CHAPTER 35

BOARD OF MEDICAL EXAMINERS

Authority

N.J.S.A. 45:9–2.

Source and Effective Date

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

Executive Order No. 66(1978) Expiration Date

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

Chapter Historical Note

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 Chapter 35, except Subchapter 8, Hearing Aid Dispensers, was repealed and new rules of the Board of Medical Examiners, Subchapters 1 through 6, were adopted as R.1983 d.314, effective August 1, 1983.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

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

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 As a part of R.1994 d.522, Subchapter 7, Chiropractic Practice, was repealed, effective October 17, 1994.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

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, CLERKSHIPS AND POST–GRADUATE WORK

13:35–1.1 Externship program

(a) "Extern" 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. Externships are limited to the student's vacation period in an extra-curricular professional experience as hereafter delineated.

(b) An externship 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 extern 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 extern shall make no entries on the patient's permanent record.

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

(e) Prior to commencing participation in an externship 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 above duties by an extern, while engaged in such a program, be construed as the practice of medicine.

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

13:35–1.2 Fifth Pathway

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

1. The applicant has completed the entirety of the academic curriculum in residence at a medical school in a foreign country located outside of the United States, Puerto Rico or Canada or in a school-authorized clinical training program;
2. The medical school was approved throughout the applicant's period of education by the government of the country of domicile to confer the degree of Doctor of Medicine and Surgery or its equivalent, and was listed in the World Health Organization Directory;
3. The applicant has satisfactorily completed all the requirements for a matriculated student of that foreign medical school to receive a diploma, except for internship and/or social service;
4. The applicant has achieved a passing score on a screening examination acceptable to the Educational Commission on Foreign Medical Graduates (ECFMG) even though not eligible for ECFMG certification; and
5. The applicant has had his or her academic record reviewed and approved by a medical school approved by the Liaison Committee on Medical Education, which school has accepted the applicant in a one-academic-year program of supervised clinical training under its direction, and the applicant has satisfactorily completed that program as evidenced by receipt of a certificate issued by the sponsoring medical school.

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

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

13:35–1.3 Postgraduate training

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

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

Case Notes

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

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 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 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 AOA or listed in the World Directory of Medical Schools. 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 during the same time he or she was matriculated. With respect to podiatry residents, graduation from a podiatric school accredited by the Council on Podiatric Medical Education of the American Podiatric Medicine Association (APMA). If the applicant has attended more than one podiatric school, he or she shall certify that each school attended was accredited or listed.

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

iv. 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 the 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.

2. Has never been the subject of an administrative disciplinary proceeding by any state professional licensing agency, has never been convicted of a criminal offense of any grade or admitted to a pre-trial diversionary program, has never been denied licensure eligibility to sit for an examination or eligibility to participate in a postgraduate training program in this or any other state, has never had privileges at a hospital terminated or curtailed for cause, has never been asked to resign from a graduate medical education program or hospital staff, has never had privileges to prescribe controlled dangerous substances curtailed or limited by any regulatory authority, has never 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 regulatory authority (that is, Drug Enforcement Agency, Medicare, 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.

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 including all registration applicants and shall submit it 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 Board 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. This 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.

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 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. 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.

(s) 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.

(t) 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.

(u) 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, the Board may enter an order temporarily suspending the resident's permit to engage in the practice of medicine or podiatry pending a plenary hearing on the charge.

(v) 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.

(w) 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.

(x) 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.

(y) This rule shall be effective upon publication as an adopted rule in the New Jersey Register. With respect to the first year during which this rule is in effect, Directors shall be required to submit a master list. Registration application forms and permit application forms will be made available after the publication of the rule. Unlicensed residents intending to participate in a graduate medical education program on or after July 1, 1988 may, if they so choose, seek registration or a permit, as may be applicable for the year beginning on July 1, 1988. Registration and permits will be required, as applicable, for participants in the second year (or beyond) of a residency training program which begins on or after July 1, 1989.

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).

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 must be approved by the State Board of Medical Examiners for the purpose of placing students in New Jersey hospitals for clinical training through an academic review of the parent medical school conducted on behalf of and in conjunction with the Board of Medical Examiners by the New Jersey Department of Higher Education.

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).

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 postgraduate 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 the Department of Higher Education and an inspection team appointed by the Board in conjunction with the Department of Higher Education.

(d) Following review of the program and on-site inspection visit, if any, the Department of Higher Education 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 may evaluate program strengths and weaknesses, if any, suggestions for improvement, if any, and shall 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, 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.

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; or

2. 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.

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."

Case Notes

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

13:35–2.5 Medical standards governing screening and diagnostic medical testing offices

(a) As used in this section, the following terms shall have the following meanings:

1. "Screening facility or office" means a private practice location not licensed by the State Department of Health, which practice offers services to the medical profession or to the public in the form of one or more types of medical testing. Such a practice shall be owned and under the control, supervision and direction of a physician or group of physicians licensed and currently registered in New Jersey.

2. "Screening test" means a test which results in a determination less complete than a physical examination performed by a licensed physician and does not purport to substitute for a complete examination. The definition is not intended to include a community-sponsored one-modality service such as, for example, a hypertension or glaucoma screening sponsored by a municipal or regional health department or a community screening volunteered by a non-profit professional society at no cost to examinees.

3. "Diagnostic center" means a practice not licensed by the State Department of Health, which practice offers services to the medical profession or to the public and which contains the equipment and medical staff necessary to establish a medical diagnosis and which may recommend a course of treatment for the examinee who elects to become a patient. Such a practice shall be owned and under the control, supervision and direction of a physician or group of physicians licensed and currently registered in New Jersey.

(b) Medical screening or medical diagnostic testing (other than clinical laboratory testing), conducted primarily for persons not receiving medical treatment from the testing entity, is nevertheless deemed to be a medical service. Such a practice shall be owned and under the responsibility of one or more physicians each of whom holds a plenary license from the State Board of Medical Examiners. All such testing, irrespective of the stationary or mobile nature of the facility, shall be performed under the authority of a designated responsible physician who shall establish a protocol and a quality assurance program for the specific type of screening or study. Results of all such procedures shall be interpreted by a physician holding a plenary license in this State, and documented in a written report which is preserved by the physician as required by N.J.A.C. 13:35–6.5.

(c) A copy of the test report shall be issued promptly, by preliminary verbal report when necessary and no later than three business days from the date of receipt of the report by the testing facility, to the referring physician, if any, and upon request to the examinee 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. In the event that a report is directed by an examinee to a designated physician who has not personally ordered the test, said physician shall incur no obligation with respect to such report and the testing facility shall formally advise all examinees of this at the time of testing. All abnormalities shall be clearly identified for the attention of a physician. For an examinee without physician referral, an abnormal or questionable result shall be identified in the report with interpretation sufficient to strongly advise the examinee to seek medical consultation. The facility protocol shall make available a referral source for examinees with suspicious findings or suspected disease, which source identifies specialists pertinent to the pathology involved, such as internal medicine, gynecology, hematology, general surgery, surgical and medical oncology and radiation oncology, for follow-up when the examinee does not indicate a primary care provider as recipient of test results.

(d) Requirements for a screening or diagnostic facility not having a full-time physician present on the premises are as follows:

1. Non-invasive screening tests or diagnostic studies may be performed in facilities at which the responsible physician is not physically present at all times of facility operation. For such testing services, the responsible physician may delegate certain tasks to another licensed health care practitioner, such as a registered professional nurse or x-ray technician, consistent with that person's scope of practice. Tasks of a non-medical nature may be delegated to non-licensed employees under the supervision of a licensed employee, where not inconsistent with applicable law or rule and with accepted standards of practice pertinent to that screening or diagnostic procedure. The physician responsible for such screening or diagnostic service shall take the necessary measures to assure compliance with the requirements of this section and accepted standards of practice. Services performed from mobile facilities parked on the premises of or providing services to a licensed health care facility must have approval from the State Department of Health.

2. There shall be a written protocol which specifies at a minimum: equipment operation, procedure manuals, eligibility criteria for persons to be accepted for examination, methods for securing informed consent, record documentation, and provision for follow-up to examinees and/or referring physicians, as applicable. There shall be procedures for authorized billing, and other factors consistent with accepted standards of practice pertinent to the screening test or diagnostic procedure.

3. There shall be a quality assurance program which requires the following:

i. At least annually, documented inspection of personnel credentials upon hire and at least annually thereafter or sooner as required by circumstances including dates of certification and license renewal; review of the procedure manuals; determination of the qualifications, identity and supervision of employees designated to perform specific functions; and assessment of accuracy in test results;

ii. At least quarterly, evaluation of personnel skills and review of test performance techniques and data recordation or more frequently as required by demonstrated staff performance; verification of billing accuracy; and observance of other factors consistent with accepted standards of practice pertinent to the screening test or diagnostic study procedure;

iii. The required quality assurance program shall include documented regular mechanical inspections as customary for that equipment, but no less frequently than four times per year, and before re-use after the reporting of a mechanical or pertinent personnel problem; and

iv. Minimum safety precaution standards shall be established, observed by all personnel and confirmed by the supervising physician.

(e) For screening services accepting examinees without physician referral, the responsible physician shall prepare and produce, at the request of the Board, a report for a specified calendar year(s) designating the total number of examinees issued abnormality reports and the advisory letter required by (c) above.

(f) For radiologic procedures, the responsible physician shall assure compliance with the applicable requirements of the Radiation Protection Act, N.J.S.A. 26:2D–1 et seq. and the Radiation Protection Code, N.J.A.C. 7:28. Certification of inspection results shall be kept on the premises. The responsible physician may delegate certain tasks to a New Jersey-licensed x-ray technologist within that person's scope of practice, provided that the physician has complied with (d) above.

(g) In addition to compliance with all other subsections of this rule, a mammography screening program shall establish a written protocol which shall be documented in the facility policy and procedure manual and which shall be brought to the attention of pertinent personnel.

1. The protocol shall include specific criteria for screening: for example, age, family history, personal medical history, permissible frequency of testing and other indicators. It shall provide for palpation by a physician or by instructed licensed registered nurse personnel, and for appropriate positioning preparatory to the test. The screening program shall include instruction in breast self-examination, which may be provided in the form of written materials.

2. The physician shall require that anyone other than a physician operating mammography equipment shall be currently licensed as a diagnostic (or mammographic) radiologic technologist as shall be required by the Department of Environmental Protection and Energy in accordance with N.J.S.A. 26:2D–1 et seq. and N.J.A.C. 7:28–19 et seq. The equipment used shall conform to the applicable sections of N.J.A.C. 7:28. Baseline mammography images and periodic images shall be maintained as part of the record of the examinee or referred patient and preserved for seven years from date of last entry. The physician may release the original of any image, providing that signed documentation thereof is retained in the patient's file.

3. Mammography services offered in mobile settings shall be furnished only under the supervision of a doctor of medicine or of osteopathy who is certified by the American Board of Radiology or by the American Osteopathic Board of Radiology or who possesses equivalent certification requirements as determined by the Board of Medical Examiners and who successfully completes a minimum of 20 hours of post-graduate work in mammography interpretation every 24 months after the date he or she begins reading mammographies. Documentation shall be kept on the premises. Physicians practicing in any setting, mobile or otherwise, who offer mammography services as authorized Medicare providers or as meeting requirements of the American College of Radiology, must meet the more stringent training requirements of those programs.

4. The physician shall require that anyone operating mammography equipment, other than a physician, shall be currently licensed by the New Jersey Radiologic Technologist Board of Examiners to perform radiographic procedures. Documentation shall be kept on the premises.

(h) A physician may request a radiologist to perform diagnostic radiology services intended to confirm or rule out suspected pathology. The radiologist shall ascertain whether sufficient objective or clinical data have been provided to determine that the tests are appropriate to the apparent problem. When, in the opinion of a reasonable radiologist, further information is needed to select the appropriate test, then the radiologist, whenever feasible, shall personally consult with the referring doctor in advance of performing the test. In addition or as an alternative, at the professional discretion of the radiologist, he or she shall perform a focussed clinical examination in appropriate cases. Whenever feasible, the radiologist shall be notified of the patient's appearance at the radiologic facility and shall direct the licensed x-ray technologist as to procedure, method of obtaining the test data, scheduling 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) A patient or examinee shall not be billed for a test result which is professionally incomplete, or which is found to be non-diagnostic due to inadequate equipment or technique.

(j) This rule shall be effective April 6, 1992, except that subsections (d), (e), (f) and (g) shall be operative July 6, 1992.

Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
Recodification and reference made to specific Acts.
Repeal and New Rule, R.1992 d.169, effective April 6, 1992 (subsections (d), (e), (f) and (g) operative July 6, 1992.
See: 23 N.J.R. 2858(a), 24 N.J.R. 1367(a).
Section was "Standards concerning testing and diagnostic centers".

13:35–2.6 (Reserved)

Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
Exception of Certified Nurse Midwife added in (a), reference to specific statute deleted.
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 "Midwife and Certified Nurse Midwife Practice".

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: CERTIFIED NURSE MIDWIFERY

13:35–2A.1 Certified Nurse Midwife practice

(a) A Certified Nurse Midwife ("CNM") shall mean a registered professional nurse licensed in the State of New Jersey who, by virtue of added knowledge and skill gained through an organized program of study and clinical experience, is qualified to manage the care of women and/or newborns during the antepartum, intrapartum and postpartum periods and to provide well-woman health care as expressly limited and set forth below.

(b) A CNM shall maintain current registration with the Board of Medical Examiners (hereinafter the "Board") in order to discharge those responsibilities set forth in this subchapter.

(c) The CNM shall not work alone (that is, in an individual or independent practice) but shall function within a health care system which provides for consultation, collaborative management and referral with a physician licensed to practice medicine and surgery in the State of New Jersey.

13:35–2A.2 Qualifications

(a) A CNM shall demonstrate the following qualifications in order to be registered by the Board:

1. A diploma from a legally chartered school of nurse midwifery accredited by the American College of Nurse Midwives (hereinafter, the "ACNM");

2. Current registration as a professional nurse in the State of New Jersey;

3. Certification by the ACNM or the American College of Nurse Midwives Certification Council (the "ACC") and evidence of continuing competency as required by the ACNM; and

4. Proof of age of at least 18 years.

13:35–2A.3 Minimum conditions of practice

(a) The CNM shall establish written agreements with one or more physicians licensed in the State of New Jersey (hereinafter, the "affiliated physician(s)") who practice obstetrics and/or gynecology and who have hospital privileges in obstetrics and/or gynecology. The written agreements shall delineate the scope of practice of the CNM. In no instance, however, may the scope of practice of the CNM in any way exceed the scope of practice of the affiliated physician (as limited by the physician's privileges). All agreements shall include a written protocol setting forth:

1. All procedures and routine orders, including specific tests and treatment regimens, to be performed or provided by the CNM;

2. The circumstances under which consultation, co-management, referral and transfer of care of women and/or newborns between the CNM and the affiliated physician are to take place, and the mechanics by which each is to occur;

3. A list of all medications the CNM may dispense, administer, order and/or prescribe. Under no circumstances may the agreement provide for the use of controlled dangerous substances outside of a licensed hospital except upon prescription of the physician; and

4. A schedule setting forth or a mechanism for determining the availability of the physician (or a designated qualified substitute physician responsible for back-up care) for consultation and emergency assistance or medical management when needed.

(b) The CNM shall file with the Board a notice listing the name(s) and address(es) of the affiliated physician(s) with whom the CNM establishes written agreements and the effective date of the agreement(s) at the time of application for registration with the Board. In the event of any change of physician(s), the CNM shall notify the Board in writing within seven days of the change.

(c) The CNM shall participate in periodic conferences with the affiliated physician for review of patient records and for quality assurance.

(d) The CNM shall demonstrate a satisfactory peer review by a Peer Review Committee of the ACNM.

(e) The CNM shall function in accordance with the published Standards for the Practice of Nurse–Midwifery of the ACNM.

13:35–2A.4 Normal antepartum management

(a) Certified Nurse Midwife practice during normal antepartum stages shall include, but is not necessarily limited to, the following:

1. The CNM may order medical, therapeutic and diagnostic measures for women not classified as being at risk (see N.J.A.C. 13:35–2A.7) in accordance with the CNM protocol;

2. The CNM may administer, dispense, order and/or prescribe medications provided said medications are included within the list of approved medications in the CNM protocol; and

3. The CNM shall consult, refer or collaborate with the affiliated physician in situations where women present with significant medical problems in accordance with the CNM protocol.

