

May 28, 2014

STRATEGIC PERSPECTIVES: When is telemedicine "practicing medicine" in violation of the law? An emerging framework for compliance

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Telemedicine is the future of health care, but under current law there is an open question: when does telemedicine constitute the unlawful "practice of medicine" in violation of state or other law? This question is critical for telemedicine providers and physicians and other professionals that provide telemedicine services and, along with reimbursement and current market conditions, should be considered as part of any business plan.

After providing an brief overview of the provisions of the Patient Protection and Affordable Care Act (ACA) (P.L. 111-148) and other federal and state laws governing or effecting telemedicine, this Strategic Perspective will focus on the model policy recently issued by the <u>Federation of State Medical Boards</u> on telemedicine and identifies unanswered questions that must be addressed concerning the key issue of how to fit telemedicine within the legal "practice of medicine."

Federal and state laws

Telemedicine (also called telehealth) generally refers to the diagnosis and treatment of a condition by a physician or other provider via technology, such as video conferencing, not in a face-to-face encounter. Telemedicine has been around for years; some date its first use at a psychiatric institute in 1959. It has been difficult, however, to integrate telemedicine into the existing in-person, encounter-based health care delivery system. The development of a regulatory and reimbursement structure for telemedicine has been haphazard and cautious; however, the lack of an overall strategy for the adoption into the national health care system has not gone unnoticed. More recently, the ACA and other health care reform laws have advanced the use and regulation of telemedicine. Moreover, proposed laws that address aspects of telemedicine are continually introduced in Congress and state legislatures to further advance telemedicine.

ACA provisions. To jumpstart telemedicine's adoption, the ACA embedded telemedicine and health technology in general into some of its initiatives. Section 3021(b) of the ACA directed the newly-created Center for Medicare and Medicaid Innovation (CMI) to test new care models that rely on "electronic monitoring" of inpatients by remote means or that utilize patient-based monitoring systems, among others. CMI awards grants to applicants whose proposals test these new care models, including projects that use telemedicine to support the care of persons with complex medical conditions. Section 3022(b)(2)(G) of the ACA also requires accountable care organizations (ACOs) to define processes to coordinate care "through the use of telehealth, remote patient monitoring, and such other enabling technologies." Additionally, the ACA makes monies available for certain uses of telemedicine in delivering home health under Medicare and Medicaid.

Medicare and Medicaid. Although CMS took a first step by paying for select telepsychiatry services for Medicare patients over a decade ago, it did little over the next few years during which time one federal task force after another studied the safety and cost of telemedicine. As of 2014, the list of covered telemedicine services is slightly broader, including for instance, pharmacological management and end stage renal disease-related services. Separately, Medicare also pays for remote services that do not require a patient encounter (*i.e.*, the patient and the provider do not directly communicate electronically), such as teleradiology; however, there is still no comprehensive approach to telemedicine and other remote health care services under the basic Medicare program.

There is a similar void under the federal Medicaid program. Some states have stepped into this void by authorizing the use of telemedicine under the state's Medicaid program. Medicare and Medicaid managed care organizations and private insurers also have some latitude to offer telemedicine services based on their structure and governing requirements.

State laws. State laws govern the practice of medicine, including telemedicine, and State Boards of Medicine enforce the laws governing the field's practitioners. There is little uniformity among the states' laws on telemedicine. Many State Boards of Medicines and other health care boards, such as pharmacy boards, are known for conservatively enforcing existing (and very old) laws governing professional practice. This approach prevents many unscrupulous activities, such as over-prescribing, but also stifles innovation.

With the passage of the ACA and other important health care reform laws, such as the Health Information Technology for Economic Health Act (HITECH) (P.L.111-5), there is momentum to fit telemedicine into our health care system as a means to improve care and reduce costs. Among other things, HITECH amended the Health Information Portability and Accountability Act (HIPAA) (P.L. 104-191) to reinforce the privacy and security requirements that apply to the use and disclosure of health information, including through telemedicine. But to be fully adopted, telemedicine must be accepted by the states as a legitimate form of the practice of medicine.

California, New Jersey, and Pennsylvania explicitly permit telemedicine, but with different conditions. In Idaho, there are no laws regarding telemedicine, and the state's Board of Medicine has determined that telemedicine may violate its practice requirements – with disastrous consequences as described below. The discussion on when other professionals such as certified nurse practitioners may provide telemedicine services has yet to begin.

Recently, the Idaho Board of Medicine (State Board) sanctioned a physician who provided services through a national telemedicine company. The patient had called into the telemedicine service complaining of flu-like symptoms and was referred to the physician, who was under contract with the company. After interviewing the patient by phone, the physician prescribed medication if the patient's symptoms were to worsen. What was the physician's crime? According to the State Board, the physician failed to establish a physician-patient relationship because she did not examine the patient in person and, therefore, was not authorized to prescribe a medication. The State Board fined the physician \$10,000 and restricted her license. Her licenses to practice medicine in Idaho and other states are under review. The telemedicine service provider has pulled out of Idaho, and the state's legislature is now considering a new law to permit telemedicine.

In time, it is expected that the Medicare and Medicaid programs along with Congress and the states will develop a comprehensive, workable, regulatory framework for telemedicine.

A "Model Policy" for the use of telemedicine

On April 26, 2014, the Federation of State Medical Boards (the Federation) took a step towards resolving the "practice of medicine" problem by issuing a "*Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine*" (the <u>Model Policy</u>) for telemedicine providers that presents practical guidance and previews this framework. Using the Model Policy and existing law, telemedicine developers and service providers should take a hard look at the "practice of medicine" question as part of their business plan – and be mindful of developments at the State Medical Board level.

