Chapter 2

Telehealth Regulatory Requirements

2.1 Introduction

Sometimes referred to as telehealth "practice standards," the rules governing where and how telehealth may be used to deliver care are largely determined at the state level. Federal laws create some legal and practical considerations for telehealth providers, including through limitations on the ability to prescribe controlled substances via telehealth under the Ryan Haight Act of 2008 and standards for Medicare reimbursement for telehealth services as discussed in Chapter 3. In addition, certain other federal laws governing health care providers more generally may be implicated in new or different ways through the use of telehealth as discussed in Chapter 1. However, because medical nursing, and other health care professionals are regulated at the state level, the use of telehealth in the delivery of medical care and treatment is likewise primarily a state issue.

A flurry of legislative activity in recent years, together with increased focus on the use of telehealth by state medical boards, has resulted in some statutory or regulatory requirements governing the use of telehealth in almost every state. These requirements are codified in a number of places, including through statutes and regulations governing the use of telehealth generally, pharmacy statutes and regulations restricting the ability of providers to prescribe and/or pharmacists to dispense, and regulations or policy statements issued by medical, nursing and other professional licensing boards with authority over the professional practice of their licensees.

While not every state has promulgated a comprehensive (or in some cases, internally consistent) set of standards for the use of telehealth, there are a number of core issues that states have either addressed or that may arise for providers navigating how to use telehealth in compliance with applicable state requirements, including:

- How is "telehealth" or "telemedicine" defined? (i.e., Will the particular use of technology at issue meet the applicable definition?)
- What kinds of providers can deliver care using telehealth? Is it just physicians, or can other categories of providers and/or allied health professionals provide telehealth services?
- Can a physician or other licensed professional supervise another provider remotely?
- Can a provider establish a provider-patient relationship through a telehealth encounter, or must the relationship be established in-person prior to using telehealth in the delivery of care?
- If the provider-patient relationship can be established through a telehealth encounter, what requirements must be met? (e.g., physical evaluation or examination, disclosure of provider credentials, validation of patient location)
- What level of visual and/or auditory access to the patient, if any, is required for a telehealth encounter? (e.g., "real-time" audio and video)
- What kind of diagnostic equipment or technology, if any, must be used in a telehealth encounter? (e.g., ability to take temperature, pulse or other vitals)
- Does the provider need to obtain written or verbal informed consent from a patient prior to

the use of telehealth?

- What sort of disclosures or arrangements does the provider need to make relating to emergency or follow-up care for a patient receiving telehealth services?

In some cases, states have also created, whether intentionally or by virtue of outdated statutes or regulations, additional or differing requirements that limit the ability of a provider to prescribe medication based on a telehealth encounter or impose restrictions on the circumstances under which a pharmacist may dispense medications that involve telehealth services. These requirements generally are codified in pharmacy statutes and regulations, but can also take the form of professional conduct rules embedded in statutes and regulations governing the practice of the applicable licensed profession.

This chapter provides an overview of some of the primary considerations and limitations of state regulatory frameworks that may impact telehealth providers. Because of the evolving nature of state-based telehealth requirements and industry practices as a whole, we recommend always checking the most current laws, regulations and other guidance promulgated within a particular state to determine the applicable requirements at any given time.

2.2 Telehealth Models

2.2.1 Telehealth Communication Platforms

Telehealth services come in various shapes and sizes. The Institute of Medicine put it well when, back in 1996, it described telemedicine as

> not a single technology or a discrete set of related technologies; it is, rather, a large and very heterogeneous collection of clinical practices, technologies and organizational arrangements. In addition, widespread adoption of effective telemedicine applications depends on a complex, broadly distributed technical and human infrastructure that is only partly in place and is being profoundly affected by rapid changes in health care, information and communications systems.[1]

Though this guidance was issued over two decades ago, the IOM's description still captures today's spectrum and variety of telehealth delivery models. The key variables within these models relate to the type of communication, those involved in the communication and the equipment and infrastructure used to create the communication.

