

RULE ADOPTIONS
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LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF MEDICAL EXAMINERS

Readoption with Amendments: N.J.A.C. 13:35
Adopted Repeals: N.J.A.C. 13:35-1A and 3.9

Board of Medical Examiners Rules

Proposed: July 6, 2010 at 42 N.J.R. 1310(a).

Adopted: November 10, 2010 by the Board of Medical Examiners, Paul Jordan, MD, President.

Filed: May 3, 2011 as R.2011 d.155, **with substantive changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-3.6).

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

Effective Dates: May 3, 2011, Readoption;
June 6, 2011, Amendments and Repeals.

Expiration Date: May 3, 2018.

Federal Standards Statement

The adopted amendments to N.J.A.C. 13:35-5.1 impose the same requirements on providing prescriptions to patients upon the completion of a contact lens fitting as those imposed by the Fairness to Contact Lens Consumer Act (15 U.S.C. §§7601-7610) and Federal Trade Commission's "Contact Lens Rule," 16 CFR 315. Adopted amendments to N.J.A.C. 13:35-7.6 impose the same requirements as those imposed by 21 CFR 1306.12(b)1. None of the other readopted rules or adopted amendments are subject to any Federal standards or requirements.

Full text of the readopted rules can be found in the New Jersey Administrative Code at N.J.A.C. 13:35.

Full text of the adopted amendments follows (additions to proposal indicated in boldface with asterisks ***thus***):

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)-(g) (No change.)

13:35-1.2 Fifth Pathway

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

1. (No change.)

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.-5. (No change.)

(b) (No change.)

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

(a)-(b) (No change.)

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

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

i. (No change.)

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.-iv. (No change.)

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.-5. (No change.)

(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)-(j) (No change.)

(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)-(x) (No change.)

(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.-3. (No change.)

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 [page=1363] Review Committee through participation in the Alternative Resolution Program.

(z) (No change.)

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

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

(a)-(i) (No change.)

(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.-3. (No change.)

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. (No change.)

(k)-(s) (No change.)

SUBCHAPTER 2A. LIMITED LICENSES: MIDWIFERY

13:35-2A.4 Application for licensure

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

1.-2. (No change.)

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.-7. (No change.)

(b) (No change.)

13:35-2A.5 Independent practice

(a) (No change.)

(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)-(d) (No change.)

SUBCHAPTER 2B. LIMITED LICENSES: PHYSICIAN ASSISTANTS

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:

...

"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.

...

13:35-2B.4 Scope of practice

(a) (No change.)

(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.-3. (No change.)

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

5.-7. (No change.)

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

(a)-(d) (No change.)

(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.

SUBCHAPTER 3. LICENSING EXAMINATIONS AND ENDORSEMENTS, LIMITED EXEMPTIONS FROM LICENSURE REQUIREMENTS; POST-GRADUATE TRAINING

13:35-3.9 (Reserved)

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

(a) (No change.)

(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)-(d) (No change.)

(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)-(l) (No change.)

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 [page=1364] agency,

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

1.-2. (No change.)

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

(a) (No change.)

(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.-4. (No change.)

(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) (No change.)

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.

SUBCHAPTER 4. SURGERY

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)-(d) (No change.)

(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.-2. (No change.)

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.-7. (No change.)

(g) (No change.)

(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.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.

...

"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.

...

"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 [page=1365] pulse, oxygen saturation, blood pressure, end-tidal carbon dioxide and respiration.

...

"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.

...

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)-(b) (No change.)

(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. (No change.)

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.-6. (No change.)

(d)-(f) (No change.)

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)-(e) (No change.)

(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.-2. (No change.)

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. (No change.)

(h)-(i) (No change.)

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.

SUBCHAPTER 5. EYE EXAMINATIONS; EYEGLASSES

13:35-5.1 Minimum eye examination; contact lenses

(a)-(b) (No change.)

(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.

SUBCHAPTER 6. GENERAL RULES OF PRACTICE

13:35-6.1 Practice identification

(a) (No change.)

(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)-(f) (No change.)

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.

...

(b)-(c) (No change.)

(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)-(g) (No change.)

(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) (No change in text.)

[page=1366] 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. (No change.)

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)-(d) (No change.)

13:35-6.5 Preparation of patient records, computerized records, access to or release of information; confidentiality, transfer or disposal of records

(a) (No change.)

(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.-2. (No change.)

3. A patient record may be prepared and maintained on a personal or other computer only when it meets the following criteria:

i.-vii. (No change.)

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.-7. (No change.)

(d)-(g) (No change.)

(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. (No change.)

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. (No change.)

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

(a)-(b) (No change.)

(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.-iv. (No change.)

2.-3. (No change.)

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

1.-2. (No change.)

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.-iv. (No change.)

4. (No change.)

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)-(f) (No change.)

13:35-6.10 Advertising and solicitation practices

(a)-(g) (No change.)

(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)-(k) (No change.)

(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)-(o) (No change.)

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)-(h) (No change.)

13:35-6.15 Continuing medical education

(a)-(h) (No change.)

[page=1367] (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. (No change.)

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. (No change.)

(j)-(k) (No change.)

13:35-6.16 Professional practice structure

(a)-(e) (No change.)

(f) Acceptable professional practice forms are as follows:

1.-3. (No change.)

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.-v. (No change.)

5. (No change.)

(g)-(h) (No change.)

(i) The following pertain to laboratory service:

1.-2. (No change.)

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)-(m) (No change.)

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. (No change.)

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.-ii. (No change.)

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.-v. (No change.)

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. (No change.)

3.-6. (No change.)

(b) (No change.)

(c) The following pertain to miscellaneous monetary arrangements:

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

i. (No change.)

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.-5. (No change.)

(d) (No change.)

(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.

[page=1368] 1. (No change in text.)

(f)-(g) (No change.)

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

1.-4. (No change.)

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)-(k) (No change.)

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.

...

"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.

...

(b) (No change.)

(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.-3. (No change.)

4. Actions by the Department of Health and Senior Services;

5.-8. (No change.)

(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)-(g) (No change.)

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

(a)-(b) (No change.)

(c) A physician may direct a technologist, in the circumstances set forth in (b) above, to perform the following tasks:

1.-5. (No change.)

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)-(l) (No change.)

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

1.-5. (No change.)

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

7. Sincalide, a synthetic cholecystokinin;

8. Lexiscan; and

9. ***Compounds containing*** Technetium 99M.

(n)-(p) (No change.)

13:35-6.21 Hair replacement techniques

(a)-(f) (No change.)

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

1.-3. (No change.)

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)-(b) (No change.)

(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.-3. (No change.)

(d)-(f) (No change.)

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

13:35-7.4A 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)-(i) (No change.)

13:35-7.5 Requirements for the dispensing of drugs and special limitations applicable to the dispensing of drugs for a fee

(a)-(i) (No change.)

(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.-4. (No change.)

(k) (No change.)

[page=1369] 13:35-7.6 Limitations on prescribing, administering or dispensing of controlled substances; special exceptions for management of pain

(a)-(b) (No change.)

(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)-(g) (No change.)

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.-4. (No change.)

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 8. HEARING AID DISPENSERS

13:35-8.3 Training and experience requirements

(a) (No change.)

(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)-(f) (No change.)

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)-(c) (No change.)

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.-2. (No change.)

(b) (No change.)

SUBCHAPTER 11. ALTERNATIVE RESOLUTION PROGRAM

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.-13. (No change.)

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. (No change.)

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.