Colorado Telemedicine Rules

Statutes

» Colo. Stat. 12-36-106

» Colo. Stat. 10-16-123

» Colo. Stat 25.5-5-414

» Colo. Stat. 12-36-117

» Colo. Stat. 25.5-5-320

Other

» Board Policy re Appropriate Use of Telehealth Technologies in the Practice of Medicine No. 40-27 (2015)

» Board Policy re Physician-Patient Relationship No. 40-03 (2010)

» Board Policy re Prescribing for Unknown Patients No. 40-09 (2010)

» Colorado Medical Assistance Program Telemedicine Manual

For More Information
Learn more about how we can help you with telemedicine and health innovation matters. Please contact your Foley attorney or the following:

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The Colorado Medical Board proposed updated draft guidelines for the delivery of healthcare services via telehealth, as well as remote prescribing for new patients. Recognizing that “using telehealth technologies in the delivery of medical services offers potential benefits in the provision of medical care,” Colorado’s guidelines are intended to standardize care while increasing more widespread access for patients. And no: Colorado doctors are not allowed to prescribe medical marijuana via telehealth consults.

The proposed revisions change current Board Policy 40-3 and Policy 40-9, and introduce a new Policy 40-27. Highlights of include:

- **Licensure:** The practice of medicine occurs where the patient is located at the time of the consult. As such, a provider must be licensed in Colorado to evaluate or treat patients located in Colorado.

- **Establishment of a Provider-Patient Relationship:** A valid provider-patient relationship may be established via telehealth so long as the Board guidelines are met in light of generally accepted standards of practice. Specifically, a valid provider-patient relationship is established when the provider:
  - Agrees to “undertake diagnosis and treatment of the patient and the patient agrees to be treated – whether or not there has been an in-person encounter;”
  - Verifies and authenticates the patient’s identity and location;
  - Discloses his or her identity and applicable credential(s) to the patient; and
  - Obtains appropriate consent after disclosures regarding the delivery methods or limitations, including any special informed consents regarding
A valid provider-patient relationship has not been established when either the identity of the provider is unknown to the patient or the identity of the patient is not known to the provider.

- **Telehealth Consultations and Treatment:** Treatment and consultation recommendations, including remote prescribing, will be held to the same standards of appropriate practice as those in traditional settings. These standards include a documented medical evaluation and relevant clinical history to establish a diagnosis, as well as identifying contra-indications to care and underlying conditions prior to providing treatment. Treatment, including issuing a prescription, based solely on an online questionnaire does not constitute an acceptable standard of practice.

- **Remote Prescribing:** The guidance allows remote prescribing, and holds that prescribing medications (whether in-person or via telehealth) is at the discretion of the provider so long as the prescribing is performed consistent with current standards of practice. The guidance makes no mention of remote prescribing of controlled substances. Nor does the guidance mention the related Colorado pharmacy rule (3 CCR 719-1 section 3.00.21) ("A pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the order for such drug was issued on the basis of an internet-based questionnaire, an internet-based consultation, or a telephonic consultation, all without a valid preexisting patient-practitioner relationship."). The guidance does not allow providers to prescribe medical marijuana via telehealth consults.

- **Informed Consent:** Patient informed consent for the use of telehealth technologies must be obtained and maintained as a part of the medical record.

- **Continuity of Care:** Patients should be able to seek “with relative ease” follow-up care or information from the provider.

- **Referrals for Emergency Services:** A provider is required to maintain an emergency plan when the care indicates referral to a hospital or Emergency Department is necessary for the safety of the patient. The emergency plan should include a formal, written protocol.

- **Medical Records:** Medical records, including electronic communications, created during the telehealth consult must be documented by the provider and accessible to the patient. This includes patient informed consent and instructions provided or obtained in connection with the telehealth consult.

- **Privacy and Security of Patient Records & Exchange of Information:** Providers should meet or exceed applicable federal and state requirements for privacy and security. Providers should maintain their own written policies and procedure consistent with state and federal law in an in-person setting, including a policy for the maintenance and transmission of electronic records.

