

TELEMEDICINE, MOBILE HEALTH AND THE STANDARD OF CARE

**A Look at State-Specific Policies Altering Traditional Standard
of Care Requirements As Applied to Telemedicine and
Impacting the Utilization of Mobile Technologies**

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Telemedicine—using telecommunications technologies in connection with the delivery of healthcare services—is nothing new to healthcare providers long familiar with the use of telephone, text, and remote radiology and pathology consulting services. Add to that an increasing demand for convenience and information from a smart phone oriented society, and most now accept the growth and need for various mobile and telecommunications technologies in delivering health and wellness services, monitoring chronic conditions and treatment adherence, and facilitating patient education. In fact, healthcare providers and regulators dealing more and more with these recent advancements in telemedicine business models are now more than ever asking the question, “can and does the use of such technologies in the practice of medicine affect or alter the standard of care?”

This is an important consideration for healthcare providers as state medical boards hold the healthcare provider accountable for meeting the standard of care in each instance, including when providing care using telemedicine technologies. It is also important for various technology companies to understand how regulators consider this question and what technology models better lend themselves to achieving the standard of care in each instance. After all, if telemedicine is merely the practice of medicine using a telecommunications tool, then it is not the practice of medicine in question, rather whether the technology or method by which the technology is used enables the provider to meet that standard of care.

Currently, inconsistencies abound among state-specific guidance and regulations on the topic of both medical practice using telemedicine and electronic prescribing, creating uncertainty and differing requirements by state. That said, recent actions by a number of industry stakeholders (the Federation of State Medical Boards, the American Telemedicine Association, and others) provide regulatory frameworks for evaluating telemedicine that could assist regulators in a more uniform assessment of the standard of care and peer-reviewed guidance for providers using telemedicine, respectively. These frameworks can also be very helpful guideposts for providers and technology companies in developing functionality and use cases for mobile health.

1. Telemedicine & Mobile Health Use Case—An Overview

More traditional use cases for telemedicine typically call for the use of some form of telecommunications (phone, real-time video, or sharing of images) so that two or more healthcare providers can collaborate or “consult” across a distance on a patient’s case. In some situations this involves a specialist assisting an ER doctor in the evaluation of a patient. Other models advance multi-specialist and primary care data exchange on unique and chronic patients requiring recommendations from multiple healthcare providers. Rather than mobile devices, these models typically involve more advanced hardware, software, and connectivity needs

whereby video/audio carts and digital imaging systems have evolved to facilitate a free-flow of communications and information exchange primarily between two healthcare facilities and healthcare providers. Most teleradiology, telepathology, and teleneurology models function in this manner. This said, the various models for integrating telecommunications tools into medical practice continue to grow.

With greater consumer interest in healthcare, employer efforts to contain insurance costs, and a general desire to align healthcare with more IT and mobile society-oriented norms demanding convenience, access, and connectivity, evolution continues for healthcare delivery patterns and models using telemedicine technologies (especially consumer mobile devices). In particular, “direct to consumer” models bring healthcare providers of all types to the patient at the patient’s demand (in the patient’s home, in the patient’s workplace, and in retail locations), often using mobile devices and software applications for a variety of real-time video, monitoring, secure messaging, and audio tools for engagement between the healthcare provider and patient. Even well-respected hospitals and health systems, such as the Cleveland Clinic, Children’s Hospital-Boston, and Partners Healthcare, are exploring and participating in such “direct to consumer” telemedicine initiatives for expanded access to patients and in meeting important patient engagement and satisfaction goals.

2. Background on the Standard of Care for Medical Practice

Continually, research supports positive aspects of telemedicine as it improves health outcomes, provides access to healthcare needs, and enhances efficiencies for cost reductions and patient satisfaction.¹ With such optimism for the use of telemedicine, one might think regulators charged with supporting safe healthcare would extol the virtues of telemedicine. In some cases, they may be cautiously doing so, as evidenced by discussions in a recent workshop hosted by the Federal Trade Commission.² However, regulatory acceptance often lags behind the development of new technologies, even ones that appear to be successful. In particular, “direct to consumer” models are inherently atypical from traditional delivery models for healthcare because there is not a “trusted intermediary” (a healthcare provider) in-person with the patient. Rather, the remote physician is directly engaging with the patient, resulting in regulators struggling to find the right balance in regulation.

