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NEW JERSEY ADMINISTRATIVE CODE

TITLE 13

LAW AND PUBLIC SAFETY

CHAPTER 35

BOARD OF MEDICAL EXAMINERS

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SUBCHAPTER 1.
MEDICAL SCHOOLS, COLLEGES, EXTERNSHIPS AND CLERKSHIPS

13:35-1.1 OBSERVERSHIP PROGRAM

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

b) An observership program shall be limited to:

1) Observation of operative procedures;

2) The taking of histories;

3) The performance of physical examinations;

4) The performance of non-invasive procedures under the direct supervision of and in the immediate presence of the supervising licensed physician; and

5) The participation in patient rounds and other organized patient care activities of the supervising physician.

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

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

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

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

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

13:35-1.2 FIFTH PATHWAY

h) 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 either the World Health Organization Directory published by the World Health Organization or the International Medical Education Directory (IMED) published by the Educational Commission for Foreign Medical Graduates (ECFMG);

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.

i) 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.

13:35-1.3 (RESERVED)

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.

13:35-1.5 REGISTRATION AND PERMIT REQUIREMENTS FOR GRADUATE MEDICAL EDUCATION PROGRAMS IN MEDICINE OR PODIATRY

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2) Has never:

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

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

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

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

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

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

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

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

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

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

d) The Director shall obtain a registration form from each registration applicant and shall retain those forms, which may be subject to review by the Board. The Director shall certify that he or she has personally reviewed the registration form of each registration applicant who has accepted an offer of employment to ascertain that the registration applicant has certified that he or she has attained the prerequisites set forth in (c) above and that the Director is unaware of any information that would contradict any of the representations contained in that registration application form. If the Director shall have reason to question the veracity or reliability of those representations, he or she shall direct the registration applicant to supply the supporting documentation. The Director shall prepare a master list, which contains the names of all registration applicants and the names and addresses of the institutions from which the applicants attended or graduated and shall submit the master list to the Board, along with his or her certification,

no later than one month before the registration applicants are to begin participating in the graduate medical education program.

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

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

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

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

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

of good cause the applicant will be granted an appearance before a committee of the Board.

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

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

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

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

k) Upon a duly verified application of the Attorney General, alleging a violation of any act or regulation administered by the Board, which palpably demonstrates that the resident's continued practice would constitute a clear and imminent danger to the public health, safety and welfare, upon notice, the Board may enter an order temporarily suspending the resident's authority to engage in the practice of medicine or podiatry pending a. plenary hearing on the charge. If the Board determines that, although continued practice would not constitute clear and imminent danger, the resident's continued practice could pose a risk to the public health, safety and welfare, it may order the resident to submit to medical or diagnostic testing and monitoring or psychological evaluation or an assessment of skills to determine whether the resident can continue to practice with reasonable skill and safety.

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

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

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

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

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

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

1) Permit application, completed by the applicant.

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

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

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

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

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

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

o) Upon receipt of the permit application packet, the Board shall review each permit packet and if it is satisfied that the permit applicant has the necessary prerequisites, it shall issue to the applicant a permit authorizing that person to engage in either the practice of medicine or the practice of podiatry, as appropriate, in the second year (or beyond) of a graduate medical education program.

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

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

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

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

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

s) The residency program director shall:

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

i) Name of the permit holder;

ii) Field of practice;

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

iv) Type of facility;

v) Telephone number; and

vi) Street address of the facility; and

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

t) The supervising physician shall:

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

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

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

v) The Board may refuse to issue a permit to a permit applicant if he or she has not certified that the prerequisites set forth in (c) above have been satisfied, if the supporting

documentation set forth in (/) above has not been produced or if the Board is in possession of any information contradicting the representations made in the permit application form or supporting documentation. The Board shall give the Director and the applicant notice of its refusal, allowing the submission of documentary evidence in rebuttal. Upon a showing of good cause the applicant will be granted an appearance before a committee of the Board.

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

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

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

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

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

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

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

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

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

4) Report to the Board if any resident is granted a leave of absence for any reason, relating to a medical or psychiatric illness or to medical competency or conduct, which would represent cause for the withdrawal of the authority to practice, providing an explanation. This duty to report shall not apply if the resident is known to the Board's Impairment Review Committee through participation in the Alternative Resolution Program.

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

SUBCHAPTER 1A.
(RESERVED)

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.

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).

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.

13:35-2.4 PODIATRIST SUPERVISION AND ADMINISTRATION OF HYPERBARIC OXYGEN THERAPY

a) The purpose of this section is to set forth standards for the supervision and/or administration of hyperbaric oxygen therapy by a licensed podiatrist. A licensed podiatrist who meets and complies with all requirements of this section may supervise and/or administer hyperbaric oxygen therapy to his or her patient, for the purpose of treating conditions of the lower leg, foot or ankle, provided such conditions are within the scope of the practice of podiatry, as defined in N.J.S.A. 45:5-7.

b) For purposes of this section, “hyperbaric oxygen therapy” or “HBOT” means a treatment in which a patient intermittently breathes 100 percent pure oxygen while inside a treatment chamber at two to three times the atmospheric pressure at sea level.

c) A licensed podiatrist may supervise and/or administer HBOT treatment for conditions of the lower leg, foot, or ankle, provided such conditions are within the scope of the practice of podiatry, as defined in N.J.S.A. 45:5-7, and provided that he or she has:

    1) Received educational training in the administration of HBOT; and

    2) Been credentialed to perform the supervision and administration of HBOT by a hospital licensed by the Department of Health pursuant to N.J.S.A. 26:2H-1 et seq.

d) A licensed podiatrist shall supervise and administer HBOT only:

    1) Within the confines of a hospital licensed by the Department of Health pursuant to N.J.S.A. 26:2H-1 et seq., where a plenary licensed physician with knowledge of hyperbaric medicine is physically present on-site and readily available to manage any complications that may occur; and

2) When the patient has been cleared to receive HBOT by a plenary licensed physician prior to the initiation of treatment. The podiatrist supervising and/or administering HBOT shall maintain documentation of physician clearance to receive HBOT in the patient's medical record.

13:35-2.5 (RESERVED)

13:35-2.6 MEDICAL STANDARDS GOVERNING SCREENING AND DIAGNOSTIC MEDICAL TESTING OFFICES; DETERMINATIONS WITH RESPECT TO THE VALIDITY OF CERTAIN DIAGNOSTIC TESTS

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

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

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

1. Personally performed a physical examination, making an assessment of any current and/or historical subjective complaints, observations, objective findings, neurological indications;

2. Considered any and all previously performed test relating the patient's medical condition and the results; and.

3. Documented in the patient record positive and negative findings, observations and medical indications to justify the test.

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

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

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

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

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

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

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

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

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

1) Is authorized, if consistent with the practitioner's scope of practice, to perform the diagnostic test, for which a specific CPT code is assigned and for which a fee shall be charged, upon the attainment of education and supervised training in the pertinent test;

2) May directly request a specific diagnostic test, for which a specific CPT code is assigned and for which a fee shall be charged, when clinically supported, provided that referring practitioner:

   i) Is capable of recognizing scientifically supportable and practical indications for the test;

   ii) Has knowledge in the proper administration of the test;

   iii) Possesses skill at proper interpretation of the test; and

   iv) Has obtained training in how to integrate the test results into management of the patient's condition; or

3) May refer the patient to a practitioner who is deemed to meet the criteria identified at (b)2i through iv above.

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

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

   i) Spinal diagnostic ultrasonography/ultrasound imaging of the spine;

   ii) Iridology;

   iii) Reflexology;

   iv) Surrogate arm mentoring;

   v) Brain mapping, when not done in conjunction with appropriate neurodiagnostic testing;

vi) Surface EMG;

vii) Mandibular tracking and stimulation;

viii) Videofluoroscopy; and

ix) Computer supported range of motion tests.

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

i) i. Thermography when used to evaluate pain associated with reflex sympathic dystrophy ("RSD"), in a controlled setting by a physician experienced in such use and properly trained.

ii) Needle electromyography (needle EMG) when used in the evaluation and diagnosis of neuropathies and radicular syndrome where clinically supported findings reveal a loss of sensation, numbness or tingling. A needle EMG is not indicated in the evaluation of TMJD and is contraindicated in the presence of infection on the skin or cellulitis. This test should not normally be performed within 14 days of a traumatic injury and should not be repeated where initial results are negative. Only one follow-up exam is normally appropriate.

iii) Somasensory evoked potential (SSEP), visual evoked potential (VEP), brain audio evoked potential (BAEP), or brain evoked potential (BEP), nerve conduction velocity (NCV) and H-reflex Study when used to evaluate neuropathies and/or signs of atrophy, but not within 21 days following the traumatic injury.

iv) Electroencephalogram (EEG) when used to evaluate head injuries, where there are clinically supported findings of an altered level of sensorium and/or a suspicion of seizure disorder. This test, if indicated by clinically supported findings, can be administered immediately following a traumatic injury. Repeat testing is not normally conducted more than four times per year.

v) Magnetic resonance imaging (MRI) when used in accordance with the guidelines contained in the American College of Radiology, Appropriateness Criteria to evaluate injuries in numerous parts of the body, particularly the assessment of nerve root compression and/or motor loss. MRI is not normally performed within

five days of a traumatic injury. However, clinically supported indications of neurological gross motor deficits, incontinence or acute nerve root compression with neurologic symptoms may justify MRI testing during the acute phase immediately post injury.

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

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

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

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

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

1) Be solely owned and under the responsibility of one or more physicians (or practitioners, in the case of an office offering only tests within the scope of that practitioner's practice);

2) Ensure that all test results are interpreted by a practitioner licensed by the Board and acting within the scope of licensed practice, documented in a written report and maintained in accordance with the requirements of N.J.A.C. 13:35-6.5; and

3) Designate a physician owner or employee (or practitioner owner or employee, in the case of an office offering only tests within the scope of that practitioner's practice) to be responsible for the management of the office and the specific obligations set forth in this section.

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

1) Establish and make available to personnel written policies and procedures concerning the following:

i) The specific tests which may be performed in the office;

ii) The standards for equipment operation;

iii) The procedures to be followed in obtaining informed consent;

iv) The standards with regard to record documentation;

v) The procedures relating to follow-up reporting to examinees, patients, and/or referring practitioners, as applicable; and

vi) Minimum safety precautions;

2) Delineate or approve billing procedures;

3) Ensure that any equipment which emits radiation shall conform to the applicable sections of N.J.A.C. 7:28 and maintain documentation with respect to those requirements at the office;

4) Verify, through a documented review of credentials, upon hiring and on at least an annual basis, that:

i) All personnel, other than physicians, operating testing equipment which emits radiation are licensed by the New Jersey Radiologic Technology Board of Examiners as shall be required by the Department of Environmental Protection in accordance with N.J.S.A. 26:2D-1 et seq. and N.J.A.C. 7:28-19;

ii) All personnel, other than physicians, operating magnetic resonance imaging equipment are licensed as may be required by the Department of Environmental Protection (DEP), or demonstrate technical training to perform MRIs and are not otherwise precluded by any requirements of the DEP; and

iii) All personnel, other than physicians, operating ultrasound equipment are certified by the American Registry of Diagnostic Medical Sonographers or by the American Registry of Radiologic Technologists, or demonstrate technical training to perform ultrasounds and are not otherwise precluded by any requirements of the Department of Environmental Protection; and

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

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

1) On at least a quarterly basis, requires the following:

i) An evaluation of personnel skills and performance;

ii) An assessment of the supervision being provided to employees; and

iii) A review of test performance techniques, accuracy and data recordation; and

2) On at least an annual basis, requires the following:

i) An audit of billing records for accuracy; and

ii) Documented regular inspections of equipment.

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

1) Ensure that all bills accurately describe screening tests performed and do not misrepresent tests to be diagnostic;

2) Establish a written protocol identifying professionally recognized criteria to be evaluated in accepting eligible examinees for each type of screening test and providing a procedure for excluding examinees who do not meet the criteria. For example, for bone densitometry, mammography, and other screening tests, the protocol shall include specific criteria relating to age, family history, personal medical history, and permissible frequency of testing and shall specify contraindications and foreseeable risks;

3) Designate in writing those employees who have been assigned responsibility for the implementation of the protocol and quality control review, reflecting the type of credentials held;

4) Develop informed consent forms or other mechanisms to provide information to examinees;

5) Devise a system by which screening office records are maintained in accordance with the basic information standards set forth in N.J.A.C. 13:35-6.5; and

6) Upon the request of the Board, prepare statistical reports reflecting the total number of screening examinees, and the total number of abnormality reports issued and the advisory letter required by (h) below.

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

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

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

i) Guidance to the performer of the test with respect to appropriate positioning preparatory to the test;

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

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

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

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

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

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

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

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

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

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

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

communication contemporaneously documented in the examinee record) to insure notification to the examinee;

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

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

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

k) Any practitioner performing a diagnostic test in any location, whether or not licensed by the Department of Health and Senior Services, shall retain raw data or graphs arising out of a diagnostic test administration and shall prepare and retain a comprehensive report, on professional letterhead bearing the practitioner's full name and title or degree ("Dr." alone is insufficient) and office name, address and telephone number. (However, raw data, graphs and reports, for example, but not limited to, radiographic images, which have been prepared as part of the patient record for a licensed health care facility such as a hospital or nursing home, may be entrusted by the preparing/interpreting practitioner to the secured custody of the licensed health care facility as part of the facility's permanent records.) The report shall include at least the following:

1) The date on which the test was performed;

2) The location at which the test was performed;

3) A summary of the pertinent medical/psychological history;

4) An identification of the specific test(s) performed;

5) An identification of any unlicensed individual performing the test unless reflected in the patient record or in a logbook maintained by the supervising practitioner, who shall be identified as the supervisor;

6) The length of time of all electrodiagnostic tests (including EMG and NCV) and invasive procedures, unless reflected in the patient record or in a logbook maintained by the supervising practitioner, who shall be identified as the supervisor;

7) A description of the pertinent findings, diagnosis or impression and any recommendations;

8) Cross-references to any other tests performed on the same patient pertinent to the patient's presenting medical condition or injuries, if not addressed in a consolidated report; and

9) The date on which the report was prepared.

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

1) The patient's reported symptoms and objective signs, if any, pertinent to the problem;

2) A brief history of the reported medical condition; and

3) An indication of prior testing relating to the medical condition and results thereof.

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

1) Require that the referral be preceded by verbal communication or delivery of the written request (which may be faxed) as set forth in (*l*) above;

2) Retain a copy of the referring request or document the personal communication in the patient record;

3) Institute a procedure to assure that sufficient clinical data has been provided to justify the requested test;

4) Personally consult with the referring practitioner in advance of performing the test, if additional information is needed to determine if the diagnostic test requested is the most appropriate test to elicit the clinical information sought;

5) Perform a focused clinical examination if, in the practitioner's discretion, such examination is necessary;

6) Verify the indications for and appropriateness of diagnostic testing, if the referral has been made by a practitioner with a limited license to a plenary licensee;

7) Prepare a report containing the information set forth in section (k) above; and

8) Assure that explanation has been provided to the patient and, where there is significant risk or likelihood of side effects, obtain informed consent.

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

1) 1. All invasive tests, including transesophageal echocardiography and needle electromyography, are personally performed and interpreted by a physician;

2) Direct personal supervision by the physician, whereby the physician is immediately available, is provided for all diagnostic tests requiring anesthesia or contrast as set forth in N.J.A.C. 13:35-4A and, in particular, N.J.A.C. 13:35-4A.8 through 4A.11;

3) Direct physician presence, supervision and interpretation is provided for all diagnostic tests which, although not invasive, require a sequential analysis with respect to the extent of medically necessary testing, for example, nerve conduction studies, somatosensory evoked potentials, and similar studies;

4) Direct supervision by a knowledgeable physician present in the office suite, immediately available to furnish assistance, is provided for cardiovascular stress tests;

5) Direct supervision is provided for diagnostic tests delegated to a trained radiologic technologist (LRT(R)). Such tests include but are not necessarily limited to MRI with

contrast and CT with contrast. Except in a documented emergency, such studies shall not be scheduled or performed in the absence of the physician. Studies utilizing contrast material shall be performed only as permitted by N.J.A.C. 13:35-6.20;

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

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

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

i) Plain film radiology;

ii) CT or MRI studies without contrast, and without sedation; and

iii) Electrocardiograms.

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

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

1) The name of provider and licensure status;

2) The office address of the billing practitioner;

3) The location where the test was performed, if different from the billing practitioner's office addresses;

4) The date on which the test was performed; and

5) No charge for any test:

i) Designated pursuant to (c) above to be without apparent clinical value and thus lacking validity;

ii) Performed at a stage or frequency or in a manner not consistent with the limitations set forth in (c) above; or

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

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

1) Be responsible for ascertaining and documenting, identifying the indications for and the medical necessity of the diagnostic or screening test;

2) Understand the purpose and use of the equipment including benefits, risks and contraindications for the patient;

3) Recognize proper calibration and other functioning of the equipment used;

4) Be capable of properly using the equipment in the performance of the diagnostic testing;

5) Be competent to interpret the resulting data;

6) Ensure that no technician or other unlicensed person conducts an intake inquiry through direct questioning or by the use of a "checklist" of sample signs and

symptoms to elicit information from the patient as the sole historical or other basis for the performance of a diagnostic test which shall be determined by the practitioner pursuant to (q)1 above;

7) Not provide the lessor with a "certificate of medical necessity" or any document which implies authority to issue a bill for services to anyone other than the leasing practitioner;

8) Not allow the lessor entity or its technician prior or subsequent access to any portion of a patient or examinee record regarding treatment or billing or financial information;

9) Not allow the technician to conduct a clinical interview of the patient or to make any decisions regarding which tests are to be performed or their sequence or the method of performance of the test;

10) Not be a party to a contract, whether written or verbal, with the lessor of the equipment, its technicians or any other agent, whereby the lessor or agent would recommend or provide a consultant practitioner to read or overread and interpret the test data;

11) (Reserved);

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

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

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

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

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

s) A practitioner who transmits diagnostic test data/ records, other than bioanalytical specimens to a clinical laboratory under the jurisdiction of the Department of Health and Senior Services pursuant to N.J.S.A. 45:9-42.27 et seq., for interpretation by a consultant who is not a licensee of the Board shall assure that advance written consent for such interpretation service by such consultant has been obtained from the patient/third party payor. Utilization of the provisions in this subsection shall be consistent with the requirements of (n) above. This subsection is intended to be available for special, occasional or emergent consultations only. A consultant or consultant entity rendering medical services interpreting diagnostic test data/records, whether in or out of this State, by means of any media, for 10 or more patients under treatment in New Jersey on an annual basis is deemed to be rendering medical services in this State and requires licensure by the Board. However, the exchange of information, which may include patient specific information, between a licensee and a physician licensed in another state, a possession of the United States or the District of Columbia shall not be deemed to be rendering medical services.

13:35-2.7 (RESERVED)

13:35-2.8 (RESERVED)

13:35-2.9 (RESERVED)

13:35-2.10 (RESERVED)

13:35-2.11 (RESERVED)

13:35-2.12 (RESERVED)

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.

13:35-2.14 (RESERVED)

SUBCHAPTER 2A.
LIMITED LICENSES: MIDWIFERY

13:35-2A.1 PURPOSE AND SCOPE

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

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

13:35-2A.2 DEFINITIONS

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

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

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

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

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

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

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

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

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

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

13:35-2A.3 MIDWIFERY LIAISON COMMITTEE

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

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

c) Functions of the Committee shall include the following:

1) Advising and assisting the Board in the evaluation of applicants for midwifery licensure and certified nurse midwife applicants for prescriptive authorization;

2) Investigating complaints against licensees and unlawful conduct by licensees;

3) Approving professional education programs; and

4) Advising and assisting the Board in drafting and reviewing rules to govern midwifery practice.

13:35-2A.4 APPLICATION FOR LICENSURE

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

1) A completed application for licensure requesting information regarding the applicant's address, telephone number, date of birth and social security number;

2) Proof that the applicant is 18 years old or older;

3) An official transcript from a midwifery program, accredited by the Accreditation Commission for Midwifery Education (ACME), ACC or the Midwifery Education Accreditation Council (MEAC), or their predecessors or successors;

4) A notarized copy of Certification from either ACNM, ACC, NARM or their predecessors or successors;

5) The applicant's curriculum vitae;

6) Three photographs of the applicant, signed, dated and notarized; and

7) The application fee pursuant to N.J.A.C. 13:35-6.13.

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

13:35-2A.5 INDEPENDENT PRACTICE

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

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

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

b) Certified nurse midwives and certified midwives shall conduct their practice pursuant to standards set forth by the ACNM in Standards for the Practice of Midwifery 2003, as amended and supplemented, available from the American College of Nurse-Midwives, 8403 Colesville Rd., Suite 1550, Silver Spring, MD 20910, which is incorporated herein by reference as part of this rule.

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

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

13:35-2A.6 AFFILIATED PHYSICIANS; CLINICAL GUIDELINES

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

1) Holds hospital privileges in operative obstetrics/gynecology;

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

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

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

c) The clinical guidelines shall set forth:

1) An outline of routine care;

2) Procedures the licensee will perform or provide;

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

4) The circumstances under which consultation, collaborative management, referral and transfer of care of women between the licensee and the affiliated physician are to take place, and the manner by which each is to occur;

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

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

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

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

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

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

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

13:35-2A.7 LICENSURE; BIENNIAL LICENSE RENEWAL; LICENSE SUSPENSION; REINSTATEMENT OF SUSPENDED LICENSE; INACTIVE STATUS; RETURN FROM INACTIVE STATUS

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

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

c) If a licensee does not renew the license prior to its expiration date, the licensee may renew the license within 30 days of its expiration by submitting a renewal application, a renewal fee and a late fee, as set forth in N.J.A.C. 13:35-6.13. During this 30-day period,

the license shall be valid, and the licensee shall not be deemed to be practicing without a license.

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

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

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

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

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

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

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

1) Payment of the reinstatement fee; and

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

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

13:35-2A.8 ANTEPARTUM MANAGEMENT

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

1) Ordering medical, therapeutic and diagnostic measures in accordance with clinical guidelines; and

2) Identifying women with medical, obstetrical or gynecological risk factors outlined in N.J.A.C. 13:35-2A.9.

13:35-2A.9 MANAGEMENT OF ANTEPARTUM WOMEN AT INCREASED RISK

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

1) The affiliated physician and licensee shall have agreed to include the woman at increased risk in the caseload;

2) The affiliated physician and licensee shall have established and documented a management plan for all women identified as at increased risk, which shall delineate the role of both the affiliated physician and the licensee in the care of the woman. The management plan shall set forth the following:

i) Frequency of physician visits;

ii) Timing of indicated diagnostic and evaluative procedures;

iii) Specific parameters for consultation; and

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

3) The management plan shall be reviewed periodically by the licensee and the affiliated physician and revised when necessary.

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

1) Maternal health status:

i) Acute and/or chronic hypertension;

ii) Congenital or acquired heart disease;

iii) Anti-phospholipid syndrome;

iv) HIV positive or AIDS;

v) Chronic renal disease;

vi) Seizure disorder requiring medications;

vii) Chronic anemia and/or hemoglobinopathy;

viii) Diabetes mellitus;

ix) Drug addiction;

x) Psychosis;

xi) Asthmatic on daily oral medication;

xii) Any connective tissue disorder;

xiii) Multiple sclerosis;

xiv) History of cerebrovascular accident; or

xv) History of cancer.

2) Maternal reproductive health history:

i) Incompetent cervix;

ii) Two or more second or third trimester fetal losses;

iii) Preterm labor and/or delivery;

iv) Parity of six or more;

v) Previous cesarean delivery;

vi) Surgery involving the uterine wall;

vii) Previous placental abruption;

viii) Previous postpartum blood transfusion;

ix) Previous cervical surgeries including Loop Electrosurgical Excision Procedures (LEEP), cone biopsies or three or more surgical cervical dilitations; or

x) Intra-uterine growth restriction and/or delivery of an infant weighing less than 2,500 grams at 36 weeks or more.

3) Current maternal obstetrical status:

i) Obstructive uterine myomata;

ii) Polyhydramnios or oligohydramnios;

iii) Isoimmunization;

iv) Multiple gestation;

v) Intrauterine growth restriction;

vi) Current evidence of fetal chromosome disorder confirmed by amniocentesis and/or congenital anomaly;

vii) Gestational diabetes;

viii) Maternal age less than 14 years or more than 40 years;

ix) PAP smear indicating dysplasia;

x) Placenta previa;

xi) Medicated pre-term labor; or

xii) Preeclampsia.

13:35-2A.10 INTRAPARTUM MANAGEMENT

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

1) Managing labor and birth for women not classified as being at increased risk pursuant to N.J.A.C. 13:35-2A.11, in accordance with clinical guidelines;

2) Performing immediate screening of the newborn and resuscitation of the newborn when necessary. The licensee shall refer newborns with acute medical conditions to a physician trained in the care of a newborn;

3) Performing an episiotomy;

4) Repairing first and second degree episiotomies and lacerations; and

5) Using local anesthesia.

b) Every licensee shall ensure that at the birth site:

1) There is a person who is certified in Basic Life Support (BLS) and in Neonatal Resuscitation Program (NRP) by the American Academy of Pediatrics; and

2) The following equipment is present:

i) Oxygen;

ii) A neonatal bag and mask;

iii) An adult oxygen mask;

iv) Suction equipment;

v) IV fluids; and

vi) Oxytoxics.

c) In addition to the tasks outlined in (a) above, a Certified Nurse Midwife (CNM) or Certified Midwife (CM) may:

1) Repair third degree lacerations upon the direction of the affiliated physician;

2) Repair fourth degree lacerations under the direct supervision of a physician who has hospital obstetrical privileges; and

3) Administer pudendal anesthesia in a licensed healthcare facility, which includes birthing centers. No licensee shall administer pudendal anesthesia in any other setting.

13:35-2A.11 MANAGEMENT OF INTRAPARTUM WOMEN AT INCREASED RISK

a) If a woman receiving care from a licensee evidences any of the following conditions, the licensee shall only participate in the birth if it takes place in a licensed hospital:

1) Pre-term labor less than 37 weeks. If pre-term labor is less than 34 weeks, an affiliated physician shall be present at the birth;

2) Premature rupture of membranes more than 24 hours before onset of regular contractions;

3) Assessment of infant weight less than 2,500 grams or more than 4,500 grams;

4) Vaginal birth after previous cesarean delivery;

5) The need for prescriptive medication to induce or augment labor;

6) Post-datism (greater than 42 weeks completed gestation);

7) Multiple gestation;

8) Malpresentation; or

9) Evidence of chorioamnionitis.

b) If a woman receiving care from a licensee evidences the following during the intrapartum phase the licensee shall arrange for the presence of an affiliated physician at the hospital; or, if the woman is not in a hospital, arrange for the immediate transfer of the woman to a hospital obstetric unit:

1) Development of hypertension or preeclampsia;

2) Non-reassuring fetal heart pattern, unresponsive to conservative measures;

3) Prolapse of cord;

4) Intrapartum hemorrhage;

5) Multiple gestation;

6) Malpresentation; or

7) Any condition requiring operative intervention.

13.35-2A.12 POSTPARTUM CARE

a) A licensee's scope of practice during the postpartum stage includes:

1) Assessment and treatment; and

2) Contraceptive services.

13:35-2A.13 WELL WOMAN CARE

a) A certified nurse midwife or certified midwife may provide well woman care throughout the life cycle which shall include:

1) Gynecological and primary health care screening, assessment and treatment; and

2) Contraceptive services.

13:35-2A.14 PRESCRIPTIVE AUTHORIZATION

a) A CNM who is licensed 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 in pharmacology, which included instruction in fundamentals of pharmacology and therapeutics, including principles and terminology of pharmacodynamics and pharmaco-kinetics, which was either:

i) Part of the midwifery program the CNM completed pursuant to N.J.A.C. 13:35-2A.4(a)3; or

ii) A pharmacology course offered by, or affiliated with, a college or university accredited by an accrediting association recognized by the U.S. Department of Education.

b) If the 30 contact hours in pharmacology required pursuant to (a)3 above was included as part of the midwifery program the CNM completed pursuant to N.J.A.C. 13:35-2A.4(a)3, the CNM shall have graduated from the midwifery program within the two years immediately preceding the date on which the application for prescriptive authority is made.

c) If the 30 contact hours in pharmacology required pursuant to (a)3 above was not part of the midwifery program the CNM completed pursuant to N.J.A.C. 13:35-2A.4(a)3, the CNM shall have completed the pharmacology course within the two years immediately preceding the date on which the application for prescriptive authority is filed.

d) Notwithstanding (a), (b) and (c) above, a CNM who holds prescriptive authorization in another state shall be authorized to prescribe drugs in New Jersey, if the CNM submits proof to the Committee that he or she:

1) Holds current prescriptive authorization, without disciplinary restrictions, in another state; and

2) Has completed 30 contact hours in pharmacology, which meets the requirements of (a)3 above.

e) Notwithstanding (a), (b) and (c) above, a CNM who also holds certification as an advanced practice nurse from the New Jersey Board of Nursing shall be authorized to prescribe drugs pursuant to N.J.S.A. 45:10-17 et seq., if the CNM submits proof to the Committee that he or she:

1) Holds current, unencumbered certification as an advanced practice nurse from the New Jersey Board of Nursing; and

2) Has completed 30 contact hours in pharmacology, which meets the requirements of (a)3 above.

f) A CNM who is authorized to prescribe drugs may prescribe only those drugs which are categorized in the formulary of drugs established in the clinical guidelines.

g) 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 certification in good standing with the ACNM or ACC, or their successors;

3) Uses prescriptive authorization for other than therapeutic purposes; or

4) Uses prescriptive authorization to prescribe substances or devices not included in the formulary of drugs established in the CNM's clinical guidelines.

h) Prescriptions written by a CNM shall conform to the dictates of N.J.S.A. 45:14-14 et seq. and N.J.A.C. 13:35-7.2.

13:35-2A.15 LIMITED ULTRASOUND EXAMINATION

a) A licensee who has completed a course as required in (b) below may perform a limited ultrasound examination. For purposes of this section, "limited ultrasound" shall mean the use of ultrasound to assess any of the following: fetal number, fetal cardiac activity, fetal position and presentation, placental location, amniotic fluid parameters, biophysical

profile parameters, uterine position, uterine size, the number and size of early gestational sac and the presence and length of embryonic poles.

b) A licensee who wishes to perform limited ultrasound shall complete a 12-hour course given by a college or university accredited by an accrediting association recognized by the U.S. Department of Education or an organization which grants ACNM, American College of Obstetrics and Gynecology (ACOG), American Osteopathic Association (AOA) or American Medical Association-Physicians Recognition Award (AMA-PRA) category one continuing education credits.

c) Limited ultrasound course instruction shall include:

1) Ultrasound instrumentation;

2) Accountability of the licensee;

3) Components of informed consent;

4) Principles of anatomy and physiology relevant to limited ultrasound examinations;

5) Elements of antepartum and intrapartum fetal surveillance;

6) Components of ultrasound examination:

i) Fetal number;

ii) Fetal cardiac activity;

iii) Fetal position and presentation;

iv) Placental location;

v) Amniotic fluid evaluation; and

vi) Biophysical profile parameters;

7) Components of gynecological ultrasound examination:

i) Identification of uterine position;

ii) Evaluation of uterine size;

iii) Assessment of number, size and location of early gestational sac(s) and presence and length of embryonic pole(s); and

iv) Recognition of early fetal cardiac activity; and

8) Formulation of a plan of care based on assessments made, including the need for consultation, referral and follow-up.

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

13:35-2A.16 COLPOSCOPIES

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

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

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

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

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

13:35-2A.17 CIRCUMCISIONS

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

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

1) The theory of circumcisions, including the procedure's benefits and risks, and alternatives to the procedure;

2) Providing informed consent to the parents;

3) Indications and contraindications for circumcision; and

4) Potential complications.

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

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

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

SUBCHAPTER 2B.
LIMITED LICENSES: PHYSICIAN ASSISTANTS

13:35-2B.1 PURPOSE AND SCOPE

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

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

13:35-2B.2 DEFINITIONS

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

"Board" means the State Board of Medical Examiners.

"Committee" means the Physician Assistant Advisory Committee.

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

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

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

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

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

"Physician" means a person, either an M.D. or D.O., 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.

13:35-2B.3 PRACTICE REQUIREMENTS

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

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

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

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

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

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

b) The licensee shall file with the Committee a notice of employment for each full-time, part-time or per diem place of employment, on forms provided by the Committee, within 10 days after the date on which employment commences. Furthermore, the licensee shall report to the Committee any change in employment and/or supervising physician within 10 days of the change.

13:35-2B.4 SCOPE OF PRACTICE

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

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

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

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

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

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

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

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

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

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

10) Applying and removing medical and surgical appliances and devices such as splints, casts, immobilizers, traction, monitors and medication delivery systems;

11) Management of emergency and life threatening conditions;

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

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

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

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

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

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

4) Ordering and prescribing medications and writing orders to implement therapeutic plans identified pursuant to (a)4 above;

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

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

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

ii) The supervising physician shall maintain documentation, or ensure that documentation is maintained, evidencing that the physician assistant has the training, experience and proficiency to perform such procedures; and

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

13:35-2B.5 ELIGIBILITY FOR LICENSURE

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

1) Is at least 18 years of age;

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

3) Has successfully completed an education program for physician assistants which is approved by the Accreditation Review Commission on Education for the Physician Assistant, Inc. (ARC-PA), or its successor; and

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

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

13:35-2B.6 REFUSAL TO ISSUE, SUSPENSION OR REVOCATION OF LICENSE

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

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

13:35-2B.7 LICENSE RENEWAL, CONTINUING EDUCATION REQUIREMENT

a) The Board shall not issue a biennial license renewal unless the applicant submits, with the renewal application, proof that he or she completed courses of continuing

professional education of the types and number of credits specified in N.J.A.C. 13:35-2B.8.

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

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

13:35-2B.8 CREDIT-HOUR REQUIREMENTS

a) Each applicant for a biennial license renewal shall be required to complete, during the preceding biennial period, a minimum of 50 continuing education credit hours in category 1 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 a period of time designated by the Committee for reasons of hardship, such as illness or disability, or other good cause.

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

13:35-2B.10 SUPERVISION

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

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

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

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

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

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

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

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

5) The supervisory ratio shall be no more than four physician assistants to one physician at any one time.

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

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

13:35-2B.11 RECORDKEEPING

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

1) The dates and times of all treatments;

2) The patient complaint;

3) The history;

4) Findings on appropriate examination;

5) Any orders for tests or consultations and the results thereof;

6) Diagnosis or medical impression; and

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

i) Specific dosages, quantities and strengths of medications;

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

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

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

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

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

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

13:35-2B.12 REQUIREMENTS FOR ISSUING PRESCRIPTIONS FOR MEDICATIONS; SPECIAL REQUIREMENTS FOR ISSUANCE OF CDS

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

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

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

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

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

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

5) The date of issuance of the prescription;

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

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

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

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

10) The words "substitution permissible" and "do not substitute" and shall contain space for the physician assistant's initials next to the chosen option, in addition to the space required for the signature required by (b)9 above; and

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

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

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

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

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

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

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

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

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

e) Written prescriptions shall be issued only on New Jersey Prescription Blanks (NJPB), secured from an approved vendor and subject to the required security mandates of the prescription blank program pursuant to N.J.S.A. 45:14-55.

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.

13:35-2B.14 TEMPORARY LICENSURE; SCOPE OF PRACTICE

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

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

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

13:35-2B.15 SUPERVISION OF TEMPORARY LICENSE HOLDER

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

1) In any setting, the supervising physician, physician designee or a designated physician assistant:

i) Is continuously present on-site; and

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

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

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

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

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 referenced in N.J.A.C. 13:35-2B.13(a).

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.

13:35-2B.17 LICENSURE; BIENNIAL LICENSE RENEWAL; LICENSE SUSPENSION; REINSTATEMENT OF SUSPENDED LICENSE; INACTIVE STATUS; RETURN FROM INACTIVE STATUS

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

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

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

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

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

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

2) Completion of the Board-approved continuing education units required for each biennial registration period for which the licensee was suspended; and

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

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

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

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

1) Payment of the reinstatement fee;

2) The completion of the Board-approved continuing education units required for each biennial registration period for which the licensee was on inactive status; and

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

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

13:35-2B.18 SEXUAL MISCONDUCT

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

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

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

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

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

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

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

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

    1) Physician assistant services are actively terminated by way of written notice to the patient and is documented in the patient record; or

    2) The last physician assistant services were rendered more than one year ago.

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

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

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

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

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

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

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

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

1) The patient solicited or consented to sexual contact with the licensee; or

2) The licensee is in love with or held affection for the patient.

13:35-2B.19 CREDIT TOWARDS LICENSURE FOR EDUCATION, TRAINING, AND EXPERIENCE RECEIVED WHILE SERVING AS A MEMBER OF THE ARMED FORCES

a) An applicant who has served in the Armed Forces of the United States (Armed Forces) and who does not meet all of the training, education, and experience requirements for licensure under N.J.A.C.13:35-2B.5 may apply to the Board for recognition of the applicant’s training, education, or experience received while serving as a member of the Armed Forces, which the Board shall consider, together with any training, education, and experience obtained outside of

the Armed Forces, for determining substantial equivalence to the training, education, and experience required for licensure.

b) The Board shall issue a license to the applicant, if the applicant presents evidence to the Board that:

1) The applicant has been honorably discharged from active military service;

2) The relevant training, experience, and education the applicant received in the military, together with any training, education, and experience obtained outside of the Armed Forces, is substantially equivalent in scope and character to the training, experience, and education required for licensure under N.J.A.C. 13:35-2B.5.

i. An applicant seeking credit for military training and experience shall submit to the Board the applicant's Verification of Military Experience and Training (VMET) Document, DD Form 2586 or a successor form, as amended and supplemented.

ii. An applicant seeking credit for education courses and/or training completed while in the military who has not successfully completed an education program for physician assistants that is approved by the Accreditation Review Commission on Education for the Physician Assistant, Inc. (ARC-PA), or its successor, shall submit to the Board a Joint Services Transcript of his or her education/training for a determination that the education courses and/or training completed are substantially equivalent in level, scope, and intent to the educational requirements under N.J.A.C. 13:35-2B.5. For the purpose of determining substantial equivalence of the applicant's military education and/or training, the Board shall consider only those education courses and/or training relevant to the practice of a physician assistant that have been evaluated by the American Council on Education for substantial equivalence to civilian postsecondary curricula; and

3) The applicant complies with all other requirements for licensure, including successful completion of the examination administered by the National Commission on Certification of Physician Assistants (NCCPA), or its successor, as set forth in N.J.A.C. 13:35-2B.5.

c) It is the applicant's responsibility to provide timely and complete evidence of the education, training, and/or service gained in the military for review and consideration.

d) If the applicant's military training, education, or experience, or a portion thereof, is not deemed to be substantially equivalent to that required for licensure, the Board shall credit whatever portion of the military training, education, or experience that is substantially equivalent towards meeting the requirements under N.J.A.C. 13:35-2B.5 for the issuance of the license.

e) Satisfactory evidence of such education, training, or service shall be assessed on a case-by-case basis.

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

13:35-3.1 LICENSING EXAMINATION; PHYSICIANS

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

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

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

1) USMLE Step 1 or National Board Part 1 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.

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.

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.

13:35-3.4 (RESERVED)

13:35-3.5 (RESERVED)

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 anatomic pathology or is Board-eligible, and can demonstrate to the satisfaction of the Board 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: toxicological chemistry, microbiology (including bacteriology, parasitology, virology and mycology), cytogenetics, biochemical genetics, clinical chemistry (including urinalysis, endocrinology and toxicology), andrology, diagnostic laboratory immunology, embryology, hematology (including flow cytometry), serology and molecular diagnostics, 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, the American Board of Histocompatibility and Immunogenetics, the American Board of Molecular Genetics and the American Society of Cytogenetics, or any other national accrediting board recognized by the State 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 and Laboratory Directors Licensing Act, as amended (N.J.S.A. 45:9-42.1 et seq.).

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.

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.

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.

13:35-3.9 (RESERVED)

13:35-3.10 SUBVERSION OR ATTEMPT TO SUBVERT THE LICENSING EXAMINATION PROCESS

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

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

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

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

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

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

13:35-3.11 STANDARDS FOR LICENSURE OF PHYSICIANS GRADUATED FROM MEDICAL SCHOOLS NOT APPROVED BY AMERICAN NATIONAL ACCREDITING AGENCIES

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

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

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

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

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

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

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

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

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

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

k) An applicant, who has graduated from a medical school on or after July 1, 1985 and before July 1, 2003 and has received a medical degree from a medical school which is

not eligible for and not accredited by the LCME or the AOA, shall demonstrate to the Board, through the submission of documentation, that after receiving a medical degree the applicant has successfully completed a three-year post-graduate training program accredited by the ACGME, the AOA, or any other equivalent group or agency which the Board, upon review, has determined has comparable standards.

