New Jersey Register
VOLUME 33, NUMBER 4
TUESDAY, **FEBRUARY 20, 2001**RULE ADOPTION
LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
**STATE BOARD OF MEDICAL EXAMINERS**
MEDICAL STANDARDS GOVERNING SCREENING AND DIAGNOSTIC MEDICAL TESTING IN PRACTITIONER OFFICES

Additions to proposal indicated in boldface with astericks ***thus***;
Deletions from proposal indicated in brackets with astericks *****[thus]*****
Changes in tables are made but not highlighted.

Adopted Repeal: N.J.A.C. 13:35-2.5
Adopted Amendment: N.J.A.C. 13:35-2.6

Proposed: January 3, 2000 at 32 N.J.R. 19(a).

Adopted: November 8, 2000 by the State Board of Medical Examiners, Gregory Rokosz, D.O., J.D., President.

Filed: January 3, 2001 as R.2001 d.43, with substantive and technical changes not requiring additional public notice and comment (see N.J.A.C 1:30-4.3).

Authority: N.J.S.A. 45:1-3.2, 45:9-3 and P.L. 1998, c.21.

Effective Date: **February 20, 2001.**
Expiration Date: **September 20, 2004.**

**Summary** of Changes Upon Adoption:

1. The term physician appearing at N.J.A.C. 13:35-2.6(d)2 has been replaced with practitioner acting within the scope of license practice in recognition of the fact that non-physician licensees are authorized to interpret sometests. This language change reflects the definition of practitioner set forth in subsection (a) to indicate that a practitioner, for the purpose of this rule, is one who is a licensee of the Board of Medical Examiners and functioning within the licensed scope of practice.

2. In recognition of the fact that at present MRI and ultrasounds are often performed by unlicensed persons and since no licensure category presently exists for such individuals, N.J.A.C. 13:35-2.6(e)4ii and iii are amended to require that those operating MRI and ultrasound equipment must be adequately trained and licensed in the event that DEP requires such licensure in the future. The subparagraphs are also amended to reflect the current name of the organization which recognizes ultrasonographers.

3. The provision at N.J.A.C. 13:35-2.6(e)1iii requiring eligibility criteria to be established for persons accepted for examination has been moved to paragraph (g)2 as more properly pertaining to screening test offices. Paragraph (e)6 requiring that practitioners secure prior written approval from DOHSS before offering tests in a mobile facility as modified to simply require that the practitioner ensure that notice has been given to DOHSS when the contract for such services is executed.

4. Reference within N.J.A.C. 13:35-2.6(f) to facility has been replaced by the term office which appears throughout the rule.

5. Further explication has been added to N.J.A.C. 13:35-2.6(g)2 to make clear that the policies and protocols that are required in terms of eligibility criteria for certain tests are to be particularized to individual screening tests. Amended language at paragraph (g)5 will also clarify that the recordkeeping requirements impose no more than that which is already required by N.J.A.C. 13:35-6.5.

6. At N.J.A.C. 13:35-2.6(h)1, amendments simplifying the provisions concerning supervision of mammography testing and further clarifying at subparagraph (h)2iv that direction should be provided to the patient in lay language, and at paragrpah (h)3 that images are to be provided upon request.

7. N.J.A.C. 13:35-2.6(j) has been restructured to clarify practitioner responsibilities in reporting abnormal results to patients. No change in substance is effected by the restructuring, however, the obligations are made more understandable, in the face of comments suggesting considerable confusion.

8. At N.J.A.C. 13:35-2.6(k), language has been added to make clear that obligations that are to be placed on practitioners are applicable to their practicing in any location. Specifically, those performing diagnostic tests, whether in an office or in a hospital, will be required to adhere to the standards set forth at subsection (k). The burdens associated with these requirements are, however, lessened by allowing practitioners to satisfy some of the requirements by including information in the patient record instead of the report. Likewise, if the physician maintains a log elsewhere within the office which reflects the identity of the unlicensed individual performing a test, the report will not need to contain this information. Also, in response to comments made with respect to the proposed rule requirement regarding the inclusion of a description of findings in the report, the rule has been modified to require only those findings, diagnosis or impressions which are pertinent.

9. The language appearing at N.J.A.C. 13:35-2.6(l) has been modified so that a referral could be made upon written request; a formalized written report will not be mandated. Accordingly, a prescription will be sufficient, so long as the pertinent information is included.

