

MEDICINE BOARD[653]

Adopted and Filed

Pursuant to the authority of Iowa Code section 147.76, the Board of Medicine hereby amends Chapter 13, “Standards of Practice and Principles of Medical Ethics,” Iowa Administrative Code.

This rule establishes the standards of practice for physicians who use telemedicine, which is the practice of medicine using electronic communication, information technology or other means of interaction between a licensee in one location and a patient in another location with or without an intervening health care provider.

The Board approved the Notice of Intended Action for this rule making during a regularly scheduled meeting on October 3, 2014. The Notice was published in the Iowa Administrative Bulletin on December 10, 2014, as **ARC 1769C**. A public hearing on **ARC 1769C** was held on January 15, 2015.

Five comments were received at the hearing, and 18 written comments were received. The Board received written comments from Rebecca J. Hafner-Fogarty, M.D., Zipnosis; Timothy G. Abrahamson, M.D., Greater Des Moines Dermatology; Susan Koehler, Iowa Board of Physician Assistants; Sara Allen, Iowa Hospital Association; David Erickson, M.D., Avera Health; Thomas G. Seaman, Teladoc; Karla Fultz McHenry, Fultz McHenry Consulting; Clare M. Kelly, Iowa Medical Society; Jonathan D. Linkous, American Telemedicine Association; Laurie Clair, Iowa Physician Assistant Society; Dale F. Andres, D.O., Mercy Health Network; Andrew Zinkel, M.D., HealthPartners; Kate Walton, UnityPoint Health; Gretchen Borchelt, National Women’s Law Center; Ted Stopulos, Iowa Health Care Association and Iowa Center for Assisted Living; Craig Sieverding, Davis Brown Law Firm; Leah J. McWilliams, Iowa Osteopathic Medical Association; and Planned Parenthood of the Heartland. Comments were made at the hearing by Ken Croken, Genesis Health System; Dennis Tibben, Iowa Medical Society; Mike Falkstrom, Planned Parenthood of the Heartland; Dale Andres, D.O., Mercy Health Network; and Stephanie Cooper, Mercy Physician Services.

The Board continued a public discussion of **ARC 1769C** at a regularly scheduled meeting on February 6, 2015, at which time it was determined to accept public comments until March 20, 2015.

Several revisions were made to proposed rule 653—13.11(147,148,272C) based on comments received between October 3, 2014, and March 20, 2015:

In subrule 13.11(1), the definition of “asynchronous store-and-forward transmission” was added and, in the definition of “telemedicine,” the adjective “asynchronous” was added to the phrase “store-and-forward transmission.” The definition of “telemedicine” was enhanced to recognize that telemedicine includes store-and-forward technologies, remote monitoring, and real-time interactive services, including teleradiology and telepathology.

In subrule 13.11(2), language was changed to acknowledge that some nationally recognized medical specialty organizations have established comprehensive telemedicine practice guidelines that address the clinical and technological aspects of telemedicine.

In subrule 13.11(3), a citation to 653—subrule 9.2(2) was added to identify the exceptions to Iowa licensure.

In subrule 13.11(7), changes were made to clarify that a physician-patient relationship can be established under some circumstances involving a telemedicine encounter with a patient.

Subrule 13.11(8) notes that generally a licensee shall perform an in-person medical interview and physical examination for each patient but also recognizes that the in-person interview and in-person physical examination may not be necessary if the technology utilized in a telemedicine encounter is sufficient to establish an informed diagnosis. This subrule was revised to define characteristics of an appropriate Internet questionnaire to collect information on a patient’s medical history and current health issues.

In subrule 13.11(9) as revised, the licensee will not be required to personally assess the qualifications of each nonphysician health care provider, but the licensee must ensure that systems are in place to make certain that a nonphysician health care provider is qualified and appropriately trained.

In subrule 13.11(16), the adjective “asynchronous” was added to the phrase “store-and-forward technologies.”

In subrule 13.11(17), the phrase “if these differ from an in-person encounter” was added in paragraph “e” pertaining to the requirement to disclose fees for medical services provided via telemedicine.

In subrule 13.11(19), language was added to acknowledge that there may be state and federal laws that govern the financial interests of licensees who practice medicine by using telemedicine.

In subrule 13.11(20), language was revised to reflect that the standard of care may not require a licensee to personally interview and examine a patient prior to the provision of care in certain circumstances, including both in the use of telemedicine and in in-person encounters with a patient.

In subrule 13.11(21) as revised, it is recognized that without a valid physician-patient relationship, or outside of circumstances described in subrule 13.11(20), the prescribing of any prescription medications, not limited to controlled substances, based solely on an Internet request, an Internet questionnaire or a telephonic evaluation is prohibited.