13:35–2A.5 Normal intrapartum management

(a) Certified Nurse Midwife practice during normal intrapartum periods shall include, but is not necessarily limited to, the following:

1. The CNM may manage the labor and delivery of the patient not classified as being at risk (see N.J.A.C. 13:35–2A.8) at any location as long as such management is in accordance with mutually agreed upon protocols that comply with both the published standards of the ACNM and current practice standards. These protocols shall include the medical, therapeutic and diagnostic measures that may be utilized by the CNM;

2. The CNM shall perform immediate screening of the newborn. When necessary, the CNM shall initiate immediate resuscitation of the newborn. In accordance with the written protocol with the affiliated physician, the CNM shall refer problems with the newborn to a physician. When practicing outside the hospital setting, the CNM shall establish a written protocol for transfer of the newborn to a hospital;

3. When labor and delivery take place at the home, the CNM may use a local anesthetic and may perform and repair episiotomies; and

4. When labor and delivery take place in a licensed health care facility (which may include a licensed birthing center), the CNM may administer and/or order medications in accordance with the mutually agreed upon protocols, may perform and repair episiotomies and may use local or pudendal block anesthesia. Additionally, the CNM may repair third degree lacerations upon the direction of the affiliated physician and fourth degree lacerations under the direct supervision of a plenary-licensed physician who has obstetrical privileges.

13:35–2A.6 Postpartum and well-woman health care

The CNM may provide postpartum care and well-woman health care, which may include family planning, reproductive health care counseling and reproductive systems health care screening. The CNM's participation in periodic well-woman health care shall be in accord with written protocol(s) which shall require the prompt referral of women with medical or gynecological abnormalities to the appropriate physician.

13:35–2A.7 Management of antepartum women at risk

(a) The CNM may participate in the management of antepartum patients at risk under the following conditions:

1. The physician/CNM team shall have both agreed to include the patient at risk in the caseload.

2. The physician/CNM team shall have established a management plan for all patients identified as at risk, which plan shall delineate the role of both the physician and the CNM in the care of the patient. The management plan shall set forth the following:

i. Frequency of physician visits;

ii. Timing of appropriate diagnostic and evaluative procedures;

iii. Parameters for consultation; and

iv. A proposed plan for the delivery, including the type, place and provider.

3. All patients at risk shall be classified as either Schedule "A" or Schedule "B" patients, in accordance with the schedules set forth in (a)4 and 6 below. The minimum standards of physician participation in the management of the at risk patient shall vary dependent upon whether the patient is classified as Schedule "A" or Schedule "B." The minimum standards of physician participation for Schedule "A" patients are set forth in (a)5 below and for Schedule "B" patients in (a)7 below.

4. Patients with the following risk factors shall be deemed to be Schedule "A" patients:

i. Documented problems in maternal medical history:

(1) Acute and/or chronic hypertension;

(2) Congenital or acquired heart disease;

(3) Deep vein thrombosis (current or recent history);

(4) HIV positive, AIDS or AIDS Related Complex;

(5) Renal disease;

(6) Severe urinary tract infection;

(7) Seizure disorder requiring medications;

(8) Hemolytic anemia; or

(9) Insulin dependence.

ii. Documented problems in past maternal obstetrical history:

(1) Incompetent cervix;

(2) Two or more second or third trimester fetal losses; or

(3) Preterm delivery; or

iii. Documented problems in present maternal obstetrical history:

(1) Significant uterine myomata;

(2) Hydramnios or oligohydramnios;

(3) Isoimmunization;

(4) Multiple gestation;

(5) Intrauterine growth retardation; or

(6) Current evidence of fetal chromosome or other disorder confirmed by amniocentesis or ultrasound.

5. For all patients classified within Schedule "A", the physician shall be in the office on each patient visit and shall review the care of the patient on each visit. Prior to the Schedule "A" patient's discharge from each scheduled visit, the physician shall review and sign the chart. The physician shall examine the Schedule "A" patient at least once during each trimester and, at that time, the management plan shall be reviewed and revised as necessary by the Physician/CNM team.

6. Patients with the following risk factors shall be deemed to be Schedule "B" patients:

i. Documented problems in maternal medical history:

(1) Drug addiction;

(2) Psychotic episode;

(3) Controlled asthmatics currently on medication; or

(4) Hematologic disease;

ii. Documented problems in past maternal obstetrical history:

(1) Parity of six or more;

(2) Previous cesarean delivery;

(3) Surgery involving the uterine wall;

(4) Previous placental abruption;

(5) Previous significant postpartum hemorrhage; or

(6) Preterm labor; or

iii. Documented problems in present maternal obstetrical history:

(1) Any recent history or visible evidence of genital herpes;

(2) Gestational diabetes;

(3) No prenatal care prior to the 28th week;

(4) Maternal age less than 16 years or more than 35 years; or

(5) Significantly abnormal PAP smear.

7. For all patients classified within Schedule "B", the affiliated physician or his or her designee shall be available for consultation during hours of prenatal visits. The physician shall evaluate the management plan and current status of the Schedule "B" patient at least once each trimester. The plan shall be reviewed and revised as necessary by the physician/CNM team.

8. The patient at risk shall receive all scheduled prenatal care in a licensed ambulatory care clinic, a licensed hospital clinic or a professional office.

13:35–2A.8 Care of intrapartum women at risk

(a) The CNM may participate in the management of labor and delivery of patients in the following circumstances, providing the physician is readily available:

1. Abnormal fetal heart rate tracing responsive to conservative measures;

2. Premature labor at less than 37 weeks, but more than 34 weeks with appropriate pediatric coverage;

3. Premature rupture of membranes more than 24 hours before onset of regular contractions;

4. Failure to progress normally in labor;

5. Assessment of infant less than 2,000 gms or more than 4,000 gms;

6. Vaginal birth after previous cesarean delivery;

7. Soft tissue problems such as severe vulvar varicosities or marked edema of the cervix; or

8. Pitocin infusion.

(b) The CNM may participate in the management of the labor and delivery of patients in the following circumstances, providing the physician is present in the hospital:

1. Development of pregnancy-induced hypertension or signs of preeclampsia;

2. Evidence of active infection;

3. Premature labor at less than 34 weeks; or

4. Significant meconium staining.

(c) Conditions which require immediate physician presence in the delivery suite include, but are not limited to, the following:

1. Abnormal fetal heart rate tracing unresponsive to conservative measures;

2. Prolapse of the cord;

3. Intrapartum hemorrhage;

4. Severe medical/surgical problems;

5. Need for cesarean section/forceps delivery;

6. Multiple gestation;

7. Malpresentation; or

8. Any other condition requiring operative intervention.

13:35–2A.9 Certified Nurse Midwife Liaison Committee

(a) A Certified Nurse Midwife Liaison Committee shall be established by the Board of Medical Examiners. The Committee shall consist of six members who shall serve as consultants to the Board and who shall be appointed by the Board. The Committee shall include at least three certified nurse midwives and at least two physicians, one of whom shall be a member of the Board of Medical Examiners and one of whom shall be Board-certified by the American Board of Obstetrics and Gynecology. The Committee shall meet no less than four times per year but may meet more frequently as needed.

(b) Functions of the Committee shall include, but are not limited to, the following:

1. Advising and assisting the Board in the evaluation of applicants for certified nurse-midwifery registration and applicants for prescriptive authorization, investigation of unlawful conduct and approval of professional training programs;

2. Advising and assisting the Board in establishing a formulary of drugs that may be ordered, administered, dispensed or prescribed by CNMs;

3. Periodic and ongoing review of the appropriateness and viability of all rules concerning CNM practice in the

State of New Jersey, specifically to include (but not necessarily limited to) periodic review of the categorizations of at risk patients set forth within N.J.A.C. 13:35–2A.7 and 2A.8. In the event the Committee should determine that any changes in any regulations or in any schedules within said rules are appropriate, the Committee may report said recommendations to the Board and may recommend that the Board seek to revise the rules accordingly; and

4. Ongoing review of CNM practice in the State of New Jersey.

Amended by R.1994 d.170, effective April 4, 1994.
See: 25 N.J.R. 4583(a), 26 N.J.R. 1520(a).

13:35–2A.10 Limited privileges and conditions of practice permitted for a graduate nurse midwife pending results of certifying examination and licensure

(a) A graduate of a program of nurse midwifery approved by the American College of Nurse Midwives and by the Board of Medical Examiners of this State, who is awaiting results of the A.C.N.M. certifying examination, and who demonstrates satisfaction of all requirements of N.J.A.C. 13:35–2.6 other than attainment of a passing grade on said examination, may enroll in a preceptorship program in certain New Jersey licensed health care facilities upon compliance with all provisions of this section.

(b) The graduate shall file a complete application for registration with the Board, including payment of the registration examination fee and a proposal of acceptance in a preceptorship program.

(c) The proposal shall include sufficient information to demonstrate to the satisfaction of the Board the following:

1. The preceptorship program is established in association with an ongoing nurse midwifery service in a licensed hospital or clinic, and is approved by the Board of Trustees responsible for the facility and the institutional midwifery training program is approved by the A.C.N.M.

2. The preceptorship is under the direct supervision of the nurse midwifery service director, who agrees to be responsible for selection of graduates and preceptors; development; implementation and evaluation of the program; and provision of preceptor's evaluation of the participants.

3. The program provides that the graduate shall work only under the direct personal on-site supervision of a duly registered C.N.M. or a duly licensed physician of this State.

4. The graduate shall wear a name tag identifying such person by name as a graduate nurse-midwife.

(d) The Board shall issue a certificate which shall state the limited nature of the authorization to practice. The certificate shall be surrendered on the date the graduate is accepted for registration as a C.N.M. in this State. The certificate shall expire automatically on the date the nurse-midwife is notified of failure on the examination taken, or after six months, following its date of issuance, whichever date is later. The certificate may be renewed for one additional six-month period, for good cause shown to the Board.

(e) A graduate requesting the extension of the certificate period due to failure of the A.C.N.M. certifying examination shall submit for Board review and approval a recommendation from the facility director which includes a detailed program of increased supervision in the areas of the graduate's deficiency as demonstrated by the graduate's filed examination and clinical experience and proof that the graduate has registered to take a subsequent examination scheduled within the next six months.

R.1984 d.245, effective June 18, 1984.
See: 16 N.J.R. 685(a), 16 N.J.R. 1612(a).
Recodified from 13:35–2.14 by R.1992 d.332, effective September 8, 1992.
See: 23 N.J.R. 3632(a), 24 N.J.R. 3094(a).

13:35–2A.11 Prescriptive authorization

(a) A CNM who is currently registered with the Board of Medical Examiners may apply for authorization to prescribe drugs (as used within this section, the term "drugs" shall include drugs, medicine and devices). The CNM shall make application on forms prescribed by the Board and shall demonstrate:

1. Current registration with the Board;

2. A.C.N.M. or A.C.C. certification in good standing; and

3. Evidence of satisfactory completion of a minimum of 30 contact hours (as defined by the National Task Force on the Continuing Education Unit) in pharmacology or a pharmacology course in an accredited institution of higher education approved by the Department of Higher Education or acceptable to the Board (hereinafter, "qualifying education"). Qualifying education must have been obtained within the two years immediately preceding the date on which application is made, except that, for any application made within 90 days from the effective date of this section, qualifying education completed on or after April 1, 1989 shall be acceptable.

(b) Prescriptive authorization obtained pursuant to (a) above shall be valid for a period of two years. In order to renew prescriptive authorization, a CNM shall make application for renewal on forms prescribed by the Board and shall demonstrate:

1. Current registration with the Board;

2. A.C.N.M. or A.C.C. certification in good standing; and

3. Evidence of the satisfactory completion of seven contact hours (as defined by the National Task Force on the Continuing Education Unit) of continuing education, or equivalent education, in pharmacology and drug management (hereinafter "continuing education"). Continuing education must have been obtained within the two-year period immediately preceding the date of the renewal application.

(c) The Board has established a formulary of drugs which may be ordered, administered, prescribed or dispensed by CNMs who have prescriptive authorization. The formulary shall be reviewed, amended if deemed necessary, and published periodically. The formulary consists of:

Analgesics (IV**, IM**, PO**)

Narcotics**

Non-narcotic

Anesthetics

Injectable (Local/Pudendal)

Topical

Antacids

Antihelmintics (Topical)

Antibacterials (IV**, IM, PO, Topical)

Antiseptics (IV**, IM, PO, Topical)

Antibiotics (IV**, IM, PO, Topical)

Antihistamines

Antivirals

Anti–Emetics

Barbiturates (IV**, IM**, PO**)

Contraceptives hormonal

Devices

Topical

Barriers

Cough and Cold Preparations

Non-narcotic

Fungicides (Topical)

Hematinics

Hemorrhoidal Preparations

Hormones

Laxatives

Mineral Supplements

Oxytocics (IVII, IM, PO, Topical)

Parenteral Fluids**

Pre–Eclamptic Drugs**

Prostaglandin Gels**

RH—Immune Globulin

Stool Softeners

Tocolytics–Parenteral** (PO)

Topical

Moisturizers

Cleansers

Therapeutic Shampoo/lotion/cream

Steroids

Vaccines

Vaginal Preparations

Vitamins

(d) A CNM who is authorized to prescribe drugs may prescribe only those drugs which are specified within the formulary of drugs established by the Board. In no case may the written agreement with a licensed physician that CNM is required to maintain pursuant to N.J.A.C. 13:35–2A.3 include any substance or device not specified within the formulary.

(e) A CNM's authorization to prescribe drugs, medicine, or devices may, upon notice and an 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., be revoked or otherwise limited by the Board if the CNM:

1. Fails to maintain current licensure and registration with the Board;

2. Fails to maintain A.C.N.M. or A.C.C. certification in good standing;

3. Uses prescriptive authorization for other than therapeutic purposes;

4. Uses prescriptive authorization to prescribe substances or devices not included within the formulary of drugs established by the Board; or

5. Uses prescriptive authorization to prescribe substances or devices not specified within any written agreement maintained pursuant to N.J.A.C. 13:35–2A.3 or for purposes not intended within any written agreement.

(f) A CNM shall provide the following on all prescription blanks:

1. The CNM's full name, identification of professional practice, license number, prescriptive authorization number, address and telephone number. This information shall be printed or stamped on all prescription blanks;

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

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

4. The date of the issuance of the prescription;

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

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

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

8. The signature of the prescriber, hand-written; and

9. Every prescription blank shall be imprinted with the words "substitution permissible" and "do not substitute" and shall contain space for the CNM's initials next to the chosen option, in addition to the space required for the signature in (f)8 above.

New Rule, R.1994 d.170, effective April 4, 1994.
See: 25 N.J.R. 4583(a), 26 N.J.R. 1520(a).

** Administered in Licensed Health Care Facilities only.

SUBCHAPTER 2B. LIMITED LICENSES: PHYSICIAN ASSISTANTS

Authority

N.J.S.A. 45:9–27.28.

Source and Effective Date

R.1994 d.538, effective November 7, 1994.
See: 25 N.J.R. 5099(b), 26 N.J.R. 4411(b).

13:35–2B.1 Purpose and scope

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

(b) This subchapter shall apply to all physician assistants licensed pursuant to the provisions of this subchapter and to anyone within the jurisdiction of the Physician Assistant Advisory Committee.

13:35–2B.2 Definitions

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

"Board" means the State Board of Medical Examiners.

"Committee" means the Physician Assistant Advisory Committee.

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

"Director" means the Director of the Division of Consumer Affairs.

"Licensee" means a physician assistant licensed pursuant to this subchapter.

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

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

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

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

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

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

13:35–2B.3 Practice requirements

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

1. The licensee is under the direct supervision of a physician pursuant to the provisions of N.J.A.C. 13:35–2B.10;

2. The licensee limits his or her practice to those procedures authorized pursuant to N.J.A.C. 13:35–2B.4;

3. Upon initial involvement in a patient's course of care or treatment, the licensee or the supervising physician advises the patient that authorized procedures are to be performed by the physician assistant;

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

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

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

13:35–2B.4 Scope of practice

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

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

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

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

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

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

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

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

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

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

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

11. Management of emergency and life threatening conditions;

12. (Reserved); 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. In an inpatient setting, 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. (Reserved); 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.

13:35–2B.5 Eligibility for licensure

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

1. Is at least 18 years of age;

2. Is of good moral character, evidence of which shall require the applicant for licensure to respond to such inquiry as the Board deems appropriate regarding past and present fitness to practice, and issues pertinent thereto;

3. Has successfully completed an education program for physician assistants which is approved by the Committee on Allied Health Education and Accreditation, or its successor; and

4. Has passed the examination administered by the National Commission on Certification of Physician Assistants (NCCPA), except as set forth in (b) below.

