

51 N.J.R. 561(a)

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RULE PROPOSALS

Reporter

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Interested Persons Statement

INTERESTED PERSONS

Interested persons may submit comments, information or arguments concerning any of the rule proposals in this issue until the date indicated in the proposal. Submissions and any inquiries about submissions should be addressed to the agency officer specified for a particular proposal.

The required minimum period for comment concerning a proposal is 30 days. A proposing agency may extend the 30-day comment period to accommodate public hearings or to elicit greater public response to a proposed new rule or amendment. Most notices of proposal include a 60-day comment period, in order to qualify the notice for an exception to the rulemaking calendar requirements of [N.J.S.A. 52:14B-3](#). An extended comment deadline will be noted in the heading of a proposal or appear in a subsequent notice in the Register.

At the close of the period for comments, the proposing agency may thereafter adopt a proposal, without change, or with changes not in violation of the rulemaking procedures at [N.J.A.C. 1:30-6.3](#). The adoption becomes effective upon publication in the Register of a notice of adoption, unless otherwise indicated in the adoption notice. Promulgation in the New Jersey Register establishes a new or amended rule as an official part of the New Jersey Administrative Code.

Agency

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

Administrative Code Citation

Proposed Amendment: [N.J.A.C. 13:35-2.6](#)

Proposed New Rules: N.J.A.C. 13:35-6B

Text

Telemedicine

Authorized By: Board of Medical Examiners, William Roeder, Executive Director.

Authority: [N.J.S.A. 45:9-2](#) and P.L. 2017, c. 117.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2019-045.

Submit comments by July 5, 2019, to:

William Roeder, Executive Director
Board of Medical Examiners
140 East Front Street, 2nd Floor
PO Box 183
Trenton, New Jersey 08625

or electronically at: <http://www.njconsumeraffairs.gov/Proposals/Pages/default.aspx>.

The agency proposal follows:

Summary

P.L. 2017, c. 117, which was effective July 21, 2017, authorizes healthcare providers to engage in telemedicine and telehealth. The Board of Medical Examiners (Board) proposes new N.J.A.C. 13:35-6B to effectuate the provisions of P.L. 2017, c. 117.

New N.J.A.C. 13:35-6B.1 sets forth that Subchapter 6B implements P.L. 2017, c. 117 and establishes that the subchapter applies to licensed physicians and podiatrists. The proposed new rule requires physicians and podiatrists to hold a Board-issued license if they are physically located in New Jersey and are providing health care services by means of telemedicine or telehealth, or if they are physically located outside of New Jersey and are providing health care services by means of telemedicine or telehealth to patients located in New Jersey. The proposed new rule also states that a healthcare provider in another state who uses communications technology to consult with a New Jersey licensee and who is not directing patient care will be deemed as not providing health care services in New Jersey and will not be required to obtain a license in New Jersey.

New N.J.A.C. 13:35-6B.2 provides definitions for the terms used in Subchapter 6B.

[page=562] New N.J.A.C. 13:35-6B.3 requires a licensee to determine whether he or she can provide services through telemedicine or telehealth consistent with the standard of care for such services when provided in-person. If such provision of services would not meet that standard, a licensee cannot provide services through telemedicine or telehealth and he or she would be required to advise the patient to receive services in-person. A licensee who provides services through telemedicine or telehealth will be held to the same standard of care and practice standards as are applicable when services are provided in-person.

New N.J.A.C. 13:35-6B.4 establishes how a licensee will create a licensee-patient relationship prior to providing services through telemedicine or telehealth. A licensee must identify the patient and disclose his or her identity. Before a licensee can provide services through telemedicine or telehealth, he or she is required to review a patient's medical history and medical records. The proposed new rule requires licensees to determine if service can be provided through telemedicine or telehealth with the same standard of care as if the services were provided in-person. This determination has to be made prior to each unique patient encounter. Before providing services

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through telemedicine or telehealth, a licensee has to provide a patient with the opportunity to sign a consent form authorizing the release of medical records to the patient's primary care provider. A licensee will not have to establish a licensee-patient relationship if: services are provided as informal consultations, or on an infrequent basis, and there is no compensation for the services; services are part of episodic consultations by specialists in another jurisdiction; services are provided during an emergency or disaster without compensation; or a licensee is providing on-call or cross-coverage services.