Telehealth services may be provided through two primary categories of communication platforms: (1) synchronous communication, described as "real-time" communication, or (2) "asynchronous" communications, which is known more commonly as "store and forward." As further described below, which platform is permissible, and the standards that may apply to the use of a given platform vary among states. However, most states generally treat audio-only, fax, and email communications as being insufficient, on their own, to satisfy the definition of telehealth and/or applicable telehealth statutory or regulatory requirements.[2] Likewise, the Federation of State Medical Boards (FSMB), in its Model Policy for the Appropriate Use of Telemedicine Technologies (hereinafter FSMB Model Policy), states that telemedicine is "[g]enerally . . . not an audio-only, telephone conversation, email/instant messaging conversation, or fax. It typically involves the application of secure videoconferencing or store and forward technology to provide or support healthcare delivery . . . ."[3]

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[1] Inst. of Med., Comm. on Evaluating Clinical Applications of Telemedicine, Telemedicine: A Guide to Assessing Telecommunications for Health Care (Marilyn J. Field, ed., 1996).

[2] *See*, *e.g.*, Fla. Admin. Code Ann. r. 64B15-14.0081(1), (9) (2016); La. Stat. Ann. § 37:1262 (2008); La. Admin. Code tit. 46:XLV, §§ 7503 (2017); Tenn. Code Ann. § 63-1-155 (2015).

[3] Fed. St. Med. Boards, Model Policy for the Appropriate Use of Telemedicine Technologies § 3 (2014).

2.2.1.1 Synchronous Communication

Synchronous communication enables a provider, consumer or patient at the originating site to engage in live/real-time interaction with a provider in a remote location. The remote provider is viewing and speaking with the patient at the same time the patient is viewing and speaking with the provider. The communication is most often via an audio and visual connection. In fact, a number of states permit the provision of telehealth *only* through a synchronous connection, or require the use of a synchronous connect in certain circumstances. For example, Delaware requires that, absent a prior in-person examination, a telemedicine consult must be performed using video-audio communications.[4]

Through synchronous communication, patients who want to "see" a provider can do so. Even if the patient does not want to or cannot travel, the patient still is able to have a "live" consultation. Synchronous communication is also the clear choice in urgent situations, such as consultations regarding impending strokes. In the inpatient setting, hospitals without neurologists on staff may arrange for a neurological consult via telemedicine much more quickly than an in-person consult. That being said, a telehealth practice standard is for providers to assess when the urgency of a situation should prevent the use of telehealth and patients should be referred to in-person providers, or even to the local emergency department.

2.2.1.2 Asynchronous

Asynchronous communication is also referred to as "store and forward" because information is collected from the patient at the originating site—whether the patient's home or health care facility or physician practice—and then sent, or "*forwarded*," to the provider at the distant site who will assess the information. Common examples of data collected in a store-and-forward model are x-ray or CT images, lab test results, or pre-recorded videos or photographic images of an afflicted body part, such as throat or ear, and perhaps the patient's description of any symptoms.

Professional organizations such as the American Medical Association (AMA) and the FSMB recognize both types of telemedicine technology platforms. In the past, some states excluded asynchronous platforms from their definitions of telehealth; however, the current trend is to take a more inclusive approach like the AMA and FSMB. For example, Arkansas recently repealed a law that expressly carved out asynchronous technology from its definition of telemedicine, and new Hawaii legislation includes all models and modalities discussed herein as well as m-health to define the more global category of telehealth.[5]

Asynchronous communication can provide valuable benefits and is most suitable when immediate feedback is not needed or not possible. In asynchronistic RPM models, data is collected for later review. For example, in the traditional non-telehealth setting, diagnostic tests are processed and interpreted with the results delivered to the interpreting provider. Similarly, in the telehealth setting, real-time communication is not necessary. Diagnostic tests may be performed and the results sent electronically to the receiving provider at a distant site in a form and format that allows a specialist to properly interpret the results. In fact, if the specialist is not otherwise readily available, the use of telehealth technology may expedite the process. Further, asynchronous models can often be less expensive than services provided in the traditional setting.

Some states expressly require that asynchronous telehealth technology meet current practice standards, have security measures in place and generally be able adequately to provide the health

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[4] 24 Del. Code § 1769D(h).