Subrule 13.11(22) clarifies that nothing in rule 653—13.11(147,148,272C) shall be interpreted to contradict or supersede the requirements established in rule 653—13.10(147,148,272C).

At a regularly scheduled meeting on April 3, 2015, the Board voted to adopt this rule with the above-listed changes.

After analysis and review of this rule making, it has been determined that this rule could have a positive impact on jobs in Iowa. The new rule will facilitate the practice of medicine at more locations within the state.

This rule is intended to implement Iowa Code chapters 147, 148 and 272C.

This rule will become effective on June 3, 2015.

The following amendment is adopted.

Adopt the following **new** rule 653—13.11(147,148,272C):

653—13.11(147,148,272C) Standards of practice—telemedicine. This rule establishes standards of practice for the practice of medicine using telemedicine.

1. The board recognizes that technological advances have made it possible for licensees in one location to provide medical care to patients in another location with or without an intervening health care provider.

2. Telemedicine is a useful tool that, if applied appropriately, can provide important benefits to patients, including increased access to health care, expanded utilization of specialty expertise, rapid availability of patient records, and potential cost savings.

3. The board advises that licensees using telemedicine will be held to the same standards of care and professional ethics as licensees using traditional in-person medical care.

4. Failure to conform to the appropriate standards of care or professional ethics while using telemedicine may subject the licensee to potential discipline by the board.

13.11(1) Definitions. As used in this rule:

“*Asynchronous store-and-forward transmission*” means the collection of a patient’s relevant health information and the subsequent transmission of the data from an originating site to a health care provider at a distant site without the presence of the patient.

“*Board*” means the Iowa board of medicine.

“*In-person encounter*” means that the physician and the patient are in the physical presence of each other and are in the same physical location during the physician-patient encounter.

“*Licensee*” means a medical physician or osteopathic physician licensed by the board.

“*Telemedicine*” means the practice of medicine using electronic audio-visual communications and information technologies or other means, including interactive audio with asynchronous store-and-forward transmission, between a licensee in one location and a patient in another location with or without an intervening health care provider. Telemedicine includes asynchronous store-and-forward technologies, remote monitoring, and real-time interactive services, including teleradiology and telepathology. Telemedicine shall not include the provision of medical services only through an

audio-only telephone, e-mail messages, facsimile transmissions, or U.S. mail or other parcel service, or any combination thereof.

“Telemedicine technologies” means technologies and devices enabling secure electronic communications and information exchanges between a licensee in one location and a patient in another location with or without an intervening health care provider.

13.11(2) Practice guidelines. A licensee who uses telemedicine shall utilize evidence-based telemedicine practice guidelines and standards of practice, to the degree they are available, to ensure patient safety, quality of care, and positive outcomes. The board acknowledges that some nationally recognized medical specialty organizations have established comprehensive telemedicine practice guidelines that address the clinical and technological aspects of telemedicine for many medical specialties.

13.11(3) Iowa medical license required. A physician who uses telemedicine in the diagnosis and treatment of a patient located in Iowa shall hold an active Iowa medical license consistent with state and federal laws. Nothing in this rule shall be construed to supersede the exceptions to licensure contained in 653—subrule 9.2(2).

13.11(4) Standards of care and professional ethics. A licensee who uses telemedicine shall be held to the same standards of care and professional ethics as a licensee using traditional in-person encounters with patients. Failure to conform to the appropriate standards of care or professional ethics while using telemedicine may be a violation of the laws and rules governing the practice of medicine and may subject the licensee to potential discipline by the board.

13.11(5) Scope of practice. A licensee who uses telemedicine shall ensure that the services provided are consistent with the licensee’s scope of practice, including the licensee’s education, training, experience, ability, licensure, and certification.

13.11(6) Identification of patient and physician. A licensee who uses telemedicine shall verify the identity of the patient and ensure that the patient has the ability to verify the identity, licensure status, certification, and credentials of all health care providers who provide telemedicine services prior to the provision of care.

13.11(7) Physician-patient relationship.

a. A licensee who uses telemedicine shall establish a valid physician-patient relationship with the person who receives telemedicine services. The physician-patient relationship begins when:

- (1) The person with a health-related matter seeks assistance from a licensee;
- (2) The licensee agrees to undertake diagnosis and treatment of the person; and
- (3) The person agrees to be treated by the licensee whether or not there has been an in-person encounter between the physician and the person.

b. A valid physician-patient relationship may be established by:

- (1) In-person encounter. Through an in-person medical interview and physical examination where the standard of care would require an in-person encounter;
- (2) Consultation with another licensee. Through consultation with another licensee (or other health care provider) who has an established relationship with the patient and who agrees to participate in, or supervise, the patient’s care; or
- (3) Telemedicine encounter. Through telemedicine, if the standard of care does not require an in-person encounter, and in accordance with evidence-based standards of practice and telemedicine practice guidelines that address the clinical and technological aspects of telemedicine.

