

## 52 N.J.R. 1913(a)

VOLUME 52, ISSUE 20, OCTOBER 19, 2020

### RULE ADOPTIONS

#### Reporter

52 N.J.R. 1913(a)

*NJ - New Jersey Register > 2020 > OCTOBER > OCTOBER 19, 2020 > RULE ADOPTIONS > LAW AND PUBLIC SAFETY -- DIVISION OF CONSUMER AFFAIRS*

#### Agency

---

LAW AND PUBLIC SAFETY > DIVISION OF CONSUMER AFFAIRS > STATE BOARD OF MEDICAL EXAMINERS > GENETIC COUNSELING ADVISORY COMMITTEE

#### Administrative Code Citation

---

**Adopted New Rules: N.J.A.C. 13:35-14.19 through 14.26**

#### Text

---

##### **Genetic Counselors--Telemedicine**

Proposed: June 17, 2019, at 51 N.J.R. 919(a).

Adopted: March 11, 2020, by the State Board of Medical Examiners, Scott E. Metzger, M.D., President.

Filed: September 9, 2020, as R.2020 d.093, **without change.**

Authority: N.J.S.A. 45:9-37.115 and P.L. 2017, c. 117.

Effective Date: October 19, 2020.

Expiration Date: April 3, 2025.

##### **Summary** of Public Comment and Agency Response:

The official comment period ended August 16, 2019. The Board received comments from the following individuals:

1. Sally Ann Rodriguez, ScM, LGGC, Sequence46, LLC;
2. Chana Wiesman, MS, LCGC, Senior On-Demand Counseling & Support Genetic Counselor, Myriad Women's Health;
3. Donald E. Horton, Jr., Senior Vice President, Global Government Relations & Public Policy, LabCorp; and
4. James D. Weisberger, Chief Medical Officer, BioReference Laboratories, an OPKO Health Company.

1. COMMENT: A commenter is concerned with provisions in the new rules that state that licensed genetic counselors cannot provide services through telemedicine or telehealth if the provision of such services would not meet the standard of care when services are provided in-person. The commenter contends that some genetic counselors do not provide "full" services when providing services through telemedicine or telehealth and have phone conversations about patient test results. The commenter asks if the new rules will prohibit such practices.

RESPONSE: P.L. 2017, c. 117, states that a "health care provider providing health care services using telemedicine or telehealth shall be subject to the same standard of care or practice standards as are applicable to in-person settings." Accordingly, licensed genetic counselors cannot provide services through telemedicine or telehealth if the provision of such services do not meet the standard of care when such services are provided in-person. Licensed genetic counselors may provide patient test results through telemedicine, as long as the provision of patient test results through telemedicine meet the same standard of care as if test results were provided to patients in-person.

2. COMMENT: A commenter contends that the requirements for licensed genetic counselor-patient relationships at N.J.A.C. 13:35-14.22 do not recognize the existing practices for licensed genetic counselors. The commenter contends that licensed genetic counselors do not always have access to a patient's records. The commenter contends that it is inappropriate to impose differing standards for record review based on the mode in which a service is delivered.

RESPONSE: N.J.A.C. 13:35-14.22 does not require licensed genetic counselors to have access to a patient's records. Rather, N.J.A.C. 13:35-14.22(b) requires a licensed genetic counselor to review any available records.

3. COMMENT: A commenter opposes the provisions at N.J.A.C. 13:35-14.23, which require licensed genetic counselors to use interactive, real-time, two-way communication technologies, which include a video

component. The commenter contends that this requirement places an undue burden on licensed genetic counselors and patients. The commenter recognizes that video counseling is ideal, but contends that it is not always practical. The commenter contends that phone conversations are often the best way to disseminate information to patients. The commenter contends that requiring video communication could reduce access to genetic counseling services.

