 3870(a), 34 N.J.R. 4449(a).
Rewrote (a).

13:35–4A.18 Enforcement

(a) Any violation of N.J.A.C. 13:35–4A.3 through 4A.17 shall be deemed to be professional misconduct within the meaning of N.J.S.A. 45:1–21(e) and may further constitute violation of other law or rule, as applicable to the circumstances.

SUBCHAPTER 5. EYE EXAMINATIONS; EYEGLASSES

Subchapter Historical Note

Petition for Rulemaking. See: 30 N.J.R. 3340(b), 30 N.J.R. 3867(a), 31 N.J.R. 905(a), 31 N.J.R. 2276(a), 32 N.J.R. 609(a), 32 N.J.R. 1260(a).

13:35–5.1 Minimum eye examination; contact lenses

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

1. A complete history of visual aberrations;

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

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

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

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

(c) An ophthalmologist shall release a copy of a patient's contact lens prescription directly to a patient or to a licensed ophthalmologist, a licensed optometrist, or a New Jersey licensed ophthalmic dispenser upon either the oral or written request of a patient or a professional acting on a patient's behalf, provided that the prescription is not more than two years old.

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

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

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

PHYSICAL QUALITY AND APPEARANCE

1. Surface imperfections

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

2. Glass defects

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

3. Localized power errors

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

4. Refractive powers

TOLERANCE: 0.0. to 6.00, + or −0.12.

6.25 to 12.00, 2 per cent of power.

Above 12.00, + or −0.25.

Maximum cylinder power variation + or −0.12.

5. Refractive power addition

TOLERANCE: + or −0.12.0.

6. Cylinder Axis

TOLERANCE: 0.12 to 0.37 + or −3 degrees.

0.50 to 1.00, + or −2 degrees.

1.12 on up, + or −1 degree.

7. Prism power and location of specified optical center

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

8. Segment size

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

9. Segment location

TOLERANCE: As specified within + or −0.5 mm.

10. Lens size:

i. Rimless

TOLERANCE: + or −0.5 mm;

ii. Bevel, for plastic frames

TOLERANCE: + or −0.5 mm;

iii. Bevel, for metal frames

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

11. Heat-treated and chemically-treated industrial safety eyewear

TOLERANCE: Tolerance for power, size and the like shall be as above, except that minimum thickness edge or center shall meet the requirements of American Standard Z80.1–1972 and subsequent revisions.

12. Heat-treated and chemically-treated dress eyewear

TOLERANCE: Tolerance for power, size and the like shall be as above, except that minimum thickness edge or center shall meet the requirements of American Standard Z80.1–1972 and subsequent revisions.

(b) Provided, however, that nothing herein shall be construed to prohibit deviations beyond those established by this rule, provided that good medical cause exists therefor.

SUBCHAPTER 6. GENERAL RULES OF PRACTICE

13:35–6.1 Practice identification

(a) A physician with a plenary license to practice medicine and surgery in the State of New Jersey shall make representation for professional purposes (office identification, stationery, professional cards, signature on insurance claim forms, education, etc.) in a manner clearly indicating such plenary licensure and/or practice specialty; for example: Dr. John Doe, physician and surgeon; or Dr. Jane Smith, physician; or Dr. John Doe, surgeon; or Dr. Jane Smith, licensed to practice medicine and surgery; or Dr. Jane Doe, physician, practice limited to (name of specialty); or similar accurate descriptive terms. In addition to or as an alternative to these titles, a licensee may use the standard and accepted abbreviation of professional degree conferred by the medical school; that is, John Smith, M.D.; Jane Smith, D.O., as the case may be.

(b) An applicant or current licensee who is a graduate of both an A.M.A.-accredited allopathic professional school and an A.O.A.-accredited osteopathic professional school may elect to use either M.D. or D.O. as the primary abbreviation following the name and shall notify the Board of such election.

(c) A licensee with a limited license issued by the Board shall identify himself or herself for professional purposes in a manner clearly indicating the licensed profession by name or by using the recognized and accepted abbreviation of the degree actually conferred by the professional college; for example: Jane Smith, Podiatrist or Jane Smith, D.P.M.; John Doe, Bioanalytical Laboratory Director or John Doe, B.L.D. or John Doe, Specialty Bioanalytical Laboratory Director in Chemistry, etc.; Jane Smith, Certified Nurse Midwife or C.N.M.

(d) The use of any letters in immediate conjunction with the name of a licensee shall be deemed a representation of earned academic professional degree. Any such degree shall have been conferred by an educational institution authorized by the appropriate higher education authorities in its state of domicile to do so. The licensee may also list abbreviations of membership in non-profit incorporated professional societies.

(e) All representations by licensees of degree abbreviations or of professional society affiliations shall comply with this rule, and any use of an academic degree or professional or membership abbreviation not in accordance with these standards shall be deemed a misrepresentation and professional misconduct.

(f) All professional representations, including, but not limited to, letterhead stationery, business cards and claim forms, shall identify the street address(es) of the licensee's professional practice location(s). A post office box, whether for general mailing or for billing purposes, may be listed on the professional representation as a preferred mailing address but the professional representation shall also include the licensee's professional practice location(s).

New Rule, R.1985 d.103, effective March 4, 1985.
See: 16 N.J.R. 3178(a), 17 N.J.R. 606(a).
This adoption repealed former rule "Degree designation".
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.154, effective May 17, 1999.
See: 30 N.J.R. 4317(a), 31 N.J.R. 1360(b).
Added (f).

13:35–6.2 Pronouncement of death

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

"Attending physician" means any Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.) who, prior to the person's death, had attended, supervised or directed ongoing medical treatment of the patient as a primary care physician or as a specialist undertaking to treat a significant chronic medical illness which could lead to death. A physician providing such ongoing treatment, who has issued or renewed a prescription issued to the person within the six month period preceding the death, will be deemed to be an attending physician, regardless of whether the physician has personally examined the person within that six month period.

"Certificate of death" means the official document prepared for filing pursuant to N.J.S.A. 26:6–6 et seq. which is signed by a physician and sets forth the information pertaining to a person's last sickness, immediate and contributing causes of death and burial and the identity of the medical personnel who made the pronouncement of death.

"Covering physician" means any physician who has assumed the responsibility for providing care and treatment to an attending physician's patients during his or her unavailability. A covering physician shall also bear a responsibility to exercise his or her best medical judgment when making a pronouncement of death or drawing the conclusions called for in completing the certificate of death.

"Pronouncement of death" means the act of conducting an inquiry concerning the circumstances of a death, checking for vital signs, ascertaining pertinent history and, where appropriate, performing a complete external examination of the unclothed body and providing a medical opinion as to conclusion and cause(s) of the death.

(b) Every physician licensed by the Board and engaged in the active practice of medicine in this State shall ensure that he or she meets the obligations set forth in this section. If the physician is unavailable, he or she shall arrange for another physician to assume these responsibilities.

(c) Upon notification of an apparent death, the attending physician or designated covering physician shall proceed without inordinate delay to the location of the presumed decedent and shall make the proper determination and pronouncement of the death.

(d) Where the apparent death has occurred outside a licensed hospital and the attending or covering physician has been notified but is unable to go to the location to make the determination and pronouncement, said physician may specify another physician or may arrange with a professional nurse (R.N.) or a paramedic in accordance with N.J.A.C. 8:41–7.5, which requires the relay of findings, including telemetered electrocardiograms, if feasible to attend the presumed decedent and make the determination and pronouncement. In every such instance a written record, which may be contained within a police record, shall be prepared describing the circumstance and identifying the physician and any other person designated as above to perform the death pronouncement responsibility. Such report shall be promptly communicated orally to the attending physician for use in preparation of the death certificate. A copy of the report shall be provided to the physician as soon as practicable.

(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 pursuant to N.J.A.C. 13:35-6.22, documentation in the patient record and a minimum of 30 days has passed from the ren-

dition of the last professional service; 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).
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
In (c), rewrote the introductory paragraph.

Case Notes

Decision of the New Jersey State Board of Medical Examiners granting a doctor his requested medical license in the State but contemporaneously reprimanding him for sexual misconduct involving a patient that was not misconduct in the State of California wherein the complaint had been filed against him was upheld on appeal. The reviewing court found that the Board's exercise of discretion by imposing a condition to the grant of licensure rather than the more severe denial of licensure, was not arbitrary, capricious or unreasonable as the Board appropriately balanced the public interest against the need for the continued services of an otherwise qualified medical doctor. In re Kim, 403 N.J. Super. 378, 958 A.2d 485, 2008 N.J. Super. LEXIS 219 (App.Div. 2008).

In a professional and sexual misconduct case, evidence supported revocation of a physician's license where: (1) testimony of disinterested witnesses and documentary evidence corroborated testimony of the victim patient; (2) the patient's testimony with regard to the actual touching, a phone call by the physician to the patient's home, and sighting of the physician near her home was credible; (3) several of the physician's witnesses continued having a working relationship with the physician, which bears on the witnesses' credibility; (4) the physician's witnesses also had an interest because the working conditions at their place of employment could be adversely affected if the physician were to leave; (5) two of the physician's witnesses used the physician as their own personal physician; and (6) the patient's testimony regarding a telephone call and sighting the physician outside the patient's home did not waver throughout the pendency of the proceeding and was consistent with and supported by the patient's prior statements to other people. In re Suspension or Revocation of License of Joachim, OAL Dkt. No. BDS 7297-03, 2007 N.J. AGEN LEXIS 173, Initial Decision (April 5, 2007).

Since there was no justification for a limb length discrepancy examination in the record where a victim patient was being examined without a chaperone for a toe injury, and the surrounding circumstances showed that it was only a pretext to get the patient to disrobe, the physician's

conduct constituted sexual misconduct and sexual harassment, and therefore was in violation of N.J.S.A. 45:1-21(h). In re Suspension or Revocation of License of Hakimi, OAL Dkt. No. BDS 11873-04, 2006 N.J. AGEN LEXIS 148, Initial Decision (February 24, 2006).