[5] 2017 Ark. Laws Act 203 (S.B. 146); Haw. Rev. Stat. §§ 346-59.1, 457-17, 671-7, 431-10A-116.3, 432-1-601.5, 432D-23.5, 453-1.3, 453-2, 457-2, & 466J-6 (2017).

care service. Missouri has mandated the promulgation of regulations governing the use of asynchronous technology. Such regulations must: (1) establish appropriate standards for the use of asynchronous store-and-forward technology in the practice of telehealth; (2) provide for certification of agencies offering asynchronous store-and-forward technology in the practice of telehealth; (3) establish timelines for completion of a consultation and the communication of the results or asking for additional information; (4) determine the length of time digital files of such asynchronous store-and-forward services are to be maintained; (5) address the security and privacy of such digital files; (6) address participant consent requirements for asynchronous store-and-forward services; and (7) address payment for services by providers and establish that consulting providers are not entitled to payment unless and until an opinion is rendered.[6]

2.2.2 Participant-Type Communication Models

2.2.2.1 Provider-to-Provider Models

Provider-to-provider communications are those in which a health care provider is at both ends of the communication, (i.e., at both the originating site with the patient and the distant site). One common use of the provider-to-provider model is to facilitate a remote specialist consult. In these scenarios, the present and treating provider at the originating site determines if additional consultation is required. The provider at the originating site could, for example, be the patient's primary care provider during an office visit, a nurse practitioner within an urgent care center or retail-based clinic, or a hospital's attending physician treating an inpatient. The remote consulting specialist or other providers renders the consult in the normal course, but via telemedicine.

Depending on the telemedicine arrangement, consultations may be requested and received on demand, and perhaps in minutes, or scheduled in advance. Telehealth consultation arrangements with remote providers also could require, as a term of the engagement, that the remote consulting provider respond to the consultation request within a certain time frame, particularly in the context of urgent care. For example, individuals seeking care at a retail clinic often do not have an ongoing relationship with the clinic. In clinic situations, individuals may seek quick assessments of their symptoms to determine whether further and more specialized medical care is required. A prompt consult is thus key to the success of this provider-to-provider model and one benefit over a traditional in-person consult.

While the on-demand characteristic is a draw of telehealth use for many, it is not always necessary. Telehealth consults scheduled in advance can be very helpful for the patient and the patient's treating (in-person) provider. For example, primary care providers in a rural area may recommend specialty consults for patient care; however, there are no applicable specialists in the area. In a provider-to-provider model, the primary care provider and patient can schedule a future telehealth appointment or consultation with the specialist, at which time the patient will participate from the primary care physician's office in the presence of his or her physician.

Provider-to-provider consultations do not always take place in the patient's presence, even in the case of in-person provider-to-provider consultations. For example, when an attending physician requires a neurological consult regarding a patient's MRI, the attending physician often determines the patient's presence is not necessary or perhaps advisable in his or her medical judgment. The attending physician consults with the neurologist in the absence of the patient and later conveys any information deemed necessary. The same can occur, and often more easily, via telehealth. And, with telehealth, the spectrum of consultant options can be exponentially increased.

Another benefit of provider-to-provider consultations, as discussed in Chapter 1, is the flexibility of licensing requirements.

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[6] Mo. Rev. Stat. § 208.671 (2016).

2.2.2.2 Provider-to-Provider Extender

A provider-to-provider extender model involves a treating provider at the distant site and the patient in the company of an intervening ancillary health care provider, such as a registered nurse, at the originating site. The ancillary provider is often tasked with collecting information from the patient, such as vital signs or current symptoms of an ailment or condition, and acts as an extender of the distant site telehealth provider. The ancillary provider at the originating site communicates the data in real-time to the treating telehealth physician at the distant site through the telehealth communication connection. In these models, the ancillary provider also may have the ability to upload the patient's information into a database for the distant site treating provider's later review (i.e., "store and forward," as discussed below). Ancillary providers also are often used to assist with the patient's use of telemedicine equipment, such as cameras and scopes used to examine specific parts of the patient's body (e.g., throat, ears, eyes, wounds, skin irritations, etc.). Again, the data (i.e., images, videos, etc.) is either viewed in real-time or stored in an electronic platform for later review. Use of ancillary providers may occur not only in a facility or practice setting, but also when a patient receives telehealth services at home. In provider-to-provider extender models, relevant federal or state supervision requirements, as discussed in § 2.5.3, must be addressed.

