

Report of the State Medical Boards' Appropriate Regulation of Telemedicine (SMART) Workgroup

Adopted as policy by the Federation of State Medical Boards in April 2014

#### INTRODUCTION

The Federation of State Medical Boards (FSMB) Chair, Jon V. Thomas, MD, MBA, appointed the State Medical Boards' Appropriate Regulation of Telemedicine (SMART) Workgroup to review the "Model Guidelines for the Appropriate Use of the Internet in Medical Practice" (HOD 2002)¹ and other existing FSMB policies on telemedicine and to offer recommendations to state medical and osteopathic boards (hereinafter referred to as "medical boards" and/or "boards") based on a thorough review of recent advances in technology and the appropriate balance between enabling access to care while ensuring patient safety. The Workgroup was charged with guiding the development of model guidelines for use by state medical boards in evaluating the appropriateness of care as related to the use of telemedicine, or the practice of medicine using electronic communication, information technology or other means, between a physician in one location and a patient in another location with or without an intervening health care provider.

This new policy document provides guidance to state medical boards for regulating the use of telemedicine technologies in the practice of medicine and educates licensees as to the appropriate standards of care in the delivery of medical services directly to patients<sup>2</sup> via telemedicine technologies. It is the intent of the SMART Workgroup to offer a model policy for use by state medical boards in order to remove regulatory barriers to widespread appropriate adoption of telemedicine technologies for delivering care while ensuring the public health and safety.

In developing the guidelines that follow, the Workgroup conducted a comprehensive review of telemedicine technologies currently in use and proposed/recommended standards of care, as well as identified and considered existing standards of care applicable to telemedicine developed and implemented by several state medical boards.

<sup>&</sup>lt;sup>1</sup> The policy on the Appropriate Use of Telemedicine Technologies in the Practice of Medicine supersedes the Model Guidelines for the Appropriate Use of the Internet in Medical Practice (HOD 2002).

<sup>&</sup>lt;sup>2</sup> The policy does not apply to the use of telemedicine when solely providing consulting services to another physician who maintains the physician-patient relationship with the patient, the subject of the consultation.

### Model Guidelines for State Medical Boards' Appropriate Regulation of Telemedicine

#### Section One. Preamble

The advancements and continued development of medical and communications technology have had a profound impact on the practice of medicine and offer opportunities for improving the delivery and accessibility of health care, particularly in the area of 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 healthcare provider.<sup>3</sup> However, state medical boards, in fulfilling their duty to protect the public, face complex regulatory challenges and patient safety concerns in adapting regulations and standards historically intended for the in-person provision of medical care to new delivery models involving telemedicine technologies, including but not limited to: 1) determining when a physician-patient relationship is established; 2) assuring privacy of patient data; 3) guaranteeing proper evaluation and treatment of the patient; and 4) limiting the prescribing and dispensing of certain medications.

The [Name of Board] recognizes that using telemedicine technologies in the delivery of medical services offers potential benefits in the provision of medical care. The appropriate application of these technologies can enhance medical care by facilitating communication with physicians and their patients or other health care providers, including prescribing medication, obtaining laboratory results, scheduling appointments, monitoring chronic conditions, providing health care information, and clarifying medical advice.<sup>4</sup>

These guidelines should not be construed to alter the scope of practice of any health care provider or authorize the delivery of health care services in a setting, or in a manner, not otherwise authorized by law. In fact, these guidelines support a consistent standard of care and scope of practice notwithstanding the delivery tool or business method in enabling Physician-to-Patient communications. For clarity, a physician using telemedicine technologies in the provision of medical services to a patient (whether existing or new) must take appropriate steps to establish the physician-patient relationship and conduct all appropriate evaluations and history of the patient consistent with traditional standards of care for the particular patient presentation. As such, some situations and patient presentations are appropriate for the utilization of telemedicine technologies as a component of, or in lieu of, in-person provision of medical care, while others are not.<sup>5</sup>

The Board has developed these guidelines to educate licensees as to the appropriate use of telemedicine technologies in the practice of medicine. The [Name of Board] is committed to assuring patient access to the convenience and benefits afforded by telemedicine technologies, while promoting the responsible practice of medicine by physicians.

It is the expectation of the Board that physicians who provide medical care, electronically or otherwise, maintain the highest degree of professionalism and should:

- · Place the welfare of patients first;
- Maintain acceptable and appropriate standards of practice;

<sup>&</sup>lt;sup>3</sup> See Center for Telehealth and eHealth Law (Ctel), http://ctel.org/ (last visited Dec. 17, 2013).

<sup>&</sup>lt;sup>4</sup> Id.

<sup>&</sup>lt;sup>5</sup> See Cal. Bus. & Prof. Code § 2290.5(d).

- Adhere to recognized ethical codes governing the medical profession;
- Properly supervise non-physician clinicians; and
- · Protect patient confidentiality.