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

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

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

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

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

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

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

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

13:35–2B.8 Credit-hour requirements

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

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

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

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

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

13:35–2B.10 Supervision

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

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

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

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

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

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

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

ii. In an outpatient setting, within a maximum of seven days of the physician assistant's entry of the order in the patient record; and

5. The following supervisory ratios are met:

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

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

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

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

13:35–2B.11 Recordkeeping

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

1. The dates and times of all treatments;

2. The patient complaint;

3. The history;

4. Findings on appropriate examination;

5. Progress notes;

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

7. Diagnosis or medical impression; and

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

i. Specific dosages, quantities and strengths of medications;

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

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

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

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

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

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

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

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

1. A physician assistant may issue prescriptions only in an in-patient setting.

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

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

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

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

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

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

v. The date of issuance of prescription;

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

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

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

ix. The signature of the prescriber, hand-written; and

x. Every prescription blank shall be imprinted with the words "substitution permissible" and "do not substitute" and shall contain space for the physician assistant's initials next to the chosen option, in addition to the space required for the signature in (a)3ix above.

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

(a) An individual who has filed an application for licensure and is waiting to take the next scheduled examination administered by the National Commission on Certification of Physician Assistants (NCCPA) or awaiting the results of

the examination may apply to the Board for a temporary license to be employed under the direct supervision of a physician, as defined in N.J.A.C. 13:35–2B.2 and 2B.15.

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

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

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

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

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

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

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

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

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

i. Is continuously present on-site; and

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

2. The supervising physician or physician designee:

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

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

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

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

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

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

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

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

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

13:35–3.1 Licensing examination; physicians

(a) Effective December 1994, the standard medical and surgical licensing examination in the State of New Jersey shall be the United States Medical Licensing Examination (USMLE), Step 3.

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

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

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

2. FLEX Component I.

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

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

Amended by R.1985 d.224, effective May 6, 1985.
See: 17 N.J.R. 561(a), 17 N.J.R. 1131(c).
Substantially amended.
Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
Added alternate method for taking FLEX exam; deleted (e).
Amended by R.1994 d.522, effective October 17, 1994.
See: 26 N.J.R. 2526(a), 26 N.J.R. 4195(a).

Case Notes

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

13:35–3.2 Endorsement; physicians

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

1. Has presented certification of either the National Board of Medical Examiners or Osteopathic Examiners that the applicant has attained diplomate status from either of those organizations;

2. Has been licensed in another state upon successful passage of a non-FLEX written plenary examination taken in English prior to December 31, 1972, and submits proof of active and reputable practice of medicine and surgery for 10 or more years;

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

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

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

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

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

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

Amended by R.1985 d.224, effective May 6, 1985.
See: 17 N.J.R. 561(a), 17 N.J.R. 1131(c).
Added text: "in an examination ... a five year period."
Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
Deleted reference to specific statute.
Amended by R.1994 d.522, effective October 17, 1994.
See: 26 N.J.R. 2526(a), 26 N.J.R. 4195(a).

13:35–3.3 Endorsement; podiatric physicians

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

As amended, R.1983 d.510, effective November 7, 1983.
See: 15 N.J.R. 784(a), 15 N.J.R. 1865(e).
Added (c).
Amended by R.1985 d.224, effective May 6, 1985.
See: 17 N.J.R. 561(a), 17 N.J.R. 1131(c).
Added text to (a) 4. "prior to June 1985, ... 75 or better."
Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
Deleted reference to specific statute and added reference to taking test "in English".
Amended by R.1994 d.522, effective October 17, 1994.
See: 26 N.J.R. 2526(a), 26 N.J.R. 4195(a).

13:35–3.4 (Reserved)

Amended by R.1985 d.224, effective May 6, 1985.
See: 17 N.J.R. 561(a), 17 N.J.R. 1131(c).
Added text "Component II".
Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
Deleted reference to specific statute.
Repealed by R.1994 d.522, effective October 17, 1994.
See: 26 N.J.R. 2526(a), 26 N.J.R. 4195(a).
Section was "Examination in FLEX Component II after proof of passing the first two parts of the National Boards of Medical or Osteopathic Examiners".

13:35–3.5 Endorsement; certified nurse midwives

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

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

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

(a) The Board shall grant to any person licensed in this State to practice medicine and surgery a plenary license to

direct and supervise a registered bioanalytical laboratory, without examination, provided that:

1. Such person is certified in clinical pathology by a specialty board approved by the A.M.A. or the A.O.A.; or

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

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

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

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

Amended by R.1987 d.368, effective September 8, 1987.
See: 19 N.J.R. 1179(a), 19 N.J.R. 1647(a).
Substantially amended.
Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
At (a)2, added requirement of completion of residency program in pathology in a laboratory.
Amended by R.1991 d.565, effective November 18, 1991.
See: 23 N.J.R. 23(a), 23 N.J.R. 3520(b).
Added (d).

13:35–3.7 Limited exemption from licensure; physicians

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

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

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

1. Satisfy all statutory and regulatory requirements preceding examination required by law;

2. Take and pass the earliest USMLE Step 3 examination given subsequent to the physician's start of employment;

3. Make application for licensure within 10 days after notification of successfully passing USMLE or cease employment.

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

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 or the American Osteopathic Association, must 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 must demonstrate successful completion of the full medical curriculum (including clinical training) prescribed by the medical school and by the country in which it 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 basic science studies (or the equivalent of the first two years of an American medical school) in the foreign medical school and has been given academic credit for successful completion of clinical training programs in United States hospitals, shall

demonstrate that the medical school was approved by the New Jersey State Board of Medical Examiners to conduct such a program in this State, or that the program was performed in a sister-state and recognized as acceptable by this 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 New Jersey Medical Board for purposes of medical licensure in this State.

(i) An applicant who has successfully completed the full medical curriculum in a foreign medical school approved by the Board of Medical Examiners pursuant to law 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) Any applicant having received a medical degree from a medical school not eligible for and not accredited by the Liaison Committee on Medical Education or the American Osteopathic Association on or after July 1, 1985 shall also demonstrate successful completion of a three-year postgraduate training program.

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).

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 one half of the required credits and/or the required subjects if the credentials presented include proof of successful completion of the full term of a fellowship program accredited by the American College of Graduate Medical Education or American Osteopathic Association acceptable to the Board.

(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).

SUBCHAPTER 4. SURGERY

13:35–4.1 Major surgery; qualified first assistant

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

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

2. A procedure performing a major amputation;

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

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

(c) A duly qualified surgeon, duly qualified assistant physician, and duly qualified resident 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.

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

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).

Cross References

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

Case Notes

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

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

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

13:35–4.2 Termination of pregnancy

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

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

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

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

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

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

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

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

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

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

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

6. The procedure shall be performed in an LACF providing adequate staff support and resources for the operative procedure as well as interim follow-up and 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).

SUBCHAPTER 5. EYE EXAMINATIONS; EYEGLASSES

13:35–5.1 Minimum eye examination; contact lenses

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

1. A complete history of visual aberrations;

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

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

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

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

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

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

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

PHYSICAL QUALITY AND APPEARANCE

1. Surface imperfections

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

2. Glass defects

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

3. Localized power errors

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

4. Refractive powers

TOLERANCE: 0.0. to 6.00, + or −0.12.

6.25 to 12.00, 2 per cent of power.

Above 12.00, + or −0.25.

Maximum cylinder power variation + or −0.12.

5. Refractive power addition

TOLERANCE: + or −0.12.0.

6. Cylinder Axis

TOLERANCE: 0.12 to 0.37 + or −3 degrees.

0.50 to 1.00, + or −2 degrees.

1.12 on up, + or −1 degree.

7. Prism power and location of specified optical center

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

8. Segment size

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

9. Segment location

TOLERANCE: As specified within + or −0.5 mm.

10. Lens size:

i. Rimless

TOLERANCE: + or −0.5 mm;

ii. Bevel, for plastic frames

TOLERANCE: + or −0.5 mm;

iii. Bevel, for metal frames

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

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.

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).

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 (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 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.
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."

13:35–6.4 (Reserved)

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

See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
At (a)3 added ... "purchasing or" 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).
Old section was "prohibition of kickbacks, rebates or receiving a payment for services not rendered."

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 agent 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.

"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 initialled 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 initialled 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 initialled 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 may be harmed by release of the subjective information contained in the professional treatment record or a summary thereof, the licensee may refuse to provide such information. That record or the summary, with an accompanying notice setting forth the reasons for the original refusal, shall nevertheless be provided upon request of and directly to:

i. The patient's attorney;

ii. Another licensed health care professional; or

iii. The patient's health insurance carrier.

4. Licensees may require a record request to be in writing and may charge a fee for the reproduction of records, which shall be no greater than $1.00 per page or $100.00 for the entire record, whichever is less. (If the record requested is less than 10 pages, the licensee may charge up to $10.00 to cover postage and the miscellaneous costs associated with retrieval of the record.) If the licensee is electing to provide a summary in lieu of the actual record, the charge for the summary shall not exceed the cost that would be charged for the actual record.

5. If the patient or a subsequent treating health care professional is unable to read the treatment record, either because it is illegible or prepared in a language other than English, the licensee shall provide a transcription at no cost to the patient.

6. The licensee shall not refuse to provide a professional treatment record on the grounds that the patient owes the licensee an unpaid balance if the record is needed by another health care professional for the purpose of rendering care.

(d) Licensees shall maintain the confidentiality of professional treatment records, except that:

1. The licensee shall release patient records as directed by a subpoena issued by the Board of Medical Examiners or the Office of the Attorney General, or by a demand for statement in writing under oath, pursuant to N.J.S.A. 45:1–18. Such records shall be originals, unless otherwise specified, and shall be unedited, with full patient names. To the extent that the record is illegible, the licensee, upon request, shall provide a typed transcription of the record. If the record is in a language other than English, the licensee shall also provide a translation. All x-ray films and reports maintained by the licensee, including those prepared by other health care professionals, shall also be provided.

2. The licensee shall release information as required by law or regulation, such as the reporting of communicable diseases or gunshot wounds or suspected child abuse, etc., or when the patient's treatment is the subject of peer review.

3. The licensee, in the exercise of professional judgment and in the best interests of the patient (even absent the patient's request), may release pertinent information about the patient's treatment to another licensed health care professional who is providing or has been asked to provide treatment to the patient, or whose expertise may assist the licensee in his or her rendition of professional services.

4. The licensee, in the exercise of professional judgment, who has a good faith belief that the patient because of a mental or physical condition may pose an imminent danger to himself or herself or to others, may release pertinent information to a law enforcement agency or other health care professional in order to minimize the threat of danger.

(e) Where the patient has requested the release of a professional treatment record or a portion thereof to a specified individual or entity, in order to protect the confidentiality of the records, the licensee shall:

1. Secure and maintain a current written authorization, bearing the signature of the patient or an authorized representative;

2. Assure that the scope of the release is consistent with the request; and

3. Forward the records to the attention of the specific individual identified or mark the material "Confidential."

(f) Where a third party or entity has requested examination, or an evaluation of an examinee, the licensee rendering those services shall prepare appropriate records and maintain their confidentiality, except to the extent provided by this section. The licensee's report to the third party relating to the examinee shall be made part of the record. The licensee shall:

1. Assure that the scope of the report is consistent with the request, to avoid the unnecessary disclosure of diagnoses or personal information which is not pertinent;

2. Forward the report to the individual entity making the request, in accordance with the terms of the examinee's authorization; if no specific individual is identified, the report should be marked "Confidential"; and

3. Not provide the examinee with the report of an examination requested by a third party or entity unless the third party or entity consents to its release, except that should the examination disclose abnormalities or conditions not known to the examinee, the licensee shall advise the examinee to consult another health care professional for treatment.

(g) (Reserved)

(h) If a licensee ceases to engage in practice or it is anticipated that he or she will remain out of practice for more than three months, the licensee or designee shall:

1. Establish a procedure by which patients can obtain treatment records or acquiesce in the transfer of those records to another licensee or health care professional who is assuming the responsibilities of that practice;

2. Publish a notice of the cessation and the established procedure for the retrieval of records in a newspaper of general circulation in the geographic location of the licensee's practice, at least once each month for the first three months after the cessation; and

3. Make reasonable efforts to directly notify any patient treated during the six months preceding the cessation, providing information concerning the established procedure for retrieval of records.

Repeal and New Rule, R.1990 d.176, effective March 19, 1990.
See: 21 N.J.R. 3253(a), 22 N.J.R. 978(a).
Amended by R.1992 d.429, effective October 19, 1992.
See: 24 N.J.R. 50(a), 24 N.J.R. 3729(d).
Revised (b).
Amended by R.1994 d.119, effective April 4, 1994.
See: 25 N.J.R. 4862(a), 26 N.J.R. 1522(a).

Case Notes

Verification may be required before personal injury protection benefits are paid. State Farm Mut. Auto. Ins. Co. v. Dalton, 234 N.J.Super. 128, 560 A.2d 683 (A.D.1989) certification denied 117 N.J. 664, 569 A.2d 1356, certiorari denied 110 S.Ct. 1131, 493 U.S. 1078, 107 L.Ed.2d 1037.

Reprimand by Board for failure to prepare patient record noted; transcript of Board proceeding not records within the meaning of the Right to Know Law, but are public records under common law; injury action's plaintiff's right to examine and inspect records superior to Board's interest in confidentiality (citing former N.J.A.C. 13:13–6.12). Beck v. Bluestein, 194 N.J.Super. 247, 476 A.2d 842 (App.Div.1984).

Revocation of license; psychiatrist who engaged in sexual contact with patients. In the Matter of the Suspension or Revocation of the License of Schermer, 94 N.J.A.R.2d (BDS) 33.

13:35–6.6 Requirements for issuing prescriptions for and dispensing all medications; special requirements for prescribing or dispensing controlled drugs

(a) Physicians who possess a plenary license to practice medicine and surgery and podiatrists who issue prescriptions for medication shall advise all patients by adequate notice, such as but not limited to, a sign or pamphlet in the waiting room of the practitioner's office, that a request of the practitioner may be made by the patient to substitute a generic drug for any prescribed medication.

(b) Physicians and podiatrists shall provide the following on all prescriptions:

1. Prescriber's full name, address, telephone number and proper academic degree or identification of professional practice for which licensed. Identification may be in the form of a general term of plenary or limited licensure and may, in addition list a practice specialty; for example: Dr. John Doe, physician and surgeon; or Dr. Jane Smith, physician; or Dr. John Doe, surgeon; or Dr. Jane Smith, licensed to practice medicine and surgery; or Dr. John Doe, physician, practice limited to (name of specialty); or Dr. John Doe, podiatrist; or similar accurate descriptive terms;

2. Full name, age and address of patient;

3. Date of issuance of the prescription;

4. Name, strength and quantity of drug or drugs to be dispensed;

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

6. Number of refills permitted or time limit for refills, or both;

7. Prescriber's D.E.A. number when required for the prescribing of Controlled Dangerous Substances as scheduled under the Controlled Dangerous Substance Act of 1970. *Each prescription for a Controlled Dangerous Substance shall be written on a separate prescription blank;

8. Signature of prescriber, hand-written;

9. When pre-printed prescription blanks are not available, the full name of the prescriber must be printed or stamped in block letters under the signature of the prescriber;

10. Every prescription blank shall be imprinted with the words "substitution permissible" and "do not substitute" and shall contain space for the physician's or podiatrist's initials next to the chosen option, in addition to the space required for the signature in (b)8 above;

11. In no instance shall a physician or podiatrist utilize a prescription form which includes pre-printed information such as but not limited to, language, initials or other indications to discourage or prohibit substitution, which a prescriber may prohibit only by initialing or writing "do not substitute" on the individual prescription.

(c) With respect to any prescription issued for a Schedule II Controlled Dangerous Substance, and in addition to the requirements of N.J.A.C. 13:35–6.7 respecting prescribing of amphetamines, the following shall be observed:

1. The quantity of each drug shall be stated by word in addition to number; for example, ten (10) Percodan; or five (5) Ritalin 5 mg., etc.;

2. A practitioner shall not, at one time, prescribe or dispense to an individual patient in excess of 120 dosage forms or a 30–day supply, whichever is less.

(d) With respect to narcotic drugs listed in any schedule, a prescription shall not be used for "detoxification" or "maintenance treatment". Narcotic drugs may, however, be dispensed directly, but not prescribed, for these purposes, but only by a practitioner who is separately registered with the Attorney General of the State of New Jersey and the New Jersey Department of Health and authorized so to do.

