WASHINGTON
Medical
Commission

Licensing. Accountability. Leadership.

# Rules Workshop

## Telemedicine

October 9, 2020

1:00 pm via GoToMeeting

WASHINGTON Medical Commission
Licensing. Accountability. Leadership.

# Table of Contents

# Rule Workshop Notice

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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 CR-101 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

# Rules Workshop Agenda

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*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 access link can be found below.*

## Friday, October 9, 2020 – 1:00 pm

## Telemedicine Pre-Proposal Rules

| | |
|---|---|
| • Housekeeping | Amelia Boyd, Program Manager |
| • Open workshop | Christine Blake, Public Member, Presiding Officer |
| • Discuss comments | Panel, Stakeholders, Public |
| • Discuss proposed language | Panel, Stakeholders, Public |
| • Next steps | Amelia Boyd |
| • Close workshop | Christine Blake |

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

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email civil.rights@doh.wa.gov.

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# CR-101

# WSR 19-19-072
# PREPROPOSAL STATEMENT OF INQUIRY
# DEPARTMENT OF HEALTH
(Medical Quality Assurance Commission)
[Filed September 17, 2019, 10:06 a.m.]

Subject of Possible Rule Making: WAC 246-919-XXX Allopathic physicians and 246-918-XXX Allopathic physician assistants, the Washington medical commission (commission) is considering creating new rule sections to regulate the use of telemedicine.

Statutes Authorizing the Agency to Adopt Rules on this Subject: RCW 18.71.017, 18.130.050, and 18.71A.020.

Reasons Why Rules on this Subject may be Needed and What They Might Accomplish: The commission will consider rule making 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; recordkeeping 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.

Other Federal and State Agencies that Regulate this Subject and the Process Coordinating the Rule with These Agencies: None.

Process for Developing New Rule: Collaborative rule making.

Interested parties can participate in the decision to adopt the new rule and formulation of the proposed rule before publication by contacting Amelia Boyd, Program Manager, P.O. Box 47866, Olympia, WA 98504-7866, phone 360-236-2727, TTY 360-833-6388 or 711, email amelia.boyd@wmc.wa.gov, web site wmc.wa.gov.

Additional comments: To join the interested parties email list, please visit https://public.govdelivery.com/accounts/WADOH/subscriber/new?topic_id=WADOH_153.

September 13, 2019
Melanie de Leon
Executive Director

WASHINGTON
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# Proposed Language

# Rule Language for Consideration

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.

# Rule Language for Consideration

## 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:

# Rule Language for Consideration

**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.

# Rule Language for Consideration

## 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.

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# Comments

October 5, 2020

Washington Medical Commission
P.O. Box 47866
Olympia, WA 98504-7866

Dear Members of the Washington Medical Commission,

Americans for Vision Care Innovation is a bipartisan coalition of consumer and taxpayer groups, think tanks, and vision care companies who compete against each other in the contact lens marketplace. Together we represent the rights of the 46 million Americans who wear contact lenses, and we have worked closely with leading consumer, civic and medical organizations in states across the country to protect the rights of consumers to get prescriptions for contact lenses and glasses renewed online.

We are writing to express our concerns with the draft rule language for consideration released by the Washington Medical Commission (Commission) as part of the Telemedicine Rule Workshop Notice. Generally, we believe that the draft language aligns with the state's telemedicine payment law instead of general telemedicine practice law and guidance previously adopted by the Commission.[1] The intent of the telemedicine guidance is to allow practitioners to determine how best to deliver care to each individual patient, based on their unique medical history and needs. We agree that practitioners should use telemedicine as one of the tools in their tool box, and that any care delivered remotely should align with the standard of care for the same service provided in person. We believe that the draft telemedicine definitions and rules are tied too closely to reimbursement/coverage instead of appropriate clinical use.