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

1) In the same field; or

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

13:35-3.11A STANDARDS FOR LICENSURE OF PHYSICIANS GRADUATED FROM MEDICAL SCHOOLS APPROVED BY RECOGNIZED NATIONAL ACCREDITING AGENCIES

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

b) An applicant, who has graduated from a medical school on or after July 1, 2003 and has received a medical degree from a medical school approved by the. LCME or AOA or other recognized national accrediting agency, shall demonstrate to the Board, through

the submission of documentation, that after receiving a medical degree the applicant has completed and received academic credit for at least two years for post-graduate training in a program accredited by the ACGME, the AOA, or any other equivalent group or agency, which the Board, upon review, has determined has comparable standards, and has a signed contract for a third year of post-graduate training in a program accredited by the ACGME, the AOA, or any other equivalent group or agency, which the Board, upon review, has determined has comparable standards. At least two of the three years of postgraduate training shall be:

1) In the same field; or

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

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 (ABMS) or the American Osteopathic Association (AOA);

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

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

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

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

1) Proof of successful completion of the full term of a fellowship program accredited by the Accreditation Council on Graduate Medical Education (ACGME) or the AOA acceptable to the Board; or

2) Satisfactory completion of at least three years' clinical training gained through either a residency program or programs that satisfy three years of a nationally prescribed course of training in one discipline pursuant to ACGME or AOA accreditation standards for a particular specialty.

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

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.

13:35-3.13 CRIMINAL HISTORY RECORD INFORMATION

An applicant for initial licensure in the State by the Board shall submit his or her name, address and fingerprints for purposes of a criminal history background check to be conducted by the State of New Jersey pursuant to P.L. 2002, c. 104 (N.J.S.A. 45:1-28 et seq.) to determine whether criminal history record information exists that may be considered by the Board in determining whether the applicant shall be licensed in the State. Fees for criminal history record checks shall be paid by applicants for licensure in conformity with P.L. 1994, c. 60 (N.J.S.A. 53:1-20.6), P.L. 2002, c. 104 (N.J.S.A. 45:1-31) and N.J.A.C. 13:59-1.3 and 1.4. In addition to its use in evaluating an application for initial licensure, the Board may obtain criminal history record information from the Division of State Police for any other purpose authorized by statute or regulation.

13:35-3.14 BIENNIAL LICENSE RENEWAL; LICENSE SUSPENSION; REINSTATEMENT OF SUSPENDED LICENSE; INACTIVE STATUS; RETURN FROM INACTIVE STATUS

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

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

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

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

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

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

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

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

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

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

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

1) Payment of the reinstatement fee;

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

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

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

13:35-3.15 POSTGRADUATE TRAINING

Postgraduate training shall be taken under the auspices of a hospital or hospitals accredited for such training by the Accreditation Council for Graduate Medical Education (ACGME) or by the American Osteopathic Association (AOA) or by the American Podiatric Medical Association (APMA), as applicable to the profession.

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 the patient. By way of example, but not limitation, major surgical procedures include:

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

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

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

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

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

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

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

g) In the event of incapacity or unavailability of the operating surgeon during a major surgical procedure, the functions of a first assistant who is not a physician shall be

limited to maintaining the status of the patient while a substitute operating surgeon is summoned, except in matters of dire emergency. "Dire emergency" shall include only those circumstances posing a significant risk of imminent death or serious bodily injury to the patient, such as uncontrolled bleeding.

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 and Senior Services 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 and Senior Services 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. "Procedure" within the meaning of this subsection does not include the issuing of a prescription and/or the dispensing of a pharmaceutical.

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 and Senior Services. 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 that is designated by the Department of Health and Senior Services 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 and Senior Services 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 post-operative 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 post-operative 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 and Senior Services applicable to an LACF.

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

13:35-4A.1 PURPOSE

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

13:35-4A.2 SCOPE

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

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

13:35-4A.3 DEFINITIONS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Practitioner" means a physician or a podiatrist.

"Privileges" means the authorization granted to a practitioner or physician by a hospital licensed in the jurisdiction in which it is located to provide specified services or alternatively by the Board pursuant to N.J.A.C. 13:35-4A.12, such as surgery or the administration or the supervision of administration of one or more types of anesthetic agents or procedures.

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

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

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

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

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

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

13:35-4A.4 POLICIES AND PROCEDURES REQUIREMENTS

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

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

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

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

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

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

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

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

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

9) The objective criteria for discharging patients; and

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

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

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

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

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

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

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

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

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

13:35-4A.5 DUTY TO REPORT INCIDENTS RELATED TO SURGERY, SPECIAL PROCEDURES OR ANESTHESIA IN AN OFFICE

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

13:35-4A.6 STANDARDS FOR PERFORMING SURGERY AND SPECIAL PROCEDURES IN AN OFFICE; PRIVILEGES NECESSARY; PRE-PROCEDURE COUNSELING; PATIENT RECORDS; RECOVERY AND DISCHARGE

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

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

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

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

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

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

2) A history and physical examination shall be performed within the 30 days preceding the proposed surgery either by the practitioner performing the surgery or procedure (as appropriate to that practitioner's scope of practice) or by another physician or physician assistant under the supervision of a physician. Necessary laboratory tests, as guided by the patient's underlying medical condition, shall be conducted within seven days preceding the proposed surgery;

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

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

5) If the history and physical are not done on the same day as the procedure, an interim assessment shall be performed by the practitioner or a physician assistant under the

supervision of a physician immediately prior to the procedure, which assessment shall be documented and dated; and

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

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

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

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

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

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

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

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

2) Documentation reflecting that informed consent has been obtained;

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

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

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

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

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

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

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

13:35-4A.7 STANDARDS FOR ADMINISTERING OR SUPERVISING THE ADMINISTRATION OF ANESTHESIA SERVICES IN AN OFFICE; PRE-ANESTHESIA COUNSELING; PATIENT MONITORING; RECOVERY; PATIENT RECORD; DISCHARGE OF PATIENT

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

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

1) Any patient to whom anesthesia services are to be provided shall be appropriately screened by the individual administering anesthesia services. Patients who, by reason of pre-existing medical or other conditions, are at undue risk for complications (for example, morbidly obese patients; patients with severe cardiac, pulmonary, airway or neurological problems; substance abusers) shall be referred to an

appropriate specialist for a pre-procedure consultation or to another treatment setting or other appropriate facility. Only patients with an ASA physical status classification of I or II are appropriate candidates for an office surgery or special procedure for which general or regional anesthesia are to be used. Patients with an ASA physical classification of I, II or III are appropriate candidates for conscious sedation.

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

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

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

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

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

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

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

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

c) A physician who administers or supervises the administration or monitoring of any anesthesia services (general anesthesia, regional anesthesia or conscious sedation) in

an office shall ensure that monitoring is provided as follows when clinically feasible for the patient:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5) Whenever a patient is present in the recovery area, the recovery area shall be staffed by at least one registered professional nurse or physician assistant who is trained and experienced in advanced cardiac life support and post anesthesia care. This includes recognizing the actions and interactions of anesthetic techniques, managing of airway and ventilatory function and managing patients during altered states of consciousness, as well as cardiopulmonary resuscitation, monitoring of cardiac function, recognition of arrhythmias, and the recognition and treatment of life-threatening emergencies. For every additional two patients present in the recovery area, there shall be one additional professional registered nurse or physician assistant present, having the requisite training;

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

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

f) A practitioner who administers or supervises the administration and monitoring of anesthesia services may allow a patient dischargeable to home pursuant to N.J.A.C. 13:35-4A.4(a)9 and 4A.6(d) to remain in the office for a period not to exceed 23 hours in an overnight stay area, if the patient may benefit from additional care. The overnight stay area shall be staffed by at least one registered professional nurse or physician assistant for each two patients in the overnight stay area, the patient's vital signs shall be taken

and recorded at least every four hours and a physician shall be able to reach the office within 20 minutes. Appropriate sleeping accommodations, as well as food, shall be provided for the patient.

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

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

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

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

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

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

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

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

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

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

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

6) The plan for follow-up care.

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

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

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

13:35-4A.8 PERFORMANCE OF GENERAL ANESTHESIA; AUTHORIZED PERSONNEL

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

1) A physician privileged by a hospital or the Board pursuant to N.J.A.C. 13:35-4A.12 to provide general anesthesia services and who, during every consecutive three-year period beginning July 1, 2004, completes at least 60 Category I hours of continuing medical education in anesthesia which either meet the criteria for credit towards the Physician's Recognition Award of the American Medical Association or have been approved by the American Osteopathic Association; or

2) A certified registered nurse anesthetist (CRNA), under the supervision of a physician qualified under (a)1 above.

b) The administration and monitoring of general anesthesia shall be provided by an individual who meets the requirements of (a) above and who is at all times present in the anesthetizing location and who is not the practitioner performing the surgery or special procedure. This subsection shall not be construed to preclude the conversion of conscious sedation to general anesthesia in an emergency to protect the health of the patient, even if there is no physician present who would be qualified to administer and monitor general anesthesia pursuant to (a)1 above.

c) When the administration and monitoring of general anesthesia is being performed by a CRNA, the supervising physician shall be physically present and available to immediately diagnose and treat the patient in an emergency without concurrent responsibilities to administer anesthesia or perform surgery, other than minor surgery.

d) An advanced cardiac life support-trained physician, registered-professional nurse or physician assistant shall remain with the patient at all times that the patient is receiving or recovering from general anesthesia.

13:35-4A.9 ADMINISTRATION OF REGIONAL ANESTHESIA; AUTHORIZED PERSONNEL

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

1) A physician privileged by a hospital pursuant to N.J.A.C. 13:35-4A.12 to provide regional anesthesia and who, during every consecutive three-year period beginning July 1, 2004, completes at least eight Category I hours of continuing education in anesthesia exclusively, or in anesthesia as it relates to the physician's field of practice which either meet the criteria for credit towards the Physician's Recognition Award of the American Medical Association or have been approved by the American Osteopathic Association; or

2) A certified registered nurse anesthetist (CRNA), under the supervision of a physician qualified under (a)1 above.

b) The administration and monitoring of regional anesthesia shall be provided by an individual who meets the requirements of (a) above and who is at all times present in the anesthetizing location and who is not the practitioner performing the surgery or the special procedure.

c) When the administration and monitoring of regional anesthesia is being performed by a CRNA, the supervising physician shall be physically present and available to immediately diagnose and treat the patient in an emergency, without concurrent responsibilities to administer anesthesia or perform surgery, other than minor surgery.

d) An advanced cardiac life support trained physician, registered professional nurse or physician assistant shall be present at all times when a patient is receiving or recovering from regional anesthesia.

13:35-4A.10 ADMINISTRATION OF CONSCIOUS SEDATION; AUTHORIZED PERSONNEL

a) Conscious sedation shall be administered in an office only by the following individuals:

1) A practitioner privileged by a hospital or the Board pursuant to N.J.A.C. 13:35-4A.12 to provide conscious sedation and who, during every consecutive three-year period beginning July 1, 2004, completes at least eight Category I or II hours of continuing medical education in any anesthesia services, including conscious sedation exclusively, or in anesthesia as it relates to the physician's field of practice, which either meet the criteria for credit towards the Physician's Recognition Award of the American Medical Association or have been approved by the American Osteopathic Association;

2) A certified registered nurse anesthetist (CRNA), under the supervision of a physician qualified under (a)1 above; or

3) A registered professional nurse or physician assistant, who is trained and has experience in the use and monitoring of anesthetic agents, at the specific direction of a physician qualified under (a)1 above, but only for the purpose of administering through an established intravenous line, a specifically prescribed supplemental dose of conscious sedation which was selected and initially administered by the physician who remains continuously present in the procedure room. "Continuously present in the procedure room" does not require that a practitioner remain in the procedure room in violation of human exposure safety standards regularly employed during radiological procedures.

b) A patient under conscious sedation shall be monitored in an office by a physician, CRNA, or a registered professional nurse or physician assistant who has training and experience in the use of monitoring devices, under the supervision of a physician eligible under (a)1 above, to administer conscious sedation.

c) The monitoring of a patient under conscious sedation shall be provided by an individual who meets the requirements of (b) above and who is at all times present and who is not the practitioner who is performing the surgery or special procedure.

d) When the administration and monitoring of conscious sedation is being performed by a CRNA, or when the monitoring is being performed by a registered professional nurse or physician assistant, the supervising physician shall be physically present, but may be concurrently responsible for patient care.

e) An advanced cardiac life support-trained physician, registered nurse or physician assistant shall be present at all times when a patient is receiving or recovering from the administration of conscious sedation.

13:35-4A.11 ADMINISTRATION OF MINOR CONDUCTION BLOCKS; AUTHORIZED PERSONNEL

a) Minor conduction blocks (with the exception of retrobulbar blocks) shall be administered in an office for surgery or special procedures only by the following individuals:

1) A practitioner;

2) A certified registered nurse anesthetist (CRNA); or

3) A certified nurse midwife, an advanced practice nurse or physician assistant who has training and experience in the administration of minor conduction blocks.

b) Retrobulbar blocks shall be administered in the office only by a physician privileged by a hospital or by the Board pursuant to N.J.A.C. 13:35-4A.12.

13:35-4A.12 ALTERNATIVE PRIVILEGING PROCEDURE

a) A practitioner who seeks to provide or supervise the administration and monitoring of general or regional anesthesia, as well as conscious sedation, in an office, but does not hold privileges at a licensed hospital to do so, shall submit to the Board an application for these privileges. To be eligible to apply for these privileges, an applicant shall meet the following criteria and submit an application that documents the applicant's fulfillment of these criteria:

1) Demonstration of clinical experience, through an attestation as to the number of procedures for which general or regional anesthesia was provided by the applicant in the last two years for all age groups of patients within the applicant's practice for which privileges are requested;

2) Any one of the following:

i) Current certification in anesthesiology granted by the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology or any other certification entity that the applicant demonstrates has standards of comparable rigor;

ii) Successful completion of a residency training program in anesthesiology accredited by the Accreditation Council on Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA): or

iii) Supervised training in residency, fellowship or other equivalent experience in another field and active participation in the examination process leading to certification in anesthesiology; and

3) Possess clinical competence to perform the anesthesia services or procedures authorized, by the requested privileges, with such competence confirmed by the following:

i) Three references submitted directly by plenary licensed physicians addressing the applicant's current competence based on personal knowledge obtained either during a residency training completed during the two years preceding the application or through personal observation during the two years preceding the application;

ii) Submission of a log listing all patients for whom the applicant provided any of the anesthesia services in an office setting or licensed ambulatory care facility setting for which privileges have been requested during the two years preceding the date of the application. The log shall include a patient number, the type of anesthesia service provided, the surgery or special procedure performed and the date(s) of service. Patient names and other identifying data shall be redacted. The applicant shall maintain a list or other means to identify the patient, based on the number included in the log;

iii) Identification of any patients in the log who have experienced complications relating to the applicant's provision of anesthesia services in an office setting or licensed ambulatory care facility setting and their resulting outcomes; and

iv) Submission of no fewer than five patient records or charts (or the pertinent portions thereof with patient names redacted) which have been identified and requested by the Board or other reviewing entity, designated pursuant to (e) below, along with a completed case summary form for each submitted case, utilizing such forms as are provided in the application materials.

b) A practitioner who seeks to administer or supervise the administration and monitoring of only conscious sedation in an office, but does not currently hold clinical privileges at a licensed hospital to do so, shall submit to the Board an application for this privilege. To be eligible to apply for this privilege, an applicant shall meet the following criteria and submit an application that documents the applicant's fulfillment of these criteria:

1) Demonstration of clinical experience, through an attestation as to the number of procedures for which conscious sedation was provided by the applicant in the last two years for all age groups within the applicant's practice of patients for which privileges are requested, except age groups as are specifically excluded from the applicant's practice;

2) Any one of the following:

i) Current certification in anesthesiology granted by the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology or any other certification entity the applicant demonstrates has standards of comparable rigor;

ii) Current certification in Critical Care Medicine or Emergency Medicine by a specialty board or certifying entity recognized by the American Board of Medical Specialties ("ABMS") or the American Osteopathic Association ("AOA") or any other certification entity the applicant demonstrates has standards of comparable rigor; or

iii) Satisfactory evidence that the applicant is advanced cardiac life support trained with updated training from a recognized accrediting organization and either:

(1) Successful completion of an educational home study program, with a test of basic knowledge obtained from the Board; or

(2) A course in conscious sedation offered by a licensed hospital or for continuing medical education credits; and

3) Submission of a list of all patients who have experienced complications relating to the applicant's provision of conscious sedation in an office setting or licensed ambulatory care facility setting and their resulting outcomes. Patient names and other identifying data shall be redacted. The applicant shall maintain a list or other means to identify the patient, based on the number included in the log.

c) A practitioner who seeks to perform surgery (other than minor surgery) or special procedures in an office, but does not hold privileges at a licensed hospital to perform these procedures shall submit to the Board an application for these privileges, including a completed privilege request form appropriate to the privileges requested. To be eligible to apply for this privilege, an applicant shall meet the following criteria and submit an application that documents the applicant's fulfillment of these criteria:

1) Demonstration of clinical experience, through an attestation as to the number and type of procedures performed by the applicant in the last two years for all age groups of patients for which privileges are requested;

2) Any one of the following:

   i) Current certification in the field(s) of practice in which the privileges are sought granted by a specialty board or certifying entity recognized by the American Board of Medical Specialties (ABMS), the American Osteopathic Association (AOA), the American Podiatric Medicine Association (APMA) or any other certification entity that the applicant demonstrates has standards of comparable rigor;

   ii) Successful completion of an Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA) residency or fellowship training program in the field(s) of practice in which privileges are sought; or

   iii) Supervised training in a residency or fellowship training or other equivalent experience in another field and active participation in the examination process leading to certification in the practice field(s) in which privileges are sought; and

3) Possess clinical competence to perform the procedures authorized by the requested privileges, with such competence confirmed by the following:

   i) Three references submitted directly by plenary licensed physicians (or licensed podiatrists as to podiatric applicants) addressing the applicant's current competence based on personal knowledge obtained either during a residency training completed during the two years preceding the application or through personal observation during the two years preceding the application;

   ii) Submission of a log listing all patients for whom the applicant has performed surgery or special procedures in an office setting or licensed ambulatory care facility setting for which privileges have been requested during the two years preceding the date of the application. The log shall include a patient number, the surgery or special procedure performed and the indications for that procedure and the date(s) of service. Patient names and other identifying data shall be redacted. The applicant shall maintain a list or other means to identify the patient, based on the number included in the log;

iii) Identification of any patients in the log who have experienced complications relating to the applicant's performance of surgery or special procedures in an office setting or licensed ambulatory care facility setting and their resulting outcomes; and

iv) Submission of no fewer than five patient records or charts (or the pertinent portions thereof with patient names redacted) which have been identified and requested by the Board or other reviewing entity, along with a completed case summary form for each submitted case, utilizing such forms as are provided in the application materials.

d) A practitioner who seeks to utilize laser surgery techniques in an office, but does not hold privileges at a licensed hospital to do so, shall submit to the Board an application, which shall include:

1) Certification of successful completion of an accredited laser training program, in which the curriculum includes instruction in laser care, physics and clinical indications for utilization of the specific laser; or

2) Documentation from the program director of an accredited residency training program which the applicant has successfully completed, attesting to the inclusion of training 111 the specific laser therapy for which privileges are being sought during residency training.

e) The Board may delegate to a reviewing entity the responsibility to conduct a preliminary review of an application to ascertain whether the applicant has met the criteria established in (a) through (d) above, which review shall be undertaken at the expense of the applicant. The Board shall thereafter review the summary report including any recommendation concerning the applicant prepared by the reviewer and make a decision on the application for privileges.

f) If the Board or any entity or person to which the Board may delegate the preliminary application review finds that the applicant has not submitted sufficient information upon which a determination as to the applicant's current competence may be made, the Board or the reviewing entity may require:

1) A personal interview;

2) The submission of a representative sample of patient records substantiating the experience of the applicant;

3) The submission of any patient records relating to an identified complication;

4) An inspection of the office, which may include a review of additional patient records and written policies and procedures; and/or

5) The submission of such additional information as may be necessary to determine an applicant's clinical competence to perform the privileges requested.

g) Upon review of the summary report prepared by the Board or the reviewing entity, the Board may take any of the following actions:

1) Grant all or some of the privileges requested;

2) Condition its approval of all or some of the privileges requested on the applicant's successful completion of additional training;

3) Condition its approval of all or some of the privileges on the applicant's successful completion of a period of observation;

4) Deny all or some of the privileges requested; and/or

5) Require such additional information as may be necessary to act on the application.

h) Practitioners who have been granted privileges through the alternative privileging procedure of this section shall submit a renewal application to the Board within two years from the date on which privileges were granted. Practitioners shall notify the Board within 21 days should there be any change in the information provided in the application and renewal.

13:35-4A.13 REQUIREMENTS FOR ANESTHETIZING LOCATIONS; EMERGENCY EQUIPMENT AND SUPPLIES

a) An office in which any anesthesia services are to be provided shall be equipped with the appropriate medical equipment, supplies and pharmacological agents which are required or might be needed in order to provide anesthetic and recovery services, as well us to treat any likely complication which might arise as a result of these services, in such manner that complies with the accepted standards of care as set forth in the "Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists" of the American Society of Anesthesiology (520 Northwest Highway, Park Ridge, IL 60068-2573), appearing in Anesthesiology, Vol. 84, No. 2, February 1996, incorporated herein by reference, as amended and supplemented.

b) An office in which general anesthesia is to be provided shall be equipped with the following additional emergency equipment:

1) Special equipment to manage a difficult airway;

2) Drugs and equipment to treat malignant hyperthermia, shock and anaphylactic reactions;

3) A precordial stethoscope or esophageal stethoscope; and

4) A peripheral nerve stimulator.

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

13:35-4A.14 REQUIREMENTS FOR ANESTHETIZING LOCATIONS; SAFETY SYSTEMS, MONITORING DEVICES

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

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

2) A continuous electrocardiograph with paper recorder;

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

4) A defibrillator; and

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

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

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

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

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

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

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

6) Pressure-compensated anesthesia vaporizers, designed to administer a constant non-pulsatile output, which shall not be placed in the circuit downstream of the oxygen flush valve; agent being administered and prevent oxygen mixtures of less than 21 percent from being administered;

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

8) Alarm systems for high (disconnect), low (sub-atmospheric), and minimum ventilator pressures in the breathing circuit for each patient under general anesthesia; and

9) A gas evacuation system.

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

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

13:35-4A.15 EQUIPMENT REQUIREMENTS FOR RECOVERY AREAS

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

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

2) A continuous electrocardiogram monitor with paper recorder;

3) A defibrillator;

4) Drugs adequate for cardiopulmonary resuscitation;

5) Emergency equipment for intubation and extubation; and

6) Basic airway management equipment as follows:

i) A source of compressed oxygen (tank with regulator or pipeline supply with flow meter);

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

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

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

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

13:35-4A.16 MAINTENANCE REQUIREMENTS

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

1) A record shall be maintained of all service and maintenance including that performed on all anesthesia machines, ventilators and vaporizers. The record shall include machine identification; the name of the servicing agent; the problem, if any; the work performed and the date of the work. Maintenance shall conform with maintenance requirements established by the machine manufacturer. Credentials of each servicing agent shall be approved by the machine manufacturer or shall be reasonably determined by the permit holder to be equivalent to the credentials of the manufacturer's servicing agents.

2) All anesthesia equipment shall be inspected fully at the beginning of each day of use by a physician, or a certified registered nurse anesthetist (CRNA), under the supervision of a physician, credentialed to utilize that equipment. A record of each such inspection, including the date of the inspection and the identity of the individual

conducting the inspection, shall be maintained for each machine. The inspection shall conform with a checklist that is supplied by the manufacturer of the machine, or issued by the Federal Food and Drug Administration or, alternatively, reasonably developed by the physician and set forth in an appropriate written protocol.

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

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

13:35-4A.17 COMPLIANCE TIMETABLES

a) A practitioner who does not hold privileges at a hospital shall submit an application to the Board seeking approval pursuant to the alternative privileging process set forth at N.J.A.C. 13:35-4A.12, prior to offering such services. Notwithstanding any other provision in this subchapter, a practitioner who has submitted an application for alternative privileging by December 16, 2003, may continue to offer services for which privileges have been requested until such time as the Board acts upon that application.

b) A practitioner or physician who offers anesthesia services in an office setting shall purchase and install the equipment and safety systems, as required pursuant to this rule prior to offering such services.

13:35-4A.18 ENFORCEMENT

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

SUBCHAPTER 5.
EYE EXAMINATIONS; EYEGLASSES

13:35-5.1 MINIMUM EYE EXAMINATION; CONTACT LENSES

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

1) A complete history of visual aberrations;

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

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

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

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

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

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 a Liaison Committee on Medical Education (LCME)-accredited allopathic professional school and an American Osteopathic Association (AOA)-accredited osteopathic professional school may elect to use either M.D. or D.O. as the primary abbreviation following the name and shall notify the Board of such election.

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

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

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

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

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 Osteopathic Medicine (D.O.) who, prior to the person's death, had attended, supervised or directed 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 treatment, who has issued or renewed a prescription issued to the person within the 12-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 12-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. 8:41-3.9, 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 apparent death has occurred outside a licensed hospital and the attending or covering 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. 8:41-3.9 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) Pursuant to N.J.S.A. 26:8-24.1 and N.J.A.C. 8:2A-3.1, an attending or covering physician shall utilize the New Jersey Electronic Death Registration System (NJ-EDRS) to provide the information required by this section.

i) 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.

13:35-6.3 SEXUAL MISCONDUCT

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

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

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

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

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

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

5) "Sexual harassment" means solicitation of any sexual act, physical advances, or verbal or non-verbal conduct that is sexual in nature, and which occurs in connection with a licensee's activities or role as a provider of medical services, and that either: is unwelcome, offensive to a reasonable person, or creates a hostile workplace environment, and the licensee knows, should know or is told this; or is sufficiently

severe or intense to be abusive to a reasonable person in that context. "Sexual harassment" may consist of a single extreme or severe act or of multiple acts and may include, but is not limited to, conduct of a licensee with a patient, co-worker, employee, student or supervisee whether or not such individual is in a subordinate position to the licensee.

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

c) A licensee shall not engage in sexual contact with a patient with whom he or she has a patient-physician relationship. The patient-physician relationship is considered ongoing for purposes of this section in all contexts other than the provision of psychiatric or psychotherapeutic services, unless: actively terminated, by way of written notice to the patient pursuant to N.J.A.C. 13:35-6.22, documentation in the patient record and a minimum of 30 days has passed from the rendition of the last professional service; or the last professional service was rendered more than one year ago.

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

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

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

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

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

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

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

j) Violation of any of the prohibitions or directives set forth at (c) through (i) above shall be deemed to constitute gross or repeated malpractice pursuant to N.J.S.A. 45.1-21(c) or (d) or professional misconduct pursuant to N.J.S.A. 45:1-21(e).

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

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

1) The patient solicited or consented to sexual contact with the licensee; or

2) The licensee was in love with or had affection for the patient.

APPENDIX

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

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

A. **Background.** It is well established that sexual activity between physicians and patients is almost always harmful to the patient and is prohibited. Whether harkening back to the proscription of the Hippocratic oath,[1] or referring to more recent pronouncements such as the Code of Medical Ethics of the Council of Ethical and Judicial Affairs of the American

Medical Association which term sexual activities between physicians and patients harmful,[2] commentators have uniformly condemned such activities by physicians.

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

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

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

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

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

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

B. **Recommendations and Guidelines for Conduct.**

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

(ii) **Maintaining Boundaries in Psychotherapeutic Relationships—**A licensee bears an even greater responsibility to establish and maintain boundaries between physician and

patient in psychotherapeutic relationships. In furtherance of that obligation, a licensee should ensure that to the greatest extent possible, treatment should take place during the licensee's usual working hours in a professional setting, unless the specific therapy mandates otherwise (i.e. home visits for the housebound, in vivo desensitization as part of behavioral therapy). A licensee should not engage in economic dealings with psychotherapy patients.

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

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

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

(vi) **Avoidance of Discussion of Personal Matters—**While it is appropriate for a licensee to discuss for example his or her training and qualifications with patients, in furtherance of the maintenance of appropriate boundaries, licensees should avoid any discussion of their own intimate personal problems or disclosure of details of their sexual lives.

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

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

13:35-6.4 DELEGATION OF ADMINISTRATION OF SUBCUTANEOUS AND INTRAMUSCULAR INJECTIONS TO CERTIFIED MEDICAL ASSISTANTS

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

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

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

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

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

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

2) The physician shall examine the patient to ascertain the nature of the trauma, disease or condition of the patient; to determine the appropriate treatment of the patient including administration of an injection; to assess the risks of such injection

for a given patient and the diagnosed injury, disease or condition; and to determine that the anticipated benefits are likely to outweigh those risks.

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

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

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

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

13:35-6.5 PREPARATION OF PATIENT RECORDS, COMPUTERIZED RECORDS, ACCESS TO OR RELEASE OF INFORMATION; CONFIDENTIALITY, TRANSFER OR DISPOSAL OF RECORDS

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

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

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

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

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

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

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

i) The dates of all treatments;

ii) The patient complaint;

iii) The history;

iv) Findings on appropriate examination;

v) Progress notes;

vi) Any orders for tests or consultations and the results thereof;

vii) Diagnosis or medical impression;

viii) Treatment ordered, including specific dosages, quantities and strengths of medications including refills if prescribed, administered or dispensed, and recommended follow-up;

ix) The identity of the treatment provider if the service is rendered in a setting in which more than one provider practices;

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

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

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

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

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

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

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

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

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

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

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

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

(2) To a representative of the Board of Medical Examiners, the Attorney General or the Division of Consumer Affairs as soon as practicable and no later than 10 days after notice; and

(3) To a patient as authorized by this rule within 30 days of request (or promptly in the event of emergency); and

viii) A licensee shall maintain, as a permanent part of a patient record, any printout of computerized records maintained by the licensee while he or she modified a computer recordkeeping system, so that it complied with the requirements of (b)3i through vii above.

c) Licensees shall provide access to professional treatment records, including records from other licensees or other health care providers that are part of a patient's record, to a patient or an authorized representative in accordance with the following:

1) No later than 30 days from receipt of a request from a patient or an authorized representative, the licensee shall provide a copy of the professional treatment record, and/or billing records as may be requested. The record shall include all pertinent objective data including test results and x-ray results, as applicable, and subjective information.

2) Unless otherwise required by law, a licensee may elect to provide a summary of the record in lieu of providing a photocopy of the actual record, so long as that summary adequately reflects the patient's history and treatment. A licensee may charge a reasonable fee for the preparation of a summary which has been provided in lieu of the actual record, which shall not exceed the cost allowed by (c)4 below for that specific record.

3) If, in the exercise of professional judgment, a licensee has reason to believe that the patient's mental or physical condition will be adversely affected upon being made

aware of the subjective information contained in the professional treatment record or a summary thereof, with an accompanying notice setting forth the reasons for the original refusal, shall nevertheless be provided upon request and directly to:

i) The patient's attorney;

ii) Another licensed health care professional;

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

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

4) Licensees may require a record request to be in writing and may charge a fee for:

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

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

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

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

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

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

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

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

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

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

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

4) The licensee, in the exercise of professional judgment, who has had a good faith belief that the patient because of a mental or physical condition may pose an imminent danger to himself or herself or to others, may release pertinent information to a law enforcement agency or other health care professional in order to minimize the threat of danger. Nothing in this paragraph, however, shall be construed to authorize the release of the content of a record containing identifying information about a person who has AIDS or an HIV infection, without patient consent, for any purpose other than those authorized by N.J.S.A. 26:5C-8. If a licensee, without the consent of the patient, seeks to release information contained in an AIDS/HIV record to a law enforcement agency or other health care professional in order to minimize

the threat of danger to others, an application to the court shall be made pursuant to N.J.S.A. 26:5C-5 et seq.

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

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

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

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

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

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

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

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

g) (Reserved)

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

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

2) Publish a notice of the cessation and the established procedure for the retrieval of records, and the location at which the records will be permanently maintained, 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. Such notice shall be submitted to the Board after the first publication; 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.

13:35-6.6 STANDARDS FOR JOINT PROTOCOLS BETWEEN ADVANCED PRACTICE NURSES AND COLLABORATING PHYSICIANS

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

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

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

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

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

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

1) In writing;

2) Signed by both the advanced practice nurse and the physician, with an acknowledgment that any inappropriate professional behavior or violation of the protocol on the part of either the physician or the advanced practice nurse will be reported to his or her respective licensing board;

3) Maintained on the premises of every office in which the advanced practice nurse practices;

4) Updated on an ongoing basis to reflect changes in the practice, office personnel, skills of the advanced practice nurse, frequency of record review, and reference materials containing practice guidelines or accepted standards of practice; and

5) Reviewed at least on an annual basis.

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

1) The nature of the practice, the patient population (for example, pediatric patients) and settings (for example, inpatient, nursing home, patient residences or other alternative care environments);

2) Any particular circumstances for which, prior to prescribing, a specific examination is to be performed or a definitive diagnosis made;

3) The recordkeeping methodology to be used in the practice (for example, the protocol might indicate that records should contain subjective complaints, objective findings, an assessment and a plan of treatment);

4) A list of categories of medications appropriate to the practice;

5) A delineation of specific medications and the specific number of refills, to be prescribed pursuant to the direction of the physician;

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

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

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

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

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

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

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

13:35-6.7 MINIMUM STANDARDS FOR THE PERFORMANCE OF NEW OR NOVEL PROCEDURES IN THE OFFICE SETTING

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5) Contains provisions for pre-operative screening;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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 and Senior Services;

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 and Senior Services.

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 and Senior Services.

6) Copies of records shall be forwarded to State Department of Health and Senior Services 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.

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.

13:35-6.10 ADVERTISING AND SOLICITATION PRACTICES

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

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

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

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

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

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

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

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

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

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

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

2) Any misrepresentation of a material fact;

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

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

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

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

7) Any personal testimonial attesting to the quality or competence of a service or treatment by a licensee involving medical or technical assessments which are beyond

the patient's competency to assess, or any testimonial not in compliance with (n) below;

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

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

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

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

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

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

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

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

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

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

specific delineation of additional services contemplated in the fee to be charged therefor.

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

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

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

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

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

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

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

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

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

h) The name and nature of professional practice of every licensee practicing independently or as an employee of another licensee or of a professional service corporation shall appear on professional stationery and shall be conspicuously displayed and kept at the entrance of the place where the licensed practice is conducted. The name of every licensee employed by an ambulatory health care facility licensed by the New Jersey Department of Health and Senior Services 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 and Senior Services.

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

n) The requirements for testimonial advertisements are as follows:

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

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

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

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

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

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

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

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.

13:35-6.12 (RESERVED)

13:35-6.13 FEE SCHEDULE

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

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

i) Initial application fee $325.00

ii) Initial license fee

(1) If paid during the first year of a biennial renewal period 580.00

(2) If paid during the second year of a biennial renewal period 290.00

iii) N.J.S.A. 45:9-21(n)—exemption 225.00

iv) N.J.S.A. 45:9-21(b)—temporary license 50.00

v) Endorsement 225.00

vi) Biennial license 580.00

vii) Biennial license for licensee over 65 without health care facility or HMO affiliation 125.00

viii) Permit 50.00

2) Podiatry (license)

i) Application fee $125.00

ii) Examination $150.00

iii) Initial license fee

(1) If paid during the first year of a biennial renewal period 580.00

(2) If paid during the second year of a biennial renewal period 290.00

iv) Endorsement 150.00

v) Biennial license 580.00

vi) Biennial license for licensee over 65 without health care facility or HMO affiliation 85.00

vii) Permit 50.00

3) Bioanalytical laboratory directorship, plenary or specialty license

i) Application fee 125.00

ii) Examination 350.00

iii) Exemption 150.00

iv) Initial license fee

(1) If paid during the first year of a biennial renewal period 390.00

(2) If paid during the second year of a biennial renewal period 195.00

v) Biennial license 390.00

4) Midwifery (license)

i) Application fee 125.00

ii) Examination 50.00

iii) Endorsement 50.00

iv) Initial license fee

(1) If paid during the first year of a biennial renewal period 270.00

(2) If paid during the second year of a biennial renewal period 135.00

v) Biennial license 270.00

vi) Biennial prescriptive authorization (Certified Nurse Midwife) 50.00

5) Physician assistant (license)

i) Application fee 125.00

ii) Temporary license fee 50.00

iii) Initial license fee

(1) If paid during the first year of a biennial renewal period 220.00

(2) If paid during the second year of a biennial renewal period 110.00

iv) License renewal fee, biennial 220.00

v) Late renewal fee 100.00

vi) Reinstatement fee 175.00

vii) Duplicate license fee 40.00

viii) Duplicate wall certificate 50.00

6) General .....

i) Recording of name change and issuance of replacement license 50.00

ii) Replacement of lost engrossed copy/certified true copy/biennial registration certificate 50.00

iii) Preparation of certification papers for applicants to other states 50.00

iv) Late renewal fee 100.00

v) Reinstatement fee 175.00

vi) Inactive license fee ..... (to be determined by Director by regulation)

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. "Licensed health care provider" also includes, for purpose of this section, an individual who holds a current, valid license as an occupational therapist, except that nothing shall authorize the delegation of a physical modality, which pursuant to N.J.A.C. 13:44K-5.4 is deemed to be an advanced physical agent modality without the occupational therapist having complied with N.J.A.C. 13:44K-5.4(e).

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.

13:35-6.15 CONTINUING MEDICAL EDUCATION

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

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

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

b) Except as provided in (c) below, a licensee applying for a biennial license renewal shall complete 100 continuing medical education credits in Category I or Category II courses, of which at least 40 of such credits shall be in Category I. Commencing with the biennial renewal period beginning on July 1, 2013, two of the 40 credits in Category I courses shall, pursuant to P.L. 2011, c. 145 (N.J.S.A. 45:9-7.7), be in programs or topics related to end-of-life care.

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

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

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

f) Licensees holding an inactive or retired license shall be exempt from continuing medical education requirements, except that any licensee holding an inactive or retired license, or whose license is suspended or revoked, who applies to resume practice shall provide proof of having attained 50 credits of continuing medical education for each year out of practice in New Jersey. At least 50 credits shall have been obtained in the year

preceding the application to resume practice. At the time of application to resume practice, the licensee shall provide proof of the completed continuing medical education during the period while out of practice in New Jersey. The Board may accept such continuing medical education credits or require additional credits as a condition to return to practice.

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

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

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

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

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

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

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

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

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

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

13:35-6.16 PROFESSIONAL PRACTICE STRUCTURE

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

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

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

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

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

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

3) Cleanliness of premises;

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

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

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

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

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

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

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

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

e) A licensee may invest in a health care service as defined in N.J.A.C. 13:35-6.17(a). Said service shall be owned solely by one or more licensed health care professionals except as otherwise permitted by licensure granted by another State agency. Whether or not any or all of the owners, partners or directors all regularly practice on the premises or

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

f) Acceptable professional practice forms are as follows:

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

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

prescribe; shall designate the practice of each listed prescriber as required by N.J.A.C. 13:35-6.1; and shall comply with the data requirements of N.J.A.C. 13:35-6.6.

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

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

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

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

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

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

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

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

5) A licensee may also have an equity or employment interest in a professional practice (including a professional service corporation or limited liability company) which is a limited partner to a general business corporation which, in turn, has a contractual agreement with the professional service entity, in the following circumstances only. The general business corporation may contract to provide the professional practice with services exclusively of a nonprofessional 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 that 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. 45:9-42.1 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.

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 and Senior Services 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 Accreditation Council on Graduate Medical Education, the American Osteopathic Association or the American Podiatric Medicine Association under which the facility pays the licensee (either directly or through a professional corporation or nonprofit corporation or other appropriate entity) for administration, teaching, supervision and/or hands-on care, and under which the facility or licensee (directly or indirectly) bills patients and third-party payors for hands-on care; or

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

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

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

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

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

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

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

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

(LIST APPLICABLE HEALTH CARE SERVICES)

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

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

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

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

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

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

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

c) The following pertain to miscellaneous monetary arrangements:

1) 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 Accreditation 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. 13:35-7. A licensee may also offer to and provide to a patient, at fair market value, medical goods and devices such as hearing aids, eyeglasses, contact lenses, prosthetic devices, orthotics, etc.

1) 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.

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 and Senior Services, 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.

13:35-6.18 MEDICAL MALPRACTICE COVERAGE; LETTER OF CREDIT

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

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

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

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

"Maintaining a professional practice with responsibility for patient care" means the furnishing of professional services to patients in New Jersey, including, but not limited to, the

testing for, or diagnosis of, or the offering or furnishing of treatment, preventative medical care or consultation relating to human disease or dysfunction or physical condition, including the prescribing, administering or dispensing of products, devices or drugs at a place, such as an office (even if located in a home), hospital or clinic, or through a business entity, such as a laboratory or mobile van service.

"Not available" means that a physician or podiatrist is unable to purchase medical malpractice insurance coverage from a carrier authorized to write medical malpractice insurance, including through programs relating to risk retention groups deemed eligible by the Department of Banking and Insurance, surplus lines registered with the Department of Banking and Insurance, self-insurance trusts or captive insurance companies approved by the New Jersey Health Care Facilities Financing Authority in the Department of Health and Senior Services. "Not available" for purposes of this section does not mean "not affordable."