During years before adoption of regulation prohibiting licensee from engaging in sexual contact with a patient with whom he or she had a patient-physician relationship, it was not per se violation of the Medical Practices Act for a physician to engage in consensual sexual relations with patient. In the Matter of the Suspension or Revocation of the License of Costino, Jr. to Practice Medicine and Surgery in the State of New Jersey, 1998 N.J. AGEN LEXIS 1, N.J. Adm., Feb 24, 1998, (OAL DKT. NO. BDS 10628-94).

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:

i. 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; and/or

ii. The reproduction of x-rays or any other material within a patient record which cannot be routinely copied or duplicated on a commercial photocopy machine, which shall be no more than the actual cost of the duplication of the materials, or the fee charged to the licensee for duplication, plus an administrative fee of the lesser of $10.00 or 10 percent of the cost of reproduction to compensate for office personnel time spent retrieving or reproducing the materials and overhead costs.

5. Licensees shall not charge a patient for a copy of the patient's record when:

i. The licensee has affirmatively terminated a patient from practice in accordance with the requirements of N.J.A.C. 13:35–6.22; or

ii. The licensee leaves a practice that he or she was formerly a member of, or associated with, and the patient requests that his or her medical care continue to be provided by that licensee.

6. 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.

7. 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, pro-

viding 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).
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
Rewrote (c).

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, 356 N.J. Super. 4, 811 A.2d 460 (App. Div. 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, 796 A.2d 283 (App. Div. 2002).

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, 764 A.2d 433 (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).

Physician who committed gross negligence by removing the middle and lower lobes of the wrong lung from a patient and by failing to obtain a second CT scan before commencing surgery also was found by the Board of Medical Examiners to have attempted to conceal the error by altering the medical records (adopting in part and modifying in part 2008 N.J. AGEN LEXIS 280). In re Perera, OAL Dkt. No. BDS 11295-05, Final Decision (June 5, 2008).

Physician licensee, a compulsive gambler, was guilty of professional misconduct by soliciting money loans from a patient on two occasions in violation of Medical Board orders and by failing to prepare and maintain truthful patient records. Physician's license was suspended for 24 months and physician was ordered to reimburse the improper loans, cease gambling, participate in the Gamblers Anonymous program, perform community service, and pay attorney fees and costs. In re Suspension or Revocation of License of Singh, OAL Dkt. No. BDS 1638-05N, 2006 N.J. AGEN LEXIS 426, Initial Decision (June 30, 2006).

Since there was no justification for a limb length discrepancy examination in the record where a victim patient was being examined without a chaperone for a toe injury, and the surrounding circumstances showed that it was only a pretext to get the patient to disrobe, the physician's conduct constituted sexual misconduct and sexual harassment, and therefore was in violation of N.J.S.A. 45:1-21(h). In re Suspension or Revocation of License of Hakimi, OAL Dkt. No. BDS 11873-04, 2006 N.J. AGEN LEXIS 148, Initial Decision (February 24, 2006).

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 refills;

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 Minimum standards for the performance of new or novel procedures in the office setting

(a) This section contains minimum standards for the performance of new or novel procedures as defined in (b) below which are performed in the office setting and are not performed under the jurisdiction of an Institutional Review Board (IRB) which complies with the requirements of the Federal Food and Drug Administration.

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

"Diagnostic or therapeutic modality" means a modality intended for use in the diagnosis of disease or conditions in humans or in the cure, mitigation, treatment or prevention of disease in humans or a modality intended to affect the structure of or any function of the human body.

"Generally recognized as safe and effective" means there exists substantial evidence by means of at least two well-controlled clinical studies that the new or novel procedure will have the effect that is represented and the procedure does not pose a significant risk to the physical or emotional health of the patient and has a low reported incidence of adverse reactions or significant side effects.

"New or novel procedure" means a diagnostic or therapeutic modality performed by a Board licensee that:

1. Is not yet generally recognized as safe and effective by experts in the field who are qualified by scientific training and experience to evaluate the safety and effectiveness of the procedure for its intended use and poses a potential risk of physical or emotional harm to a patient; or

2. Is a new application of a procedure which has been generally recognized as safe and effective for its traditional use but is not yet generally recognized as safe and effective by experts in the field who are qualified by scientific training and experience to evaluate the safety and effectiveness of the procedure for its new application and the new application poses a potential risk of physical or emotional harm to a patient.

"New or novel procedure" does not include responses to emergent and unexpected issues that arise during surgery or the use of a medication that has been approved by the Food and Drug Administration (FDA), even if the medication is being used for a purpose not specifically approved by the FDA.

"Office setting" means a location at which medical, surgical or podiatric services are rendered and is not licensed by the New Jersey Department of Health and Senior Services.

(c) A licensee shall not perform a procedure in an office setting that is generally recognized as ineffective and unsafe by experts in the field who are qualified by scientific training and experience to evaluate the safety and effectiveness of the procedure for its intended use.

(d) A licensee shall establish a procedural protocol prior to performing a new or novel procedure in the office setting. The protocol shall at a minimum:

1. Provide for protection of human subjects consistent with FDA guidelines set forth in 21 C.F.R. §50 (2004) available from the United States Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857-0001, which are incorporated by reference herein, and as may be amended and supplemented;

2. Ensure the procedure is performed by physicians qualified by training, education, or experience to perform such procedure;

3. Ensure the physician performing the procedure is able to demonstrate the scientific merits of the procedure;

4. Ensure the procedure is supported by adequate and well-controlled animal studies or the weight of the scientific and medical literature;

5. Contains provisions for pre-operative screening;

6. Delineate specific diagnoses for which the procedure is indicated;

7. Delineate specific contraindications to the procedure, if any;

8. Provide for fully informed consent in accordance with prevailing New Jersey law, including full explanation of risks, benefits, alternative treatments and likely outcome without treatment;

9. Provide for and demonstrate operator and staff training, experience, and ongoing competency;

10. Provide for a period of post procedure observation and management commensurate with the complexity, invasiveness and risks of the procedure and any concomitant anesthesia;

11. Provide for written discharge instructions, follow-up and any associated aftercare;

12. Maintain documentation of complete care rendered in accordance with Board rules, N.J.A.C. 13:35-6.5, and maintain records of any associated morbidity, mortality and clinical outcomes;

13. Ensure that procedures are described with specificity including use of pharmaceutical agents and their dosages, anticipated side effects, and projected short and long-term treatment; and

14. Where applicable, ensure compliance with the rules regarding surgery and anesthesia services performed in an office setting (N.J.A.C. 13:35-4A).

(e) A licensee shall provide the Board with a procedural protocol upon request in order to ensure that the licensee has complied with the requirements of (d) above.

(f) If the requirements of (d) above cannot be met, a licensee may request Board approval to perform a new or novel procedure. Such request shall include a statement identifying which protocols in (d) above cannot be met and the reason therefor. The Board shall not approve a request under this subsection unless the licensee demonstrates to the satisfaction of the Board that:

1. The procedure may be effective for its intended use and will not expose patients to an unreasonable and significant additional risk of illness or injury;

2. The procedure is intended to treat a serious or immediately life-threatening disease and no comparable or satisfactory therapeutic alternatives are available to treat that stage of the disease in the intended patient population and there is a reasonable likelihood that death will occur within a matter of months or premature death is likely without early intervention;

3. The procedure is under investigation in controlled clinical trials or all clinical trials have been completed but not yet reported; and

4. The licensee has provided to the Board all information known to the licensee, regarding the studies referred to in (f)3 above.

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".
New Rule by R.2005 d.360, effective, November 7, 2005.
See: 36 N.J.R. 4367(a), 37 N.J.R. 4277(b).

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

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

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

1. Generally:

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

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

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

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

3. As a prophylactic medication.

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

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

i. Original copy to State Department of Health;

ii. Copy to be retained by the physician;

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

iv. Copy to pharmacist.

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

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

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

1. Copy of signed informed request.

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

i. Surgery;

ii. Radiation;

iii. Chemotherapy.

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

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

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

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 purchaser 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 current certification by a specialty board or certifying entity. Specialty boards recognized by the American Board of Medical Specialties (ABMS), the American Osteopathic Association (AOA), and/or the American Podiatric Medicine Association (APMA) shall be approved by the Board and included in a list maintained by the Board. A licensee advertising board certification shall conspicuously specify in the advertisement the specific specialty board or certifying entity granting the certification (for example, the American Board of Psychiatry and Neurology, the American Board of Radiology, etc.), the national organization recognizing such specialty board or certifying entity (for example, ABMS, AOA, APMA, etc.), if any, and, if not included in the name of the specialty board or certifying entity itself, the field of medical or surgical specialty in which the certification was conferred.

(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.
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
Rewrote (m).
Petition for Rulemaking.
See: 42 N.J.R. 859(b), 1255(d), 2150(c).

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 antitrust 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.

Case Notes

Physician found guilty by New York Board of Regents properly had New Jersey medical license revoked. In the Matter of the Suspension or Revocation of the License of Del Gizzo, 94 N.J.A.R.2d (BDS) 1.

13:35-6.12 (Reserved)

Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
Superfluous language deleted from (f).
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 "Excessive fee review committees".

