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

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

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

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

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

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

1. Approval for a period of two years;

2. Probationary approval for a specified period, with status reporting requirements;

3. Denial of approval, with reason;

4. Revocation of prior approval, with reasons;

5. Reapproval of prior approved program following review of status report updating all the elements of prior application.

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

Amended by R.1999 d.356, effective October 18, 1999.
See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).
In (c), rewrote the last sentence; in (d), substituted a reference to the inspection committee for a reference to the Department of Education in the first sentence, and rewrote the last sentence; and in (h), inserted "a listing of the facilities and locations at which all didactic education is to be received" following "program,".

13:35–1A.7 Public record

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

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

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

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

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

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

Amended by R.1999 d.356, effective October 18, 1999.
See: 31 N.J.R. 1742(a), 31 N.J.R. 3117(a).
In (a)2, inserted "substantial change is made by the medical school relative to the site of the didactic education of the students participating in the program, or any" following "Any".

13:35–1A.9 Violations

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

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

13:35–1A.10 Severability

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

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

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

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

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

13:35–2.1 Approved colleges of podiatry

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

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

13:35–2.2 Podiatry internship or postgraduate work

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

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

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

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

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

13:35–2.4 (Reserved)

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

Case Notes

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

13:35–2.5 (Reserved)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ii. Iridology;

iii. Reflexology;

iv. Surrogate arm mentoring;

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

vi. Surface EMG;

vii. Mandibular tracking and stimulation;

viii. Videofluoroscopy; and

ix. Computer supported range of motion tests.

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

i. Thermography when used to evaluate pain associated with reflex 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 followup exam is normally appropriate.

iii. Somasensory evoked potential (SSEP), visual evoked potential (VEP), brain audio evoked potential (BAEP), or brain evoked potential (BEP), nerve condition 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-abnormal bleeding. These tests are not normally used to assess joints (knee and elbow) because other tests are more appropriate. Where MRI is performed, sonograms/ultrasound are not necessary. These tests should not be used to evaluate TMJD. However, echocardiogram is appropriate in the evaluation of possible cardiac injuries when clinically supported.

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

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

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

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

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

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

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

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

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

ii. The standards for equipment operation;

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

iv. The standards with regard to record documentation;

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

vi. Minimum safety precautions;

2. Delineate or approve billing procedures;

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

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

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

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

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

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

6. Ensure that, when entering into a contract for the provision of diagnostic or screening test to be provided by a mobile entity for or on the premises of any licensed health care facility, notice is given by the health care facility to the Department of Health and Senior Services of the name of the testing entity and the identity of the practitioner(s) designated to be responsible for the provision of the diagnostic or screening tests.

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

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

i. An evaluation of personnel skills and performance;

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

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

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

i. An audit of billing records for accuracy; and

ii. Documented regular inspections of equipment.

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

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

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

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

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

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

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

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

1. Ensure that mammography screening tests are performed only under the supervision of a physician who meets the requirements as mandated by the Mammography Quality Standards Act (MQSA), 42 U.S.C. §§ 263(b)

et seq., and that such tests are interpreted only by a physician who meets the MQSA requirements. The supervising and interpreting physician(s) shall maintain proof on the premises of having attained such credentials;

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

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

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

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

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

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

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

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

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

1. The date on which the test was performed;

2. The location at which the test was performed;

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

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

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

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

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

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

9. The date on which the report was prepared.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5. Direct supervision is provided for diagnostic tests delegated to a trained radiologic technologist (LRT(R)). Such tests include but are not necessarily limited to MRI with contrast and CT with contrast. Except in a documented emergency, such studies shall not be scheduled or performed in the absence of the physician. Studies utilizing contrast material shall be performed only as permitted by N.J.A.C. 13:35–6.20;

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

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

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

i. Plain film radiology;

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

iii. Electrocardiograms.

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

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

1. The name of provider and licensure status;

2. The office address of the billing practitioner;

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

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

5. No charge for any test:

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

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

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

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

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

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

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

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

5. Be competent to interpret the resulting data;

6. Ensure that no technician or other unlicensed person conducts an intake inquiry through direct questioning or by the use of a "checklist" of sample signs and symptoms to elicit information from the patient as the sole historical or other basis for the performance of a diagnostic test which shall be determined by the practitioner pursuant to (q)1 above;

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

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

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

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

11. (Reserved);

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

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

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

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

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

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

New Rule, R.1999 d.70, effective March 1, 1999.
See: 30 N.J.R. 3751(a), 31 N.J.R. 659(a).
Amended by R.2001 d.43, effective February 20, 2001.
See: 32 N.J.R. 19(a), 33 N.J.R. 670(a).
In (a), added "Diagnostic office", "Screening office", and "Screening test"; added (d) through (s).

13:35–2.7 (Reserved)

Amended by R.1989 d.532, effective October 16, 1989.
See: 21 N.J.R. 2226(b), 21 N.J.R. 3307(a).
Deleted qualification of 2 years Obstetrical clinical experience.
Repealed by R.1992 d.332, effective September 8, 1992.
See: 23 N.J.R. 3682(a), 24 N.J.R. 3094(a).
Section was "Qualifications".

13:35–2.8 (Reserved)

Repealed by R.1992 d.332, effective September 8, 1992.
See: 23 N.J.R. 3682(a), 24 N.J.R. 3094(a).
Section was "Minimum conditions of practice".

13:35–2.9 (Reserved)

Repealed by R.1992 d.332, effective September 8, 1992.
See: 23 N.J.R. 3682(a), 24 N.J.R. 3094(a).
Section was "Minimum standards for C.N.M. and lay midwife practice during prenatal stages".

13:35–2.10 (Reserved)

Repealed by R.1992 d.332, effective September 8, 1992.
See: 23 N.J.R. 3682(a), 24 N.J.R. 3094(a).
Section was "Management by a physician C.N.M. team for high-risk patients".

13:35–2.11 (Reserved)

Repealed by R.1992 d.332, effective September 8, 1992.
See: 23 N.J.R. 3682(a), 24 N.J.R. 3094(a).
Section was "Intrapartum management".

13:35–2.12 (Reserved)

Repealed by R.1992 d.332, effective September 8, 1992.
See: 23 N.J.R. 3682(a), 24 N.J.R. 3094(a).
Section was "Postpartum and other care".

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

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

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

R.1984 d.138, effective April 16, 1984.
See: 16 N.J.R. 216(a), 16 N.J.R. 920(a).
Amended by R.1994 d.522, effective October 17, 1994.
See: 26 N.J.R. 2526(a), 26 N.J.R. 4195(a).

13:35–2.14 (Reserved)

R.1984 d.245, effective June 18, 1984.
See: 16 N.J.R. 685(a), 16 N.J.R. 1612(a).
Repealed by R.1992 d.332, effective September 8, 1992.
See: 23 N.J.R. 3682(a), 24 N.J.R. 3094(a).
Old section "Reserved" recodified to 13:35–2A.10. Section was "Limited privileges and conditions of practice permitted for a graduate nurse midwife pending results of certifying examination and licensure".

SUBCHAPTER 2A. LIMITED LICENSES: CERTIFIED NURSE MIDWIFERY

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

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

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