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

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

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

    1) A demand for payment on the letter has been made;

    2) The continuing viability of the letter has been affected, for whatever reason; or

    3) There has been a change in status affecting whether the physician or podiatrist is or continues to be exempt from the requirement.

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

13:35-6.19 DUTY TO REPORT CHANGES IN STATUS

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

"Ability to practice" means and is construed to include all of the following:

1. The cognitive capacity to make appropriate clinical diagnoses and exercise reasoned medical judgments and to learn and keep abreast of medical developments;

2. The ability to communicate those judgments and medical information to patients and other health care providers, with or without the use of aids or devices, such as voice amplifiers; and

3. The physical capability to perform medical tasks such as physical examination and surgical procedures, with or without the use of aids or devices, such as corrective lenses or hearing aids.

"Affiliation" means a professional relationship, including an employment relationship, a position as an independent contractor or the grant of privileges by a health care facility or health maintenance organization in this State or any other jurisdiction.

"Alternative Resolution Program" refers to the program established pursuant to N.J.A.C. 13:35-11 by which licensees suffering from medical conditions or chemical dependency may confidentially enter into a rehabilitation and monitoring program, under the sponsorship of an approved professional assistance program, subject to the periodic submission of coded status reports and continuing confidential review by the Board's Impairment Review Committee. To be deemed a participant in the Alternative Resolution Program, the licensee must be accepted by the Impairment Review Committee and assigned a code number.

"Biennial renewal form" means the form provided to a licensee by the Board, which must be completed in order to renew and keep current a license to practice in this State.

"Chemical substances" is to be construed to include alcohol, drugs or medications, including those taken pursuant to a valid prescription for legitimate medical purposes and in accordance with the prescriber's direction, as well as those used illegally.

"Conviction" means a judgment of conviction entered following plea agreement or trial on an arrest, indictment, accusation or bill of particulars in a state or Federal criminal proceeding, or the resolution of such charges, whether by a plea of no contest or nolo contendere or by pre-trial diversion program.

"Directly associated" means a professional relationship including an employment relationship, partnership arrangement or a shareholder status in a professional service

corporation or general business corporation. "Directly associated" does not include any relationship established pursuant to preferred provider agreements, IPA's or other provider panels.

"Disciplinary order" means a disposition suspending or revoking licensure privileges or imposing civil penalties or ordering the restoration of money or ordering corrective action or medical or other professional treatment or monitoring, or censuring or reprimanding a licensee.

"Financial interest" means a monetary interest of any amount held by a practitioner personally or through immediate family, as defined at N.J.S.A. 45:9-22.4 et seq.

"Health care facility" means a facility or institution, whether public or private, engaged in providing medical services, including diagnosis or treatment of human disease, pain, injury, deformity or physical condition, including, but not limited to, a general hospital, special hospital, mental hospital, health maintenance organizations, public health center, diagnostic center, treatment center, rehabilitation center, extended care facility, skilled nursing home, nursing home, intermediate care facility, tuberculosis hospital, chronic disease hospital, maternity hospital, outpatient clinic, dispensary, home health care agency, boarding home for the sheltered care of adult persons, and bio-analytical laboratory or central services facilities serving one or more such institutions but excluding institutions that provide healing solely by prayer.

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

"Health maintenance organization" means any entity licensed by the State Department of Health and Senior Services, which directly or through contracts with providers furnishes health care services on a prepaid basis to enrollees.

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

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

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

"Medical condition" includes physiological, mental or psychological conditions or disorders, such as, but not limited to, orthopedic, visual, speech, or hearing impairments, cerebral palsy, epilepsy, muscular dystrophy, multiple sclerosis, cancer, heart disease, diabetes, mental retardation, emotional or mental illness, specific learning disabilities, HIV disease, tuberculosis, drug addiction and alcoholism.

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

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

"Practitioner" means physician or podiatrist licensed by the Board.

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

1) The name and address of all practice locations;

2) The name of all practitioners directly associated with the practice, or the practice name if five or more practitioners are offering professional services through the same practice entity;

3) The name and address of each licensed health care facility and health maintenance organization with which the licensee has an affiliation, except that with respect to health maintenance organization affiliations, the licensee shall be relieved of this reporting obligation if the entities with which the licensees has an affiliation have agreed to provide the Board with a list of participating providers on a quarterly basis;

4) The name and address of the licensee's medical malpractice insurer, if any; and

5) The name and address of any health care service entity in which the licensee or any member of his or her immediate family has acquired a financial interest, the date on which that interest was acquired and whether the licensee refers patients to that service.

c) A licensee shall provide notice to the Board in writing within 10 days of any changes in circumstances that would alter the response last provided by the licensee to questions on the biennial renewal form eliciting information pertaining to pending or finalized actions, including those predicated on a no contest or nolo contendere plea or other consensual or voluntary agreement, or a surrender or resignation of license or of privileges or a consent to limitations on practice, which occurred in the face of an investigation or of pending action. Reporting of the following actions is required:

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

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

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

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

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

2) Actions by a health care facility or health maintenance organization grounded, in whole or in part, upon patient care concerns which actions condition, curtail, limit, suspend or revoke privileges;

3) Disciplinary actions by state licensing authorities;

4) Actions by the Department of Health and Senior Services;

5) Actions by the Drug Enforcement Administration or any state drug enforcement agency;

6) Actions by Medicaid, Medicare, CHAMPUS, or other governmental insurance program;

7) Actions by professional review organizations or utilization review organizations; or

8) Actions by a medical malpractice insurance carrier declining coverage or a continuation of coverage, assessing a surcharge based on claims experience,

imposing new limitations or restrictions on practice, or requiring remedial education or office monitoring.

d) A licensee, who is not already known to the Board's Impairment Review Committee through participation in the Alternative Resolution Program, shall provide notice to the Board in writing within 21 days of any changes in circumstances that would alter the response last provided by the licensee to questions on the biennial renewal form pertaining to medical conditions and use of chemical substances, which in any way impair or limit the licensee's ability to practice with reasonable skill and safety. Licensees shall provide notice to the Board of any hospitalization, in-patient treatment or participation in supervised rehabilitation programs relating to these medical conditions. Licensees shall notify the Board of any leave of absence taken from a health care facility or health maintenance organization for reasons related to these medical conditions. (Parental leaves need not be reported.) Any notices received by the Board pursuant to this subsection shall be retained by the Board in a confidential manner and shall not be deemed to be government records within the meaning of N.J.S.A. 47:1A-1 et seq.

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

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

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

13:35-6.20 PHYSICIAN DELEGATION OF TASKS TO RADIOLOGIC TECHNOLOGISTS AND NUCLEAR MEDICINE TECHNOLOGISTS

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

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

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

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

"Licensed nuclear medicine technologist" or "LNMT" shall mean an individual holding a license issued directly by the Department of Environmental Protection.

"Limited technologist license" shall mean a license in chest x-ray (LRT(C)), dental x-ray (LRT(D)), podiatric x-ray (LRT(P)), orthopedic x-ray (LRT(O)) or urologic x-ray (LRT(U)) issued by the New Jersey Radiologic Technology Board of Examiners.

"Medical resident" shall mean a graduate physician who is authorized to practice medicine and surgery by means of a valid permit issued by the Board of Medical Examiners to a person authorized to engage in the practice of medicine and surgery while in the second year or beyond of a graduate medical education program pursuant to N.J.A.C. 13:35-1.5.

"Physician," unless otherwise specified, shall mean an individual holding a plenary license to practice medicine and surgery issued by the State Board of Medical Examiners.

"Technologist" shall mean an individual who holds a current license in a specific category of radiologic practice from the New Jersey Radiologic Technology Board of Examiners or the Department of Environmental Protection, as applicable.

b) A physician may direct a technologist holding the license for general diagnostic radiology (LRT(R)) from the New Jersey Radiologic Technology Board of Examiners to perform the tasks set forth in (c) below provided that:

1) The physician (or another plenary-licensed physician in the office or, in a licensed health care facility, the head of the pertinent Department) has personally certified and documented the radiologic technologist's training and competency to perform the task. The documents shall be preserved in the personnel record and retained for at least the duration of such technologist's employment by or for that physician or facility;

2) A physician or a medical resident is on the premises and immediately available to physically attend to the patient;

3) The physician is responsible for the choice and ordering of all pharmaceuticals and contrast materials and for the determination of dosage and route of administration; and

4) For pediatric patients, the physician shall have experience in the performance of the pertinent procedures with such patients.

c) A physician may direct a technologist, in the circumstances set forth in (b) above, to perform the following tasks:

1) Establish a peripheral intravenous line;

2) Administer contrast material into a peripheral intravenous line or into a pre-existing central intravenous line;

3) Administer contrast material through the use of a power injector;

4) Administer contrast materials into pre-existing urinary catheters, whether indwelling or otherwise;

5) Administer contrast materials into pre-existing nasogastric tubes or other gastric or intestinal feeding tubes;

6) Administer intravenous flush solutions, such as saline or heparin;

7) Administer glucagon and such other pharmaceuticals as shall be approved by the Board; and

8) Administer compounds containing filtered sulfur colloid.

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

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

1) Administer contrast material into the subarachnoid space;

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

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

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

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

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

i) Prior to delegating the tasks set forth in (g) and (h) above, the physician (or another physician in the office or, in a licensed health care facility, the head of the pertinent Department) shall personally certify and document the radiologic technologist's training and competency to perform the task. The documents shall be preserved in the personnel record and retained for at least the duration of such technologist's employment by or for that physician/facility.

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

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

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

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

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

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

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

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

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

2) Aminophylline in conjunction with nuclear medicine stress tests;

3) Diuretics;

4) Angiotensin converting enzyme-inhibitor agents;

5) Vitamin B-12;

6) Intravenous flush solutions, such as saline or heparin;

7) Sincalide, a synthetic cholecystokinin;

8) Lexiscan; and

9) Compounds containing Technetium 99M.

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

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

p) The physician shall be responsible for the choice and ordering of all nonradioactive pharmaceuticals and for the determination of dosage and route of administration. The physician who is also an authorized user shall be responsible for the choice and ordering of all radioactive pharmaceuticals and for the determination of dosage and route of administration. For pediatric patients, the physician shall have experience in the performance of the pertinent procedures with such patients.

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. 45:9-37.

h) Licensees who are in possession of information that 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. 45:9-37.

13:35-6.22 TERMINATION OF LICENSEE-PATIENT RELATIONSHIP

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

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

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

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

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

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

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

1) Notify the patient, in writing, that the licensee shall no longer provide care to the patient as of a date certain. The notification required by this paragraph shall be made no less than 30 days prior to the date on which care is to be terminated, and shall be made by certified mail, return receipt requested, or other proof of delivery, sent to the patient's last known address;

2) Provide, all necessary emergency care or services, including the provision of necessary prescriptions, until the date on which services are terminated. The provision of any such emergency care or services shall not be deemed to manifest any intention to reestablish a licensee-patient relationship; and

3) Comply with all requirements set forth in N.J.A.C. 13:35-6.5 for access to and transfer of patient records.

d) Notwithstanding (c) above, a licensee shall not terminate a licensee-patient relationship in the following circumstances:

1) Where to do so would be for any discriminatory purpose and/or would violate any laws or rules prohibiting discrimination; or

2) Where the licensee knows, or reasonably should know, that no other licensee is currently able to provide the type of care or services that the licensee is providing to the patient.

e) A licensee need not comply with the requirements set forth in (c)1 above if:

1) The licensee-patient relationship has been terminated by the patient as evidenced by conduct manifesting a deliberate intention to terminate the relationship; or

2) The reason for the termination of an ongoing licensee-patient relationship is because the licensee has discontinued providing services to a particular managed care provider or health maintenance organization, in which the patient is enrolled and such managed care provider or HMO has discharged its notice obligation pursuant to N.J.S.A. 26:2S-5a(1).

f) When requested by the patient, the licensee shall make reasonable efforts to assist the patient in obtaining medical services from another licensee qualified to meet the patient's medical needs. These efforts may include, but are not limited to, providing referrals to the patient.

13:35-6.23 PRESENCE OF CHAPERONES

a) In all office settings, a licensee shall provide notice to a patient, or any other person who is to be examined, of the right to have a chaperone present:

1) During breast and pelvic examinations of females; and

2) During genitalia and rectal examinations of both males and females.

b) The notice required by (a) above shall either be provided in written form to the patient or by conspicuously posting a notice in a manner in which patients or any other person who is to be examined are made aware of the right to request a chaperone and to decline care if a chaperone acceptable to the patient is not available. In circumstances where the posting or the provision to the patient of the written notice would not convey the right to have a chaperone present, the licensee shall use another means to ensure that the patient or person to be examined understands his or her right to have a chaperone present.

c) A licensee shall not be obligated to provide further care for the immediate medical problem presented if the licensee is unable to provide a requested chaperone acceptable to the patient.

d) A licensee shall not be obligated to provide further care for the immediate medical problem presented if the patient refuses to have a chaperone present and it is the licensee's desire to have a chaperone present during the examination.

e) If care is not to be provided to a patient under the circumstances described in (c) or (d) above, the licensee shall, consistent with the principles of informed consent, discuss with the patient the risks of not receiving further care.

13:35-6.24 REPORTING OF COMMUNICABLE DISEASES BY LICENSEES

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

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

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

13:35-6.25 CULTURAL COMPETENCY TRAINING

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

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

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

educational activity by the Accreditation Council on Continuing Medical Education (ACCME), the AOA, the AAFP, or as to podiatrists, the CPME.

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

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

"Podiatrist" means an individual holding a D.P.M. degree licensed pursuant to N.J.S.A. 45:5-1 et seq.

"Post-secondary education" means education obtained in a professional school, graduate medical education or continuing medical education consisting of courses with content deemed, by the Board, to be substantially equivalent to cultural competency curriculum criteria established by the Board.

"Practitioner" means a physician or a podiatrist.

b) Each college of medicine in this State shall provide cultural competency training, as identified in (d) below, completion of which shall be required as a condition of receiving a diploma from a college of medicine in this State.

c) Cultural competency training for CME credit shall be offered by each college of medicine in this State. The training shall satisfy the criteria for cultural competency training established by the Board.

d) To be recognized in satisfaction of the cultural competency training requirement applicable to licensees, any CME program of instruction shall be of at least six hours duration, offered in the classroom, or through workshops, over the internet or through other venues, that provides:

1) A context for the training, common definitions of cultural competence, race, ethnicity and culture and tools for self-assessment;

2) An appreciation for the traditions and beliefs of diverse patient populations, at multiple levels — as individuals, in families and as part of a larger community;

3) An understanding of the impact that stereotyping can have on medical decision-making;

4) Strategies for recognizing patterns of health care disparities and eliminating factors influencing them;

5) Approaches to enhance cross-cultural clinical skills, such as those relating to history-taking, problem solving and promoting patient compliance; and

6) Techniques to deal with language barriers and other communication needs, including working with interpreters.

e) A physician who was licensed to practice medicine prior to March 24, 2005, and who did not receive instruction in cultural competency training as part of the curriculum of a college of medicine shall, as a condition of the next renewal after March 24, 2008, document completion of CME or equivalent post-secondary education in cultural competency training pursuant to (d) above before being granted licensure renewal by the Board. Cultural competency training shall be in addition to the CME required by the Board at N.J.A.C. 13:35-6.15.

f) A podiatrist who was licensed to practice podiatry prior to March 24, 2005, and who did not receive instruction in cultural competency training as part of the curriculum of a college of medicine shall, as a condition of the next renewal after March 24, 2008, document completion of CME or equivalent post-secondary education in cultural competency training pursuant to (d) above before being granted licensure renewal by the Board. Cultural competency training may be included in the CME required by the Board at N.J.A.C. 13:35-6.15.

g) A practitioner licensed to practice after March 24, 2005, but on or before June 29, 2007, who did not receive instruction in cultural competency training as part of the curriculum of a college of medicine, as a condition of the next renewal after March 24, 2008, shall document completion of CME or equivalent post-secondary education in cultural competency training pursuant to (d) above before being granted licensure renewal by the Board. Cultural competency training may be included in the CME required by the Board at N.J.A.C. 13:35-6.15.

h) A practitioner licensed to practice on or after the date of the expiration of the next licensure cycle (June 30, 2007 for physicians and October 31, 2007 for podiatrists) who did not receive instruction in cultural competency training as part of the curriculum of a college of medicine, shall document completion of CME or equivalent post-secondary education in cultural competency training pursuant to (d) above by the end of the next

complete renewal cycle after he or she was licensed. Cultural competency training may be included in the CME required by the Board at N.J.A.C. 13:35-6.15.

i) The Board, or its designee, may waive the cultural competency training CME requirement for an applicant who is applying for relicensure and who can demonstrate to the satisfaction of the Board that he or she has attained the substantial equivalent of the cultural competency training CME requirement through completion of a similar course in his or her post-secondary education.

13:35-6.26 PROCEDURES FOR PHYSICIAN ORDERED IMMUNIZATIONS PERFORMED BY LICENSED PHARMACISTS

a) A New Jersey licensed physician may participate in an immunization program with a licensed pharmacist pursuant to N.J.S.A. 45:14-63 of the Pharmacy Practice Act, provided that the pharmacist is authorized to engage in such activities by the Board of Pharmacy pursuant to N.J.A.C. 13:39-4.20, and provided the pharmacist administers vaccines and related emergency medications, which shall be limited to diphenhydramine and epinephrine, pursuant to:

1) A prescription for the vaccine, related emergency medications, and pharmacist administration of the vaccine that is patient specific; and/or

2) A physician's standing order for the vaccine, related emergency medications above, and administration instructions that are not patient specific.

b) A physician shall supervise a licensed pharmacist who is participating in an immunization program implemented pursuant to the physician's standing order. Supervision by the delegating physician shall be deemed adequate if the delegating physician:

1) Is responsible for formulating or approving a standing order, which shall include compliance with Centers for Disease Control and Prevention (CDC) guidelines for vaccine administrations, set forth in Appendix D of "Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book: Course Textbook)," updated 10th edition, February 2007. The CDC vaccine administration guidelines are incorporated herein by reference, as amended and supplemented, and can be found at the CDC website, www.cdc.gov, specifically, http://www.cdc.gov/vaccines/pub/pinkbook/downloads/appendices/appdx-full-d.pdf. The standing order shall also include compliance with the American Heart Association (AHA) Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (2005). The AHA Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (2005) are incorporated herein by reference, as amended and supplemented, and can be found at the AHA website, www.americanheart.org, specifically,

http://circ.ahajournals.org/content/vol112/24_suppl/. The order shall also include procedures which shall be followed for the reporting of adverse events. The delegating physician shall annually review the order and the services provided to patients under the order;

2) Is geographically located to be easily accessible to the pharmacy practice site and, if applicable, to the immunization location.

3) Is available through direct telecommunication for consultation, assistance, and direction; and

4) Receives annual status reports on the immunization program as administered by the pharmacist.

13:35-6.27 STANDARDS FOR COLLABORATIVE PRACTICE FOR DRUG THERAPY MANAGEMENT WITH LICENSED PHARMACISTS

(a) The following words and terms, as used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Bona fide physician-patient relationship" means a relationship in which the physician has ongoing responsibility for assessment, care, and treatment of the patient's medical condition for which collaborative drug therapy management is utilized. For purposes of this definition, "ongoing responsibility" means:

1. The physician-patient relationship has existed for at least one year;

2. The physician has seen and/or assessed the patient on at least four visits; or

3. The physician assumes responsibility for providing management and care of the patient's condition after conducting a comprehensive medical history and physical examination.

"Collaborative drug therapy management" means the cooperative management of a patient's drug, biological, and device-related health care needs, pursuant to a written protocol directed on a voluntary basis by a patient's physician with the patient's informed consent, by the patient's physician and a pharmacist who has signed a collaborative practice agreement with the physician.

"Collaborative practice" means that practice whereby one or more physicians have jointly agreed to work in conjunction with one or more pharmacists for the purpose of collaborative drug therapy management of patients.

"Collaborative practice protocol" means a written document that identifies the collaborative drug therapy management actions that a pharmacist is authorized to perform for a patient and that is developed jointly by the pharmacist and the physician, and meets the requirements set forth at (c) below.

"Informed consent" means the written document that is signed by a patient whereby the patient agrees to collaborative drug therapy management by the patient's physician and a pharmacist who has entered into a collaborative practice agreement with the physician.

"Therapeutic interchange" means the substitution and dispensing of a drug chemically dissimilar from the prescription drug originally prescribed.

(b) A physician may enter into a collaborative practice agreement with one or more licensed pharmacists, as provided in N.J.S.A. 45:14-61 of the Pharmacy Practice Act, provided the collaboration that the physician agrees to conduct with the pharmacist is within the scope of the physician's practice and the pharmacist is authorized to engage in such activities pursuant to Board of Pharmacy requirements set forth at N.J.A.C. 13:39-13.

(c) A physician who engages in collaborative practice with one or more pharmacists shall provide the Board, upon request, with a signed copy of a collaborative practice agreement. The collaborative practice agreement shall be consistent with the example contained in N.J.A.C. 13:35-6.27 Appendix, which is incorporated herein by reference. The written agreement shall:

1. Identify, by name and title, each physician and each pharmacist who is permitted to participate in a patient's collaborative drug therapy management, including all covering physicians and/or pharmacists. Each covering physician shall meet the requirements of (b) above and each covering pharmacist shall meet the requirements of N.J.A.C. 13:39-13.3. The agreement shall establish the means by which the physician and/or pharmacist will be notified about covering practitioners for collaborative practice purposes;

2. Specify the functions and responsibilities, including the scope of practice and authority, to be exercised by the pharmacist;

3. Indicate any restrictions placed on the use of certain types or classes of drugs or drug therapies;

4. Indicate any diagnosis or types of diseases that are specifically included or excluded;

5. Include copies of all protocols to be used in the collaborative practice;

6. Contain an effective date for the agreement; and

7. Be signed and dated by the physician(s) and pharmacist(s).

(d) Any changes, additions, or deletions to the collaborative practice agreement shall be submitted to the Board upon request.

(e) The physician shall establish a method for monitoring both the compliance with the collaborative practice agreement and the clinical outcomes of the patients.

(f) Collaborative practice protocols shall be developed for each different type of collaborative drug therapy management authorized by the physician under the collaborative practice agreement and shall identify those activities that may be performed by the collaborating pharmacist. Each protocol shall:

1. Be jointly developed by the physician and the pharmacist, consistent with standards and practices that are deemed commonly accepted and recognized by national standard setting organizations, or national or State professional organizations of the same discipline as the treating physician, and signed and dated by both the physician and the pharmacist;

2. Be initiated and utilized at the sole discretion of the physician for a specific patient with whom the physician has a bona fide physician-patient relationship;

3. Be agreed to by both the physician and the pharmacist with the written informed consent of the patient consistent with (g) below;

4. Be available at the practice sites of the pharmacist and physician and made available at each site to the patient;

5. Establish the means by which the patient will be advised of the right to elect to participate in and withdraw from the collaborative drug therapy management;

6. Establish when physician notification is required, the physician chart update interval, and an appropriate time frame within which the pharmacist shall notify the physician of any change in dose, duration, or frequency of medication prescribed. Written notification, by either facsimile or electronic means, shall be provided to the physician no later than eight hours after any change in prescribed medication is made by the pharmacist;

7. Identify the method and time frame for notification of the physician if an adverse event occurs; and

8. Be reviewed at least once per year by the parties to determine whether the protocol should be renewed, modified or terminated.

(g) Written informed consent shall be obtained from each individual patient participating in collaborative drug therapy management. Both the physician and the pharmacist shall retain a copy of the patient's written informed consent. The written informed consent shall:

1. Contain the specific patient's name;

2. Identify the risks and benefits of collaborative drug therapy management, including the fact that services provided under collaborative drug therapy management may not be covered by the patient's insurance provider;

3. Identify the fact that covering physicians and/or pharmacists may be utilized in the collaborative drug therapy management of the patient's care;

4. Identify the patient's right to elect to participate in and withdraw from the collaborative drug therapy management; and

5. Be signed and dated by the patient.

(h) The collaborative practice agreement may be terminated at any time by either the physician or the pharmacist by written documentation. Upon termination of a collaborative practice agreement, the physician and the pharmacist shall provide notice of the termination to each individual patient who is undergoing collaborative drug therapy management. Upon termination of the agreement, the patient's informed consent for collaborative drug therapy management under the agreement shall be voided.

(i) Collaborative drug therapy management shall be between a single patient with whom the physician has a bona fide physician-patient relationship, the physician, and the pharmacist and shall address that patient's specific condition, disease, or diseases.

(j) Collaborative drug therapy management may include the collecting, analyzing, and monitoring of patient data; ordering or performing of laboratory tests based on the standing orders of a physician as set forth in the written collaborative practice protocols, consistent with (k) below; ordering of clinical tests based on the standing orders of a physician as set forth in the written collaborative practice protocols; modifying, continuing, or discontinuing drug or device therapy; and therapeutic drug monitoring with appropriate modification to dose, dosage regimen, dosage forms, or route of administration.

(k) A pharmacist may perform laboratory tests that are granted waived status in accordance with the provisions of the "New Jersey Clinical Laboratory Improvement Act," P.L. 1975, c. 166 (N.J.S.A. 45:9-42.26 et seq.), Department of Health and Senior Services rules set forth at N.J.A.C. 8:44, and Department of Health and Senior Services CLIA Program requirements, available at http://www.state.nj.us/health/phel/instruct116.shtml, provided the tests are consistent with the pharmacy practice area or disease state covered by the collaborative practice agreement.

(l) The interpretation of clinical or laboratory tests under a written collaborative practice protocol shall be performed by a pharmacist only in direct consultation with a physician.

(m) Collaborative drug therapy management shall not include therapeutic interchange at the time of dispensing without the prior, specific informed consent of the patient and the consent of the patient’s physician.

(n) Participation in, or withdrawal from, a collaborative practice agreement shall be voluntary on the part of a physician and a pharmacist.

(o) Participation in, or withdrawal from, collaborative drug therapy management shall be voluntary on the part of the individual patient.

(p) All records relating to a collaborative practice agreement shall be maintained in either hard copy or electronic form for a period of not less than seven years from the date of termination of the agreement and shall be supplied to the Board upon request.

(q) Any violation of the collaborative practice agreement or protocols on the part of the physician may be deemed professional misconduct and may subject the physician to discipline consistent with N.J.S.A. 45:1-21.

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:

b) Requirements, by specialty or expertise, for physicians authorized to perform a clinical brain death examination and declare death upon the basis of neurological criteria; and

c) Accepted medical standards, including criteria, tests and procedures, to govern declarations of death upon the basis of neurological criteria.

13:35-6A.2 DEFINITIONS

The following words and terms, when used in this subchapter, shall have the following meanings unless the context clearly indicates otherwise.

"Apnea" means the absence of respiration and a terminal PC02 greater than 60 mmHG or a terminal PC02 at least 20 mmHg over the initial normal baseline PC02.

"Brain death" means the irreversible cessation of all functions of the entire brain, including the brainstem.

"Examining physician" means a physician who performs a clinical brain death examination and meets the qualifying criteria set forth at N.J.A.C. 13.35-6A.3. The term "examining physician" may refer to one or more physicians involved in the clinical brain death examination.

13:35-6A.3 REQUIREMENTS FOR PHYSICIANS AUTHORIZED TO DECLARE DEATH ON THE BASIS OF NEUROLOGICAL CRITERIA

a) A physician performing a clinical brain death examination shall be plenary licensed and shall hold the following qualifications, dependent on the age of the patient upon whom a declaration of brain death is to be made:

1) Age below two months: When declarations of brain death are to be made upon children below two months of age, the examining physician shall be a specialist in neonatology, pediatric neurology or pediatric neurosurgery.

2) Age between two months and 12 months: When declarations of brain death are to be made upon children at or above two months of age, and at or below 12 months of age, the examining physician shall be a specialist in pediatric critical care, pediatric neurology or pediatric neurosurgery.

3) Age greater than 12 months: When declarations of brain death are to be made upon patients above 12 months of age, the examining physician shall be duly qualified by training and experience to declare brain death. For purposes of this section, neurologists, neurosurgeons, critical care specialists and trauma surgeons shall be deemed to be duly qualified physicians. In addition, any physician who has been granted privileges by a hospital to declare brain death may serve as the examining physician pursuant to this subchapter.

13:35-6A.4 STANDARDS FOR DECLARATION OF BRAIN DEATH

a) Declarations of brain death shall be made in accordance with accepted medical standards. A patient may be pronounced dead if a physician meeting the requirements set forth in N.J.A.C. 13:35-6A.3 determines in accordance with the criteria set forth in this section that brain death has occurred.

b) The examining physician who is to pronounce brain death shall:

1) Determine a reasonable basis to suspect brain death. Brain death may be declared where the etiology of the insult or injury is sufficient to cause brain death and, in the judgment of the examining physician, is irreversible;

2) Exclude complicating medical conditions that may confound the clinical assessment of brain death, including:

i) Severe hypothermia, defined as core body temperature at or below 92 degrees Fahrenheit in adults, or outside the clinically established age specific range in a child;

ii) The effects of neuromuscular blockade(s). In the event a neuromuscular blockade was used to treat the patient, the examining physician shall establish that the effects of the blockade are reversed prior to performing clinical examinations for brain death;

iii) The effects of CNS depressants. If CNS depressants are present and serum blood level is therapeutic or below the therapeutic range, a clinical examination may be initiated. If serum blood levels are not available, above the therapeutic range or unknown, or there is an overdose or toxic exposure of an unknown agent, a brain death evaluation may proceed without reliance on clinical examination if, in the judgment of the examining physician, the injury or cause of coma is non-survivable. In such event, an objective measure of intracranial circulation shall be used as a confirmatory test;

iv) Severe metabolic imbalances, unless in the judgment of the examining physician any such imbalances do not confound the clinical assessment of brain death; and

v) Mean arterial pressure less than 60 mmHg in an adult or outside the clinically established age specific range in a child;

3) Perform a clinical examination to evaluate the patient for the presence of brain death. The following clinical findings, if present, are indicative of brain death:

i) A determination that supraspinal motor response(s) to pain is absent;

ii) A determination that brainstem reflexes are absent, which determination may be established by ascertaining all of the following:

(1) No pupillary response to light;

(2) No deviation of the eyes to irrigation of each ear with 50 ml of cold water. The tympanic membrane shall be determined to be intact;

(3) No corneal reflex; and

(4) No response to stimulation of the posterior pharynx and/or no cough response to tracheobronchial suctioning; and

iii) The presence of apnea, which shall be established in accordance with the following testing procedure:

(1) Arterial PC02 is normalized to greater or equal to 40 mmHg;

(2) 100 percent oxygen is delivered via the ventilator for 10 minutes prior to starting the test;

(3) A baseline arterial blood gas is drawn;

(4) A pulse oximeter is connected and the ventilator is disconnected;

(5) 100 percent oxygen is delivered into the trachea via cannula in the ET tube, at six liters/minute;

(6) If tolerated, the patient is left off the ventilator for eight to 10 minutes and the patient is observed carefully for respiratory movements. Another blood gas is drawn at the end of the eight to 10 minutes and the ventilator is reconnected;

(7) The length of the apnea test and the PCO2 at the end of the test are documented in the patient record; and

(8) If the patient does not tolerate the apnea test, as evidenced by significant drops in blood pressure and/or oxygen saturation, or the development of significant arrhythmias, the test shall be discontinued and either repeated or supplanted with a confirmatory test.

iv) When, in the judgment of the examining physician, a clinical examination cannot be performed due to the nature of injuries, intoxication, patient instability, electrolyte imbalances or any other reason, a confirmatory test such as an intracranial blood flow, four vessel cerebral angiography, radionuclide angiography, transcranial Doppler ultrasound, CT angiogram, or MR angiogram shall be substituted for the clinical examination; and

4) Confirm the diagnosis with a confirmatory test or by a repeat clinical examination, consistent with the following:

i) When a clinical examination of a patient shows the absence of all supraspinal and brain stem reflexes as established by the criteria in (b)3 above, the examining physician shall confirm the diagnosis of brain death with an objective confirmatory test measuring intracranial circulation such as an intracranial blood flow, four vessel cerebral angiography, radionuclide angiography, transcranial Doppler ultrasound, CT angiogram or MR angiogram.

ii) In the event confirmatory testing is not available or is clinically precluded, the examining physician shall repeat the clinical examination after a period of observation, which period shall be not less than 48 hours for patients below the age of two months, not less than 24 hours for patients between the ages of two

months to one year, and not less than six hours for patients greater than one year of age.

13:35-6A.5 ORGAN DONATION

If the person to be declared dead upon the basis of neurological criteria is or may be an organ donor, then the examining physician shall not have any responsibility for any contemplated recovery or transplant of that person's organs, and shall not serve in the capacity of organ transplant surgeon, the attending physician of the organ recipient, or otherwise an individual subject to a potentially significant conflict of interest relating to procedures for organ procurement.

13:35-6A.6 EXEMPTION TO ACCOMMODATE PERSONAL RELIGIOUS BELIEFS

Death shall not be declared on the basis of neurological criteria if the examining physician has reason to believe, on the basis of information in the patient's available medical records, or information provided by a member of the patient's family or any other person knowledgeable about the patient's personal religious beliefs, that such a declaration would violate the personal religious beliefs of the patient. In these cases, death shall be declared, and the time of death fixed, solely upon the basis of cardio-respiratory criteria.

13:35-6A.7 PRONOUNCEMENT OF DEATH

The examining physician shall document within the patient record the results of all tests performed and shall sign the chart. After a clinical examination and a confirmatory test or examination have been completed and documented on the patient's chart, and if the examining physician has been able to make all requisite determinations consistent with N.J.A.C. 13:35-6A.4, then the examining physician may authorize the pronouncement of death. The actual pronouncement of death may thereafter be made by the examining physician or any plenary licensed physician acting upon the authorization of the examining physician.

SUBCHAPTER 7.
PRESCRIPTION, ADMINISTRATION AND DISPENSING OF DRUGS

13:35-7.1 DEFINITIONS

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Actual acquisition cost" means the cost actually incurred by the practitioner in acquiring a drug from a supplier and shall not include any amounts charged by any entity in which the practitioner has a direct or indirect financial or other beneficial interest.

"Administer" means the physical, in-person provision of a drug by way of injection, vaccine, allergenic extract or nebulized preparation or the provision of multiple dose vials of injectable medications.

"Amphetamine or sympathomimetic amine" means a drug which, chemically and pharmacologically, acts as a central nervous system stimulant.

"Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogen, progestin and corticosteroids), which promotes muscle growth, as well as any salt, ester, or isomer of such substance which acts in a similar manner in the human body.

"Controlled substance" means a drug classified in any of the schedules (I through V) of the Controlled Dangerous Substances Act, N.J.S.A. 24:21-5 to 24:21-8.1, recognized to have a potential for abuse or to lead to physical or psychological dependence.

"Dispensing" means the distribution of drugs intended by the physician for the personal use of the patient. "Dispensing" as used in this subchapter does not include the in-office administration of injections, vaccines, allergenic extracts or nebulized preparations or the provision of multiple dose vials of injectable medication.

"Drug" means any article recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement to those sources, including, but not limited to, a controlled substance, a prescription legend drug, an over-the-counter preparation, a vitamin or food supplement, or any compounded combination of any of the above or a transdermal patch or strip, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or medical condition in humans or intended to affect the structure or function of the human body. The term, as used in this subchapter, is synonymous with "medicine" as used in N.J.S.A. 45:9-22.11. "Drug," as used in this subchapter, does not mean a device or durable medical equipment.

"Intractable pain" means pain which has been shown to be refractory or resistant to management with standard methods of treatment or for which insufficient relief has been found after reasonable efforts.

"Narcotic" means an analgesic drug which chemically and pharmacologically acts as an opioid.

"Non-prescription substance" means an over-the-counter preparation, a vitamin or food supplement, or any compounded combination of any of these preparations and supplements or a transdermal patch or strip for which no prescription is required pursuant to law.

"Practitioner" means any licensee subject to the regulatory authority of the Board authorized to prescribe or dispense drugs, including physicians, podiatrists and, to the extent permitted by law and rule, registered residents, resident permit holders, physician assistants and certified nurse midwives.

"Prescribing" means the act of directing that a patient take a drug included in prescription legend through either a written or verbal order.

"Terminal illness" means a diagnosed medical condition with a prognosis of less than one year.

13:35-7.1A EXAMINATION OF PATIENT'S CONDITION REQUIRED PRIOR TO DISPENSING DRUGS OR ISSUING A PRESCRIPTION; EXCEPTIONS

a) Except as provided in (b) below, a practitioner shall not dispense drugs or issue prescriptions to an individual, pursuant to the requirements of this subchapter, without first having conducted an examination, which shall be appropriately documented in the patient record. As part of the patient examination, the practitioner shall:

1) Perform an appropriate history and physical examination;

2) Make a diagnosis based upon the examination and all diagnostic and laboratory tests consistent with good medical care;

3) Formulate a therapeutic plan and discuss such plan, along with the basis for the plan and the risks and benefits of various treatment options, with the patient; and

4) Ensure the availability of the physician or coverage for the patient for appropriate follow-up care.

b) Notwithstanding (a) above, an examination of the patient's condition shall not be required prior to the dispensing of drugs or the issuance of a prescription under the following circumstances:

1) In admission orders for a newly hospitalized patient;

2) For a patient of another physician for whom the practitioner is taking calls;

3) For continuation medications on a short term basis for a new patient prior to the patient's first appointment;

4) For an established patient who, based on sound medical practice, the physician believes does not require a new examination before issuing a new prescription;

5) For a patient examined by a healthcare professional who is in collaborative practice with the practitioner; and

6) When treatment is provided by a practitioner for an emergency medical condition.

c) For purposes of this section, the term "emergency medical condition" as used in (b) above means:

1) A medical condition manifesting itself by acute symptoms of sufficient severity, including severe pain, such that the absence of immediate medical attention could reasonably be expected to result in:

2) Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;

3) Serious impairment to bodily functions; or

4) Serious dysfunction of any bodily organ or part.

13:35-7.2 REQUIREMENTS FOR ISSUING WRITTEN PRESCRIPTIONS FOR MEDICINES

a) A practitioner, acting within the scope of lawful practice and after an examination or evaluation of the patient's condition, may issue a written prescription for a drug to a patient, guardian or authorized representative in the form authorized by this section. The practitioner shall assure that appropriate follow-up is provided and that the effects of the drug are properly evaluated and integrated into the treatment plan for the patient.

b) (Reserved)

c) Written prescriptions shall be issued only on New Jersey Prescription Blanks (NJPB), secured from an approved vendor and subject to the required security mandates of the prescription blank program.

d) A practitioner shall include the following information on each written prescription:

1) The prescribing practitioner's full name, address, telephone number, license number, and proper academic degree or identification of professional practice for which licensed;

2) The full name, age and address of the patient;

3) The date of issuance;

4) The name, strength and quantity of the drug prescribed;

5) Words, in addition to numbers, to indicate the drug quantity authorized if the prescription is for a Schedule II controlled substance, for example: ten (10) Percodan; or five (5) Ritalin 5 mg;

6) The number of refills permitted or time limit for refills, or both;

7) The handwritten original signature of the prescribing practitioner;

8) An explicit indication, by initials placed next to "do not substitute" (see (e) below), if it is the prescribing practitioner's intention that a specified brand name drug be dispensed;

9) The prescribing practitioner's D.E.A. number, if the drug is a controlled substance; and

10) Adequate instruction for the patient as to frequency; a direction of "p.r.n." or "if needed" alone may be used if appropriate.

e) A prescribing practitioner shall advise each patient by adequate notice, for example, by a sign or pamphlet in the waiting room of the office that the patient may request the practitioner to substitute a generic drug for any brand name drug prescribed.

f) Each practitioner shall use only written prescription blanks which shall be imprinted with the words "substitution permissible" and "do not substitute," with a space for the prescribing practitioner's initials next to the chosen option, and which shall not include preprinted information designed to discourage or prohibit substitution.

g) When using health care facility or multi-prescriber prescription blanks, the full name and license number of the prescribing practitioner shall be legibly printed at the top of the prescription or the identity of the prescriber shall be designated by a checkmark or other legible means.

h) Each prescription for a controlled substance shall be written on a separate NJPB.

1) An NJPB that contains prescriptions for two or more controlled substances shall be invalid.

2) An NJPB that contains a prescription for only one controlled substance and contains other prescription(s) other than another controlled substance shall be valid.

