

Notice of Agency Rule-making Proposal

AGENCY: 02-373 Board of Licensure in Medicine; 02-383 Board of Osteopathic Licensure

CHAPTER NUMBER AND TITLE: Chapter 6 Telemedicine Standards of Practice (new joint rule for both Boards)

PROPOSED RULE NUMBER (*leave blank; to be assigned by Secretary of State*):

BRIEF SUMMARY: The Board of Licensure in Medicine and the Board of Osteopathic Licensure propose a new joint rule to establish standards for the practice of medicine using telemedicine in providing health care. The proposed rule defines terms and sets forth practice guidelines, including provisions regarding establishing a physician-patient relationship in the telemedicine setting, technology requirements for physicians using electronic communications, and maintaining privacy and security. The text of the proposed rule may be obtained from www.maine.gov/md or www.maine.gov/osteo.

Date, time and location of PUBLIC HEARING (*if any*): none planned

COMMENT DEADLINE: Friday, July 15, 2016 at 5:00 p.m.

CONTACT PERSON FOR THIS FILING (*include name, mailing address, telephone, fax, TTY, e-mail*):
Dennis E. Smith, Executive Director, Board of Licensure in Medicine, 137 State House Station, Augusta, ME 04333, tel. (207) 287-3605, fax (207) 287-6590, dennis.smith@maine.gov.

Susan E. Strout, Executive Secretary, Board of Osteopathic Licensure, 142 State House Station, Augusta, ME 04333, tel. (207) 287-2480, fax (207) 536-5811, susan.e.strout@maine.gov.

CONTACT PERSON FOR SMALL BUSINESS IMPACT STATEMENT (*if different*): same as above

FINANCIAL IMPACT ON MUNICIPALITIES OR COUNTIES (*if any*): none

STATUTORY AUTHORITY FOR THIS RULE: 32 M.R.S. §§ 3269(3), 3269(7) (Board of Licensure in Medicine); 32 M.R.S. § 2562 (Board of Osteopathic Licensure)

SUBSTANTIVE STATE OR FEDERAL LAW BEING IMPLEMENTED (*if different*):

AGENCY WEBSITE: www.maine.gov/md (Board of Licensure in Medicine); www.maine.gov/osteo (Board of Osteopathic Licensure)

E-MAIL FOR OVERALL AGENCY RULE-MAKING LIAISON: maureen.s.lathrop@maine.gov (Board of Licensure in Medicine); susan.e.strout@maine.gov (Board of Osteopathic Licensure)

* Check one of the following two boxes.

☒ The summary provided above is for publication in both the newspaper and website notices.

☐ *The summary provided above is for the newspaper notice only. Title 5 §8053, sub-§5 & sub-§7, ¶D. A more detailed summary is attached for inclusion in the rule-making notice posted on the Secretary of State's website. Title 5 §8053, sub-§3, ¶D & sub-§6.*

Please approve bottom portion of this form and assign appropriate AdvantageME number.

APPROVED FOR PAYMENT _____ DATE: _____
(authorized signature)

Split cost equally between the following two licensing boards:

FUND	AGENCY	ORG	APP	JOB	OBJT	AMOUNT
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Rule-Making Fact Sheet

(5 MRSA §8057-A)

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NAME, ADDRESS, PHONE NUMBER, E-MAIL OF AGENCY CONTACT PERSON: Dennis E. Smith, Executive Director, Board of Licensure in Medicine, 137 State House Station, Augusta, ME 04333, tel. (207) 287-3605, fax (207) 287-6590, dennis.smith@maine.gov.

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CHAPTER NUMBER AND RULE TITLE: Chapter 6 Telemedicine Standards of Practice (new joint rule for both Boards)

STATUTORY AUTHORITY: 32 M.R.S. §§ 3269(3), 3269(7) (Board of Licensure in Medicine); 32 M.R.S. § 2562 (Board of Osteopathic Licensure)

DATE, TIME AND PLACE OF PUBLIC HEARING: none planned

COMMENT DEADLINE: Friday, July 15, 2016 at 5:00 p.m.