New N.J.A.C. 13:35-6B.5 permits a licensee to provide health care services through telemedicine and to support and facilitate the provision of health care services to patients through telehealth if he or she has established a licensee-patient relationship with the patient or qualifies for an exemption to the licensee-patient relationship requirement. Prior to providing services, the licensee must determine the site at which the patient is located and record this in the patient's record. When a licensee provides services through telemedicine, he or she must use interactive, real-time, two-way communication technologies, which include a video component. A licensee will not have to use technology that includes a video component if he or she determines, after reviewing a patient's records, that he or she can meet the standard of care for such services provided in-person without video. In such a situation, the licensee must use interactive, real-time, two-way audio in combination with technology that permits the transmission of images, diagnostics, data, and medical information.

A licensee is required to review a patient's medical history and records prior to an initial encounter with the patient and, for subsequent interactions, review the history and records either prior to or during interactions. A licensee who provides services through telemedicine or telehealth is required to provide contact information to a patient by which the patient can contact the licensee, or an alternative licensee, for at least 72 hours after the provision of services. A licensee must provide patients with medical records upon request and provide medical information to a patient's primary care provider upon written request. A licensee is required to provide a referral for follow-up care whenever it is necessary.

New N.J.A.C. 13:35-6B.6 permits a licensee to issue a prescription to a patient when services are provided through telemedicine or telehealth. A prescription cannot be issued based solely on the responses to an online questionnaire, unless a licensee has established a licensee-patient relationship with the patient. A licensee is prohibited from issuing a prescription for a Schedule II controlled dangerous substance unless the licensee has an initial in-person examination of the patient and sees the patient in-person at least every three months during the time the patient is prescribed the Schedule II controlled dangerous substance. The in-person examination requirement is established by P.L. 2017, c. 117, and is appropriate due to public safety concerns with Schedule II controlled dangerous substances. This prohibition does not apply when a licensee prescribes a stimulant for a patient who is under the age of 18, as long as the licensee uses interactive, real-time, two-way audio and video technology to provide services to the patient and the patient's parent or guardian has a signed written consent waiving the in-person examination.

New N.J.A.C. 13:35-6B.7 requires licensees to maintain records of care provided to patients through telemedicine or telehealth. Such records must comply with the requirements at [N.J.A.C. 13:35-6.5](#) and all other statutes and rules governing recordkeeping, confidentiality, and disclosure.

New N.J.A.C. 13:35-6B.8 requires licensees to establish written protocols to prevent fraud and abuse. Such protocols must address: authentication of users, patients, and the origin of information; the prevention of unauthorized access to a system or information; system security; maintenance of documentation; information storage, maintenance, and transmission; and verification of patient data.

New N.J.A.C. 13:35-6B.9 requires licensees to establish privacy practices for electronic communications that comply with the standards of [45 CFR 160](#) and [164](#), which are incorporated by reference, as amended and supplemented. These Federal rules implement the privacy requirements of the Health Insurance Portability and Accountability Act of 1996 and protect the privacy of individually identifiable health information. These privacy practices must include measures to protect confidentiality and patient-identifiable information and transmissions must be protected by passwords, encryption, or other authentication techniques. If a licensee becomes aware of a breach of confidentiality, he or she must report this as required by [45 CFR § 164](#). Licensees must provide patients

with copies of privacy practices and obtain written acknowledgement of receipt from patients. The proposed new rule also requires licensees to provide patients with notice regarding telemedicine and telehealth, which includes the risks and information on how to receive follow-up care. Licensees must obtain a signed and dated statement from the patient recognizing receipt of this notice. If the provision of services through telemedicine or telehealth cannot provide all clinical information necessary to provide care, a licensee will have to inform the patient of this and advise the patient that he or she should receive an in-person evaluation to meet his or her needs.