13:35-7.3 VERBAL PRESCRIPTIONS (RESERVED)

13:35-7.4 FACSIMILE TRANSMITTED PRESCRIPTIONS

a) A practitioner, acting within his or her scope of lawful practice and after an examination of the patient's condition, consistent with the requirements of N.J.A.C. 13:35-7.1A, may transmit, or have an authorized agent transmit, a facsimile prescription to a pharmacy which has been approved by a patient, a patient's guardian, or a patient's authorized representative, consistent with the requirements of this section. For purposes of this section, "facsimile prescription" means a prescription issued by the practitioner which is transmitted by a device which sends an exact image to the receiver.

b) A practitioner shall comply with all requirements set forth in this subchapter, and shall ensure that all information required to be included on a written prescription pursuant to

N.J.A.C. 13:35-7.2(d) is provided on each facsimile prescription, except that an NJPB shall not be required for the prescription.

c) The transmission of a facsimile prescription shall contain the following:

1) The identification number of the facsimile machine which is used to transmit the prescription to the pharmacy;

2) The time and date of the transmission of the prescription;

3) The name, address, telephone number and facsimile number of the pharmacy to which the prescription is being transmitted; and

4) If an authorized agent transmits the facsimile prescription, the full name and title of the transmitting agent.

d) A practitioner shall provide verbal verification of the facsimile prescription upon request of the pharmacy when the pharmacist has a question regarding the authenticity, accuracy or appropriateness of the prescription. A practitioner's authorized agent may provide verbal verification of the facsimile prescription to the pharmacy when the pharmacist has a question regarding the authenticity or legibility of the prescription.

e) A practitioner or his or her authorized agent may transmit a facsimile prescription to a pharmacy for a Schedule II controlled substance, provided that the patient is given the original signed NJPB which is presented to the pharmacist prior to the dispensing of the controlled substance, except as provided in (e)1, 2 and 3 below:

1) A prescription for a Schedule II narcotic substance prescribed for pain management to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription.

2) A prescription for a Schedule II substance prescribed for pain management for a resident of a long term care facility may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The facsimile shall serve as the original written prescription.

3) A prescription for a Schedule II narcotic substance prescribed for pain management for a patient receiving services from a hospice certified by Medicare under Title XVIII or licensed by the State may be transmitted by the practitioner or the practitioner's

agent to the dispensing pharmacy by facsimile. The practitioner or the practitioner's agent shall note on the facsimile prescription that the patient is a hospice patient. The facsimile shall serve as the original written prescription.

f) A practitioner or his or her authorized agent may transmit a facsimile prescription to a pharmacy for a Schedule III, IV, or V controlled substance consistent with the requirements of this section. The facsimile shall serve as the original written prescription.

g) If a facsimile prescription is provided for a Schedule II substance prescribed for pain management to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion, or for a resident of a long term care facility, or for a patient receiving services from a hospice certified by Medicare under Title XVIII or licensed by the State, or for a Schedule III, IV or V controlled substance, the practitioner shall not provide the patient, the patient's guardian, or the patient's authorized representative with the original written prescription.

h) A practitioner shall not enter into any agreement with a pharmacy that requires facsimile prescriptions be transmitted to that particular pharmacy or in any way denies a patient the right to have his or her prescription transmitted by facsimile to a pharmacy of the patient's choice.

13:35-7.4A ELECTRONICALLY TRANSMITTED PRESCRIPTIONS

a) A practitioner, acting within his or her scope of lawful practice and after an examination of the patient's condition, consistent with the requirements of N.J.A.C. 13:35-7.1A, may transmit, or have an authorized agent transmit, an electronic prescription to a pharmacy that has been approved by a patient, a patient's guardian or a patient's authorized representative, consistent with the requirements of this section. For purposes of this section, "electronic prescription" means a prescription, which is transmitted by a computer device in a secure manner, including computer-to-computer and computer-to-facsimile transmissions.

b) A practitioner shall comply with all requirements set forth in this subchapter, and shall ensure that all information required to be included on a written prescription pursuant to N.J.A.C. 13:35-7.2(d) is provided in each electronic prescription, except that a handwritten original signature and an NJPB shall not be required for the prescription.

c) A practitioner's electronic signature, or other secure method of validation, shall be provided with the electronic prescription unless the prescription is transmitted by an authorized agent as provided in (e) below.

d) To maintain confidentiality of electronic prescriptions, the practitioner shall ensure that the electronic system used to transmit the electronic prescription has adequate security and system safeguards designed to prevent and detect unauthorized access, modification or manipulation of such records, and shall include, at a minimum, electronic encryption.

e) A practitioner may authorize an agent to electronically transmit a prescription provided that the full name and title of the transmitting agent is included on the transmission, and provided that the practitioner's authorized agent does not sign the electronic prescription.

f) A practitioner shall provide verbal verification of an electronic prescription upon request of the pharmacy when the pharmacist has a question regarding the authenticity, accuracy or appropriateness of the prescription. A practitioner's authorized agent may provide verbal verification of the electronic prescription to the pharmacy when the pharmacist has a question regarding the authenticity or legibility of the prescription.

g) A practitioner or the practitioner's authorized agent may transmit an electronic prescription to a pharmacy for a Schedule II controlled substance, provided that the original signed prescription is presented to the pharmacist prior to the dispensing of the controlled substance. If permitted by Federal law, and in accordance with Federal requirements, the electronic prescription shall serve as the original signed prescription and the practitioner shall not provide the patient, the patient's guardian, or the patient's authorized representative with a signed, written prescription.

h) A practitioner or his or her authorized agent may transmit an electronic prescription to a pharmacy for a Schedule III, IV, or V controlled substance, provided that the original signed prescription for presentation at the pharmacy, an oral prescription, or a facsimile prescription is provided. If permitted by Federal law, and in accordance with Federal requirements, the electronic prescription shall serve as the original signed prescription and the practitioner shall not provide the patient, the patient's guardian, or the patient's authorized representative with a signed, written prescription.

i) A practitioner shall not enter into any agreement with a pharmacy which requires that electronic prescriptions be transmitted to a particular pharmacy or in any way denies a patient the right to have his or her prescription transmitted electronically to a pharmacy of the patient's choice.

13:35-7.5 REQUIREMENTS FOR THE DISPENSING OF DRUGS AND SPECIAL LIMITATIONS APPLICABLE TO THE DISPENSING OF DRUGS FOR A FEE

a) A practitioner, acting within the scope of lawful practice and after an examination or evaluation of the patient's condition, may dispense a drug directly to a patient, guardian or authorized representative under the circumstances and limitations set forth in this

section. The practitioner shall assure that appropriate follow-up is provided and that the effects of the drug are properly evaluated and integrated into the treatment plan for the patient.

b) A practitioner who dispenses drugs in the office shall maintain those drugs in an area kept in an orderly and sanitary manner, and in accordance with standard pharmaceutical practice and manufacturer recommendations concerning storage conditions, including refrigeration, where necessary. A practitioner shall not maintain in inventory any drugs which are outdated, misbranded, deteriorated, adulterated, recalled, unlabeled, damaged, discontinued or which were previously dispensed to a patient. A practitioner shall be responsible for the disposal of such drugs in a manner which will not pose a health hazard and in accordance with all local, State and Federal requirements.

c) All drugs dispensed shall be recorded in the applicable patient record.

d) All drugs dispensed, with the exception of samples of drugs which are not controlled substances and which are packaged and labeled by the manufacturer, shall be recorded in a permanent, contemporaneous dispensing log which shall contain, at a minimum, the following:

1) The full name of the patient;

2) The complete name of each drug dispensed;

3) The strength and quantity of the drug dispensed;

4) Instructions as to the frequency of use;

5) The date of dispensing; and

6) The identity of the dispensing practitioner, if more than one practitioner dispenses in the office.

e) Each different drug dispensed, in whatever dosage form, shall be placed in a separate container with a safety closure cap, unless the patient requests otherwise or the drug is a pharmaceutical sample which has been packaged and labeled by the manufacturer.

f) Each drug dispensed, including pharmaceutical samples, shall bear a legible label which includes the following:

1) The complete name of the drug dispensed;

2) The strength and quantity of the drug dispensed;

3) Instructions as to the frequency of use;

4) Special precautions, as appropriate; and

5) The expiration date of the drug.

g) With respect to any drug which is not packaged by the manufacturer as a sample, the label shall also include the following:

1) The full name of the patient;

2) A list of the ingredients if the drug was compounded, not manufactured;

3) The date of dispensing; and

4) The identity of the dispensing practitioner.

h) A practitioner shall not charge any patient a fee for a drug packaged and labeled by a manufacturer as a sample. For any drug dispensed which is not packaged by the manufacturer as a sample, a practitioner may charge a fee to allow for a recoupment of a portion of overhead and administrative costs, which fee shall not exceed the actual acquisition cost plus an additional sum not to exceed 10 percent of the actual acquisition cost.

i) Subject to the exception in (j) below, if a practitioner charges a fee for the drug dispensed, either directly or through a global office visit charge which is more than that practitioner's usual and customary visit charge, the practitioner:

1) Shall not dispense that drug or a substantially equivalent drug in a quantity or in dosages greater than that which would allow the patient a seven-day supply;

2) Shall not dispense that medicine or a substantially equivalent medicine at a frequency greater than once every 30 days;

3) Shall assure that information is given to the patient regarding the alternative availability of the drug outside of the practitioner's office; and

4) Shall disclose to the patient in advance of purchase and again on the bill the actual acquisition cost of the drug.

j) In accordance with N.J.S.A. 45:9-22.11, the requirements set forth at (h) and (i) above shall not apply to a practitioner:

1) If the office at which the dispensing occurs is situated 10 or more miles from the nearest licensed pharmacy;

2) If the drug is dispensed pursuant to an oncological or AIDS protocol;

3) If the drug dispensed is a salve, ointment or drops; or

4) If the drug is dispensed in, and directly related to the services rendered to the patient at:

i) A hospital emergency room;

ii) A student health center at an institution of higher education; or

iii) A publicly subsidized community health center, family planning clinic or prenatal clinic.

k) The requirements set forth in (d) through (g) above shall not apply to the dispensing of non-prescription substances.

13:35-7.5A LIMITATIONS ON PRESCRIBING, ADMINISTERING OR DISPENSING OF DRUGS FOR THE TREATMENT OF OBESITY

a) The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

"Bariatric practice" means the practice of medicine by any physician relating to the treatment of obesity, in conjunction with those co-morbidities affected by obesity.

"Body mass index" means a calculation determined by dividing the measured body weight in kilograms by body height in meters square (kg/m^2).

"Co-morbidities" means any disease, psychiatric or medical condition that may be negatively influenced by obesity, such as diabetes, hypertension, hyperlipidemia, osteoarthritis, cardiac conditions, stroke, respiratory disease and certain cancers.

"Informed consent" means the agreement of the patient to follow the therapeutic regimen established by a practitioner, which follows the disclosure by a practitioner of that information which a patient needs as to available choices with respect to the proposed treatment, including the inherent and potential risks of such treatment.

"Obesity" means a complex, multi-factorial condition characterized by a documented diagnosis of excess adipose tissue as determined by the calculation of a body mass index greater than 27.

b) A practitioner who engages in bariatric practice shall not prescribe, order, dispense, administer, sell or transfer any drug for the treatment of obesity except in accordance with the provisions of this subchapter and in conformity with the following requirements:

1) A practitioner shall personally, or through a licensed health care practitioner working within his or her lawful scope of practice and acting on the treating practitioner's order or protocol, take a complete history of the patient and conduct a comprehensive physical examination and order or perform any laboratory and/or diagnostic tests as indicated by the clinical evaluation. The history, physical examination and laboratory and/or diagnostic tests shall be undertaken in an effort to determine the existence of any co-morbidities and if the use of any prescription medication is contraindicated. The practitioner shall also assess the possible existence of any psychiatric or psychological condition (such as, but not limited to, depression or substance abuse) which shall be evaluated and treated prior to or contemporaneous with the treatment of obesity and which may pose a contraindication to the use of prescription medications. The practitioner shall fully document the findings of the history, physical examination and laboratory and/or diagnostic tests in the patient record and shall also indicate the methods and goals of treatment in the patient record;

2) A practitioner shall provide for nutritional counseling, recommendations for behavior modification and appropriate exercise for weight loss, and document such recommendations in the patient record;

3) A practitioner shall obtain written or verbal informed consent from the patient before prescribing, ordering, dispensing, administering, selling or transferring medication, pursuant to the provisions of this subchapter, for the treatment of obesity. The practitioner shall, either verbally or in writing, identify the risks associated with the use of such medications; and

4) (Reserved)

5) A practitioner shall monitor the progress of the patient's weight loss or gain at the time of each of the patient's follow-up visits. The practitioner shall personally, or through a licensed health care practitioner working within his or her lawful scope of practice and acting on the treating practitioner's order or protocol, conduct a physical examination and shall perform laboratory tests as indicated by the clinical evaluation. The findings of the physical examination shall be fully documented in the patient record.

6) (Reserved)

c) Any violations of this section shall be subject to the enforcement provisions of N.J.A.C. 13:35-7.10.

13:35-7.6 LIMITATIONS ON PRESCRIBING, ADMINISTERING OR DISPENSING OF CONTROLLED SUBSTANCES; SPECIAL EXCEPTIONS FOR MANAGEMENT OF PAIN

a) When prescribing, dispensing or administering controlled substances, a practitioner shall ensure that a patient's medical history has been taken and physical examination accomplished, including an assessment of physical and psychological function, underlying or coexisting diseases or conditions, any history of substance abuse and the nature, frequency and severity of any pain. The medical record shall reflect:

1) A recognized medical indication for the use of the controlled substance;

2) The complete name of the controlled substance;

3) The dosage, strength and quantity of the controlled substance; and

4) The instructions as to frequency of use.

b) With respect to Schedule II controlled substances, unless the requirements of (c) below are met, a practitioner shall not authorize a quantity calculated to exceed 120 dosage units or a 30-day supply, whichever is less.

c) A practitioner may exceed the 120 dosage unit or 30-day supply limitations for Schedule II controlled substances in (b) above in the following circumstances:

1) For the 120 dosage unit limitation, the practitioner follows a treatment plan designed to achieve effective pain management, which has been tailored to the needs of a patient who is suffering pain from cancer, intractable pain or terminal illness. The treatment plan shall state objectives by which treatment success is to be evaluated, such as pain relief and improved physical and psychological function, and shall indicate if any further diagnostic evaluations or other treatments are planned. The practitioner shall discuss the risks and benefits of the use of controlled substances with the patient, guardian or authorized representative;

2) With regards to the 30-day supply limitation, a practitioner may prescribe the use of an implantable infusion pump which is utilized to achieve pain management for patients suffering from cancer, intractable pain or terminal illness. A prescription for such an implantable infusion pump may provide up to a 90-day supply, as long as the physician evaluates and documents the patient's continued need at least every 30 days; and

3) With regards to the 30-day supply limitation, a practitioner may prescribe multiple prescriptions authorizing a patient to receive a total of up to a 90-day supply of a Schedule II controlled dangerous substance provided that:

   i) Each separate prescription is issued for a legitimate medical purpose by the practitioner acting in the usual course of professional practice;

   ii) The practitioner provides written instructions on each prescription, other than the first prescription if it is to be filled immediately, indicating the earliest date on which a pharmacy may fill each prescription;

   iii) The practitioner determines that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse; and

   iv) The practitioner complies with all other applicable State and Federal laws and regulations.

d) When controlled substances are continuously prescribed for management of pain for three months or more, the practitioner:

1) Shall review, at a minimum of every three months, the course of treatment, any new information about the etiology of the pain and the patient's progress toward treatment objectives;

2) Shall remain alert to problems associated with physical and psychological dependence; and

3) Shall periodically make reasonable efforts, unless clinically contraindicated, to either stop the use of the controlled substance, decrease the dosage, try other drugs such as nonsteroidal anti-inflammatories, or treatment modalities in an effort to reduce the potential for abuse or the development of physical or psychological dependence.

e) If treatment objectives are not being met, the practitioner:

1) Shall assess the appropriateness of continued treatment with controlled substances or undertake a trial of other drugs or treatment modalities; and

2) Shall consider referring the patient for independent evaluation or treatment in order to achieve treatment objectives.

f) A practitioner shall remain alert to the possibility that controlled substances may be misused or diverted. A practitioner managing pain in a patient with a history of substance abuse shall exercise extra care by way of monitoring, documentation and possible consultation with addiction medicine specialists, and should consider the use of an agreement between the practitioner and the patient concerning controlled substance use and consequences for misuse.

g) The practitioner shall keep accurate and complete records including that information required by (a) above as well as:

1) The medical history and physical examination of the patient;

2) Other evaluations and consultations;

3) Treatment plan objectives;

4) Evidence of informed consent;

5) Treatments and drugs prescribed or provided, as in (a) above;

6) Any agreements with the patient; and

7) Periodic reviews conducted.

13:35-7.7 PROHIBITIONS ON PRESCRIBING, ADMINISTERING OR DISPENSING OF CONTROLLED SUBSTANCES FOR DETOXIFICATION; LIMITED EXCEPTIONS

a) A practitioner shall not issue a prescription for a narcotic drug or for a depressant drug listed in any schedule which drug is intended for the purpose of "detoxification" or "maintenance treatment."

b) Unless registered with the Division of Consumer Affairs to conduct a narcotic treatment program pursuant to N.J.S.A. 24:21-10 and N.J.A.C. 13:45H-11.2, a practitioner shall not dispense or administer a narcotic drug or a depressant drug listed in any schedule which drug is intended for the purpose of "detoxification" or "maintenance treatment," except:

1) To relieve acute withdrawal symptoms, provided that:

i) Such treatment shall not exceed 72 hours;

ii) No more than one day's supply of the drug is provided to the patient at a time; and

iii) Arrangements are made for referring the patient to an addiction specialist or a drug treatment program for treatment; or

2) As an adjunct to other medical or surgical treatment for conditions other than addiction in a licensed health care facility.

13:35-7.8 PROHIBITIONS AND LIMITATIONS IN THE PRESCRIBING, ADMINISTERING OR DISPENSING OF AMPHETAMINES AND SYMPATHOMIMETIC AMINES

a) A practitioner shall not prescribe, order, dispense, administer, sell or transfer any amphetamine or sympathomimetic amine designated as a Schedule II controlled substance for use in weight management, dieting or any other anorectic purpose, or for the treatment of fatigue.

b) A practitioner may prescribe, dispense or administer amphetamine or sympathomimetic amine drugs or compounds designated as Schedule II controlled substances, only as follows:

1) For the treatment of the following conditions:

i) Narcolepsy established by recognized diagnostic criteria;

ii) Idiopathic Central Nervous System Hypersomnia established by recognized diagnostic criteria;

iii) Attention Deficit Disorder established by recognized diagnostic criteria;

iv) Drug-induced brain dysfunction;

v) Epilepsy;

vi) Depression shown to be refractory to other therapeutic modalities; and

vii) Senile apathetic behavior;

2) For immediate use in a hospital for acute conditions such as depression associated with illness or surgery;

3) For the differential diagnostic psychiatric evaluation of depression; or

4) For the clinical investigation of the effects of such drugs or compounds in which case, in addition to other requirements of applicable law, prior application therefor shall have been made to the Board and approval granted before any such investigation is begun.

c) A practitioner, who prescribes, dispenses or administers amphetamines or sympathomimetic amines shall prepare and maintain patient medical records which accurately reflect the utilization of any drug subject to this section, the specific diagnosis, the information upon which the diagnosis is based, including testing and consultations, and the treatment objectives for which the drug is being prescribed.

d) The following list, although not exhaustive or exclusive, includes many of the generic and brand-name Schedule II drugs which are subject to this section:

Adderall
Amphetamine

Desoxyn

Dexedrine

Dextroamphetamine

Methamphetamine

Methylphenidate

Ritalin

13:35-7.9 PROHIBITIONS AND SPECIAL LIMITATIONS ON PRESCRIBING, ADMINISTERING OR DISPENSING ANABOLIC STEROIDS AND HUMAN GROWTH HORMONE OR ITS SIMILAR ANALOGS

a) A practitioner shall not prescribe, order, dispense, administer, sell, or transfer any anabolic steroid or human growth hormone or its similar analogs, unless there is a bona fide relationship with the patient, a medical history has been obtained, and a full physical examination has been performed, establishing a valid medical indication and necessity as provided in (b), (c), or (d) below.

b) Valid medical indication and necessity for human growth hormone or its similar analogs is established when there is:

1. A documented diagnosis of hormonal deficiency causing short stature in children;

2. A record of long-term treatment of growth failure due to lack of endogenous GH secretion;

3. A record of long-term treatment of short stature associated with Turner's syndrome;

4. A documented diagnosis of adult short bowel syndrome;

5. A documented diagnosis of adult deficiency due to pituitary tumors or their treatment or muscle wasting disease associated with HIV/AIDS; or

6. A documented diagnosis of any other medical condition specifically recognized by the U.S. Secretary of Health and Human Services as appropriate for treatment with human growth hormone or its similar analogs.

c) Valid medical indication and necessity for use of anabolic steroids may be established when there is:

1. A documented diagnosis of the condition specified in this paragraph in an adult male patient, associated with a deficiency or absence of endogenous testosterone:

i. Primary hypogonadism (congenital or acquired); or

ii. Hypogonadotropic hypogonadism (congenital or acquired);

2. A record of treatment of delayed puberty in males;

3. A documented need in a female patient for palliative treatment of breast cancer; or

4. A documented diagnosis of a valid medical indication specific to an identified anabolic steroid for the following conditions:

i. AIDS wasting syndrome;

ii. Anemia accompanying renal failure;

iii. Bone marrow failure anemia;

iv. Refractory red cell production anemia;

v. Constitutional delay in growth (androgenic anabolic steroids);

vi. Growth failure in children with growth hormone deficiency (treatment adjunct);

vii. Endometriosis, fibrocystic breast disease, or hereditary angioedema;

viii. Microphallus (androgenic anabolic steroids);

ix. Severe burn injury;

x. Weight loss from cancer chemotherapy; or

xi. Wasting due to prolonged corticosteroid use.

(d) Valid medical indication and necessity for human growth hormone or its similar analogs and anabolic steroids also may be established for use in treatment of conditions other than those identified at (b) and (c) above, only if the practitioner:

1. Obtains and maintains documentation of the receipt of informed consent after the provision of information concerning the risks and benefits of short- and long-term treatment and its less-intrusive alternatives, the consequences of the cessation of treatment, and the financial costs associated with treatment;

2. Obtains and maintains documentation of the appropriate clinical data and laboratory tests undertaken prior to the start of treatment that support the medical indication and necessity; and

3. Provides and maintains documentation of proper follow up at appropriate intervals during the course of treatment and adheres to monitoring protocols consistent with professional standards.

e) A practitioner shall not prescribe, order, dispense, administer, sell, or transfer any anabolic steroid or human growth hormone, or its similar analogs, to any person for the purpose of hormonal manipulation intended to increase muscle mass, strength, stamina, or weight, except as permitted under (b) and (c) above. Body building, muscle enhancement, or increasing muscle bulk or strength through the use of anabolic steroid or human growth hormone by a person in good health for the intended purpose of improving performance in any form of exercise, sport, or game is not a valid medical indication or necessity.

f) The following list, although not exhaustive or exclusive, includes many of the generic and brand-name anabolic steroids and human growth hormones or its similar analogs subject to this section:

Bolenone

Chlorotestosterone(4-chlortestosterone)

Chorionic gonadotropin

Closebol

Dehydrochlormethyltestosterone

Dihydrotestosterone(4-dihydrotesterone)

Ethylestrenol

Fluoxymesterone

Mesterolone

Methandienone

Methandriol

Methandrostenolone

Methenolone

Methyltestosterone

Mibolerone

Nandrolone

Norethandrolone

Oxandrolone

Oxymesterone

Oxymetholone

Somatrem

Somatropin

Stanolone

Stanozolol

Testolactone

Testosterone

Trebolone

13:35-7.10 ENFORCEMENT

a) A violation of N.J.A.C. 13:35-7.1 through 7.9 may be deemed to constitute one or more of the following:

1) Distribution or dispensing of a controlled substance in an indiscriminate manner, or not in good faith, or without good cause, as prohibited by N.J.S.A. 45:1-21(e);

2) Gross or repeated malpractice, neglect, or incompetence in the practice of medicine, as prohibited by N.J.S.A. 45:1-21(c) and (d);

3) Professional misconduct, as prohibited by N.J.S.A. 45:1-21(e);

4) A failure to comply with the provisions of an Act or regulation administered by the Board, as prohibited by N.J.S.A. 45:1-21(h); and

5) Unprofessional conduct, which would present an imminent danger to an individual patient or to the public health, safety or welfare, within the meaning of N.J.S.A. 45:1-37(a).

b) A practitioner, who is in possession of information that reasonably indicates that another practitioner has prescribed, dispensed or administered any drug or drugs in a manner that jeopardizes the public health, safety or welfare or for purposes deemed to be unlawful pursuant to this subchapter shall report such information to the Board pursuant to N.J.S.A. 45:1-37.

SUBCHAPTER 7A.
COMPASSIONATE USE MEDICAL MARIJUANA

13:35-7A.1 PURPOSE AND SCOPE

a) The rules in this subchapter implement certain provisions of the New Jersey Compassionate Use Medical Marijuana Act, P.L. 2009, c. 307.

b) The rules in this subchapter shall apply to physicians who provide certifications and written instructions for patients seeking marijuana for medical use pursuant to rules adopted by the Board and by the Department of Health and Senior Services.

13:35-7A.2 DEFINITIONS

The following words and terms when used in this subchapter shall have the following meanings, unless the context indicates otherwise.

"Bona fide physician-patient relationship" means a relationship in which the physician has ongoing responsibility for the assessment, care and treatment of a patient's debilitating medical condition, consistent with the requirements of N.J.A.C. 13:35-7A.5. For purposes of this definition, "ongoing responsibility" means:

1. The physician-patient relationship has existed for at least one year;

2. The physician has seen and/or assessed the patient for the debilitating medical condition on at least four visits; or

3. The physician assumes responsibility for providing management and care of the patient's debilitating medical condition after conducting a comprehensive medical history and physical examination, including a personal review of the patient's medical record maintained by other treating physicians reflecting the patient's reaction and response to conventional medical therapies.

"Certification" means a statement signed by a physician with whom a patient has a bona fide physician-patient relationship, which attests to the physician's authorization for the patient to be registered to use marijuana.

"Debilitating medical condition" means:

1. One of the following conditions, if resistant to, or if the patient is intolerant to, conventional medical therapy: seizure disorder, including epilepsy; intractable skeletal muscular spasticity; or glaucoma;

2. One of the following conditions, if severe or chronic pain, severe nausea or vomiting, cachexia or wasting syndrome results from the condition or its treatment: positive status for human immunodeficiency virus, acquired immune deficiency syndrome or cancer;

3. Amyotrophic lateral sclerosis, multiple sclerosis, terminal cancer, muscular dystrophy or inflammatory bowel disease, including Crohn's disease;

4. Terminal illness, if the physician has determined a prognosis of less than 12 months of life; or

5. Any other medical condition or its treatment that is approved by the Department of Health and Senior Services by rule.

"Medical use of marijuana" means the acquisition, possession, transport or use of marijuana or paraphernalia by a qualified patient registered with the Department of Health and Senior Services under P.L. 2009, c. 307.

13:35-7A.3 REQUIREMENT FOR PHYSICIAN PARTICIPATION

a) A physician shall provide a certification and written instructions for a patient for the medical use of marijuana only if:

1) The physician holds an active New Jersey license in good standing issued by the Board and possesses an active controlled dangerous substances registration issued by the Division of Consumer Affairs that is not subject to limitation; and

2) The physician has a bona fide physician-patient relationship with the patient.

13:35-7A.4 CERTIFICATION REQUIREMENTS

a) Prior to issuing a certification for the medical use of marijuana, the physician shall have conducted a comprehensive medical history and physical examination of the patient to determine whether the patient suffers from a debilitating medical condition that qualifies the patient to receive marijuana pursuant to N.J.S.A. 24:61-3.

b) The certification shall be signed and dated by the physician and shall attest to the physician's authorization for the patient to be registered with the Department of Health and Senior Services for the medical use of marijuana. If authorized by the Department of Health and Senior Services, the certification shall be electronically transmitted to the Department of Health and Senior Services. The certification shall include the following information:

1) Physician name, address and telephone number;

2) Physician license number and CDS registration number;

3) Patient name, address, telephone number and date of birth;

4) If applicable, caregiver name, address, telephone number and date of birth;

5) Diagnosis of debilitating medical condition; and

6) Any other information required by the Department of Health and Senior Services by rule.

c) Prior to issuing a certification for the medical use of marijuana for a minor patient, a physician shall:

1) Obtain written confirmation from a physician trained in the care of pediatric patients and from a psychiatrist, establishing that, in their respective professional opinions, following review of the minor patient's medical record or examination of the minor patient, the minor patient is likely to receive therapeutic or palliative benefits from the medical use of marijuana to treat or alleviate symptoms associated with his or her debilitating medical condition. If the certifying physician is trained in the care of pediatric patients, he or she shall only be required to obtain written confirmation from a psychiatrist; and

2) Explain the potential risks and benefits of the medical use of marijuana to the minor patient and to a parent, guardian or person having legal custody of the minor patient. Such explanation shall be documented in the minor patient's medical record.

13:35-7A.5 WRITTEN INSTRUCTION REQUIREMENTS; REASSESSMENT; RECORDS

a) A physician may provide written instructions for the medical use of marijuana for a qualified patient registered with the Department of Health and Senior Services, provided the requirements in this section are satisfied. If authorized by the Department of Health and Senior Services, the physician may provide the written instruction by electronic or other means directly to an alternative treatment center on behalf of a registered qualifying patient.

b) The physician's written instructions shall include the following information:

1) Physician name, address and telephone number;

2) Physician license number and CDS registration number;

3) Patient name, address, telephone number, date of birth and registry identification number;

4) If applicable, caregiver name, address, telephone number, date of birth and registry identification number;

5) Name of the permitted alternative treatment center;

6) Quantity of marijuana to be dispensed; and

7) Any other information required by the Department of Health and Senior Services by rule.

c) A physician authorizing the medical use of marijuana shall review, at a minimum of every three months, the course of treatment for the patient's debilitating medical condition, and the patient's progress toward treatment objectives as a result of the use of medical marijuana, including whether the patient is achieving the therapeutic results intended, has developed significant untoward side effects, or is experiencing any physical or psychological problems associated with marijuana use. If the physician determines that the patient is achieving treatment objectives, and is not experiencing untoward side effects or physical or psychological problems associated with marijuana use, the physician may continue the patient's treatment with medical marijuana without alteration.

d) If treatment objectives for the patient's debilitating medical condition are not being met as a result of the use of medical marijuana, or the patient is experiencing untoward side effects or physical or psychological problems associated with marijuana use, the physician shall:

1) Modify the dosage of medical marijuana or mode of delivery authorized, provided the authorized amount does not exceed two ounces in a 30-day period consistent with (g) below, undertake a trial of other drugs or treatment modalities, or discontinue the use of medical marijuana; and

2) Consider referring the patient for independent evaluation or treatment in order to achieve treatment objectives.

e) The physician shall remain alert to the possibility that marijuana may be misused or diverted. A physician issuing written instructions for a patient with a history of substance abuse shall exercise extra care by way of monitoring, documentation and possible consultation with addiction medicine specialists, and should consider the use of an agreement between the physician and the patient concerning the medical use of marijuana and consequences for misuse.

f) The physician shall keep accurate and complete records that include:

1) The medical history and physical examination of the patient;

2) The diagnosis of the debilitating medical condition, including the patient's symptoms and their severity and the patient's reaction and response to conventional medical therapies, which qualify the patient for the medical use of marijuana;

3) Other evaluations and consultations;

4) Treatment plan objectives;

5) Evidence of informed consent. In obtaining informed consent, the physician shall advise the patient about the lack of scientific consensus for the medical use of marijuana, its sedative properties and the risks for addiction;

6) Treatments and other drugs prescribed or provided;

7) Any agreements with the patient; and

8) Periodic reviews conducted.

g) A physician shall not issue written instructions authorizing a patient to receive more than two ounces of marijuana in a 30-day period.

h) A physician may issue multiple written instructions at one time authorizing the patient to receive a total of up to a 90-day supply of marijuana, provided that the following conditions are met:

1) Each separate set of instructions is issued for the treatment of the patient's documented debilitating medical condition;

2) Each separate set of instructions indicates the earliest date on which the alternative treatment center may dispense the marijuana, except for the first dispensation if it is to be filled immediately; and

3) The physician has determined that providing the patient with multiple instructions in this manner does not create an undue risk of diversion or abuse.

i) The physician shall keep a copy of the patient's, or if applicable, the caregiver's registry identification card, in the patient's medical record.

j) If the physician determines that the patient's underlying debilitating medical condition no longer exists or that the patient's continued use of marijuana is no longer appropriate, the physician shall notify the Department of Health and Senior Services of his or her findings.

13:35-7A.6 DUTY TO REPORT INFORMATION TO THE DIVISION

a) A physician shall comply with all requests for information from the Division of Consumer Affairs concerning the issuance of certifications and written instructions for the medical use of marijuana as provided in N.J.A.C. 13:45A-33.

b) Failure on the part of a physician to comply with the requirements of N.J.A.C. 13:45A-33 may subject the physician to disciplinary action pursuant to N.J.S.A. 45:1-21 et seq.

SUBCHAPTER 8.
HEARING AID DISPENSERS

13:35-8.1 PURPOSE

The rules in this subchapter are established pursuant to N.J.S.A. 45:9A-7 and govern the licensing and the practice of hearing aid dispensing in the State of New Jersey.

13:35-8.2 DEFINITIONS

The following words and terms when used in this subchapter shall have the following meaning unless the context clearly indicates otherwise.

"Act" means the New Jersey Hearing Aid Dispensers Act, N.J.S.A. 45:9A-1 et seq. as amended and/or supplemented.

"Advertisement" means any attempt, directly or indirectly, by publication, display, dissemination or circulation, in print or electronic media, which induces or attempts to induce any person to purchase or enter into an agreement to purchase a hearing aid, services and/or merchandise from a licensee.

"Board" means the State Board of Medical Examiners.

"Committee" means the Hearing Aid Dispensers Examining Committee.

"Hearing aid" means a hearing aid as defined by N.J.S.A. 45:9A-2(c) and includes the earmold system.

"Licensee" means any person who has been duly issued a license to fit and dispense hearing aids in accordance with N.J.S.A. 45:9A-1 et seq. and this subchapter.

"Place of practice" means the actual physical location of the office and business address from which the licensee conducts his or her business and where relevant books and records are maintained.

"Sponsor" means any person holding a valid license pursuant to N.J.S.A. 45:9A-1 et seq. for two or more years who is deemed qualified by the Committee to instruct, train and supervise in the requisite skills, methods and techniques so as to insure competency in the fitting and dispensing of hearing aids and who has assumed the responsibilities for supervising and training in accordance with N.J.S.A. 45:9A-16 and the provisions of this subchapter.

"Temporary license" means a temporary license as defined by N.J.S.A. 45:9A-16(a) and the provisions of this subchapter.

"Training permit" means a temporary license as defined by N.J.S.A. 45:9A-16(b) and the provisions of this subchapter.

13:35-8.3 TRAINING AND EXPERIENCE REQUIREMENTS

a) An applicant for licensure as a hearing aid dispenser shall submit one of the following to the Committee:

1) Proof of completion of a minimum of six months continuous or interrupted training within a 24-month period ending with the deadline for making application to take the next examination;

2) Proof of successful completion of a college curriculum in hearing aid selection and fitting approved by the Committee and/or the Commission on Higher Education; or

3) Proof of successful completion of a master's degree in audiology from an American Speech Language Hearing Association accredited college or university after January 1, 1993.

b) An individual, including a New Jersey licensed audiologist, who has met training and experience requirements set forth in (a) above shall not dispense a hearing aid as defined by N.J.A.C. 13:35-8.8 until he or she passes the written and practical examination administered by the Committee, unless the individual is under supervision as the holder of a training permit or a temporary license.

c) No person shall commence training as a hearing aid dispenser until such time as he or she has received a training permit. The training period shall be calculated to have commenced on the date the permit is issued.

d) Upon being issued a training permit, the trainee shall train in the same office or business location as that of his or her sponsor and in the physical presence of the sponsor. The training shall consist of the following:

1) 40 hours of training with an audiometer;

2) 160 hours of hearing aid dispensing procedures, including the taking of earmold impressions, the alteration of earmolds and hearing aids, and application and fitting techniques;

3) Reading all the books and articles relating to hearing aid dispensing specified in a list formulated by the Committee.

e) No trainee shall be permitted to sell, fit or dispense hearing aids or to engage in the potential fitting or dispensing of hearing aids except in the same office or business location of his or her sponsor and in the physical presence of the sponsor.

f) A trainee shall complete the training only with the sponsor designated by the Committee and only during regular business hours.

13:35-8.4 TRAINING PERMITS; ISSUANCE AND PRACTICE

The Committee shall issue a training permit in accordance with N.J.S.A. 45:9A-16(b) and the provisions of this subchapter.

13:35-8.5 TEMPORARY LICENSES; ISSUANCE

a) The Committee may issue a temporary license in accordance with N.J.S.A. 45:9-16(a) and the provisions of this subchapter to an applicant provided he or she has not previously held a training permit or has not previously taken the licensing examination described in N.J.S.A. 45:9A-10 and N.J.A.C. 13:35-8.17. A temporary license shall not be

renewed when an applicant has failed the licensing examination, except on showing of good cause (such as illness or emergency precluding the taking of the examination).

b) Persons from another jurisdiction who are not eligible for license by endorsement under N.J.S.A. 45:9A-13 who wish to sit for the licensing examination shall demonstrate a minimum of two years of full-time independent experience in dispensing, fitting and selling hearing aids as defined by N.J.S.A. 45:9A-2(d) and N.J.A.C. 13:35-8.8. The applicant must submit documentation and verification of said experience satisfactory to the Committee, or submit verification of current licensure to practice audiology in the State of New Jersey.

c) Applicants may be interviewed by the Committee, at which time their education, training and experience will be examined. Where an applicant's documentation of education, training and experience appears unsatisfactory, the Committee may deny a temporary license, but may permit the applicant to sit for the next licensing examination.

13:35-8.6 TEMPORARY LICENSES; PRACTICE

a) A temporary licensee shall spend a minimum of 20 days in the office or business location of his or her sponsor within any 60-day period.

b) A temporary licensee shall not maintain an independent office or a place of business for the purpose of dispensing hearing aids, but shall at all times operate in the sponsor's office in a manner consistent with the ability of his or her sponsor to provide responsible supervision.

c) No temporary licensee shall complete a sale of hearing aids without the physical presence of his or her sponsor, and without obtaining the sponsor's signature on the purchase agreement.

d) Every temporary licensee shall submit a daily written report of his or her activities to his or her sponsor which shall be retained as part of the permanent records.

e) Upon submitting an application for a license, every temporary licensee shall submit an affidavit from his or her sponsor attesting to the supervision requirements of N.J.S.A. 45:9A-1 et seq. and this subchapter.

f) Upon request, all records shall be made available to the Committee for its review and evaluation.

13:35-8.7 SPONSORS

a) Every trainee and temporary licensee shall be supervised and trained by a sponsor who has fulfilled the requirements of N.J.S.A. 45:9A-16 and the provisions of this subchapter.

b) In addition, a sponsor shall:

1) Supervise at any one time no more than a total of two persons who may be temporary licensees and/or permit holders;

2) Be present in the same physical location for purposes of training and supervision;

3) Not pre-sign purchase agreements;

4) Maintain a daily log for each day of supervision and training as part of the permanent record;

5) Provide an affidavit attesting to the supervision requirements of N.J.S.A. 45:9A-1 et seq. and this subchapter; and

6) Notify the Committee within five days of any termination in the sponsorship arrangement, stating the reasons therefor.

13:35-8.8 SCOPE OF PRACTICE

a) The practice of fitting a hearing aid as defined by N.J.S.A. 45:9A-2(d) shall include:

1) The evaluation or measurement of the power or range of human hearing utilizing customary and appropriate instrumentation available in the field;

2) The making of an ear impression;

3) Pursuant to N.J.A.C. 13:35-8.9, the fitting and dispensing of a deep ear canal hearing aid device that requires an impression taking technique involving instruments applied to the tympanic membrane;

4) The cleaning, change of design or alteration of an earmold (including tubing);

5) The change of frequency response of any instrument;

6) The selection or adaptation of a hearing aid; and

7) The interpretation and evaluation of hearing tests and the physical examination of a person's ear, where such interpretation, evaluation or examination is used in conjunction with the dispensing of a hearing aid.

b) The practice of dispensing a hearing aid as defined by N.J.S.A. 45:9A-2(d) shall include the sale, rental or lease of hearing aids, the evaluation of the necessity for repair of a hearing aid, and the delivery after repair.

c) The practice of fitting and dispensing a hearing aid shall include any activity which reasonably may be expected to result in the sale of a hearing aid, including but not limited to canvassing, counseling, 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.

13:35-8.9 FITTING AND DISPENSING OF DEEP EAR CANAL HEARING AID DEVICES

a) A licensee may fit and dispense a deep ear canal hearing aid device that requires an impression taking technique involving instruments applied against the tympanic membrane, provided that the licensee advises the Committee, on a form provided by the Committee, of the name and address of a Board-certified ENT physician licensed in this State who has agreed to be constantly accessible through electronic communications during the impression taking process and who is available to render immediate in-person assistance when required.

b) The licensee shall not initiate the impression taking process unless the licensee has ensured that a physician is available as required by (a) above and that the consumer has, within seven days prior to the impression taking process, received a medical evaluation from an ENT physician licensed in the State. The physician's evaluation shall determine whether a deep ear canal hearing aid device may be safely and effectively worn by the consumer and shall be documented by written medical clearance, which the licensee shall place in the consumer's patient records.

c) The licensee shall immediately refer any consumer who develops any complications during the impression taking or fitting process to the physician identified in (a) above or to a physician selected by the consumer.

d) The licensee shall refer the consumer, following the impression taking process, to the physician who performed the pre-impression taking evaluation or to another plenary physician licensed in the State and shall secure a written evaluation regarding the placement of the deep ear canal hearing aid device and the consumer's continuing ability to safely and effectively wear the device.

e) The licensee shall maintain documentation of the evaluations required pursuant to subsection (b) and (d) above consistent with the provisions of N.J.A.C. 13:35-6.5(b).