Often the lynchpin to most health regulatory requirements, the standard of care in healthcare is a concept that (even apart from telemedicine) constantly evolves as new research, teaching standards, and procedures make the case for change to advance positive patient health and wellness. After all, there is no specific definition for the standard of care; rather, it is

¹ Largest Study of Critical Care Telehealth Reveals Improvements in Patient Outcomes and Reductions in Health Care Costs, WALL ST. JOURNAL, Dec. 5, 2015, <http://online.wsj.com/article/PR-CO-20131205-908869.html?dsk=y>. Press Release, UC Davis Health System, Telemedicine Consultations Significantly Improve Pediatric Care in Rural Emergency Rooms (Aug. 8, 2013), <http://www.ucdmc.ucdavis.edu/publish/news/newsroom/7757>.

² FTC Workshop Examining U.S. Health Care Competition (March 20-21, 2014), <http://www.ftc.gov/news-events/events-calendar/2014/03/examining-health-care-competition>.

principle arising from 100+ years of legal cases.³ Medical malpractice law is based on determining whether the physician in question conformed to “the standard of conduct to which one must conform...as a reasonable man under like circumstances.”⁴ Said another way, what was the “duty” of the physician under the facts presented (i.e. the standard of care) and did the physician act consistent with that duty.

As such, it is really no surprise that the use of telemedicine technologies has kick-started a new debate on the standard of care. The interesting point, however, when it comes to telemedicine, is that we are really not talking about a new medical procedure, rather merely a modification in the delivery methods for practicing medicine. As such, many feel there is essentially no difference in the standard of care between models using telemedicine and models that do not, with the standard of care generally necessitating the taking of a patient history, a physical exam, and the making of an appropriate diagnosis and/or provision of treatment plan under the circumstances.⁵ Under historical constructs for the standard of care, the notion of physician discretion is central and is judged against whether the data gathered would reasonably avail a physician of the necessary information given the attendant facts and circumstances to make an appropriate diagnosis and treatment decision. Despite this, various state-specific regulations are attempting to establish a different standard of care when a physician engages with a patient by means of telemedicine, thereby limiting how they can establish the physician patient relationship, what they can prescribe, and how often they must “see” the patient in-person, notwithstanding the facts and circumstances of the patient situation.

3. Varied State Rulemaking on Telemedicine and the Standard of Care

Many states are silent on telemedicine specific regulations and others have quite specific rules and guidance on practicing using telemedicine. While healthcare providers may prefer silence to specific telemedicine rules, the lack of a specific rule often requires an evaluation of telemedicine activities using a law or rule written with more traditional, in-person, bricks and mortar health care concepts in mind. These concepts include topics like supervision and patient exam standards, which are often tied to patients and practitioners being in the same physical presence—concepts not conducive to telemedicine and mobile technologies. It is easy to see how these traditional rules (while not written to limit telemedicine) practically do so, because they speak to being within the same building or a hands-on-exam.

For this reason, among others, over the last ten years, some states, including Alabama, New York, California, Texas, Georgia, North Carolina, and Florida,⁶ developed detailed laws,

³ Moffett, Peter, MD and Gregory Moore, MD, The Standard of Care: Legal History and Definitions: the Bad and Good News, West J Emerg Med. 2001; 12(1): 109-112, http://escholarship.org/uc/uciem_westjem.

⁴ *Id.*

⁵ See e.g., O.A.C. 435:10-7-13.