The term telemedicine is generally accepted to include both the synchronous and asynchronous technologies. This includes recognition by both the American Medical Association (AMA) and American Telemedicine Association (ATA).[2, 3] Additionally, the definitions of practice of medicine and store and forward technology should not include any reference to compensation. The Commission should expect practitioners to deliver quality care to a patient based on medical need and not on compensation. To this end, we propose the following changes in the definition section:

> **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.
>
> **Telemedicine:** The practice of medicine and delivery of health care services through the use of store and forward technology or interactive audio and video technology, permitting ~~real-time communication~~ interaction 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.
>
> **Store and forward technology:** means use of an asynchronous transmission of a ~~covered person's~~ patient's medical information from an originating site to the health care provider at a distant site which results in medical

[1] "Appropriate Use of Telemedicine," Washington Medical Commission, https://wmc.wa.gov/sites/default/files/public/Telemedicine%20Guideline.pdf.
[2] "AMA Telehealth Quick Guide," American Medical Association, https://www.ama-assn.org/practice-management/digital/ama-telehealth-quick-guide.
[3] "Telehealth: Defining 21st Century Care," American Telemedicine Association, https://www.americantelemed.org/resource/why-telemedicine/.

diagnosis,~~and~~ management, or referral of the patient ~~covered person~~, and does not include the use of audio-only telephone, facsimile, or email.

We agree that a valid relationship must be established before a practitioner can deliver care to a patient through telemedicine services. As currently drafted, the proposed rule would require a real-time interaction even though this is not required under Washington State's telemedicine law. In fact, store and forward technologies can be used to establish a relationship, and are routinely used in many specialties. The AMA and ATA both recognize that a real-time interaction is not necessary for all services. The rule should recognize that synchronous and asynchronous technologies can be used to establish a relationship so long as the practitioner is meeting the standard of care for the delivered service. Finally, not all telemedicine technologies require approval by the Food and Drug Administration (FDA). Many technologies currently in the marketplace are predicated on a technology previously approved by the FDA and only require registration. We request that the rule be revised to recognize this distinction. As such, we propose the following changes to the draft rule language:

> **1.Practitioner-Patient Relationship:** When practicing telemedicine, a practitioner ~~must~~ may establish a practitioner-patient relationship with the patient through direct and real-time communication or store and forward technology~~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.

We urge the Commission to make these simple yet necessary changes to the proposed telemedicine rule. Adopting these recommendations will allow Washington to continue to have the most flexible, forward thinking and pro-innovative telemedicine policies in the country.

Sincerely,

Americans for Vision Care Innovation

## Boyd, Amelia (WMC)

**From:** Berry Edwards <behavenet@gmail.com>
**Sent:** Monday, October 5, 2020 2:12 PM
**To:** Boyd, Amelia (WMC)
**Subject:** Re: Telemedicine Rules

**Follow Up Flag:** Follow up
**Flag Status:** Flagged

Does this work for you?

Terms defined but not found in body of document:
Enabling Technology
Store and forward technology

TELEphone was the first TELEmedicine. Rules should apply to audio-only communication unless only used for setting or cancelling appointments, requesting refills, etc.. Using videoconference technology does not guarantee continuous visual contact. If there are few or no rules governing audio-only, it gives incentive to avoid use of superior video technology.

Whether an encounter constitutes "Practice of medicine" should not be restricted based on compensation.

"Practitioner-Patient Relationship: The relationship between a provider of medical services (practitioner) and a receiver [recipient] of medical services"
"Establishment..." deserves a separate definition.
Patient "agreement" precludes unconscious pts or those unable to communicate or comprehend.
"The parameters of the practitioner-patient relationship for telemedicine should
mirror those that would be expected for similar in-person medical encounters." not part of the definition. The term "parameter" is vague.

"The use of the term "established patients" assumes the history and documentation necessary for informed health management." Nonsense: please rewrite this sentence.

Store and forward technology: Define "covered person." Covered how or by what? "Audio-only telephone"??? Should "texting" be included with other exclusions? Transmission of photograph or video? "online service sites"?? Define, please.