(e) Nothing in this rule shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary, while arrangements are being made for referral for treatment. Not more than one day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three days and may not be renewed or extended.

(f) Nothing in this rule is intended to limit a physician or authorized hospital staff from administering or dispensing narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction.

(g) Nothing in this rule is intended to limit a physician from prescribing or dispensing narcotic drugs to person with intractable pain from which no relief or cure is possible or none has been found after reasonable efforts. When protected prescribing is utilized for the alleviation of intractable pain, practitioners shall remain alert to the availability of new or alternative types of treatment which may be less addictive than the present treatment. The practitioner should attempt periodically to either cease the medication or taper down the dosage, or try other medication or treatment modalities in a regular and vigilant effort to reduce the addiction propensity for the patient.

(h) Every physician and podiatrist shall assure that each container of medication dispensed directly to a patient is labeled in a legible manner with at least the following information:

1. Physician's or podiatrist's full name;

2. Full name of patient;

3. Date medication is dispensed;

4. Expiration date of medication;

5. Name, strength and quantity of medication dispensed;

6. Adequate instructions for the patient regarding the frequency of administration of the medication;

7. When a physician or podiatrist dispenses a pharmaceutical sample which has been packaged and labeled by the manufacturer and such sample package contains the information required by 5. and 6. above, the information listed in 1 through 3, inclusive, above need not be added;

8. When a physician or podiatrist dispenses a medication, other than a sample exempted pursuant to 7. above, in a container without sufficient space for the information required by this subsection, the container shall be placed in a large container or envelope, and the larger container or envelope shall be labeled as indicated in this subsection;

9. Each container of medication dispenses shall contain only one type of medication.

(i) In no instance shall a physician or podiatrist dispense drugs or signs a blank prescription form without complying with the above standards.

As amended, R.1984 d.197, eff. May 21, 1984.
See: 16 N.J.R. 416(a), 16 N.J.R. 1281(a).
(h) amended concerning labeling of drugs.
Amended by R.1984 d.600, effective January 7, 1985.
See: 15 N.J.R. 2415(a), 17 N.J.R. 102(a).
(b)1 substantially amended.
Amended by R.1985 d.505, effective October 7, 1985.
See: 17 N.J.R. 1866(a), 17 N.J.R. 2442(a).
(h)4 added; (b) 4 through (h)8 recodified to (h)5 through (h)9.
Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
NOTE added.

* NOTE: A practitioner must be separately and concurrently registered with the State Department of Health and the Federal Drug Enforcement Administration.

Case Notes

Physician; prescribing controlled substances; suspension. In the Matter of the Suspension or Revocation of the License of Caragine, 94 N.J.A.R.2d (BDS) 2.

13:35-6.7 Prescribing of amphetamines and sympathomimetic amine drugs

(a) No physician shall prescribe, order, dispense, administer, sell or transfer any amphetamine or sympathomimetic amine drug or compound designated as a Schedule II Controlled Dangerous Substance pursuant to the laws of New Jersey, to or for any person except:

1. For the treatment of the following conditions. A patient's records shall contain documentation to justify the prescribing including the use of appropriate testing, and with respect to those conditions which are not readily diagnosed by objective testing, documentation that appropriate consultation has been secured.

i. Narcolepsy established by recognized diagnostic criteria;

ii. Idiopathic Central Nervous System Hypersomnia established by recognized diagnostic criteria;

iii. Attention Deficit Disorder established by recognized diagnostic criteria;

iv. Drug induced brain dysfunction;

v. Epilepsy;

vi. Depression shown to be refractory to other therapeutic modalities;

vii. Senile apathetic behavior; or

2. Immediate use in a hospital for acute conditions such as depression associated with illness, medical or surgical; or

3. For the differential diagnostic psychiatric evaluation of depression; or

4. For the clinical investigation of the effects of such drugs or compounds in which case, in addition to other requirements of applicable law, prior application therefor shall have been made to the Board of Medical Examiners and approval granted before any such investigation is begun.

(b) In addition to the prohibitions set forth in (a) above, no physician shall prescribe, order, dispense, administer, sell or transfer any amphetamine or sympathomimetic amine drug or compound designated as a Schedule II Controlled Dangerous Substance pursuant to the laws of New Jersey, for use in weight management, dieting or any other anorectic purpose, or for the treatment of fatigue.

(c) Violation of any of the foregoing shall be deemed to constitute one or more of the following:

1. Distribution or dispensing of a controlled dangerous substance in an indiscriminate manner, not in good faith, or without good cause, pursuant to N.J.S.A. 45:1-13; or

2. Gross or repeated malpractice, gross neglect, or gross incompetence in the practice of medicine pursuant to N.J.S.A. 45:1-21 (c) and/or (d); or

3. Professional misconduct in the practice of medicine, pursuant to N.J.S.A. 45:1-21(e).

(d) The following list, although not exhaustive or exclusive, does include many of the generic and brand-name Schedule II drugs which fall within the above regulation:

Amphetamine
Benzedrine
Biphetamine
Desoxyn
Dexamyl
Dexedrine
Dextroamphetamine
Eskatrol
Fetamin
Methamphetamine
Methylphenidate
Obetrol

Obotan
Phenmetrazine
Preludin
Ritalin

Amended by R.1983 d.490, effective November 7, 1983.
See: 15 N.J.R. 785(a), 15 N.J.R. 1866(a).
In (c)2., added "or repeated" malpractice and added section (c) to statutory cite.
Amended by R.1991 d.597, effective December 16, 1991.
See: 23 N.J.R. 2248(a), 23 N.J.R. 3763(a).
Revised (a)1.
Amended by R.1994 d.522, effective October 17, 1994.
See: 26 N.J.R. 2526(a), 26 N.J.R. 4195(a).

Cross References

See N.J.A.C. 10:51–1.13, Pharmaceutical services requiring prior authorization.

Case Notes

Regulation proscribing physician use of amphetamines in obesity treatment valid and reasonably related to government objective of controlling controlled dangerous substance traffic (cited as N.J.A.C. 13:35–6.16). Lemmon Co. v. New Jersey State Bd. of Medical Examiners, 175 N.J.Super. 40, 417 A.2d 568 (App.Div.1980) certification denied 85 N.J. 148, 425 A.2d 299 (1980).

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

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

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

1. Generally:

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

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

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

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

3. As a prophylactic medication.

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

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

i. Original copy to State Department of Health;

ii. Copy to be retained by the physician;

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

iv. Copy to pharmacist.

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

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

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

1. Copy of signed informed request.

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

i. Surgery;

ii. Radiation;

iii. Chemotherapy.

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

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

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

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 and television.

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

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

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

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

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

2. Any misrepresentation of a material fact;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2. All offers of free services or discounts shall include a statement of the specific charges for all associated or reasonably anticipated services which are not included in the offer of free or discounted services. If the discount or free service does not apply to all services to be rendered, the advertisement shall specify any associated or reasonably anticipated services which are not included (for example, free eye screening for senior citizens does not include charges for refraction, eyeglasses and contact lens fitting).

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

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

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

6. A patient record shall be maintained for all discounted or free services for seven years from the date of

last entry except in the case of massive screening programs done off-site (out of the office) as a community service, and which are sponsored by a governmental or non-profit organization.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

R.1984 d.139, effective April 16, 1984.
See: 16 N.J.R. 32(a), 16 N.J.R. 921(a).
A rule entitled "Advertising and Solicitation" formerly at this cite was repealed and replaced.
Amended, R.1984 d.372, effective August 20, 1984.
See: 16 N.J.R. 1026(b), 16 N.J.R. 2286(a).
Subsection (m) new.

Amended by R.1986 d.467, effective December 1, 1986.
See: 18 N.J.R. 1788(d), 18 N.J.R. 2390(a).
Text added to (h) and (*l*).
Amended by R.1989 d.325, effective June 19, 1989.
See: 21 N.J.R. 696(a), 21 N.J.R. 1710(b).
In (a): deleted "Definitions" and added new 7 regarding graphic representation. Revised language throughout to modify an existing prohibition on use of testimonials, discounts and offering of free services.
Added new (c)11 and 12, deleting old (c)11.
Added new (g)1–8 and new (m) and (n), recodifying old "n" as new "o".
Amended by R.1994 d.329, effective July 5, 1994.
See: 26 N.J.R. 1219(b), 26 N.J.R. 2795(c).
Amended by R.1994 d.522, effective October 17, 1994.
See: 26 N.J.R. 2526(a), 26 N.J.R. 4195(a).

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 registration fee	
	(1) If paid during the first year of a biennial renewal period	340.00
	(2) If paid during the second year of a biennial renewal period	170.00
	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 registration	340.00
	vii. Biennial registration	250.00
	viii. Biennial registration for licensee over 65 without health care facility or HMO affiliation	125.00
	ix. Permit	50.00
2.	Podiatry (license)	
	i. Application fee	125.00
	ii. Examination	150.00
	iii. Initial registration fee	
	(1) If paid during the first year of a biennial renewal period	230.00

(2) If paid during the second year of a biennial renewal period 115.00
iv. Endorsement 150.00
v. Biennial registration $230.00
vi. Biennial registration for licensee over 65 without health care facility or HMO affiliation 85.00
vii. Permit 50.00
3. Bio-analytical laboratory directorship, plenary license
i. Application fee 125.00
ii. Examination (plenary license) 350.00
iii. Exemption 150.00
iv. Initial registration fee
(1) If paid during the first year of a biennial renewal period 230.00
(2) If paid during the second year of a biennial renewal period 115.00
v. Biennial registration $230.00
4. Bio-analytical laboratory directorship, specialty license
i. Application fee 125.00
ii. Examination (specialty license) 350.00
iii. Exemption (specialty license) 150.00
iv. Initial registration fee
(1) If paid during the first year of a biennial renewal period 230.00
(2) If paid during the second year of a biennial renewal period 115.00
v. Biennial registration $230.00
5. Midwifery (license)
i. Application fee 125.00
ii. Examination (lay midwife license) 50.00
iii. Endorsement (lay midwife license) 50.00
iv. Initial registration fee
(1) If paid during the first year of a biennial renewal period 230.00
(2) If paid during the second year of a biennial renewal period 115.00
v. Biennial registration $230.00
6. Certified Nurse Midwifery (registration)
i. Application fee 125.00
ii. Examination, C.N.M. 50.00
iii. Endorsement (C.N.M.) 50.00
iv. Initial registration fee
(1) If paid during the first year of a biennial renewal period 230.00
(2) If paid during the second year of a biennial renewal period 115.00
v. Biennial registration, C.N.M. $230.00
vi. Biennial prescriptive authorization 50.00
7. Orthoptist (registration)
i. Application fee 125.00
ii. Registration by credentialing 25.00
iii. Initial registration fee
(1) If paid during the first year of a biennial renewal period 170.00
(2) If paid during the second year of a biennial renewal period 85.00
iv. Biennial registration 170.00
8. 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 190.00
(2) If paid during the second year of a biennial renewal period 95.00
iv. License renewal fee, biennial 190.00
v. Late renewal fee 100.00
vi. Reinstatement fee 175.00
vii. Duplicate license fee 40.00
viii. Duplicate wall certificate 50.00
9. 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

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.

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 Delegation of tasks to physician assistants

(a) A physician participating in a physician assistant program that is sponsored by an eligible institution, meets the criteria set forth in (b) below, and is approved by the Board, may direct and supervise an agreed upon number of physician assistants who meet the qualifications set forth in (c) below in the performance of tasks as delineated in (d) below

but only at the sponsoring entity after appropriate notice has been provided to patients as required by (e) below, and only so long as the delegated tasks are within the protocol, training and experience of both the physician and the physician assistant.

(b) In order to be approved by the Board pursuant to (a) above, a physician assistant program shall:

1. Complete such application as the Board may require;

2. During the first year following the implementation of this rule, be sponsored by a hospital licensed by the New Jersey State Department of Health which has established one or more accredited post-graduate training programs in a clinical department (such as internal medicine, pediatrics, surgery, obstetrics and gynecology or family practice) or by an institution, facility or program regulated by the New Jersey State Department of Human Services or at an infirmary within a correctional facility regulated by the New Jersey State Department of Corrections, which sponsoring entity will employ physician assistants. During the second year following the implementation of this rule, the Board in its discretion may review and approve applications from licensed hospitals which do not maintain training programs;

3. Have a designated director who is a plenary licensed physician in good standing in this State, with supervisory experience, who shall have a continuing responsibility to provide the Board with the names, license numbers and qualifications of all participating supervising physicians as well as the names and addresses of those participating physician assistants meeting the qualifications set forth in (c) below and any updates on such lists as may be necessary. In advance of such designation, the sponsoring entity shall submit to the Board a copy of the proposed director's *curriculum vitae* for its review and approval;

4. Establish a written delineation of the tasks delegable to physician assistants which is consistent with (d) below, a written protocol setting forth the supervising physician's responsibilities and a specific ratio of physicians to physician assistants (or physician assistants to physicians) applicable to that setting in accordance with (f) below and a mechanism for the revocation of the privilege of participating in the program in accordance with (g) and (h) below, all of which shall be acceptable to the Board;

5. Establish a method for the continuing and ongoing evaluation of the program, supervising physicians and participating physician assistants. Programs sponsored by entities regulated by the Department of Corrections and the Department of Human Services shall establish a collaborative relationship with a clinical department within a licensed hospital which will supervise and assist in an evaluative process on a regular periodic basis;

6. File periodic reports with the Board providing such information as the Board may require; and

7. Cooperate with the Board or any independent consulting panel which the Board may choose to appoint in order to evaluate the continued appropriateness of the program.

(c) In order to be qualified pursuant to (a) above, a physician assistant shall have submitted to the director of the program the following. The program director shall secure and maintain all proofs required under this subsection and make these proofs available to the Board upon request.

1. An application for participation in the entity's program which shall be supported by an affidavit of good moral character;

2. Proof of successful completion of a curriculum for the education and training of physician assistants or surgeon assistants, approved by the American Medical Association Committee on Allied Health Education and Accreditation; and

3. Proof of certification by the National Commission on Certification of Physician Assistants ("NCCPA"); or

4. In the case of persons having graduated from a program for the education and training of physician assistants in New Jersey, proof that an application has been made to take the next examination scheduled by the NCCPA or proof that the examination has been taken and results are forthcoming. Failure of that examination shall disqualify the physician assistant from continued participation in a program, until such time as he or she has received certification from NCCPA.

(d) The tasks which are delegable pursuant to (a) above subject to the supervision as required by (f) below are as follows. In no case may a physician assistant prescribe, administer or dispense medication without the supervising physician's order or direction.

1. Obtaining and recording of case histories, performing an appropriate preliminary physical examination (which shall not include rectal, pelvic or breast examinations unless expressly specified in the program protocol), presenting the resulting data to the physician and making pertinent progress note entries. All entries by a physician assistant in the clinical record should be appropriately signed and followed by the designation "P.A.". Such histories and physicals performed by a physician assistant shall not be a substitute for that required of the physician as part of an admitting process;

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

3. Giving injections, administering medications, and requesting diagnostic studies which have been ordered, prescribed or directed by the supervising physician or are specified in a protocol approved by the program director (which shall not include intravenous injections or medications unless specified in the program protocol);

4. Suturing and caring for wounds including removing sutures and clips and changing dressings, except that physicians may not delegate to physician assistants the care of facial wounds or traumatic wounds requiring suturing in layers or infected wounds and shall in all cases retain the responsibility for post-operative care;

5. Providing patient counseling services and patient education consistent with orders made by the supervising physician;

6. Assisting the supervising physician in delivery of services to patients, including recording progress notes, requesting non-invasive diagnostic studies (that is, studies that do not involve the physical penetration of the body for the purpose of the study, except for routine administration of intravenous fluids) transcribing or executing studies, transcribing or executing specific orders at the direction of the supervising physician, recording detailed narrative case summaries; and

7. Assisting a supervising surgeon in the operating room when a qualified first assistant surgeon is not required pursuant to N.J.A.C. 13:35–4.1.