[N.J.A.C. 13:35-2.6\(t\)](#) addresses the transmission of diagnostic test data/records. It establishes a licensing requirement for individuals who provide medical services by interpreting diagnostic test data/records for 10 or more patients annually. [N.J.A.C. 13:35-2.6\(t\)](#) does not conform to the requirements of P.L. 2017, c. 117, and the Board proposes to delete this subsection.

The Board has provided a 60-day comment period for this notice of proposal. Therefore, this notice is excepted from the rulemaking calendar requirement pursuant to [N.J.A.C. 1:30-3.3\(a\)5](#).

Social Impact

The Board believes the rulemaking will have a positive social impact in that it will facilitate the use of communication technologies to provide health care services, while protecting patients who receive such services through telemedicine or telehealth.

Economic Impact

The Board anticipates that the proposed new rules and amendment may have an economic impact on licensees who choose to provide health care services through telemedicine or telehealth. The proposed new rules and amendment requires licensees to use communication technologies that provide for interactive, real-time, two-way communication that include a video component. Licensees may incur costs in obtaining such communication technologies. The Board does not anticipate that the proposed new rules and amendment will have any other economic impact.

Federal Standards Statement

Requirements at N.J.A.C. 13:35-6B.9 impose the same standards for privacy of communications as are imposed by [45 CFR 160](#) and [164](#), which are incorporated by reference, as amended and supplemented, into the rule. There are no other applicable Federal laws or standards.

Jobs Impact

The Board does not believe that proposed new rules and amendment will result in the creation or loss of jobs in the State.

Agriculture Industry Impact

The proposed new rules and amendment will have no impact on the agriculture industry in the State.

[page=563] Regulatory Flexibility Analysis

Since physicians and podiatrists are individually licensed by the Board, under the Regulatory Flexibility Act (the Act), [N.J.S.A. 52:14B-16](#) et seq., they may be considered "small businesses" for the purposes of the Act.

The economic impact on small businesses will be the same as that imposed on all businesses as detailed in the Economic Impact statement. The Board does not believe that physicians or podiatrists will need to employ any additional professional services to comply with the requirements of the proposed new rules and amendment. The proposed new rules impose no reporting requirements, but impose compliance and recordkeeping requirements upon physicians and podiatrists as detailed in the Summary above.

The proposed new rules and amendment will protect the health, safety, and welfare of patients who receive health care services through telemedicine or telehealth; therefore, no differing compliance requirements are provided to physicians or podiatrists based upon the size of a business.

Housing Affordability Impact Analysis

The proposed new rules and amendment will have an insignificant impact on the affordability of housing in New Jersey and there is an extreme unlikelihood that the proposed new rules and amendment would evoke a change in the average costs associated with housing because the proposed new rules and amendment concern the provision of health care services through telemedicine or telehealth.

Smart Growth Development Impact Analysis

The proposed new rules and amendment will have an insignificant impact on smart growth and there is an extreme unlikelihood that the proposed new rules and amendment would evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan in New Jersey because the proposed new rules and amendment concern the provision of health care services through telemedicine or telehealth.

Racial and Ethnic Community Criminal Justice and Public Safety Impact

The Board has evaluated this rulemaking and determined that it will not have an impact on pretrial detention, sentencing, probation, or parole policies concerning adults and juveniles in the State. Accordingly, no further analysis is required.

Regulations

Full text of the proposal follows (additions indicated in boldface **thus**; deletions indicated in brackets [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)-(s) (No change.)

[(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.]