#### Section Two. Establishing the Physician-Patient Relationship

The health and well-being of patients depends upon a collaborative effort between the physician and patient.<sup>6</sup> The relationship between the physician and patient is complex and is based on the mutual understanding of the shared responsibility for the patient's health care. Although the Board recognizes that it may be difficult in some circumstances to precisely define the beginning of the physician-patient relationship, particularly when the physician and patient are in separate locations, it tends to begin when an individual with a health-related matter seeks assistance from a physician who may provide assistance. However, the relationship is clearly established when the physician agrees to undertake diagnosis and treatment of the patient, and the patient agrees to be treated, whether or not there has been an encounter in person between the physician (or other appropriately supervised health care practitioner) and patient.

The physician-patient relationship is fundamental to the provision of acceptable medical care. It is the expectation of the Board that physicians recognize the obligations, responsibilities, and patient rights associated with establishing and maintaining a physician-patient relationship. A physician is discouraged from rendering medical advice and/or care using telemedicine technologies without (1) fully verifying and authenticating the location and, to the extent possible, identifying the requesting patient; (2) disclosing and validating the provider's identity and applicable credential(s); and (3) obtaining appropriate consents from requesting patients after disclosures regarding the delivery models and treatment methods or limitations, including any special informed consents regarding the use of telemedicine technologies. An appropriate physician-patient relationship has not been established when the identity of the physician may be unknown to the patient. Where appropriate, a patient must be able to select an identified physician for telemedicine services and not be assigned to a physician at random.

#### Section Three. Definitions

For the purpose of these guidelines, the following definitions apply:

"Telemedicine" means the practice of medicine using electronic communications, information technology or other means between a licensee in one location, and a patient in another location with or without an intervening healthcare provider. Generally, telemedicine is not an audio-only, telephone conversation, e-mail/instant messaging conversation, or fax. It typically involves the application of secure videoconferencing or store and forward technology to provide or support healthcare delivery by replicating the interaction of a traditional, encounter in person between a provider and a patient.<sup>7</sup>

"Telemedicine Technologies" means technologies and devices enabling secure electronic communications and information exchange between a licensee in one location and a patient in another location with or without an intervening healthcare provider.

<sup>&</sup>lt;sup>6</sup> American Medical Association, Council on Ethical and Judicial Affairs, Fundamental Elements of the Patient-Physician Relationship (1990), available at http://www.ama-assn.org/resources/doc/code-medical-ethics/1001a.pdf.

<sup>&</sup>lt;sup>7</sup> See Ctel.

### Section Four. Guidelines for the Appropriate Use of Telemedicine Technologies in Medical Practice

The [Name of Board] has adopted the following guidelines for physicians utilizing telemedicine technologies in the delivery of patient care, regardless of an existing physician-patient relationship prior to an encounter:

#### Licensure:

A physician must be licensed, or under the jurisdiction, of the medical board of the state where the patient is located. The practice of medicine occurs where the patient is located at the time telemedicine technologies are used. Physicians who treat or prescribe through online services sites are practicing medicine and must possess appropriate licensure in all jurisdictions where patients receive care.<sup>8</sup>

#### Establishment of a Physician-Patient Relationship:

Where an existing physician-patient relationship is not present, a physician must take appropriate steps to establish a physician-patient relationship consistent with the guidelines identified in Section Two, and, while each circumstance is unique, such physician-patient relationships may be established using telemedicine technologies provided the standard of care is met.

#### **Evaluation and Treatment of the Patient:**

A documented medical evaluation and collection of relevant clinical history commensurate with the presentation of the patient to establish diagnoses and identify underlying conditions and/or contra-indications to the treatment recommended/provided must be obtained prior to providing treatment, including issuing prescriptions, electronically or otherwise. Treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional (encounter in person) settings. Treatment, including issuing a prescription based solely on an online questionnaire, does not constitute an acceptable standard of care.

#### Informed Consent:

Evidence documenting appropriate patient informed consent for the use of telemedicine technologies must be obtained and maintained. Appropriate informed consent should, as a baseline, include the following terms:

- Identification of the patient, the physician and the physician's credentials;
- Types of transmissions permitted using telemedicine technologies (e.g. prescription refills, appointment scheduling, patient education, etc.);
- The patient agrees that the physician determines whether or not the condition being diagnosed and/or treated is appropriate for a telemedicine encounter;
- Details on security measures taken with the use of telemedicine technologies, such as encrypting data, password protected screen savers and data files, or utilizing other reliable authentication techniques, as well as potential risks to privacy notwithstanding such measures;
- · Hold harmless clause for information lost due to technical failures; and
- · Requirement for express patient consent to forward patient-identifiable information to a third party.

<sup>&</sup>lt;sup>8</sup> Federation of State Medical Boards, A Model Act to Regulate the Practice of Medicine Across State Lines (April 1996), available at http://www.fsmb.org/pdf/1996\_grpol\_telemedicine.pdf.

#### Continuity of Care:

Patients should be able to seek, with relative ease, follow-up care or information from the physician [or physician's designee] who conducts an encounter using telemedicine technologies. Physicians solely providing services using telemedicine technologies with no existing physician-patient relationship prior to the encounter must make documentation of the encounter using telemedicine technologies easily available to the patient, and subject to the patient's consent, any identified care provider of the patient immediately after the encounter.