The Federation is encouraging its members, which include State Medical Boards across the country, to adopt the Model Policy "to remove regulatory barriers to widespread appropriate technologies for delivering care while ensuring the public health and safety." The Model Policy identifies the important issues concerning telemedicine and offers recommendations for evaluating a telemedicine provider.

In the Model Policy, the Federation recognizes the major concerns with telemedicine: (1) defining the physician-patient relationship, (2) protecting patient data, (3) ensuring that patients are properly evaluated and treated, and (4) controlling the prescribing and dispensing of drugs. The Model Policy responds to these concerns by proposing a set of standards and parameters for an acceptable telemedicine program as summarized below:

- **Physician-Patient Relationship**: The Model Policy indicates that it may be difficult to define exactly when the physician-patient relationship begins, but "it is clearly established when the physician agrees to undertake the diagnosis and treatment of the patient, and the patient agrees to be treated." The physician should: (1) verify and authenticate the location (*i.e.*, is the location a state where the physician is licensed to provide services) and, if the patient's initial contact is anonymous, obtain patient information, if possible; (2) disclose and validate his or her identity and credentials; and (3) obtain proper consents.
- **Licensure**: The physician must be appropriately licensed in the state in which he or she is providing services.
- **Evaluation and Treatment**: The medical evaluation and clinical history must be documented as in any other physician-patient encounter and must be obtained prior to treatment including prescriptions. Treatment "based solely on an online questionnaire, does not constitute an acceptable standard of care."
- **Informed Consent**: The patient should provide informed consent specifically for the use of telemedicine technologies. Recommended components of an appropriate informed consent include, but are not limited to, details on security features and express patient consent to forward information to a third party.
- Continuity of Care: The patient must be able to seek follow-up care and have ready access to his or her patient record or other information regarding the encounter (such as an electronic health record), including to share with another provider.
- **Referrals for Emergency Services**: The physician must have a protocol for responding to a patient that needs acute or emergency care by providing an emergency plan.
- **Records**: Similar to any patient record, the telemedicine record should describe or include all communications, prescriptions, lab reports, consents, etc. Physician-patient emails also should be in the record. The patient record must be readily accessible to the patient.

- **Privacy and Security**: Telemedicine providers must comply with the privacy, security, breach, business associate, and other provisions under HIPAA and any other applicable federal or state privacy, security and breach laws, including appropriate policies and procedures.
- **Disclosures and Functionality:** The telemedicine provider must disclose pertinent information to the patient such as how to contact the physician, any fees, use and response times, and passive tracking mechanisms. There should be mechanisms for receiving complaints. Advertising is generally prohibited especially when the physician may profit financially or has a special relationship with a pharmacy; educational links are permitted.
- **Prescribing:** The physician may prescribe medicines but must maintain measures governing prescription to "uphold patient safety in the absence of traditional physical examination," *i.e.*, hold prescribing to a higher standard. Thorough documentation is required. Recommended practices include integration with an e-prescribing system and formularies.
- **Parity of Professional and Ethical Standards**: The physician should comply with online standards developed by the American Medical Association and other organizations and should apply the same ethical standards to all aspects of his or her practice. The physician's discretion should not be impacted by nonclinical considerations (*e.g.*, the patient's ease of using telemedicine), or outcomes.

Questions raised by the Model Policy

The Model Policy significantly contributes to the debate on how to fit telemedicine within the "practice of medicine," and will offer an approach to states that are particularly struggling with the issue, like Idaho. It is a thorough document, and the drafters should be commended, but it does raise a few questions, such as:

- What is "telemedicine" for purposes of the Model Policy? This is a huge issue, and the Model Policy is not clear. It states that telemedicine "typically" involves video-conferencing or store-and-forward technology but generally is not a telephone conversation, email, instant messaging, or fax. This is not the case in practice, where numerous telemedicine services are phone-only. It may be that the Federation intentionally left the language vague in recognition of different state laws and guidance. But the Federation must clarify this issue for the Model Policy to be maximally useful.
- When does the physician-patient relationship end? This is a critical issue that is not meaningfully addressed. The Model Policy discusses how the patient can obtain follow-up care, but not when the physician can assume that his or her obligations as a telepractitioner (other than related to documentation) are ended.
- How do these policy recommendations apply to physician groups? When a patient goes to a visit at a physician group office, the patient may see one physician one day and another physician the next. It is likely that telemedicine providers will do the same. How does the policy apply in this situation?
- What is an inappropriate financial interest? Physicians may provide telemedicine services by contracting with a telemedicine company, but they also may provide these services as an adjunct to their practices, through a related company, or an arrangement with another provider. While these may be similar to other health care arrangements, technology creates new, relatively easy modes of delivery of care and opportunities for patient education. When is a patient induced to choose telemedicine over an office visit? Why can't a physician advertise goods or services that may be of benefit to the patient for which he/she is receiving reimbursement if that is disclosed to the patient?
- What is an "emergency plan" for a patient that calls with an emergency or acute condition? Under licensure and ethical requirements, a physician must direct a patient who requires acute or emergency care to the appropriate provider. Is the telephysician required to follow-up beyond what an office-based

physician provides, such as a video-conference or phone call? This issue overlaps with the issue of when the physician-patient relationship ends, and both must be addressed.

Conclusion

What's next in the debate over telemedicine? There are numerous government and private groups looking at this new approach to diagnosing and treating patients and calling upon Congress and the state legislatures to create a regulatory framework. In the meantime, the telemedicine provider or telemedicine service developer must ensure they remain apprised of relevant developments and build the "practice of medicine" and other potential legal complications into the business plan.

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