PRINCIPAL REASON(S) OR PURPOSE FOR PROPOSING THIS RULE: [see §8057-A(1)(A)&(C)]

The Board of Licensure in Medicine and the Board of Osteopathic Licensure propose a new joint rule to establish standards for the practice of medicine using telemedicine in providing health care.

IS MATERIAL INCORPORATED BY REFERENCE IN THE RULE? ___ YES X NO [§8056(1)(B)]

ANALYSIS AND EXPECTED OPERATION OF THE RULE: [see §8057-A(1)(B)&(D)]

This is a consolidated rulemaking proceeding of the Board of Licensure in Medicine and the Board of Osteopathic Licensure to adopt a joint rule relating to the practice of medicine using telemedicine in providing health care. The proposed joint rule will define terms and set forth practice guidelines, including provisions regarding establishing a physician-patient relationship in the telemedicine setting, technology requirements for physicians using electronic communications, and maintaining privacy and security.

FINDINGS UNDER CRITERIA CONTAINED IN EXECUTIVE ORDER 20 FY 11/12: (A) The Boards do not anticipate that the proposed rule will negatively impact job growth or creation; (B) The proposed rule does not include any fees; (C) There is no cost to the public in terms of time and money required to comply with the rule; (D) No other state laws or rules already address the subject matter of this rule; and (E) There are no relevant federal standards.

BRIEF SUMMARY OF RELEVANT INFORMATION CONSIDERED DURING DEVELOPMENT OF THE RULE (including up to 3 primary sources relied upon) [see §§8057-A(1)(E) & 8063-B]

Professional judgement of the Boards; research conducted on telemedicine rules in other jurisdictions, including a recent telemedicine rule adopted by the Iowa Board of Medicine; the Federation of State Medical Board's Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine; the Board of Licensure in Medicine's Telemedicine Guidelines; and input was solicited from representatives of the Maine Medical Association and the Maine Hospital Association.

ESTIMATED FISCAL IMPACT OF THE RULE: [see §8057-A(1)(C)] Minimal

FOR EXISTING RULES WITH FISCAL IMPACT OF \$1 MILLION OR MORE, ALSO INCLUDE:

ECONOMIC IMPACT, WHETHER OR NOT QUANTIFIABLE IN MONETARY TERMS:
[see §8057-A(2)(A)]

INDIVIDUALS, MAJOR INTEREST GROUPS AND TYPES OF BUSINESSES AFFECTED
AND HOW THEY WILL BE AFFECTED: [see §8057-A(2)(B)]

BENEFITS OF THE RULE: [see §8057-A(2)(C)]

Note: If necessary, additional pages may be used.

ECONOMIC IMPACT STATEMENT
(5 M.R.S. § 5052 (5-A))

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TYPES AND NUMBER OF SMALL BUSINESSES SUBJECT TO THE RULE: The Board of Licensure in Medicine licenses 5,778 physicians and 786 physician assistants. The Board of Osteopathic Licensure licenses 1,061 physicians and 119 physician assistants.

Title 5 M.R.S. § 8052(5-A) defines “small business” as businesses that have 20 or fewer employees. The Boards do not collect sufficient information to reliably estimate the number of licensees that are small businesses as defined in 5 M.R.S. § 8052 (5-A).

PROJECTED REPORTING, RECORDKEEPING AND OTHER ADMINISTRATIVE COSTS REQUIRED FOR COMPLIANCE WITH THE PROPOSED RULE, INCLUDING THE TYPE OF PROFESSIONAL SKILLS NECESSARY FOR PREPARATION OF THE REPORT OR RECORD: The proposed joint rule includes a provision regarding medical recordkeeping which reflects the current standard. There are not any recordkeeping or other compliance costs that licensees do not currently bear.

PROBABLE IMPACT ON AFFECTED SMALL BUSINESSES: Minimal

LESS INTRUSIVE OR LESS COSTLY, REASONABLE ALTERNATIVE METHODS OF ACHIEVING THE PURPOSES OF THE PROPOSED RULE: none

02 DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION

373 BOARD OF LICENSURE IN MEDICINE

383 BOARD OF OSTEOPATHIC LICENSURE

Chapter 6 TELEMEDICINE STANDARDS OF PRACTICE

SUMMARY: Chapter 6 establishes standards for the practice of medicine using telemedicine in providing health care.