⁶ Ala. State Bd. of Med. Exam’rs. Ch. 540-X-15; Ca. Bus. & Prof. Code § 2290.5; Ga. Comp. R. & Regs. 360-3-.07 (Adopted March 2014); Rule 64B8-9.0141, F.A.C.; 22 T.A.C. §174; <http://www.health.ny.gov/professionals/doctors/conduct/telemedicine.htm>; http://www.ncmedboard.org/position_statements/detail/telemedicine/.

rules, and guidance specific to telemedicine. Most interestingly, while most of the states with telemedicine regulations claim that medical practice via telemedicine should be held to the same standard of care as traditional medical practices, they diverge quickly in how they define “traditional medical practices.”

a. *Prior “In-Person” Requirements*

Arguably the most burdensome of the state telemedicine regimes, especially for “direct to consumer” telemedicine models using mobile technologies in a patient’s home, are found in Texas and Alabama regulations, and more recently disciplinary actions of the Idaho medical board.⁷ These regimes indicate that meeting the “traditional” standard of care necessitates prior interaction, in particular an in-person “hands on” exam, notwithstanding the facts and circumstances, merely because the physician and patient are using telecommunications technologies to communicate.⁸ The Texas rule states, “treatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional in-person clinical settings.” However, for the “direct to consumer” use case, the Texas regulators’ traditional standards would dictate the location of an exam (e.g. in-person) and prohibit telemedicine in the home without a prior in-person exam.⁹

b. *Physician-Extender Requirements*

Earlier this year, Georgia adopted rules that in certain circumstances would require that some licensed healthcare professional (or peripheral) be with the patient when a physician engages with the patient by telemedicine.¹⁰ Here, the Georgia medical board appears to be indicating that it is uncomfortable relying on traditional notions of a physician’s standard of care, as they feel that a physician can only gather adequate patient data if another healthcare provider is present with the patient during the telemedicine exchange.

c. *Electronic Prescribing Limitations*

Another closely aligned topic is that of electronic prescribing rules and regulations. While many such rules were intended to corral the inappropriate online prescribing practices of “pill mills” and other such schemes in the 1990s, the rules can significantly affect telemedicine, especially as it relates to prescribing controlled substances on the basis of an electronic (remote) exam and where the mobile technologies are not real-time with both video and audio capabilities.

⁷ See Idaho Code § 54-1733(1) (2013). Because the state’s legislature is now asking the medical board to adopt a more “welcoming” approach to telemedicine, however, this could change.

⁸ Ala. State Bd. of Med. Exam’rs. Ch. 540-X-15-11; 22 T.A.C. §174.8.

⁹ 22 T.A.C. §174.8(b).

¹⁰ Ga. Comp. R. & Rules. r. 360-3-.07(a)(3)(d) (Adopted March 2014).

For example, under Ohio regulations, a physician must “personally physically examine and diagnose a patient” before prescribing.¹¹ The applicable Ohio interpretive guidance states that “before prescribing a non-controlled substance, a physician should (a) have a valid relationship; (b) have appropriate diagnostic equipment capable of transmitting in *real-time images* of the patient’s symptoms; (c) have sufficient dialogue with patient regarding treatment,” among other requirements. Such rule structures limit the types of drugs a physician can prescribe, even though they have conducted an exam merely because the exam occurred outside the in-person environment and require that real-time video technologies are used, thereby limiting the types of mobile technologies available for physician use. In these situations, a provider may be faced with a legal quagmire where she might diagnose consistent with the standard of care when using a mobile telemedicine technology, but she may be prohibited from prescribing based on that diagnosis if the diagnosis was based on an evaluation conducted via asynchronous telemedicine (i.e. store-and-forward sharing of images).