13:35-6.13 Fee schedule

(a) The following fees shall be charged by the Board of Medical Examiners:

1. Medicine and Surgery (M.D. or D.O. license)

i.	Initial application fee	$325.00
ii.	Initial license fee	
(1)	If paid during the first year of a biennial renewal period	580.00
(2)	If paid during the second year of a biennial renewal period	290.00
iii.	N.J.S.A. 45:9-21(n)—exemption	225.00
iv.	N.J.S.A. 45:9-21(b)—temporary license	50.00
v.	Endorsement	225.00
vi.	Biennial license	580.00
vii.	Biennial license for licensee over 65 without health care facility or HMO affiliation	125.00
viii.	Permit	50.00

2. Podiatry (license)

i.	Application fee	$125.00
ii.	Examination	$150.00

iii.	Initial license fee	
(1)	If paid during the first year of a biennial renewal period	580.00
(2)	If paid during the second year of a biennial renewal period	290.00
iv.	Endorsement	150.00
v.	Biennial license	580.00
vi.	Biennial license for licensee over 65 without health care facility or HMO affiliation	85.00
vii.	Permit	50.00

3. Bioanalytical laboratory directorship, plenary or specialty license

i.	Application fee	125.00
ii.	Examination	350.00
iii.	Exemption	150.00
iv.	Initial license fee	
(1)	If paid during the first year of a biennial renewal period	390.00
(2)	If paid during the second year of a biennial renewal period	195.00
v.	Biennial license	390.00

4. Midwifery (license)

i.	Application fee	125.00
ii.	Examination	50.00
iii.	Endorsement	50.00
iv.	Initial license fee	
(1)	If paid during the first year of a biennial renewal period	270.00
(2)	If paid during the second year of a biennial renewal period	135.00
v.	Biennial license	270.00
vi.	Biennial prescriptive authorization (Certified Nurse Midwife)	50.00

5. Physician assistant (license)

i.	Application fee	125.00
ii.	Temporary license fee	50.00
iii.	Initial license fee	
(1)	If paid during the first year of a biennial renewal period	220.00
(2)	If paid during the second year of a biennial renewal period	110.00
iv.	License renewal fee, biennial	220.00
v.	Late renewal fee	100.00
vi.	Reinstatement fee	175.00
vii.	Duplicate license fee	40.00
viii.	Duplicate wall certificate	50.00

6. General

i.	Recording of name change and issuance of replacement license	50.00
ii.	Replacement of lost engrossed copy/certified true copy/biennial registration certificate	50.00
iii.	Preparation of certification papers for applicants to other states	50.00
iv.	Late renewal fee	100.00
v.	Reinstatement fee	175.00
vi.	Inactive license fee	(to be determined by Director by regulation)

New Rule, R.1983 d.510, effective November 7, 1983.
See: 15 N.J.R. 784(a), 15 N.J.R. 1865(e).
Deleted old fee schedule and added new fee schedule.
Amended by R.1985 d.223, effective May 6, 1985.
See: 17 N.J.R. 562(a), 17 N.J.R. 1132(a).
Substantially amended.
Amended by R.1987 d.201, effective May 4, 1987.
See: 19 N.J.R. 353(a), 19 N.J.R. 772(a).
Both components raised from $300.00 to $425.00; Component I raised from $200.00 to $250.00 and Component II raised from $225.00 to $300.00.
Amended by R.1987 d.371, effective September 8, 1987.
See: 19 N.J.R. 1054(a), 19 N.J.R. 1648(a).
Increased the biennial registration fee.
Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
Biennial registration fee decreased from $120 to $60 and endorsement fee set at $60.
Amended by R.1990 d.525, effective November 5, 1990.
See: 22 N.J.R. 1988(a), 22 N.J.R. 3384(a).
Medicine and surgery examination fees increased.
Amended by R.1991 d.286, effective June 3, 1991.
See: 23 N.J.R. 833(a), 23 N.J.R. 1815(a).
Added (a)1viii and (a)2v.
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).
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
Rewrote the section.
Amended by R.2005 d.175, effective June 6, 2005.
See: 37 N.J.R. 206(a), 37 N.J.R. 1203(a), 37 N.J.R. 2041(b).
In (a), increased the fees in 1ii(1), 1ii(2), 1vi, 2iii(1), 2iii(2), 2v, 3iv(1), 3iv(2), 3v, 5iv(1), 5iv(2) and 5v.
Administrative correction.
See: 37 N.J.R. 2553(a).
Amended by R.2005 d.378, effective November 7, 2005.
See: 37 N.J.R. 1918(a), 37 N.J.R. 4281(a).
Increased fees in (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:

1. Certify, on the application for biennial renewal, completion of the required number of continuing medical education credits; and

2. Maintain all evidence of verification of continuing medical education requirements for a period of six years after completion of the credits and submit such documentation to the Board upon request.

(i) The Board may extend the time period for completion of continuing medical education requirements or may waive continuing medical education requirements on an individual basis for reasons of hardship, such as severe illness, disability or military service, consistent with the following:

1. A licensee seeking an extension and/or waiver of the continuing medical education requirements shall apply to the Board in writing and set forth in specific detail the reasons for requesting the extension and/or waiver. The licensee shall submit to the Board all documentation in support of the extension and/or waiver;

2. A licensee shall apply for an extension and/or waiver within 60 days of the expiration of the biennial renewal period. All requests shall be sent to the Board office, by certified mail, return receipt requested; and

3. An extension and/or waiver granted pursuant to this section shall be effective for the biennial licensure period in which the extension and/or waiver is granted. If the condition(s) which necessitated the extension and/or waiver continues into the next biennial period, the licensee

shall apply to the Board for the renewal of such extension and/or waiver for the new biennial period.

(j) A licensee shall provide verification and proof of compliance with continuing medical education requirements for the prior biennial renewal period when appearing before an investigative committee of the Board or the Medical Practitioner Review Panel, or when required to do so pursuant to a Board Order, Directive or request.

(k) Failure to complete continuing medical education requirements or falsification of any information submitted on a renewal application shall provide cause for penalties and/or license suspension pursuant to N.J.S.A. 45:1-21.

New Rule, R.1991 d.56, effective February 4, 1991 (operative May 12, 1991).
See: 22 N.J.R. 2135(b), 23 N.J.R. 311(a).
Repealed by R.1999 d.356, effective October 18, 1999.
See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).
Section was "Delegation of tasks to physician assistants".
New Rule, R.2004 d.232, effective June 21, 2004.
See: 36 N.J.R. 607(a), 36 N.J.R. 3057(b).

13:35-6.16 Professional practice structure

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

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

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

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

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

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

3. Cleanliness of premises;

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

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

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

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

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

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

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

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

(e) A licensee may invest in a health care service as defined in N.J.A.C. 13:35-6.17(a). Said service shall be owned solely by one or more licensed health care professionals except as otherwise permitted by licensure granted by another State agency. Whether or not any or all of the owners, partners or directors all regularly practice on the premises or within the entity, each such person who is a licensee of this Board shall be responsible to the Board for requiring maintenance of all professional practice standards

and control set forth in this rule, except as excused by (g) below. A licensee who has invested in a health care service in which he or she has a significant beneficial interest as defined in N.J.A.C. 13:35-6.17(a)5, to which he or she refers patients, shall assure that professional justification for the referred service is documented in the patient record maintained at that entity. Referred services include but are not limited to prescriptions for devices such as hearing aids, eyeglasses, intraocular lenses, requests for radiologic studies, etc. Referral of patients is now limited to the exceptions set forth in N.J.S.A. 45:9-22.4 as amended.

(f) Acceptable professional practice forms are as follows:

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

2. Partnership, professional association or limited liability company: A practitioner may practice in a partnership, professional association, or limited liability company, but such entity shall be composed solely of health care professionals, each of whom is duly licensed or otherwise authorized to render the same or closely allied professional service within this State. A limited liability company means a limited liability company formed under the laws of this State, pursuant to the New Jersey Limited Liability Company Act, N.J.S.A. 42:2B-1 et seq., except where inconsistent with these rules. A practitioner who is a member, employee, agent, or representative of the limited liability company shall remain personally responsible for his or her own negligence, wrongful acts, or misconduct, and that of any person under his or her direct supervision and control while rendering professional services on behalf of the limited liability company in this State to the person for whom such professional service was being rendered. The professional services offered by each practitioner, whether a partner, member or shareholder, shall be the same or in a closely allied medical or professional health care field. For the purpose of this rule, closely allied fields, pursuant to the Professional Service Corporation Act, N.J.S.A. 14A:17-1 et seq., shall be deemed to include the health care professions licensed by the State Professional Boards under the Division of Consumer Affairs, for example, chiropractic, dentistry, nursing, nurse midwifery, optometry, physical therapy, podiatry, psychology, social work, etc. If the scope of practice authorized by law for each such person differs, any document used in connection with professional practice including, but not limited to, professional stationery, business cards, advertisements or listings and bills, shall designate the field to which such person's practice is limited. Prescriptions shall list only those practitioners authorized by law to prescribe; shall designate the practice of each listed prescriber as required by N.J.A.C. 13:35-6.1; and shall comply with the data requirements of N.J.A.C. 13:35-6.6.

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

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

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

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

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

treatment and health monitoring records shall apply to persons receiving care or evaluation in this setting.

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

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

v. The corporation is licensed by the State Department of Insurance as an insurance carrier offering coverage for medical treatment and the licensee is employed to perform quality assurance services for the insurance carrier.

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

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

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

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

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

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

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

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

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

(i) The following pertain to laboratory service:

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

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

good cause shown. Patient referral may be made only by a licensee holding such financial interest prior to July 31, 1991.

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

(j) The following pertain to physical therapy:

1. A physician may perform and/or prescribe physical therapy to be administered in the physician's office. Billing shall be done only in the name used by the physician's office. A bill for services of a physician's employees, which were rendered by licensed professionals authorized to provide services without medical supervision, shall identify the provider of service by name and degree.