13.11(8) Medical history and physical examination. Generally, a licensee shall perform an in-person medical interview and physical examination for each patient. However, the medical interview and physical examination may not be in-person if the technology utilized in a telemedicine encounter is sufficient to establish an informed diagnosis as though the medical interview and physical examination had been performed in-person. Prior to providing treatment, including issuing prescriptions, electronically or otherwise, a licensee who uses telemedicine shall interview the patient to collect the relevant medical history and perform a physical examination, when medically necessary, sufficient for the diagnosis and treatment of the patient. An Internet questionnaire that is a static set of questions provided to the patient, to which the patient responds with a static set of answers, in contrast

to an adaptive, interactive and responsive online interview, does not constitute an acceptable medical interview and physical examination for the provision of treatment, including issuance of prescriptions, electronically or otherwise, by a licensee.

13.11(9) *Nonphysician health care providers.* If a licensee who uses telemedicine relies upon or delegates the provision of telemedicine services to a nonphysician health care provider, the licensee shall:

a. Ensure that systems are in place to ensure that the nonphysician health care provider is qualified and trained to provide that service within the scope of the nonphysician health care provider's practice;

b. Ensure that the licensee is available in person or electronically to consult with the nonphysician health care provider, particularly in the case of injury or an emergency.

13.11(10) *Informed consent.* A licensee who uses telemedicine shall ensure that the patient provides appropriate informed consent for the medical services provided, including consent for the use of telemedicine to diagnose and treat the patient, and that such informed consent is timely documented in the patient's medical record.

13.11(11) *Coordination of care.* A licensee who uses telemedicine shall, when medically appropriate, identify the medical home or treating physician(s) for the patient, when available, where in-person services can be delivered in coordination with the telemedicine services. The licensee shall provide a copy of the medical record to the patient's medical home or treating physician(s).

13.11(12) *Follow-up care.* A licensee who uses telemedicine shall have access to, or adequate knowledge of, the nature and availability of local medical resources to provide appropriate follow-up care to the patient following a telemedicine encounter.

13.11(13) *Emergency services.* A licensee who uses telemedicine shall refer a patient to an acute care facility or an emergency department when referral is necessary for the safety of the patient or in the case of an emergency.

13.11(14) *Medical records.* A licensee who uses telemedicine shall ensure that complete, accurate and timely medical records are maintained for the patient when appropriate, including all patient-related electronic communications, records of past care, physician-patient communications, laboratory and test results, evaluations and consultations, prescriptions, and instructions obtained or produced in connection with the use of telemedicine technologies. The licensee shall note in the patient's record when telemedicine is used to provide diagnosis and treatment. The licensee shall ensure that the patient or another licensee designated by the patient has timely access to all information obtained during the telemedicine encounter. The licensee shall ensure that the patient receives, upon request, a summary of each telemedicine encounter in a timely manner.

13.11(15) *Privacy and security.* A licensee who uses telemedicine shall ensure that all telemedicine encounters comply with the privacy and security measures of the Health Insurance Portability and Accountability Act to ensure that all patient communications and records are secure and remain confidential.

a. Written protocols shall be established that address the following:

- (1) Privacy;
- (2) Health care personnel who will process messages;
- (3) Hours of operation;
- (4) Types of transactions that will be permitted electronically;
- (5) Required patient information to be included in the communication, including patient name, identification number and type of transaction;
- (6) Archiving and retrieval; and
- (7) Quality oversight mechanisms.

b. The written protocols should be periodically evaluated for currency and should be maintained in an accessible and readily available manner for review. The written protocols shall include sufficient privacy and security measures to ensure the confidentiality and integrity of patient-identifiable information, including password protection, encryption or other reliable authentication techniques.

13.11(16) *Technology and equipment.* The board recognizes that three broad categories of telemedicine technologies currently exist, including asynchronous store-and-forward technologies,

remote monitoring, and real-time interactive services. While some telemedicine programs are multispecialty in nature, others are tailored to specific diseases and medical specialties. The technology and equipment utilized for telemedicine shall comply with the following requirements:

a. The technology and equipment utilized in the provision of telemedicine services must comply with all relevant safety laws, rules, regulations, and codes for technology and technical safety for devices that interact with patients or are integral to diagnostic capabilities;

b. The technology and equipment utilized in the provision of telemedicine services must be of sufficient quality, size, resolution and clarity such that the licensee can safely and effectively provide the telemedicine services; and

c. The technology and equipment utilized in the provision of telemedicine services must be compliant with the Health Insurance Portability and Accountability Act.