SUBCHAPTER 6B. TELEMEDICINE

13:35-6B.1 Purpose and scope

(a) The purpose of this subchapter is to implement the provisions of P.L. 2017, c. 117 ([N.J.S.A. 45:1-16](#) et seq.), which authorizes healthcare providers to engage in telemedicine and telehealth.

(b) This subchapter shall apply to all persons who are licensed by the Board as physicians or podiatrists.

(c) Pursuant to [N.J.S.A. 45:1-62](#), a physician or podiatrist must hold a license issued by the Board if he or she:

1. Is located in New Jersey and provides health care services to any patient located in or out of New Jersey by means of telemedicine or telehealth; or

2. Is located outside of New Jersey and provides health care services to any patient located in New Jersey by means of telemedicine or telehealth.

(d) Notwithstanding [N.J.S.A. 45:1-62](#) and (c) above, a healthcare provider located in another state who consults with a licensee in New Jersey through the use of information and communications technologies, but does not direct patient care, will not be considered as providing health care services to a patient in New Jersey consistent with [N.J.S.A. 45:9-1](#) et seq., and will not be required to obtain licensure in New Jersey in order to provide such consultation.

13:35-6B.2 Definitions

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

"Asynchronous store-and-forward" means the acquisition and transmission of images, diagnostics, data, and medical information either to, or from, an originating site or to, or from, the licensee at a distant site, which allows for the patient to be evaluated without being physically present.

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

"Cross-coverage" means a licensee engages in a remote medical evaluation of a patient, without in-person contact, at the request of another licensee who has established a proper licensee-patient relationship with the patient.

"Distant site" means a site at which a licensee is located while providing health care services by means of telemedicine or telehealth.

"Licensee" means an individual licensed by the Board as a physician or podiatrist.

"On-call" means a licensee is available, where necessary, to physically attend to the urgent and follow-up needs of a patient for whom the licensee has temporarily assumed responsibility, as designated by the patient's primary care licensee or other health care provider of record.

"Originating site" means a site at which a patient is located at the time that health care services are provided to the patient by means of telemedicine or telehealth.

"Proper licensee-patient relationship" means an association between a licensee and patient wherein the licensee owes a duty to the patient to be available to render professional services consistent with his or her training and experience, which is established pursuant to the requirements of N.J.A.C. 13:35-6B.4.

"Telehealth" means the use of information and communications technologies, including telephones, remote patient monitoring devices, or other electronic means, to support clinical health care, provider consultation, patient and professional health-related education, public health, health administration, and other services in accordance with the provisions of P.L. 2017, c. 117 ([N.J.S.A. 45:1-61](#) et seq.).

"Telemedicine" means the delivery of a health care service, including supportive mental health services, using electronic communications, information technology, or other electronic or technological means to bridge the gap between a health care licensee who is located at a distant site and a patient who is located

at an originating site, either with or without the assistance of an intervening licensee, and in accordance with the provisions of P.L. 2017, c. 117 ([N.J.S.A. 45:1-61](#) et seq.). "Telemedicine" does not include the use, in [page=564] isolation, of audio-only telephone conversation, electronic mail, instant messaging, phone text, or facsimile transmission.

13:35-6B.3 Standard of care

(a) Prior to providing services through telemedicine or telehealth, a licensee shall determine whether providing those services through telemedicine or telehealth would be consistent with the standard of care applicable for those services when provided in-person.

(b) If a licensee determines, either before or during the provision of health care services, that services cannot be provided through telemedicine or telehealth in a manner that is consistent with in-person standards of care, the licensee shall not provide services through telemedicine or telehealth.

(c) A licensee who determines that services cannot be provided through telemedicine or telehealth pursuant to (b) above shall advise the patient to obtain services in-person.

(d) A licensee who provides a diagnosis, treatment, or consultation recommendation, including discussions regarding the risk and benefits of a patient's treatment options, through telemedicine or telehealth, shall be held to the same standard of care or practice standards as are applicable to in-person settings.