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

(k) The following pertain to radiology:

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

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

(*l*) The following pertain to ophthalmology:

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

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

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

New Rule, R.1992 d.75, effective February 18, 1992 (operative April 15, 1992, except as noted).
See: 23 N.J.R. 161(a), 23 N.J.R. 1063(a), 24 N.J.R. 626(a).
Amended by R.2005 d.193, effective June 20, 2005.
See: 36 N.J.R. 3499(a), 37 N.J.R. 2210(a).
In (f), rewrote 2 and inserted "or limited liability company" following "professional service corporation" in 5.
Petition for Rulemaking.
See: 38 N.J.R. 848(a), 1246(b), 1608(b), 4762(a), 5419(b).
Petition for Rulemaking.
See: 42 N.J.R. 859(b), 1255(d), 2150(c).

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. Tamborlane, 136 N.J.L.J. No. 11, 10 (1994).

Joint Physician-Chiropractor Practice in New Jersey. Markley S. Roderick, 154 N.J.L.J. 966 (1998).

Case Notes

Suspension of doctor's license appropriate; negligence and suspension in another state. In the Matter of the Suspension or Revocation of the License of Tjoa, 95 N.J.A.R.2d (BDS) 26.

Revocation of doctor's license proper; gross negligence. In the Matter of the Suspension or Revocation of the License of Cohen, 95 N.J.A.R.2d (BDS) 23.

Doctor's license revoked; failure to adhere to minimum standard of medical care appropriate for symptoms presented. Attorney General of New Jersey v. Metzler, 95 N.J.A.R.2d (BDS) 17.

Suspension of doctor's license appropriate; doctor was guilty of repeatedly harassing and distracting colleagues. In the Matter of the Suspension or Revocation of the License of Cham, 95 N.J.A.R.2d (BDS) 1.

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

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

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

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

i. A straight salary or an annual retainer which is not related to the volume of patients treated;

ii. A contractual arrangement with a licensed health care facility or health care service to provide non-clinical services such as quality assurance review, peer review, administrative or supervisory services, duties (other than hands-on care) of a department chair or medical director, or similar services;

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

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

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

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

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

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

practitioner's spouse's siblings and parents, and the spouses of the practitioner's children.

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

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

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

(b) A practitioner shall not refer a patient or direct an employee of the practitioner to refer a patient to a health care service in which the practitioner or the practitioner's immediate family, or the practitioner in combination with the practitioner's immediate family, has a significant beneficial interest, unless the practitioner held the interest prior to July 31, 1991 and discloses that interest to the patient as required herein or as otherwise permitted in this rule. Such a practitioner shall be deemed to be grandfathered. If a licensee professionally affiliated with a grandfathered practitioner obtains a significant beneficial interest in the same health care service in which the grandfathered practitioner holds an interest, on or after July 31, 1991, that practitioner shall not refer patients to that service. A licensee professionally affiliated with a grandfathered practitioner who does not hold an interest in that health care service may refer patients to that service so long as all of the disclosure requirements set forth below are met. Disclosure shall be made by the practitioner in ways appropriate to the professional circumstances including conspicuous posting of a written disclosure form prepared as set forth below, at least 8 1/2 by 11 inches in size, in the practitioner's waiting room in all office locations. The patient shall also be provided with a personal copy of the notice. The notice format shall be as follows:

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

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

(LIST APPLICABLE HEALTH CARE SERVICES)

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

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

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

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

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

i. A health care service that is provided at the practitioner's medical office for which the patient is billed directly by and in the practitioner's name; or

ii. Radiation therapy pursuant to an oncological protocol, or lithotripsy or renal dialysis treatment, provided that there is disclosure of the financial interest.

(c) The following pertain to miscellaneous monetary arrangements:

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

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

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

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

3. All other categories of licensees who bill for professional services shall submit the bill directly or via a named designee entity to the patient or patient representative if for treatment services, or to the recipient of the professional services in a non-patient capacity, as applicable.

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

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

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

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

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

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

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

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

2. (Reserved)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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. Tamborlane, 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.

"Authorized" means recognized by a governmental agency to offer medical malpractice insurance products.

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

"Letter of credit" means a non-assignable, non-transferable, unexpired, continuous irrevocable obligation, liability bond or other instrument 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 risk retention groups deemed eligible by the Department of Banking and Insurance, surplus lines registered with the Department of Banking and Insurance, self-insurance trusts or captive insurance companies approved by the New Jersey Health Care Facilities Financing Authority in the Department of Health and Senior Services. "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).

Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
In (a), added "Authorized, inserted "or other entity" following "issued by a carrier" in "Covered", inserted ", liability bond or other instrument" following "irrevocable obligation" in "Letter of credit", and rewrote "Not available".

Case Notes

That a workers' compensation insurer's doctor, an independent contractor who only performed independent medical examinations, did not have malpractice insurance did not make the insurer vicariously liable for the doctor's alleged malpractice in diagnosing a claimant. At the time of the diagnosis, N.J.A.C. 13:35-6.18 had not yet been adopted, so carrying malpractice insurance was not yet a clear legal condition of the doctor's existing license; therefore, the incompetent-contractor exception to non-liability did not apply. Basil v. Wolf, 193 N.J. 38, 935 A.2d 1154, 2007 N.J. LEXIS 1419 (2007).

N.J.S.A. 45:9-19.17(a) requires a physician maintaining a "professional medical practice," which was later defined by N.J.A.C. 13:35-6.18, to obtain a minimum amount of medical malpractice insurance as a condition for licensure; after the effective date of N.J.A.C. 13:35-6.18, a workers' compensation insurer that engages an independent medical evaluation contract physician must ensure that the physician has the requisite malpractice insurance. Basil v. Wolf, 193 N.J. 38, 935 A.2d 1154, 2007 N.J. LEXIS 1419 (2007).

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 licensees 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 within 10 days 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. Pending or final actions by criminal authorities for violations of law or regulation, or any arrest or conviction for any criminal or quasi-criminal offense pursuant to the laws of the United States, this State or another state, including, but not limited to:

i. Criminal homicide pursuant to N.J.S.A. 2C:11–2;

ii. Aggravated assault pursuant to N.J.S.A. 2C:12–1;

iii. Sexual assault, criminal sexual contact or lewdness pursuant to N.J.S.A. 2C:14–2 through 2C:14–4; or

iv. An offense involving any controlled dangerous substance or controlled substance analog as set forth in N.J.S.A. 2C:35–1 et seq.;

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 within 21 days 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 the required time period 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).
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
In (c), inserted "within 10 days" preceding "of any changes" in the introductory paragraph and rewrote 1; in (d), inserted "within 21 days" preceding "of any changes"; in (g), substituted "the required time period" for "21 days" preceding "of the change".

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.

(d) Under (c) above, for pediatric patients, the physician shall have experience in the performance of the pertinent procedures with such patients.

(e) A physician shall not direct a diagnostic radiologic technologist holding the LRT(R) license to perform the following tasks:

1. Administer contrast material into the subarachnoid space;

2. Administer to a patient pharmaceutical materials other than those approved in accordance with (c) above; or

3. Administer radioactive materials in any form for any purpose.

(f) A physician who allows a medical resident to supervise a diagnostic radiologic student technologist shall assure that the supervision is performed concurrently with a licensed radiologic technologist or with the physician.

(g) A physician may direct an individual holding a general diagnostic or limited technologist license to perform such radiologic procedures as are authorized by the laws and rules of the State Department of Environmental Protection applicable to that licensure. A physician or a podiatric physician (DPM) may direct either a technologist holding the LRT(R) license or a technologist holding the limited license for podiatric x-ray LRT(P) to perform such radiologic procedures as are authorized and applicable to the holder of a LRT(P) license.

(h) A physician may direct a technologist holding the LRT(U) license to administer a contrast medium injection into a pre-existing peripheral intravenous line or into a pre-existing urinary catheter, whether indwelling or otherwise, so long as a physician or a medical resident is on the premises and is readily available to physically attend to the patient. The physician shall be responsible for the choice and ordering of all contrast materials and for the determination of dosage and route of administration. For pediatric patients, the physician shall have experience in the performance of the pertinent procedures with such patients or shall assure consultation with a physician having such experience.

(i) Prior to delegating the tasks set forth in (g) and (h) above, the physician (or another physician in the office or, in a licensed health care facility, the head of the pertinent Department) shall personally certify and document 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/facility.

(j) Except as set forth in (h) above, a physician shall not direct a technologist holding the LRT(C), LRT(D), LRT(P), LRT(O), or LRT(U) license to perform any of the tasks set forth in (c) or (e) above.

(k) A supervising physician may direct the LNMT to establish a peripheral intravenous line.

(*l*) A physician who is an authorized medical user, as specified on a Byproduct Materials License issued by the Nuclear Regulatory Commission or on the Radioactive Materials License issued by the New Jersey Department of Environmental Protection, may direct an LNMT to inject radioactive materials used for diagnostic purposes when specifically designated by the supervising physician, and only as follows:

1. Into pre-existing urinary catheters, whether indwelling or otherwise;

2. Into pre-existing nasogastric tubes or other gastric or intestinal feeding tubes;

3. Into a peripheral intravenous line, into a pre-existing central intravenous line, or by direct intravenous injection; and

4. Into a spinal needle placed into the subarachnoid space by a physician who is continuously present with the patient throughout the procedure.

(m) A physician may direct the LNMT to administer, under direct physician supervision, nonradioactive pharmaceuticals as follows:

1. Adenosine and dipyridamole for use in nuclear medicine stress tests;

2. Aminophylline in conjunction with nuclear medicine stress tests;

3. Diuretics;

4. Angiotensin converting enzyme-inhibitor agents;

5. Vitamin B–12;

6. Intravenous flush solutions such as saline or heparin; and

7. Sincalide, a synthetic cholecystokinin.

(n) The Board may, from time to time, add or delete pharmaceuticals by amendment to (m) above, on its own initiative or through a petition for rulemaking.

(*o*) A physician shall not direct the LNMT to administer Controlled Dangerous Substances or other pharmaceuticals, including, but not limited to, atropine, neostigmine, other cardioactive medications or any other pharmaceuticals except as set forth in (m) above.