13.11(17) *Disclosure and functionality of telemedicine services.* A licensee who uses telemedicine shall ensure that the following information is clearly disclosed to the patient:

a. Types of services provided;

b. Contact information for the licensee;

c. Identity, licensure, certification, credentials, and qualifications of all health care providers who are providing the telemedicine services;

d. Limitations in the drugs and services that can be provided via telemedicine;

e. Fees for services, cost-sharing responsibilities, and how payment is to be made, if these differ from an in-person encounter;

f. Financial interests, other than fees charged, in any information, products, or services provided by the licensee(s);

g. Appropriate uses and limitations of the technologies, including in emergency situations;

h. Uses of and response times for e-mails, electronic messages and other communications transmitted via telemedicine technologies;

i. To whom patient health information may be disclosed and for what purpose;

j. Rights of patients with respect to patient health information; and

k. Information collected and passive tracking mechanisms utilized.

13.11(18) *Patient access and feedback.* A licensee who uses telemedicine shall ensure that the patient has easy access to a mechanism for the following purposes:

a. To access, supplement and amend patient-provided personal health information;

b. To provide feedback regarding the quality of the telemedicine services provided; and

c. To register complaints. The mechanism shall include information regarding the filing of complaints with the board.

13.11(19) *Financial interests.* Advertising or promotion of goods or products from which the licensee(s) receives direct remuneration, benefit or incentives (other than the fees for the medical services) is prohibited to the extent that such activities are prohibited by state or federal law. Notwithstanding such prohibition, Internet services may provide links to general health information sites to enhance education; however, the licensee(s) should not benefit financially from providing such links or from the services or products marketed by such links. When providing links to other sites, licensees should be aware of the implied endorsement of the information, services or products offered from such sites. The maintenance of a preferred relationship with any pharmacy is prohibited. Licensees shall not transmit prescriptions to a specific pharmacy, or recommend a pharmacy, in exchange for any type of consideration or benefit from the pharmacy.

13.11(20) *Circumstances where the standard of care may not require a licensee to personally interview or examine a patient.* Under the following circumstances, whether or not such circumstances involve the use of telemedicine, a licensee may treat a patient who has not been personally interviewed, examined and diagnosed by the licensee:

a. Situations in which the licensee prescribes medications on a short-term basis for a new patient and has scheduled or is in the process of scheduling an appointment to personally examine the patient;

b. For institutional settings, including writing initial admission orders for a newly hospitalized patient;

- c. Call situations in which a licensee is taking call for another licensee who has an established physician-patient relationship with the patient;
- d. Cross-coverage situations in which a licensee is taking call for another licensee who has an established physician-patient relationship with the patient;
- e. Situations in which the patient has been examined in person by an advanced registered nurse practitioner or a physician assistant or other licensed practitioner with whom the licensee has a supervisory or collaborative relationship;
- f. Emergency situations in which the life or health of the patient is in imminent danger;
- g. Emergency situations that constitute an immediate threat to the public health including, but not limited to, empiric treatment or prophylaxis to prevent or control an infectious disease outbreak;
- h. Situations in which the licensee has diagnosed a sexually transmitted disease in a patient and the licensee prescribes or dispenses antibiotics to the patient's named sexual partner(s) for the treatment of the sexually transmitted disease as recommended by the U.S. Centers for Disease Control and Prevention; and
- i. For licensed or certified nursing facilities, residential care facilities, intermediate care facilities, assisted living facilities and hospice settings.

13.11(21) *Prescribing based solely on an Internet request, Internet questionnaire or a telephonic evaluation—prohibited.* Prescribing to a patient based solely on an Internet request or Internet questionnaire (i.e., a static questionnaire provided to a patient, to which the patient responds with a static set of answers, in contrast to an adaptive, interactive and responsive online interview) is prohibited. Absent a valid physician-patient relationship, a licensee's prescribing to a patient based solely on a telephonic evaluation is prohibited, with the exception of the circumstances described in subrule 13.11(20).

13.11(22) *Medical abortion.* Nothing in this rule shall be interpreted to contradict or supersede the requirements established in rule 653—13.10(147,148,272C).

This rule is intended to implement Iowa Code chapters 147, 148 and 272C.

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