13:35-8.10 SUPERVISING LICENSEE

a) Every corporation, partnership, trust, association or unincorporated business entity operating for the purpose of fitting and dispensing hearing aids shall designate a duly licensed hearing aid dispenser to act as a supervising licensee.

b) All such businesses shall file annually with the Committee the name and license number of the designated supervising licensee.

c) The supervising licensee shall be responsible for assuring that all records are maintained in accordance with N.J.A.C. 13:35-8.16.

13:35-8.11 NOTIFICATION TO THE COMMITTEE; BIENNIAL LICENSE RENEWAL; LICENSE SUSPENSION; REINSTATEMENT OF SUSPENDED LICENSE; INACTIVE STATUS; RETURN FROM INACTIVE STATUS

a) Every licensee shall notify the Committee of any change of residence or place of practice within seven days following such change.

b) Every licensee, temporary licensee or trainee whose license or permit has expired or has been terminated shall return the license or permit to the Committee office within five days of such invalidation.

c) All licenses issued by the Committee shall be issued for a two-year biennial licensure period. A licensee who seeks renewal of the license shall submit a renewal application and the renewal fee set forth in N.J.A.C. 13:35-8.19 prior to the expiration date of the license.

d) The Board shall send a notice of renewal to each licensee at the address registered with the Board at least 60 days prior to the expiration of the license. If the notice to renew is not sent at least 60 days prior to the expiration date, no monetary penalties or fines shall apply to the holder for failure to renew.

e) If a licensee does not renew the license prior to its expiration date, the licensee may renew the license within 30 days of its expiration by submitting a renewal application, a renewal fee and a late fee, as set forth in N.J.A.C. 13:35-8.19. During this 30-day period, the license shall be valid, and the licensee shall not be deemed to be practicing without a license.

f) A license that is not renewed within 30 days of its expiration shall be automatically suspended. An individual who continues to practice with a suspended license shall be deemed to be engaged in unlicensed practice.

g) A licensee whose license has been automatically suspended for five years or less for failure to renew pursuant to (f) above may be reinstated by the Committee upon completion of the following:

1) Payment of the reinstatement fee and all past delinquent biennial renewal fees pursuant to N.J.A.C. 13:35-8.19;

2) Completion of the continuing education units required for each biennial registration period for which the licensee was suspended; and

3) Submission of an affidavit of employment listing each job held during the period of suspended license which includes the name, address, and telephone number of each employer.

h) In addition to the fulfilling the requirements set forth in (g) above, a licensee whose license has been automatically suspended for more than five years who wishes to return to the dispensing of hearing aids shall reapply for licensure and shall demonstrate that he or she has maintained proficiency. An applicant who fails to demonstrate to the satisfaction of the Committee that he or she has maintained proficiency while suspended may be subject to an examination or other requirements as determined by the Committee prior to reinstatement of his or her license.

i) Renewal applications shall provide the licensee with the option of either active or inactive status. A licensee electing inactive status shall pay the inactive license fee set forth in N.J.A.C. 13:35-8.19 and shall not engage in the dispensing of hearing aids.

j) A licensee who elected inactive status and has been on inactive status for five years or less may be reinstated by the Committee upon completion of the following:

1) Payment of the reinstatement fee;

2) The completion of the continuing education units required for each biennial registration period for which the licensee was on inactive status; and

3) Submission of an affidavit of employment listing each job held during the period the licensee was on inactive status which includes the name, address, and telephone number of each employer.

k) In addition to the fulfilling the requirements set forth in (j) above, a licensee who has been on inactive status for more than five years who wishes to return to the dispensing of hearing aids shall reapply for licensure and shall demonstrate that he or she has maintained proficiency. An applicant who fails to demonstrate to the satisfaction of the Committee that he or she has maintained proficiency while on inactive status may be subject to an examination or other requirements as determined by the Committee prior to reinstatement of his or her license.

13:35-8.12 EQUIPMENT

a) The equipment necessary to dispense hearing aids in accordance with N.J.S.A. 45:9A-1 et seq. and the provisions of this subchapter shall be available for use at all place(s) of practice.

b) All electrical equipment used in testing hearing aids including the audiometer shall be inspected as often as necessary to assure accuracy and calibrated no less often than once a year. Audiometers shall be calibrated in accordance with the American National Standard Specifications for Audiometers (ANSI S3.6-1969) and the American National Standard for an Artificial Head Bone for the Calibration of Bone Vibrations (ANSI S3.13-1972). Complete records of calibration shall be maintained as part of the licensee's permanent records.

13:35-8.13 HEARING TESTING

a) No hearing aid shall be sold to a person who has not first been given a hearing examination, within the previous six months, 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.

13:35-8.14 ADVERTISING AND SOLICITATION

a) Any licensee who engages in the use of advertising, stationery, business cards or signs which contain any of the following shall be deemed to have committed professional misconduct in violation of N.J.S.A. 45:1-21:

1) Any statement, claim or format which is false, fraudulent, misleading or deceptive;

2) Any misrepresentation of material fact;

3) Any omission or concealment of material fact, under circumstances where a licensee knows or should know that the omission is improper or is likely to hamper a customer from making a full and informed judgment on the basis of the information set forth;

4) Any claim that the service performed or the materials used are superior to that which is ordinarily performed or used in the business unless such claim can be documented as truthful and not misleading;

5) A technique or communication which appears to intimidate, exert undue pressure or undue influence on a customer;

6) The use of terms such as "prescription made" and "certified hearing aid audiologist" or "audiologist," unless the person to whom reference made is a licensed audiologist as defined by N.J.S.A. 45:3B-2(a);

7) The use of any term that connotes a medical competence that does not exist; or

8) The use of the name of a temporary licensee or trainee in an advertisement, sign, stationery or business card.

b) The name, license number and title designation ("Hearing Aid Dispenser") of the supervising licensee shall appear on every advertisement, stationery or business card. The name and title designation of the supervising licensee shall appear on every sign.

c) The responsibility for the form and content of every advertisement, sign, stationery or business card shall be jointly and severally that of each licensee who is a principal, partner or officer of the firm or entity so identified as well as the supervising licensee whose name and license number is displayed therein.

d) It shall be professional misconduct for a licensee to visit the home or office of a potential customer for the purpose of inducing a sale of a hearing aid without having obtained the express prior consent of such potential customer.

13:35-8.15 ABANDONMENT; EXCESSIVE FEES

a) It shall be professional misconduct for a licensee to unilaterally terminate without good cause as determined by the Committee, an agreement to deliver service(s) and/or equipment to a customer without first making arrangements for the orderly continuation of said services and/or equipment delivery.

b) It shall be professional misconduct for any licensee to demand or accept excessive fees for service(s) or equipment rendered in connection with the sale or fitting of hearing aids. The excessiveness of such fee shall be determined by the Committee based on whether, after a review of the facts, a reasonable person would be left with a definite and firm conviction that the fee is so high as to be manifestly unconscionable or overreaching under the circumstances and as further described in N.J.A.C. 13:35-6.11(c).

13:35-8.16 ITEMIZATION OF SERVICES AND EQUIPMENT; RETENTION OF RECORDS

a) In addition to the written specified data and receipt requirements defined in N.J.S.A. 45:9A-23, a written itemization of the costs of all services and equipment shall be presented to a customer before dispensing a hearing aid. The itemization shall include all services and equipment including:

1) Hearing test and examination of the ear;

2) Fitting of an earmold;

3) Dispensing services;

4) Necessary cleaning, servicing and refitting for at least the first year following sale;

5) The cost of the earmold; and

6) The cost of the hearing aid.

b) Every licensee shall prepare and retain a copy of all records including the itemization for a period of seven years following the sale.

c) Every licensee shall obtain and maintain a medical waiver or medical clearance in accordance with applicable federal law.

d) Every licensee shall designate his or her name or initials and license number and the date the service was rendered on all records maintained for the purpose of fitting or dispensing hearing aids.

e) Every licensee shall make available upon the request of the Committee any and all records maintained for the purpose of fitting or dispensing hearing aids. Every customer or authorized representative of the customer shall be promptly given a copy of his or her own record as described in N.J.A.C. 13:35-6.5.

13:35-8.17 LICENSING EXAMINATION

a) The licensing examination shall consist of a written and practical examination in accordance with N.J.S.A. 45:9A-11.

b) The written examination shall consist of two sections, one section relating to theory and knowledge about fitting and dispensing hearing aids and the other section testing knowledge relating to the laws and regulations governing the practice of fitting and dispensing hearing aids.

1) In order to pass the licensing examination the candidate shall attain a passing score as determined by the examining agency on the written section of the examination relating to theory and knowledge about fitting and dispensing hearing aids and a score of 70 or greater on the written section of the examination relating to laws and regulations.

2) Candidates who fail all or any section of the written examination shall be required to sit for the entire licensing examination during the next regularly scheduled

examination with one exception: candidates failing only the law and regulation section may be admitted to a re-examination for this section only.

c) In order to pass the practical examination, a candidate shall attain a passing grade on each part of the practical examination. A candidate shall be eligible to 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 except for the re-examination of the law and regulation section.

13:35-8.18 VIOLATION OF THE RULES

a) Failure to comply with any provision of N.J.S.A. 45:9A-1 et seq., or this subchapter shall be deemed a violation of the Hearing Aid Dispensers Act and may result in disciplinary action pursuant to N.J.S.A. 45:1-21 and 45:1-22.

b) The notice of proposed suspension or revocation shall inform the licensed individual of the right to request a hearing. The hearing shall be pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and 52:14F-1 et seq. and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1-1 et seq.

13:35-8.19 FEE SCHEDULE

a) The fee schedule for the Hearing Aid Dispensers Examining Committee of the State Board of Medical Examiners, in the Division of Consumer Affairs in the Department of Law and Public Safety, shall be as follows:

1) Application fee .....$50.00 (non-refundable)

2) Temporary licenses..... $50.00

3) Training permits $50.00

4) Examination

i) Written $50.00

ii) Practical $25.00

5) Initial License Fee

i) If paid during the first year of a biennial renewal period $180.00

ii) If paid during the second year of a biennial renewal period $90.00

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 license renewal..... $180.00

8) Renewal or Extension of Temporary License and Training Permit $20.00

9) Late fee $50.00

10) Reinstatement, Biennial License $100.00

11) Inactive license fee ..... (to be determined by the Director by regulation)

12) Duplicate or replacement of biennial registration certificate..... $25.00

13) 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.

13:35-8.20 LICENSE RENEWAL; CONTINUING EDUCATION REQUIREMENT

a) No license renewal shall be issued by the Director unless the applicant confirms on his or her renewal application to the Hearing Aid Dispensers Examining Committee that during the two calendar years preceding application for renewal he or she participated in

courses of continuing education of the type and number of credits specified in this section. Such continuing education is a mandatory requirement for license renewal. Licensees shall be solely responsible for obtaining and maintaining documentation on his or her completion of the required continuing education courses during the registration period. Such documentation shall be submitted to the Committee upon request, and will be surveyed on a random basis. The provisions of this 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 International Hearing Society (IHS), and the Committee. A licensee who completes a three or more credit course in hearing aid dispensing at an accredited college or university shall upon the approval of the Committee 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.

SUBCHAPTER 9.
ACUPUNCTURE

13:35-9.1 PURPOSE AND SCOPE

a) The rules of this subchapter are established pursuant to N.J.S.A. 45:2C-1 et seq. ("The Acupuncture Act") and set forth requirements for the practice of acupuncture in the State of New Jersey.

b) These rules shall apply to all persons certified as acupuncturists by the State of New Jersey, applicants for such certification, guest acupuncturists granted temporary permission by the Board to perform acupuncture pursuant to N.J.A.C. 13:35-9.13,

students participating in an approved course of study, school or tutorial program in acupuncture and persons licensed in New Jersey as physicians or dentists who practice acupuncture, provided that their courses of training have included acupuncture.

13:35-9.2 DEFINITIONS

For purposes of this subchapter, the following terms shall have the following meanings:

"ACAOM" means the Accreditation Commission for Acupuncture and Oriental Medicine.

"Acupuncture" means the practice of Oriental medicine based on traditional Oriental medical theories, including stimulation of a certain point or points on or near the surface of the body by the insertion of special needles to prevent or modify the perception of pain or to normalize physiological functions including pain control and for the treatment of diseases or dysfunctions of the body. "Acupuncture" includes the techniques electroacupuncture, mechanical stimulation, adjunctive therapies, and moxibustion.

"Acupuncture program" means a course of study in acupuncture that is at least three years long and which is in addition to and separate from a baccalaureate degree program.

"Acupuncturist" means an individual licensed by the Board to perform acupuncture services.

"Adjunctive therapies" means those practices taught in ACAOM-approved schools and through NCCAOM-approved continuing education courses that are complementary to the performance of acupuncture.

"Baccalaureate Degree" means a bachelor degree granted upon the conclusion of a program that consists of at least 120 credits by a college or university that is accredited by a regional accreditation agency recognized by the Council for Higher Education Accreditation (CHEA) or the United States Department of Education.

"Board" means the Acupuncture Examining Board established by N.J.S.A. 45:2C-1 et seq.

"Electroacupuncture" means the therapeutic use of weak electric currents at acupuncture loci to diagnose or to treat diseases or conditions.

"Glandulars" means non-prescriptive supplements that are derived from glands.

"Gua sha" means scraping applied to the surface of the skin with a round edged tool for therapeutic purposes.

"Guest acupuncturist" means an individual legally authorized to perform acupuncture services in another state or in another country, who is not a certified acupuncturist in this State and who is permitted to perform acupuncture services pursuant to N.J.A.C. 13:35-9.14.

"Herbology" means the administration or recommendation of botanical, mineral, or animal substances, and includes prepared and raw forms of single herbs or formulas, and dietary supplements that incorporate herbs as ingredients. "Herbology" does not include the injection of herbs.

"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.

"NCCAOM" means the National Certification Commission for Acupuncture and Oriental Medicine.

"Oriental dietary therapy" means dietary and nutritional counseling and the recommendation of foods for therapeutic purposes.

"Oriental medicine" means a whole medical system originating in East Asia that aims to treat disease and support the body's ability to heal itself with a diverse range of traditional and modern therapeutic interventions.

"Qigong" means breathing techniques and exercises that promote health.

"Sterilize" or "sterilization" means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

"Surface stimulation" means the application of purposeful stimuli to the surface of the body.

"Tuina" means a form of massage therapy based on traditional Oriental medical theories using or incorporating traction, manipulation of acupressure points, acupoint stimulation, and joint mobilization for therapeutic purposes.

13:35-9.3 CREDENTIALS REQUIRED FOR CERTIFICATION

a) At the time of application, an applicant shall submit to the Board:

1) A completed application form;

2) Legal proof of having attained the age of 21, evidenced by a document issued by a governmental agency;

3) Proof that the person has passed the English version of each of the following modules of the NCCAOM examination:

i) Foundations of Oriental Medicine;

ii) Acupuncture;

iii) Point Location; and

iv) Biomedicine;

4) If an applicant's entire education (high school, college or university and acupuncture program) was conducted in a language other than English, proof that the applicant has achieved a passing score on the Test of English as a Foreign Language (TOEFL) examination; and

5) Proof that the applicant has completed the education requirements of N.J.A.C. 13:37-9.4.

b) An applicant who passed the NCCAOM examination prior to January 1, 2003 shall submit proof that he or she has passed the NCCAOM biomedicine module.

c) Any credentials required to be submitted pursuant to (a) above, which are written in a language other than English shall be accompanied by an English translation prepared at the applicant's expense. A list of translation services shall be provided by the Board to an applicant upon request.

13:35-9.4 EDUCATION REQUIRED FOR LICENSURE

a) In order to qualify for licensure, an applicant shall meet one of the following education requirements:

1) Obtain a baccalaureate degree from a school within the United States and graduate from an acupuncture program, which meets the requirements of (e) below; or

2) Obtain the equivalent of a baccalaureate degree from a school in another country and complete either:

i) An acupuncture program, which meets the requirements of (e) below in the United States; or

ii) An acupuncture program that is part of the baccalaureate degree program or its equivalent in another country.

b) An individual who obtains his or her education in the United States shall submit proof that he or she has obtained a baccalaureate degree. An applicant shall arrange for the college or university to submit a certified transcript directly to the Board.

c) An individual who obtains his or her education in another country shall arrange for a transcript evaluating company recognized by NCCAOM to submit a credential evaluation directly to the Board.

d) The credential evaluation required by (c) above shall demonstrate that the applicant obtained a degree:

1) That is equivalent to a combined baccalaureate degree and an acupuncture program from a college or university in another country that is accredited in that country;

2) That is equivalent to a masters degree or doctoral degree for which a baccalaureate degree or its equivalent was a prerequisite, and an acupuncture program from a college in another country that is accredited in that country;

3) From a college or university in another country that is equivalent to a baccalaureate degree. The college or university shall be accredited in the other country. An applicant who qualifies for certification by this method shall submit proof that he or she completed an acupuncture program in the United States that complies with (e) below; or

4) From a college in another country that is equivalent to a masters degree or doctoral degree for which a baccalaureate degree or its equivalent was a prerequisite. The college or university shall be accredited in the other country. An applicant who qualifies for certification by this method shall submit proof that he or she completed an acupuncture program in the United States that complies with (e) below.

e) An acupuncture program that is required for licensure shall be given by a school accredited by the Accreditation Commission for Acupuncture and Oriental Medicine, the Commission on Recognition of Post-Secondary Accreditation, or the United States Department of Education. A list of accredited acupuncture schools shall be maintained by the Board and provided to an applicant upon request. An applicant shall arrange for the school of acupuncture to submit a certified transcript confirming that a diploma was awarded to the applicant directly to the Board.

f) Commencing June 21, 2014, the acupuncture program required by (e) above shall consist of at least 2,500 hours of instruction.

g) Any credentials required to be submitted pursuant to (a), (b) or (d) above, which are written in a language other than English shall be accompanied by an English translation prepared at the applicant's expense. A list of translation services shall be provided by the Board to an applicant upon request.

13:35-9.5 NEW JERSEY ACUPUNCTURE SAFETY AND JURISPRUDENCE EXAMINATION

a) An applicant shall pass the acupuncture safety and jurisprudence examination in English administered by the Board.

b) An applicant shall complete all of the requirements set forth in N.J.A.C. 13:35-9.3 before he or she may take the Board administered acupuncture safety and jurisprudence examination.

c) An applicant who has passed the acupuncture safety and jurisprudence examination shall become licensed within six months of passing the examination. If an applicant fails to become licensed within the six months, he or she shall be required to retake and pass the examination before being issued a license.

13:35-9.6 (RESERVED)

13:35-9.7 PROHIBITED TITLES

a) An acupuncturist shall not represent that he or she has a doctoral degree in the field of acupuncture and/or oriental medicine, or use the title "doctor" of "Dr.," unless the educational program that awarded his or her degree is:

1) Approved by the Accreditation Commission of Acupuncture and Oriental Medicine (ACAOM) or is a college or university that is accredited by an regional accrediting agency recognized by the Council for Higher Education Accreditation (CHEA) or the United States Department of Education; or

2) Approved by the ministry of education of a foreign country to grant doctoral degrees.

b) An acupuncturist who uses the title "doctor" or "Dr." pursuant to (a) above shall indicate that the doctoral degree is in acupuncture and/or oriental medicine.

c) An acupuncturist shall not represent that he or she has a master's degree in the field of acupuncture and/or oriental medicine unless the educational program that awarded his or her degree is:

1) Approved by the Accreditation Commission of Acupuncture and Oriental Medicine (ACAOM) or is a college or university that is accredited by an regional accrediting agency recognized by the Council for Higher Education Accreditation (CHEA) or the United States Department of Education; or

2) Approved by the ministry of education of a foreign country to grant master's degrees.

d) An acupuncturist who has a doctoral or master's degree in a field other than acupuncture and/or oriental medicine may, in advertising or other materials visible to the public pertaining to the acupuncturist's practice, include this degree provided that the field in which the degree was awarded is specified without using an abbreviation and the doctoral or master's degree was obtained from an educational program, which meets the requirements of (a) or (c) above.

e) An acupuncturist who has a doctorate in a field other than acupuncture or oriental medicine shall not use the title "doctor" in advertising or other materials visible to the public pertaining to the acupuncturist's acupuncture practice.

13:35-9.8 FEE SCHEDULE; REFUNDS

a) The Board shall charge the following fees:

1) Application Fee $100.00

2) Initial Certification Fee

i) If paid during the first year of a biennial renewal period $270.00

ii) If paid during the second year of a biennial renewal period $135.00

3) Biennial Certification $270.00

4) Duplicate or replacement of biennial certificate $25.00

5) Late Fee (biennial certification) $50.00

6) Inactive Certificate Fee ..... (to be determined by Director by regulation)

7) Reinstatement Fee $150.00

8) 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

9) Preparation of certification papers for applicants to other states $25.00

10) Continuing education sponsor fee $100.00

b) The application fee is non-refundable.

13:35-9.9 BIENNIAL LICENSE RENEWAL; LICENSE SUSPENSION; REINSTATEMENT OF SUSPENDED LICENSE; INACTIVE STATUS; RETURN FROM INACTIVE STATUS

a) All licenses to practice acupuncture issued by the Board shall be issued for a two-year biennial licensure period. A licensee who seeks renewal of the license shall submit a renewal application and the renewal fee set forth in N.J.A.C. 13:35-9.8 prior to the expiration date of the license.

b) The Board shall send a notice of renewal to each licensee at the address registered with the Board at least 60 days prior to the expiration of the license. If the notice to renew is not sent at least 60 days prior to the expiration date, no monetary penalties or fines shall apply to the holder for failure to renew.

c) If a licensee does not renew the license prior to its expiration date, the licensee may renew the license within 30 days of its expiration by submitting a renewal application, a renewal fee, and a late fee, as set forth in N.J.A.C. 13:35-9.8. During this 30-day period, the license shall be valid, and the licensee shall not be deemed to be engaged in unauthorized practice.

d) A license that is not renewed within 30 days of its expiration shall be automatically suspended. An individual who continues to practice with a suspended license shall be deemed to be engaged in unauthorized practice.

e) A licensee whose license has been automatically suspended for five years or less for failure to renew pursuant to (d) above may be reinstated by the Board upon completion of the following:

1) Payment of the reinstatement fee and all past delinquent biennial renewal fees pursuant to N.J.A.C. 13:35-9.8;

2) Completion of the continuing education units required for each biennial registration period for which the license was suspended; and

3) Submission of an affidavit of employment listing each job held during the period of the suspended license, which includes the name, address, and telephone number of each employer.

f) In addition to the fulfilling the requirements set forth in (e) above, a licensee whose license has been automatically suspended for more than five years who wishes to have his or her license reinstated shall reapply for licensure and shall demonstrate that he or she has maintained proficiency. An applicant who fails to demonstrate to the satisfaction of the Board that he or she has maintained proficiency while suspended may be subject to an examination or other requirements as determined by the Board prior to reinstatement of his or her license.

g) Renewal applications shall provide the licensee with the option of either active or inactive status. A licensee electing inactive status shall pay the inactive license fee set forth in N.J.A.C. 13:35-9.8 and shall not engage in the practice of acupuncture.

h) A licensee who elected inactive status and has been on inactive status for five years or less may be reinstated by the Board upon completion of the following:

1) Payment of the reinstatement fee;

2) The completion of the continuing education units required for each biennial registration period for which the licensee was on inactive status; and

3) Submission of an affidavit of employment listing each job held during the period the licensee was on inactive status, which includes the name, address, and telephone number of each employer.

i) In addition to the fulfilling the requirements set forth in (h) above, a licensee who has been on inactive status for more than five years who wishes to return to practice shall reapply for licensure and shall demonstrate that he or she has maintained proficiency. An applicant who fails to demonstrate to the satisfaction of the Board that he or she has maintained proficiency while on inactive status may be subject to an examination or other requirements as determined by the Board prior to reinstatement of his or her license.

13:35-9.10 DISPLAY OF LICENSE

A licensed acupuncturist shall post his or her license in a conspicuous location in his or her office. If a licensed acupuncturist has more than one office, he or she shall obtain from the Board a duplicate license for each location.

13:35-9.11 INFORMED CONSENT; MEDICAL MALPRACTICE

a) The acupuncturist shall fully disclose to the patient such information as will enable the patient to make an evaluation of the nature of the treatment and of any attendant risks, as well as of available alternative options and the risks and likely outcomes of those alternatives. The acupuncturist shall obtain, and maintain as part of his or her patient records, informed written consent from the patient before beginning acupuncture treatment.

b) A licensed acupuncturist shall advise every patient as to the importance of consulting with a licensed physician regarding the patient's condition.

c) A licensed acupuncturist shall maintain as part of his or her patient records a form, with the date and the signatures of the patient and the licensed acupuncturist, indicating that the licensed acupuncturist has advised the patient as required under (b) above and shall provide a copy of this form to the patient.

d) Licensed acupuncturists shall maintain medical malpractice insurance in the sum of $ 1 million per occurrence and $ 3 million per policy year.

13:35-9.12 SCOPE OF PRACTICE

a) The use of any of the following to effect the stimulation of acupuncture points and channels is within the scope of practice of licensed acupuncturists and shall be performed only by acupuncturists licensed by the Board, individuals permitted to practice pursuant to N.J.S.A. 45:2C-8, students in acupuncture programs that meet the requirements of N.J.A.C. 13:35-9.4(e), or guest acupuncturists permitted to perform acupuncture in New Jersey pursuant to N.J.A.C. 13:35-9.13:

1) Needles;

2) Moxibustion;

3) Teishin (pressure needles); and

4) Electroacupuncture (utilizing electrodes on the surface of the skin or current applied to inserted needles).

b) Licensed acupuncturists, individuals permitted to practice pursuant to N.J.S.A. 45:2C-8, students in acupuncture programs that meet the requirements of N.J.A.C. 13:35-9.4(e), or guest acupuncturists permitted to perform acupuncture in New Jersey pursuant to N.J.A.C. 13:35-9.13 may, in addition to the methods listed in (a) above, use any of the following as part of his or her professional practice:

1) Acupatches;

2) Acuform;

3) Manual acutotement (stimulation by an instrument that does not pierce the skin);

4) Acupressure;

5) Cupping;

6) Gua sha scraping techniques;

7) Cold laser used for needle-less acupuncture;

8) Tuina;

9) Massage, bodywork and somatic therapy;

10) Ultrasonic;

11) Thermal methods;

12) Magnetic stimulation;

13) Breathing techniques;

14) Therapeutic exercise and techniques;

15) Oriental dietary therapy;

16) Lifestyle and behavioral education;

17) Percutaneous and transcutaneous electrical nerve stimulation;

18) Qigong;

19) Biofeedback and other devices that utilize color, light, sound, and electromagnetic energy for therapeutic purposes;

20) Diagnostic and assessment techniques that are taught in ACAOM-approved schools and through NCCAOM-approved continuing education courses and which assist in acupuncture and Oriental medicine diagnosis, corroboration, and monitoring of a treatment plan or in making a determination to refer a patient to another healthcare provider;

21) Taiji; and

22) Energetic therapy.

c) Licensed acupuncturists, individuals permitted to practice pursuant to N.J.S.A. 45:2C-8, students in acupuncture programs that meet the requirements of N.J.A.C. 13:35-9.4(e), or guest acupuncturists permitted to perform acupuncture in New Jersey pursuant to N.J.A.C. 13:35-9.13 may recommend to patients the use of:

1) Meditation; and

2) Products that facilitate health, such as:

i) Homeopathic medicine that is recognized in the official Homeopathic Pharmacopoeia of the United States;

ii) Vitamins;

iii) Minerals;

iv) Enzymes;

v) Glandulars;

vi) Amino acids;

vii) Nonprescription substances; and

viii) Nutritional or dietary supplements that meet Food and Drug Administration labeling requirements, 21 CFR 101.36, unless otherwise prohibited by State or Federal law.

d) Licensed acupuncturists, individuals permitted to practice pursuant to N.J.S.A. 45:2C-8, students in acupuncture programs that meet the requirements of N.J.A.C. 13:35-9.4(e),

or guest acupuncturists permitted to perform acupuncture in New Jersey pursuant to N.J.A.C. 13:35-9.13 may use the following when providing acupuncture:

1) Solid filiform needles;

2) Dermal needles;

3) Plum blossom needles;

4) Intradermal/press needles;

5) Prismatic needles;

6) Lancets; and

7) Non-insertive pressure needles.

e) Licensed acupuncturists, students in acupuncture programs that meet the requirements of N.J.A.C. 13:35-9.4(e), or guest acupuncturists permitted to perform acupuncture in New Jersey pursuant to N.J.A.C. 13:35-9.13 shall not use the following when providing acupuncture:

1) Staples;

2) Hypodermic needles; and

3) Subcutaneous permanently implanted needles or sutures.

f) The only licensed acupuncturists who may practice herbology are those qualified to do so under N.J.A.C. 13:35-9.12A.

g) Licensed acupuncturists may offer and provide to a patient, at fair market value, goods and devices.

13:35-9.12A HERBOLOGY

a) Except as set forth in (b) and (c) below, a licensed acupuncturist shall practice herbology only if he or she submits proof to the Board of current certification in Chinese Herbology or Oriental Medicine from the NCCAOM and has a letter from the Board recognizing that the licensed acupuncturist has submitted this information.

b) Prior to October 21, 2014, a licensed acupuncturist who obtained his or her license on or before November 2, 2009, may obtain a letter from the Board recognizing that he or she may practice herbology if he or she:

1) Successfully completed an herbology program from a school accredited by the ACAOM;

2) Passed the NCCAOM herbology examination;

3) Was ever certified in Chinese Herbology or Oriental Medicine by NCCAOM; or

4) Passed the NCCAOM herbology examination module.

c) Prior to October 21, 2014, a licensed acupuncturist who was enrolled in a school accredited by the ACAOM on or before November 2, 2009, may obtain a letter from the Board recognizing that he or she may practice herbology if:

1) He or she graduated from the ACAOM accredited school in which he or she was enrolled in on or before November 2, 2009; and

2) The school had a program in Chinese herbal medicine.

d) A licensed acupuncturist who is permitted to practice herbology pursuant to (a), (b), or (c) above shall complete at least 10 hours of continuing education related to the practice of herbology as part of the 30 hours of continuing education he or she is required to complete pursuant to N.J.A.C. 13:35-9.20.

13:35-9.13 GUEST ACUPUNCTURIST

a) An individual who is not a licensed acupuncturist, an individual who is permitted to practice pursuant to N.J.S.A. 45:2C-8, or a student in an acupuncture program that meets the requirements of N.J.A.C. 13:35-9.4(e) may perform acupuncture services as a guest acupuncturist if:

1) The individual receives permission from the Board to act as a guest acupuncturist pursuant to (c) below;

2) The individual performs acupuncture services as an instructor in a baccalaureate degree program, an acupuncture program that meets the requirements of N.J.A.C.

13:35-9.4(e) or a continuing education course that meets the requirements of N.J.A.C. 13:35-9.20(d); and

3) The individual is legally authorized to perform acupuncture services in another state or in another country.

b) An individual seeking permission to act as a guest acupuncturist shall arrange for an individual in charge of the baccalaureate degree program, acupuncture program or continuing education course in which he or she will act as an instructor to submit a request for permission to the Board, in writing, no later than 60 days prior to the guest acupuncturist's initial educational presentation in New Jersey. A resume or summary of the guest acupuncturist's credentials, written in English, shall accompany the request for approval.

c) An individual performing acupuncture services pursuant to this section shall not:

1) Perform acupuncture services in New Jersey for more than 30 days within a calendar year; or

2) Open an office or appoint a place to meet patients or receive calls from patients in New Jersey.

13:35-9.14 UNLICENSED PRACTICE OF ACUPUNCTURE

a) An individual is engaging in the unlicensed practice of acupuncture if the individual engages in any of the practices outlined in N.J.A.C. 13:35-9.12(a) and is not:

1) Licensed by the Board as an acupuncturist;

2) A physician or dentist whose course of training has included acupuncture pursuant to N.J.S.A. 45:2C-8;

3) A guest acupuncturist permitted to perform acupuncture services pursuant to N.J.A.C. 13:35-9.13; or

4) A student participating in an acupuncture program pursuant to N.J.A.C. 13:35-9.4(e).

13:35-9.15 PRECAUTIONARY AND STERILIZATION PROCEDURES

a) All non-disposable needles and acupuncture equipment that comes into contact with the patient's blood or bodily fluids or penetrates the skin, and equipment used to handle or store needles or other acupuncture equipment that comes into contact with the patient's blood or bodily fluids or penetrates the skin, shall be sterilized prior to each use. Prior to sterilization, all equipment to be sterilized shall be thoroughly cleaned with a disinfectant or cleansing solution.

b) Sterilization shall be accomplished before use by one of the following methods:

1) Steam autoclave at 250 degrees Fahrenheit (120 degrees Celsius) and 15 pounds per square inch of pressure for 30 minutes;

2) Equivalent dry heat; or

3) Ethylene oxide gas sterilization.

c) Sterilization equipment shall be used and maintained strictly in accordance with the guidelines of the manufacturer of the equipment, and shall be monitored regularly in accordance with the manufacturer's guidelines to determine whether the equipment is functioning properly.

d) The following methods of sterilization are prohibited: boiling acupuncture equipment, soaking acupuncture equipment in alcohol or other antiseptic solution, or glass bead sterilization.

e) Disposable acupuncture needles shall be placed in a rigid, puncture-proof, sealable container. The container shall be sealed and labeled as a disposal container and shall be labeled as bio-hazardous material. The disposal container shall be wiped with a disinfectant if blood or other bodily fluids are spilled on the outside of the container. The acupuncturist shall dispose of the container pursuant to the requirements of the Department of Environmental Protection implementing the Comprehensive Regulated Medical Waste Management Act, N.J.S.A. 13:1E-48.1 et seq., and N.J.A.C. 7:26-3A. The acupuncturist may delegate the responsibility to dispose the container to an agent approved by the Department of Environmental Protection.

f) If a licensee learns that a patient has a blood-borne infectious disease, the certificate holder shall use only disposable needles in treating the patient.

g) The acupuncturist shall ensure that personnel responsible for performing sterilization procedures pursuant to this rule are adequately trained and supplied with a written outline of sterilization procedures. A copy of the outline shall be maintained on the premises.

13:35-9.16 PREPARATION OF PATIENT RECORDS; COMPUTERIZED RECORDS; ACCESS TO OR RELEASE OF INFORMATION; CONFIDENTIALITY, TRANSFER OR DISPOSAL OF RECORDS

a) The following words and terms, as used in this section, shall have the following meanings unless the context clearly indicates otherwise:

1) "Authorized representative" means a person who has been designated by the patient or a court to exercise rights under this section. An authorized representative may be the patient's attorney or an employee of an insurance carrier with whom the patient has a contract which provides that the carrier be given access to records to assess a claim for monetary benefits or reimbursement. If the patient is a minor, a parent or guardian who has custody (whether sole or joint) shall be deemed to be an authorized representative.

2) "Patient" means any person who is the recipient of acupuncture.

b) Acupuncturists shall prepare contemporaneous, permanent professional treatment records. Acupuncturists shall also maintain records relating to billings made to patients and third-party carriers for professional services. All treatment records, bills, and claim forms shall accurately reflect the treatment or services rendered. Treatment records shall be maintained for a period of seven years from the date of the most recent entry.

1) To the extent applicable, professional treatment records shall reflect:

i) The dates of all treatments;

ii) The patient complaint;

iii) The history;

iv) Progress notes;

v) Any orders for tests or consultations and the results thereof;

vi) Documentation indicating that informed consent was given by the patient;

vii) Findings from examinations;

viii) If a physician has referred a patient for acupuncture, an indication that a referral or diagnosis was made by a physician, including the name of the physician; and

ix) Documentation of any recommendations made to a patient for the use of meditation or products that facilitate health.

2) Corrections and/or additions may be made to an existing record, provided that each change is clearly identified as such, dated and initialed by the licensee;

3) A patient record that is prepared and maintained on a personal or other computer shall be prepared and maintained as follows:

i) The patient record shall contain at least two forms of identification, for example, name and record number or any other specific identifying information;

ii) The entry made by the acupuncturist shall be made contemporaneously with the treatment and shall contain the date of service, date of entry, and full printed name of the treatment provider. The acupuncturist shall finalize or "sign" the entry by means of a confidential personal code ("CPC") and include date of the "signing";

iii) The acupuncturist may dictate a dated entry for later transcription. The transcription shall be dated and identified as "preliminary" until reviewed, finalized and dated by the acupuncturist as provided in (b)3ii above;

iv) The computer system shall contain an internal permanently activated date and time recordation for all entries, and shall automatically prepare a back-up copy of the file;

v) The computer system shall be designed in such manner that after "signing" by means of the CPC, the existing entry cannot be changed in any manner. Notwithstanding the permanent status of a prior entry, a new entry may be made at any time and may indicate correction to a prior entry;

vi) Where more than one acupuncturist is authorized to make entries into the computer file of any professional treatment record, the acupuncturist responsible for the acupuncture practice shall assure that each such person obtains a CPC and uses the file program in the same manner; and

vii) A copy of each day's entry, identified as preliminary or final as applicable, shall be made available to a physician responsible for the patient's care, to a representative of the Board, the Attorney General or the Division of Consumer Affairs no later than 10 days after a request for the record, or to a patient within 30 days of the request or promptly in the event of emergency.

c) Acupuncturists shall provide access to professional treatment records to a patient or an authorized representative in accordance with the following:

1) No later than 30 days from receipt of a request from a patient or an authorized representative, the acupuncturist shall provide a copy of the professional treatment record, and/or billing records as may be requested. The record shall include all pertinent objective data including test results, as applicable, and subjective information.

2) Unless otherwise required by law, an acupuncturist may, if a patient requests, provide a summary of the record in lieu of providing a photocopy of the actual record, so long as that summary adequately reflects the patient's history and treatment. An acupuncturist may charge a reasonable fee for the preparation of a summary, which has been provided in lieu of the actual record, which shall not exceed the cost allowed by (c)3 below for that specific record.

3) Acupuncturists may require that a record request be in writing and may charge a fee for the reproduction of records, which shall be no greater than $ 1.00 per page or $ 100.00 for the entire record, whichever is less. If the record requested is less than 10 pages, the acupuncturist may charge up to $ 10.00 to cover postage and the miscellaneous costs associated with retrieval of the record. If the acupuncturist provides a summary in lieu of the actual record, the charge for the summary shall not exceed the cost that would be charged for the actual record.

4) If the patient or a subsequent treating health care professional is unable to read the treatment record, either because it is illegible or prepared in a language other than English, the acupuncturist shall provide a transcription at no cost to the patient.

5) The acupuncturist shall not refuse to provide a professional treatment record on the grounds that the patient owes the licensee an unpaid balance if the record is needed by another health care professional for the purpose of rendering care.

d) Acupuncturists shall maintain the confidentiality of professional treatment records, except that:

1) The acupuncturist shall release patient records as directed by a subpoena issued by the Board or the Office of the Attorney General, or by a demand for statement in writing under oath from the Board or the Office of the Attorney General, pursuant to N.J.S.A. 45:1-18. Such records shall be originals, unless otherwise specified, and shall be unedited, with full patient names. To the extent that the record is illegible, the acupuncturist, upon request, shall provide a typed transcription of the record. If the record is in a language other than English, the acupuncturist shall also provide a translation.

2) The acupuncturist shall release information as required by law or regulation.

3) The acupuncturist, in the exercise of professional judgment and in the best interests of the patient (even absent the patient's request), may release pertinent information about the patient's treatment to another licensed health care professional who is providing or has been asked to provide treatment to the patient, or whose expertise may assist the acupuncturist in his or her rendition of professional services.

e) Where the patient has requested the release of a professional treatment record or a portion thereof to a specified individual or entity, in order to protect the confidentiality of the records, the acupuncturist shall:

1) Secure and maintain a current written authorization, bearing the signature of the patient or an authorized representative;

2) Assure that the scope of the release is consistent with the request; and

3) Forward the records to the attention of the specific individual identified or mark the material "Confidential."

f) If an acupuncturist ceases to engage in practice or it is anticipated that he or she will remain out of practice for more than three months, the acupuncturist or designee shall:

1) Establish a procedure by which patients can obtain a copy of the treatment records or acquiesce in the transfer of those records to another licensee who is assuming responsibilities of the practice. However, an acupuncturist shall not charge a patient, pursuant to (c)3 above, for a copy of the records, when the records will be used for purposes of continuing treatment or care.

2) Publish a notice of the cessation and the established procedure for the retrieval of records in a newspaper of general circulation in the geographic location of the acupuncturist's practice, at least once each month for the first three months after the cessation; and

3) Make reasonable efforts to directly notify any patient treated during the six months preceding the cessation, providing information concerning the established procedure for retrieval of records.