RESPONSE: P.L. 2017, c. 117, requires that health care providers use communications technology with a video component when providing services through telemedicine or telehealth. The law provides for an exemption to the video component requirement when a health care provider uses interactive, real-time, two-way audio in combination with asynchronous store-and-forward technology and the provision of such care would meet the same standard of care as if the health care services were being provided in-person.

4. COMMENT: A commenter contends that N.J.A.C. 13:35-14.23, which requires licensed genetic counselors to use interactive, real-time, two-way communication technologies that include a video component, will curtail consumer choice. The commenter contends that the majority of patients do not want to use video-based communication and that most want to use telephonic communication to conduct genetic counseling services.

RESPONSE: As stated in the Response to Comment 4, P.L. 2017, c. 117, requires video-based communication, but provides an exemption to this video-based communication requirement. N.J.A.C. 13:35-14.23 permits a licensed genetic counselor to use telephonic communication when the licensed genetic counselor uses interactive, real-time, two-way audio in combination with asynchronous store-and-forward technology and the provision of such care would meet the same standard of care as if the health care services were being provided in-person.

5. COMMENT: N.J.A.C. 13:35-14.23(e) permits a licensed genetic counselor to use interactive, real-time, two-way audio in combination with asynchronous store-and-forward technology without a video component if the licensed genetic counselor believes that he or she is able to meet the standard of care for services if they were being provided in person without using the video component. A commenter is concerned that that the term "real-time" will require asynchronous store-and-forward technology to be provided at the same time that the two-way audio communication is being provided. The commenter contends it is not always possible to transmit images, diagnostics, data, and medical information during an audio communication. The commenter recommends that either the definition of "asynchronous store-and-forward technology" or N.J.A.C. 13:35-14.23(e) [page=1914] be amended

to clarify that asynchronous store-and-forward technology may be used before or after a real-time audio conversation.

RESPONSE: N.J.A.C. 13:35-14.23(e) does not require that the storing or forwarding functions of asynchronous store-and-forward technology be used at the same time that the licensed genetic counselor uses interactive, real-time two-way audio. Rather, the rule requires that audio communication be used in combination with asynchronous store-and-forward technology, which need not be in real-time.

6. COMMENT: A commenter contends that N.J.A.C. 13:35-14.26 requires licensed genetic counselors to determine whether a telephonic patient interaction is more appropriate than a video interaction. The commenter contends that there are no standards for a licensed genetic counselor to make such a decision and that licensed genetic counselors have been providing services over the phone for years.

RESPONSE: N.J.A.C. 13:35-14.26 does not require licensed genetic counselors to determine whether patient interaction over the telephone is more appropriate than video interaction. The rule requires licensed genetic counselors to develop written privacy practices when licensees do not use the telephone or facsimile to communicate with patients.

7. COMMENT: N.J.A.C. 13:35-14.26 requires licensed genetic counselors to provide patients with privacy practices and a notice regarding telemedicine and telehealth, including the risks and benefits of being treated via telemedicine or telehealth and how to receive follow-up care. Licensed genetic counselors must obtain written acknowledgement of receipt of these notices. A commenter contends that these requirements impose bureaucratic burdens on licensed genetic counselors. The commenter contends that patients will be unable to provide written acknowledgement if a patient does not have access to a fax machine, which would force counselors to provide in-person services. The commenter also contends that the rule should not require licensed genetic counselors to provide notice as to the risks of providing services through telemedicine or telehealth, as there is no proof that such risks exist.

RESPONSE: There is no requirement that written acknowledgement be provided in real-time with the provision of services by a licensed genetic counselor and N.J.A.C. 13:35-14.26 does not require a licensed genetic counselor to have access to a fax machine. Written acknowledgement can be provided through electronic means, such as an email. The rule requires that licensed genetic counselors provide patients with a notice regarding telemedicine and telehealth, including the risks and benefits of being treated through telemedicine or telehealth. If a licensed genetic counselor believes there are no risks

involved with providing services through telemedicine or telehealth, the required notice should indicate this for patients. The rule may impose some bureaucratic burdens, but this is outweighed by the benefits it provides to patients.

