

TELEMEDICINE: REGULATORY AND LIABILITY TRENDS

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Introduction

There has been a rapid adoption of telemedicine and telehealth technology in the United States over the last decade. In this article we briefly review the growth of telemedicine and telehealth technology and examine some of the main regulatory and liability considerations pertinent to insuring and managing the risk of health care services arising out of a patient-provider video encounter, what we will deem “classic telemedicine”. The goal is to provide an overview of the growth of telemedicine/telehealth, the types of telemedicine and telehealth technologies in common use today, and applicable regulatory and legal issues pertinent to medical professional liability.

The Growth of Telemedicine/ Telehealth

Major factors that have driven the growth of telemedicine and telehealth include lower cost; patient demand; better acceptance for reimbursement by payers; and a more favorable regulatory environment.¹ There also have been great strides in the development of telemedicine and telehealth technology.²

The ongoing investment in new digital telehealth technology is in the billions of dollars. There were 7 million patient encounters via telemedicine in 2018 and this number is expected to almost triple by 2020 and to continue to increase dramatically in the years ahead.³ Telemedicine provides two key advantages in delivering care: lower cost and easier patient access - convenience.⁴

Telemedicine/telehealth has been adopted by many medical specialties and many types of facilities, especially hospitals. Examples of patient-physician video encounters can best be seen in the primary care specialties of internal medicine, family practice and pediatrics, as well as in psychiatry and neurology (especially stroke care), but utilization goes well beyond those disciplines. Telehealth technology allows for remote diagnosis and improved care in such specialties as radiology, cardiology, obstetrics, dermatology, pathology and many others.⁵

Many hospitals and health care systems as well as physician groups are beginning to use telemedicine for follow-up visits after surgery⁶ as well as for helping patients manage chronic conditions such as heart failure or diabetes through remote monitoring as well as video encounters.⁷ Telemedicine offers promise for treating substance use disorder and thereby helping address the opioid problem.⁸

Telemedicine and Telehealth

It is not easy to define the terms telemedicine and telehealth and they are sometimes used interchangeably. “Telemedicine” has at least 100 definitions in peer-reviewed publications. It has been around longer than “telehealth.” For our purposes in this article, “telemedicine” can be thought of as the patient-provider video encounter. But many think telemedicine came into its own through teleradiology, sending films and scans across state lines and even across international borders.

Telemedicine is defined by the American Telemedicine Association as “the use of medical information exchanged from one site to another via electronic communications to improve patients’ health status.”⁹ “Telehealth” is a broader term that encompasses the many and varied applications of distance care technology, often consumer facing, in a rapidly evolving health care environment.¹⁰ The increasing emphasis on care management, particularly for patients with chronic conditions, and the focus on health and wellness for disease management and prevention all fall within the purview of telehealth.

Telehealth

In September of 2017, the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services defined telehealth as: “the

use of electronic information and telecommunications technologies to support and promote long-distance clinical health care, patient and professional health-related education, public health and health administration. Technologies include videoconferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications.”¹¹

Telehealth technology can be either synchronous (in real-time, as with electronic fetal monitoring) or asynchronous, a/k/a “store-and-forward” (not concurrent, as with radiology films/scans). Below are examples of telehealth technology.

Remote Monitoring Technology

This modality of telehealth involves the collection of a patient’s personal health and medical data via electronic communication technologies. Patients can be monitored in non-clinical environments as well as in clinical ones. Once collected, the data are then transmitted to providers at another location. Remote monitoring is a form of telehealth that can be either synchronous or asynchronous. It can be used for conditions requiring immediate treatment or to monitor chronic conditions over time.¹²

Wearable Devices/mHealth

There are many wearable devices at present and they continue to be developed and improved. These devices can monitor patients outside an acute care or long term care setting. Such monitoring has the potential to markedly reduce health care costs. The future is exciting, as these devices can help not only with real-time monitoring, but also with prevention and early diagnosis. They can help patients remember to take medications and can detect non-adherence. They can serve as medical alarms when patients have an event putting them at risk. Commercial products such as Fitbits and smartphones can also be used track health and wellness.¹³