(e) Before any tasks as set forth at (d) above may be undertaken by a qualified physician assistant, the patient shall have been notified verbally (and if appropriate by supplemental printed material) that the physician assistant:

1. Is not a physician; in addition, the physician assistant shall conspicuously wear an identification tag which uses the term "physician assistant";

2. May perform services delegated and directed by the supervising physician; and

3. Will notify the supervising physician if the patient elects to be treated directly by the physician.

(f) Any participating physician may delegate specific tasks consistent with (d) above to a qualified physician assistant, so long as the physician:

1. Is in good standing with the Board and possesses unrestricted privileges at the sponsoring institution and a knowledge of pertinent regulations;

2. Maintains proper supervision in the form of direct continuing presence or intermittent presence while on site, with constant accessibility through electronic communication;

3. Engages in active and continuing overview of the activities of the physician assistant to ensure that delegated tasks are being implemented, such as would be provided through the personal and regular review of patient records and periodic education and review sessions during which specific conditions, protocols, procedures and patients are discussed;

4. Establishes written transport and back-up procedures to be implemented when the supervising physician is not on the premises to provide for immediate care of patients needing emergency care beyond the physician assistant's scope of practice;

5. Countersigns all chart entries documenting his or her direction; test and treatment orders shall be countersigned within 24 hours;

6. Confirms in writing, to the director of the program, that he or she is professionally and legally responsible for all of those services rendered by physician assistants under his or her direction; and

7. Complies with program protocols as to applicable ratios of physicians to physician assistants which are to be designed to ensure that each supervising physician will have sufficient experience with an assigned physician assistant to adequately evaluate his or her work.

(g) The director of an approved program shall give notice to the Board and immediately revoke or suspend the privilege of any physician assistant participating in the program if the director has information indicating that the physician assistant:

1. Has obtained certification through fraud, deception or misrepresentation;

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

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

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

5. Has had his or her authority to engage in the activities of a physician assistant revoked, suspended, rescinded or limited by any other state, agency or authority;

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

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

8. Has engaged in activities or performed tasks without physician direction and supervision, beyond the scope of those permitted herein or beyond the abilities, experi-

ence or training of the physician assistant or the supervising physician.

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

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

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

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

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

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

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

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

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

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

(k) This section shall be operative May 12, 1991. Two years following that operative date, the Board shall determine after study and consultation with such experts as it may deem warranted whether the program established pursuant to this rule should be continued, altered or expanded.

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

13:35-6.16 Professional practice structure

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

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

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

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

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

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

3. Cleanliness of premises;

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

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

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

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

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

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

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

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

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

(f) Acceptable professional practice forms are as follows:

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

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

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

i. A practitioner may be employed, as so defined, within the scope of the practitioner's licensed practice and in circumstances where quality control of the employee's professional practice can be and is lawfully supervised and evaluated by the employing practitioner. Thus, a practitioner with a plenary license shall not be employed by a practitioner with a limited scope of license, nor shall a practitioner with a limited license be employed by a practitioner with a more limited form of limited license. By way of example, a physician with a plenary license may be employed by another plenary licensed physician, but an M.D. or D.O. may not be

employed by a podiatrist (D.P.M.) or chiropractor (D.C.) or midwife or certified nurse midwife (R.M., C.N.M.). A podiatrist may not employ a chiropractor. This section shall not preclude any licensee from employing licensed personnel such as nurses, x-ray technologists, physical therapists, ophthalmic dispensers and ophthalmic technicians, etc., as appropriate to the primary practice of the employer.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) The following pertain to laboratory service:

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

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

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

(j) The following pertain to physical therapy:

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

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

(k) The following pertain to radiology:

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

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

(*l*) The following pertain to ophthalmology:

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

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

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

New Rule, R.1992 d.75, effective February 18, 1992 (operative April 15, 1992, except as noted).
See: 23 N.J.R. 161(a), 23 N.J.R. 1063(a), 24 N.J.R. 626(a).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(LIST APPLICABLE HEALTH CARE SERVICES)

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

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

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

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

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

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

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

(c) The following pertain to miscellaneous monetary arrangements:

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

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

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

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

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

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

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

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

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

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

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

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

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

2. (Reserved)

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

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

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

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

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

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

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

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

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

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

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

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

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

(j) A licensee having a significant beneficial interest, as defined in (a) above, in a health care service including a

professional service corporation or a general business corporation (see N.J.A.C. 13:35–6.16(f)) shall notify the Board of such interest no later than February 18, 1993. Notice is not required for a practice conducted under the practitioner's own name.

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

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

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13:35–6.18 Prescribing, dispensing or administering anabolic steroids

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

1. "Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogen, progestin and corticosteroids) that promotes muscle growth, including the substances listed below as well as any salt, ester, or isomer of such substance which act in a similar manner in the human body:

Bolenone
Chlorotestosterone
(4–chlortestosterone)
Chorionic gonadotropin
Clostebol
Danazol
Dehydrochlormethyltestosterone
Dihydrotestosterone
(4–dihydrotesterone)
Drostanolone
Ethylestrenol
Fluoxymesterone
Formebulone (formebolone)
Mesterolone
Methandienone
Methandranone
Methandriol
Methandrosterone
Methenolone
Methyltestosterone
Mibolerone
Nandrolone
Norethandrolone
Oxandrolone
Oxymesterone
Oxymetholone
Stanolone
Stanozolol
Testolactone
Testosterone
Trenbolone

2. "Human growth hormone" ("hGH") means any polypeptide hormone of recombinant DNA origin and includes the following substances:

Somatrem
Somatropin

3. "Licensee" means a physician, registered resident or resident permit holder, podiatrist or certified nurse midwife subject to regulation by the New Jersey Board of Medical Examiners.

(b) No licensee shall prescribe, order, dispense, administer, sell or transfer any anabolic steroid or human growth hormone, for the purpose of hormonal manipulation intended to increase muscle mass, strength, or weight without an accepted medical necessity to do so, or for the intended purpose of improving performance in any form of exercise, sport or game. Body building, muscle enhancement, or increasing muscle bulk or strength through the use of anabolic steroid or human growth hormone by a person in good health is not a valid medical purpose.

(c) Licensees shall complete and maintain patient medical records which accurately reflect the utilization of any substance or drug included in this rule, which records must indicate the diagnosis, any additional information upon which the diagnosis is based and the purpose for which the substance or drug is being used.

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

1. Distribution or dispensing of a controlled dangerous substance in an indiscriminate manner, not in good faith, or without good cause, pursuant to N.J.S.A. 45:1–13;

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

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

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

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

(e) Licensees who are in possession of information which reasonably indicates that another licensee has prescribed, dispensed or administered an anabolic steroid for the purpose of hormonal manipulation that is apparently intended to increase muscle mass, strength or weight without a medical necessity to do so or for apparent purpose of improving performance in any form of exercise, sport or game shall be obligated to report such information to the Board pursuant to N.J.S.A. 45:9–19.5.

New Rule, R.1993 d.604, effective December 6, 1993.
See: 24 N.J.R. 4012(a), 25 N.J.R. 5487(a).

13:35–6.19 through 13:35–6.20 (Reserved)

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).

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 declare death upon the basis of neurological criteria; and

2. Currently 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.

"Appropriate period of observation" means the minimum amount of time which must pass between the performance of the initial examination to determine whether brain death has occurred and the second corroborative examination.

"Attending physician" means the physician (or his or her designee) primarily responsible for the care and treatment of the individual upon whom a declaration of brain death is to be made.

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

"Corroborating physician" means the physician responsible for performance of the second examination to determine whether brain death has occurred.

"Duly qualified" means the satisfactory completion of a residency program approved by the Accreditation Council for Graduate Medical Education.

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

(a) The attending physician shall be a plenary licensed physician. The attending physician may specialize or engage in any area of practice.

(b) The corroborating physician shall be a plenary licensed physician, who shall:

1. When determinations of brain death are to be made upon individuals above two months of age, be either a duly qualified neurologist or a neurosurgeon;

2. When determinations of brain death are to be made upon individuals at or below two months of age, be either a duly qualified neonatologist, a pediatric neurologist or a pediatric neurosurgeon, or a neurologist or neurosurgeon who has been trained in or is experienced in pediatric cases.

(c) In the event the attending physician meets the standards for qualification as a corroborating physician set forth in (b) above, then the corroborating physician may specialize or engage in any area of practice.

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

(a) A person may be pronounced dead if it is determined by that person's attending physician, and confirmed independently by a corroborating physician, that brain death has occurred. Either the attending physician or the corroborating physician shall perform the initial clinical examination. After passage of an appropriate period of time, in accordance with the standards set forth in N.J.A.C. 13:35-6A.5(a)3iii, the physician who did not perform the initial clinical examination (that is, the corroborating physician if the initial clinical examination was performed by the attending physician or the attending physician if the initial clinical examination was performed by the corroborating physician) shall perform a second independent clinical examination. Determinations of brain death shall be made in accordance with the mandatory criteria set forth in N.J.A.C. 13:35-6A.5.

(b) If the individual to be declared dead upon the basis of neurological criteria is or may be an organ donor, then neither the attending physician nor the corroborating physician shall have any responsibility for any contemplated recovery or transplant of that individual's organs, including, but not limited to, being the 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.

(c) Death shall not be declared on the basis of neurological criteria if either the attending physician or the corroborating physician has any reason to believe, on the basis of information in the individual's available medical records, or information provided by a member of the individual's family or any other person knowledgeable about the individual's personal religious beliefs that such a declaration would violate the personal religious beliefs of the individual. In these cases, death shall be declared, and the time of death fixed, solely upon the basis of cardiorespiratory criteria.

13:35-6A.5 Criteria and testing for establishment of brain death

(a) Declarations of brain death shall be made in accordance with accepted medical standards. At a minimum, each examining physician must be able to make the mandatory determinations set forth below and must document the method(s) by which said determinations are made within the patient's chart:

1. Clinical determination that the individual is in a deep coma as marked by cerebral unreceptivity and unresponsivity: Each examining physician must be able to clinically determine that the individual is in a deep coma as marked by cerebral unreceptivity and unresponsivity. In making that determination, the examining physician shall test to ensure that the individual has no behavioral or reflex response to painful stimuli presumed to be mediated at a level above the spinal cord. If, in the opinion of the examining physician, medical circumstances require confirmation of the determination, the examining physician shall confirm the determination with appropriate studies, including but not necessarily limited to an electroencephalogram or blood-flow study.

2. Clinical determination that brain stem functions are absent: Each examining physician must be able to clinically determine that brain stem functions are absent. In making said determination, the examining physician shall test pupillary light, corneal, oculocephalic, oculovestibular, oropharyngeal and respiratory (apnea) reflexes. Absence of all such reflexes must be found. In testing for apnea, pupillary response to light and ocular movements, the examining physician must be able to make the determinations specified below and, in so doing, perform the tests specified below:

i. Apnea: Spontaneous respirations must be determined to be absent. Confirmation of apnea may be made using the technique of apneic oxygenation or by using other appropriate tests;

ii. Pupils: Pupillary response to light must be determined to be absent. The effect of mydriatic agents must be excluded; and

iii. Ocular responses: Ocular responses must be determined to be absent to passive head turning and to cold caloric testing.

3. Clinical determination of irreversibility: Each examining physician must be able to establish that the cessation of all functions of the entire brain is irreversible. In making said determination, the examining physician shall:

i. Make reasonable efforts to establish the cause of the coma, which cause should be determined to be sufficient to account for the loss of brain functions. The determination may be made by careful clinical examination and investigation of history. If the history is unknown, relevant knowledge of causation may be acquired by computed tomographic scan, measurement of core temperature, drug screening, electroencephalogram, angiography, or other appropriate procedures;

ii. Establish that there is no possibility of any recovery of any brain functions by excluding the possibility of reversible conditions such as hypothermia, neuromuscular blockade, shock, or drug or metabolic intoxication. Toxicology screening is required unless there is a reliable history that the individual did not use any sedative drugs, including ethanol; and

iii. Establish that the cessation of all brain functions persists for an appropriate period of observation. In order to so determine, all of the required findings specified above shall be independently made by both examining physicians, and the second examination shall be performed no sooner than:

(1) Six hours after the initial examination, in all instances where the individual upon whom the determination of brain death is to be made is above the age of one year and has not sustained anoxic brain damage, only so long as the cause of coma can be established to be irreversible and the diagnosis has been established with appropriate confirmatory tests such as an electroencephalogram or a blood flow study;

(2) Twelve hours after the initial examination, in all instances where the individual upon whom the determination of brain death is to be made is:

(A) Above the age of one year and has not sustained anoxic brain damage, so long as the cause of coma can be well established to be irreversible without confirmatory tests; or

(B) Above the age of one year and has sustained anoxic brain damage, so long as irreversibility has been established with confirmatory tests; or

(C) At or below the age of one year and has not sustained anoxic brain damage, so long as the cause of coma can be established to be irreversible and the diagnosis has been established with confirmatory tests.

(3) Twenty-four hours after initial examination, in all instances where the individual upon whom the determination of brain death is to be made:

(A) Has sustained anoxic brain damage, where irreversibility has not been established by confirmatory tests; or

(B) Is at or below the age of one year, where the diagnosis has not been established with confirmatory tests.

13:35–6A.6 Objective documentation

When objective documentation shall be needed to substantiate clinical findings, confirmation shall be made by appropriate tests such as an electroencephalogram, four-vessel angiography or radioisotope cerebral angiography.

13:35–6A.7 Certification of death

The attending physician and the corroborating physician shall both document within the patient record the results of all tests performed during their examinations, and shall both sign the chart. After the two clinical examinations and appropriate confirmatory tests have been completed and documented on the patient's chart, and if both examiners have been able to make all requisite determinations, then brain death may be declared. The two physicians who performed the clinical examinations shall both certify death in the patient's chart and the attending physician shall certify death on the death certificate.

SUBCHAPTER 7. (RESERVED)

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 permits; issuance and practice

(a) The Committee may issue a training permit in accordance with N.J.S.A. 45:9A–16(b) and the provisions of this subchapter.

(b) The requisite training and experience referred to in N.J.S.A. 45:9A–9 and 16(b) shall be 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. Where proof of successful completion of a course of study approved by the State Board of Education or the Department of Higher Education is presented to the Committee, the Committee may accept this training as a substitute for any portion of the training and experience requirement.

(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.

13:35–8.4 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. 13:35–8.15. 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. 13:35–8.7. 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.

13:35–8.5 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.

13:35–8.6 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.

13:35–8.7 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. 13:35–8.8, 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).

13:35–8.8 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).

13:35–8.9 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. 13:35–8.14.

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).

13:35–8.10 Notification to the Committee; suspension of license for failure to renew

(a) Every licensee shall notify the Committee of any change of residence or place of practice within seven days following such change.

(b) Every licensee, temporary licensee or trainee whose license or permit has expired or has been terminated shall return the license or permit to the Committee office within five days of such invalidation.

(c) Every licensee who does not respond to the computerized notice for renewal of his or her registration prior to the renewal deadline but who files a renewal application within 60 days after the expiration of the biennial registration period shall be assessed a late fee of $25.00. Thereafter, licensees who seek to renew their registrations shall be assessed a reinstatement fee of $100.00.

1. A licensee may petition for license reinstatement by making written application to the Committee.

2. The Committee may require payment for any missed registration period caused by his or her failure to renew.

3. The Committee may make reasonable inquiry to evaluate his or her qualifications for continued licensure.

(d) A licensee may retire his or her licensure by surrendering the registration for any period of time when he or she is not engaged in hearing aid dispensing. Prior to reinstatement of the license, the Committee may make reasonable inquiry to evaluate his or her qualifications for continued licensure.

Amended by R.1991 d.458, effective September 3, 1991.
See: 23 N.J.R. 1895(a), 23 N.J.R. 2651(a).
In (c), added explanation for assessment of late fee of $25.00 and reinstatement of $100.00. Deleted language regarding failure to respond to computerized notice of renewal. In heading, deleted "suspension of license for".
Recodified from 13:35–8.9 by R.1994 d.595, effective December 5, 1994.
See: 26 N.J.R. 1301(b), 26 N.J.R. 4780(b).

13:35–8.11 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).

13:35–8.12 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).

13:35–8.13 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).

13:35–8.14 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).

13:35–8.15 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).

13:35–8.16 Licensing examination

(a) The licensing examination shall consist of a written and practical examination in accordance with N.J.S.A. 45:9A–11.

(b) The written examination shall contain sections relating to theory and knowledge about fitting and dispensing hearing aids and knowledge relating to the laws and regulations governing the practice of fitting and dispensing hearing aids.

1. In order to pass the licensing examination the candidate shall attain a score of 70 percent or greater on each section.

2. Candidates who fail all or any section of the written examination shall be required to sit for the entire written examination during the next regularly scheduled examination with one exception: candidates failing only the law and regulation section may be admitted to a make-up examination for this section only.