8. COMMENT: A commenter contends that licensed genetic counselors do not treat patients and that there are accordingly no risks to being treated by telemedicine and that there are no risks associated with telemedicine or telehealth. The commenter contends that there is no requirement in P.L. 2017, c. 117, for a notice as to risks of telemedicine or telehealth or a notice of how to receive follow up care or assistance in the event of an adverse reaction to treatment. The commenter believes that N.J.A.C. 13:35-14.26(e) is not necessary to implement P.L. 2017, c. 117, and could impede access to care. The commenter contends that licensed genetic counselors should not be required to provide patients with a notice that is not applicable to the services they provide. The commenter recommends that N.J.A.C. 13:35-14.26(e) be amended to delete the phrases "the risks and benefits of being treated through telemedicine or telehealth and," "follow up care or," and "an adverse reaction to the treatment or in the event of."

RESPONSE: N.J.A.C. 13:35-14.26(e) ensures that patients receive adequate notice as to the nature of the provision of services through telemedicine and telehealth. Similar provisions apply to all of the health care professionals included in P.L. 2017, c. 117, and it would be inappropriate to deprive patients who receive services from genetic counselors from the protections this rule provides. As stated in the response to prior comments, if a licensed genetic counselor believes that there are no risks associated with providing services through telemedicine or telehealth, the notice provided to patients should indicate this.

#### **Federal Standards Statement**

Requirements at N.J.A.C. 13:35-14.26 impose the same standards for privacy of communications as are imposed by 45 CFR Parts 160 and 164, which are referred to in the rule. There are no other applicable Federal laws or standards.

**Full text** of the adopted new rules follows:

13:35-14.19 Telemedicine: purpose and scope

(a) The purpose of N.J.A.C. 13:35-14.20 through 14.26 and this section is to implement the provisions of P.L. 2017, c. 117 (N.J.S.A. 45:1-61 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 Committee as genetic counselors or are permitted to provide genetic counseling pursuant to N.J.A.C. 13:35-14.4.

(c) Except as provided in N.J.A.C. 13:35-14.5, a genetic counselor must hold a license issued by the Committee 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, a healthcare provider located in another state who consults with a licensed genetic counselor 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 and will not be required to obtain licensure in New Jersey in order to provide such consultation.

#### 13:35-14.20 Telemedicine: definitions

The following words and terms, when used in N.J.A.C. 13:35-14.19 and 14.21 through 14.26 and this section, 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 licensed genetic counselor at a distant site, which allows for the patient to be evaluated without being physically present.

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

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

"On-call" means a licensed genetic counselor is available, where necessary, to attend to the urgent and follow-up needs of a patient for whom the licensed genetic counselor has temporarily assumed

responsibility, as designated by the patient's primary care licensed genetic counselor 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.

"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 using electronic communications, information technology, or other electronic or technological means to bridge the gap between a licensed genetic counselor 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 licensed genetic counselor, 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 isolation, of audio-only telephone conversation, electronic mail, instant messaging, phone text, or facsimile transmission.

[page=1915] 13:35-14.21 Telemedicine: standard of care

(a) Prior to providing services through telemedicine or telehealth, a licensed genetic counselor 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 licensed genetic counselor determines, either before or during the provision of services, that services cannot be provided through telemedicine or telehealth in a manner that is consistent with in-person standards of care, the licensed genetic counselor shall not provide services through telemedicine or telehealth.

(c) A licensed genetic counselor 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 licensed genetic counselor 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.

13:35-14.22 Telemedicine: licensed genetic counselor-patient relationship

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

1. Identifying the patient with, at a minimum, the patient's name, date of birth, phone number, and address. A licensed genetic counselor 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 licensed genetic counselor's identity, license, title, and, if applicable, specialty and board certifications.

