

Clearinghouse Rule 15-087

STATE OF WISCONSIN
MEDICAL EXAMINING BOARD

IN THE MATTER OF RULEMAKING : PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE : MEDICAL EXAMINING BOARD
MEDICAL EXAMINING : ADOPTING RULES
BOARD : (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Medical Examining Board to create chapter Med 24 relating to telemedicine.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted:

None.

Statutory authority:

Sections 15.08 (5) (b), 227.11 (2) (a), and 448.40 (1), Stats.

Related statute or rule:

None.

Explanation of agency authority:

Section 15.08 (5) (b), Stats., provides examining boards, “shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains. . .”

Section 227.11 (2) (a), Stats., sets forth the parameters of an agency’s rule-making authority, stating an agency, “may promulgate rules interpreting provisions of any statute enforced or administered by the agency. . .but a rule is not valid if the rule exceeds the bounds of correct interpretation.”

Section 448.40 (1), Stats., provides that the Medical Examining Board “may promulgate rules to carry out the purposes of this subchapter, including rules requiring the completion of continuing education, professional development, and maintenance of

certification or performance improvement or continuing medical education programs for renewal of a license to practice medicine and surgery.”

Plain language analysis:

The current administrative code is silent with regards to telemedicine practice. The proposed rule will define telemedicine, explain how a valid physician-patient relationship can be established in a telemedicine setting, and identify technology requirements for physicians who use electronic communications, information technology or other means of interaction with patients who are not physically present. The proposed rule will specify out-of-state physicians to hold a valid Wisconsin medical license in order to diagnose and treat patients located in Wisconsin.

Summary of, and comparison with, existing or proposed federal regulation:

2015 HR 691 - Telehealth Modernization Act of 2015 – the proposed bill seeks to establish a federal standard for telehealth and serve as guidance for states, subject to a number of specified conditions.

Comparison with rules in adjacent states:

Illinois: Illinois statutes require an individual who engages in telemedicine to hold a medical license issued by the state of Illinois. Telemedicine is defined as including but not limited to rendering written or oral opinions concerning diagnosis or treatment of a patient in Illinois by a person located outside the State of Illinois as a result of transmission of individual patient data by telephonic, electronic, or other means of communication from within this State. Telemedicine specifically does not include periodic consultations between a licensee and a person outside the State of Illinois, a second opinion provided to a licensee; and the diagnosis or treatment services provided to a patient in Illinois following care or treatment originally provided to the patient in the state in which the provider is licensed to practice medicine (225 Ill. Comp. Stat. Ann. s. 60/49.5). The telemedicine provisions are scheduled to be repealed on December 31, 2015.

Iowa: Iowa Administrative Code 653-13.11 establishes the standards of practices of physicians who use telemedicine. Similar to the proposed rule, Iowa Administrative Code defines telemedicine, explains how a valid physician-patient relationship can be established in a telemedicine setting, and identifies technology requirements for physicians who use electronic communications, information technology or other means of interaction with patients who are not physically present. The rule requires out-of-state physicians to have a valid Iowa medical license in order to diagnose and treat patients located in Iowa.

Michigan: Michigan statutes and administrative code are silent with regards to the provision of telemedicine services. The standards are the same as in-person care.

Minnesota: Minnesota does not have any unique laws regulating the practice of telemedicine. Standards are the same as in person care (Minn. Stat. s. 147.032).

Summary of factual data and analytical methodologies:

Other states' requirements as well as the Federation of State Medical Boards model policy were reviewed when drafting the proposed rule change.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

The rule were posted for public comment on the economic impact of the proposed rule, including how this proposed rule may affect businesses, local government units, and individuals, for a period of 14 days. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis document is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Eric.Esser@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Katie Vieira, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8935, Madison, Wisconsin 53708; telephone 608-261-4472; email at Kathleen.Vieira@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Katie Vieira, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, WI 53708-8935, or by email to Kathleen.Vieira@wisconsin.gov. Comments must be received on or before the public hearing on January 20, 2016 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Chapter Med 24 is created to read:

CHAPTER MED 24

TELEMEDICINE

Med 24.01 Authority and purpose. The rules in this chapter are adopted by the medical examining board pursuant to the authority delegated by ss. 15.08 (5), 227.11, and 448.40, Stats., and govern the standards of practice for the practice of medicine using telemedicine.