Data Storage and Review

This component of telehealth has been utilized for some time. Teleradiology is one of the earliest, and to date most common, uses. It is also called store-and-forward telehealth and is the collection of clinical information in various formats. These include videos; images; radiologic

scans, films and studies; sound files; laboratory reports and other medical records. It facilitates second opinions and, since its use is asynchronous, it is more convenient to both practitioners' and patients' schedules. This technology is used by many physician specialties such as radiology and also dermatology and ophthalmology, among others.¹⁴

Communication/Education

Patient and family education and communication can be greatly facilitated using software apps and online portals. Information to promote health and communication with health care professionals is available on demand.

Telemedicine (in real-time care delivery)

This component of telehealth is the "classic telemedicine" patient-provider encounter and the primary focus of this article. It is a live, two-way interaction between a provider and a patient in real-time using audiovisual equipment. It is performed using audio-visual equipment and the patient's phone, tablet or computer. It can be done in a dedicated kiosk, such as often occurs in a commercial pharmacy setting. It can also involve video monitoring of the patient as in Tele-ICU monitoring, for example. The audio-visual technology used for these encounters has improved greatly in recent years.

CMS defines telemedicine as:

"A two-way, real-time interactive communication between a patient and a physician or practitioner at a distant site through telecommunications equipment that includes, at a minimum, audio and visual equipment."¹⁵

Telemedicine Improves Care/ Reduces Costs

Video visits with primary care providers offer access, convenience and speed to patients. They promote care in the lowest cost, often most appropriate setting. This form of telemedicine can prevent over-utilization in the form of reduced visits to physician offices, urgent care centers, and the emergency department; it can also avoid long waits for primary care. The telemedicine encounter typically costs appreciably less than office and urgent care visits and far

less than ED visits.¹⁶ The biggest savings of all arise when because of distance care, admission to a hospital can be avoided.

Reimbursement is the Key

While there has been rapid adoption of many of the various components of telehealth and telemedicine, the key to future growth is reimbursement, especially by CMS. Commercial payers and employers have perceived the advantages of telemedicine and telehealth, and this has led to much greater acceptance in recent years of telemedicine and telehealth for reimbursement.¹⁷ Most major commercial health insurers are now offering various types of telehealth benefits.

A full discussion of reimbursement for distance care is beyond the scope of this piece. Until very recently, however, Medicare reimbursement has been limited to paying for only certain services, and only for beneficiaries who live in underserved or rural areas and who, at the time of care, were in health care facilities.¹⁸ Under its current leadership, however, CMS has embraced new codes for telehealth reimbursement. Two examples in 2019 are payment by CMS for care by telehealth methodologies for stroke and dialysis patients.¹⁹ CMS has also authorized reimbursement for some services rendered to beneficiaries in their homes, including patients undergoing home dialysis.

Regulatory and Statutory Issues

Licensure

Licensure is the primary mechanism states use to regulate the practice of medicine. They tend to guard their sovereignty jealously. States do not wish to cede this authority to the Federal government. That's understandable, but it has created problems for professionals seeking to offer telemedicine services.

In traditional in-person care, of course, the physician and the patient are present together at a given location. A defining characteristic of telemedicine, however, is that the doctor is in one location; the patient, in another. Those locations could be in the same state, the same town, or even the same building, but they might be in different states or countries. One party could be here on

earth and the other in outer space. In every American jurisdiction that expressly answers the question, if the two participants are in different jurisdictions, the law (statute or regulation) provides that the care occurs at the patient's location.²⁰ In no jurisdiction, however, in any reported case, has any state's highest court addressed the issue. In a few jurisdictions, the law is silent on where the care is provided in such circumstances. One of us has argued that, where the law is silent, one could take the position that the care is rendered at the provider's location.²¹

Why does the question matter? Because the doctor must be licensed where the care occurs. If that were the physician's own jurisdiction, he would already be licensed there, presumably, and would have no need for licensure elsewhere. Were the Board to make inquiry, the investigation and any potential formal or informal hearing would be in the doctor's state. If, however, the care occurs at the patient's out-of-state location, the physician needs to hold a license adequate under the laws of that state to care for its patients from afar, to submit to the jurisdiction of that state's Board, and to be prepared to travel there if need be to defend himself before a hearing panel.