(p) The physician shall be responsible for the choice and ordering of all nonradioactive pharmaceuticals and for the determination of dosage and route of administration. The physician who is also an authorized user shall be responsible for the choice and ordering of all radioactive pharmaceuticals and for the determination of dosage and route of administration. For pediatric patients, the physician shall

have experience in the performance of the pertinent procedures with such patients.

New Rule, R.1999 d.155, effective June 7, 1999.
See: 30 N.J.R. 1752(a), 31 N.J.R. 1496(a).
Petition for Rulemaking.
See: 32 N.J.R. 2166(a).
Amended by R.2003 d.286, effective July 21, 2003.
See: 34 N.J.R. 3058(a), 35 N.J.R. 3368(a).
In (m), added 7.

13:35–6.21 Hair replacement techniques

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

1. "Cosmetic suturing retaining process" means a method of attaching a unit of hair to the scalp via a suturing (retaining) process.

2. "Implanted prolene loop procedure" means a surgical insertion of continuous prolene sutures in and out of the scalp in concentric circles to which a hair weave is attached.

3. "Licensee" means a physician subject to regulation by the New Jersey Board of Medical Examiners.

(b) No licensee shall perform or assist in the performance of a hair replacement technique using the implanted prolene loop procedure or any other cosmetic suturing retaining process involving the use of suture material in the scalp.

(c) Nothing in this section shall preclude licensees from performing medically recognized hair transplantation techniques.

(d) Licensees shall complete and maintain patient medical records pursuant to N.J.A.C. 13:35–6.5 which accurately reflect the transplantation technique utilized in any hair replacement procedure, a brief history pertinent to the procedure, any complications which ensued, any medications prescribed and follow-up directed.

(e) Licensees shall assure that prior to the initiation of a permitted hair transplantation technique, the risks and benefits have been discussed with the patient and informed consent has been obtained.

(f) Licensees shall, by means of a telephone number by which they shall be available, provide appropriate medical coverage on a 24–hour basis to all patients undergoing a hair transplantation technique and shall maintain a log for the sole purpose of recording all complications. This log shall be available for inspection by the Board upon request.

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

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

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

3. A failure to comply with the provisions of an act or regulation administered by the Board, pursuant to N.J.S.A. 45:1–21(h); or

4. Unprofessional conduct which would present an imminent danger to the individual patient or to the public health, safety or welfare, within the meaning of N.J.S.A. 45:9–19.5.

(h) Licensees who are in possession of information which reasonably indicates that another licensee has engaged in a prohibited hair replacement technique shall be obligated to report such information to the Board pursuant to N.J.S.A. 45:9–19.5.

New Rule, R.1994 d.86, effective February 22, 1994.
See: 25 N.J.R. 5444(a), 26 N.J.R. 1104(a).
Stay of Operative Date until February 23, 1994; further stay until April 13. 1994.
See: 26 N.J.R. 1354(a).
Withdrawal of stay of Operative Date.
See: 26 N.J.R. 4083(a).

13:35–6.22 Termination of licensee-patient relationship

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

"Emergency care or service" means the provision of medical care or services to an individual in circumstances where the individual's life or health may be threatened or compromised unless timely medical care is provided.

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

"Licensee-patient relationship" means an association between a licensee and patient wherein the licensee owes a continuing duty to the patient to be available to render professional services consistent with his or her training, experience and current scope of practice.

"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.

(b) The licensee-patient relationship shall be deemed to exist where the licensee has provided services to the patient within one year preceding the date on which care is to be terminated or in such other circumstances where a patient has indicated to the licensee that the patient anticipates that the licensee will provide continued professional services to the patient.

(c) In order to terminate a licensee-patient relationship, a licensee shall:

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).

Case Notes

Since there was no justification for a limb length discrepancy examination in the record where a victim patient was being examined without a chaperone for a toe injury, and the surrounding circumstances showed that it was only a pretext to get the patient to disrobe, the physician's conduct constituted sexual misconduct and sexual harassment, and therefore was in violation of N.J.S.A. 45:1-21(h). In re Suspension or Revocation of License of Hakimi, OAL Dkt. No. BDS 11873-04, 2006 N.J. AGEN LEXIS 148, Initial Decision (February 24, 2006).

13:35-6.24 Reporting of communicable diseases by licensees

(a) A licensee shall report a case of a communicable disease in accordance with Department of Health and Senior Services regulations at N.J.A.C. 8:57-1.

(b) A licensee shall report a case of Acquired Immunodeficiency Syndrome (AIDS) and infection with Human Immunodeficiency Virus (HIV) in accordance with Department of Health and Senior Services regulations at N.J.A.C. 8:57-2.

(c) Failure to report pursuant to the requirements of this section shall constitute professional misconduct subjecting the licensee to disciplinary action by the Board.

New Rule, R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).

13:35-6.25 Cultural competency training

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

"College of medicine" means a college accredited by the Liaison Committee on Medical Education, the American Osteopathic Association (AOA), or other accrediting agency with comparable accrediting standards as recognized by the New Jersey Board of Medical Examiners. Schools accredited by the Council of Podiatric Medical Education (CPME) to confer the degree D.P.M. in New Jersey shall be considered colleges of medicine for purposes of this section.

"Continuing medical education" or "CME" means post-secondary educational activity, which must be: 1. designated Category 1, as defined in the American Medical Association (AMA) Physicians Recognition Award booklet, incorporated herein by reference, as amended and supplemented and available at www.ama-assn.org; 2. designated Category 1a, 1b or 2A in the AOA CME Guide for Osteopathic Physicians, incorporated herein by reference, as amended and supplemented, and available at www.do-online.org; 3. prescribed credit, as designated by the American Academy of Family Physicians (AAFP) Commission on Continuing Professional Development in the AAFP CME Guidelines, incorporated herein by reference, as amended and supplemented and available at www.aafp.org; or 4. approved contact hours, as designated by the Council on Podiatric Medical Education (CPME); and which must be provided by sponsors accredited, recognized or approved at the time of the educational activity by the Accreditation Council on Continuing Medical Education (ACCME), the AOA, the AAFP, or as to podiatrists, the CPME.

"Cultural competency training" means a curriculum developed in consultation with the Association of American Medical Colleges (AAMC) or another nationally recognized organization, which reviews medical school curricula, designed to address the problem of race and gender-based disparities in medical treatment decisions and to improve the sensitivity to and awareness of values in diverse communities that may affect the delivery of health care.

"Physician" means an individual holding an M.D. or D.O. degree licensed pursuant to N.J.S.A. 45:9-1 et seq.

"Podiatrist" means an individual holding a D.P.M. degree licensed pursuant to N.J.S.A. 45:5-1 et seq.

"Post-secondary education" means education obtained in a professional school, graduate medical education or continuing medical education consisting of courses with content deemed, by the Board, to be substantially equivalent to cultural competency curriculum criteria established by the Board.

"Practitioner" means a physician or a podiatrist.

(b) Each college of medicine in this State shall provide cultural competency training, as identified in (d) below, completion of which shall be required as a condition of receiving a diploma from a college of medicine in this State.

(c) Cultural competency training for CME credit shall be offered by each college of medicine in this State. The training shall satisfy the criteria for cultural competency training established by the Board.

(d) To be recognized in satisfaction of the cultural competency training requirement applicable to licensees, any CME program of instruction shall be of at least six hours duration, offered in the classroom, or through workshops, over the internet or through other venues, that provides:

1. A context for the training, common definitions of cultural competence, race, ethnicity and culture and tools for self-assessment;

2. An appreciation for the traditions and beliefs of diverse patient populations, at multiple levels — as individuals, in families and as part of a larger community;

3. An understanding of the impact that stereotyping can have on medical decision-making;

4. Strategies for recognizing patterns of health care disparities and eliminating factors influencing them;

5. Approaches to enhance cross-cultural clinical skills, such as those relating to history-taking, problem solving and promoting patient compliance; and

6. Techniques to deal with language barriers and other communication needs, including working with interpreters.

(e) A physician who was licensed to practice medicine prior to March 24, 2005, and who did not receive instruction in cultural competency training as part of the curriculum of a college of medicine shall, as a condition of the next renewal after March 24, 2008, document completion of CME or equivalent post-secondary education in cultural competency training pursuant to (d) above before being granted licensure renewal by the Board. Cultural competency training shall be in addition to the CME required by the Board at N.J.A.C. 13:35-6.15.

(f) A podiatrist who was licensed to practice podiatry prior to March 24, 2005, and who did not receive instruction in cultural competency training as part of the curriculum of a college of medicine shall, as a condition of the next renewal after March 24, 2008, document completion of CME or equivalent post-secondary education in cultural competency training pursuant to (d) above before being granted licensure renewal by the Board. Cultural competency training may be included in the CME required by the Board at N.J.A.C. 13:35-6.15.

(g) A practitioner licensed to practice after March 24, 2005, but on or before June 29, 2007, who did not receive instruction in cultural competency training as part of the

curriculum of a college of medicine, as a condition of the next renewal after March 24, 2008, shall document completion of CME or equivalent post-secondary education in cultural competency training pursuant to (d) above before being granted licensure renewal by the Board. Cultural competency training may be included in the CME required by the Board at N.J.A.C. 13:35-6.15.

(h) A practitioner licensed to practice on or after the date of the expiration of the next licensure cycle (June 30, 2007 for physicians and October 31, 2007 for podiatrists) who did not receive instruction in cultural competency training as part of the curriculum of a college of medicine, shall document completion of CME or equivalent post-secondary education in cultural competency training pursuant to (d) above by the end of the next complete renewal cycle after he or she was licensed. Cultural competency training may be included in the CME required by the Board at N.J.A.C. 13:35-6.15.

(i) The Board, or its designee, may waive the cultural competency training CME requirement for an applicant who is applying for relicensure and who can demonstrate to the satisfaction of the Board that he or she has attained the substantial equivalent of the cultural competency training CME requirement through completion of a similar course in his or her post-secondary education.