#### Referrals for Emergency Services:

An emergency plan is required and must be provided by the physician to the patient when the care provided using telemedicine technologies indicates that a referral to an acute care facility or ER for treatment is necessary for the safety of the patient. The emergency plan should include a formal, written protocol appropriate to the services being rendered via telemedicine technologies.

#### Medical Records:

The medical record should include, if applicable, copies of all patient-related electronic communications, including patient-physician communication, prescriptions, laboratory and test results, evaluations and consultations, records of past care, and instructions obtained or produced in connection with the utilization of telemedicine technologies. Informed consents obtained in connection with an encounter involving telemedicine technologies should also be filed in the medical record. The patient record established during the use of telemedicine technologies must be accessible and documented for both the physician and the patient, consistent with all established laws and regulations governing patient healthcare records.

## Privacy and Security of Patient Records & Exchange of Information:

Physicians should meet or exceed applicable federal and state legal requirements of medical/health information privacy, including compliance with the Health Insurance Portability and Accountability Act (HIPAA) and state privacy, confidentiality, security, and medical retention rules. Physicians are referred to "Standards for Privacy of Individually Identifiable Health Information," issued by the Department of Health and Human Services (HHS).9 Guidance documents are available on the HHS Office for Civil Rights Web site at: www.hhs.gov/ocr/hipaa.

Written policies and procedures should be maintained at the same standard as traditional face-to-face encounters for documentation, maintenance, and transmission of the records of the encounter using telemedicine technologies. Such policies and procedures should address (1) privacy, (2) health-care personnel (in addition to the physician addressee) 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, such as patient name, identification number and type of transaction, (6) archival and retrieval, and (7) quality oversight mechanisms. Policies and procedures should be periodically evaluated for currency and be maintained in an accessible and readily available manner for review.

Sufficient privacy and security measures must be in place and documented to assure confidentiality and integrity of patient-identifiable information. Transmissions, including patient e-mail, prescriptions, and laboratory

<sup>&</sup>lt;sup>9</sup> 45 C.F.R. § 160, 164 (2000).

results must be secure within existing technology (i.e. password protected, encrypted electronic prescriptions, or other reliable authentication techniques). All patient-physician e-mail, as well as other patient-related electronic communications, should be stored and filed in the patient's medical record, consistent with traditional record-keeping policies and procedures.

<u>Disclosures and Functionality on Online Services Making Available Telemedicine Technologies</u>:

Online services used by physicians providing medical services using telemedicine technologies should clearly disclose:

- · Specific services provided;
- Contact information for physician;
- Licensure and qualifications of physician(s) and associated physicians;
- Fees for services and how payment is to be made;
- Financial interests, other than fees charged, in any information, products, or services provided by a physician;
- Appropriate uses and limitations of the site, including emergency health situations;
- Uses and response times for e-mails, electronic messages and other communications transmitted via telemedicine technologies;
- To whom patient health information may be disclosed and for what purpose;
- · Rights of patients with respect to patient health information; and
- Information collected and any passive tracking mechanisms utilized.

Online services used by physicians providing medical services using telemedicine technologies should provide patients a clear mechanism to:

- Access, supplement and amend patient-provided personal health information;
- Provide feedback regarding the site and the quality of information and services; and
- Register complaints, including information regarding filing a complaint with the applicable state medical and osteopathic board(s).

Online services must have accurate and transparent information about the website owner/operator, location, and contact information, including a domain name that accurately reflects the identity.

Advertising or promotion of goods or products from which the physician receives direct remuneration, benefits, or incentives (other than the fees for the medical care services) is prohibited. Notwithstanding, online services may provide links to general health information sites to enhance patient education; however, the physician should not benefit financially from providing such links or from the services or products marketed by such links. When providing links to other sites, physicians should be aware of the implied endorsement of the information, services or products offered from such sites. The maintenance of preferred relationships with any pharmacy is prohibited. Physicians shall not transmit prescriptions to a specific pharmacy, or recommend a pharmacy, in exchange for any type of consideration or benefit form that pharmacy.

#### Prescribing:

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 both enforced and independently kept. Measures to assure informed, accurate, and error prevention prescribing practices (e.g. integration with e-Prescription systems) are encouraged. To further assure patient safety in the absence of physical examination, telemedicine technologies should limit medication formularies to ones that are deemed safe by [Name of Board].

Prescribing medications, in-person or via telemedicine, is at the professional discretion of the physician. The indication, appropriateness, and safety considerations for each telemedicine visit prescription must be evaluated by the physician in accordance with current standards of practice and consequently carry the same professional 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.

### Section Five. Parity of Professional and Ethical Standards

Physicians are encouraged to comply with nationally recognized health online service standards and codes of ethics, such as those promulgated by the American Medical Association, American Osteopathic Association, Health Ethics Initiative 2000, Health on the Net and the American Accreditation HealthCare Commission (URAC). There should be parity of ethical and professional standards applied to all aspects of a physician's practice. A physician's professional discretion as to the diagnoses, scope of care, or treatment should not be limited or influenced by non-clinical considerations of telemedicine technologies, and physician remuneration or treatment recommendations should not be materially based on the delivery of patient-desired outcomes (i.e. a prescription or referral) or the utilization of telemedicine technologies.

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