13:35-9.17 (RESERVED)

13:35-9.18 (RESERVED)

13:35-9.19 (RESERVED)

13:35-9.20 CONTINUING PROFESSIONAL EDUCATION REQUIREMENTS

a) For purposes of this section, "contact hour" means at least 50 minutes of instruction.

b) The provisions of this section shall apply to all acupuncturists applying for biennial license renewal except those seeking renewal for the first time.

c) No license renewal shall be issued by the Board unless the acupuncturist confirms on the renewal application that he or she completed at least 30 hours of continuing education.

d) Credit for continuing professional education shall be granted as follows for each biennial period:

1) Publishing in a national professional journal, an article related to the practice of acupuncture: three continuing education hours per article, up to 15 hours;

2) Attending seminars and conferences related to the practice of acupuncture: one continuing education hour per contact hour;

3) Successfully completing graduate course work related to the practice of acupuncture taken beyond that required for a professional license in a college or university that is regionally accredited or accredited by the ACAOM: one continuing education hour per credit hour;

4) Teaching new courses or seminars related to the practice of acupuncture. "New" means that the acupuncturist has never taught or developed curriculum for that seminar or lecture in any educational setting: one continuing education hour per contact hour, up to 15 hours;

5) Acting as a clinical supervisor in an acupuncture program that meets the requirements of N.J.A.C. 13:35-9.4(e): one continuing education hour per each 15 hours of supervision, up to 10 hours;

6) Successfully completing a continuing education course that has been approved by NCCAOM or by boards or committees regulating acupuncture in other states: one continuing education hour for each contact hour;

7) Successfully completing a distance learning course approved by NCCAOM: one continuing education hour for each contact hour, up to 15 hours;

8) Successfully completing continuing education courses or programs that are pre-approved by the Board pursuant to (e) below: one continuing education hour for each contact hour; and

9) Successfully completing a course that an acupuncturist submits for approval to the Board pursuant to (f) below, one continuing education hour for each contact hour.

e) Sponsors of continuing education programs or courses seeking Board approval shall obtain Board approval every biennial period prior to representing that any course, program or seminar fulfills the requirements of (c) above and shall:

1) At least 90 days prior to the commencement of the course, submit the following for each course, program or seminar offered for evaluation by the Board:

i) A detailed descriptive outline of course content and estimated hours of instruction; and

ii) The curriculum vitae of each lecturer, including specific background information, which qualifies the individual as a lecturer in the area of instruction;

2) Monitor the attendance at each approved course, program or seminar and furnish to each enrollee a written verification of attendance, which shall include at least the following information:

i) The title, date and location of the course, program or seminar offering;

ii) The name and license number of the attendee;

iii) The hours of instruction provided; and

iv) The name and signature of the sponsor and the seal of the organization;

3) Evaluate course offerings. Evaluations shall be solicited from both the attendees and the instructors; and

4) Submit a fee pursuant to N.J.A.C. 13:35-9.8(a)11 for each submission of new courses, programs or seminars reviewed by the Board during the biennial licensing period.

f) An acupuncturist may apply to the Board for approval of a course that does not meet the requirements of (d)2, 3, 6, 7 or 8 above. The acupuncturist shall submit to the Board the title, date and location of the course, program or seminar for which approval is being sought and the information required of a continuing professional education provider pursuant to (e)1 above.

g) The Board may perform audits on randomly selected acupuncturists to determine compliance with continuing education requirements. An acupuncturist shall maintain the following documentation for a period of four years after completion of the hours and shall submit such documentation to the Board upon request:

1) For publication of an article: the published item, including the date of publication;

2) For attendance at seminars and conferences or completion of continuing education courses: a certificate of completion from the provider;

3) For completion of graduate course work: an official transcript;

4) For teaching a course or seminar: documentation, including a copy of the curriculum, location, date and time of course or seminar, duration of course or seminar by hour and letter from provider confirming that the acupuncturist taught the course or seminar; and

5) For clinical supervision: documentation signed by the director of the acupuncture program indicating the number of hours of clinical supervision the acupuncturist provided.

h) Credits taken in excess of the 30 required for biennial license renewal shall not be carried over for use in subsequent renewal periods.

i) The Board may waive continuing education requirements on an individual basis for reasons of hardship, such as illness, disability, active service in the military, or other

good cause. An acupuncturist who seeks a waiver of the continuing education requirements shall apply to the Board in writing at least 90 days prior to license renewal and set forth in specific detail the reasons for requesting the waiver. The acupuncturist shall provide the Board with such supplemental materials as will support the request for waiver. A waiver of continuing education requirements granted pursuant to this subsection shall be effective only for the biennial period in which such waiver is granted. If the condition(s) that necessitated the waiver continue into the next biennial period, an acupuncturist shall apply to the Board for the renewal of such waiver for the new biennial period.

j) The Board may direct or order an acupuncturist to successfully complete continuing education credits:

1) As part of a disciplinary or remedial measure in addition to the required credits of continuing education; or

2) To correct a deficiency in the acupuncturist's continuing education requirements.

k) Any continuing education credits completed by the acupuncturist in compliance with an order or directive from the Board as set forth in (i) above shall not be used to satisfy the minimum continuing education requirements as set forth in this section.

APPENDIX A
(RESERVED)

SUBCHAPTER 10.
ATHLETIC TRAINERS

13:35-10.1 SCOPE AND PURPOSE

a) This subchapter is promulgated by the New Jersey State Board of Medical Examiners, pursuant to N.J.S.A. 45:9-37.35 et seq., providing for the licensure and regulation of athletic trainers within the State of New Jersey.

b) The rules contained in this subchapter shall apply to all individuals currently practicing as athletic trainers, as well as those individuals studying to become athletic trainers within

this State and applicants for licensure. The rules are designed to better define the allowable activities, professional standards, and the educational requirements of athletic trainers.

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 strenuous physical exercise, physical conditioning or a sport.

"Athletic training" means the practice of physical conditioning and reconditioning of athletes and the prevention of injuries incurred by athletes. "Athletic training" also includes the application of physical treatment modalities to athletes under a plan of care designed and overseen by a supervising physician licensed in New Jersey, as recommended by the Advisory Committee and defined in N.J.A.C. 13:35-10.7(b).

"Board" means the State Board of Medical Examiners.

"Bracing" means the provision of fabric and elastic supports, corsets, arch supports, trusses, elastic hose, canes, crutches, cervical collars, dental appliances or other similar devices carried in stock and sold by drug stores, department stores, corset shops or surgical supply facilities.

"Licensed athletic trainer" means an individual who is licensed by the Board to practice athletic training.

"Physician" means a physician and surgeon licensed pursuant to N.J.S.A. 45:9-1 et seq.

"Plan of care" means a documented arrangement between a licensed athletic trainer and a physician, which sets forth:

1. The physical treatment modalities a licensed athletic trainer will utilize while providing services to athletes in an interscholastic, intercollegiate, intramural or professional athletic setting; and

2. Any athletic training services, including physical treatment modalities, the athletic trainer will provide when he or she is working with an athlete outside of an interscholastic, intercollegiate, intramural or professional athletic setting.

"Supervising physician" means a physician with whom an athletic trainer has a plan of care.

"Supervision" means that a physician licensed in this State is accessible to a licensed athletic trainer, either on-site or through voice communication, during athletic training.

13:35-10.3 APPLICATION FOR LICENSURE

a) An applicant for athletic trainer licensure shall submit to the Board:

1) A completed application form;

2) Proof that the applicant has completed a program of education, training and experience, which is approved by the Commission on Accreditation of Athletic Training Education, or its successor;

3) Proof that the applicant has passed the examination administered by the National Athletic Trainers' Association Board of Certification, Inc., or its successor, or an equivalent examination as adopted by the Board; and

4) The application fee pursuant to N.J.A.C. 13:35-10.19.

13:35-10.4 LICENSURE; BIENNIAL LICENSE RENEWAL; LICENSE SUSPENSION; REINSTATEMENT OF SUSPENDED LICENSE; INACTIVE STATUS; RETURN FROM INACTIVE STATUS

a) All licenses issued by the Board shall be issued for a two-year licensure period. A licensed athletic trainer who seeks renewal of the license shall submit a completed renewal application and the renewal fee as set forth in N.J.A.C. 13:35-10.19 prior to the expiration date of the license.

b) The Board shall send a notice of renewal to each licensee at the address registered with the Board at least 60 days prior to the expiration of the license. If the notice to renew is not sent at least 60 days prior to the expiration date, no monetary penalties or fines shall apply to the holder for failure to renew.

c) If a licensed athletic trainer does not renew the license prior to its expiration date, the licensed athletic trainer may renew the license within 30 days of its expiration by submitting a renewal application, a renewal fee and a late fee, as set forth in N.J.A.C. 13:35-10.19. During this 30-day period, the license shall be valid, and the licensed athletic trainer shall not be deemed to be practicing without a license.

d) A license that is not renewed within 30 days of its expiration shall be automatically suspended. An individual who continues to practice with a suspended license shall be deemed to be engaged in unlicensed practice and shall be subject to penalties for practicing without a license.

e) A licensed athletic trainer whose license has been automatically suspended for five years or less for failure to renew pursuant to (d) above may be reinstated by the Board upon completion of the following:

1) Payment of the reinstatement fee and all past delinquent biennial renewal fees pursuant to N.J.A.C. 13:35-10.19; and

2) Submission of an affidavit of employment listing each job held during the period of suspended license which includes the name, address, and telephone number of each employer.

f) In addition to fulfilling the requirements set forth in (e) above, a licensed athletic trainer whose license has been automatically suspended for more than three years who wishes to return to practice shall submit proof that he or she is currently certified by the National Athletic Trainers Association Board of Certification, or its successor.

g) In addition to fulfilling the requirements set forth in (e) and (f) above, a licensed athletic trainer whose license has been automatically suspended for more than five years who wishes to return to practice shall reapply for licensure and shall demonstrate that he or she has maintained proficiency. An applicant who fails to demonstrate to the satisfaction of the Board that he or she has maintained proficiency while suspended may be subject to an examination or other requirements as determined by the Board prior to reinstatement of his or her license.

h) Renewal applications shall provide the licensed athletic trainer with the option of either active or inactive status. A licensed athletic trainer electing inactive status shall pay the inactive license fee set forth in N.J.A.C. 13:35-10.19 and shall not engage in practice.

i) A licensee who elected inactive status and has been on inactive status for five years or less may be reinstated by the Board upon completion of the following:

1) Payment of the reinstatement fee; and

2) Submission of an affidavit of employment listing each job held during the period the licensee was on inactive status which includes the name, address, and telephone number of each employer.

j) In addition to fulfilling the requirements set forth in (i) above, a licensed athletic trainer who has been on inactive status for more than five years who wishes to return to the practice of athletic training shall reapply for licensure and shall demonstrate that he or she has maintained proficiency. An applicant who fails to demonstrate to the satisfaction of the Board that he or she has maintained proficiency while on inactive status may be subject to an examination or other requirements as determined by the Board prior to reinstatement of his or her license.

13:35-10.5 PLAN OF CARE GUIDELINES

a) Every licensed athletic trainer shall enter into a written plan of care with a supervising physician, which sets forth the practices in which a licensed athletic trainer shall engage in while providing physical treatment modalities to athletes in an interscholastic, intercollegiate, intramural or professional athletic setting and all athletic training services, including physical treatment modalities, provided outside of these settings. The plan of care shall be signed and dated by both the licensed athletic trainer and the supervising physician.

b) A licensed athletic trainer and his or her supervising physician shall meet at least once a year to review the plan of care and revise it as necessary.

c) A supervising physician shall be available, either in person or through voice communication, whenever a licensed athletic trainer is practicing athletic training.

d) A licensed athletic trainer shall make a plan of care available to the Board upon request.

13:35-10.6 PRACTICE OUTSIDE OF SCHOOLS AND PROFESSIONAL TEAMS

a) Except as provided in (b) below, if a licensed athletic trainer is working outside of an interscholastic, intercollegiate, intramural or professional athletic setting, the licensed athletic trainer shall provide athletic training services only when a physician (who may, in this instance, be licensed in another state) has referred the athlete for athletic training after physically examining the athlete.

b) A licensed athletic trainer who is providing athletic training services during an athletic event outside of an interscholastic, intercollegiate, intramural, or professional athletic

setting may evaluate an injury suffered by an athlete during that event and provide immediate athletic training services for that injury. After the initial response to the injury, the licensed athletic trainer shall refer the athlete to a physician for a physical examination. The licensed athletic trainer shall not provide any further athletic training services to such an athlete until a physician has referred the athlete for further athletic training services.

c) When a licensed athletic trainer is working outside of an interscholastic, intercollegiate, intramural or professional athletic setting with an athlete, the licensed athletic trainer's plan of care shall include provisions for supervision from a supervising physician during all aspects of athletic training, not just during the provision of physical modalities.

13:35-10.7 SCOPE OF PRACTICE

a) A licensed athletic trainer in an interscholastic, intercollegiate, intramural or professional athletic setting, in a setting where he or she is providing evaluation and immediate athletic training services for an injury suffered outside of the interscholastic, intercollegiate, intramural or professional athletic setting pursuant to N.J.A.C. 13:35-10.6(b) or in any other setting pursuant to a referral from a physician, may provide to an athlete:

1) Evaluation of injuries;

2) Conditioning programs for the prevention and management of injuries including:

i) Maintenance programs;

ii) Reconditioning programs;

iii) Exercise programs; and

iv) Bandaging, wrapping, taping, padding, bracing and splinting procedures;

3) Testing of neuromotor and musculoskeletal functional capability for the purposes of conditioning, reconditioning or otherwise evaluating the athlete's performance capability; and

4) First-aid.

b) Notwithstanding (a) above, a licensed athletic trainer may provide bandaging, wrapping, taping, padding, bracing, and splinting procedures to uninjured parts of an athlete's body in any setting without a referral from a physician.

c) If they are included in the licensed athletic trainer's plan of care with a supervising physician, a licensed athletic trainer may administer physical treatment modalities, such as:

1) Cold;

2) Heat;

3) Light;

4) Sound;

5) Electricity;

6) Electromagnetic waves;

7) Water; and

8) Traditional mobilization techniques, rehabilitative exercise programs, traction and massage.

d) A licensed athletic trainer shall not conduct electromyographic testing or nerve conduction velocity studies.

e) A licensed athletic trainer shall not diagnose an injury or illness. Prior to implementing or continuing athletic training services, the licensed athletic trainer shall exercise professional judgment to determine whether any intervening circumstances have adversely affected the athlete's ability to participate in or continue to participate in athletic training.

f) A licensed athletic trainer shall immediately refer an athlete to a health care professional licensed in this State if the licensed athletic trainer has cause to believe that athletic training is contraindicated or symptoms or conditions are present that require services outside the scope of a licensed athletic trainer's practice.

13:35-10.8 RECORDS

a) A licensed athletic trainer shall prepare and maintain for each athlete a contemporaneous, permanent record that accurately reflects the evaluation and treatment of the athlete's illness or injury by the licensed athletic trainer.

b) A licensed athletic trainer shall not falsify a record.

c) A record shall include, in addition to personal identifying information, consents and disclosures, at least the following information:

1) The full name, as it appears on the license, and license number of the licensed athletic trainer who rendered care. This information shall be legible and shall appear at least once on each page of the record;

2) Dates of all athletic training services;

3) The findings of the evaluation including test results;

4) Documentation of health care practitioner referrals, if any;

5) Established measurable goals of the athletic training with stated time frames, the type of athletic training and the frequency and expected duration of athletic training;

6) A contemporaneous note that accurately represents the services rendered during the athletic training sessions including the components of athletic training, the athlete's response to activities and current status;

7) Progress notes in accordance with stated goals at a frequency consistent with the evaluated findings and changes in the athlete's conditions;

8) Communication with other health care professionals relative to the athlete's care;

9) A discharge or return to activity summary, which includes the reason for discharge from and outcome of athletic training relative to established goals at the time of discharge; and

10) Pertinent legal document(s).

d) Records shall be maintained for at least seven years from the date of the last entry.

e) A student in a Commission on Accreditation of Athletic Training Education approved athletic training education program may enter information in an athlete's record, as long as the licensed athletic trainer supervising the student co-signs his or her full name and license number next to the student's entry.

f) A licensed athletic trainer shall maintain his or her plan of care as part of his or her records.

13:35-10.9 USE OF PERSONAL OR OTHER COMPUTER TO PREPARE RECORDS

a) A licensed athletic trainer who prepares a record maintained solely on a personal or other computer shall use a write-protected program that:

1) Contains an internal permanently activated date and time recordation for all entries;

2) Automatically prepares a back-up copy of the file; and

3) Is designed in such manner that, after the licensed athletic trainer "signs" by means of a confidential personal code (CPC), the entry cannot be changed in any manner.

b) The licensed athletic trainer shall include in the record at least two forms of identification; for example, name and record number of the athlete or any other specific identifying information.

c) The licensed athletic trainer shall finalize or "sign" the entry by means of a CPC. Where more than one individual is authorized to make entries into the computer file of any record, the licensed athletic trainer responsible for the facility at which the licensed athletic trainers work shall assure that each such person obtains a CPC and uses the program in the same manner.

d) The licensed athletic trainer shall generate a hard copy of the complete record upon request.

13:35-10.10 RELEASE OF RECORDS

a) A licensed athletic trainer shall provide a copy of the athlete's record within 30 days of a written request by the athlete or any person whom the athlete has designated to receive that record, or, if the athlete is a minor, the athlete's legal guardian.

b) Licensed athletic trainers 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 licensed athletic trainer may charge up to $10.00 to cover postage and the miscellaneous costs associated with retrieval of the record.) If the athlete requests 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.

c) If the athlete 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 licensed athletic trainer shall provide a transcription at no cost to the athlete or the person requesting the record.

d) Where the athlete has requested the release of all or part of a professional treatment record to a specified individual or entity, in order to protect the confidentiality of the records, the licensed athletic trainer shall:

1) Secure and maintain a current written authorization, bearing the signature of the athlete 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 or entity identified and mark the material "Confidential."

e) A licensed athletic trainer shall not withhold or delay providing a record because the athlete or any other payor failed to pay for services rendered.

13:35-10.11 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) "Advertisement" shall mean any attempt directly or indirectly by publication, dissemination or circulation in print or electronic media to induce directly or indirectly any person or entity to purchase or enter into an agreement to purchase services, treatment or goods related thereto from a licensed athletic trainer.

2) "Electronic media" shall include radio, television, telephone, facsimile machine or computer.

3) "Fee schedule" refers to the fees charged for services or goods offered by a licensed athletic trainer.

4) "Graphic representation" shall mean the use of drawings, animations, clinical photographs, dramatizations, music or lyrics.

5) "Print media" shall refer to newspapers, magazines, periodicals, professional journals, telephone directories, circulars, handbills, fliers or other publications, the content of which is disseminated by means of the printed word.

6) "Routine professional service" refers to a service that a licensed athletic trainer or professional association routinely performs.

b) Subject to the limitation of (c) and (e) through (i) below, a licensed athletic trainer may provide information to the public by advertising in print or electronic media.

c) A licensed athletic trainer who engages in the use of advertising that contains any of the following shall be deemed to have engaged in professional misconduct:

1) Any statement, claim or format including a graphic representation that 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 that the licensed athletic trainer knows or should have known is improper or prevents an athlete 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 those ordinarily performed or used in the profession;

5) Any promotion of professional service that the licensed athletic trainer knows or should know is beyond the licensed athletic trainer's ability to perform;

6) A technique or communication that appears to intimidate, exert undue pressure or to unduly influence an athlete;

7) Any personal testimonial attesting to the quality or competence of service or treatment by a licensed athletic trainer involving medical or technical assessments that are beyond the athlete's competency to assess, or any testimonial not in compliance with N.J.A.C. 13:35-10.13;

8) The communication of any fact, data or information that may personally identify an athlete without the athlete'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 an athlete;

10) Any print, language or format that directly or indirectly obscures a material fact; or

11) Any guarantee of results from any procedure.

d) The Board may require a licensed athletic trainer to substantiate the truthfulness of any assertion or representation set forth in an advertisement.

e) Any violations of (f) through (i) below shall be deemed professional misconduct.

f) A licensed athletic trainer shall not engage, either directly or through the use of any agent, employee or representative, in solicitation of an athlete. This subsection shall not prohibit a licensed athletic trainer from offering services through materials provided to a community service organization that makes known the availability of all professional services listed; nor shall it prohibit the offering of services by a licensed athletic trainer to any bona fide representative of an athlete including, employers, labor union representatives or insurance carriers.

g) Advertising making reference to or setting forth fees shall be limited to a stated fee for specifically described routine professional services or goods offered by licensed athletic trainers.

1) A licensed athletic trainer who advertises a fee shall disclose all relevant and material variables and considerations that are ordinarily included in such a service, so that the fee will be clearly understood by athletes.

2) In the absence of such disclosure referred to in (g)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 specifically delineates the additional services contemplated and the fee to be charged.

h) 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.

i) Any licensed athletic trainer advertising a specialty certification shall have been certified by a certifying entity and shall maintain documentary proof of certification from the entity as part of his or her records. A licensed athletic trainer who advertises a specialty certification shall include the full name of the certification and the certifying entity in any advertisements and shall not use initials or acronyms for the certification or certifying entity. For example, a licensed athletic trainer may indicate in advertisements that he or she is a Certified Strength and Conditioning Specialist certified by the National Strength and Conditioning Association but shall not indicate that he or she is a CSCS certified by the NSCA.

13:35-10.12 ADVERTISING FREE OR DISCOUNTED SERVICES; REQUIRED DISCLOSURES

a) An advertisement offering a fee reduction shall state the reduced fee and the licensed athletic trainer's usual fee for each service for which a reduction is advertised. The usual fee shall be the fee charged for the advertised service for a period of not less than 90 days prior to the publication of the advertised reduction.

b) 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 that are not included and a statement of the specific charges for all associated or reasonably anticipated services that are not included.

c) Except for those services specifically excluded in the advertisement offering free services, the licensed athletic trainer shall not charge for any service whatsoever rendered during a period of 72 hours from the time the free service was rendered.

13:35-10.13 TESTIMONIAL ADVERTISING

a) All testimonials involving a specific or identifiable procedure shall truthfully reflect the actual experience of the athlete.

b) The licensed athletic trainer shall be able to substantiate any objective, verifiable statement of fact appearing in a testimonial. The failure to do so, if required by the Board, may be deemed professional misconduct.

c) Where a licensed athletic trainer directly or indirectly provides compensation to a testimonial giver, the fact of such compensation shall be conspicuously disclosed in a clear, legible and readable manner in any advertisement as follows: "COMPENSATION HAS BEEN PROVIDED FOR THIS TESTIMONIAL."

13:35-10.14 MINIMUM CONTENT

a) A licensed athletic trainer shall include the following in all advertisements and professional representations (other than an office entry sign), including advertisements in a classified directory, business cards and professional stationery:

1) The name and license number of at least one licensed athletic trainer working at the advertised practice location; and

2) The street address and telephone number of the practice.

13:35-10.15 ADVERTISING BY A BUSINESS ENTITY OFFERING ATHLETIC TRAINING

The responsibility for the form and content of any advertisement offering services or goods by a licensed athletic trainer shall be jointly and severally that of each licensed athletic trainer who is a principal, partner, officer or employee of the firm or entity identified in the advertisement.

13:35-10.16 ADVERTISING RECORD RETENTION

a) A licensed athletic trainer shall retain, for a period of three years from the date of initial publication or dissemination, a copy of every advertisement for his or her services appearing in print media, as well as a video or audio tape of every advertisement communicated by electronic media. A licensed athletic trainer shall indicate on all advertisements in his or her possession the date and place of publication.

b) Documentation relating to the use of testimonials shall be retained for a period of three years from the date of last use of the testimonial. Documentation shall include the name, address and telephone number of the testimonial giver and the type and amount or value of compensation, if any.

13:35-10.17 USE OF PROFESSIONAL CREDENTIALS AND CERTIFICATIONS

a) A licensed athletic trainer shall accurately and objectively represent his or her competence, education, training and experience.

b) A licensed athletic trainer shall use the designation "athletic trainer" or "licensed athletic trainer" or the abbreviation "AT" or "LAT" in conjunction with the use of his or her name and license number. Academic degree designations may be placed after the name and the title.

c) An advertisement that includes information on professional credentials shall contain the academic degrees attained related to the practice of athletic training and shall refer only to degrees obtained from accredited academic institutions.

13:35-10.18 VIOLATIONS

Without limiting the prosecution of any practices which may be unlawful under any other state or Federal law, a violation of this subchapter shall be deemed to be a violation of the Athletic Training Licensure Act, N.J.S.A. 45:9-37.35 et seq., and shall be subject to the sanctions and penalties of N.J.S.A. 45:1-1 et seq.

13:35-10.19 FEES

a) The following fees shall be charged by the Board for athletic trainer licensure:

1) Application Fee $100.00

2) Temporary licensure or authorized licensure without examination $60.00

3) Initial Licensure Fee

i) If paid during the first year of a biennial renewal period $80.00

ii) If paid during the second year of a biennial renewal period $40.00

4) Biennial renewal $80.00

5) Endorsement $60.00

6) Late renewal fee $50.00

7) Reinstatement fee $60.00

8) Inactive license fee ..... (to be determined by the Director by regulation)

13:35-10.20 SEXUAL MISCONDUCT

a) The purpose of this section is to identify for licensed athletic trainers conduct which shall be deemed sexual misconduct.

b) As used in this section, the following terms have the following meanings, unless the context indicates otherwise:

"Athlete" means any person who is the recipient of athletic training services rendered by a licensed athletic trainer as set forth in N.J.A.C. 13:35-10.4.

"Athlete-athletic trainer relationship" means a relationship between a licensed athletic trainer and an athlete wherein the licensed athletic trainer is responsible to render athletic training services for the athlete.

"Sexual contact" means the knowing touching of a person's body directly or through clothing, where the circumstances surrounding the touching would be construed by a reasonable person to be motivated by the licensed athletic trainer's own prurient interest or for sexual arousal or gratification. "Sexual contact" includes, but is not limited to, the imposition of a part of the licensed athletic trainer's body upon the part of the athlete's body, sexual penetration, or the insertion or any imposition of any object or any part of a licensed athletic trainer's or athlete's body into or near the genital, anal or other opening of the other person's body. "Sexual contact" does not include the touching of an athlete's body which is necessary during a generally accepted and recognized athletic training procedure.

"Sexual harassment" means solicitation of any sexual act, physical advances, or verbal or nonverbal conduct that is sexual in nature, and which occurs in connection with a licensed athletic trainer's activities or role as a provider of athletic training services, and that either is unwelcome, offensive to a reasonable person, or creates a hostile workplace environment, and the licensed athletic trainer knows, should know, or is told this; or is sufficiently severe or intense to be abusive to a reasonable person in that context. "Sexual harassment" may consist of a single extreme or severe act or of multiple acts and may include, but is not limited to, conduct of a licensed athletic trainer with an athlete, coworker, employee, student or supervisee, whether or not such individual is in a subordinate position to the licensed athletic trainer.

"Spouse" means the husband, wife or fiancée of the licensed athletic trainer or an individual involved in a long-term committed relationship with the licensed athletic trainer. For the purposes of the definition of "spouse," a long-term committed relationship means a relationship which is at least six months in duration.

c) A licensed athletic trainer shall not seek or solicit sexual contact with an athlete with whom he or she has an athlete-athletic trainer relationship and shall not seek or solicit sexual contact with any person in exchange for professional services.

d) A licensed athletic trainer shall not engage in any discussion of an intimate sexual nature with an athlete with whom the licensed athletic trainer has an athlete-athletic trainer

relationship unless that discussion is directly related to a proper athletic training purpose. Such discussion shall not include disclosure by the licensed athletic trainer of his or her own sexual relationships.

e) A licensed athletic trainer shall provide draping or other measures which prevent the unnecessary exposure of the unclothed body of the athlete while examining the injured area.

f) A licensed athletic trainer shall not engage in sexual contact with a student who is enrolled in a high school at which the licensed athletic trainer is employed.

g) If a licensed athletic trainer has an athlete-athletic trainer relationship, the licensed athletic trainer shall not engage in sexual contact with the athlete if either:

1) Such sexual contact is prohibited by (f) above; or

2) The athlete-athletic trainer relationship is ongoing. The athlete-athletic trainer relationship is ongoing for the purposes of this section, unless:

i) Athletic training services are terminated by way of written notice to the athlete, the termination is documented in the licensed athletic trainer's records and alternative athletic training services are provided; or

ii) The athlete has left the school, college, university or team for which the licensed athletic trainer works.

h) A licensed athletic trainer shall not engage in sexual harassment either within or outside of the professional setting.

i) A licensed athletic trainer shall not engage in any other activity which would lead a reasonable person to believe that the activity serves the licensed athletic trainer's personal prurient interests or which is for the sexual arousal, or sexual gratification of the licensed athletic trainer or athlete or which is an act of sexual abuse.

j) Violation of any of the prohibitions or directives set forth in (c) through (i) above shall constitute professional misconduct pursuant to N.J.S.A. 45:1-21(e).

k) Nothing in this section shall be construed to prevent a licensed athletic trainer from rendering athletic training services to a spouse, providing that the rendering of such athletic training services is consistent with accepted standards of athletic training and

that the performance of athletic training is not utilized to exploit the athlete spouse for the sexual arousal or sexual gratification of the licensed athletic trainer.

l) It shall not be a defense to any action under this section that:

1) The athlete solicited or consented to sexual contact with the licensed athletic trainer; or

2) The licensed athletic trainer is in love with or had affection for the athlete.

SUBCHAPTER 11.
ALTERNATIVE RESOLUTION PROGRAM

13:35-11.1 DEFINITIONS

As used in this subchapter the following words and terms have the following meanings, unless the context indicates otherwise:

"Alternative Resolution Program" or "ARP" means a program established pursuant to this subchapter for those subject to Board jurisdiction who are suffering from chemical dependencies and other impairments which shall permit such licensees to disclose their status to an entity which would allow for confidential oversight.

"Board" means the New Jersey State Board of Medical Examiners.

"Chemical dependency" means a condition involving the continued misuse of chemical substances.

"Chemical substances" is to be construed to include alcohol, drugs or medications, including those taken pursuant to a valid prescription for legitimate medical purposes and in accordance with the prescriber's direction, as well as those used illegally.

"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. 45:1-36, except that nothing in this subsection shall preclude the Board, the IRC or the Attorney General from conducting appropriate investigation of the relevant facts, securing opinions from consultants and complying with judicial directives; and

15) Shall, upon a licensee's successful completion of the terms as provided by the letter agreement, advise the Board that it deems the matter to be closed without a finding of cause for action, except that nothing herein shall preclude the Board or the Panel from reviewing and relying upon all relevant materials should it receive a subsequent referral regarding the licensee.

13:35-11.5 PROFESSIONAL ASSISTANCE PROGRAM: APPROVAL AND DISCONTINUANCE

a) A professional assistance program seeking to sponsor participants in the ARP first shall seek approval from the Board. A PAP applying for approval shall be required to enter into a formal agreement with the Board, attesting to its willingness and ability to provide necessary services to participants and to work with the IRC in the discharge of its responsibilities. Upon request, any PAP seeking approval shall provide the Board with sufficient information concerning its staffing, the services it provides, available treatment referrals and monitoring contracts so that the Board can be assured that the program is in a position to discharge its obligations under the agreement. Each program shall designate a plenary licensed physician who shall serve as program director and who shall be responsible to assure that the program fulfills its obligations under the

agreement. By that agreement the Board shall grant its approval and delineate the conditions upon which the approval could be rescinded.

b) Should an approved professional assistance program cease offering services, the Board shall allow participating licensees a period of 30 days to seek the sponsorship of another approved professional assistance program provided that interim monitoring provisions are proposed and acceptable to the Board.

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. 45:1-37 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. 45:1-37. If the reporting practitioner elects to file a report directly with the IRC, the Panel or the Board, he or she may utilize that licensee's code number in the report. These reports shall be retained confidentially if the licensee agrees to the terms of participation in the program.

13:35-11.7 (RESERVED)

SUBCHAPTER 12.
ELECTROLOGISTS ADVISORY COMMITTEE; LICENSURE OF ELECTROLOGISTS AND ELECTROLOGY INSTRUCTORS; ELECTROLOGY STANDARDS OF PRACTICE

13:35-12.1 PURPOSE AND SCOPE

(a) The rules in this subchapter implement the provisions of P.L. 1997, c.347 (N.J.S.A. 45:9-37.76 et seq.), which created the Electrologists Advisory Committee under the State Board of Medical Examiners.

(b) This subchapter shall apply to all applicants seeking licensure as an electrologist, electrology instructor, or an office license and licensed electrologists, licensed electrology instructors and licensed offices.

13:35-12.2 DEFINITIONS

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Act" means the Electrology Practice Act, N.J.S.A. 45:9-37.76 et seq.

"Authorized representative" means a person who has been designated by the client or a court to exercise rights under this section. An authorized representative may be the client's attorney. If the client is a minor, a parent or guardian who has custody (whether sole or joint) shall be deemed to be an authorized representative.

"Board" means the State Board of Medical Examiners.

"Certified Professional Electrologist Examination" means the examination administered by the American Electrology Association.

"Certified Technical Trainer Examination" means the examination administered by the Educational Testing Service.

"Client" means any person who is the recipient of a professional service rendered by a licensee for purposes of treatment.

"Committee" means the Electrologists Advisory Committee established pursuant to section 3 of P.L. 1997, c.347 (N.J.S.A. 45:9-37.76 et seq.).

"Electrologist" means a person who is licensed to practice electrology pursuant to the provisions of P.L. 1997, c.347 (N.J.S.A. 45:9-37.76 et seq.).

"Electrology" means the removal of hair permanently through the utilization of solid probe electrode-type epilation, including thermolysis, being of a short wave, high frequency type, and

including electrolysis, being of a galvanic type, or a combination of both, which is accomplished by a superimposed or sequential blend. This definition specifically excludes laser and other intense light source hair removal from the definition of electrology.

"Electrology instructor" means a person who is licensed to teach the clinical and theoretical practice of electrology pursuant to the provisions of P.L. 1997, c.347 (N.J.S.A. 45:9-37.76 et seq.).

"Instrument" means any tool or implement used in electrology procedures.

"Licensee" means an individual holding a license issued by the Electrology Advisory Committee of the State Board of Medical Examiners.

"Office" means any fixed establishment or place where one or more persons engage in the practice of electrology.

13:35-12.3 OFFICE OF THE COMMITTEE

The office of the Committee shall be maintained at 124 Halsey Street, Newark, New Jersey. The mailing address of the Committee is PO Box 45041, Newark, New Jersey 07101.

13:35-12.4 NOTIFICATION OF CHANGE OF ADDRESS

a) Licensees shall notify the Committee in writing of any change from the address currently registered with the Committee and shown on the most recently issued certificate. Such notice shall be sent to the Committee no later than 30 days following the change of address.

b) Failure to notify the Committee of any change of address pursuant to (a) above may result in disciplinary action in accordance with N.J.S.A. 45:1-21(h).

c) Service of an administrative complaint or other Board initiated process at the licensee's address currently on file with the Committee shall be deemed adequate notice for the purposes of N.J.A.C. 1:1-7.1 and the commencement of any disciplinary proceedings.

13:35-12.5 (RESERVED)

13:35-12.6 LICENSING REQUIREMENTS FOR ELECTROLOGIST

a) To be eligible for licensure as an electrologist, an applicant shall fulfill the following

requirements:

1) Be at least 18 years of age;

2) Be of good moral character;

3) Have successfully completed high school or its equivalent;

4) Have successfully completed:

   i) An electrology education program accredited by the Council on Accreditation of Electrology Educational Institutions/Programs of the American Electrology Association, or its successor, which includes at least 200 hours of instruction in the theory of electrology and at least 400 hours of instruction in the clinical practice of electrology taught by an electrology instructor licensed pursuant to N.J.A.C. 13:35-12.7; or

   ii) An electrology education program which is determined by the Board to be substantially equivalent to an accredited program in this State;

5) Have passed the Certified Professional Electrology (CPE) Examination or its successor; and

6) Have passed the New Jersey Electrology Jurisprudence Examination.

13:35-12.7 LICENSING REQUIREMENTS FOR ELECTROLOGY INSTRUCTOR

a) To be eligible for licensure as an electrology instructor, an applicant shall fulfill the following requirements:

1) Be licensed as an electrologist pursuant to the provisions of N.J.S.A. 45:9-37.76 et seq. and N.J.A.C. 13:35-12.6;

2) Have been actively engaged in the practice of electrology for at least five years immediately preceding the date of application for licensure as an electrology instructor. For the purposes of this paragraph, "actively engaged in the practice of electrology" means that a person has been performing electrology as defined in N.J.A.C. 13:35-12.2 for a minimum of 400 hours per year for each of the five years immediately preceding the date of the application; and

3) Have passed the Certified Technical Trainer (CTT) Examination.

13:35-12.8 APPLICATION FOR LICENSE: ELECTROLOGIST

a) An applicant for license as an electrologist shall submit the following to the Committee:

1) A completed application form provided by the Board, including supporting documents;

2) High school diploma or its equivalent;

3) Proof of completion of an electrology program pursuant to N.J.A.C. 13:35-12.6; and

4) The application fee set forth in N.J.A.C. 13:35-12.22.

b) If the applicant meets the requirements of (a) above, the Committee shall advise the applicant that he or she is eligible to take the Certified Professional Electrology (CPE) Examination, or its successor, and the New Jersey Electrology Jurisprudence Examination.

13:35-12.9 APPLICATION FOR LICENSE: ELECTROLOGY INSTRUCTOR

a) An applicant for license as an electrology instructor shall submit the following to the Committee:

1) A completed application form provided by the Board;

2) A notarized affidavit stating that the applicant has been actively engaged in the practice of electrology for a minimum of 400 hours per year for each of the last five years immediately preceding the date of application; and

3) The application fee set forth in N.J.A.C. 13:35-12.22.

b) If the applicant meets the requirements of (a) above, the Committee shall advise the applicant that he or she is eligible to take the Certified Technical Trainers (CTT) Examination.

13:35-12.10 LICENSING REQUIREMENTS FOR OFFICE PREMISES

a) To be eligible for an office license, a person, firm, corporation, partnership, or other legal entity intending to open and operate an electrologist's office shall:

1) Submit a completed application form provided by the Board;

2) Permit and pass inspections of the premises; and

3) Submit the fees as required by N.J.A.C. 13:35-12.22.

b) An electrology office shall be completely separate from living quarters and shall:

1) Maintain separate treatment and waiting room or rooms;

2) Have at least 48 square feet in each treatment room;

3) Have solid floor to ceiling walls in each treatment room;

4) Have a sink with hot and cold running water in each treatment room;

5) Provide sufficient lighting to perform the procedure and adequate ventilation in each treatment room;

6) Maintain clean and sanitary conditions in all rooms;

7) Provide a restroom;

8) Provide a separate outside entrance which leads directly to a waiting room if the electrology office is located within or adjacent to living quarters;

9) Maintain separate electrical outlets in each treatment room;

10) Comply with all local zoning requirements;

11) Prohibit smoking in all rooms; and

12) Prohibit animals in the treatment room, except as otherwise permitted by law.

c) An electrology office shall maintain the following equipment and supplies in each treatment room on the premises:

1) Epilators, except radio tube epilators shall not be permitted;

2) Single use, presterilized, unexpired disposable needles;

3) A sharps container;

4) A professional treatment table or professional treatment reclinable chair;

5) Magnification equipment;

6) Disposable towels, disposable client drapes and treatment table paper stored in a closed cabinet;

7) A plastic-lined trash can;

8) Non-sterile disposable examination gloves;

9) Hospital grade disinfectant detergent;

10) A covered instrument holding container for forceps;

11) FDA-approved antiseptic skin cleansing agent;

12) Liquid soap in disposable container; and

13) 70 percent Isopropyl alcohol.

d) An electrology office shall maintain:

1) An ultrasonic cleaner;

2) An autoclave or dry-heat oven manufactured for the purpose of sterilization of medical instruments;

3) Monthly reports of biological indicators;

4) Client files maintained to protect privacy and confidentiality;

5) Clean lab coats or uniforms;

6) Protein dissolving solution;

7) Treatment solutions and if not stored in an original container, labeled as to its contents;

8) Sterilization pouches; and

9) Heat indicators.

e) Any premises where electrology services have been or are being rendered shall be subject to inspection by the Committee or its representative for the purpose of enforcing the provisions of this subchapter.

f) The Board may provide exemptions to the licensing requirements of this section for a maximum of two years if an applicant can demonstrate that the applicant cannot comply with these requirements due to a pre-existing lease agreement and that such exemption or exemptions will not impair the health, safety or welfare of clients. This subsection shall expire on July 19, 2006.