(c) A candidate will only be permitted to take the practical examination if he or she has successfully passed the written examination. In order to pass the practical examination, a candidate shall attain a passing grade on each part of the practical examination. A candidate shall be eligible to re-take the part(s) failed for one additional examination. No passing credit shall be carried over to a third examination and the candidate failing two exam sessions shall be required to take all sections of the examination.

(d) All examinations and re-examinations will be offered only during the regularly scheduled examination session.

Recodified from 13:35–8.15 by R.1994 d.595, effective December 5, 1994.
See: 26 N.J.R. 1301(b), 26 N.J.R. 4780(b).

13:35–8.17 Violation of the Rules

(a) Failure to comply with any provision of N.J.S.A. 45:9A–1 et seq., or this subchapter shall be deemed a violation of the Hearing Aid Dispensers Act and may result in disciplinary action pursuant to N.J.S.A. 45:1–21 and 45:1–22.

(b) The notice of proposed suspension or revocation shall inform the licensed individual of the right to request a hearing. The hearing shall be pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B–1 et seq. and 52:14F–1 et seq. and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1–1 et seq.

Recodified from 13:35–8.16 by R.1994 d.595, effective December 5, 1994.
See: 26 N.J.R. 1301(b), 26 N.J.R. 4780(b).
Amended by R.1995 d.330, effective June 19, 1995.
See: 27 N.J.R. 640(a) (see also 27 N.J.R. 1746(a)), 27 N.J.R. 2410(a).

13:35–8.18 Fee schedule

(a) The fee schedule for the Hearing Aid Dispensers Examining Committee of the State Board of Medical Examiners, in the Division of Consumer Affairs of the Department of Law and Public Safety, shall be as follows:

1. Application fee: $20.00 (non-refundable)	
2. Temporary licenses:	$50.00
3. Training permits:	$50.00
4. Examination:	
i. Written:	$50.00
ii. Practical:	$25.00
5. Initial Registration Fee	
i. If paid during the first year of a biennial renewal period:	$150.00
ii. If paid during the second year of a biennial renewal period:	$75.00
6. Endorsement:	
i. Review of credentials:	$30.00
ii. Endorsement fee:	
During the first year of a biennial renewal period:	$110.00
During the second year of a biennial renewal period:	$55.00
7. Biennial registration renewal	$150.00
8. Renewal or Extension of Temporary License and Training Permit:	$20.00

9.	Late fee:	$25.00
10.	Reinstatement, Biennial Registration:	$100.00
11.	Duplicate or replacement of biennial registration certificate:	$25.00
12.	Preparation of certification papers for applicants to other states:	$25.00

(b) The Committee will refund the examination fee only if the application is rejected by the Committee or withdrawn by the applicant within 14 days after the Committee's receipt of the application.

(c) An applicant who fails to sit for an examination for which payment has been submitted may, one time only, have the fee credited toward the next scheduled examination. If the applicant fails to sit for such next scheduled examination, the fee will be forfeited.

R.1977 d.7, effective January 17, 1977.
See: 8 N.J.R. 425(a), 9 N.J.R. 94(c).
Amended by R.1987 d.370, effective September 8, 1987.
See: 19 N.J.R. 1055(a), 19 N.J.R. 1649(a).
Biennial registration raised from $50.00 to $80.00; (a)6 and 7 added.
Recodified by R.1988 d.112, effective March 7, 1988.
See: 19 N.J.R. 1949(a), 20 N.J.R. 538(a).
Recodified from 8.25.
Amended by R.1991 d.458, effective September 3, 1991.
See: 23 N.J.R. 1895(a), 23 N.J.R. 2651(a).
In (a), substantial alteration of fee schedule. Added (b) and (c).
Recodified from 13:35–8.17 by R.1994 d.595, effective December 5, 1994.
See: 26 N.J.R. 1301(b), 26 N.J.R. 4780(b).
Amended by R.1995 d.330, effective June 19, 1995.
See: 27 N.J.R. 640(a) (see also 27 N.J.R. 1746(a)), 27 N.J.R. 2410(a).
Increased some of the fees.

13:35–8.19 License renewal; continuing education requirement

(a) No license renewal shall be issued by the Director unless the applicant confirms on his or her renewal application to the Hearing Aid Dispensers Examining Committee that during the two calendar years preceding application for renewal he or she participated in courses of continuing education of the type and number of credits specified in this section. Such continuing education is a mandatory requirement for license renewal. Licensees shall be solely responsible for obtaining and maintaining documentation on his or her completion of the required continuing education courses during the registration period. Such documentation shall be submitted to the Committee upon request, and will be surveyed on a random basis. The provisions of this subsection shall not apply to licensees renewing their licenses for the first time.

(b) Evidence of 20 documented course hours of continuing education shall be required of each applicant as a condition of biennial license renewal.

(c) The number of creditable course hours and course contents must be accepted and approved by the National Institute for Hearing Instruments Studies (NIHIS), the educational arm of the National Hearing Aid Society (NHAS), and the Committee except for courses completed through an accredited college or university. A course in hearing aid dispensing creditable by the institution toward three or more credits completed at an accredited college or university shall receive credit for 10 continuing education course hours.

(d) Acceptable continuing education courses shall be in any area which will update and refresh the clinical skills or knowledge of a hearing aid dispenser. Notwithstanding that the continuing education course meets the requirements, the Committee at its discretion may at any time examine and review any course claimed for credit. If, in the opinion of the Committee, such course does not clearly meet the requirements of this section, the course shall be disallowed for credit toward the required 20 continuing education credits.

(e) In the event that a candidate for license renewal shall complete in two years a number of hours in excess of the number of hours required by this section, the documented hours in excess of those required shall not be credited toward license renewal for subsequent years.

New Rule, R.1989 d.548, effective November 6, 1989.
See: 21 N.J.R. 1648(a), 21 N.J.R. 3474(a).
Recodified from 13:35–8.18 by R.1994 d.595, effective December 5, 1994.
See: 26 N.J.R. 1301(b), 26 N.J.R. 4780(b).

SUBCHAPTER 9. ACUPUNCTURE

13:35–9.1 Purpose and scope

(a) The rules of this subchapter are established pursuant to N.J.S.A. 45:2C–1 et seq. ("The Acupuncture Act") and set forth requirements for the practice of acupuncture in the State of New Jersey.

(b) These rules shall apply to all persons certified as acupuncturists by the State of New Jersey, applicants for such certification, and guest acupuncturists granted temporary permission by the Board to perform acupuncture pursuant to N.J.A.C. 13:35–9.12.

13:35–9.2 Definitions

For purposes of this subchapter, the following terms shall have the following meanings:

"Acupressure" means manual surface stimulation of a certain acupuncture point, combination of points, or meridians on the body.

"Acupuncture" means the stimulation of a certain point or points on or near the surface of the body by the insertion of special needles to prevent or modify the perception of pain or to normalize physiological functions including for the purpose of pain control and for the treatment of certain diseases or dysfunctions of the body. The performance of

electroacupuncture, mechanical stimulation and moxibustion constitute the practice of acupuncture.

"Acupuncture tutorial" means an acupuncture tutorial program which has been approved by the Acupuncture Examining Board and which provides applicants who successfully complete the program with the requirements to sit for the examination for certification as an acupuncturist.

"Board" means the Acupuncture Examining Board, which is located at 28 West State Street, Trenton, New Jersey 08608.

"Certificate" (license) as used in N.J.S.A. 45:2C–6, 9 and 11 shall be deemed synonymous with the word "licensure" as used in the statutes of the Board of Medical Examiners. The words "certification" or "certified" in these sections of the Act shall mean that the licensee has been determined by the Acupuncture Examining Board to possess the qualifications required in New Jersey for the practice of acupuncture. Such certification does not expire and remains valid until suspended or revoked; for this reason, the document issued does not include an address or expiration date. However, this certification alone does not permit one to practice in New Jersey; the certified person must also hold a document denoting current practice registration, as set forth in N.J.A.C. 13:35–9.7.

"Certificate" as used in N.J.S.A. 45:2C–12 refers to a biennial registration. The right to practice commences and ends with the effective and expiration dates of this document and it is not valid for more than two years.

"Electroacupuncture" means the therapeutic use of weak electric currents at acupuncture loci.

"Experience" means proof to the satisfaction of the Board that the applicant has accrued full-time independent acupuncture practice experience consisting of at least 750 patient treatment sessions annually for three years prior to January 18, 1986.

"Guest acupuncturist" means an acupuncturist from another state or country who is not a certified acupuncturist in this State and is the invited guest of a professional acupuncture association, scientific acupuncture foundation, or an acupuncture training program approved by the Board.

"Mechanical stimulation" means stimulation of a certain acupuncture point or points on or near the surface of the body by means of apparatus or instrument.

"Moxibustion" means the therapeutic use of thermal stimulus at acupuncture loci by burning artemisia alone or artemisia formulations.

"Oriental massage" means a system of acupressure or massage movements following Oriental principles.

"Sterilization" means the use of a steam autoclave or equivalent dry heat or ethylene oxide gas in order to destroy all microbial life, including viruses, thereby creating sterility.

"Supervising acupuncturist" or "supervisor" means a certified acupuncturist who is approved by the Board to provide an acupuncture tutorial to a trainee.

"Surface stimulation" means the application of purposeful stimuli to the surface of the body.

"Trainee" means a person who is registered with the Board in order to participate in an acupuncture tutorial under a supervising acupuncturist.

"Training agreement" means the written tutorial agreement between the supervisor and the trainee.

"Training plan" means the written tutorial plan that is filed with and approved by the Board.

"Training program" means and encompasses the agreement and the plan.

13:35–9.3 Credentials required for certification

(a) At the time of application, an applicant shall provide the following credentials:

1. Proof of having attained the age of 21, in the form of a certified copy of birth record, required of all applicants;

2. Affidavits from two persons, unrelated to the applicant, attesting to the applicant's moral character, required of all applicants; the signatures on any affidavits emanating from foreign jurisdictions must be authenticated as required by (a)5i(2) below;

3. Proof of possession of a baccalaureate degree, unless the applicant is a New Jersey-plenary licensed physician or presents proof of sufficient experience or successful completion of a tutorial within New Jersey, so as to be exempted by the Board from the baccalaureate requirement;

i. If the candidate has been awarded a baccalaureate degree from a college or university within the United States, a certified transcript shall be forwarded directly to the Board from that institution, which shall have been accredited by a regional accreditation agency recognized by the Council on Post–Secondary Accreditation or the United States Department of Education;

ii. If the candidate has been awarded a baccalaureate degree from a school located outside the United States, the applicant shall submit to the board an original and one photocopy of the applicant's transcript showing that a degree was awarded, and an evaluation of credits earned as determined by a Board-approval credential evaluation service. A list of such credential evaluation services shall be provided by the Board;

4. Applicants presenting a baccalaureate degree shall also provide evidence of graduation from a Board-approved two-year course of study or program at a Board-approved school of acupuncture. If the applicant was enrolled in a course of study of duration greater than two years, completion of only two years shall not satisfy this requirement. Evidence shall consist of a certified transcript from that school confirming that a diploma was awarded to the applicant. A list of approved acupuncture schools shall be provided by the Board. Candidacy status or accredited status with the National Accreditation Commission for Schools and Colleges of Acupuncture and Oriental Medicine is required in order for a school to be on the Board's approved list;

5. As an alternative to the primary pathway of a baccalaureate degree plus two or more years of acupuncture schooling as set forth in (a)3 and 4 above, an applicant shall provide evidence of either successful completion of a Board-approved tutorial program in acupuncture in New Jersey as set forth in N.J.A.C. 13:35–9.13 or experience acceptable to the Board, which experience shall be no less than 750 patient treatment sessions as a full-time acupuncturist during a 12–month period for each of three years prior to January 18, 1986. Such experience shall consist of the general practice of acupuncture.

i. Acceptable proof of experience shall include letters from past or present employers written to the Board on professional letterhead, which must be sent directly to the Board from the employer or the appropriate official at that office or institution. Such letters must clearly establish that the business existed and was offering acupuncture service during the period of time in question.

(1) When a letter from an employer, office or institution does not clearly and credibly indicate the required experience, the Board may at its discretion require that the applicant submit patient records of 750 treatment sessions or such other proof as the Board deems necessary.

(2) The signature(s) on letters of documentation emanating from foreign jurisdictions must be properly notarized and authenticated by an appropriate governmental official.

ii. If the applicant was self-employed, original patient records which clearly indicate the required 750 patient treatment sessions shall be submitted to the Board; such records shall be legible and well-organized. The Board may require records to be translated into English at the expense of the applicant; and

6. If the applicant is a physician and surgeon, the applicant must submit the following documentation in addition to that required by (a)1 and 2 above:

i. Proof that the applicant holds a current plenary license and registration to practice medicine in the State of New Jersey; and

ii. Proof that the applicant has completed the required specific training in acupuncture, pursuant to N.J.A.C. 13:35–9.16.

(b) Documents, other than patient records, written in a language other than English must be accompanied by an English translation done by a Board-approved translation service; a list of such translation services shall be provided by the Board. Translations by any other services or persons will not be accepted. The Board may, at its discretion, send such documents received from a source other than the applicant back to the applicant to be translated by an acceptable translation service at the applicant's expense.

13:35–9.4 Examination requirements

(a) An applicant shall successfully complete the comprehensive written examination developed by the National Commission for Certification of Acupuncturists ("NCCA"), provided that the examination is administered in the English language under conditions and circumstances approved by the Board. The Board at its discretion may reject a particular sitting of the examination if it receives evidence that the integrity of the examination was compromised. For the purposes of this subsection, "successful completion" means achieving a passing grade as established by NCCA for that sitting of the examination; nevertheless, the Board at its discretion may establish its own passing grade, which may be higher or lower than that of NCCA, for future exams.

(b) An applicant shall successfully complete an oral/practical examination administered annually by the Board.

13:35–9.5 Prohibited acts

A person, including a physician and surgeon or a dentist, who is not certified under the Acupuncture Act shall not hold himself or herself out as a practicing acupuncturist nor use a descriptive title such as "Certified Acupuncturist," "Acupuncturist," "C.A.," or any other letters or words denoting that the person is certified to practice acupuncture in this State.

13:35–9.6 Fee schedule

(a) The fee schedule for certification as an acupuncturist is as follows:

1.	Application Fee	$ 50.00
2.	Examination, Oral/Practical	$225.00
3.	Examination, Written	$350.00
4.	Initial Registration Fee:	
	i. If paid during the first year of a biennial renewal period:	$230.00
	ii. If paid during the second year of a biennial renewal period:	$115.00
5.	Biennial Registration	$230.00
6.	Duplicate or replacement of biennial registration certificate	$ 25.00
7.	Delinquency Fee (biennial registration) (up to 60 days)	$ 50.00
8.	Delinquency Fee (61 days or more)	$150.00
9.	Reinstatement Fee	$150.00
10.	Tutorials:	

i. Supervisor:	
(1) Application Fee	$ 50.00
(2) Initial Registration	$125.00
(3) Renewal, Annually	$125.00
(4) Delinquency Fee	$ 50.00
ii. Trainee:	
(1) Application Fee	$ 25.00
(2) Initial Registration	$ 60.00
11. Preparation of certification papers for applicants to other states:	$ 25.00

(b) If a license lapses due to nonpayment of the biennial registration fee, it may be reinstated within five years, provided that the pertinent delinquency fee and all past due registration fees are submitted with the application.

(c) The examination fee will be refunded only if the application is rejected by the Board or withdrawn by the candidate within 14 days of receipt of the application by the Board.

(d) After the 14–day period in (c) above, an applicant who fails to sit for an examination for which payment has been submitted may, one time only, have the fee credited toward the next scheduled examination. The fee will be entirely forfeited if the applicant fails to sit for the succeeding examination.

(e) The application fee is non-refundable.

Amended by R.1995 d.330, effective June 19, 1995.
See: 27 N.J.R. 640(a) (see also 27 N.J.R. 1746(a)), 27 N.J.R. 2410(a).
Increased some of the fees.

13:35–9.7 Term of lawful practice; biennial registration

(a) Licensure as an acupuncturist is not effective until, pursuant to N.J.S.A. 45:2C–12, the applicant receives a biennial registration from the Board denoting completion of all requirements. This certificate shall confer the right to practice in the State of New Jersey during the period of its validity; the right to practice in this State commences with the effective date of this certificate and ends on its expiration date. The expiration date shall be June 30 of the next year ending with an odd number (that is, 1993, 1995, 1997, etc.) after the date of issue. The certificate shall be valid for not more than two years.

(b) It shall be an unlawful practice to engage in the practice of acupuncture prior to receipt of the biennial registration, after it has expired, or after the license certificate has been suspended or revoked by order of the Board.

