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RULE ADOPTIONS

Reporter
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Agency

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

Administrative Code Citation

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

Text

Medical Standards Governing Screening and Diagnostic Medical Testing in Practitioner Offices

Proposed: June 19, 2017, at 49 N.J.R. 1660(a).

Adopted: November 8, 2017, by the State Board of Medical Examiners, George J. Scott, D.P.M., D.O., President.

[page=210] Filed: November 29, 2017, as R.2018 d.005, **with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 45:9-2.

Effective Date: January 2, 2018.

Expiration Date: May 3, 2018.

Summary of Public Comments and Agency Reponses:

The official comment period ended August 18, 2017. The State Board of Medical Examiners (Board) received comments from:

1. John D. Fanburg, Brach Eichler, LLC, on behalf of the Radiological Society of New Jersey; and

2. Melinda R. Martinson, General Counsel, Medical Society of New Jersey.

1. COMMENT: The commenters expressed appreciation and support for the Board to undertake this rulemaking to clarify and augment N.J.A.C. 13:35-2.6, concerning medical standards for screening and diagnostic testing. One commenter, in particular, appreciated that the Board has acknowledged that it is the Board's intent under the applicable standard that the practitioner who makes the request for a specific diagnostic test is responsible for determining the medical necessity for the specifically requested test and the way in which the test results will inform treatment decision.

RESPONSE: The Board thanks the commenters for their support.

2. COMMENT: One commenter expressed support for the Board's language at proposed N.J.A.C. 13:35-2.6(k)4, which requires a practitioner responsible for the management of a diagnostic office to ensure that timely notification is provided to a patient, or the requesting or referring health care professional, of results or the need to repeat the test. The commenter stated that this provision will allow physicians to exercise appropriate discretion based upon patient need and circumstances in each case.

RESPONSE: The Board thanks the commenter for its support.

3. COMMENT: One commenter expressed support for proposed N.J.A.C. 13:35-2.6(n)2ii, which would require the practitioner who refers a patient for evaluation to provide an indication of prior testing or ancillary studies relating to the medical condition and results thereof, because it facilitates the testing practitioner's ability to provide appropriate patient care.

RESPONSE: The Board thanks the commenter for its support.

4. COMMENT: One commenter stated that it accepts the proposition at N.J.A.C. 13:35-2.6(o)1iii that the performing practitioner should inquire if the purpose and scope of the ordered test is not clear. The commenter noted that this is particularly appropriate when the performing practitioner accepts a referral for the evaluation and determination of the appropriate diagnostic test (see N.J.A.C. 13:35-2.6(o)2i).

RESPONSE: The Board thanks the commenter for this information.

5. COMMENT: One commenter expressed concern about the language in proposed new N.J.A.C. 13:35-2.6(l)1 addressing electromyography (EMG). The commenter stated that the New Jersey Supreme Court's decision in Selective Insurance Co. of America v. Rothman, 208 N.J. 580 (2012), makes clear that needle electromyography may only be performed and interpreted by a plenary licensee. The commenter also referenced N.J.S.A. 45:9-5.2. The commenter is concerned that the proposed language could be interpreted to allow a non-plenary licensee to conduct the test after a focused medical exam. The commenter suggested modifying the language to avoid any confusion as follows:

"Needle electromyography testing is personally performed and interpreted by a plenary-licensed physician with necessary education and training after a focused physical examination."

Alternatively, the commenter sought clarification in the adoption narrative that needle electromyography may be performed and interpreted only by a plenary licensee.

RESPONSE: The Board believes that the proposed rule language is consistent with N.J.S.A. 45:9-5.2 by requiring that needle electromyography be performed and interpreted by a plenary licensee. The Board, however, believes that the commenter's suggested modification will clarify that the focused physical examination does not need to be performed by a plenary-licensed physician and, upon adoption, the Board will make this change to N.J.A.C. 13:35-2.6(l)1. Additional public notice of this change is not required because it does not change the effect of this rule so it does not destroy the value of the original notice.