New Rule, R.2008 d.77, effective April 7, 2008.
See: 39 N.J.R. 2202(a), 40 N.J.R. 1889(b).

13:35-6.26 Procedures for physician ordered immunizations performed by licensed pharmacists

(a) A New Jersey licensed physician may participate in an immunization program with a licensed pharmacist pursuant to N.J.S.A. 45:14-63 of the Pharmacy Practice Act, provided that the pharmacist is authorized to engage in such activities by the Board of Pharmacy pursuant to N.J.A.C. 13:39-4.20, and provided the pharmacist administers vaccines and related emergency medications, which shall be limited to diphenhydramine and epinephrine, pursuant to:

1. A prescription for the vaccine, related emergency medications, and pharmacist administration of the vaccine that is patient specific; and/or

2. A physician's standing order for the vaccine, related emergency medications above, and administration instructions that are not patient specific.

(b) A physician shall supervise a licensed pharmacist who is participating in an immunization program implemented pursuant to the physician's standing order. Supervision by the delegating physician shall be deemed adequate if the delegating physician:

1. Is responsible for formulating or approving a standing order, which shall include compliance with Centers for Disease Control and Prevention (CDC) guidelines for vaccine administrations, set forth in Appendix D of "Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book: Course Textbook)," updated 10th edition, February 2007. The CDC vaccine administration guidelines are incorporated herein by reference, as amended and supplemented, and can be found at the CDC website, www.cdc.gov, specifically, http://www.cdc.gov/vaccines/pub/pinkbook/downloads/appendices/appdx-full-d.pdf. The standing order shall also include compliance with the American Heart Association (AHA) Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (2005). The AHA Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (2005) are incorporated herein by reference, as amended and supplemented, and can be found at the AHA website, www.americanheart.org, specifically, http://circ.ahajournals.org/content/vol112/24_suppl/. The order shall also include procedures which shall be followed for the reporting of adverse events. The delegating physician shall annually review the order and the services provided to patients under the order;

2. Is geographically located to be easily accessible to the pharmacy practice site and, if applicable, to the immunization location.

3. Is available through direct telecommunication for consultation, assistance, and direction; and

4. Receives annual status reports on the immunization program as administered by the pharmacist.

New Rule, R.2009 d.104, effective April 6, 2009.
See: 40 N.J.R. 1072(a), 41 N.J.R. 1493(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:

1. Requirements, by specialty or expertise, for physicians authorized to perform a clinical brain death examination and declare death upon the basis of neurological criteria; and

2. Accepted medical standards, including criteria, tests and procedures, to govern declarations of death upon the basis of neurological criteria.

13:35-6A.2 Definitions

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

"Apnea" means the absence of respiration and a terminal PCO2 greater than 60 mmHG or a terminal PCO2 at least 20 mmHg over the initial normal baseline PCO2.

"Brain death" means the irreversible cessation of all functions of the entire brain, including the brainstem.

"Examining physician" means a physician who performs a clinical brain death examination and meets the qualifying criteria set forth at N.J.A.C. 13:35-6A.3. The term "examin-

ing physician" may refer to one or more physicians involved in the clinical brain death examination.

13:35-6A.3 Requirements for physicians authorized to declare death on the basis of neurological criteria

(a) A physician performing a clinical brain death examination shall be plenary licensed and shall hold the following qualifications, dependent on the age of the patient upon whom a declaration of brain death is to be made:

1. Age below two months: When declarations of brain death are to be made upon children below two months of age, the examining physician shall be a specialist in neonatology, pediatric neurology or pediatric neurosurgery.

2. Age between two months and 12 months: When declarations of brain death are to be made upon children at or above two months of age, and at or below 12 months of age, the examining physician shall be a specialist in pediatric critical care, pediatric neurology or pediatric neurosurgery.

3. Age greater than 12 months: When declarations of brain death are to be made upon patients above 12 months of age, the examining physician shall be duly qualified by training and experience to declare brain death. For purposes of this section, neurologists, neurosurgeons, critical care specialists and trauma surgeons shall be deemed to be duly qualified physicians. In addition, any physician who has been granted privileges by a hospital to declare brain death may serve as the examining physician pursuant to this subchapter.

13:35-6A.4 Standards for declaration of brain death

(a) Declarations of brain death shall be made in accordance with accepted medical standards. A patient may be pronounced dead if a physician meeting the requirements set forth in N.J.A.C. 13:35-6A.3 determines in accordance with the criteria set forth in this section that brain death has occurred.

(b) The examining physician who is to pronounce brain death shall:

1. Determine a reasonable basis to suspect brain death. Brain death may be declared where the etiology of the insult or injury is sufficient to cause brain death and, in the judgment of the examining physician, is irreversible;

2. Exclude complicating medical conditions that may confound the clinical assessment of brain death, including:

i. Severe hypothermia, defined as core body temperature at or below 92 degrees Fahrenheit in adults, or outside the clinically established age specific range in a child;

ii. The effects of neuromuscular blockade(s). In the event a neuromuscular blockade was used to treat the patient, the examining physician shall establish that the effects of the blockade are reversed prior to performing clinical examinations for brain death;

iii. The effects of CNS depressants. If CNS depressants are present and serum blood level is therapeutic or below the therapeutic range, a clinical examination may be initiated. If serum blood levels are not available, above the therapeutic range or unknown, or there is an overdose or toxic exposure of an unknown agent, a brain death evaluation may proceed without reliance on clinical examination if, in the judgment of the examining physician, the injury or cause of coma is non-survivable. In such event, an objective measure of intracranial circulation shall be used as a confirmatory test;

iv. Severe metabolic imbalances, unless in the judgment of the examining physician any such imbalances do not confound the clinical assessment of brain death; and

v. Mean arterial pressure less than 60 mmHg in an adult or outside the clinically established age specific range in a child;

3. Perform a clinical examination to evaluate the patient for the presence of brain death. The following clinical findings, if present, are indicative of brain death:

i. A determination that supraspinal motor response(s) to pain is absent;

ii. A determination that brainstem reflexes are absent, which determination may be established by ascertaining all of the following:

(1) No pupillary response to light;

(2) No deviation of the eyes to irrigation of each ear with 50 ml of cold water. The tympanic membrane shall be determined to be intact;

(3) No corneal reflex; and

(4) No response to stimulation of the posterior pharynx and/or no cough response to tracheobronchial suctioning; and

iii. The presence of apnea, which shall be established in accordance with the following testing procedure:

(1) Arterial PCO2 is normalized to greater or equal to 40 mmHg;

(2) 100 percent oxygen is delivered via the ventilator for 10 minutes prior to starting the test;

(3) A baseline arterial blood gas is drawn;

(4) A pulse oximeter is connected and the ventilator is disconnected;

(5) 100 percent oxygen is delivered into the trachea via cannula in the ET tube, at six liters/minute;

(6) If tolerated, the patient is left off the ventilator for eight to 10 minutes and the patient is observed carefully for respiratory movements. Another blood gas is drawn at the end of the eight to 10 minutes and the ventilator is reconnected;

(7) The length of the apnea test and the PCO2 at the end of the test are documented in the patient record; and

(8) If the patient does not tolerate the apnea test, as evidenced by significant drops in blood pressure and/or oxygen saturation, or the development of significant arrhythmias, the test shall be discontinued and either repeated or supplanted with a confirmatory test.

iv. When, in the judgment of the examining physician, a clinical examination cannot be performed due to the nature of injuries, intoxication, patient instability, electrolyte imbalances or any other reason, a confirmatory test such as an intracranial blood flow, four vessel cerebral angiography, radionuclide angiography, transcranial Doppler ultrasound, CT angiogram, or MR angiogram shall be substituted for the clinical examination; and

4. Confirm the diagnosis with a confirmatory test or by a repeat clinical examination, consistent with the following:

i. When a clinical examination of a patient shows the absence of all supraspinal and brain stem reflexes as established by the criteria in (b)3 above, the examining physician shall confirm the diagnosis of brain death with an objective confirmatory test measuring intracranial circulation such as an intracranial blood flow, four vessel cerebral angiography, radionuclide angiography, transcranial Doppler ultrasound, CT angiogram or MR angiogram.

ii. In the event confirmatory testing is not available or is clinically precluded, the examining physician shall repeat the clinical examination after a period of observation, which period shall be not less than 48 hours for patients below the age of two months, not less than 24 hours for patients between the ages of two months to one year, and not less than six hours for patients greater than one year of age.

13:35-6A.5 Organ donation

If the person to be declared dead upon the basis of neurological criteria is or may be an organ donor, then the examining physician shall not have any responsibility for any contemplated recovery or transplant of that person's organs, and shall not serve in the capacity of organ transplant surgeon, the attending physician of the organ recipient, or otherwise an individual subject to a potentially significant conflict of interest relating to procedures for organ procurement.

13:35-6A.6 Exemption to accommodate personal religious beliefs

Death shall not be declared on the basis of neurological criteria if the examining physician has reason to believe, on the basis of information in the patient's available medical records, or information provided by a member of the patient's family or any other person knowledgeable about the patient's personal religious beliefs, that such a declaration would violate the personal religious beliefs of the patient. In these cases, death shall be declared, and the time of death fixed, solely upon the basis of cardio-respiratory criteria.

13:35-6A.7 Pronouncement of death

The examining physician shall document within the patient record the results of all tests performed and shall sign the chart. After a clinical examination and a confirmatory test or examination have been completed and documented on the patient's chart, and if the examining physician has been able to make all requisite determinations consistent with N.J.A.C. 13:35-6A.5, then the examining physician may authorize the pronouncement of death. The actual pronouncement of death

may thereafter be made by the examining physician or any plenary licensed physician acting upon the authorization of the examining physician.

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"; and 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 appropriately 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.

