Rule Workshop Notice



Meeting Announcement
For the Washington Medical Commission
*CR-101 for Telemedicine Rules
WAC 246-919-XXX Physicians
WAC 246-918-XXX Physician Assistants

Rulemaking

The Washington Medical Commission (commission) has officially filed a <u>CR-101</u> with the Office of the Code Reviser on September 17, 2019. The WSR# is 19-19-072.

The commission is considering rulemaking to address the practice of physicians and physician assistants engaging in telemedicine with Washington patients. Possible subjects the commission may address are: what, if any requirements for licensure; record keeping requirements; establishing a patient-practitioner relationship; prescribing issues; and standard of care. Regulating the use of telemedicine would place the commission in an active patient safety role.

Proposed Telemedicine Rules Workshop Meeting

In response to the filing, the Commission will conduct an open public rules workshop on Friday, October 9, beginning at 1:00 pm via GoToWebinar:

Please join this meeting from your computer, tablet or smartphone. https://global.gotomeeting.com/join/767475165

You can also dial in using your phone.
United States: +1 (571) 317-3112
Access Code: 767-475-165

This meeting will be open to the public.

In response to the COVID-19 public health emergency, and to promote social distancing, the Medical Commission will not provide a physical location for this meeting. A virtual public meeting, without a physical meeting space, will be held instead.

The purpose of the rules workshop will be to:

- Explain the state's rulemaking process and timeline;
- Invite committee members and members of the public to present draft rule language; and
- Consider possible dates, times, and locations of proposed rules workshops to be scheduled.

Interested parties, stakeholders, and the general public are invited to participate in the rules workshops or provide comments on draft rules. For continued updates on rule development, interested parties are encouraged to join the Commission's rules GovDelivery.

For more information, please contact Amelia Boyd, Program Manager, Washington Medical Commission at (360) 236-2727 or by email at amelia.boyd@wmc.wa.gov.

Attachments:

CR-101

Proposed draft language

^{*}CR means Code Reviser

Submitted by Micah Matthews, Deputy Executive Director

Definitions

Artificial Intelligence: Artificial intelligence (AI) in healthcare is the use of complex algorithms and software to emulate human cognition in the analysis of complicated medical data. Specifically, AI is the ability for computer algorithms to approximate conclusions without direct human input. Because AI can identify meaningful relationships in raw data, it can be used to support diagnosing, treating and predicting outcomes in many medical situations.

Enabling Technology: Technology and devices allowing a practitioner to engage in telemedicine. Typically this is electronic in nature. These technologies may simply transmit audio information and/or images at one end of the spectrum, or at the other end they may enable one to perform complex invasive procedures employing robotics.

In-person contact: Interaction between a practitioner and patient in the physical presence of each other as opposed to remote interaction that characterizes telemedicine.

Practice of medicine: For the purposes of this rule, this is evaluation, diagnosis or treatment of a patient for which the practitioner receives, or would reasonably be expected to receive, compensation in some form. The practice of medicine occurs at the location of the patient.

Practitioner: The word "practitioner" throughout this rule means allopathic physicians licensed under Chapter 18.71 RCW and physician assistants licensed under Chapter 18.71A RCW.

Practitioner-Patient Relationship: The relationship between a provider of medical services (practitioner) and a receiver of medical services (patient) based on mutual understanding of their shared responsibility for the patient's health care. The relationship is clearly established when the practitioner agrees to undertake diagnosis and/or treatment of the patient and the patient agrees that the practitioner will diagnose and/or treat, whether or not there has been or is an in-person encounter between the parties. The parameters of the practitioner-patient relationship for telemedicine should mirror those that would be expected for similar in-person medical encounters.

Telemedicine: The practice of medicine and delivery of health care services through the use of interactive audio and video technology, permitting real-time communication between the patient at the originating site and the provider, for the purpose of diagnosis, consultation, or treatment. Telemedicine does not include the use of audio-only, telephone, facsimile, or email.

Established patients: as used in this chapter refers exclusively to patients with existing and ongoing treatment relationships with licensed practitioners. The use of the term "established patients" assumes the history and documentation necessary for informed health management.

Store and forward technology: means use of an asynchronous transmission of a covered person's medical information from an originating site to the health care provider at a distant site which results in medical diagnosis and management of the covered person, and does not include the use of audio-only telephone, facsimile, or email.

Appropriate use of Telemedicine

A. Licensure: A practitioner using telemedicine to practice medicine on patients in Washington must be licensed to practice medicine in Washington.

1. This includes practitioners who treat or prescribe to Washington patients through online service sites.

B. Exceptions to Licensure

Continuity of Care

Under certain circumstances, non-Washington-licensed practitioners may use telemedicine to provide follow-up care to their established patients in Washington.

To promote continuity of care while ensuring patient safety, a practitioner not licensed in Washington may provide medical care to a patient in Washington if the following conditions are met:

- 1. The non-Washington-licensed practitioner is licensed in another state or US territory;
- 2. The non-Washington-licensed practitioner has an established patient-practitioner relationship with the patient and provides follow-up care to treatment previously performed in the practitioner's state of licensure;
- 3. The continuous or follow-up care is infrequent or episodic; and
- 4. The non-Washington-licensed practitioner does not set up an office or place of meeting patients in Washington.

Peer-to-Peer Consultations

Telemedicine technologies are making peer-to-peer consultations a common part of medical practice. The Commission interprets RCW 18.71.030(6) to permit a Washington-licensed practitioner who is treating a patient in Washington to consult with a non-Washington licensed physician using telemedicine provided that the following conditions are met:

- 1. The out-of-state physician is licensed in another state or United States Territory;
- 2. The consultation is infrequent or episodic;
- 3. The Washington-licensed practitioner remains professionally responsible for the primary diagnosis and any testing or treatment provided to the Washington patient; and
- 4. The non-Washington-licensed physician does not set up an office or place of meeting patients, physical or virtual, in Washington.