Med 24.02 Definitions. For the purposes of this chapter:

(1) “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.

(2) “Board” means the medical examining board.

(3) “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.

(4) “Licensee” means an individual licensed by the board.

(5) “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.

(6) “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.

Med 24.03 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.

Med 24.04 Wisconsin medical license required. A physician who uses telemedicine in the diagnosis and treatment of a patient located in Wisconsin shall hold an active Wisconsin medical license.

Med 24.05 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.

Med 24.06 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.

Med 24.07 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.

Med 24.08 Physician-patient relationship. The physician-patient relationship begins when a person with a health-related matter seeks assistance from a licensee, the licensee agrees to undertake diagnosis and treatment of the person, and 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. A licensee who uses telemedicine shall establish a valid physician-patient relationship with the person who receives telemedicine services. A valid physician-patient relationship may be established through any of the following:

(1) An in-person medical interview and physical examination where the standard of care would require an in-person encounter.

(2) A 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.

(3) 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.

Med 24.09 Medical history and physical examination. A licensee shall perform a medical interview and physical examination for each patient. 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.

Med 24.10 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 ensure that all of the following are met:

(1) 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.

(2) 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.

Med 24.11 Informed consent. In accordance with ch. Med 18, 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.

Med 24.12 Coordination of care. A licensee who uses telemedicine shall, when medically appropriate, identify the medical home or treating physicians 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 physicians.

Med 24.13 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.

Med 24.14 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.

Med 24.15 Medical records. A licensee who uses telemedicine shall ensure that complete, accurate and timely medical records are maintained for the patient in accordance with ch. Med 21, 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.

Med 24.16 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. Written protocols shall be established by the licensee meet all of the following:

(1) Written protocols shall address all of the following:

- (a) Privacy.
- (b) Health care personnel who will process messages.
- (c) Hours of operation.
- (d) Types of transactions that will be permitted electronically.
- (e) Required patient information to be included in the communication, including patient name, identification number and type of transaction.
- (f) Archiving and retrieval.
- (g) Quality oversight mechanisms.

(2) 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.

Med 24.17 Technology and equipment. The board recognizes that three broad categories of telemedicine technologies 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:

(1) 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.

(2) 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.

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

Med 24.18 Disclosure and functionality of telemedicine services. A licensee who uses telemedicine shall disclose all of the following information to the patient:

(1) Types of services provided.

(2) Contact information for the licensee.

(3) Identity, licensure, certification, credentials, and qualifications of all health care providers who are providing the telemedicine services.

(4) Limitations in the drugs and services that can be provided via telemedicine.

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

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

(7) Appropriate uses and limitations of the technologies, including in emergency situations.

(8) Uses of and response times for e-mails, electronic messages and other communications transmitted via telemedicine technologies.

(9) To whom patient health information may be disclosed and for what purpose.

(10) Rights of patients with respect to patient health information.

(11) Information collected and passive tracking mechanisms utilized.

Med 24.19 Patient access and feedback. A licensee who uses telemedicine shall ensure that the patient has easy access to a mechanism for the following purposes:

(1) To access, supplement and amend patient-provided personal health information.

(2) To provide feedback regarding the quality of the telemedicine services provided.

(3) To register complaints. The mechanism shall include information regarding the filing of complaints with the board.

Med 24.20 Financial interests. Advertising or promotion of goods or products from which the licensee 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 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.

Med 24.21 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:

(1) 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.

(2) For institutional settings, including writing initial admission orders for a newly hospitalized patient.

(3) Call situations in which a licensee is taking call for another licensee who has an established physician-patient relationship with the patient.

(4) Cross-coverage situations in which a licensee is taking call for another licensee who has an established physician-patient relationship with the patient.

(5) 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.

(6) Emergency situations in which the life or health of the patient is in imminent danger.

(7) 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.

(8) 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 partners for the treatment of the sexually transmitted disease as recommended by the U.S. Centers for Disease Control and Prevention.

(9) For licensed or certified nursing facilities, residential care facilities, intermediate care facilities, assisted living facilities and hospice settings.

Med 24.22 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 such as 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.

Med 24.23 Medical abortion. Nothing in this rule shall be interpreted to contradict or supersede the requirements under ch. Med 11.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

Dated _____

Agency _____

Chairperson
Medical Examining Board