1. An NJPB that contains prescriptions for two or more controlled substances shall be invalid.

2. An NJPB that contains a prescription for only one controlled substance and contains other prescription(s) other than another controlled substance shall be valid.

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).
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
In (h), added 1 and 2.

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 recorded in a permanent, contemporaneous dispensing log which shall contain, at a minimum, the following:

1. The full name of the patient;

2. The complete name of each drug dispensed;

3. The strength and quantity of the drug dispensed;

4. Instructions as to the frequency of use;

5. The date of dispensing; and

6. The identity of the dispensing practitioner, if more than one practitioner dispenses in the office.

(e) Each different drug dispensed, in whatever dosage form, shall be placed in a separate container with a safety closure cap, unless the patient requests otherwise or the drug is a pharmaceutical sample which has been packaged and labeled by the manufacturer.

(f) Each drug dispensed, including pharmaceutical samples, shall bear a legible label which includes the following:

1. The complete name of the drug dispensed;

2. The strength and quantity of the drug dispensed;

3. Instructions as to the frequency of use;

4. Special precautions, as appropriate; and

5. The expiration date of the drug.

(g) With respect to any drug which is not packaged by the manufacturer as a sample, the label shall also include the following:

1. The full name of the patient;

2. A list of the ingredients if the drug was compounded, not manufactured;

3. The date of dispensing; and

4. The identity of the dispensing practitioner.

(h) A practitioner shall not charge any patient a fee for a drug packaged and labeled by a manufacturer as a sample. For any drug dispensed which is not packaged by the manufacturer as a sample, a practitioner may charge a fee to allow for a recoupment of a portion of overhead and administrative costs, which fee shall not exceed the actual acquisition cost plus an additional sum not to exceed 10 percent of the actual acquisition cost.

(i) Subject to the exception in (j) below, if a practitioner charges a fee for the drug dispensed, either directly or through a global office visit charge which is more than that practitioner's usual and customary visit charge, the practitioner:

1. Shall not dispense that drug or a substantially equivalent drug in a quantity or in dosages greater than that which would allow the patient a seven-day supply;

2. Shall not dispense that medicine or a substantially equivalent medicine at a frequency greater than once every 30 days;

3. Shall assure that information is given to the patient regarding the alternative availability of the drug outside of the practitioner's office; and

4. Shall disclose to the patient in advance of purchase and again on the bill the actual acquisition cost of the drug.

(j) In accordance with N.J.S.A. 45:9–22.11, the requirements set forth at (i) above shall not apply to a practitioner:

1. If the office at which the dispensing occurs is situated 10 or more miles from the nearest licensed pharmacy;

2. If the drug is dispensed pursuant to an oncological or AIDS protocol;

3. If the drug dispensed is a salve, ointment or drops; or

4. If the drug is dispensed in, and directly related to, the services rendered to the patient at:

i. A hospital emergency room;

ii. A student health center at an institution of higher education; or

iii. A publicly subsidized community health center, family planning clinic or prenatal clinic.

(k) The requirements set forth in (d) through (g) above shall not apply to the dispensing of non-prescription substances.

Amended by R.2000 d.400, effective October 2, 2000.
See: 31 N.J.R. 2454(a), 32 N.J.R. 3576(a).
Rewrote (i)2; inserted (k).

13:35–7.5A Limitations on prescribing, administering or dispensing of drugs for the treatment of obesity

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

"Bariatric practice" means the practice of medicine by any physician relating to the treatment of obesity, in conjunction with those co-morbidities affected by obesity.

"Body mass index" means a calculation determined by dividing the measured body weight in kilograms by body height in meters square (kg/m^2).

"Co-morbidities" means any disease, psychiatric or medical condition that may be negatively influenced by obesity, such as diabetes, hypertension, hyperlipidemia, osteoarthritis, cardiac conditions, stroke, respiratory disease and certain cancers.

"Informed consent" means the agreement of the patient to follow the therapeutic regimen established by a practi-

tioner, which follows the disclosure by a practitioner of that information which a patient needs as to available choices with respect to the proposed treatment, including the inherent and potential risks of such treatment.

"Obesity" means a complex, multi-factorial condition characterized by a documented diagnosis of excess adipose tissue as determined by the calculation of a body mass index greater than 27.

(b) A practitioner who engages in bariatric practice shall not prescribe, order, dispense, administer, sell or transfer any drug for the treatment of obesity except in accordance with the provisions of this subchapter and in conformity with the following requirements:

1. A practitioner shall personally, or through a licensed health care practitioner working within his or her lawful scope of practice and acting on the treating practitioner's order or protocol, take a complete history of the patient and conduct a comprehensive physical examination and order or perform any laboratory and/or diagnostic tests as indicated by the clinical evaluation. The history, physical examination and laboratory and/or diagnostic tests shall be undertaken in an effort to determine the existence of any co-morbidities and if the use of any prescription medication is contraindicated. The practitioner shall also assess the possible existence of any psychiatric or psychological condition (such as, but not limited to, depression or substance abuse) which shall be evaluated and treated prior to or contemporaneous with the treatment of obesity and which may pose a contraindication to the use of prescription medications. The practitioner shall fully document the findings of the history, physical examination and laboratory and/or diagnostic tests in the patient record and shall also indicate the methods and goals of treatment in the patient record;

2. A practitioner shall provide for nutritional counseling, recommendations for behavior modification and appropriate exercise for weight loss, and document such recommendations in the patient record;

3. A practitioner shall obtain written or verbal informed consent from the patient before prescribing, ordering, dispensing, administering, selling or transferring medication, pursuant to the provisions of this subchapter, for the treatment of obesity. The practitioner shall, either verbally or in writing, identify the risks associated with the use of such medications; and

4. (Reserved)

5. A practitioner shall monitor the progress of the patient's weight loss or gain at the time of each of the patient's follow-up visits. The practitioner shall personally, or through a licensed health care practitioner working within his or her lawful scope of practice and acting on the treating practitioner's order or protocol, conduct a physical examination and shall perform laboratory tests as indicated by the clinical evaluation. The findings of the physical examination shall be fully documented in the patient record.

6. (Reserved)

(c) Any violations of this section shall be subject to the enforcement provisions of N.J.A.C. 13:35–7.10.

New Rule, R.2000 d.401, effective October 2, 2000.
See: 31 N.J.R. 2457(a), 32 N.J.R. 3577(a).

13:35–7.6 Limitations on prescribing, administering or dispensing of controlled substances; special exceptions for management of pain

(a) When prescribing, dispensing or administering controlled substances, a practitioner shall ensure that a patient's medical history has been taken and physical examination accomplished, including an assessment of physical and psychological function, underlying or coexisting diseases or conditions, any history of substance abuse and the nature, frequency and severity of any pain. The medical record shall reflect:

1. A recognized medical indication for the use of the controlled substance;

2. The complete name of the controlled substance;

3. The dosage, strength and quantity of the controlled substance; and

4. The instructions as to frequency of use.

(b) With respect to Schedule II controlled substances, unless the requirements of (c) below are met, a practitioner shall not authorize a quantity calculated to exceed 120 dosage units or a 30–day supply, whichever is less.

(c) A practitioner may exceed the 120 dosage unit or 30–day supply limitations for Schedule II controlled substances in (b) above in the following circumstances:

1. For the 120 dosage unit limitation, the practitioner follows a treatment plan designed to achieve effective pain management which has been tailored to the needs of a patient who is suffering pain from cancer, intractable pain or terminal illness. The treatment plan shall state objectives by which treatment success is to be evaluated, such as pain relief and improved physical and psychological function, and shall indicate if any further diagnostic evaluations or other treatments are planned. The practitioner shall discuss the risks and benefits of the use of controlled substances with the patient, guardian or authorized representative; and

2. With regards to the 30–day supply limitation, a practitioner may prescribe the use of an implantable infusion pump which is utilized to achieve pain management for patients suffering from cancer, intractable pain or terminal illness. A prescription for such an implantable infusion pump may provide up to a 90–day supply as long as the physician evaluates and documents the patient's continued need at least every 30 days.

(d) When controlled substances are continuously prescribed for management of pain for three months or more, the practitioner:

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 Division of Consumer Affairs to conduct a narcotic treatment program pursuant to N.J.S.A. 24:21-10 and N.J.A.C. 13:45H-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.
Administrative change.
See: 43 N.J.R. 1204(b).

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-chlortestosterone)
Chorionic gonadotropin
Closebol
Dehydrochlormethyltestosterone
Dihydrotestosterone
(4-dihydrotesterone)
Ethylestrenol
Fluoxymesterone
Mesterolone
Methandienone
Methandriol
Methandrostenolone
Methenolone
Methyltestosterone
Mibolerone
Nandrolone
Norethandrolone
Oxandrolone
Oxymesterone
Oxymetholone
Somatrem
Somatropin
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 college curriculum 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).
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
In (a), substituted "completion of a college curriculum" for "completion of a county college course" preceding "in hearing aid selection" in 2.

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; biennial license renewal; license suspension; reinstatement of suspended license; inactive status; return from inactive status

(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) All licenses issued by the Committee shall be issued for a two-year biennial licensure period. A licensee who seeks renewal of the license shall submit a renewal application and the renewal fee set forth in N.J.A.C. 13:35–8.19 prior to the expiration date of the license.

(d) The Board shall send a notice of renewal to each licensee at the address registered with the Board at least 60 days prior to the expiration of the license. If the notice to renew is not sent at least 60 days prior to the expiration date, no monetary penalties or fines shall apply to the holder for failure to renew.

(e) If a licensee does not renew the license prior to its expiration date, the licensee may renew the license within 30 days of its expiration by submitting a renewal application, a renewal fee and a late fee, as set forth in N.J.A.C. 13:35–8.19. During this 30–day period, the license shall be valid, and the licensee shall not be deemed to be practicing without a license.