- **Disclosures and Functionality for Providing Online Services:** The guidance states that certain disclosures should be made when using online
services to provide medical care via telehealth including: the specific services provided; contact information; licensure and qualifications; financial interests; uses and limitations of the website; uses and response times for email or electronic messages; information collected and any tracking mechanisms utilized; and the ability to provide feedback or register complaints with the Board of Medicine.

- **Patient Functionality for Online Services:** Online services used by providers offering telehealth services 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.
  - Register complaints, including information regarding filing a complaint with the Board.
  - 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.

- **Disclosures for Providing Online Services:** The guidance states that certain disclosures should be made when using online services to provide medical care via telehealth including:
  - Specific services provided.
  - Contact information for provider.
  - Licensure and qualifications of provider(s) and associated providers.
  - 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 provider.
  - 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 telehealth technologies.
  - To whom patient health information may be disclosed and for what purpose.
  - Rights of patients with respect to patient health information.
  - Information collected and any passive tracking mechanisms utilized.

Colorado’s Board Policy Workgroup meeting to review the proposed guidelines is currently scheduled for the week of July 20 or 27, 2015 followed by presentation to the Medical Board for consideration on August 21, 2015.

**TAGS:** DATA PRIVACY, TELEHEALTH
Telehealth Compliance Checklist

SAMPLE CHECKLIST ONLY — FOR EDUCATIONAL PURPOSES/ DOES NOT CONSTITUTE LEGAL ADVICE

Professionals
☐ Are the telehealth professionals licensed in the state where patient located?
☐ Are there practice standards for patient examinations and remote prescribing?
☐ Are professionals documenting and maintaining patient records of the encounters?
☐ Does insurance policy cover telehealth services?
☐ Is insurance carrier licensed in every state where services are provided (patient located)?

Medicare/Medicaid
☐ Do services qualify as covered telehealth services?
☐ Are services being coded to properly reflect the place of service?
☐ Is the telehealth service provider located internationally?

Commercial Insurance, Medicare Advantage, and Medicaid Managed Care
☐ Does the state require commercial coverage of services provided via telehealth?
☐ Does the provider’s contracts reflect said coverage and include negotiated payment amounts?
☐ Has reimbursement other than FFS been evaluated, such as PMPM, capitation add-ons, or hybrid risk-bearing?

Consent
☐ Does the informed consent form account for services provided via telehealth?
☐ Does is recognize patient freedom of choice?

Credentialing
☐ Is there a credentialing by proxy agreement in place that meets all the elements?
☐ Does the hospital relying on proxy credentialing have such provisions in its bylaws?
☐ Is the hospital engaging in periodic re-credentialing assessments and reporting?

Privacy & Security
☐ Are there privacy and security protocols for the telehealth offerings?

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Telemedicine Business and Legal Considerations

Sample Business Models and Provider Arrangements

1. **Direct-to-Consumer/Patient**
   - DTC urgent care access
   - Patient contracts with provider for on-demand telemedicine services

2. **Institution-to-Institution**
   - Telesstroke PSA with critical access hospital
   - Rural hospital contracts with academic medical center for on-demand telesstroke services with 24/7 availability

3. **Clinician-to-Clinician**
   - Peer-to-peer specialty consulting services
   - PCP group contracts with telepsychiatry specialist to consult on difficult cases

4. **Oversight and Processes**
   - eICU
   - Hospital creates internal eICU to have monitoring, responsiveness and oversight over inpatients

5. **Chronic Care Management**
   - RPM and follow-up for existing patients
   - CCM provider contracts with physician group for chronic care management and RPM services

6. **Online Patient Access/Portals/Tech**
   - Online second opinions and HIT portals
   - Dermatological oncology specialist offers online-based second opinion services to patients and their PCPs across the country, resulting in medical tourism opportunities

7. **mHealth, Medical Apps**
   - Self-tracking apps, diagnostics, care support
   - mHealth-based smoking cessation and medication adherence software with RT-transmittal of data analysis and patient utilization to provider group

8. **Hardware/Software**
   - On-site kiosks (schools, factories, oil rigs)
   - Professional telemedicine-based services in remote areas using kiosks or other telediagnostic equipment modules