SECTION 1. STATEMENT REGARDING TELEMEDICINE

1. The Board recognizes that technological advances have made it possible for licensees in one location to provide health 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 in providing health care will be held to the same standards of care and professional ethics as licensees providing traditional in-person health care.
4. Failure to conform to the appropriate standards of care or professional ethics while using telemedicine in providing health care may subject the licensee to potential discipline by the Board.

SECTION 2. DEFINITIONS

1. “Asynchronous store-and-forward transmission” means the collection of a patient’s relevant health information and the subsequent transmission of the information from an originating site to a health care provider at a distant site without the presence of the patient.
2. “Board” means the Maine Board of Licensure in Medicine or the Board of Osteopathic Licensure.
3. “Distant site” means the location of the licensee providing telemedicine services.

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4. “In-person encounter” means that the licensee and the patient are in the physical presence of each other and are in the same physical location during the physician-patient encounter.
5. “Licensee” means a physician or physician assistant licensed by the Board.
6. “Originating site” means the location of the patient at the time of the examination, diagnosis, consultation or treatment.
7. “Patient-Physician Relationship” has the same meaning as defined by Opinion 10.015 in the American Medical Association Code of Medical Ethics 2014-2015 Edition.
8. “Telemedicine” means the practice of medicine or the rendering of health care services 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, instant messaging, facsimile transmission, or U.S. mail or other parcel service, or any combination thereof.
9. “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.

SECTION 3. PRACTICE GUIDELINES

1. 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.

2. MAINE MEDICAL LICENSE REQUIRED

A licensee who uses telemedicine in the examination, diagnosis, consultation or treatment of a patient located in Maine shall hold an active Maine medical license or shall hold an active registration in Maine to provide interstate consultative telemedicine services.

3. STANDARDS OF CARE AND PROFESSIONAL ETHICS

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A licensee who uses telemedicine in providing health care 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.

4. SCOPE OF PRACTICE

A licensee who uses telemedicine in providing health care 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.

5. IDENTIFICATION OF PATIENT AND PHYSICIAN

A licensee who uses telemedicine in providing health care 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.

6. PHYSICIAN-PATIENT RELATIONSHIP

A. A licensee who uses telemedicine in providing health care 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 the licensee;
- (2) The licensee agrees to undertake examination, diagnosis, consultation or treatment of the person; and
- (3) The person agrees to receive health care services from the licensee whether or not there has been an in-person encounter between the licensee and the person.

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

- (1) In-person encounter. Through an in-person medical interview and physician examination. In some circumstances the standard of care requires an in-person encounter;
- (2) Consultation with another licensee. Through consultation with another licensee (or other health care provider) who has an established

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relationship with the patient upon agreement 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.

7. 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 physician examination had been performed in-person. Prior to providing treatment, including issuing prescriptions, electronically or otherwise, a licensee who uses telemedicine in providing health care 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 the licensee.

8. NON-PHYSICIAN HEALTH CARE PROVIDERS

- A. If a licensee who uses telemedicine in providing health care relies upon or delegates the provision of telemedicine services to a non-physician health care provider, the licensee shall:
 - (1) Ensure that systems are in place to ensure that the non-physician health care provider is qualified, trained, and authorized to provide that service; and
 - (2) Ensure that the licensee is available in person or electronically to consult with the non-physician health care provider, particularly in the case of injury or an emergency.

9. INFORMED CONSENT

A licensee who uses telemedicine in providing health care shall ensure that the patient provides appropriate informed consent for the health care services provided, including

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consent for the use of telemedicine to examine, consult, diagnose and treat the patient, and that such informed consent is timely documented in the patient's medical record.

10. COORDINATION OF CARE

A licensee who uses telemedicine in providing health care shall, when medically appropriate, identify the location and 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 records to the location or treating physician(s).

11. FOLLOW-UP CARE

A licensee who uses telemedicine in providing health care 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.