The Commission does not interpret RCW 18.71.030(6) to permit a practitioner not licensed in Washington to analyze a specimen or read an image and then report findings back to the Washington practitioner. The Commission does not consider this a peer-to-peer consultation but instead a normal specialty consult or over-read situation.

C. Standard of Care: Practitioners using telemedicine will be held to the same standard of care as practitioners engaging in more traditional in-person care delivery, including the requirement to meet all technical, clinical, confidentiality and ethical standards required by law. Some elements of the standard of care as applied to telemedicine include:

- **1. Practitioner-Patient Relationship:** When practicing telemedicine, a practitioner must establish a practitioner-patient relationship with the patient through direct and real-time communication as defined in statute. Patient completion of a questionnaire does not, by itself, establish a practitioner-patient relationship. Treatment, including prescriptions, based solely on a questionnaire does not constitute acceptable standard of care.
- **2. Informed Consent**: A practitioner should obtain and document appropriate informed consent for t telemedicine encounters to include the credentials of the practitioner.
- **3. Patient Evaluation**: An appropriate history and evaluation of the patient must precede the rendering of any care, including provision of prescriptions. Not all patient situations will be appropriate for telemedicine. Since, by definition, telemedicine does not involve in-person contact between practitioner and patient, if circumstances require in-person contact, an appropriate surrogate examiner acceptable to the telemedicine practitioner and the patient must be present, with the patient, to provide necessary in-person observations, or the telemedicine practitioner should advise the patient to be seen by a practitioner in-person. Evaluating the adequacy and significance of any surrogate examination remains the responsibility of the telemedicine practitioner.
- 4. Allowable Treatment Parameters: The telemedicine practitioner may provide any treatment deemed appropriate for the patient, including prescriptions, if the evaluation performed is adequate to justify the action taken. The practitioner is responsible for knowing the limitations of the care he or she can provide, no matter how the care is delivered. Just as in a traditional setting, telemedicine practitioners should recognize situations that are beyond their expertise, their ability, or the limits of available technology to adequately evaluate or manage in the existing circumstances, and refer such patients for appropriate care.
- **5. Medical Records**: Practitioners providing telemedicine services must document the encounter appropriately and completely so that the record clearly, concisely and accurately reflects what occurred during the encounter. Such records should be permanent and easily available to or on behalf of the patient and other practitioners in accordance with patient consent, direction and applicable standards. Practitioners should maintain security and confidentiality of the medical record in compliance with applicable laws and regulations related to the maintenance and transmission of such records.
- **6. Prescriptions**: Prescribing medications, whether in person or via telemedicine, is at the professional discretion of the practitioner. The practitioner, in accordance with current standards of practice, must evaluate the indications, appropriateness, and safety considerations for each telemedicine prescription. Telemedicine prescriptions entail the same professional accountability as prescriptions incident to an in-person contact. Where appropriate clinical procedures and considerations are applied and documented, practitioners may exercise their judgment and prescribe medications as part of telemedicine. Especially careful consideration should apply before prescribing controlled substances as defined in 69.50 RCW, and compliance with all laws and regulations pertaining to such prescriptions is expected. Measures to assure informed, accurate and error-free prescribing practices such as integration with e-Prescription services, are encouraged.

Mobile Medical Technology

The Federal Food and Drug Administration (FDA) regulates the safety and efficacy of medical devices, including mobile medical applications (apps) that meet the definition of "device" under the FDA Act, particularly apps that pose a higher risk if they do not work as intended.

The Commission advises practitioners who use or rely upon such technology to ensure the technology has received FDA approval and is in compliance with applicable federal law. Additionally, those apps used by a practitioner or patient that do not have the data to support their claims may be investigated by the consumer protection division of the Federal Trade Commission (FTC). If the Commission receives complaints about such apps or devices that are deemed outside its jurisdiction, the Commission will forward the complaint to the FDA or the FTC as appropriate.

Artificial Intelligence

The medical practice act RCW 18.71 and 18.71A does not give the WMC jurisdiction over A.I. and related tools. It is the duty of those licensees utilizing these tools for care delivery to Washington patients that they understand their legal obligations:

- 1. Use of the A.I. tools are at the discretion of the licensee;
- 2. Similar to a peer consult or a radiologic over read, the licensee must decide whether to accept the diagnosis and/or treatment plan of the A.I. tool;
- 3. The licensee accepts full responsibility for the diagnosis, treatment plan, and outcomes for the patient based all or in part by the recommendation of the A.I. tool.

It is the duty of those developing these tools and using them on Washington patients to be mindful of bias introduced through flawed data or testing on populations that are not adequately represented.

Discipline

The Commission may investigate and take disciplinary action against a practitioner, whether licensed in Washington or not, who treats a resident of Washington via telemedicine and fails to meet the required standard of care. The Commission may also investigate and take disciplinary action against a practitioner or who does not meet the conditions for consultations or continuity of care. RCW 18.71.230 permits the Commission to discipline physicians practicing in Washington under certain exemptions in RCW 18.71.030. An out-of-state practitioner is also subject to action by the Department of Health for the unlicensed practice of a profession under RCW 18.130.190. The Commission reaffirms its position that establishing a telemedicine presence accessible to Washington patients through a website or other access portal is not exempt from Washington licensure, unless used in conjunction with the parameters in this chapter.