Missing from definitions:
online service sites
non-Washington-licensed practitioners: Use language to imply licensure in another jurisdiction is required. Define.
Appropriate use of Telemedicine

A: (1) "treat or prescribe" These are not mutually exclusive. Prescribing IS a kind of treatment. Why "1" if there is no "2"?
B:
Continuity of Care
2: "follow-up care to treatment previously performed" redundant. Implies illegal for practitioners in other countries.
3: Define "infrequent or episodic"
4: "does not set up an office or place of meeting patients in Washington" When? This implies occurrence after the fact.

Do you expect the ability to predict the future??

GENERAL
Location? How to determine remotely. Rely on patients' claims? Begs the question of how the practitioner can ascertain the patient's location in WA, another state or country or international waters. Furthermore, the patient's location could easily change during the encounter with use of mobile devices.

Peer-to-Peer Consultations
Change "are making" to make.
Reality: practitioners routinely "consult" on Internet fora with practitioners all around the world.
4: "non-Washington-licensed physician": should be practitioner? See B4 above.
Define: "normal specialty consult" & "over-read situation"

C: standard of care does not depend on type of encounter. It includes type of encounter. Care rendered by telephone does not meet standard of care if the patient's status demands videoconference or in-person encounter.

1: Define: "direct and real-time communication as defined in statute."
2: Define: "credentials of the practitioner"
3: "history and evaluation" History is part of evaluation. Define: "surrogate examination"
4: Define: "traditional setting" & "telemedicine practitioner"
5: "Such records should be permanent ": No record is permanent. Digital records can be deleted. Paper records can be shredded or burned. What are you trying to say here? Records should be kept for 10 years? Indefinitely?
6: "telemedicine prescription" does not exist. If you think it does, define it! Prescribing can be done via paper, fax, telephone or online order via app or web site. WHAT to prescribe may be based on a telemedicine encounter, but that is NOT prescribing.
"e-Prescription": Why the capital P?? eprescription or e-prescription

Mobile Medical Technology

The FDA's mistakes notwithstanding, "apps" (programs or applications) are not "devices". They are software. Devices are hardware.

Artificial Intelligence

"radiologic over read" Definition, pleas.
" based all or in part by" Did you mean " based all or in part ON"?
"The Commission may also investigate and take disciplinary action against a practitioner or who... " Omit "or".

Thanks

Berry Edwards, MD
BehaveNet, LLC

On Mon, Oct 5, 2020 at 8:47 AM Boyd, Amelia (WMC) <Amelia.Boyd@wmc.wa.gov> wrote:

> Good morning Dr. Edwards,

Yes, if your comments are submitted by the end of today, Monday, they will be included in the workshop packet which will be available tomorrow. If not, they will be presented to the panel at the workshop.

Thank you

Amelia Boyd
Program Manager
Washington Medical Commission
Office: (360) 236-2727
Mobile: (360) 918-6336

Were you satisfied with the service you received today? Yes or No

**From:** Berry Edwards <behavenet@gmail.com>
**Sent:** Friday, October 2, 2020 3:06 PM
**To:** Boyd, Amelia (WMC) <Amelia.Boyd@wmc.wa.gov>
**Subject:** Telemedicine Rules

I may not be able to attend the workshop. May I submit comments via email prior to the meeting?

Thanks

Berry Edwards, MD

BehaveNet, LLC

October 5, 2020

Chairman John Maldon
Washington Medical Commission
111 Israel Road SE
Turnwater, WA 98501

**RE: Telehealth Industry Support for Amending Draft Rule Language for Consideration Released by the Washington Medical Commission**.

Chairman John Maldon and Medical Commission Members:

On behalf of the telehealth industry, and the over 400 organizations we as the American Telemedicine Association represent, I am writing to express our thoughts on the draft rule language for consideration released by the Washington Medical Commission as part of the Telemedicine Rule Workshop Notice. We so appreciate the Commission's interest in and support for telemedicine. As you know, telemedicine effectively connects individuals and their healthcare providers when in-person interaction is not clinically necessary and facilitates physician to physician's consultation. It has been shown to be a safe and quality care modality that improves efficiencies, helps to reduce costs, and enables healthcare providers and hospital systems to do more good for more people.