13:35-6B.4 Licensee-patient relationship

(a) Prior to providing services through telemedicine or telehealth, a licensee shall establish a licensee-patient relationship by:

1. Identifying the patient with, at a minimum, the patient's name, date of birth, phone number, and address. A licensee may also use a patient's assigned identification number, Social Security number, photo, health insurance policy number, or other identifier associated directly with the patient; and

2. Disclosing and validating the licensee's identity, license, title, and, if applicable, specialty and board certifications.

(b) Prior to initiating contact with a patient for the purpose of providing services to the patient using telemedicine or telehealth, a licensee shall:

1. Review the patient's medical history and any available medical records;

2. Determine as to each unique patient encounter, whether he or she will be able to provide the same standard of care using telemedicine or telehealth as would be provided if the services were provided in-person; and

3. Provide the patient the opportunity to sign a consent form that authorizes the licensee to release medical records of the encounter to the patient's primary care provider or other healthcare provider identified by the patient.

(c) Notwithstanding (a) and (b) above, health care services may be provided through telemedicine or telehealth without a proper licensee-patient relationship if the provision of health care services is:

1. For informal consultations with another healthcare provider performed by a licensee outside the context of a contractual relationship, or on an irregular or infrequent basis, without the expectation or exchange of direct or indirect compensation;

2. During episodic consultations by a medical specialist located in another jurisdiction who provides consultation services, upon request, to a licensee in this State;
3. Related to medical assistance provided in response to an emergency or disaster, provided that there is no charge for the medical assistance; or
4. Provided by a substitute licensee acting on behalf of, and at the designation of, an absent licensee in the same specialty on an on-call or cross-coverage basis.

13:35-6B.5 Provision of health care services through telemedicine or telehealth

(a) As long as a licensee has satisfied the requirements of N.J.A.C. 13:35-6B.4, a licensee may provide health care services to a patient through the use of telemedicine and may engage in telehealth to support and facilitate the provision of health care services to patients.

(b) Prior to providing services through telemedicine or telehealth, a licensee shall determine the patient's originating site and record this information in the patient's record.

(c) A licensee providing healthcare services through telemedicine shall use interactive, real-time, two-way communication technologies, which shall include, except as provided in (e) below, a video component that allows a licensee to see a patient and the patient to see the licensee during the provision of health care services.

(d) A licensee providing services through telemedicine or telehealth may use asynchronous store-and-forward technology to allow for the electronic transmission of:

1. Images;
2. Diagnostics;
3. Data; and
4. Medical information.

(e) If, after accessing and reviewing the patient's medical records, a licensee determines that he or she is able to meet the standard of care for such services as if they were being provided in person without using the video component described in (c) above, the licensee may use interactive, real-time, two-way audio in combination with asynchronous store-and-forward technology, without a video component.

(f) Prior to providing services through telemedicine or telehealth, a licensee shall review any medical history or medical records provided by a patient as follows:

1. For an initial encounter with a patient, medical history and medical records shall be reviewed prior to the provision of health care services through telemedicine or telehealth; and
2. For any subsequent interactions with a patient, medical history and medical records shall be reviewed either prior to the provision of health care services through telemedicine or telehealth or contemporaneously with the encounter with the patient.

(g) During and after the provision of health care services through telemedicine or telehealth, a licensee, or another designated licensee, shall provide his or her name, professional credentials, and contact information to the patient. Such contact information shall enable the patient to contact the licensee for at least 72 hours following the provision of services, or for a longer period, if warranted, by the patient's circumstances and accepted standards of care.

(h) After the provision of health care services through telemedicine or telehealth, a licensee shall provide the patient, upon request, with his or her medical records reflecting the services provided.

(i) A licensee shall provide, upon a patient's written request, the patient's medical information to the patient's primary care provider or to other health care providers.

(j) A licensee engaging in telemedicine or telehealth shall refer a patient for follow-up care when necessary.