6. COMMENT: Two commenters raised concern with proposed N.J.A.C. 13:35-2.6(l)6, which allows a trained radiologic technologist to administer a diagnostic test with contrast, if a physician or physician assistant or advanced practice nurse is present in the office, except when there is a documented emergency. The commenter stated, however, that this provision is inconsistent with the Department of Health regulations for licensed health care facilities, set forth at N.J.A.C. 8:43A-25.2, which require that a radiologist be available on the premises whenever a contrast medium is used. The commenter further stated that, as all locations that perform magnetic resonance imaging (MRI) or computerized axial tomography (CT) must be licensed by the Department of Health, this regulation is not necessary as it pertains to MRI and CT. The commenter suggested that, to avoid confusion, as to any other modalities the regulation should be made consistent with the Department of Health regulation.

7. COMMENT: One commenter recommended deleting the reference to MRI and CT at N.J.A.C. 13:35-2.6(l)7. The commenter stated that this provision addresses when a trained radiologic technologist may perform non-invasive testing including CTs and MRIs and that because all locations that perform these tests must be licensed by the Department of Health, this provision is not necessary for CTs and MRIs.

8. COMMENT: One commenter expressed concern with proposed N.J.A.C. 13:35-2.6(d)1, which sets forth that a practitioner with a financial interest or investment in a diagnostic or screening office must ensure that the office is wholly owned through an authorized business structure. The commenter stated that, specifically, the regulation requires that ownership must be comprised of practitioners or practitioners with closely allied health professionals, so long as the majority interest is held by practitioners who are authorized to perform and interpret all the tests offered at the diagnostic or screening office. The commenter believes that these regulations do not apply to any locations that are licensed by the Department of Health, however, because of the amendments to paragraphs (l)6 and 7, which relate to MRI and CT services, there is ambiguity in the proposed regulations.

RESPONSE TO COMMENTS 6, 7, AND 8: The commenters are correct that, pursuant to N.J.S.A. 26:2H-12(f), an entity that provides magnetic resonance imaging or computerized axial tomography services shall be required to obtain a license from the Department of Health to

operate those services. By definition, a "diagnostic office" does not include a practice location that is licensed by the Department of Health. Accordingly, to resolve this inconsistency and to avoid confusion, upon adoption, the Board is changing N.J.A.C. 13:35-2.6(l)6 and 7 to remove reference to MRIs and CTs. Additional public notice of this change is not required because it does not change the effect of this rule so it does not destroy the value of the original notice. Because the definition of diagnostic office excludes an office licensed by the Department of Health and, by statute, an entity performing an MRI or CT must be licensed by Health, including the examples of MRIs and CTs was inherently contradictory and the amendments resolve this contradiction.

9. COMMENT: One commenter stated that N.J.A.C. 13:35-2.6(o)2i, which requires a practitioner who accepts a referral for the evaluation and the determination as to the appropriate diagnostic test to institute a procedure to assure that sufficient clinical data has been provided to assist in determining the appropriateness of testing, determining which tests to perform, and generating the clinical information necessary to inform treatment decisions, is ambiguous in that it does not provide sufficient specificity to allow for an understanding of what it means to "institute a procedure."

RESPONSE: The Board notes that the rule deliberately provides for flexibility, so each practitioner can create a process appropriate for the specific practice location.

[page=211] **Federal Standards Statement**

A Federal standards analysis is not required because the adopted amendments are governed by N.J.S.A. 45:9-1 et seq., and are not subject to any Federal law, requirements, or standards.

Regulations

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

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

. . .

"Clinically supported" means that a practitioner who has identified a need for a diagnostic test, prior to personally performing or directly requesting that another practitioner administer a specific test, has:

1. Evaluated the findings of a physical and/or psychiatric examination, as applicable, making an assessment of any current and/or historical subjective complaints, observations, objective findings, and neurological indications;

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

3. (No change.)

"Closely allied health professional" means an individual licensed to practice a health care profession by a regulatory board within the New Jersey Division of Consumer Affairs.

"Diagnostic office" means a practice location, whether stationary or mobile, not licensed by the State Department of Health, 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.

. . .

"Screening office" means a practice location, whether stationary or mobile, not licensed by the State Department of Health, 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.

. . .