d. *Limitations on the Type of Telecommunications Technology*

Even more concerning, perhaps, are more recent actions by state medical boards that indicate an audio-only encounter (phone) is likely not enough to meet the requirements of an “appropriate” exam and thus did not meet the standard of care for diagnosing or prescribing. The examples involve a case in Idaho where a telemedicine provider with no prior physician-patient relationship used a phone to engage with a patient prior to prescribing medication and was subsequently deemed in violation of the state’s rule that prescription drugs can only be issued for a “legitimate medical purpose arising from a prescriber-patient relationship which includes a documented patient evaluation *adequate* to establish diagnoses and identify underlying conditions and/or contraindications to the treatment.”¹² The rule further states that treatment based solely on a “consultation outside of an ongoing clinical relationship” is not a legitimate medical purpose.¹³

Under a similar fact pattern, last fall the North Carolina Medical Board issued a “letter of concern” to an out of state health care provider licensed to practice in North Carolina stating that a physician who just reviewed a patient history file and conducted a phone call with a patient (without a prior physician-patient relationship) “did not perform a physical examination of the patient” prior to diagnosis and treatment, which was contrary to the North Carolina Medical Board’s position statement on telemedicine requiring an “appropriate” exam be conducted prior to diagnosis or treatment.¹⁴

¹¹ Ohio Admin. Code 4731-11-09.

¹² Idaho Code 54-1733(1) (2013). See minutes of the March 2, 2012 Idaho Medical Board where action was taken to send a cease and desist notification to telephone service physicians who are providing legend drugs to Idaho patients based solely on telephone consultations outside of an established patient-physician relationship in violation of Idaho Code §54-1733. See also a news story detailing the Idaho Medical Board’s actions against telemedicine provider, Dr. Ann De Jong at <http://www.ktvb.com/story/local/2014/08/03/12161905/>.

¹³ *Id.*

¹⁴ North Carolina Medical Board Letter to Dr. Eric Joseph Rodriguez, M.D., October 23, 2013.

e. *Equal Standards of Care*

New York, North Carolina, Florida and California view telemedicine as a “tool in medical practice, not a form of medicine” and, as such, rules and guidance indicate that the standard of care should be the same as traditional medicine, applying a facts and circumstances approach left to the physician, albeit necessitating appropriate exam, patient verification, and record-keeping, but not dictating how and where that exam is conducted.¹⁵ After all, most regulators do not, in the context of an emergency room, specify particular tests that must be ordered before a physician has achieved the standard of care for a patient they have never met before. Rather the physician acts in his or her discretion to meet the patients’ needs in performing tasks that most peers would deem relevant and appropriate given the facts and circumstances.

In March 2014, Florida’s medical board adopted an amendment to its electronic prescribing rule¹⁶ conveying that the standard of care is the same for in-person care as it is for care provided by telemedicine with the only limiting factor being a restriction on the prescribing of controlled substances based solely on an exam conducted by telemedicine. This Florida rule comes the closest to a recently adopted model policy on the appropriate practice of telemedicine of the Federation of State Medical Boards (FSMB) discussed below. Given that the Florida rule had the benefit of reviewing an early draft of the new FSMB model policy when considering its new rule on telemedicine, Florida could serve as an indicator for how medical boards may pursue the topic going forward.

While we need regulations specific to telemedicine or at least updated traditional health regulations to remove notions of physical requirements, as the above examples evidence, states adopting such regulations have done so with tremendously varied approaches. These disparate structures require healthcare providers who employ mobile devices and operate in multiple jurisdictions to consider multiple different legal and regulatory structures, often affecting their operations and documentations by state. The legal and regulatory burdens arising from compliance with multiple structures can be a significant hurdle to telemedicine and mobile health companies, and in many cases early stage companies (often the most innovative) just cannot sustain the attendant costs to comply with numerous regulatory frameworks.

Interestingly, notwithstanding the view of some regulators as it relates to certain telemedicine models, primarily the “direct to consumer” model, case law may trend to add telemedicine to the standard of care for in-person medical services. If telemedicine essentially becomes a “duty of care” to bring the appropriate providers to a patient and a physician fails to use telemedicine in a way that could have advanced patient outcomes, such as by coordinating with a specialty physician, he or she could be viewed as having breached his duty to act

¹⁵ See Rule 64B8-9.0141(2), F.A.C.; <http://www.mbc.ca.gov/Licensees/Telehealth.aspx>;
<http://www.health.ny.gov/professionals/doctors/conduct/telemedicine.htm>;
http://www.ncmedboard.org/position_statements/detail/telemedicine/.