The ATA is committed to ensuring that everyone has access to safe, affordable and appropriate care when and where they need it. The ATA represents a broad and inclusive network of technology solution providers, delivery systems and payers, as well as partner organizations and alliances, working together to advance adoption of telehealth, promote responsible policy, advocate for government and market normalization, and provide education and resources to help integrate virtual care into emerging value-based delivery models.

AMERICAN TELEMEDICINE ASSOCIATION
901 N. Glebe Road, Ste. 850 | Arlington, VA 22203
T: 703.373.9600

We support the Commission's efforts to update the Telemedicine Rules and to implement a consistent regulatory framework that promotes telehealth adoption. In its current form, however, the draft rule language does not align with ATA's values and would restrict the availability of quality care in Washington. Unlike the Commission's current guidelines, the proposed rules (i) narrowly define telemedicine to care delivery through audio-visual technologies and (ii) unnecessarily mandates that providers use a real-time interaction to establish a valid practitioner-patient relationship.

This language gives undue weight to the delivery tools enabling a clinical encounter rather than the clinical components and competencies which make up a standard clinical practice. These limitations also do not capture how telemedicine providers are increasingly relying on asynchronous (or "store and forward") telehealth technologies to establish patient relationships, perform patient evaluations, and appropriately prescribe medication in many fields. Asynchronous (or "store and forward") technologies are critical to the industry as they are used to quickly and conveniently transmit a patient's health data, vital signs, digital diagnostic images, and other physiologic data.

The ATA has a long-standing position that policies related to tech-enabled health delivery should be modality neutral and enable a healthcare professional to practice optimally. Rather than mandating specific telehealth technologies, the Commission should develop a regulatory framework that empowers providers to use their clinical judgment to determine the appropriate telehealth modality --whether real-time or non-real time-- to uphold the standard of care and serve the best interest of their patients. Technology-neutral language will also provide flexibility to account for emerging clinical technologies that contain costs and improve quality.

The proposed definitions of both the practice of medicine and store and forward technology should not include any reference to compensation. The Commission should expect practitioners to deliver quality care to a patient based on medical need and not on compensation.

Furthermore, we also respectfully suggest that the Commission is not best suited to define Artificial Intelligence for the first time in the Washington Administrative Code as it

relates to health care. It would be more appropriate for the Commission to receive policy guidance from the legislature on this issue before moving forward.

The ATA proposes the following changes, which we believe properly puts the focus on the standard of care and ensure providers have a range of telehealth tools to meaningfully engage with their patients:

**In the definition section of the proposed rule**:

**Telemedicine**: A mode of delivering healthcare services through the use of telecommunications technologies, including but not limited to asynchronous and synchronous technology, and remote patient monitoring technology, by a healthcare practitioner to a patient or a practitioner at a different physical location than the healthcare practitioner.

"**Asynchronous" (or "store and forward")**: The exchange of information regarding a patient that does not occur in real time, including the secure collection and transmission of a patient's medical information, clinical data, clinical images, laboratory results, or a self-reported medical history.

**"Synchronous":** The exchange of information regarding a patient occurring in real time.

**Practice of medicine**: For the purposes of this rule, this is the evaluation, diagnosis or treatment of a patient.

**In the Standard of Care Requirements (C.1) of the proposed rule:**

**Practitioner-Patient Relationship**: A valid practitioner-patient relationship may be established via synchronous or asynchronous telehealth communication without a prior in-person exam. As a condition of establishing a valid practitioner-patient relationship, the practitioner must:

1. Obtain the patient's consent for the use of telehealth as an acceptable mode of delivering healthcare services. Acknowledgement of such consent shall be documented in the patient's medical record; and
2. Verify the patient's identity and disclose the practitioner's identity and applicable credentials.

We appreciate the Commission seeking stakeholder comment and look forward to working together in the months ahead to develop rules that will allow Washington to continue to have the most flexible, forward thinking and pro-innovative telemedicine policies in the country. Thank you so much for your consideration.