12. EMERGENCY SERVICES

A licensee who uses telemedicine in providing health care 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. MEDICAL RECORDS

A licensee who uses telemedicine in providing health care 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 and in accordance with applicable law.

14. PRIVACY AND SECURITY

A. A licensee who uses telemedicine in providing health care shall ensure that all telemedicine encounters comply with the privacy and security measures of the Health Insurance Portability and Accountability Act and applicable law to ensure that all patient communications and records are secure and remain confidential.

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- (1) Written protocols shall be established that address 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 any communication, including patient name, identification number and type of transaction;
 - (f) Archiving and retrieval; and
 - (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.

15. TECHNOLOGY AND EQUIPMENT

- A. 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:
 - (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;

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- (3) The technology and equipment utilized in the provision of telemedicine services must be compliant with the Health Insurance Portability and Accountability Act and other applicable law;
- (4) The technology and equipment utilized in the provision of telemedicine services must be able to verify the identity and location of the patient; and
- (5) The technology and equipment utilized in the provision of telemedicine services must be able to specify and disclose the identity and credentials of the health care provider(s).

16. DISCLOSURE AND FUNCTIONALITY OF TELEMEDICINE SERVICES

- A. Except for health care provider to health care provider direct consultation, a licensee who uses telemedicine in providing health care shall ensure that the following information is clearly disclosed 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;
 - (6) Financial interests, other than fees charged, in any information, products, or services provided by the licensee(s);
 - (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; and

- (11) Information collected and passive tracking mechanisms utilized.

17. PATIENT ACCESS AND FEEDBACK

- A. A licensee who uses telemedicine in providing health care 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; and
 - (3) To register complaints. The mechanism shall include information regarding the filing of complaints with the Board.

18. 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 health care 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 unless pursuant to a collaborative practice agreement. 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 unless pursuant to a collaborative practice agreement.

19. CIRCUMSTANCES WHERE THE STANDARD OF CARE MAY NOT REQUIRE A LICENSEE TO PERSONALLY INTERVIEW OR EXAMINE A PATIENT

- A. Under the following circumstances, whether or not such circumstances involve the use of telemedicine in providing health care, a licensee may treat a patient who has not been personally interviewed, examined and diagnosed by the licensee:
 - (1) Situations in which the licensee prescribed medications on a short-term basis for a new patient and has scheduled an appointment to personally examine the patient;

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- (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 partner(s) for the treatment of the sexually transmitted disease as recommended by the U.S. Centers for Disease Control and Prevention; and
- (9) Situations where the patients are in a licensed or certified long term care facility, nursing facility, residential care facility, intermediate care facility, assisted living facility or hospice setting and doing so is within the practice standards for that setting.

20. PRESCRIBING BASED SOLELY ON AN INTERNET REQUEST, INTERNET QUESTIONNAIRE OR A TELEPHONIC INTERVIEW PROHIBITED

Prescribing to a patient based solely on an Internet request or Internet questionnaire (i.e. 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 Section 19, subsection 3 of this rule.

Telemedicine technologies, where prescribing may be contemplated, must implement measures to uphold patient safety in the absence of traditional physical examination. Such measures should guarantee that the identity of the patient and provider is clearly established and that detailed documentation for the clinical evaluation and resulting prescription is required. Measures to assure informed, accurate and error prevention prescribing practices (e.g. integration with e-Prescription systems) are encouraged. All applicable law shall be complied with.

Prescribing medications, in-person or via telemedicine, is at the professional discretion of the physician. The physician prescribing via telemedicine must ensure that the clinical evaluation, indication, appropriateness, and safety consideration for the resulting prescription are appropriately documented and meets the applicable standard of care. Consequently, prescriptions via telemedicine carry the same accountability as prescriptions delivered during an encounter in person. However, where such measures are upheld, and the appropriate clinical consideration is carried out and documented, physicians may exercise their judgment and prescribe medications as part of telemedicine encounters.

STATUTORY AUTHORITY:

32 M.R.S. §§ 3269(3), 3269(7) (Board of Licensure in Medicine)

32 M.R.S. § 2562 (Board of Osteopathic Licensure)