9. **International**
   - U.S. to China telemedicine
   - U.S.-based hospital contracts with China-based medical center to provide telemedicine-based consults, fellowship educational opportunities, research collaboration, and other services
Under the Ryan Haight Act, no controlled substance may be delivered, distributed, or dispensed by means of the internet (including telemedicine technologies) without a valid prescription.¹

A valid prescription means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by: 1) a practitioner who has conducted at least one in-person medical evaluation of the patient; or 2) a covering practitioner.²

“In-person medical evaluation” means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.³

Once the prescribing practitioner has conducted an in-person medical evaluation, the Act does not set an expiration period or a mandatory requirement of subsequent annual examinations (although specific drugs may have their own rules for subsequent exams). This should not be construed to imply that one in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is on the prescribing practitioner.

There are some exceptions to the in-person exam requirement, but none readily apply to a telemedicine service where the patient is at his or her home.

The DEA is currently drafting a proposed rule that will create a special registration process allowing physicians to prescribe controlled substances via telemedicine without an in-person exam, regardless of the patient’s location.

Notwithstanding the DEA federal rules, physicians still must comply with state laws on controlled substance prescribing. If a state law is more restrictive than the federal rules, the more restrictive provisions apply.

Physicians must also comply with other state and federal regulations, such as licensure, state DEA registration, etc.

The Ryan Haight Act does not apply to all prescription drugs; only controlled substances.

**Ryan Haight Act and Federal DEA Regulations**

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 was designed to combat the rogue internet pharmacies that proliferated in the late 90s, selling controlled substances online. The Act took effect April 13, 2009, and the Drug Enforcement Agency issued regulations effective that same date.⁴ The Act essentially imposed a federal prohibition on form-only online prescribing for controlled substances. Although the Act was intended to target “rogue” internet pharmacies, legitimate telemedicine providers who prescribe controlled substances must carefully review the regulations to ensure compliance. Among other things, the Act requires a practitioner to have conducted at least one in-person medical evaluation of the patient, in the physical presence of the practitioner, before issuing a prescription for a controlled substance.
Telemedicine Exceptions to the In-Person Exam Requirement

The Act offers seven telemedicine exceptions to the in-person exam requirement, but they are very narrow and do not reflect contemporary accepted clinical telemedicine remote prescribing practices. They are summarized as follows:

1. The patient is being treated in a DEA-registered hospital or clinic.
2. The patient is being treated in the physical presence of a DEA-registered practitioner.
3. The telemedicine consult is conducted by a DEA-registered practitioner for the Indian Health Service, who is designated as an Internet Eligible Controlled Substances Provider by the DEA.
4. The telemedicine consult is conducted during a public health emergency declared by the Secretary of the U.S. Department of Health and Human Services.
5. The telemedicine consult is conducted by a practitioner who has obtained a DEA special registration for telemedicine.
6. The telemedicine consult is conducted by a Veterans Health Administration practitioner during a medical emergency recognized by the VHA.
7. The telemedicine consult is conducted under other circumstances specified by future DEA regulations.

Unfortunately, most of the exceptions have limited utility in contemporary telemedicine arrangements, most notably telemedicine services directly to the patient’s home. Some of the exceptions are suitable in institutional telemedicine arrangements.

State Law Requirements

The federal regulations are more stringent than many state laws or state medical board requirements. Some states allow controlled substance prescribing via telemedicine without an in-person exam. But practitioners must comply with both state and federal laws, as the DEA considers a physician who engages in the unauthorized practice of medicine under state law to be someone who is not acting in the usual course of their professional practice. According to the DEA, a controlled substance prescription issued by a physician who lacks the license or other authority necessary to practice medicine within the state is not a valid prescription under federal law.

Forthcoming Rule Changes

The DEA has announced plans to issue a proposed rule that will activate the special registration process allowing physicians to use telemedicine to prescribe controlled substances without an in-person exam. The DEA published a revised notice of rulemaking, stating the proposed rule would be published in January 2017. As of this printing, the proposed rule has not yet been issued.

For More Information

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121 CFR 1306.09(a).
21 CFR 1300.04(j)(1); 21 USC 829(e)(2)(A).
21 CFR 1300.04(j); 21 USC 829(e)(2)(B).
721 CFR 1306.04(a); 21 CFR 1306.03(a)(1).
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