(b) Prior to an initial contact with a patient for the purpose of providing services to the patient using telemedicine or telehealth, a licensed genetic counselor shall review the patient's history and any available records.

(c) Prior to initiating contact with a patient for the purpose of providing services through telemedicine or telehealth, a licensed genetic counselor shall determine 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. The licensed genetic counselor shall make this determination prior to each unique patient encounter.

(d) Notwithstanding (a), (b), and (c) above, service may be provided through telemedicine or telehealth without a proper licensed genetic counselor-patient relationship if:

1. The provision of services is for informal consultations with another healthcare provider performed by a licensed genetic counselor 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. The provision of services is during episodic consultations by a medical specialist located in another jurisdiction who provides consultation services, upon request, to a licensed genetic counselor in this State;

3. A licensed genetic counselor furnishes medical assistance in response to an emergency or disaster, provided that there is no charge for the medical assistance; or

4. A substitute licensed genetic counselor, who is acting on behalf of an absent licensed genetic counselor, provides health care services on an on-call or cross-coverage basis, provided that the absent licensed genetic counselor has designated the substitute licensed genetic counselor as an on-call licensed genetic counselor or cross-coverage service provider.

13:35-14.23 Telemedicine: provision of services through telemedicine or telehealth

(a) As long as a licensed genetic counselor has satisfied the requirements of N.J.A.C. 13:35-14.22, a licensed genetic counselor 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 licensed genetic counselor shall determine the patient's originating site and record this information in the patient's record.

(c) A licensed genetic counselor 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 licensed genetic counselor to see a patient and the patient to see the licensed genetic counselor during the provision of services.

(d) A licensed genetic counselor 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 records, a licensed genetic counselor determines that he or she is able to meet the standard of care for such services if they were being provided in person without using the video component described in (c) above, the licensed genetic counselor may use interactive, real-time, two-way audio in combination with asynchronous store-and-forward technology, without a video component.

(f) During the provision of services through telemedicine or telehealth, and after the provision of services, a licensed genetic

counselor, or another designated licensed genetic counselor, shall provide his or her name, professional credentials, and contact information to the patient. Such contact information shall enable the patient to contact the licensed genetic counselor 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.

(g) Prior to providing services through telemedicine or telehealth, a licensed genetic counselor shall review any history or records provided by a patient as follows:

1. For an initial encounter with a patient, history and records shall be reviewed prior to the provision of services through telemedicine or telehealth; and

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

(h) After the provision of services through telemedicine or telehealth, a licensed genetic counselor shall provide the patient, upon request, with his or her records created due to the services provided.

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

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

#### 13:35-14.24 Telemedicine: records

A licensed genetic counselor who provides services through telemedicine or telehealth shall maintain a record of the care provide to a patient. Such records shall comply with the requirements of N.J.A.C. 13:35-14.15, and all other applicable State and Federal statutes, rules, and regulations for recordkeeping, confidentiality, and disclosure of a patient's record.

#### 13:35-14.25 Telemedicine: prevention of fraud and abuse

(a) In order to establish that a licensed genetic counselor has made a good faith effort to prevent fraud and abuse when providing services through telemedicine or telehealth, a licensed genetic counselor 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. 13:35-14.22(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.

[page=1916] 13:35-14.26 Telemedicine: privacy and notice to patients

(a) Licensed genetic counselors 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 Parts 160 and 164, as amended and supplemented, which are incorporated herein by reference, 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 e-mail, prescriptions, and laboratory results must be password protected, encrypted electronic prescriptions, or protected through substantially equivalent authentication techniques.

(c) A licensed genetic counselor 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 Part 164.

(d) Licensed genetic counselors, 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) Licensed genetic counselors 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 licensed genetic counselor 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 licensed genetic counselor exercising ordinary skill and care would deem reasonably necessary to provide care to a patient, the licensed genetic counselor 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.

NEW JERSEY REGISTER

Copyright © 2020 by the New Jersey Office of Administrative Law

---

End of Document