13:35-12.11 INFECTION CONTROL STANDARDS

a) Electrologists shall comply with the standard precautions for infection control as set forth in this section.

b) Electrologists shall perform the handwashing technique as described in (c) below in the following instances:

1) Before and after treatment of each client;

2) Before putting on gloves and immediately after gloves are removed; and

3) Immediately upon contact with blood, bodily fluids, secretions or any item that has touched a client or that has been contaminated with blood, bodily fluids or secretions.

c) Handwashing shall be performed as follows:

1) With the use of liquid soap and water;

2) A vigorous rubbing together of all surfaces of lathered hands, including between fingers and fingernail areas, for at least 10 seconds;

3) A thorough rinsing under a stream of water; and

4) Hands dried thoroughly with a clean disposable paper towel and then the faucet turned off with the paper towel.

d) Liquid soap containers shall not be refilled and shall be disposed of when empty.

e) Electrologists shall wear a new pair of non-sterile disposable examination gloves during the treatment of each client and during the procedures of soaking, cleaning, rinsing and drying of forceps and other instruments. Gloves shall be removed, discarded, hands washed and new gloves put on:

1) When a treatment session is interrupted causing the gloves to be contaminated; or

2) When the gloves are torn or perforated.

f) Electrologists shall clean and sterilize instruments in the following circumstances:

1) Unused instruments before initial use;

2) All containers used for storing contaminated instruments, and their lids on a daily basis or whenever contaminated; or

3) Instruments contaminated before use, such as by dropping or touching a soiled surface.

g) Instruments shall be cleaned prior to sterilization by:

1) Placing in a sterilizable covered holding container and submerged in a solution of a protein dissolving enzyme detergent and cool water;

2) Thoroughly rinsing with water; or

3) Cleaning in an ultrasonic cleaning unit according to manufacturer's instructions.

h) Instruments shall be packaged individually or in packages of several instruments that would be used for an individual client and must contain a heat indicator.

i) Dry heat sterilizers and autoclaves shall be:

1) Approved by the Food and Drug Administration (FDA);

2) Contain visible physical indicators, for example, thermometers and timers; and

3) Cleaned, used and maintained according to the manufacturer's instructions.

j) Cleaned instruments shall be sterilized in accordance with the manufacturer's instructions for individual sterilizers and by one of the following methods:

1) Dry heat method which shall, at a minimum, conform to the following time-temperature relationships which relate to the time of exposure after attainment of the specific temperature does not include a heat-up lag time:

i) 338 degrees Fahrenheit (170 degrees Centrigrade)—one hour;

ii) 320 degrees Fahrenheit (160 degrees Centrigrade)—two hours; or

2) Autoclave method which shall, at a minimum, be performed for 15 to 20 minutes at 121 degrees Centrigrade (250 degrees Fahrenheit); 15 to 20 pounds per square inch for packaged instruments and items, or other time-temperature relationships recommended by the manufacturer of the units which relate to the time the material is at temperature, and shall not include a penetration or heat-up lag time.

k) Biological indicators using spore cultures must be utilized at least monthly to assure adequacy of sterilization. The spore testing shall be performed by an outside laboratory. Lab reports of biological indicators shall be filed in a sterility assurance file for two years.

l) The electrologist shall take the following safety precautions:

1) To prevent accidental puncture injuries, disposable or damaged needles shall not be recapped, bent, or otherwise manipulated by hand prior to disposal. Disposable or damaged needles shall be placed in a sharps container. The sharps container shall be securely sealed and removed by a Department of Environmental Protection regulated hauler of medical waste as required by N.J.A.C. 7:26-3A; and

2) Removable tips for epilator needle holders shall be removed after each treatment soaked in an FDA-approved chemical disinfectant in accordance with manufacturer recommendations. The covered container used to hold the disinfectant shall be emptied daily or whenever visibly contaminated, then cleaned, dried, and refilled with fresh disinfectant.

m) Soiled disposable items, other than instruments, shall be discarded into a container lined with a plastic bag, securely fastened, and disposed of daily into the regular trash disposal, unless otherwise specified by State and local health regulations.

n) A hospital-grade disinfectant registered with the Environmental Protection Agency (EPA) shall be used to disinfect:

1) Equipment, such as an epilator or lamp used during treatment, between the use of each client; and

2) Exposed surfaces such as counter tops, tables and sinks on a daily basis.

13:35-12.12 POSTING OF LICENSES AND REQUIRED NOTICES

a) All licensed office premises shall clearly display the following:

1) The office license;

2) The licenses of all electrologists rendering services within the office; and

3) A list of all services performed and the charge for each service.

b) All licensed office premises shall display the following notice:

NOTICE

This office and the electrologists herein are licensed to engage in the practice of electrology by the State of New Jersey, Division of Consumer Affairs. Any member of the public having a complaint concerning the manner in which electrology practice is conducted may notify the State Board of Medical Examiners, Electrologists Advisory Committee at PO Box 45041, Newark, New Jersey 07101.

13:35-12.13 EXAMINATION REQUIREMENTS; REEXAMINATION

a) Except as provided in N.J.A.C. 13:35-12.5, an applicant for licensure as an electrologist shall successfully complete the Certified Professional Electrology (CPE) Examination, or its successor, and the New Jersey Electrology Jurisprudence Examination.

b) An applicant, who has previously taken the Certified Professional Electrology Examination (CPE), or its successor, shall have successfully completed the examination within five years of application for an electrologist license.

c) An applicant for licensure as an electrology instructor shall successfully complete the Certified Technical Trainer Examination, or its successor.

d) The applicant shall be eligible to take either the Certified Professional Electrology (CPE) Examination or the Certified Technical Trainer Examination (CTT), or their successor, for one year from the date the Committee advises the applicant that he or she is eligible to sit for the examination or for two administrations of the examination unless the applicant can demonstrate undue hardship to the Committee.

e) If an applicant fails the Certified Professional Electrology (CPE) Examination, or its successor, twice, the applicant may take the examination a third time only if the applicant completes an electrology course(s) as directed by the Committee, from an accredited electrology education program and submits to the Committee a certification of program completion.

13:35-12.14 LICENSE ISSUANCE, RENEWAL; CHANGE OF LICENSE STATUS: INACTIVE TO ACTIVE; REINSTATEMENT OF SUSPENDED LICENSE

a) Licenses to practice electrology, electrology instructor licenses and office premises licenses shall be issued for a period of two years and be renewed biennially.

1) A licensee who seeks renewal of his or her license shall submit a license renewal application and the license renewal fee set forth in N.J.A.C. 13:35-12.22 to the Committee at least 30 days prior to the expiration of the current license. An office license is not transferable or assignable. If the holder of an office license changes, a new office license application shall be filed with the Committee within 10 days of the change.

2) Renewal applications shall provide the applicant with the option of either active or inactive status. A licensee electing inactive status shall pay the inactive license fee set forth in N.J.A.C. 13:35-12.22 and shall not engage in the practice of electrology.

3) If a licensee does not renew his or her license prior to its expiration date, the licensee may renew the license within 30 days of its expiration by submitting a renewal application, a license renewal fee and a late fee, as set forth in N.J.A.C. 13:35-12.22.

A license that is not renewed within 30 days of its expiration date shall be automatically suspended. Any individual who continues to practice with a suspended

license after 30 days following the license expiration date shall be deemed to be engaged in unlicensed practice.

4) At the time of renewal, each licensed electrologist shall certify the completion of the required number of continuing education credits as prescribed in N.J.A.C. 13:35-12.19.

5) Falsification of any information submitted with the renewal application may result in penalties, suspension of the license, or any other action deemed appropriate by the Board, pursuant to N.J.S.A. 45:1-21 through 45:1-25 and N.J.A.C. 13:35-12.17.

b) A licensee, upon application to the Board, may change from inactive to active status upon payment of the renewal fee as set forth in N.J.A.C. 13:35-12.22 and complied with the continuing education requirements as set forth in N.J.A.C. 13:35-12.19(d).

c) An individual whose license has been automatically suspended for nonpayment of a biennial renewal fee pursuant to N.J.A.C. 13:35-12.22 may be reinstated by the Board, provided the applicant otherwise qualifies for licensure pursuant to N.J.A.C. 13:35-12.6, 12.7 and 12.8, has complied with the continuing education requirements as set forth in N.J.A.C. 13:35-12.22(d), and submits a completed reinstatement application and one of the following to the Board:

1) A certification of licensure in good standing from any other state or jurisdiction in which the applicant has practiced electrology, has practiced as an electrology instructor or has held an electrology office premises license during the period the license was suspended in this State;

2) Certification by the applicant stating that he or she has practiced electrology, has practiced as an electrology instructor or has held an electrology office premises license in a state or jurisdiction which does not require certification or licensure, during the period the license was suspended in this State; or

3) Certification stating that the applicant has not practiced electrology, has practiced as an electrology instructor or has held an electrology office premises license, in this or any other jurisdiction during the period the license was suspended in this State;

d) In addition to the requirements of (c) above, an individual who has practiced electrology, has practiced as an electrology instructor or has held an electrology office premises license in the manner described in (a)1 or 2 above shall submit written verification, on a form provided by the Board, from all of the applicant's employers. The verification shall document dates of employment from the date the New Jersey license was suspended to

the date of application for reinstatement, and the name, address and telephone number of each employer.

e) An individual seeking reinstatement whose license has been automatically suspended for a period of five or more years shall successfully complete the examination required for initial licensure as set forth in N.J.A.C. 13:35-12.13.

f) Prior to reinstatement, an applicant shall pay a reinstatement fee and all past delinquent biennial renewal fees pursuant to N.J.A.C. 13:35-12.22.

13:35-12.15 UNLICENSED PRACTICE

a) No person shall practice electrology, whether or not compensation is received or expected, unless the person holds a valid license to practice electrology in this State. No person shall teach electrology, whether or not compensation is received or expected, unless the person holds a valid license to teach electrology in this State. Nothing in these rules shall be construed to:

1) Prohibit any person licensed to practice or certified to teach electrology in this State under any other law or rule from engaging in the practice or teaching for which he or she is licensed, regulated or certified; or

2) Prohibit any student enrolled in an approved clinical electrology education program from performing that which is necessary to the student's course of study.

b) No person, firm, corporation, partnership or other legal entity shall operate, maintain or use premises for the rendering of any service as provided in the definition of electrology at N.J.A.C. 13:35-12.2 without first having secured an office license from the Board.

c) No person, business entity or its employees, agents or representatives shall use the titles "licensed electrologist" or "licensed electrology instructor" or the letters "L.E." or "L.E.I.," or any other title, designation, words, letters, abbreviations or insignia indicating the practice or teaching of electrology, unless licensed to practice or teach electrology pursuant to the provisions of this subchapter.

d) The holder of an office license shall not aid, abet, or permit a person not licensed by the Board to render any services encompassed within the definition of electrology pursuant to N.J.A.C. 13:35-12.2.

13:35-12.16 LICENSURE BY CREDENTIALS (COMITY LICENSE)

a) Any person with a valid registration, certification or license to practice electrology or as an electrology instructor issued by another state or possession of the United States or the District of Columbia shall, upon submission of an application provided by the Committee and payment of a fee as set forth in N.J.A.C. 13:35-12.22, be issued a license to provide electrology services or to act as an electrology instructor, whichever is applicable, provided that:

1) The education, training, and examination requirements in such other jurisdiction are substantially equivalent to those required by this State at the time of application;

2) The applicant has not previously failed the Certified Professional Electrology (CPE) Examination or the Certified Technical Trainer (CTT) Examination or their successors, required by N.J.A.C. 13:35-12.6 and 12.7;

3) All other State registrations, certificates, or licenses are current, active, and in good standing; and

4) The applicant has passed the New Jersey Electrology Jurisprudence Examination.

b) If the out-of-State applicant has failed the examination required by N.J.A.C. 13:35-12.6 and 12.7, licensing shall be at the discretion of the Committee. The Committee shall take the following into consideration to determine the applicant's qualification for licensure:

1) Educational history;

2) Consumer complaint history;

3) Examinations taken and date(s) and number of failures, if any;

4) Employment history; and

5) Length of licensure in the other jurisdiction(s).

13:35-12.17 SUSPENSION, REVOCATION OR REFUSAL TO RENEW LICENSE

a) The Board may refuse to grant or may suspend or revoke a license to practice or teach electrology or operate an electrology office upon proof that the licensee:

1) Has employed unlicensed persons to practice electrology or supervised or aided an unlicensed person in the practice of electrology;

2) Has advertised the practice of electrology so as to disseminate false, deceptive or misleading information, whether as an individual, through a professional service corporation, or through a third party;

3) Has promoted the sale of devices, appliances, or goods to a client so as to exploit the client for financial gain;

4) Has used instruments or procedures in the practice of electrology that are not approved by the Board or Committee as set forth in N.J.A.C. 13:35-12.10 and 12.11;

5) Has maintained an office not in compliance with the standards for sanitary conditions set forth in N.J.A.C. 13:35-12.10 and 12.11;

6) Has acted in a manner inconsistent with the standards of practice of electrology at N.J.A.C. 13:35-12.10, 12.11, 12.18, 12.19, 12.20 and 12.21;

7) Has obtained a certificate, registration, license or authorization to sit for an examination, as the case may be, through fraud, deception or misrepresentation;

8) Has engaged in the use or employment of dishonesty, fraud, deception, misrepresentation, false promise or false pretense;

9) Has engaged in gross negligence, gross malpractice or gross incompetence which damaged or endangered the life, health, welfare, safety or property of any person;

10) Has engaged in repeated acts of negligence, malpractice or incompetence;

11) Has engaged in professional or occupational misconduct as may be determined by the Board;

12) Has been convicted of, or engaged in acts constituting, any crime or offense involving moral turpitude or relating adversely to the activity regulated by the Board. For the purpose of this subchapter, a judgment of conviction or a plea of guilty, non vult, nolo contendere or any other such disposition of alleged criminal activity shall be deemed a conviction;

13) Has had his or her authority to engage in the practice of electrology revoked or suspended by any other state, agency or authority for reasons consistent with this subchapter;

14) Has violated or failed to comply with the provisions of any Act or regulation administered by the Board;

15) Is incapable, for medical or any other good cause, of discharging the functions of a licensee in a manner consistent with the public's health, safety and welfare;

16) Has repeatedly failed to submit completed applications, or parts of, or documentation submitted in conjunction with such applications, required to be filed with the Department of Environmental Protection;

17) Has violated any provision of P.L. 1983, c.320 (C.17:33A-1 et seq.) or any insurance fraud prevention law or Act of another jurisdiction or has been adjudicated, in civil or administrative proceedings, of a violation of P.L. 1983, c.320 (C.17:33A-1 et seq.) or has been subject to a final order, entered in civil or administrative proceedings, that imposed civil penalties under the Act against the applicant or holder;

18) Is presently engaged in drug or alcohol use that is likely to impair the ability to practice the profession or occupation with reasonable skill and safety. For purposes of this subchapter, the term "presently" means at this time within the previous 365 days;

19) Has permitted an unlicensed person or entity to perform an act for which a license or certificate of registration or certification is required by the Board, or aided and abetted an unlicensed person or entity in performing such an act; or

20) Has advertised fraudulently in any manner.

b) In addition to the consequences listed in (a) above, the Board may impose additional or alternative penalties pursuant to N.J.S.A. 45:1-14 et seq. for violations of any provision of the Act and this subchapter.

c) The refusal to renew, temporarily suspend or revoke a license, and/or the issuance of a civil penalty under this section may be ordered by the Board provided that the licensee has an opportunity to be heard by the Board or Committee.

13:35-12.18 RECORDKEEPING

a) Licensees shall make contemporaneous, permanent entries into client records which shall accurately reflect the electrology services rendered. Client records shall be maintained for a period of seven years from the date of the most recent entry. The client record shall contain:

1) A Health History Assessment, only to the extent that it relates to the practice of electrology;

2) The dates and duration of each treatment;

3) The client's presenting problem and/or condition;

4) The name of the treating electrologist if there is more than one electrologist practicing at the office;

5) Areas treated, size of needle, modality and settings;

6) Progress notes;

7) Any referral to a physician; and

8) Fees charged and paid.

b) Corrections and/or additions may be made to a client record, provided that each change is clearly identified as such, dated and initialed by the licensee.

c) A client record which is prepared and maintained on a personal or other computer shall be producible as hard copy upon demand.

d) Licensees shall provide a copy of a client treatment record to a client or an authorized representative no later than 30 days from receipt of a written request from the client or an authorized representative.

e) Licensees shall maintain the confidentiality of professional treatment records, except that:

1) The licensee shall release client 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 client names; and

2). The licensee shall release information as required by law or regulation.

13:35-12.19 CONTINUING EDUCATION, PROGRAMS, STANDARDS

a) A licensed electrologist applying for biennial license renewal shall complete, during the preceding biennial period, continuing education in the continuing education credits specified in (c) below. Licensees during their initial period of licensure are exempt from the continuing education requirements of this section.

b) Each licensee shall confirm on the application for biennial licensure renewal that he or she has completed the required number of continuing education credits as provided for in (c) below. Falsification of any information submitted with the renewal application may result in penalties and/or license suspension pursuant to the Uniform Enforcement Act, N.J.S.A. 45:1-21.

c) Each applicant for a biennial license renewal shall complete during the preceding biennial period 20 credits of continuing education, consistent with the following requirements:

1) Six credits shall be in courses pertaining to universal precautions. All six credits pertaining to universal precautions shall be in courses that require personal attendance.

2) Fourteen credits shall be in courses and/or other activities directly related to the practice of electrology. At least four of the required 14 credits shall be in courses that require personal attendance. The remaining 10 credits may be obtained in any manner specified in (h) below.

d) A licensee whose license has been automatically suspended for nonpayment of a biennial renewal fee pursuant to "N.J.A.C. 13:35-12.17 and a licensee who seeks to reactivate the license shall submit to the Committee proof of successful completion of 10 continuing education credits per year for up to five years. If the licensee has failed to renew for five years, he or she shall retake the Certified Professional Electrology (CPE) Examination or its successor pursuant to N.J.A.C. 13:35-12.8.

e) Any continuing education credits earned that are in excess of the 20 credits specified in (c) above during a biennial licensure period shall not be carried forward into the following biennial licensure period.

f) A licensee who is required to complete remedial continuing education pursuant to Board action shall not receive credit for such imposed continuing education toward the mandatory 20 credits of biennial continuing education.

g) The Board may direct a licensee to complete continuing education credits to correct a deficiency in the licensee's continuing education requirement.

h) A licensee may obtain continuing education credits from the following:

1) Successful completion of programs, courses or seminars approved by the Continuing Education Review (CER) Committee of the American Electrology Association or the Committee pursuant to (i) below. The Committee shall approve only such continuing education programs as are available to all electrologists in this State on a reasonable nondiscriminatory basis. Programs may be held within or out of the State, but shall be held, so as to allow electrologists in all areas of the State to attend. The Committee shall maintain a list of all approved programs, courses and lectures at the Committee office and shall furnish this information to licensees upon request;

2) Post-graduate work at electrology schools whose curriculum has been approved by the Board pursuant to N.J.A.C. 13:35-12.6, transcripts of which shall be furnished to the Committee;

3) Course work in the following areas related to the practice of electrology such as:

i) Communications;

ii) Ethics;

iii) Business;

iv) Accounting;

v) Technology; and

vi) Health related subjects such as diabetes, dermatology, endocrinology, plastic surgery and allergies;

4) Authorship of peer reviewed textbooks, articles or manuals specifically related to electrology; and

5) Correspondence, self-study, televised, videotaped, teleconference and internet courses related to the practice of electrology with verification by the course provider that the course was monitored and successfully completed by the licensee.

i) Credit for continuing education shall be granted for each biennial licensure period as follows:

1) A licensee shall receive one continuing education credit for each hour of attendance at programs, courses or seminars approved by the Continuing Education Review (CER) Committee of the American Electrology Association or the Committee. Credit shall not be granted for courses that are less than one instructional hour long. Completion of an entire course is required in order to receive any continuing education credit;

2) Successful completion of post-graduate course work pursuant to (h) above: one continuing education credit for each course credit awarded;

3) Successful completion of related courses pursuant to (h) above: one continuing education credit for each course credit awarded with a maximum of five credits per biennial licensure period;

4) Publication in a peer reviewed professional journal of an article related to the practice of electrology: three credits per article with a maximum of six credits per biennial licensure period;

5) Authorship of a peer reviewed textbook or manual related to the practice of electrology: five credits for each textbook or manual with a maximum of 10 credits per biennial licensure period; and

6) Correspondence, self-study, televised, videotaped, teleconference and internet courses related to the practice of electrology: a maximum of 10 credits per biennial licensure period.

j) To report continuing credit hours, a licensee shall:

1) Certify on the application for biennial renewal completion of the required number of continuing education credits. Falsification of any information submitted on the renewal application may result in penalties and/or license suspension;

2) Maintain all evidence, as outlined in (j)3 below, of completion of continuing education requirements for a period of five years after completion of the credits and shall submit

such documentation to the Committee upon request;

3) Provide to the Committee, upon request, documentation of continuing education requirements as follows:

i) For programs, courses, seminars and conferences approved by the Board pursuant to (i) above: the course provider's written verification of attendance;

ii) For post-secondary courses: a transcript;

iii) For articles published in a peer reviewed professional journal: the published article;

iv) For authored textbooks or manuals: the textbook or manual; and

v) Correspondence, self-study, televised, videotaped teleconference and internet courses: verification from the course provider.

k) The Committee will, from time to time, conduct random audits to determine licensee compliance with continuing education requirements.

l) The Committee may, upon receipt of a request for waiver, waive continuing education requirements on an individual basis for reasons of hardship, such as severe illness, disability or military service.

1) Any licensee seeking a waiver of the continuing education requirements shall apply to the Committee in writing and set forth in specific detail the reasons for requesting the waiver. The licensee shall provide the Committee with such supplemental materials as will support the request for waiver.

m) All sponsors of continuing education shall:

1) Submit the following for each course, program or seminar offered, for evaluation by the Committee:

i) A detailed description of course content and estimated hours of instruction; and

ii) The curriculum vitae of each lecturer, including specific background which qualifies the individual as a lecturer in the area of instruction;

2) Obtain Committee approval prior to representing that any course, seminar, or program fulfills the requirements of this section;

3) Monitor the attendance at each approved course, program or seminar and furnish to each enrollee a verification of attendance, which shall include at least the following information:

   i) The title, date and location of the course, program or seminar offering;

   ii) The name and license number of the attendee;

   iii) The number of credits awarded; and

   iv) The name and signature of the sponsor and the seal of the organization;

4) Evaluate course offerings. Evaluations shall be solicited from both the attendees and the instructors; and

5) Submit a fee pursuant to N.J.A.C. 13:35-12.22 for each submission of courses, programs or seminars reviewed by the Committee.

13:35-12.20 SEXUAL MISCONDUCT

a) A licensee shall not engage in sexual contact with a client during the course of electrology treatment. "Sexual contact" means the knowing touching of a person's body directly or through clothing, where the circumstances surrounding the touching would be construed by a reasonable person to be motivated by the licensee's own prurient interest or for sexual arousal or gratification. "Sexual contact" includes, but is not limited to, the imposition of a part of the licensee's body upon the part of the client's body, sexual penetration, or the insertion or any imposition of any object of any part of a licensee's or client's body into or near the genital, anal or other opening of the other person's body. "Sexual contact" does not include the touching of a client's body which is necessary during a generally accepted and recognized electrology procedure.

b) A licensee shall not engage in any discussion of an intimate sexual nature with a client during the course of treatment unless that discussion is directly related to a proper electrology purpose. Such discussion shall not include disclosure by the licensee of his or her own sexual relationships.

c) A licensee shall provide privacy and examination conditions which prevent the exposure of the unclothed body of the client. Appropriate draping measures shall be employed to protect the client's privacy.

d) A licensee shall not engage in sexual harassment during the course of electrology treatment. "Sexual harassment" means solicitation of any sexual act, physical advances, or verbal or non-verbal contact that is sexual in nature, and which occurs in connection with a licensee's activities or role as a provider of electrology services, and that either: is unwelcome, offensive to a reasonable person, or creates a hostile workplace environment, and the licensee knows, should know, or is told this; or is sufficiently severe or intense to be abusive to a reasonable person in that context.

e) A licensee shall not engage in any other activity during the course of treatment which would lead a reasonable person to believe that the activity serves the licensee's personal prurient interests or which is for the sexual arousal, or sexual gratification of the licensee or client or which is construed as an act of sexual abuse.

f) Violation of any of the prohibitions or directives set forth in (a) through (e) above shall constitute professional misconduct pursuant to N.J.S.A. 45:1-21 (e).

g) It shall not be a defense to any action under this section that the client solicited or consented to sexual contact with the licensee.

13:35-12.21 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.

"Advertisement" means 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 to purchase or enter into an agreement for treatment from a licensee.

"Electronic media" means radio, television, and Internet.

"Graphic representation" means the use of drawings, animations, clinical photographs, dramatizations, music or lyrics.

"Print media" means 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.

"Range of fees" means a stated upper and lower limit on the fees charged for services or goods offered by a licensee.

"Routine professional service" means a service which a licensee routinely performs.

b) A licensee may provide information to the public by advertising in print or electronic media.

c) An advertisement by a licensee shall include:

1) The name of the licensee;

2) The address of the licensee's office;

3) The licensee's office phone number; and

4) The license number and/or premises license number.

d) A 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 such as a graphic representation, which is false, fraudulent, misleading or deceptive;

2) Any claim that the treatment performed or the materials and/or equipment used are superior to that which is ordinarily performed or used in the profession unless the claim is objective and can be substantiated;

3) Any promotion of a professional service which the licensee knows or should know is beyond the licensee's ability to perform or any guarantee of results from any treatment not consistent with the definition of electrology in N.J.A.C. 13:35-12.2;

4) The communication of any fact, data or information which may personally identify a client without that client's signed written permission obtained in advance; or

5) Any violations of (e) through (j) below.

e) The Committee may require a licensee to substantiate the truthfulness of any assertion or representation set forth in an advertisement. Failure of a licensee to provide factual

substantiation to support a representation or assertion shall be deemed professional misconduct.

f) An advertisement offering free services or a fee reduction, including coupons, shall state the reduced fee or range of fees and the licensee'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.

g) The responsibility for the form and content of any advertisement offering treatment by a licensee shall be:

1) Jointly and severally that of each licensee who is a principal of the firm or entity identified in the advertisement; and

2) Borne by the licensee even if the advertisement is placed by an unlicensed entity.

h) 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.

i) A video or audio tape of every advertisement communicated by electronic media shall be retained by the licensee and shall be made available for review upon request by the Committee. 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.

j) Testimonial advertisement shall be conducted as follows:

1) All testimonials involving a specific or identifiable procedure shall truthfully reflect the actual experience of the client and shall include the following statement:

"This procedure may not be suitable for every client. All clients must be evaluated by an electrologist as the appropriateness of performing the procedure and informed of any potential risks and complications."

Where compensation has been paid 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."

2) A licensee 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, at a minimum, the name, address and telephone number of the individual in the advertisement, the type and amount or value of compensation.

3) The testimonial shall not guarantee any specific results from any treatment.

13:35-12.22 FEE SCHEDULE

k) The following fees shall be charged by the Committee:

1) Application fee:

i) Electrologist $100.00

ii) Electrology instructor..... $ 75.00

iii) Office premises $200.00

2) Initial license fee:

i) Electrologist:

(1) First year of the biennial period $200.00

(2) Second year of the biennial period $100.00

ii) Electrology Instructor:

(1) First year of the biennial period $100.00

(2) Second year of the biennial period… $50.00

iii) Office premises:

(1) First year of the biennial period $90.00

(2) Second year of the biennial period $45.00

3) Biennial license renewal fee:

i) Electrologist $200.00

ii) Electrology instructor..... $100.00

iii) Office premises $90.00

4) Duplicate license $25.00

5) Duplicate wall certificate $40.00

6) Reinstatement fee..... $150.00

7) Late fee $50.00

8) Jurisprudence examination $50.00

9) Comity license $75.00

10) Continuing education sponsor fee $100.00

11) License verification fee $40.00

12) Inactive license fee .....(Reserved)

SUBCHAPTER 13.
PERFUSIONISTS ADVISORY COMMITTEE

13:35-13.1 PURPOSE AND SCOPE

a) This subchapter implements the Perfusionist Licensing Act, N.J.S.A. 45:9-37.94 et seq., and shall apply to all applicants seeking licensure as a perfusionist and all perfusionists licensed in the State of New Jersey.

b) This subchapter shall not apply to any person:

1) Licensed to practice under any other law and who is engaging in the practice for which he or she is licensed, registered or certified;

2) Enrolled as a student in a bona fide perfusion training program recognized by the Committee in performing those duties which are necessary for the student's course of study, provided the duties are performed under the supervision and direction of a licensed perfusionist;

3) Practicing perfusion within the scope of his or her official duties when employed by an agency, bureau or division of the Federal government, serving in the Armed Forces or the Public Health Service of the United States, or employed by the Veterans Administration; or

4) Performing autotransfusion or blood conservation techniques under the supervision of a licensed physician.

13:35-13.2 DEFINITIONS

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Act" means the Perfusionist Licensing Act, N.J.S.A. 45:9-37.94 et seq.

"Address of record" means an address designated by a licensee which is part of the public record and which may be disclosed upon request made to the Committee. "Address of record" may be a licensee's home, business, mailing address, or a post office box.

"Board" means the State Board of Medical Examiners.

"Committee" means the Perfusionists Advisory Committee established pursuant to section 4 of P.L. 1999, c.126 (N.J.S.A. 45:9-37.97 et seq.)

"Licensee" means an individual holding a license issued by the Perfusionist Advisory Committee under the State Board of Medical Examiners.

"Extracorporeal circulation" means the diversion of a patient's blood through a heart-lung machine or a similar device that assumes the functions of the patient's heart, lungs, kidney, liver or other organs.

"Perfusionist" means a person who is licensed to practice perfusion pursuant to the provisions of P.L. 1999, c.126 (N.J.S.A. 45:9-37.94 et seq.).

"Perfusion" means the functions necessary for the support, treatment, measurement or supplementation of the cardiovascular, circulatory or respiratory system or other organs, or a combination of those activities, and to ensure the safe management of physiologic functions by monitoring and analyzing the parameters of the systems under an order and under the supervision of a licensed physician, including:

1. The use of extracorporeal circulation, long-term cardiopulmonary support techniques including extracorporeal carbon-dioxide removal and extracorporeal membrane oxygenation, and associated therapeutic and diagnostic technologies;

2. Counterpulsation, ventricular assistance, autotransfusion, blood conservation techniques, myocardial and organ preservation, extracorporeal life support and isolated limb perfusion;

3. The use of techniques involving blood management, advanced life support and other related functions;

4. In the performance of the activities described above, the administration of:

   i. Pharmacological and therapeutic agents;

   ii. Blood products or anesthetic agents through the extracorporeal circuit or through an intravenous line as ordered by a physician;

5. In the performance of the activities described above, the performance and use of:

   i. Anticoagulation monitoring and analysis;

   ii. Physiologic monitoring and analysis;

   iii. Blood gas and chemistry monitoring and analysis;

   iv. Hematologic monitoring and analysis;

   v. Hypothermia;

   vi. Hyperthermia;

   vii. Hemoconcentration and hemodilution;

viii. Modified extracorporeal circulatory hemodialysis; and

6. The observation of signs and symptoms related to perfusion services, the determination of whether the signs and symptoms exhibit abnormal characteristics and the implementation of appropriate reporting, perfusion protocols, or changes in or the initiation of emergency procedures.

13:35-13.3 OFFICE OF THE COMMITTEE

The office of the Committee shall be maintained at 124 Halsey Street, Newark, New Jersey. The mailing address of the Committee is PO Box 45049, Newark, New Jersey 07101.

13:35-13.4 NOTIFICATION OF CHANGE OF ADDRESS AND RECORD

a) Licensees shall notify the Committee in writing of any change of the licensee's address of record from the address filed with the Committee and shown on the most recently issued certificate. Such notice shall be sent to the Committee no later than 30 days following the date on which the address of record is changed. If a PO Box is used as the address of record, the licensee must also provide the committee with another address which includes a street, city, state and zip code.

b) Failure to notify the Committee of any change of the address of record pursuant to (a) above may result in disciplinary action in accordance with N.J.S.A. 45:1-21(h).

c) Service of an administrative complaint or other Board or Committee-initiated process at the licensee's address of record on file with the Committee shall be deemed adequate notice for the purposes of N.J.A.C. 1:1-7.1 and the commencement of any disciplinary proceedings.

13:35-13.5 LICENSURE UNDER GRANDFATHERING

a) Upon submission of an application provided by the Committee for licensure as a perfusionist and payment of the application fee set forth at N.J.A.C. 13:35-13.17, the Committee shall issue a license to any person who applies for licensure by September 3, 2005 and submits documentation demonstrating that the applicant has at least five year's experience immediately preceding the submission of the application for licensure, operating cardiopulmonary bypass systems for cardiac surgical patients as the applicant's primary function in a licensed health care facility.

1) An applicant who is certified by the American Board of Cardiovascular Perfusion (the "ABCP") shall be deemed to have demonstrated that he or she has the requisite experience operating cardiopulmonary bypass systems for cardiac surgical patients as his or her primary function in a health care facility provided that the applicant

submits evidence that he or she has performed not less than 40 perfusion procedures per calendar year.

2) An applicant who is not ABCP certified shall be deemed to have demonstrated that he or she has the requisite experience operating cardiopulmonary bypass systems for cardiac surgical patients as his or her primary function in a health care facility provided that the applicant submits evidence that he or she has performed not less than 75 perfusion procedures per calendar year.

b) An applicant for licensure under (a) above shall complete a clinical activity report form provided by the Committee. The applicant shall list on the clinical activity report each perfusion procedure he or she performed for which experience credit is claimed, within the five years preceding the date of application and shall, for each procedure listed, provided information to include:

1) The date on which the procedure was performed;

2) The medical record number of the procedure performed;

3) A description of the procedure performed;

4) The name of the surgeon who performed the procedure; and

5) The health care facility at which the procedure was performed.

c) All application materials and fees required under this section shall be received by the Committee or bear a postmark dated prior to September 3, 2005 in order to be considered timely filed.

13:35-13.6 LICENSING REQUIREMENTS FOR PERFUSIONIST

a) To be eligible for licensure as a perfusionist, an applicant shall fulfill the following requirements:

1) Be at least 18 years of age;

2) Be of good moral character;

3) Have successfully completed:

i) A perfusion education program which complies with standards established by the Accreditation Committee for Perfusion Education, approved by the Commission on Accreditation of Allied Health Education Programs (CAAHEP), or its successors; or a foreign program that has been approved by an entity with substantially equivalent standards as CAAHEP or the Conjoint Committee under the Canadian Medical Association; or a program with substantially equivalent standards; and

ii) The two-part certification examination composed of the Clinical Applications in Perfusion Examination and the Perfusion Basic Science Examination offered by the American Board of Cardiovascular Perfusion (ABCP), or its successor, or the Canadian Certification Examination.

13:35-13.7 GRACE PERIOD FOR PRACTICING WITHOUT LICENSURE PENDING APPLICATION

a) Any person who submits an application for perfusionist licensure, whether by grandfathering pursuant to N.J.A.C. 13:35-13.5 or pursuant to the licensing requirements of N.J.A.C. 13:35-13.6, by September 3, 2005, may continue to practice as a perfusionist until the application is approved or denied by the Committee. During this six-month time period, such person shall not hold himself or herself out as being licensed or certified as a perfusionist by the Committee.

b) Any person who engages in the practice of perfusion after September 3, 2005 who has not submitted an application for licensure within the time period set forth in (a) above, shall be deemed to be engaged in the unlicensed practice of perfusion.

13:35-13.8 LICENSURE BY RECIPROCITY

a) A perfusionist with a valid license, registration or certification issued by another state or possession of the United States, or the District of Columbia shall, upon the submission of an application provided by the Committee, and payment of a fee as set forth in N.J.A.C. 13:35-13.17, be issued a perfusionist license without examination, provided that:

1) The education, training and examination requirements in such other jurisdiction are substantially equivalent to those required by New Jersey at the time application; and

2) All licenses, in such other jurisdiction, are current, active and in good standing.

13:35-13.9 LICENSE REQUIRED FOR DESIGNATION AS PERFUSIONIST

a) No person shall engage or offer to engage in the practice of perfusion in the State of New Jersey unless that person holds a New Jersey license issued pursuant to N.J.S.A. 45:9-37.94 et seq., and this subchapter.

b) No person shall use the title "perfusionist" or the abbreviation "LP" or any other title, designation, words, letters, abbreviations or insignia indicating the practice of perfusion, unless licensed to practice perfusion under the provisions of P.L. 1999, c.126 (N.J.S.A. 45:9-37.94 et seq.) and the rules of this subchapter.

13:35-13.10 TEMPORARY LICENSE; SUPERVISION

a) The Committee shall issue a temporary license to practice perfusion to a graduate perfusionist who:

1) Is at least 18 years of age;

2) Is of good moral character;

3) Has successfully completed a perfusion education program which complies with standards established by the Accreditation Committee for Perfusion Education, approved by the Commission on Accreditation of Allied Health Education Programs (CAAHEP), or its successors; or a foreign program that has been approved by. an entity with substantially equivalent standards as CAAHEP or the Conjoint Committee under the Canadian Medical Association; or a program with substantially equivalent standards; and

4) Has not yet passed the certification examination required by N.J.A.C. 13:35-13.6(a)3ii.

b) An applicant for temporary licensure shall submit to the Committee:

1) A completed application form;

2) A transcript sent directly from the perfusion program;

3) A letter from the medical director of the perfusion program stating that the applicant has successfully completed the perfusion program; and

4) The required fee as set forth in N.J.A.C. 13:35-13.17.

c) A temporary perfusionist license shall expire one year from its date of issuance. A temporarily licensed perfusionist whose license expires may apply for renewal of the temporary license for one additional one-year period.

d) The temporary license shall be surrendered to the Committee upon expiration or upon the issuance of the initial license.

e) The temporarily licensed perfusionist shall practice only under the direct supervision of a licensed perfusionist. For purposes of this subsection, "direct supervision" means:

1) Immediate, constant oversight of a temporarily licensed perfusionist by a supervising licensed perfusionist for a minimum of the first 50 cases; and

2) After a minimum of the first 50 cases, the supervising licensed perfusionist shall be immediately available within the operating room suite in order to render any physical assistance to the temporarily licensed perfusionist, if required.

f) At no time shall a supervising licensed perfusionist supervise more than one temporarily licensed perfusionist.

g) A supervising licensed perfusionist shall not perform perfusion at the same time as supervising a temporarily licensed perfusionist.

h) The supervising licensed perfusionist shall be certified by the American Board of Cardiovascular Perfusion for a minimum of three years and be license by the Committee.

i) The supervising licensed perfusionist shall be responsible for the care of the patient while under extracorporeal support administered by the temporarily licensed perfusionist.

j) A temporarily licensed perfusionist shall be supervised at all times. In the event that a supervising licensed perfusionist is no longer available to supervise, the temporarily licensed perfusionist may not practice until a new supervisor is available, who shall assume responsibility for the ongoing supervision of any temporarily licensed perfusionist providing care to the patient.

k) Notwithstanding (j) above, if an emergency situation arises which potentially threatens the life or well-being of a patient, a temporarily licensed perfusionist may render perfusion services during the unanticipated absence of the supervising licensed perfusionist.

l) Every effort shall be made by the supervising licensed perfusionist and/or the temporarily licensed perfusionist to obtain direct supervision in any emergent situation as described in (k) above.

13:35-13.11 LICENSE RENEWAL

a) The Committee shall send a notice of renewal to all licensees at least 60 days prior to the date of license expiration. If the notice to renew is not sent at least 60 days prior to the license expiration date, no monetary penalties or fines shall apply to a licensee for failure to renew.

b) A license to practice perfusion shall be issued for a period of two years. A licensee who seeks renewal of his or her license shall submit a license renewal application and the license renewal fee as set forth in N.J.A.C. 13:35-13.17 to the Committee prior to the expiration of the current license. The applicant shall also certify successful completion of the continuing education requirements prescribed in N.J.A.C. 13:35-13.16.

c) Renewal applications shall provide the applicant with the option of either active or inactive status. Licensees electing inactive status shall pay the inactive license fee as set forth in N.J.A.C. 13:35-13.17 and shall not engage in the practice of perfusion.

d) If a licensee does not renew his or her license prior to its expiration, the licensee may renew the license within 30 days of its expiration by submitting a renewal application, a license renewal fee and a late fee, as set forth in N.J.A.C. 13:35-13.17.

e) A license that is not renewed within 30 days of its expiration shall be automatically suspended. An individual who continues to practice with a suspended license shall be deemed to be engaged in unlicensed practice.

f) Falsification of any information submitted with a renewal application may result in penalties and/or suspension of the license pursuant to N.J.S.A. 45:1-21, 45:1-22 and 45:1-25 and N.J.A.C. 13:35-13.15.

13:35-13.12 CHANGE OF LICENSE STATUS: INACTIVE TO ACTIVE

a) A licensee who has placed his or her license in inactive status pursuant to N.J.A.C. 13:35-13.11(b) may, upon application to the Committee and payment of the renewal fee as set forth in N.J.A.C. 13:35-13.17, return to active status.

b) Upon application to the Committee, the licensee shall present proof of completion of the continuing education credits which would have been required for license renewal at the time the licensee elected inactive status.

c) A licensee who has been on inactive status shall complete 15 continuing education credits for each year the licensee is on inactive status.

d) A licensee who has been on inactive status for one year or more shall complete all continuing education credits as required in (b) and (c) above and shall also demonstrate:

1) That the licensee has maintained certification by the American Board of Cardiovascular Perfusion (ABCP) continuously for the entire time period that the license has been inactive;

2) If the licensee has not maintained certification by the ABCP and has been inactive for more than one year but less than three years, the licensee shall take and pass the Clinical Applications in Perfusion Examination administered by the ABCP; or

3) If the licensee has not maintained certification by the ABCP and has been inactive for more than three years, the licensee shall take and pass the certification examination required in N.J.A.C. 13:35-13.6(a)3ii.