(f) A license that is not renewed within 30 days of its expiration shall be automatically suspended. An individual who continues to practice with a suspended license shall be deemed to be engaged in unlicensed practice.

(g) A licensee whose license has been automatically suspended for five years or less for failure to renew pursuant to (f) above may be reinstated by the Committee upon completion of the following:

1. Payment of the reinstatement fee and all past delinquent biennial renewal fees pursuant to N.J.A.C. 13:35–8.19;

2. Completion of the continuing education units required for each biennial registration period for which the licensee was suspended; and

3. Submission of an affidavit of employment listing each job held during the period of suspended license which includes the name, address, and telephone number of each employer.

(h) In addition to the fulfilling the requirements set forth in (g) above, a licensee whose license has been automatically suspended for more than five years who wishes to return to the dispensing of hearing aids shall reapply for licensure and shall demonstrate that he or she has maintained proficiency. An applicant who fails to demonstrate to the satisfaction of the Committee that he or she has maintained proficiency while suspended may be subject to an examination or other requirements as determined by the Committee prior to reinstatement of his or her license.

(i) Renewal applications shall provide the licensee with the option of either active or inactive status. A licensee electing inactive status shall pay the inactive license fee set forth in N.J.A.C. 13:35–8.19 and shall not engage in the dispensing of hearing aids.

(j) A licensee who elected inactive status and has been on inactive status for five years or less may be reinstated by the Committee upon completion of the following:

1. Payment of the reinstatement fee;

2. The completion of the continuing education units required for each biennial registration period for which the licensee was on inactive status; and

3. Submission of an affidavit of employment listing each job held during the period the licensee was on inactive status which includes the name, address, and telephone number of each employer.

(k) In addition to the fulfilling the requirements set forth in (j) above, a licensee who has been on inactive status for more than five years who wishes to return to the dispensing of hearing aids shall reapply for licensure and shall demonstrate that he or she has maintained proficiency. An applicant who fails to demonstrate to the satisfaction of the Committee that he or she has maintained proficiency while on inactive status may be subject to an examination or other requirements as determined by the Committee prior to reinstatement of his or her license.

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.
Amended by R.2005 d.120, effective April 18, 2005.
See: 36 N.J.R. 4633(a), 37 N.J.R. 1203(a).
Rewrote the section.

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 consist of two sections, one section relating to theory and knowledge about fitting and dispensing hearing aids and the other section testing 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 passing score as determined by the examining agency on the written section of the examination relating to theory and knowledge about fitting and dispensing hearing aids and a score of 70 or greater on the written section of the examination relating to laws and regulations.

2. Candidates who fail all or any section of the written examination shall be required to sit for the entire licensing examination during the next regularly scheduled examination with one exception: candidates failing only the law and regulation section may be admitted to a re-examination for this section only.

(c) 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 retake 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.

ii. What services will be provided by the sponsoring program;

iii. What practice restrictions should be imposed, if any;

iv. What monitoring regimen should be instituted, if any;

v. What supervision and reporting should be required and by whom; and

vi. At what frequency periodic interviews with the IRC should be scheduled;

8. Shall conduct such supplemental inquiry as may be directed by the Board;

9. Shall review coded letter agreements between the PAP and participating licensees embodying the terms of participation as reviewed by the Board and mandating that certain notice shall be provided to other jurisdictions if the licensee should elect to leave this State or should apply for initial licensure in another state, or in response to a particular inquiry from another state or regulatory agency or a health care facility at which the participating licensee has applied for privileges;

10. Shall notify the Board of any rejection by the licensee of a term of participation, including a refusal to consent to the release of records, and if no new agreement can be reached, shall notify the licensee that he or she may not participate in the program and shall disclose the licensee's identity and transmit the entire IRC file to the Board for appropriate disciplinary review;

11. Shall promptly review all reports submitted pursuant to such letter agreements, requesting supplemental investigation or appearances, as appropriate;

12. Shall immediately review any report indicating that a participating licensee has not complied with the terms of the letter agreement or has otherwise demonstrated a relapse or impairment, and shall thereafter provide the Board with notice of any information, which appears to be reliable and for which no acceptable explanation has been proffered, concerning noncompliance;

13. Shall provide the Board with periodic coded reports, submitted in accordance with a schedule established by the IRC, as to the status of all participating licensees and any recommendations for modification of the terms of agreement;

14. Shall, throughout the duration of the term of the agreement, maintain the agreement and information relating to the licensee as a matter under investigation relating to possible licensee misconduct and thus shall, except as provided herein, afford confidentiality pursuant to N.J.S.A. 45:9–19.3, except that nothing herein shall preclude the Board, the IRC or the Attorney General from conducting appropriate investigation of the relevant facts, securing opinions from consultants and complying with judicial directives; and

15. Shall, upon a licensee's successful completion of the terms as provided by the letter agreement, advise the Board that it deems the matter to be closed without a finding of cause for action, except that nothing herein shall preclude the Board or the Panel from reviewing and relying upon all relevant materials should it receive a subsequent referral regarding the licensee.

13:35–11.5 Professional assistance program: approval and discontinuance

(a) A professional assistance program seeking to sponsor participants in the ARP first shall seek approval from the Board. A PAP applying for approval shall be required to enter into a formal agreement with the Board, attesting to its willingness and ability to provide necessary services to participants and to work with the IRC in the discharge of its responsibilities. Upon request, any PAP seeking approval shall provide the Board with sufficient information concerning its staffing, the services it provides, available treatment referrals and monitoring contracts so that the Board can be assured that the program is in a position to discharge its obligations under the agreement. Each program shall designate a plenary licensed physician who shall serve as program director and who shall be responsible to assure that the program fulfills its obligations under the agreement. By that agreement the Board shall grant its approval and delineate the conditions upon which the approval could be rescinded.

(b) Should an approved professional assistance program cease offering services, the Board shall allow participating licensees a period of 30 days to seek the sponsorship of another approved professional assistance program provided that interim monitoring provisions are proposed and acceptable to the Board.

Amended by R.1999 d.356, effective October 18, 1999.
See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).
Designated the former section as (a); and added (b).

13:35–11.6 Colleague referrals

The Board authorizes the IRC and approved professional assistance programs to accept reports from practitioners pursuant to N.J.S.A. 45:9–19.5 and any practitioner who files such a report directly with the IRC, an approved PAP or with any of the report recipients otherwise authorized by law shall be deemed to have discharged the obligation imposed by statute. Although the PAP need not disclose to the IRC, the Panel or the Board the identity of colleagues who file such report, it shall maintain that information on file and shall make it available to the Board in the event that an inquiry is initiated as to whether the reporting colleague discharged his or her obligation pursuant to N.J.S.A. 45:9–19.5. If the reporting practitioner elects to file a report directly with the IRC, the Panel or the Board, he or she may utilize that licensee's code number in the report.

These reports shall be retained confidentially if the licensee agrees to the terms of participation in the program.

13:35–11.7 (Reserved)

Repealed by R.1999 d.356, effective October 18, 1999.
See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).
Section was "Alternative Resolution Program pilot period".

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

Authority

N.J.S.A. 45:9–37.76 et seq.

Source and Effective Date

R.2004 d.279, effective July 19, 2004.
See: 35 N.J.R. 3263(a), 36 N.J.R. 3401(a).

13:35–12.1 Purpose and scope

(a) The rules in this subchapter implement the provisions of P.L. 1997, c.347 (N.J.S.A. 45:9–37.76 et seq.), which created the Electrologists Advisory Committee under the State Board of Medical Examiners.

(b) This subchapter shall apply to all applicants seeking licensure as an electrologist, electrology instructor, or an office license and licensed electrologists, licensed electrology instructors and licensed offices.

13:35–12.2 Definitions

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

"Act" means the Electrology Practice Act, N.J.S.A. 45:9–37.76 et seq.

"Authorized representative" means a person who has been designated by the client or a court to exercise rights under this section. An authorized representative may be the client's attorney. If the client is a minor, a parent or guardian who has custody (whether sole or joint) shall be deemed to be an authorized representative.

"Board" means the State Board of Medical Examiners.

"Certified Professional Electrologist Examination" means the examination administered by the American Electrology Association.

"Certified Technical Trainer Examination" means the examination administered by the Educational Testing Service.

"Client" means any person who is the recipient of a professional service rendered by a licensee for purposes of treatment.

"Committee" means the Electrologists Advisory Committee established pursuant to section 3 of P.L. 1997, c.347 (N.J.S.A. 45:9–37.76 et seq.).

"Electrologist" means a person who is licensed to practice electrology pursuant to the provisions of P.L. 1997, c.347 (N.J.S.A. 45:9–37.76 et seq.).

"Electrology" means the removal of hair permanently through the utilization of solid probe electrode-type epilation, including thermolysis, being of a short wave, high frequency type, and including electrolysis, being of a galvanic type, or a combination of both, which is accomplished by a super-imposed or sequential blend. This definition specifically excludes laser and other intense light source hair removal from the definition of electrology.

"Electrology instructor" means a person who is licensed to teach the clinical and theoretical practice of electrology pursuant to the provisions of P.L. 1997, c.347 (N.J.S.A. 45:9–37.76 et seq.).

"Instrument" means any tool or implement used in electrology procedures.

"Licensee" means an individual holding a license issued by the Electrology Advisory Committee of the State Board of Medical Examiners.

"Office" means any fixed establishment or place where one or more persons engage in the practice of electrology.

13:35–12.3 Office of the Committee

The office of the Committee shall be maintained at 124 Halsey Street, Newark, New Jersey. The mailing address of the Committee is PO Box 45041, Newark, New Jersey 07101.

13:35–12.4 Notification of change of address

(a) Licensees shall notify the Committee in writing of any change from the address currently registered with the Committee and shown on the most recently issued certificate. Such notice shall be sent to the Committee no later than 30 days following the change of address.