13:35-6B.6 Prescriptions

(a) Notwithstanding the requirements for in-person interaction in N.J.A.C. 13:35-7, a licensee providing services through telemedicine or telehealth may issue a prescription to a patient, if the issuance of such a prescription is consistent with the standard of care or practice standards applicable to the in-person setting.

(b) A licensee shall not issue a prescription based solely on responses provided in an online questionnaire, unless the licensee has established a proper licensee-patient relationship pursuant to N.J.A.C. 13:35-6B.4.

(c) Notwithstanding (a) above, and except as provided in (d) below, a licensee shall not issue a prescription for a Schedule II controlled dangerous substance unless the licensee has had an initial in-person examination of the patient and a subsequent in-person visit with the patient at least every three months for the duration of the time the patient is prescribed the Schedule II controlled dangerous substance.

(d) The prohibition of (c) above shall not apply when a licensee prescribes a stimulant for a patient under the age of 18 years, as long as the licensee is using interactive, real-time, two-way audio and video technologies and the licensee has obtained written consent for a waiver of in-person examination requirements from the patient's parent or guardian.

13:35-6B.7 Records

A licensee who provides services through telemedicine or telehealth shall maintain a record of the care provided to a patient. [page=565] Such records shall comply with the requirements of [N.J.A.C. 13:35-6.5](#), and all other applicable State and Federal statutes, rules, and regulations for recordkeeping, confidentiality, and disclosure of a patient's medical record.

13:35-6B.8 Prevention of fraud and abuse

(a) In order to establish that a licensee has made a good faith effort to prevent fraud and abuse when providing services through telemedicine or telehealth, a licensee must establish written protocols that address:

1. Authentication and authorization of users;
2. Authentication of the patient during the initial intake pursuant to N.J.A.C. 13:35-6B.4(a)1;
3. Authentication of the origin of information;
4. The prevention of unauthorized access to the system or information;
5. System security, including the integrity of information that is collected, program integrity, and system integrity;
6. Maintenance of documentation about system and information usage;
7. Information storage, maintenance, and transmission; and
8. Synchronization and verification of patient profile data.

13:35-6B.9 Privacy and notice to patients

(a) Licensees who communicate with patients by electronic communications, other than telephone or facsimile, shall establish written privacy practices that are consistent with Federal standards under [45 CFR 160](#) and [164](#), which are incorporated herein by reference, as amended and supplemented, relating to privacy of individually identifiable health information.

(b) Written privacy practices required by (a) above shall include privacy and security measures that assure confidentiality and integrity of patient-identifiable information. Transmissions, including patient email, prescriptions, and laboratory results must be password protected, encrypted electronic prescriptions, or protected through substantially similar authentication techniques.

(c) A licensee who becomes aware of a breach in confidentiality of patient information, as defined in [45 CFR 164.402](#), shall comply with the reporting requirements of [45 CFR 164](#).

(d) Licensees, or their authorized representatives, shall provide a patient, prior to evaluation or treatment, with copies of written privacy practices and shall obtain the patient's written acknowledgement of receipt of the notice.

(e) Licensees who provide services through telemedicine or telehealth, or their authorized representatives, shall, prior to providing services, give patients notice regarding telemedicine and telehealth, including the risks and benefits of being treated through telemedicine or telehealth and how to receive follow-up care or assistance in the event of an adverse reaction to the treatment or in the event of an inability to communicate as a result of a technological or equipment failure. A licensee shall obtain a signed and dated statement indicating that the patient received this notice.

(f) When telemedicine or telehealth is unable to provide all pertinent clinical information that a licensee exercising ordinary skill and care would deem reasonably necessary to provide care to a patient, the licensee shall inform the patient of this prior to the conclusion of the provision of care through telemedicine or telehealth and shall advise the patient regarding the need for the patient to obtain an additional in-person medical evaluation, reasonably able to meet the patient's needs.

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