13:35-13.13 REINSTATEMENT OF SUSPENDED LICENSE

a) A person seeking reinstatement following the suspension of a license, pursuant to N.J.A.C. 13:35-13.11(d) for nonrenewal of a biennial license, may be reinstated by the Committee, provided the applicant otherwise qualifies for licensure pursuant to N.J.A.C. 13:35-13.6 and submits to the Committee the following information and materials:

1) A completed reinstatement application;

2) Payment of all past delinquent renewal fees as set forth in N.J.A.C. 13:35-13.17;

3) Payment of a reinstatement fee as set forth in N.J.A.C. 13:35-13.17;

4) An affidavit, on a form provided by the Committee and submitted by the applicant, that states whether or not the applicant has been practicing perfusion in this or any other state;

5) An affidavit verifying completion of the continuing education credits required for the renewal of an active license; and

6) If the applicant has been practicing perfusion, the applicant shall obtain an affidavit(s), on a form provided by the Committee, from all of the applicant's employers, documenting the dates of employment from the date that the New Jersey

license was suspended to the date of application for reinstatement and the name, address and telephone number of each employer.

b) An applicant whose license has been suspended for nonrenewal of a biennial license shall meet the following requirements as a condition of reinstatement:

1) Maintenance of certification by the American Board of Cardiovascular Perfusion (ABCP) continuously for the entire time period that the license has been suspended in this State;

2) If the applicant has not maintained certification by the ABCP and the license has been suspended for more than one year but less than three years, the applicant shall take and pass the Clinical Applications in Perfusion Examination administered by the ABCP; or

3) If the license has been suspended for a period of three years or more, even if the applicant has maintained certification by the ABCP, the licensee shall take and pass the certification examination required in N.J.A.C. 13:35-13.6(a)3ii.

13:35-13.14 DUTY TO REPORT CHANGE IN STATUS

a) A licensee shall notify the Committee in writing, within 30 days, of any change in status at each licensed health care facility with which the licensee has an affiliation. The licensee shall further indicate the effective date of the change in status and provide an explanation therefor.

b) A licensee shall notify the Committee, in writing, of any changes in circumstances which would alter the response last provided by the licensee to questions on the biennial renewal form eliciting information pertaining to pending or finalized actions, including those predicated on a no contest or nolo contendere plea or other consensual or voluntary agreement, or a surrender or resignation of license or of privileges or a consent to limitations on practice which occurred as a result of an investigation or of pending action. The following actions shall be reported:

1) Actions by law enforcement authorities for statutory or regulatory violations;

2) Actions by a New Jersey health care facility which condition, curtail, limit, suspend or revoke privileges;

3) Disciplinary actions by New Jersey or out-of-State licensing authorities;

4) Actions by the Department of Health and Senior Services;

5) Actions by professional review organizations or utilization review organizations;

6) Actions by a medical malpractice insurance carrier which decline coverage or decline continuation of coverage, assess a surcharge based on claims experience, impose new limitations or restrictions on practice, or require remedial education or monitoring; and

7) Entry of judgment in any malpractice actions or settlements.

c) A licensee shall notify the Committee, in writing, of any changes in circumstances which would alter the response last provided by the licensee to questions on the biennial renewal form pertaining to medical conditions and use of chemical substances which in any way impair or limit the licensee's ability to practice with reasonable skill and safety.

d) Failure by a licensee to provide the Committee with notice of any information required pursuant to this section within 30 days of the change or the event necessitating the filing of the notice may be deemed professional misconduct within the meaning of N.J.S.A. 45:1-21(e).

13:35-13.15 SUSPENSION, REVOCATION OR REFUSAL TO RENEW LICENSE

a) The Board may refuse to grant or may suspend or revoke a license to practice perfusion upon proof that the licensee:

1) Has permitted an unlicensed person or entity to perform an act for which a license is required by the Committee, or aided and abetted an unlicensed person or entity in performing such an act;

2) Used procedures and/or acted in a manner inconsistent with the standards of the practice of perfusion;

3) Has obtained a license or authorization to sit for an examination, as the case may be, through fraud, deception or misrepresentation;

4) Has engaged in the use or employment of dishonesty, fraud, deception, misrepresentation, false promise or false pretense;

5) Has engaged in gross negligence, gross malpractice or gross incompetence which damaged or endangered the life, health, welfare, safety or property of any person;

6) Has engaged in repeated acts of negligence, malpractice or incompetence;

7) Has engaged in professional or occupational misconduct as may be determined by the Board or Committee;

8) Has been convicted of, or engaged in acts constituting any crime or offense involving moral turpitude or relating adversely to the activity regulated by the Committee. For the purpose of this subchapter, a judgment of conviction or a plea of guilty, non vult, nolo contendere or any other such disposition of alleged criminal activity shall be deemed a conviction;

9) Has had his or her authority to engage in the practice of perfusion revoked or suspended by any other state, agency or authority for reasons consistent with this subchapter;

10) Has violated or failed to comply with the provisions of any Act or regulation administered by the Committee;

11) Is incapable, for medical or any other good cause, of discharging the functions of a licensee in a manner consistent with the public's health, safety and welfare;

12) Has violated any provision of P.L. 1983, c.320 (N.J.S.A. 17:33A-1 et seq.) or any insurance fraud prevention law or Act of another jurisdiction or has been adjudicated, in civil or administrative proceedings, of a violation of P.L. 1983, c.320 (N.J.S.A. 17:33A-1 et seq.) or has been subject to a final order, entered in civil or administrative proceedings, that imposed civil penalties;

13) Is presently engaged in drug or alcohol use that is likely to impair the ability to practice the profession or occupation with reasonable skill and safety. For purposes of this subchapter, the term "presently" means at any time within the previous 365 days; or

14) Advertised the practice of perfusion so as to disseminate false, deceptive or misleading information, whether as an individual, through a professional service corporation or through a third party.

b) In addition to the consequences listed in (a) above, the Board may impose additional or alternative penalties pursuant to N.J.S.A. 45:1-22 and 45:1-25 for violations of any provision of N.J.S.A. 45:9-37.94 et seq., and this subchapter.

c) The Board may order a refusal to renew license, suspension of license, temporary suspension of license or revocation of license, and/or the issuance of a civil penalty under this section, provided that the licensee has an opportunity to be heard by the Board pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.

13:35-13.16 CONTINUING EDUCATION

a) A licensee applying for biennial license renewal shall complete, during the preceding biennial period, 30 continuing education (CE) credits as specified under this section. Applicants for initial licensure are exempt from the continuing education requirements of this section for the initial biennial period of licensure.

b) Each licensee shall confirm on the application for biennial licensure renewal that he or she has completed 30 continuing education credits. The Committee may conduct random audits to determine licensee compliance with continuing education requirements.

c) A licensee who completes credit hours in excess of the 30 credits required may apply no more than 15 of those credits to the continuing education requirement for the following biennial period only.

d) A licensee who is required to complete remedial continuing education pursuant to Board or Committee action shall not receive credit for such imposed continuing education toward the mandatory 30 credits of biennial licensure period.

e) The Committee may direct a licensee to complete continuing education credits to correct a deficiency in the licensee's continuing education requirement.

f) A licensee may obtain continuing education credits from the following:

1) Successful completion of programs, courses or seminars approved by the Committee, pursuant to (j) below. The Committee shall approve only such continuing education programs as are available to all perfusionists in this State on a reasonable, non-discriminatory basis. The Committee shall maintain a list of all approved programs, courses and lectures at the Committee office and shall furnish this information to licensees upon request;

2) Courses approved by the American Board of Cardiovascular Perfusion (ABCP);

3) Post-graduate courses at Commission on Accreditation of Allied Health Education Programs (CAAHEP) approved perfusion schools;

4) Courses offered in Pediatric Advanced Cardiac Life Support (PALS) and/or Advanced Cardiac Life Support (ACLS) and courses offered by the American Heart Association (AHA), the Society of Thoracic Surgeons, the American Association for Thoracic Surgery, the American College of Cardiology (ACC), the American Academy of Cardiovascular Perfusion (AACP), the American Society of Extracorporeal Technology (AmSect), the American Society of Anesthesiology (ASA), the Society of Cardiovascular Anesthesiologists (SCA), the American Society of Blood Banks, the American College of Chest Physicians, the Joint Commission on Accreditation of Healthcare Organizations, the National Heart, Lung and Blood Institute, the New England Journal of Medicine, the New Jersey State Perfusion Society and the American College of Surgeons (ACS) and the Cardiovascular Research Education Foundation (CREF);

5) Medical science courses relevant to the scope of practice of perfusion, as defined in N.J.A.C. 13:35-13.2;

6) Professional presentations consisting of new courses specifically related to perfusion. For purposes of this paragraph, "new" means a course which the licensee has never taught before in an educational setting;

7) Authorship of peer reviewed textbooks, articles or manuals specifically related to perfusion: and

8) Videotaped, teleconference and Internet courses related to the practice of perfusion, with verification by the course provider that the course was monitored and successfully completed by the licensee.

9)

g) Credit for continuing education shall be granted for each biennial licensure period as follows:

1) A licensee shall receive one continuing education credit for each hour of attendance at programs, courses or seminars approved by the Committee pursuant to (j) below. Credit shall not be granted for courses that are less than one instructional hour long. For purposes of this subchapter, an "instructional hour" represents a 60-minute clock hour with no less than 50 minutes of content within the hour. Programs may include one 10-minute break for each instructional hour;

2) Successful completion of courses approved by the ABCP pursuant to (f)2 above: one continuing education credit for each course credit awarded;

3) Successful completion of post-graduate courses pursuant to (f)3 above: one continuing education credit for each course credit awarded;

4) Successful completion of perfusion related courses pursuant to (f)4 and/or (f)5 above: one continuing education credit for each course credit awarded and a maximum of 15 credits per biennial licensure period;

5) Professional presentations pursuant to (f)6 above: three credits per new course presentation with a maximum of six credits per biennial licensure period;

6) Publication in a peer-reviewed professional journal of an article related to the practice of perfusion pursuant to (f)7 above: three credits per article with a maximum of six credits per biennial licensure period;

7) Authorship of a peer-reviewed textbook or manual related to the practice of perfusion pursuant to (f)7 above: five credits for each textbook or manual with a maximum of 10 credits per biennial licensure period; and

8) Videotaped, teleconference and Internet courses related to the practice of perfusion pursuant to (f)8 above: one credit for each course with a maximum of 10 credits per biennial licensure period.

h) To report continuing education credit hours, a licensee shall:

1) Certify on the application for biennial renewal, completion of the required number of continuing education credits. Falsification of any information submitted on the renewal application shall provide cause for penalties and/or license suspension;

2) Maintain all evidence of verification of continuing education requirements for a period of four years after completion of the credits and submit such documentation to the Committee upon request; and

3) Provide to the Committee upon request, documentation of continuing education requirements as follows:

i) For programs, courses, seminars and conferences approved by the Committee: the course provider's written verification of attendance;

ii) For post-graduate courses: an official transcript;

iii) For articles published in a peer-reviewed professional journal: the published article;

iv) For professional presentations: brochure, announcement or written evidence of presentation;

v) For authored textbooks or manuals: the textbook or manual; and

vi) Videotaped, teleconference and Internet courses: written verification from the course provider.

i) The Committee may extend and/or waive the time period for completion of continuing education requirements on an individual basis for reasons of hardship, such as severe illness, disability or military service.

1) A licensee seeking an extension and/or waiver of the continuing education requirements shall apply to the Committee in writing and set forth in specific detail the reasons for requesting the extension and/or waiver. The licensee shall submit to the Committee all documentation in support of the request for extension and/or waiver.

2) A licensee shall apply for an extension and/or waiver within 60 days of the expiration of the biennial renewal period. All requests shall be sent to the Office of the Committee, as defined in N.J.A.C. 13:35-13.3, by certified mail, return receipt requested.

j) All sponsors of continuing education seeking approval under (f)1 above shall:

1) Submit for each course, program or seminar offered, for evaluation by the Committee:

i) A detailed description of course content and estimated hours of instruction;

ii) The curriculum vitae of each lecturer, including the specific background which qualifies the individual as a lecturer in the area of instruction; and

iii) A form of verification of attendance that will be provided to attendees.

2) Obtain Committee approval prior to representing that any course, seminar or program fulfills the requirements of this section;

3) Monitor the attendance at each approved course, program or seminar and furnish to each enrollee a verification of attendance, which shall include at least the following information:

i) The title, date and location of the course, program or seminar;

ii) The name of the attendee;

iii) The number of credits awarded; and

iv) The name and signature of the sponsor and the official documentation of the organization.

4) Submit course evaluations. The sponsor shall conduct post-course evaluations. Evaluations shall be solicited from both the participants and instructors. Courses shall be evaluated to determine whether:

i) Objectives have been met;

ii) Prerequisites were necessary or desirable;

iii) Facilities were satisfactory;

iv) The instructor was effective;

v) Advanced preparation materials were satisfactory; and

vi) The course content was timely and effective; and

5) Submit a fee pursuant to N.J.A.C. 13:35-13.17 for each new course, program or seminar reviewed by the Committee.

k) Failure of a sponsor to comply with the content requirements for continuing education courses and the responsibilities of course sponsors as specified in (j) above may result in the suspension of the pre-approved status for courses offered by the sponsor. The Committee may rescind course approval based on the content of the post-course evaluations.

13:35-13.17 FEE SCHEDULE

k) The fee schedule for the Committee shall be as follows:

1) Application fee: (non-refundable) $20.00

2) Temporary license $75.00

   i) Extension of temporary license $75.00

3) 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

4) Biennial registration renewal $150.00

5) Application for reciprocal license.....$150.00 plus the applicable initial certification fee set forth in (a)3 above

6) Inactive license fee .....(to be established by rule by the Director)

7) Reinstatement fee.....(to be established by rule by the Director)

8) Sponsor course approval fee $100.00

9) Late fee $25.00

10) Duplicate or replacement of biennial registration certificate..... $25.00

11) Preparation of certification papers for applicants to other states $25.00

SUBCHAPTER 14.

GENETIC COUNSELING ADVISORY COMMITTEE

13:35-14.1 PURPOSE AND SCOPE

a) The purpose of this subchapter is to implement the provisions of P.L. 2009, c. 41 (N.J.S.A. 45:9-37.111 et seq.), which created the Genetic Counseling Advisory Committee under the Board of Medical Examiners.

b) This subchapter shall apply to all applicants who seek licensure by the Committee as a genetic counselor and to all persons who are licensed by the Committee as genetic counselors in this State.

c) This subchapter does not apply to any person who is:

1) Licensed by the State to practice medicine and surgery, so long as the person does not hold him- or herself out to the public as a licensed genetic counselor;

2) Licensed by the State as a registered professional nurse, when acting within the scope of the person's profession and performing work of a nature consistent with the person's training, so long as the person does not hold him- or herself out to the public as a genetic counselor;

3) A student enrolled in an educational program accredited by the American Board of Genetic Counseling or its successor, so long as the student is practicing as part of a supervised course of study and is clearly designated by the title "genetic counseling intern" or a title of similar import;

4) A graduate from an educational program accredited by the American Board of Genetic Counseling, the American Board of Medical Genetics, or their successors, who meets the requirements of N.J.A.C. 13:35-14.4; or

5) A genetic counselor from another state providing genetic counseling services in New Jersey pursuant to N.J.A.C. 13:35-14.5.

13:35-14.2 DEFINITIONS

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise:

"Board" means the State Board of Medical Examiners.

"Committee" means the Genetic Counseling Advisory Committee.

"Direct review" means a supervisor is immediately available in person or by electronic means.

"Genetic conditions" means a disease caused in whole or in part by a change in the DNA sequence away from the normal sequence, which may include chromosome abnormalities, single gene disorders, complex conditions, conditions due to genetic variants, gene environment interactions, epigenetics, and issues related to pharmacogenomics.

"Genetic counseling" means a communication process, conducted by one or more appropriately trained individuals, that may include: obtaining and interpreting individual, family, medical, and developmental histories; determining the mode of inheritance and risk of transmission of genetic conditions and birth defects; discussing the inheritance features, natural history, means of diagnosis, and management of genetic conditions and birth defects; identifying, coordinating, and explaining the clinical implications of genetic laboratory tests and other diagnostic studies and their results; integrating genetic laboratory test results and other diagnostic studies with personal and family medical history to assess and communicate risk factors for genetic or medical conditions and diseases; assessing psychosocial factors; recognizing social, educational, and cultural issues; evaluating the client's or family's responses to the condition or risk of recurrence and providing client-centered counseling and anticipatory guidance; and facilitating informed decision making about testing, management, and alternatives.

"Licensed genetic counselor" means a person who holds a current, valid license issued by the Committee.

"Medical geneticist" means a physician licensed by the Board who is certified by the American Board of Medical Genetics or its successor.

"Supervision" means the direct review of an unlicensed individual for the purpose of teaching, training, administration, accountability, or clinical review by a supervisor in the same area of specialized practice.

"Supervisor" means a licensed genetic counselor or a medical geneticist.

13:35-14.3 APPLICATION FOR LICENSURE

a) An applicant for a license shall submit to the Committee:

1) A completed application for license on a form available from the Committee;

2) Proof that the applicant holds a master's degree or doctoral degree in genetic counseling from an institution accredited by either the American Board of Genetic Counseling or American Board of Medical Genetics, or their successors;

3) Proof that the applicant has passed the genetic counseling certification examination offered by the American Board of Medical Genetics, the American Board of Genetic Counseling, or their successors; and

4) The application and licensing fees from N.J.A.C. 13:35-14.18.

13:35-14.4 PRACTICE PRIOR TO PASSING THE EXAMINATION FOR LICENSURE

a) Prior to passing the genetic counseling examination for licensure, an individual who has met all of the other licensing requirements of N.J.A.C. 13:35-14.3 and has submitted a completed application to the Committee may apply to the Committee for a work permit letter authorizing the applicant to provide genetic counseling. The holder of a work permit letter shall:

1) Not hold him- or herself out to the public as a licensed genetic counselor; and

2) Practice under the supervision of a licensed genetic counselor or a medical geneticist pursuant to (b) below.

b) A licensed genetic counselor or medical geneticist providing supervision of a holder of a work permit letter shall:

1) Supervise no more than two holders of work permit letters at a time;

2) Co-sign all consultation summaries prior to release of the summaries; and

3) Conduct face-to-face reviews with a holder of a work permit letter for at least one hour a week.

c) An applicant seeking a work permit letter shall submit to the Committee:

1) Proof from the American Board of Genetic Counseling or its successor that the applicant is eligible to take the licensing examination; and

2) A signed statement from the licensed genetic counselor or medical geneticist indicating that he or she will supervise the applicant. This statement shall include the supervisor's license number.

d) The holder of a work permit letter who provides genetic counseling shall indicate that he or she is a "permitted genetic counselor" whenever he or she identifies him- or herself either in person or on a chart, report, or other document.

e) The holder of a work permit letter who provides genetic counseling shall take the first examination for which he or she is eligible. If the holder fails the first examination, he or she shall take the next examination for which he or she is eligible. If the holder fails the second examination, he or she shall surrender the work permit letter to the Committee and shall not provide genetic counseling until he or she passes the examination and obtains a license from the Committee.

f) Notwithstanding (e) above, the holder of a work permit letter who has failed to take the first or second examination for which he or she is eligible may apply to the Committee to maintain his or her work permit letter if he or she failed to take an examination for reasons of hardship. An application to maintain a work permit letter shall set forth in specific detail the reasons for requesting to maintain the work permit letter. The holder shall provide the Committee with supplemental materials that support the request to maintain the work permit letter.

g) The holder of a work permit letter who was permitted to maintain the work permit letter pursuant to (f) above shall take the first examination for which he or she is eligible. If he or she fails this examination, or fails to take the examination, he or she shall surrender the work permit letter to the Committee.

13:35-14.5 OUT-OF-STATE GENETIC COUNSELOR

a) An individual who is not a licensed genetic counselor may provide genetic counseling to clients physically present in New Jersey if the individual is either licensed in another state as a genetic counselor or is certified by the American Board of Genetic Counseling or the American Board of Medical Genetics, if the individual is from a state that does not license genetic counselors.

b) An unlicensed individual providing genetic counseling pursuant to this section shall not interact with more than six clients in New Jersey in one calendar year.

c) The requirements of this section shall not apply to an unlicensed genetic counselor who is:

1) Providing consultation to licensed genetic counselors or other health care professionals;

2) Providing genetic counseling as part of a medical study that is performed under the jurisdiction of an institutional review board; or

3) Presenting educational information to professional peers or to a not-for-profit client advocacy organization.

13:35-14.6 RENEWAL OF LICENSE

a) Licenses shall be renewed biennially on a form provided by the Committee. An applicant for license renewal shall attest that the continuing education requirements of N.J.A.C. 13:35-14.7 have been completed during the prior biennial period.

b) The Committee shall send a notice of renewal to each licensed genetic counselor at least 60 days prior to the expiration of the license. If the notice to renew is not sent at least 60 days prior to the expiration date, no monetary penalties or fines shall apply to the licensed genetic counselor for any unlicensed practice during the period following the licensure expiration, not to exceed the number of days short of 60 before the renewals were issued.

c) The licensed genetic counselor shall submit the renewal application and pay the renewal fee pursuant to N.J.A.C. 13:35-14.18 prior to the date of expiration of the license. If a licensed genetic counselor does not renew the license prior to its expiration date, he or she may renew it no later than 30 days after its expiration date by submitting a renewal application and paying a renewal fee and a late fee pursuant to N.J.A.C. 13:35-14.18. A licensed genetic counselor who fails to renew the license within 30 days after the expiration date of the license shall be suspended without a hearing.

d) Individuals who continue to practice in New Jersey or hold themselves out as licensed genetic counselors in New Jersey after being suspended shall be deemed to have violated N.J.S.A. 45:9-37.117, even if no notice of suspension had been provided to the person.

e) A person seeking reinstatement within five years following the suspension of a license pursuant to (c) above shall demonstrate his or her competency to provide genetic counseling services and shall submit the following to the Committee:

1) A completed reinstatement application;

2) Payment of the past delinquent renewal;

3) Payment of a reinstatement fee as set forth in N.J.A.C. 13:35-14.18;

4) A certification verifying completion of the continuing education credits pursuant to N.J.A.C. 13:35-14.7 for renewal of a license; and

5) An affidavit of employment listing each job held during the period of suspension, which includes the names, addresses, and telephone numbers of each employer.

f) In addition to fulfilling the requirements set forth in (e) above, a person whose license has been suspended pursuant to (c) above for more than five years who seeks to have his or her license reinstated shall demonstrate that he or she has maintained proficiency. A person who fails to demonstrate to the satisfaction of the Committee that he or she has maintained proficiency while suspended may be subject to an examination or other requirements as determined by the Committee prior to reinstatement of his or her license.

g) Renewal applications for all licenses shall provide the licensed genetic counselor with the option of either active or inactive renewal. Licensed genetic counselors electing to renew as inactive shall not practice in New Jersey or hold themselves out to the public as licensed genetic counselors in New Jersey.

h) The Committee may permit a licensed genetic counselor who has been on inactive status to return to active status upon application to the Committee.

i) A person who elected inactive status and has been on inactive status for five years or less who can demonstrate his or her competency to provide genetic counseling services may be reactivated by the Committee upon submission of the following:

1) A certification verifying completion within the last two years of the continuing education hours required pursuant to N.J.A.C. 13:35-14.7 for the renewal of a license;

2) An affidavit of employment listing each job held during the period the licensed genetic counselor was on inactive status, which includes the name, address, and telephone number of each employer; and

3) Payment of the renewal fee as set forth in N.J.A.C. 13:35-14.18.

j) In addition to the fulfilling the requirements set forth in (i) above, a person whose license has been inactive for more than five years who seeks to have his or her license reactivated shall demonstrate that he or she has maintained proficiency. A person who fails to demonstrate to the satisfaction of the Committee that he or she has maintained proficiency while inactive may be subject to an examination or other requirements as determined by the Committee prior to reactivation of his or her license.

13:35-14.7 CONTINUING EDUCATION

a) Upon biennial license renewal, licensed genetic counselors shall attest that they have completed courses of continuing education of the types and number of credit hours specified in (b) below. Falsification of any information submitted on the renewal application may require an appearance before the Committee and may subject a licensed genetic counselor to penalties and/or suspension or revocation of the license pursuant to N.J.S.A. 45:1-21 through 45:1-25.

b) Each applicant for biennial license renewal shall be required to complete, during the preceding biennial period, 40 continuing education hours related to the practice of genetic counseling, except as provided in (c) below. These 40 continuing education hours shall include at least one hour in medical ethics.

c) A licensed genetic counselor who is licensed in the second year of a biennial renewal period shall not be required to complete continuing education hours during that biennial period.

d) A licensed genetic counselor who completes more than the minimum continuing education hours set forth above during the last six months of a biennial registration period may carry no more than 20 of the additional continuing education hours into a succeeding biennial period.

e) A licensed genetic counselor may obtain continuing education hours through successful completion of continuing education courses or programs approved by the National Society of Genetic Counselors or its successor, one continuing education hour for each hour of instruction.

f) At least 30 of the continuing education hours required by (b) above shall be in courses or programs designated as "Category One" by the National Society of Genetic Counselors or its successor.

g) The Committee shall perform audits of randomly selected licensed genetic counselors to determine compliance with continuing education requirements.

h) A licensed genetic counselor shall maintain certifications from the National Society of Genetic Counselors, or its successor, attesting to completion of continuing education hours for a period of four years after completion of the hours and shall submit this certification to the Committee upon request.

i) The Committee may waive the continuing education requirements of this section, or provide a licensed genetic counselor additional time to complete continuing education requirements, on an individual basis for reasons of hardship, such as severe illness, disability, or military service.

1) A licensed genetic counselor seeking a waiver of the continuing education requirements shall apply to the Committee in writing at least 90 days prior to license renewal and set forth in specific detail the reasons for requesting the waiver. The licensed genetic counselor shall provide the Committee with supplemental materials that support the request for waiver.

2) A waiver of continuing education requirements granted pursuant to this subsection shall be effective only for the biennial period for which such waiver is granted. If the condition(s) that necessitated the waiver continue(s) into the next biennial period, a licensed genetic counselor shall apply to the Committee for the renewal of such waiver for the new biennial period.

j) The Committee may direct or order a licensed genetic counselor to complete continuing education hours:

1) As part of a disciplinary or remedial measure in addition to the required 40 hours of continuing education; or

2) To correct a deficiency in the licensed genetic counselor's continuing education requirements.

k) Any continuing education hours completed by the licensed genetic counselor in compliance with an order or directive from the Committee as set forth in (j) above shall not be used to satisfy the minimum continuing education requirements as set forth in this section.

13:35-14.8 SCOPE OF PRACTICE

a) The following is within the scope of practice of a licensed genetic counselor:

1) Obtaining and interpreting individual, family, medical, and developmental histories;

2) Determining the mode of inheritance and risk of transmission of genetic conditions and of birth defects, including evaluating the risks from exposure to possible mutagens and teratogens;

3) Discussing the inheritance features, natural history, means of diagnosis, and management of genetic conditions and birth defects;

4) Identifying, coordinating, and explaining the clinical implications of genetic laboratory tests and other diagnostic studies and their results;

5) Integrating genetic laboratory test results and other diagnostic studies with personal and family medical history to assess and communicate risk factors for genetic or medical conditions and diseases;

6) Assessing psychosocial factors;

7) Recognizing social, educational, and cultural issues;

8) Evaluating the client's or family's responses to the condition or risk of recurrence and providing client-centered counseling and anticipatory guidance; and

9) Facilitating informed decision making about testing, management, and alternatives.

13:35-14.9 SEXUAL MISCONDUCT

a) The purpose of this section is to identify for licensed genetic counselors conduct that shall be deemed sexual misconduct.

b) As used in this section, the following terms have the following meanings:

"Client" means any person who is the recipient of genetic counseling services.

"Client-genetic counselor relationship" means a relationship between a licensed genetic counselor and a client in which the licensed genetic counselor owes a continuing duty to the client to render genetic counseling services consistent with his or her training and experience.

"Licensed genetic counselor" means a person who holds a license from the Committee as a genetic counselor.

"Sexual contact" means the knowing touching of a person's body directly or through clothing, where the circumstances surrounding the touching would be construed by a reasonable person to be motivated by the licensed genetic counselor's own prurient interest or for sexual arousal or gratification. "Sexual contact" includes, but is not limited to, the imposition of a part of the licensed genetic counselor's body upon a part of the client's body, sexual penetration, or the insertion or imposition of any object or any part of a licensed genetic counselor's or client's body into or near the genital, anal, or other opening of the other person's body. "Sexual contact" does not include the touching of a client's body that is necessary during the performance of a generally accepted and recognized genetic counseling encounter.

"Sexual harassment" means solicitation of any sexual act, physical advances, or verbal or non-verbal conduct that is sexual in nature, which occurs in connection with a licensed genetic counselor's activities or role as a genetic counselor that is unwelcome or offensive to a reasonable person, or creates a hostile workplace environment, and the licensed genetic counselor knows, should know, or is told this. "Sexual harassment" may consist of a single extreme or severe act or multiple acts and may include, but is not limited to, conduct of a licensed genetic counselor with a client, co-worker, employee, student, or supervisee, whether or not such individual is in a subordinate position to the licensed genetic counselor.

"Spouse" means the husband, wife, civil union partner, domestic partner, or fiancee of the licensed genetic counselor or an individual involved in a long-term committed relationship with the licensed genetic counselor. For purposes of the definition of "spouse," a long-term committed relationship means a relationship that is at least six months in duration.

c) A licensed genetic counselor shall not engage in sexual contact with a client with whom he or she has a client-genetic counselor relationship. The client-genetic counselor relationship is ongoing for purposes of this section, unless more than three months has elapsed since the last genetic counseling was rendered or the relationship is actively terminated by way of written notice to the client and documentation in the client record.

d) A licensed genetic counselor shall not seek or solicit sexual contact with a client with whom he or she has a client-genetic counselor relationship and shall not seek or solicit sexual contact with any person in exchange for professional services.

e) A licensed genetic counselor shall not engage in any discussion of an intimate sexual nature with a person with whom the licensed genetic counselor has a client-genetic counselor relationship, unless that discussion is directly related to a proper genetic counseling purpose. Such discussion shall not include disclosure by the licensed genetic counselor of his or her own sexual relationships.

f) A licensed genetic counselor shall provide privacy conditions that prevent the exposure of the unclothed body of the client. Appropriate draping measures shall be employed to protect client privacy.

g) A licensed genetic counselor shall not engage in sexual harassment either within or outside of the professional setting.

h) A licensed genetic counselor shall not engage in any other activity that would lead a reasonable person to believe that the activity serves the licensed genetic counselor's personal prurient interests or which is for the sexual arousal, or sexual gratification, of the licensed genetic counselor or client or which constitutes an act of sexual abuse.

i) Violation of any of the prohibitions or directives set forth in (c) through (h) above shall constitute professional misconduct pursuant to N.J.S.A. 45:1-21(e).

j) Nothing in this section shall be construed to prevent a licensed genetic counselor from rendering genetic counseling to a spouse, providing that the rendering of such genetic counseling is consistent with accepted standards of genetic counseling.

k) It shall not be a defense to any action under this section that:

1) The client solicited or consented to sexual contact with the licensed genetic counselor; or

2) The licensed genetic counselor is in love with or held affection for the client.

13:35-14.10 CHANGE IN ADDRESS OF RECORD OR NAME

a) A licensed genetic counselor shall notify the Committee in writing within 30 days of changes to:

1) The licensed genetic counselor's address registered with the Committee. Service to the address registered with the Committee shall constitute effective notice pursuant to N.J.A.C. 13:45-3.2; or

2) The licensed genetic counselor's legal name. Notification of a name change shall include a copy of the marriage license or a court order that authorized the legal name change.

13:35-14.11 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) "Advertisement" means any attempt directly or indirectly by publication, dissemination, or circulation in print or electronic media to induce directly or indirectly any person or entity to purchase or enter into an agreement to purchase services, treatment, or goods related thereto from a licensed genetic counselor.

2) "Electronic media" shall include radio, television, telephone, facsimile machine, or computer.

3) "Fee schedule" refers to the fees charged for services or goods offered by a licensed genetic counselor.

4) "Graphic representation" means the use of drawings, animations, clinical photographs, dramatizations, music, or lyrics.

5) "Print media" shall refer to newspapers, magazines, periodicals, professional journals, telephone directories, circulars, handbills, fliers, or other publications, the content of which is disseminated by means of the printed word.

6) "Routine professional service" refers to a service that a licensed genetic counselor or professional association routinely performs.

b) Subject to the limitation of (c) and (f) through (h) below, a licensed genetic counselor may provide information to the public by advertising in print or electronic media.

c) A licensed genetic counselor who engages in the use of advertising that contains any of the following shall be deemed to have engaged in professional misconduct:

1) Any statement, claim, or format including a graphic representation that 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 that the licensed genetic counselor knows or should have known is improper or prevents a client 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 those ordinarily performed or used in the profession;

5) Any promotion of professional service that the licensed genetic counselor knows or should know is beyond the licensed genetic counselor's ability to perform;

6) A technique or communication that appears to intimidate, exert undue pressure, or to unduly influence a client;

7) Any personal testimonial by a client attesting to the quality or competence of service or treatment by a licensed genetic counselor involving technical assessments that are beyond the client's competency to assess, or any testimonial not in compliance with N.J.A.C. 13:35-14.13;

8) The communication of any fact, data, or information that may personally identify a client without the client'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 client;

10) Any print, language, or format that directly or indirectly obscures a material fact; or

11) Any guarantee of results from any genetic counseling encounter.

d) The Committee may require a licensed genetic counselor to substantiate the truthfulness of any assertion or representation set forth in an advertisement.

e) Any violations of (f) through (h) below shall be deemed professional misconduct.

f) A licensed genetic counselor shall not engage, either directly or through the use of any agent, employee, or representative, in solicitation of a client. This subsection shall not

prohibit a licensed genetic counselor from offering services through materials provided to a community service organization that makes known the availability of all professional services listed; nor shall it prohibit the offering of services by a licensed genetic counselor to any bona fide representative of a client including, employers, labor union representatives, or insurance carriers.

g) Advertising making reference to or setting forth fees shall be limited to a stated fee for specifically described routine professional services or goods offered by licensed genetic counselors.

1) A licensed genetic counselor who advertises a fee shall disclose all relevant and material variables and considerations that are ordinarily included in such a service, so that the fee will be clearly understood by clients.

2) In the absence of such disclosure referred to in (g)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 specifically delineates the additional services contemplated and the fee to be charged.

h) 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.

13:35-14.12 ADVERTISING FREE OR DISCOUNTED SERVICES; REQUIRED DISCLOSURES

a) An advertisement offering a fee reduction shall state the reduced fee and the licensed genetic counselor's usual fee for each service for which a reduction is advertised. The usual fee shall be the fee charged for the advertised service for a period of not less than 90 days prior to the publication of the advertised reduction.

b) 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 that are not included and a statement of the specific charges for all associated or reasonably anticipated services which are not included.

c) Except for those services specifically excluded in the advertisement offering free services, the licensed genetic counselor shall not charge for any service rendered during a period of 72 hours from the time the free service was rendered.

13:35-14.13 TESTIMONIAL ADVERTISING

a) All testimonials involving a specific or identifiable genetic counseling service shall truthfully reflect the actual experience of the client.

b) The licensed genetic counselor shall be able to substantiate any objective, verifiable statement of fact appearing in a testimonial. The failure to do so, if required by the Committee, may be deemed professional misconduct.

c) Where a licensed genetic counselor directly or indirectly provides compensation to a testimonial giver, the fact of such compensation shall be conspicuously disclosed in a clear, legible and readable manner in any advertisement as follows: "COMPENSATION HAS BEEN PROVIDED FOR THIS TESTIMONIAL."

13:35-14.14 MINIMUM CONTENT

a) A licensed genetic counselor shall include the following in all advertisements and professional representations (other than an office entry sign), including advertisements in a classified directory, business cards, and professional stationery:

1) The name and license number of at least one licensed genetic counselor working at the advertised practice location; and

2) The street address and telephone number of the practice.

b) An offer for genetic counseling services can be made only by a licensed genetic counselor or a person exempt from licensing requirements pursuant to N.J.S.A. 45:37.117 and N.J.A.C. 13:35-14.1.

13:35-14.15 RECORDKEEPING

a) Licensed genetic counselors shall make contemporaneous, permanent entries into client records, which shall accurately reflect the genetic counseling services rendered. Client records shall be maintained for a period of seven years from the date of the most recent entry. The client record shall contain, at a minimum:

1) Intake record;

2) The dates of each service;

3) Reasons for visits;

4) A summary of each session with an assessment and plan;

5) The name and title of the licensed genetic counselor or permitted genetic counselor who provided services;

6) The licensed genetic counselor's or permitted genetic counselor's initials for every entry to the records; and

7) Any referral to another healthcare professional.

b) Corrections and/or additions to existing records may be made to a client record, provided that each change is clearly identified as such, and such is dated and initialed by the licensed genetic counselor making the change.

13:35-14.16 CLIENT ACCESS TO RECORDS

a) Licensed genetic counselors shall provide access to client records to a client or an authorized representative in accordance with the following:

1) No later than 30 days from receipt of a written request from a client or an authorized representative, the licensed genetic counselor shall provide a copy of the client record, and/or billing records as may be requested;

2) The licensed genetic counselor 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; and

3) If the client or a subsequent treating health care professional is unable to read the client record, because it is illegible, the licensed genetic counselor, upon request, shall provide a typed transcription of the record. If the record is in a language other than English, the licensed genetic counselor shall also provide a translation.

b) Where the client has requested the release of all or a portion of a client record to a specified individual or entity, in order to protect the confidentiality of the records, the licensed genetic counselor shall:

1) Secure and maintain a current written authorization bearing the signature of the client or an authorized representative;

2) Ensure that the scope of the release is consistent with the request; and

3) Forward the records to the attention of the specific individual identified in the request.

13:35-14.17 CONFIDENTIALITY

a) Licensed genetic counselors shall maintain the confidentiality of client records and any confidential information acquired from a client, except that:

1) The licensed genetic counselor shall release client records as directed by a subpoena issued by the Board or Committee, or the Office of the Attorney General, or by a demand for a 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 client names;

2) The licensed genetic counselor shall release information as required by Federal or State statutes or regulations;

3) The licensed genetic counselor may disclose confidential information if he or she is party to a civil, criminal, or disciplinary action arising from the genetic counseling services provided; or

4) The client is a defendant in a criminal proceeding and keeping client records or information confidential would violate the defendant's right to present testimony and witnesses on his or her behalf.

13:35-14.18 FEE SCHEDULE

a) The following fees shall be charged by the Committee:

1) Application fee ..... $ 30.00

2) Initial license fee

   i) If paid during the first year of a biennial renewal period ..... $ 220.00

   ii) If paid during the second year of a biennial renewal period ..... $ 110.00

3) Renewal of license ..... $ 220.00

4) Late license renewal ..... $ 50.00

5) Reinstatement fee ..... $ 100.00

6) Inactive license fee ..... (to be determined by Director by regulation)

7) Duplicate/replacement license ..... $ 25.00

8) Verification of license ..... $ 25.00

APPENDIX

Collaborative Practice Agreement

The Pharmacist(s) and Physician(s) listed below are parties to this collaborative practice agreement, through which the pharmacist(s) receives authority, under the supervision of the physician(s) (or covering physician), to perform the functions outlined in accordance with applicable New Jersey statutes and regulations.

Physician:

Name: _____ Title: _____

Address: _____

Phone Number: _____ License Number: _____

Type of Practice/Specialty: _____

Pharmacist:

Name: _____

Address: _____

Phone Number: _____ License Number: _____

Qualifications for Collaborative Practice: _____

Describe the functions and responsibilities, including scope and authority, to be exercised by the pharmacist (attach extra sheets if needed):

Indicate any restrictions placed on the use of certain types or classes of drugs or drug therapies under this agreement (attach extra sheets if needed):

Indicate any diagnosis, or types of diseases which are specifically included or excluded under this agreement (attach extra sheets if needed):

Attach any protocols to be used in decision making or other activities contemplated under this agreement. This must include a protocol for treating an acute allergic or other adverse reaction related to drug therapy. Each protocol must establish when physician notification is required, the time frame within which the pharmacist must notify the physician of any change in dose, duration or frequency of medication prescribed, and the type of pharmacist documentation

required. Written notification, by either facsimile or electronic means, shall be provided to the physician no later than eight hours after any change in prescribed medication is made by the pharmacist.

Physician Signature: _____ Date: _____

Pharmacist Signature: _____ Date: _____