¹⁶ Rule 64B8-9.0141, F.A.C.

according to a professional standard of care.¹⁷ If this trend develops—and plaintiffs are successful in bringing those claims—states should provide fair warning to physicians and healthcare organizations.

4. Recent Activities by Stakeholders to Advance Streamlining the Standard of Care for Telemedicine and Mobile Technologies

a. Federation of State Medical Boards Model Policy

The FSMB State Medical Board Appropriate Regulation of Telemedicine (SMART) Workgroup comprised of members from a number of state medical boards with insight from industry-specific advisors covering the perspective of payors, technology companies, and healthcare providers developed principles for the appropriate use of telemedicine by healthcare providers in the form of a model policy. On April 26, 2014, the FSMB adopted this non-binding model policy as a framework for regulators and health care providers to consider as the use of telemedicine to provide medical care becomes even more prevalent.¹⁸ In addition to highlighting many key issues, including the importance of physician-patient relationships and the continuity of care, the policy offers guidance on how providers and policymakers might evaluate the standard of care in the context of a “direct to consumer” telemedicine model.¹⁹ Rather than establishing a different standard of care for a telemedicine encounter (the direction some state regulations have taken over the past few years), the model policy clearly requires that diagnosis and treatment using telemedicine should be held to the same standards of appropriate practice as those in traditional (“in-person”) settings. As such, consistent with traditional norms for the diagnosis and treatment of patients, a health care provider should conduct a medical evaluation and collect relevant clinical history, and then determine whether a diagnosis or treatment is possible or recommended based upon the patient and the facts and circumstances presented. Importantly, the model policy provides that an exam can be conducted using telemedicine technologies and still be within the standard of care so long as the technology allows the physician to gather the necessary patient information for a diagnosis under the facts and circumstances. As states take up this topic, as likely they will, it will be interesting to see if they take the route of the FSMB framework or pursue more restrictive processes adopted in states like Texas, Idaho, and Alabama for meeting the standard of care that only a prior “in-person” exam can provide.

b. American Telemedicine Association Guidelines

Albeit still in draft form, the American Telemedicine Association (ATA) recently proposed Practice Guidelines for Real-Time, Direct-to-Patient Primary Urgent Care

¹⁷ See e.g., *Market Trends for Telemedicine*, HEALTHCARE IT NEWS (Jan. 6, 2012).

¹⁸ FSMB Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine, available at http://www.fsmb.org/pdf/FSMB_Telemedicine_Policy.pdf.

¹⁹ *Id.* (noting at fn. 2 that “[t]he policy does not apply to the use of telemedicine when solely providing consulting services to another physician who maintains the physician-patient relationship with the patient, the subject of the consultation.”)

Telemedicine (open for public comment through June 12, 2014).²⁰ The ATA guidelines cover the provision of direct-to-consumer and urgent care services delivered by providers using real-time, two-way videoconferencing and telephonic technologies, including the use of mobile devices. Of note, the ATA guidelines set out a list of considerations for determining the appropriateness of using telemedicine for primary and urgent care, and include a schedule of conditions for which certain technologies (telephone only versus video and audio) may be appropriate, by technology type.

Developed by panels that include experts from the field and other strategic stakeholders, the ATA guidelines are designed to serve as both an operational reference and an educational tool to aid in providing appropriate care for patients. Working hand-in-hand with the regulatory framework laid-out by FSMB, these types of industry-focused guidelines can serve an important function in assisting the industry and its participants in what types of actions meet the standard of care in various circumstances.