The use of a physician extender, or "telepresenter" as he or she may also be described, can be a significant boost to efficiency in the delivery of telehealth services, while also increasing patient convenience. On the other hand, use of a telepresenter does create an additional step and, if not a required step, may create more burden than benefit. In the past, many states' telehealth laws required the use of telepresenter in the course of a telehealth consultation. Most states including Alaska, Hawaii and, most recently, Texas have repealed such requirements in the last several years.

2.2.2.3 Direct-to-Consumer Communication

The direct-to-consumer (D2C) model is just that—a telehealth model based upon direct communication between a provider and a consumer. No other providers or telepresenters are present with the patient. This can be a key "value add" for providing "on demand" and convenient health care. The ability for consumers to "see a doctor now" is often touted as resulting in higher patient satisfaction with their health care services. In direct-to-consumer models, consumers, through technologies on mobile apps, websites, etc., can connect with a provider from just about anywhere. Parents who do not want to transport sick children, and people who simply feel too sick to leave the house, view the ability to access care from home as the most convenient feature of the D2C model. Employers are increasingly offering D2C telehealth models as a benefit under their health plans and may provide telehealth "kiosks" at their business locations. D2C telehealth connections are also appearing in malls, airports, and schools, not only for the benefit of employees at those locations but also for patrons, travelers, and students.

In a D2C model, consumers connect with providers who have agreed to be available to respond to consumer requests for services. D2C telehealth providers may be subject to response time requirements, as users in this model often require more immediate service. Consumers utilizing D2C telehealth often cannot timely readily access a health care provider in a facility, and use telehealth primarily for its on-demand function. Most often the provider and consumer have not had a prior interaction, (i.e., established a provider/patient relationship). In the absence of such a relationship, consumers are often directed to receive any necessary follow-up from their existing provider or to find a local provider who can provide the necessary care. Other D2C models enable consumers to directly connect with their existing provider or provider group. In these models, the consumer is an existing patient of the provider or group practice, such that there is less uncertainty as to the provision of follow-up care.

While D2C most commonly offers on-demand services, some D2C models offer the option of scheduling future appointments. The advance scheduling option is likely selected when choice of provider is more important than the immediacy of the consultation.

Given the absence of a telepresenter with the patient in most D2C models, consideration should be given to the type of information that should be disseminated to consumers prior to commencing a telehealth consultation.

2.2.3 Remote Patient Monitoring

Through remote patient monitoring (RPM), patient data is collected and transmitted through an electronic connection to providers in remote locations. The providers are tasked with monitoring and assessing the patient's current health status and, based on the data, making any recommendations for interventions, modifications in care protocols, etc. Data collected runs the gamut, but common examples include vital signs, breathing patterns, wound care progression, heart rate, and blood pressure. The monitoring health care providers can be in a variety of locations, including hospitals, nursing facilities, physician practices or off-site centralized monitoring facilities. RPM can be performed in patients' homes or in a health care facility setting. Many states include RPM in their definition of *telehealth* or *telemedicine*. With respect to Medicaid coverage, many state Medicaid programs provide reimbursement for remote patient monitoring, though some limit the reimbursement to monitoring for certain conditions, such as congestive heart failure, COPD, asthma or diabetes (as in Colorado), or for certain services such as skilled nursing home visits (as in Minnesota).[7]

Asserted benefits of RPM include early detection and intervention of medical issues before they become critical, reduction in hospital admissions or emergency room visits and improvement in the quality of life of patients who are allowed to remain in their own homes. RPM may provide the most benefit to chronically ill patients (e.g., congestive heart failure, pulmonary disease (COPD) patients) who require constant management, which, historically, could be provided only within a facility setting. Proponents also highlight RPM as an approach to keeping the elderly population in their homes. Given these benefits, states that do not currently reimburse for or recognize RPM may soon reevaluate that position. Kentucky, for example, recently passed legislation to establish a pilot project creating coverage and reimbursement criteria for "telemonitoring" services.[8] Medicare has yet to include RPM as a reimbursable modality. However, recent expansion of reimbursement for management of chronic care via non-face-to-face encounters indicates that CMS recognizes the benefits of remote management of the chronically ill. Further, there have been numerous government mandates for studying the impact and benefits of RPM, which indicate that the government has not written it off yet as a viable and legitimate telehealth service delivery model.

[7] 10 CCR 2505-10:8.525 (2017); Minnesota Provider Manual—Home Care Services (2015).

[8] Ky. Rev. Stat. Ann. § 205.632 (2016).