(c) Registration shall be renewed biennially by the licensee on official forms supplied by the Board. Registration will be renewed only upon receipt by the Board of a properly completed renewal application form and payment of the required fee. A renewal application form submitted within 60 days after the biennial registration deadline must be accompanied by the late fee set forth in N.J.A.C. 13:35–9.6(a)8.

(d) The certificate shall be posted in a conspicuous location in the applicant's office. If an applicant has more than one office, he or she shall obtain from the Board a duplicate certificate for each location.

(e) If the certificate to practice acupuncture in New Jersey lapses for a period of five years or more, reinstatement may be requested by special application to the Board. Requirements for reinstatement are:

1. Submission of a statement giving the reasons for the lapse. The Board shall have the right to make further inquiry, as deemed necessary, into the applicant's activities during the pertinent period;

2. Submission of two new letters of good moral character as required by N.J.A.C. 13:35–9.3(a)2;

3. Payment of the initial registration fee;

4. Successful completion, within one year prior to the request for reinstatement, of the complete examination described in N.J.A.C. 13:35–9.4(a) and (b), unless the individual proves that he or she:

i. Has been engaged in full time continuing acupuncture practice in another jurisdiction throughout the period that the license was lapsed in New Jersey, and the license has been in good standing throughout that period; and

ii. Submits proof that he or she has attended continuing professional education courses in acupuncture and related topics (see N.J.A.C. 13:35–9.17(d)).

13:35–9.8 Standards of practice

(a) A certified acupuncturist may perform or prescribe the use of the following therapies only:

1. Acupuncture, as defined in N.J.A.C. 13:35–9.2;

2. Oriental massage, as defined in N.J.A.C. 13:35–9.2;

3. Breathing techniques; and

4. Exercise to promote health.

(b) A certified acupuncturist may perform initial acupuncture treatment only on presentation by the patient of a referral by or diagnosis from a licensed physician.

(c) Following an explanation by the acupuncturist of the definition of acupuncture, procedures, potential risks and potential benefits, the acupuncturist shall obtain informed written consent from each patient before performing acupuncture. See Appendix A, incorporated herein by reference, for an example of an informed consent form.

13:35–9.9 Accepted equipment and devices; procedures

(a) Licensees may use any of the following to effect the stimulation of acupuncture points and channels: needles, moxa, cupping, thermal methods, herbal applications, magnetic stimulation, gwa-sha scraping techniques, acupatches, acuform, teishin (pressure needles), manual acutotement (defined as stimulation by an instrument that does not pierce the skin), acupressure, electroacupuncture (whether utilizing electrodes on the surface of the skin or current applied to inserted needles), laser bio-stimulation in accordance with relevant Federal law including United States Food and Drug Administration rules and regulations, and ultrasonic stimulation of acupuncture points and channels.

(b) The needles used in acupuncture shall include, but not be limited to: solid filiform needles, dermal needles, plum blossom needles, press needles, prismatic needles and disposable lancets.

(c) The use of staples or hypodermic needles in the practice of acupuncture is prohibited.

13:35–9.10 Precautionary and sterilization procedures

(a) All non-disposable needles and acupuncture equipment that comes into contact with the patient's blood or bodily fluids or penetrates the skin, and equipment used to handle or store needles or other acupuncture equipment that comes into contact with the patient's blood or bodily fluids or penetrates the skin, shall be sterilized prior to each use. Prior to sterilization, all equipment to be sterilized shall be thoroughly cleaned with a disinfectant or cleansing solution.

(b) Sterilization shall be accomplished before use by one of the following methods:

1. Steam autoclave at 250 degrees Fahrenheit (120 degrees Celsius) and 15 pounds per square inch of pressure for 30 minutes;
2. Equivalent dry heat; or
3. Ethylene oxide gas sterilization.

(c) Sterilization equipment shall be used and maintained strictly in accordance with the guidelines of the manufacturer of the instrument, and shall be monitored regularly in accordance with the manufacturer's guidelines to determine whether the equipment is functioning properly.

(d) The following methods of sterilization are unacceptable: boiling acupuncture equipment or soaking acupuncture equipment in alcohol or other antiseptic solution. A glass bead sterilizer may not be used as a primary method of sterilization. Using a glass bead sterilizer is permissible only as a supplemental procedure following the use of the methods in (b) above.

(e) The acupuncturist may delegate disposal of needles to an approved agent; a list of approved agents shall be supplied, upon request, by the Acupuncture Examining Board. The needles shall be placed in a rigid, puncture-proof, sealed container for disposal. Disposal containers shall be labelled as such, and shall carry the warning "CONTAMINATED CONTENTS—USE PRECAUTIONS." Disposal containers shall be wiped with a suitable disinfectant if blood or other bodily fluids are spilled on the outside. Disposal containers shall be discarded appropriately. The acupuncturist shall comply with all requirements of the State Department of Environmental Protection and Energy and the Department of Health implementing the Comprehensive Regulated Medical Waste Management Act, P.L. 1989, c.34 (N.J.S.A. 13:1E–48.1 et seq.).

(f) If in the course of treatment of a patient, a licensee learns that the patient has a blood-borne highly infectious disease, the licensee shall use only disposable needles in treating the patient.

(g) It shall be the responsibility of the certified acupuncturist to ensure that personnel responsible for performing sterilization procedures pursuant to this rule are adequately trained and supplied with a written outline of sterilization procedures. A copy of the outline shall be maintained on the premises.

13:35–9.11 Patient records

(a) An acupuncturist shall maintain complete and accurate records on each patient who has been given acupuncture treatment. The record shall include, but not necessarily be limited to, the following: source of referral and/or diagnosis from a licensed physician; subjective complaints presented by the patient; dates of initial consultation and all treatment sessions; treatments given; and periodic reevaluation and progress notes made in the course of treatment.

(b) Complete and accurate billing records shall be prepared and maintained.

(c) The information required by (a) and (b) above shall be maintained in English.

(d) Patient and billing records shall be kept for a period of seven years from the date of the patient's last treatment.

13:35–9.12 Guest acupuncturist

(a) An acupuncturist from another state or country, who is not a certified acupuncturist in this State and is the invited guest of a professional acupuncture association, scientific acupuncture foundation, or an acupuncture training program approved by the Board, may engage solely in professional education through lectures, clinics or demonstrations, provided such acupuncturist has been granted temporary permission by the Board. The guest acupuncturist may then perform acupuncture in conjunction with these lectures, clinics or demonstrations for a maximum of 60 days in a calendar year or longer upon special permission of the Board. The guest acupuncturist shall not open an office or

appoint a place to meet patients or receive calls from patients or otherwise engage in the practice of acupuncture.

(b) The sponsoring organization shall request permission from the Board, in writing, for the guest acupuncturist no later than 60 days prior to the guest acupuncturist's initial presentation in New Jersey. A resume or summary of the guest acupuncturist's credentials, written in English, shall accompany the request for approval.

13:35–9.13 Tutorial applications and design of tutorial program

(a) No person shall practice acupuncture in an approved tutorial program in acupuncture in this State without prior approval of the Board.

(b) Tutorial applications shall be filed with the Board as follows:

1. Application as an acupuncture trainee shall be filed on a form provided by the Board and accompanied by the tutorial trainee application fee. The information to be provided on the application form shall include personal biographical and educational information and current resident status.

2. Applications for approval to supervise an acupuncture trainee shall be filed on a form provided by the Board and accompanied by a copy of the written trainee agreement, the tutorial supervision application fee, and any other pertinent documents required by the Board. The information to be provided on the application shall include personal biographic, educational and experiential requirements.

(c) Evidence of prior training and experience shall be submitted to the Board for its review with the applications for registration of the supervising acupuncturist and trainee.

(d) The applicant shall document to the Board's satisfaction that any prior training and experience obtained by the trainee outside of the State of New Jersey was completed within a state or jurisdiction having conditions and requirements equivalent to or higher than those in effect pursuant to this subchapter and N.J.S.A. 45:2C–1 et seq.

(e) The trainee shall be at least 18 years of age and shall have a minimum of 60 credits at an institution of higher learning, which must be accredited by a regional accreditation agency recognized by the Council on Post–Secondary Accreditation or the United States Department of Education.

(f) Requirements for approval of an acupuncture tutorial are as follows:

1. An acupuncture tutorial shall be designed to be completed in no less than two nor more than four calendar years;

2. An acupuncture tutorial shall be designed to provide a trainee with a structured learning experience in all the basic skills and knowledge necessary for the independent practice of acupuncture, and shall prepare the trainee for the Board's examination for certification;

3. Acupuncture tutorials which are in the nature of internships may be full-time or part-time relationships; however, the training plan and proposed supervision shall be contained in a written agreement between the supervisor and trainee, pursuant to (i) below;

4. An acupuncture tutorial shall provide formal clinical training with supplemental theoretical and didactic instruction which may be obtained in a post-secondary educational institution which is either accredited by an accrediting body recognized by the Board or specifically approved by the Board;

5. The clinical training shall consist of a minimum of 1650 hours in the following areas:

i. Practice observation;

ii. Patient history and physical examination, including traditional Oriental medical diagnostic procedures;

iii. Therapeutic treatment planning;

iv. Preparation of the patient;

v. Sterilization, use and maintenance of equipment;

vi. Moxibustion;

vii. Electroacupuncture;

viii. Body and auricular acupuncture;

ix. Treatment of emergencies, including certification in cardiopulmonary resuscitation ("CPR");

x. Pre and post-treatment and instructions to the patient;

xi. Contraindications and precautions; and

xii. Optional: Shiatsu, Acupressure, TaiChi–Chuan and Qi Gong; and

6. The theoretical and didactic training shall consist of a minimum of 600 hours in the following areas:

i. Traditional Oriental medicine;

ii. Acupuncture anatomy and physiology;

iii. Acupuncture techniques;

iv. Survey of clinical medicine;

v. History of Chinese medicine; and

vi. Study of general sciences in anatomy, physiology and pathology, which training shall be obtained in a post secondary-educational setting approved by the Board, provided that each of the courses is for at least three academic credits.

(g) The acupuncture services assigned to the trainee shall be those which are unlikely to endanger the health and welfare of patients receiving such services.

(h) No trainee shall be authorized to render acupuncture services to any patient unless the patient has been informed that such services will be rendered by a trainee. The patient, on each occasion of treatment, shall be informed of the procedure to be performed by the trainee under the supervision of the supervising acupuncturist, and shall have consented in writing prior to the initial rendering of the acupuncture procedure by the trainee. The foregoing requirements do not apply to those instances wherein the trainee merely assists the supervisor in the rendering of acupuncture services.

(i) The acupuncture tutorial training program shall be set forth in a written agreement signed by the supervisor and the trainee which shall be submitted for approval to the Board, with the application. The agreement shall set forth, but is not limited to:

1. The training plan;

2. The length of training time;

3. The method of providing the theoretical and didactic training;

4. Guidelines for supervision of the acupuncture services rendered by the trainee; and

5. Tuition fees to be paid by the trainee for participation in the program.

(j) An acupuncture tutorial shall be made available regardless of the trainee's sex, race, religion, creed, or color and regardless of physical handicap which does not unduly interfere with the capacity of the trainee to safely master the program.

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

13:35–9.14 Responsibilities of supervising acupuncturist

(a) No acupuncturist shall supervise any person in an approved tutorial program in acupuncture in this State without prior approval of the Board. Board approval shall be contingent upon submission of proof satisfactory to the Board that the supervising acupuncturist is certified to practice in New Jersey and has at least seven years of experience practicing acupuncture.

(b) The supervising acupuncturist shall have the following duties and responsibilities:

1. The supervisor shall obtain permission from the Board to supervise up to two trainees in an approved tutorial program;

2. The supervisor shall at all times be responsible for and provide supervision of the work performed by the trainee as required in this subchapter;

3. The supervisor shall assign only those patient treatments which can be safely and effectively performed by the trainee and which are consistent with the level of training received by the trainee. The supervisor shall provide continuous direction and immediate supervision of the trainee when patient services are being provided. For purposes of this subsection, "continuous direction and immediate supervision" means that the supervisor shall be in the same facility as, and in proximity to, the location where the trainee is rendering services, and shall be readily available at all times to provide advice, instruction and assistance to the trainee and the patient;

4. The supervisor shall assure that prior to the procedure an oral explanation is given and the patient's written informed consent to any procedure and its performance by the trainee is obtained;

5. The supervisor shall assure that the objectives of the training plan submitted to the Board are provided and met by the trainee;

6. The supervisor shall notify the Board in writing within 10 days of the termination of any training agreement for any reason. At the time of such notification, the registration of the trainee shall be cancelled;

7. If, at any time, the trainee plan of the acupuncture tutorial is substantially modified, the supervisor shall file with the Board a report of such modifications. There shall be no charge for the filing of such a report;

8. The supervisor shall assure that the trainee complies with accepted standards of practice, this subchapter, and applicable statutory requirements;

9. The supervisor shall file a progress report with the Board within 30 days of completion by each trainee of each year of an approved acupuncture tutorial. Information in the progress report shall follow guidelines provided by the Board. The supervisor shall file a final report within 30 days of completion of the training; and

10. The supervisor shall assure that when rendering services or otherwise engaging in professional activity, the trainee shall always identify himself or herself as an acupuncture trainee.

13:35–9.15 Responsibilities of the acupuncture trainee

(a) The acupuncture trainee shall have the following duties and responsibilities:

1. The trainee shall not provide acupuncture services independently or without the required supervision, and shall not provide any services for which he or she is not trained or being trained to competently perform;

2. The trainee shall satisfactorily meet the objectives of the training plan submitted to the Board including the necessary theoretical training;

3. The trainee shall comply with the standards of practice in these rules as well as all applicable statutory requirements;

4. The trainee shall always identify himself or herself as an acupuncture trainee when rendering services or otherwise engaging in professional activity;

5. The trainee shall report to the Board any delay, interruption or termination of the acupuncture tutorial not reported by the supervisor; and

6. At the completion of the tutorial, the trainee may file an application for examination.

13:35–9.16 Training required of a physician or dentist

(a) No physician holding a plenary license from the New Jersey Board of Medical Examiners or dentist licensed by the New Jersey Board of Dentistry shall be prevented from practicing acupuncture provided his or her course of training has included:

1. Graduation from a school approved by the National Accreditation Commission of Schools and Colleges of Acupuncture and Oriental Medicine (NACSCAOM);

2. Acupuncture training in a United States or foreign medical school or a foreign acupuncture school; or

3. Courses of training acceptable to or approved by the Board.

(b) The course of training shall be for a minimum of 300 hours, which must include a clinical training program of at least 150 hours. Such United States or foreign training must include:

1. Traditional Oriental medicine (a survey of the theory and practice of traditional diagnostic and therapeutic procedures);

2. Acupuncture anatomy and physiology (fundamentals of acupuncture including point location, the meridian system, special and extra loci, and auriculotherapy); and

3. Acupuncture techniques (instruction in the use of needling techniques, moxibustion and electroacupuncture, including precautions such as sterilization of needles, contraindications and complications).

Petition for Rulemaking.
See: 25 N.J.R. 3243(a), 25 N.J.R. 4338(b).

13:35–9.17 Continuing professional education requirements

(a) The provisions of this section shall apply to all applicants for biennial license renewal except those seeking renewal for the first time.

(b) Beginning with the biennial renewal period that starts on July 1, 1995, no license renewal shall be issued by the Board unless the applicant confirms on his or her renewal application that during the two calendar years preceding application for renewal the applicant participated in courses or activities of continuing education of the type and number of credits specified in this section. Evidence of 20 documented hours of continuing education is a mandatory requirement for license renewal, except for initial renewal.

1. "Documented" means that the applicant obtains:

i. A certificate of participation;

ii. A signed document by the instructor indicating attendance; or

iii. An official transcript from an accredited local, state or national organization or learning institution, as set forth in (d) below.

2. A licensee shall be solely responsible for obtaining and maintaining, for a period of three years, documentation on his or her completion of the required continuing education courses. Such documentation shall be submitted to the Board upon request, and will be surveyed from time to time.

(c) Credit for continuing professional education will be granted as follows for each two-year period:

1. Publication in a national professional journal of a copyrighted article on acupuncture: three hours per article to a maximum of six hours;

2. Attendance at seminars and conferences: one hour per contact hour; and

3. Successful completion of graduate course work taken beyond that required for professional license: one hour per credit hour.