10. Several changes have been made with respect to N.J.A.C. 13:35-2.6(m), all of which are intended to give the practitioner more flexibility in satisfying the intent of the Board's originally proposed requirements. Under the amended language, the practitioner need not ascertain him or herself whether there is sufficient objective or clinical data to support the referral but must institute a procedure that will ensure that such data has been provided. Likewise, the amended language in paragraph (m)4 will make clear that personal consultation needs to be undertaken if additional information is needed to assure that the test requested is the most appropriate to elicit the clinical information sought. Finally, in recognition of the broad variety of tests addressed by the terms of this rule, revised language pertaining to informed consent at N.J.A.C. 13:35-2.6(m)8 narrows the circumstances in which formalized informed consent must be obtained to those where there is significant risk of likelihood of side effects. The provision will continue to stress the need for practitioners to assure that explanations have been provided to the patients concerning the tests to be undertaken.

11. Amendments to N.J.A.C. 13:35-2.6(n) have clarified the Board's intent with regard to the type of invasive procedures that require personal physician supervision. The provision specifically references transesophageal echocardiography and needle electromyography; under this revision vaginal probes would not require physician presence. In addition, language has been included which fine-tunes the oversight requirements in a variety of circumstances, specifically making it clear that less oversight is needed with respect to tests performed without contrast.

12. As elsewhere within the rule, clarification is provided at N.J.A.C. 13:35-2.6(o) to reflect that responsibilities with regard to the issuance of test results are to be applicable regardless of the practice setting.

13. A correction is made to the language in N.J.A.C. 13:35-2.6(p)5i to properly cite to subsection (c) instead of (b) when referencing tests lacking clinical validity.

14. An amendment to N.J.A.C. 13:35-2.6(q)6 clarifies the use to which intake questionnaires can be put. While they may not be used as the sole historical or other basis for determining when a test is appropriate, they still will be permitted to be utilized for a more limited purpose. Subsection (q)10 has been clarified so that a practitioner who contracts with an equipment lessor to lease testing equipment is prohibited from allowing the lessor to require use of a particular practitioner to interpret the test data. Subsection (q)11 is reserved for further Board consideration.

15. The language concerning payments and remuneration at N.J.A.C. 13:35- 2.6(r) is modified to align with the

language utilized at N.J.A.C. 13:35- 6.17, and that portion prohibiting use of an equipment lessor as billing agent is deleted for the present time.

16. A new subsection(s) is created from the language recodified from N.J.A.C. 13:35-2.6(l) pertaining to interpretations by non-licensees.

**Federal Standards Statement**

A Federal standards analysis is not required for the adopted repeal and amendment. There is no Federal standard or requirement that directly affects the particular subject of this rulemaking, which is to set standards for responsible and ethical testing practice by licensed physicians.

The Federal Department of Health and Human Services, Health Care Financing Administration, has, however, adopted Medicare rules which have some relationship to the repeal and amendment. Those rules deal with certain forms of diagnostic testing which require various levels of supervision by a licensed physician in order to be compensable by Medicare. See 42 CFR Part 410 at Vol. 62, No. 211, adopted October 31, 1997, at 59048 et seq. Thus, section 410.32 lists diagnostic test which, for the purpose of Medicare compensability, require the general supervision of a plenary licensed physician. Certain kinds of tests require direct supervision or in-room personal supervision by a medical physician (M.D. or D.O.). Section 410.33 addresses an independent diagnostic testing facility. Section 410.33(f) explicitly advises that such entity must comply with the applicable laws of any State in which it operates, and thus would not supersede these rules in any event. Moreover, the proposed rule relates to quality of care and not to eligibility of physicians for Medicare reimbursement.

Any practitioner designated to be responsible for the management of a screening office at which mammography is offered is required to establish a written protocol in compliance with the requirements of the Mammography Quality Standards Act, 42 U.S.C. ß ß 263(b) et seq., and 21 CFR 900.1 et seq. This requirement of compliance with a Federal standard is not an exceedance of that standard.

**Full text** of the adoption follows:(additions to proposal indicated in boldface with astericks ***thus***; deletions from proposal indicated in brackets with astericks *****[thus]*****);

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. . . .

"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. . . .

"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. . . .

"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)-(c) (No change.)

(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 *[physician]* ***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 eligibility criteria for persons to be accepted for examination;]*

*****[iv]****iii.***The procedures to be followed in obtaining informed consent;

*****[v]****iv.***The standards with regard to record documentation;

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

*****[vii]****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 a diagnostic (or mammographic) radiologic technologist]* 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 a radiologic

technologist (LRT(R))]* ***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 *[Society of Medical Ultrasonographers]* ***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 ***[(d)]****(f)** below; and

6. ***[Secure prior approval in writing from the Department of Health and Senior Services before providing diagnostic or screening tests in a mobile facility for or on the premises of any licensed health care facility.]*** ****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 *[facility]* ***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 reflectingthe total number of screening examinees, and the total number of abnormalityreports 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 *****[is certified by the American Board of Radiology or by the American Osteopathic Board of Radiology or who possesses equivalent certification requirements from another Board with equivalent standards, and who meets continuing medical education]*** meets the*** requirements as mandated by the Mammography Quality Standards Act ***(MQSA)*,** 42 U.S.C. ß ß 263(b)*[, and maintains]*** 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 *****[these]*** * such*** credentials;