5. Unknown Applications – Self-Diagnosis and Advising Devices

One area of particular relevance for mobile technologies is that of self-diagnosing, coaching, and advising tools. Are these devices diagnosing and treating? The practice of medicine, requiring a license in the state where the patient is located at the time of the encounter, is generally defined as diagnosing, treating or holding oneself out as doing so. These laws and rules are not necessarily limited to an individual and could apply to device companies if they are claiming to enable self-diagnosis, especially where the device claims to provide advice that can advance the health or wellness of the consumer.

While we know that the Federal Trade Commission and the Food and Drug Administration may deem such devices and their related advice to be within the purview of FTC and FDA and thus subject to such scrutiny and requirements, as of yet we have seen little activity from state licensing boards on the topic. Could state medical boards find such activities by mobile technologies to be the unauthorized practice of medicine? Further still, can a device company meet the standard of care without a licensed provider making all the diagnostic and treatment recommendations, giving rise to not only state regulatory actions but consumer product liability claims? Given the unknown reaction to such topics, mobile device companies and health care providers affiliated with such technologies would be wise to use caution in making claims that devices can diagnose or allow for self-diagnosis. Even if this doesn't create a medical board action, it could provide a greater risk of a consumer claim of expected involvement from a medical professional thereby holding the device company to a "standard of care" for the patient.

6. Conclusion

²⁰ Practice Guidelines for Real-time, Direct-to-Patient Primary Urgent Care Telemedicine, American Telemedicine Association, May 2014 (Draft); [http://www.americantelemed.org/docs/default-source/standards/ata-primary-urgent-care-guidelines-draft-public-comment-final-\(2\).pdf?sfvrsn=2](http://www.americantelemed.org/docs/default-source/standards/ata-primary-urgent-care-guidelines-draft-public-comment-final-(2).pdf?sfvrsn=2).

States should consider the importance of nationwide uniformity in developing standard of care structures applicable to telemedicine. Physicians who only provide in-person medical services often practice solely in one state. Therefore, it is rather simple for them to identify the relevant and applicable standard of care. However, physicians providing medical services through telemedicine often treat patients in multiple states and, as such, are held to a plethora of different standards that are increasingly difficult to monitor. Moreover, without uniformity, there could be confusion about whether a physician-defendant in a medical malpractice lawsuit should be held to the standard of care in the state in which he or she is located or in the state in which the patient is located. It appears that only some states, such as Minnesota, have taken steps to clarify the answer.²¹ Finally, there have already been efforts to create uniformity in other areas of regulation affecting telemedicine, such as licensure, so stakeholders are hopeful that regulatory consideration will continue on all topics affecting telemedicine²²

There is little doubt that regulators will continue to grapple with how to evaluate the standard of care in the context of telemedicine, especially when using mobile technologies directly between patient and provider. This all comes at a time when both federal and state governments face pressure from stakeholders to keep up with how to regulate key issues that arise with the expansion of digital health technologies, such as licensure, reimbursement, and the security of technology used. The only certainty in regulatory structures for digital health is that it will likely continue to evolve as new technologies and business models create new opportunities and realities in quality care.

Frankly, given the amorphous concept of the standard of care and the fast-paced growth of use cases upending traditional notions for the way healthcare is delivered, it is no surprise that providers are without clarity in how the standard of care is evaluated. These are, after all, quite novel and complex underlying concepts. That said, it appears positive that stakeholders are acting on the topic, and healthcare providers may find this an opportunity to engage and inform medical boards and others on various research and information supporting quality outcomes using telemedicine models and mobile health technologies, including its effective use consistent with the standard of care.

²¹ See Minn. Stat. §147.032(d).

²² See e.g., Service members Telemedicine and E-Health Portability (STEP) Act, Public Law 112-81, Section 713 (eliminating state licensure requirement for qualified and credentialed Department of Defense health care professionals); A Report by the FTC and the DOJ, Improving Health Care: A Dose of Competition (July 2004), available at <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf> (encouraging states to adopt more uniform licensing standards of reciprocity arrangements).