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

1. If consistent with the practitioner's scope of practice, education, and training, perform and interpret the diagnostic test;

2. Directly request a specific diagnostic test, provided that the requesting practitioner:

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

ii. Understands how to integrate the test results into management of the patient's condition; or

3. Refer a patient for an evaluation to determine the appropriate diagnostic test(s) to a practitioner who meets the criteria identified at (b)2i above and:

i. Has knowledge of the proper administration of the test; and

ii. Possesses skill in the proper interpretation of the test.

(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 that are not recognized in the scientific community as being capable of yielding data of sufficient clinical value in the development, evaluation, or implementation of a plan of treatment, including the following:

i.-ix. (No change.)

2.-4. (No change.)

(d) A practitioner who holds a financial interest or investment in a diagnostic or screening office shall ensure that:

1. The office is wholly owned through an authorized business structure, comprised of practitioners alone or with closely allied health professionals, so long as a majority interest is held by practitioners authorized to perform and interpret all of the tests offered at the diagnostic or screening office;

2. All test results are interpreted by a practitioner acting within that practitioner's scope of practice; and

3. There is a designated physician (or practitioner if all the tests offered are within that practitioner's scope of practice), who has responsibility for the management of the office and for compliance with the specific obligations set forth in this section.

(e) A practitioner designated to be responsible for the management of a diagnostic or screening office not licensed by the Department of Health (DOH) shall:

1.-5. (No change.)

(f)-(i) (No change.)

(j) A practitioner designated to be responsible for the management of a screening office not licensed by the Department of Health 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.-5. (No change.)

(k) In addition to the obligations set forth in (e) above, a practitioner responsible for the management of a diagnostic office shall ensure, through the adoption and dissemination of policies and procedures, or standing orders, that:

1. All personnel performing diagnostic tests are familiar with the methods to be used in the performance of the test;

2. The tasks that may be delegated to other licensed health care professionals;

3. The timing and manner of issuance of the practitioner's oral and written report; and

4. Timely notification to the patient or requesting or referring health care professional of results or the need to repeat the test.

(l) In addition to the obligations set forth in (e) and (k) above, a practitioner responsible for managing the diagnostic office shall ensure that appropriate practitioner supervision or availability is provided. Specifically, a practitioner responsible for managing the diagnostic office shall ensure that:

1. Needle electromyography testing is personally performed *[after a focused physical examination]* and interpreted by a plenary-licensed physician with necessary education and training ***after a focused physical examination***;

2. Invasive tests, including transesophageal echocardiography, are personally performed by a plenary-licensed physician with the necessary education and training, or are delegated by such physician to a physician assistant or advanced practice nurse with the necessary education and training;

3. Diagnostic tests requiring anesthesia are performed in compliance with N.J.A.C. 13:35-4A;

4. Diagnostic tests that, although not invasive, require a sequential analysis, such as nerve conduction studies, somatosensory evoked potentials, and similar studies, are conducted by trained personnel, subject to physician supervision and interpreted by a physician;

5. Cardiovascular stress tests are directly supervised by a physician who is immediately available in the office suite;

6. Diagnostic tests with contrast, *[such as MRIs and CTs,]* when delegated to a trained radiologic technologist (LRT(R)), are scheduled to be, and are, performed when a physician or a physician assistant or advanced practice nurse, with necessary education and training is present in the office suite, unless there is a documented emergency; and

7. Diagnostic tests, which are not invasive, not conducted with anesthesia or contrast, or which do not require sequential analysis, such as plain film radiology, *[CT or MRI studies without contrast and without sedation,]* are performed by a trained radiologic technologist (LRT(R)), with a supervising physician immediately available by telephone or other electronic means, if not in the office suite.