Respectfully,

Kyle Zebley
Director, Public Policy
The American Telemedicine Association

October 5, 2020

Chairman John Maldon
Washington Medical Commission
111 Israel Road SE
Turnwater, WA 98501

**RE: Amending Draft Telehealth Rule Language for Consideration Released by the Washington Medical Commission**.

Chairman John Maldon and Medical Commission Members:

On behalf of Hims & Hers, a direct-to-consumer digital health company, we thank you for the opportunity to provide comments to your proposed rule in advance of your October 9th meeting. Especially during a global pandemic, it is critical that Washington State maintains a broad, modality and technology-neutral telehealth law that allows Washington patients to easily access virtual care while maintaining the highest standard of care. After reviewing the proposed rule language, we urge you to modify: (1) the definition of telemedicine beyond "the use of interactive audio and video technology" to incorporate asynchronous, store-and-forward modality, (2) the appropriate use of telemedicine re: patient-provider relationship that requires "direct and real-time communication" to permit asynchronous, store-and-forward modality, as long as the patient and provider identity are disclosed and consent is obtained, and (3) the definition of artificial intelligence to remove this term from consideration until further policy development at the state legislature and other forums is completed.

At Hims & Hers, we connect patients to licensed healthcare providers for medical consultations and treatment across all 50 states. In most states, our platform is powered by asynchronous, store-and-forward technology, which is a care delivery model that has been embraced by state legislatures, hospitals, healthcare providers and patients across the country. Since our founding two years ago, we've powered more than two million digital healthcare visits across a variety of conditions. Amid the pandemic, we've pivoted many of our operations and services to address the current crisis and added access to primary care services, behavioral health, and at-home COVID-19 testing offered through Rutgers University's clinical lab under an FDA Emergency Use Authorization.

We believe providers should always be held to the highest standard of care regardless of the mode of delivery, and that is why providers on our platform are licensed, highly-credentialed, and held to evidence-based clinical standards. Our executive team and board of directors are composed of some of the most experienced minds in healthcare, like our board member Dr. Toby Cosgrove, former CEO and current Executive Advisor of the renowned Cleveland Clinic, and Dr. Patrick Carroll, our Chief Medical Officer (CMO), the former CMO of Walgreens, and a Massachusetts-licensed medical doctor and resident of Westport, Massachusetts.

Accordingly, Hims & Hers proposes the following changes, which we believe properly puts the focus on the standard of care and ensure providers have a range of telehealth tools to meaningfully engage with their patients:

**In the definition section of the proposed rule**:

**Telemedicine**: A mode of delivering healthcare services through the use of telecommunications technologies, including but not limited to asynchronous and synchronous technology by a healthcare practitioner to a patient or a practitioner at a different physical location than the healthcare practitioner.

"**Asynchronous" (or "store and forward")**: The exchange of information regarding a patient that does not occur in real time, including the secure collection and transmission of a patient's medical information, clinical data, clinical images, laboratory results, or a self-reported medical history.

**"Synchronous":** The exchange of information regarding a patient occurring in real time.

**Practice of medicine**: For the purposes of this rule, this is the evaluation, diagnosis or treatment of a patient.

**In the Standard of Care Requirements (C.1) of the proposed rule:**

**Practitioner-Patient Relationship**: A valid practitioner-patient relationship may be established via synchronous or asynchronous telehealth communication without a prior in-person exam. As a condition of establishing a valid practitioner-patient relationship, the practitioner must:

1. Obtain the patient's consent for the use of telehealth as an acceptable mode of delivering healthcare services. Acknowledgement of such consent shall be documented in the patient's medical record; and
2. Verify the patient's identity and disclose the practitioner's identity and applicable credentials.

We are eager to continue our mission to expand access to affordable, quality care, especially for those in underserved areas, for whom synchronous modality requirements can be a roadblock to receiving virtual care. We hope that you will consider this feedback and we look

forward to working with the Commission to ensure quality care is preserved for Washington State patients.