(d) Acceptable continuing professional education courses or activities shall be in any subject area which will update and refresh the clinical skills or knowledge of an acupuncturist. However, courses must be accredited by NACSCAOM, the New Jersey Department of Higher Education, a regional accreditation agency recognized by the Council on Post–Secondary Accreditation, or the United States Department of Education. Seminars and conferences must be accredited or sponsored by a local, state, or national professional organization; a local, state or Federal education or health agency; or a local, state or national medical, psychological, dental or similar professional organization. Notwithstanding that the continuing education course or activity appears to meet these requirements, the Board at its discretion may at any time examine and review any course or activity claimed for credit. If such course or activity does not clearly meet the requirements of this section or is deemed by the Board to be not pertinent to the practice of acupuncture, the course or activity shall be disallowed for credit toward the required 20 continuing education credits.

(e) In the event that a candidate for license renewal shall complete in two years a number of hours in excess of the number required, the documented hours in excess of those required shall not be credited toward license renewal requirements for subsequent years.

(f) The Board may, at its discretion, waive any of the requirements of this section for good cause shown. An appearance before the Board may be required.

APPENDIX A

The following is an example of an informed consent form:

" 'Acupuncture' means the stimulation of a certain point or points on or near the surface of the body by the insertion of special needles to prevent or modify the perception of pain or to normalize physiological functions, including pain control, for the treatment of certain diseases or dysfunctions of the body, and includes the techniques of electroacupuncture, mechanical stimulation and moxibustion.

The potential risks are: slight pain or discomfort at the site of needle insertion, infection, bruises, weakness, fainting, nausea and even aggravation of systems existing prior to acupuncture treatment.

The potential benefits: acupuncture may allow for painless and drugless relief of one's symptoms and improved balance of bodily energies leading to prevention or elimination of the presenting problem.

With this knowledge I voluntarily consent to the above procedures."

(Signature of patient/guardian).

SUBCHAPTER 10. ATHLETIC TRAINERS

13:35–10.1 Scope and purpose

(a) This subchapter is promulgated by the New Jersey State Board of Medical Examiners, pursuant to N.J.S.A. 45:9–37.35 et seq., providing for the registration and regulation of athletic trainers within the State of New Jersey.

(b) The rules contained in this subchapter shall apply to all individuals currently practicing as athletic trainers, as well as those individuals studying to become athletic trainers within this State. The rules are designed to better define the allowable activities, professional standards, and the educational requirements of athletic trainers.

13:35–10.2 Definitions

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

"Advisory Committee" means the Athletic Training Advisory Committee established under N.J.S.A. 45:9–37.39.

"Athlete" means an individual who participates in an inter-scholastic, intercollegiate or intramural athletic activity being conducted by an educational institution licensed in the State of New Jersey or a professional athletic activity.

"Athletic trainer" means a person who practices athletic training as an employee of a school, college, university or professional athletic team.

"Athletic training" means the practice of physical conditioning and reconditioning of athletes and the prevention of injuries incurred by athletes. Athletic training shall also include, at the direction of a physician licensed in the State of New Jersey, the application of physical treatment modalities to athletes as recommended by the Advisory Committee and defined in N.J.A.C. 13:35–10.6(c).

"Board" means the State Board of Medical Examiners.

"Direction of a licensed physician" means the designing and overseeing of a plan of care for the athlete by a physician licensed in the State of New Jersey (M.D., D.O., D.C., D.P.M.) within his or her permitted scope of practice as specified by N.J.S.A. 45:9–5.1, N.J.S.A. 45:9–14.5, N.J.S.A. 45:9–41.27, N.J.S.A. 45:5–7.

"Non-injured athlete" means an athlete who has not sustained an injury or who has received medical clearance from a physician licensed in the State of New Jersey for full participation after injury/illness.

"Professional athletic team" means any team, group or individual athlete paid to perform at athletic events and activities.

13:35–10.3 Education standards

The requirement of N.J.S.A. 45:9–37.42 that an athletic trainer must provide proof of graduation or successful completion of a program of education, training, and experience approved by the Board shall be defined as the curriculum or program of education, training, and experience which was approved during the entire course of the applicant's education, training, and experience by the National Athletic Trainers Association Board of Certification, Inc.

13:35–10.4 Examinations

The requirement of N.J.S.A. 45:9–37.43 that an athletic trainer must pass an examination approved by the Board shall be deemed to have been met by evidence of passing the examination administered by the National Athletic

Trainers Association Board of Certification, Inc. The Advisory Committee, in its discretion and with prior approval of the Board, may develop and administer an alternative examination, testing the applicant's knowledge in the areas outlined in N.J.S.A. 45:9–37.43.

13:35–10.5 (Reserved)

13:35–10.6 Approved activities

(a) A registered athletic trainer may provide the full spectrum of pre-season, in-season and post-season conditioning programs. These programs include, but are not limited to, maintenance and reconditioning programs, as well as bandaging, wrapping, taping, padding, and splinting procedures for the prevention and management of injuries.

(b) Nothing in this subchapter shall be interpreted to prohibit registered athletic trainers from providing first-aid.

(c) A registered athletic trainer may, at the direction of a licensed physician as provided in N.J.A.C. 13:35–10.2, administer the following physical treatment modalities:

1. Cold;
2. Heat;
3. Light;
4. Sound;
5. Electricity;
6. Electromagnetic waves;
7. Water; and
8. Traditional mobilization techniques, rehabilitative exercise programs, traction, and massage.

(d) A registered athletic trainer may, at the direction of a licensed physician as provided in N.J.A.C. 13:35–10.2, provide testing of neuromotor and musculoskeletal functional capability for the purposes of conditioning, reconditioning or otherwise evaluating the athlete's performance capability. However, nothing in this subchapter shall be interpreted to permit a registered athletic trainer to conduct electromyographic testing or nerve conduction velocity studies.

(e) The Advisory Committee recognizes that the athletic trainer is not authorized to diagnose an injury or illness. However, prior to implementing or while maintaining the plan of care, the athletic trainer shall exercise professional judgment to determine whether any intervening circumstances have adversely affected the athlete's ability to participate in or continue to participate in the plan of care.

(f) A written record regarding the treatment of an athletic injury shall be created by the athletic trainer and maintained for a period of seven years from the date of the last entry.

(g) Nothing in this subchapter shall be interpreted to prohibit registered athletic trainers from being employed or performing activities which do not require licensure or registration provided they do not hold themselves out as being able to perform athletic training in that employment or performance.

(h) Nothing in this section shall be interpreted to prohibit unregistered individuals from applying bandaging, wrapping, taping, padding or splinting techniques to non-injured athletes.

13:35–10.7 Violations

Without limiting the prosecution of any practices which may be unlawful under any other state or Federal law, a violation of this subchapter shall be deemed to be a violation of the Athletic Training Practice Act, N.J.S.A. 45:37–35 et seq., and shall be subject to the sanctions and penalties provided for thereunder.

13:35–10.8 Fees

(a) The following fees shall be charged by the Board for athletic trainer registration:

1. Temporary registration or authorized registration without examination	60.00
2. Examination (RESERVED)	
3. Initial Registration Fee	
i. If paid during the first year of a biennial renewal period:	70.00
ii. If paid during the second year of a biennial renewal period:	35.00
4. Biennial registration	70.00
5. Endorsement	60.00
6. Late renewal fee	50.00

New Rule, R.1993 d.260, effective June 7, 1993.
See: 25 N.J.R. 1058(a), 25 N.J.R. 2487(a).
Administrative Correction.
See: 25 N.J.R. December 6, 1993.
Amended by R.1995 d.330, effective June 19, 1995.
See: 27 N.J.R. 640(a) (see also 27 N.J.R. 1746(a)), 27 N.J.R. 2410(a).
Increased some of the fees.

SUBCHAPTER 11. ALTERNATIVE RESOLUTION PROGRAM

Authority

N.J.S.A. 45:9–2 and 45:9–19.4.

Source and Effective Date

R.1995 d.339, effective June 19, 1995.
See: 27 N.J.R. 1363(a), 27 N.J.R. 2412(a).

13:35–11.1 Definitions

As used in this subchapter the following words and terms have the following meanings, unless the context indicates otherwise:

"Alternative Resolution Program" or "ARP" means a program established pursuant to this subchapter for those subject to Board jurisdiction who are suffering from chemical dependencies and other impairments which shall permit such licensees to disclose their status to an entity which would allow for confidential oversight.

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

"Chemical dependency" means a condition involving the continued misuse of chemical substances.

"Chemical substances" is to be construed to include alcohol, drugs or medications, including those taken pursuant to a valid prescription for legitimate medical purposes and in accordance with the prescriber's direction, as well as those used illegally.

"Confidential" means that a participating licensee's identity (as well as any information from which a licensee's identity could be deduced) shall be maintained in a limited access file maintained by the Impairment Review Committee ("IRC"), with disclosure provided only to those persons whom the IRC determines have a need to know, in order to perform their role in the review process.

"Impairment" means an inability to function at an acceptable level of competency, or an incapacity to continue to practice with the requisite skill, safety and judgment, as a result of alcohol and/or chemical dependency, a psychiatric and/or emotional disorder, senility or a disabling physical disorder.

"Impairment Review Committee" or "IRC" means the subcommittee of the Board created pursuant to this subchapter.

"Licensee" means a physician (including a resident or intern), podiatrist, bioanalytical laboratory director, certified nurse midwife, physician assistant or other professional subject to regulation by the Board.

"Panel" means the Medical Practitioner Review Panel.

"Professional assistance program" or "PAP" means a publicly or privately organized entity offering services to facilitate the rehabilitation of licensees suffering from chemical dependencies or other impairments. A program may limit its services to specific categories of licensees.

13:35–11.2 Creation of Impairment Review Committee

The Board shall establish a committee to review matters involving practitioners suffering from chemical dependencies or other impairments. This committee shall be comprised of five members to include: two members of either the Board or the Panel, to be appointed by the Board President; two individuals representing approved professional assistance programs which provide services to at least one third of the ARP participants; and one individual designated by the Commissioner of Health, who is acceptable to both the Board President and the individuals representing approved professional assistance programs. This committee shall be known as the Impairment Review Committee ("IRC") and shall meet on a regular basis. The Medical Director of the Board and the Executive Director of the Board shall serve as staff to the IRC and shall be available to assist the IRC at its meetings. With regard to independent referrals (not made by an approved professional assistance program), the Executive Director shall provide the IRC with all of the information, including the identity of the licensee about whom the referral has been made, which was provided with the referral, along with any information concerning concurrent investigations or consumer complaints relating to the licensee. With respect to those referrals made by approved professional assistance programs, the Executive Director shall advise the IRC of any information concerning concurrent investigations or consumer complaints, without disclosing the identity of the licensee, so that the IRC will be in a position to assess whether participation in the program is appropriate.

13:35–11.3 Duties of an approved professional assistance program

(a) An approved professional assistance program shall:

1. Promptly conduct appropriate inquiry with regard to every referral received to determine whether the information indicating licensee impairment is sufficiently reliable to warrant further review;

2. Make an initial report to the IRC concerning every referral which suggests that a licensee has a chemical dependency or any other impairment within 30 days of receipt of a referral. That report shall indicate the licensee's code number and sufficient information concerning the suspected impairment and the nature of the practice for the IRC to conduct a meaningful review. The report shall address: the nature of the impairment; whether the licensee rendered or was expected to render patient care while impaired; whether patients were harmed either directly or indirectly by the licensee's conduct; whether the licensee has engaged in an activity which could render that licensee subject to criminal penalty including, but not limited to, the illegal distribution of controlled dangerous substances or sexual abuse of patients; and whether the licensee previously has undergone a rehabilitation program, and, if so, when that occurred, the nature and the duration of the prior treatment and the results thereof. The initial report shall also include recommendation to the IRC concerning a proposed plan of treatment; the services which will be provided by the sponsoring program; practice restrictions which should be imposed, if any; the monitoring regimen to be instituted, if any; the supervision and reporting to be required and by whom and the frequency of its periodic reports to the IRC. Alternatively, the PAP may recommend no further action be taken when, after inquiry, it is determined that

there is insufficient information upon which to conclude that the licensee is suffering from a chemical dependency or any other impairment;

3. Conduct such supplemental inquiry as may be directed by the IRC and may request of the IRC that further investigation be conducted by staff, investigative personnel or the Attorney General, if appropriate;

4. Prepare a letter agreement, including a plan for recovery relating to each referral, setting forth the participant's obligations and memorializing his or her consent to the release of all pertinent medical, psychiatric or personnel records to the IRC should such documents become necessary as part of its review, as well as the licensee's consent to provide the notice to the IRC of all events as set forth in (a)7 below and notice to comparable PAPs or licensing boards as set forth in (a)8 below;

5. Secure from each participant his or her signature on both the summary report and a letter agreement, maintain the original of both in a secure place and provide a coded copy, without identifying information, to the IRC;

6. Immediately report to the IRC and disclose the identity of the participating licensee if that licensee:

i. Has not complied with the terms of the letter agreement or the plan as set forth in the summary report;

ii. Has been the subject of a urine or blood test report which is positive for the presence of a substance not appropriately prescribed for a legitimate documented reason;

iii. Has otherwise demonstrated a relapse or impairment;

iv. Has engaged in deceptive behavior (including, but not limited to, an attempt to invalidate a drug screen, substitute a specimen, present a fraudulent attendance record);

v. Has suffered an exacerbation of a condition rendering the licensee incapable of practicing with requisite skill and safety; or

vi. Has had a change of status (including, but not limited to, the initiation of a disciplinary proceeding at a health care facility, an arrest or a disappearance);

7. Provide notice of program participation to comparable professional assistance programs in other jurisdictions if the licensee should elect to leave this State or should apply for initial licensure in another state, if such programs exist. If the jurisdiction to which the licensee is planning to move does not have a professional assistance program which has an arrangement with the licensing board in that jurisdiction, the PAP shall provide notice directly to the licensing board. A copy of such notice shall be provided to the IRC; and

8. Prepare periodic reports as to the progress of all of the participants which it is sponsoring, pursuant to a schedule as established by the IRC, and, as appropriate, coordinate the submission of any other documentation directed.

13:35–11.4 Duties of the Impairment Review Committee

(a) The IRC shall perform the following duties, as well as such others as the Board may require. The IRC:

1. Shall accept from licensees, and from other members of the public, reports (with the individual's identity) concerning licensees who may be suffering from chemical dependencies or other impairments;

2. Shall accept referrals (with the individual's identity) from the Board;

3. Shall accept coded initial reports from approved professional assistance programs (without any information from which the individual's identity can be discerned);

4. May request additional information from staff, the sponsoring PAP, the participant or persons with knowledge concerning a participant's condition or progress in rehabilitation;

5. Shall promptly review each referral to determine if participation in the ARP is appropriate. In making this determination, the IRC shall give consideration to the following factors:

i. The nature of the impairment;

ii. Whether the licensee rendered or attempted to render or was expected to render care at a time when impaired;

iii. Whether patients were harmed either directly or indirectly by the licensee's conduct;

iv. Whether the licensee has engaged in an activity which could render the licensee subject to criminal penalty, including, but not limited to, the illegal distribution of controlled dangerous substances or sexual abuse of patients;

v. Whether the licensee previously has undergone a rehabilitation program, and, if so, when that occurred, the nature and the duration of the prior treatment and the results thereof; and

vi. Whether such factors in a particular case would make participation in the Alternative Resolution Program inconsistent with the public interest;

6. With respect to PAP referrals, shall transmit to the Board a coded summary report (without the disclosure of any information from which the individual's identity could be discerned) as prepared by the IRC either upon completion of its review or within 30 days, whichever occurs first;

7. With respect to referrals from the Board, the public or other practitioners, shall prepare the summary report, reflecting the factors set forth at (a)5 above to be transmitted to the Board. If the IRC review has been initiated by a self-referral or by a report by another practitioner, reports to the Board shall be coded (without the disclosure of any information from which the individual's identity could be discerned). If the IRC has concluded that, based upon its review, there is insufficient information upon which to conclude that the licensee is suffering from a chemical dependency or other impairment, it shall so state in its confidential summary report, indicating the extent of its review. If the IRC has determined that participation should be permitted, the summary report shall address the following, as appropriate:

i. What treatment is warranted;

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

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 approval could be rescinded.

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 Alternative Resolution Program pilot period

Two years following the operative date of this subchapter, the Board shall determine, after study and consultation, whether the program established pursuant to this subchapter should be continued, altered, expanded or discontinued. Should the Board conclude that the program should be terminated, those currently participating shall be permitted to continue with the confidentiality protection set forth in this subchapter. 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.