(m) A practitioner performing a diagnostic test in any location, whether or not licensed by the Department of Health, shall:

[page=212] 1. Retain test results (such as the images, raw data, graphs or tracings of nerve conduction studies, as appropriate to the test performed) arising out of a diagnostic test administration, unless that data is part of the patient record at a licensed health care facility, at which secured custody is maintained; and

2. Prepare a comprehensive report, which shall include at least the following:

i. The practitioner's full name, degree designation, street address, and telephone number;

ii. The date on which the test was performed;

iii. The location at which the test was performed;

iv. The patient's name and a summary of any available pertinent medical and/or psychological history;

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

vi. The start and stop time of electrodiagnostic tests (including EMG and NCV) and invasive procedures, unless maintained in the patient record;

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

viii. Cross-references to any other tests performed at that diagnostic office or provided along with the direct request or referral, on the same patient, which, in the opinion of the practitioner, are pertinent to the patient's presenting medical condition or injuries; and

ix. The date on which the report was prepared.

(n) Pursuant to (b) above, in circumstances not involving emergency care, a practitioner in any location, whether or not licensed by the Department of Health, who:

1. Directly requests that another practitioner perform specific diagnostic tests, shall convey that request via a prescription or other writing (which may be faxed or transmitted electronically) or by a personal communication documented in the patient record, setting forth:

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

ii. A suspected medical condition to be confirmed or ruled out; and/or

iii. A diagnosis, if known; and

2. Refers a patient for evaluation to another practitioner to determine the diagnostic test(s) to be performed, shall transmit that referral via a prescription or other writing or by a personal communication documented in the patient record, setting forth information as required by subsection (n)1i, ii, and iii above, and:

i. A brief history of the reported medical condition or the clinical reason for the referral; and

ii. An indication of prior testing or ancillary studies relating to the medical condition and results thereof.

(o) A practitioner, in circumstances not involving emergency care, in any location, whether, or not licensed by the Department of Health, who:

1. Accepts a direct request for the performance of a specific diagnostic test, shall:

i. Require that the direct request be preceded by delivery of the prescription or other writing (which may be faxed or transmitted electronically), or a personal communication documented in the patient record, as set forth in (n) above;

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

iii. Personally consult with the requesting practitioner in advance of performing the test if, in the opinion of the accepting practitioner, additional information is needed to determine whether the diagnostic test requested is the most appropriate test to elicit the clinical information sought;

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

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

vi. Make inquiry of the requesting practitioner as to the appropriateness of the testing or decline to perform the test if the pattern of requests is suggestive of fraud, or improper sequencing of testing, as may be reflected by an inordinate number of patients presenting for the performance of the same test, repetitive selection of complex testing, when less complex testing would be likely to generate comparable clinical data, or the frequent ordering of testing unlikely to generate useful information; and

2. Accepts a referral for the evaluation and the determination as to the appropriate diagnostic test shall, in addition to meeting the obligations of (o)1 above, shall also:

i. Institute a procedure to assure that sufficient clinical data has been provided to assist in determining the appropriateness of testing, determining which tests to perform, and generating the clinical information necessary to inform treatment decisions; and

ii. Perform a focused clinical examination if, in the practitioner's discretion, such examination is necessary and the practitioner has the competency to perform the examination.

(p) A practitioner performing a diagnostic test in all locations, whether or not licensed by the DOH, shall promptly issue the results of the test, by preliminary verbal report when immediate follow-up care is indicated and in any event 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.

(q) (No change in text.)

(r) 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.-5. (No change.)

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 (r)1 above;

7.-12. (No change.)

(s) (No change in text.)

(t) A practitioner who transmits diagnostic test data/records, other than bioanalytical specimens to a clinical laboratory under the jurisdiction of the Department of Health pursuant to N.J.S.A. 45:9-42.27 et seq., for interpretation by a consultant who is not a licensee of the Board shall

assure that advance written consent for such interpretation service by such consultant has been obtained from the patient/third-party payor. Utilization of the provisions in this subsection shall be consistent with the requirements of (l) above. This subsection is intended to be available for special, occasional, or emergent consultations only. A consultant or consultant entity rendering medical services interpreting diagnostic test data/records, whether in or out of this State, by means of any media, for 10 or more patients under treatment in New Jersey on an annual basis is deemed to be rendering medical services in this State and requires licensure by the Board. However, the exchange of information, which may include patient specific information, between a licensee and a physician licensed in another state, a possession of the United States, or the District of Columbia shall not be deemed to be rendering medical services.