Sincerely,

April Mims
VP of Public Policy
Hims & Hers

## Boyd, Amelia (WMC)

**From:** Drake, Tracie L (DOH)
**Sent:** Friday, October 2, 2020 4:54 PM
**To:** Boyd, Amelia (WMC)
**Subject:** FW: Telemedicine Rules

**Follow Up Flag:** Follow up
**Flag Status:** Flagged

See below – in case you are collecting comments for the workshop.

**Tracie Drake**
Program Manager
Health Systems Quality Assurance
Board of Osteopathic Medicine and Surgery
Medical Assistant Program
Washington State Department of Health
Tracie.Drake@doh.wa.gov
360-236-4766 | www.doh.wa.gov

-----Original Message-----
From: John Baumeister <j.bau@me.com>
Sent: Tuesday, September 29, 2020 3:59 PM
To: Drake, Tracie L (DOH) <Tracie.Drake@DOH.WA.GOV>
Subject: Telemedicine Rules

I am strongly in favor of requiring telemedicine providers to have had a face-to-face visit prior to initiation of telemedicine and annually thereafter.

T John Baumeister DO

October 2, 2020

Washington Medical Commission
ATTN: Amelia Boyd
111 Israel Rd SE,
Tumwater, WA 98501

Email: amelia.boyd@wmc.wa.gov

Dear Members of the Commission:

Thank you for the opportunity to comment on CR 101, Telemedicine Rules, in which the Commission will consider rulemaking to address telemedicine delivered by physicians and physician assistants.

Teladoc Health, Inc. is successfully transforming how people access and experience healthcare, with a focus on high quality, lower costs, and improved outcomes in Washington State as well as around the world. The integrated services from Teladoc Health include telehealth (including behavioral health), expert medical services, AI and analytics, and licensable platform services. With more than 2,400 employees, the organization delivers care in 175 countries and in more than 40 languages, partnering with employers, hospitals and health systems, and more than 50 health plans in the United States to transform care delivery. Headquartered in Purchase, New York, Teladoc Health serves more than 40 percent of Fortune 500 employers, as well as thousands of small businesses, labor unions, and public-sector employers, which offer our virtual care services to their employees.

Teladoc Health has a number of clients in Washington and we take our responsibility to these clients very seriously. Teladoc Health has a long history or working with policy makers and regulatory boards across the nation to ensure that all citizens have access to quality health care through the use of telemedicine or telehealth in a safe and clinically appropriate manner.

We have over 440 licensed and board-certified Washington physicians in our network. The Teladoc Health platform is HIPAA secure and HITRUST certified. We have a robust training and auditing program for our physicians with over 100 proprietary clinical guidelines in place. Nothing is more important to us than the safety of our patients. Through the end of September this year, Teladoc Health had completed over 55K virtual visits with Washington residents.

It is very clear to us that the Commission is acting very thoughtfully and deliberately as it contemplates the increasing role of telemedicine in the Washington health care system. The pandemic has caused the use of telemedicine to dramatically increase and we have seen rapid adoption from patients, employers, hospitals, and large and small physician practices. We believe that good telemedicine policy should be guided by three guiding principles:

- the standard of care must be the same for virtual care as it is for in-person care;
- a valid physician-patient relationship can be established using technology without the requirement for an in-person visit as long as the standard of care can be upheld; and
- the definition of telemedicine must include permissive language that is technology neutral and that all forms of telecommunication technology be considered as a mode of delivering health care services by a provider to a patient at a different location as long as the technology is HIPAA compliant and the standard of care can be upheld during the patient encounter.

The proposed rule contains very prescriptive language regarding the technology that can be used in a virtual patient encounter. The proposed definition of telemedicine includes the language "…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." This definition is outdated, fails to reflect the recent experience with telemedicine across the country during the COVID-19 pandemic and neither reflects nor encourages technological innovations in remote patient care.