2. Establish a written protocol in compliance with the requirements of the Mammography Quality Standards Act, 42 U.S.C. ß ß 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 *****[in accordance with the pertinent health insurance plan]*****; 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***** [may]*** * 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 shall:

1. Ensure that written reports of screening tests which yield abnormal results shall be issued no later than three business days from the date of receipt of the report by the testing entity to the referring practitioner, if any, and upon request to the examinee or other authorized person, to the extent authorized by N.J.A.C. 13:35-6.5. A report delayed pending receipt of additional material shall be issued as soon as possible after the report is complete;

2. Prepare written reports which provide clear direction concerning any abnormality to the referring practitioner;

3. Contact the referring practitioner in writing with respect to any abnormality warranting follow-up care and verbally

if immediate follow-up care is clinically indicated;

4. Where no referring or treating practitioner is identified, provide notice to the examinee that an abnormality was reported, along with a clear advisory concerning the need to seek follow-up medical consultation as well as appropriate referral information;

5. Where there is no referring practitioner, make efforts to personally contact the examinee, at least 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;

6. Where there is no referring practitioner and efforts over a period not to exceed 10 days to contact the examinee have been unsuccessful, forward a letter 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

7. Where there is no referring practitioner and efforts over a period not to exceed 10 days to contact the examinee have been unsuccessful, but the examinee has listed the name and address of a treating practitioner, make efforts to contact the treating practitioner listed, requesting that if that practitioner has seen the examinee within the last 12 months, reasonable attempts be made by the treating practitioner to notify the examinee of the report should be made.]*

***(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 *[license number,]* 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 *****[description]***summary*** of the *****[relevant]*** *pertinent*** medical/psychological history;

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

5. An identification of *****[the]*** *any unlicensed***individual performing the test *****[(and the supervising practitioner if the individual is not licensed)]*** *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 *****[the test, except as to non-interventional radiological procedures]*** *all electrodiagnostic tests (includingEMG and NCV) and invasive procedures, unless reflected in the patient recordor in a logbook maintained by the supervising practitioner, who shall be identifiedas 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 day]*** *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 *****[accompanied or preceded by a written report or a personal communication, documented in the patient record,]*** *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*****[; and]****.***

*****[4. An indication that the patient or third party payor has provided advance written consent for the interpretation of transmitted diagnostic test records if the consultant from whom the interpretation is to be performed by a non-licensee.]*****

(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. *****[Ascertain whether sufficient objective or clinical data have been provided to determine that the requested diagnostic test is appropriate]***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 *****[to request, whenever feasible]*****, 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. ***[**Obtain informed consent]*** ***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***[**, but not limited to, ultrasound diagnostic procedures requiring placement of a probe in the case of]*** transesophageal echocardiography and needle electromyography, are personally performed and interpreted by a physician;

2. *[In-room]* ***Direct*** personal supervision by the physician***, whereby the physician is immediately available,*** is provided for all diagnostic tests requiring anesthesia*[, such as MRI procedures]*** ***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 of the extremities, pelvis, vertebral column or skull;

ii. Plain films of the chest and abdomen that do not involve the use of contrast media; and]*

***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 differentfrom 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 *****[(b)]****(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 withthe 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 unanticipatedphysical condition of the patient which precludes completion of the intendedexamination, such study shall not be deemed professionally incomplete forbilling 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 *[any]*** *an*** intake inquiry *[for the practitioner for a diagnostic test]*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. *****[Neither request nor accept recommendations for a consultant practitioner to read or overread and interpret the test data from the lessor of the equipment, its technicians or any other agent]*** *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. *****[Not utilize the lessor of the equipment or technician as a billing agent]****(Reserved)***;

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

(r) *****[A]****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 *****[payment]*** *form of remuneration*** from the practitioner/professional office fo**r ***[referring]*** accepting a referral of ***a *****[referred]***** patient*[, whether in the form of a shared fee, or for rent or for administrative services or under any other description]*.

***1.*** A referring practitioner shall not request or receive, ***offer or pay, *** directly or indirectly, any *****[payment]*** *form of remuneration***from the consulting practitioner for providing a referral*****[, whether in the form of a shared fee, or for rent or for administrative services or under any other description]*****

***2.*** A practitioner shall not request or receive any *****[payment]*** *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. *****[Neither the consultant practitioner nor the referring practitioner shall have any financial relationship with a testing company other than as lessor; for example, the company shall not serve as billing agent for the practitioner.]*****

***(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.***