Alternatively, Teladoc Health proposes a more comprehensive definition that allows for innovation and the highest and best use of all technology while requiring that the standard of care be the same for virtual care as it is for in-person care, now generally accepted by states updating their support of telemedicine and telehealth including neighboring Idaho:

- "Telemedicine" means a mode of delivering health care services through the use of telecommunications technologies by a health care practitioner to a patient at a different physical location than the health care practitioner.

- The telehealth visit must create a record accessible to the patient and must share that record with the patient's physician if the patient gives his/her permission. All telehealth interactions and transactions must be HIPPA compliant.

- a health care provider cannot be provided an incentive to select a particular modality or provide a prescription to any patient.

Further, the language does not contemplate the important role that asynchronous communications provide in telehealth, particularly in the behavioral health and remote patient monitoring space as demonstrated in the Rule Language for "Practioner-Patient Relationship"; as drafted this would require a "real-time communication" which again is overly prescriptive and will not allow for the highest and best use of technology.

Lastly, we suggest that the Commission is not best suited to define **Artificial Intelligence** for the first time in the Washington Administrative Code as it relates to health care. The issues surrounding the definition and uses of "artificial intelligence" are not without some controversy in the state legislature. Accordingly, it would be more appropriate for the Commission to receive policy guidance from the legislature on this issue before moving forward.

Again, we than the Commission for its work and hope that the Commission will consider Teladoc Health as a resource.

Respectfully,

Claudia Duck Tucker
Vice President, Government Affairs
Teladoc Health

October 7, 2020

Amelia Boyd
Program Manager
Washington Medical Commission
111 Israel Rd SE
Tumwater, WA 98501

**RE:** New Telemedicine Proposed Rulemaking

Dear Ms. Boyd,

98point6 understands the Washington Medical Commission (”Commission”) is considering rulemaking to address the practice of physicians and physician assistants engaging in telemedicine with Washington patients, and is seeking comments on the proposed draft language. 98point6 provided comments in November 2019, prior to the Rule Language for Consideration. 98point6 notes the Commission's past related guidelines include the March 2, 2018 Telemedicine and Continuity of Care Policy Statement and the Appropriate Use of Telemedicine Guideline, issued on October 3, 2014.

98point6 is a Washington state-based company innovating the development of software and services for the delivery of primary care. As we continue to increase our footprint throughout the state, we respectfully request the Commission’s consideration of the following comments in the forthcoming rulemaking process.

98point6 supports the Commission in creating rules in furtherance of the Telemedicine Continuity of Care Policy Statement and the Appropriate Use of Telemedicine Guideline, which we believe aligns closely with our goals to provide high-quality, affordable and accessible primary care.

**98point6 would like the opportunity to aid in the rulemaking process by commenting on the following points:**

## Telemedicine Definition

The Appropriate Use of Telemedicine Guideline, issued on October 3, 2014, states the Commission "[r]ecogniz[es] that technology changes are developed and become applied to practice with dazzling speed, and the intent is to delineate general principles applicable both to existing and future technologies, rather than focusing on specific current technologies." 98point6 recommends any rules adopted continue to remain neutral to the types of technology leveraged to facilitate care, in accordance to the 2014 Guideline.

98point6 delivers care by leveraging innovative technologies not contemplated when many of the rules and regulations governing telemedicine services were first promulgated throughout the United States. We encourage any forthcoming rule to focus on the principles that support balancing the quality of care and continuity of care provided via telemedicine, rather than concentrate on a prescriptive approach to the technologies that may be utilized. A prescriptive statement regarding the technologies that may be leveraged or a narrow focus on how technologies must be used may inadvertently stifle the development of innovative techniques and emerging technologies that could ultimately vastly improve the quality, affordability and accessibility of care for patients in Washington state. Indeed, the definition as proposed fails to address 98point6's primary methodology of delivering care, which is text-based interactions between our patients, our software and our physicians within our secure mobile application.

Telemedicine definition - 98point6's suggested replacement text

*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.~~*

## Practitioner-Patient Relationship

The Practitioner-Patient Relationship section includes language stating that patient "treatment" based solely on a questionnaire falls below the standard of care. 98point6 would invite the Commission to remove all explicit references to questionnaires, as many A.I. systems function similarly to a questionnaire, which could deter many practitioners from using A.I. as a clinical decision support tool (as noted below in the A.I. section). The questionnaire prohibition will undermine the development and use of technologies critical to creating physician efficiencies that make care more affordable and adherence to clinical guidelines that bolster quality of care.

Practitioner-Patient Relationship section - 98point6's suggested replacement text

***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.*~~

## Mobile Medical Technology

98point6 believes the title "Mobile Medical Technology" is too limiting. There are a number of healthcare software programs not addressed by mobile medical applications. This section would be better entitled "Software Used in Telemedicine." (See revised version below.)

98point6 would like to point out that the language regarding "FDA approval" is specific to Class 3 premarket approved (PMA) high-risk medical devices and does not reflect the vast majority of software as a medical device (SaMD) and non-medical device products currently marketed. This Nature article from 9/11/20 identifies 64 medical devices with A.I./ML and only one (1) is marketed under a PMA (1.6%).

Additionally, language in the second paragraph implies that all MMA software requires a market clearance, which is not correct. The vast majority of software products used in healthcare are not defined as medical devices, and many medical devices do not require market clearance.

MMT section - 98point6's suggested replacement text

***Software Used in Telemedicine***
*This rule is not intended to regulate technologies and services regulated by the U.S. Food and Drug Administration, Federal Trade Commission and other federal agencies. There are a number of healthcare software products used in telemedicine, e.g., mobile medical applications, clinical decision support, electronic patient records and maintaining or encouraging a healthy lifestyle, some of which are regulated by the U.S. Food and Drug Administration (FDA). The majority of healthcare software products are not regulated by FDA. FDA-regulated healthcare software products are primarily moderate risk and FDA reviews each to ensure they are safe and effective for their intended use.* ~~*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~~. understand its intended use(s), indication(s) for use and functionality in order to ensure safe and effective use. The Commission also advises practitioners to use FDA-regulated healthcare software 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~~s~~ ~~the~~ complaint~~s~~ to the FDA or the FTC, as appropriate.*

## Artificial Intelligence

98point6 recommends this section be revised to treat A.I. as another data/information source a clinician uses to make their diagnosis and treatment decisions. Data and information provided to the licensee from A.I. healthcare software tools are equivalent to data and information gathered from other digital clinical decision support tools. The proposed language puts all liability for A.I. usage on the individual practitioner and essentially sends a message instructing practitioners to rely on A.I. at their own risk. 98point6 is concerned that this language could discourage practitioners from adopting A.I. solutions/integrations in their practice.

Our suggested revisions (below) remove the references to accepting a diagnosis and/or treatment plan rendered from the A.I. tool and that 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. 98point6 is concerned that keeping these references discourages physician use of A.I. generally, which decreases the opportunities to leverage technologies to improve practitioner efficiency and adherence to clinical guidelines, ultimately leading to more expensive healthcare costs with poor outcomes.

A.I. Section - 98point6's suggested replacement text

***Artificial Intelligence (A.I.)/Machine Learning (M.L.)***

*The medical practice act RCW 18.71 and 18.71A does not give the WMC jurisdiction over A.I., M.L. and related healthcare software 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 practitioner ~~licensee~~;*
2. *Similar to a peer consult or a radiologic overread, the practitioner ~~must decide whether to accept the diagnosis and/or treatment plan of the A.I. tool;~~ is responsible for appropriately using the data to inform their diagnosis and treatment decision-making;*

*3. The practitioner is responsible for said diagnosis and treatment plan. ~~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 the patient safety risk associated with potential bias introduced through flawed data or testing on populations that are not adequately represented.*

Thank you for the opportunity to provide feedback during the rulemaking process. 98point6 looks forward to working with the Commission on this and future endeavors.

Sincerely,

Tori Lallemont, JD, MPH
General Counsel
98point6 Inc.