Despite the fact that in some places the law offers no express answer, the wiser course, and the only one we can recommend, is to assume that where the law is silent it would conclude that care occurs where the patient is and that, therefore, it behooves the provider to maintain licensure in the patient's jurisdiction. The safest course for a doctor who proposes to care for patients in multiple jurisdictions, then, is to obtain and maintain licensure in each. The associated hassles are not trivial: each state charges a fee for licensure renewal, which will likely fall due on different dates; each has its own CME and documentation requirements; usually, each conducts hearings at its headquarters and will likely require the licensee to appear there in person. It would be better to learn after the fact that this multiple-license approach entailed needless effort, however, than to learn that the physician was engaged in what the applicable Board may deem to be the unauthorized practice of medicine in the patient's state.

Depending on the jurisdiction, there may be an exception obviating the need for multiple licenses. States may enter into reciprocating agreements, for example. The District of

Columbia allows a physician licensed only in Maryland to care for DC residents even though he lacks a DC license.²² Often, as in this example, the deal must be reciprocal: Maryland extends the same courtesy to DC physicians. Many states allow a doctor in another state to consult with one in-state even though the former is not licensed in the state. West Virginia, for example, allows practitioner-to-practitioner consultations, but for a single occasion only.²³ In North Carolina, consultants without a NC license are allowed to care for patients on an "irregular basis."²⁴ Under licensure by endorsement, a state board accepts the license granted by another state with similar standards.²⁵ Sometimes a state will allow a doctor in an adjoining state but within a short distance of the border to act as if he were licensed by the first state, or to provide virtual care across state lines in follow-up after a procedure such as a surgical operation. Some states issue special licenses / certificates related to the provision of telehealth services, allowing out-of-state providers holding such licenses to render services provided certain conditions are met, such as not opening an office in the state. Examples: Alabama, Louisiana, Minnesota, Montana, Nevada, New Mexico, Ohio, Tennessee, Texas, Wyoming. In many states, for a physician-to-physician communication, to which the patient is not a party, a license is not required. Sometimes this is very limited: Michigan allows consultation by an out-of-state physician only in "exceptional circumstances" (a term that does not appear to be defined).

Rhode Island offers a general consultation exception, but it appears that out-of-state physicians must obtain a Rhode Island license before providing telemedicine services in the state (even if they are just providing consultation). Other exceptions include medical emergencies and disasters, follow-up care, and free "curbside" consults.

In recent years, states have developed a compact, a kind of interstate contract, under which a physician licensed in one signatory state may shoulder a lighter administrative burden when he seeks licensure in another signatory state. Under the Interstate Medical Licensure Compact ("IMLC")²⁶, the physician must still become licensed in the second state and must still pay the fees associated with doing so. He becomes subject to the jurisdiction of the Board of Medicine in the second state. But in providing the documentation demanded by State #2, the Compact furnishes a mechanism that obviates the need to re-assemble transcripts, letters, diplomas, board certificates,

etc.; once these are gathered the first time the Compact enables them to be provided wherever needed thereafter. Psychologists and physical therapists have more-or-less analogous arrangements. The nurses have a far more sweeping Compact than do the doctors; theirs provides for recognition by one signatory state of a license issued by another signatory state.²⁷

Credentialing and Privileging

Credentialing is the process health care organizations use to obtain, verify, assess and validate physicians' experience and qualifications. Privileging is the process organizations use, after review of credentials, to grant authorization for a practitioner to provide a specific scope of patient care services. For many years, credentialing and privileging requirements hampered the growth of telemedicine, because the specialist at the academic center, for example, had to submit to the credentialing process at the community hospital where he was asked to consult from afar. This process was tedious and resource-intensive, especially for small rural hospitals under serious budgetary constraints.

In 2011, however, Medicare's Conditions of Participation were changed to simplify the process significantly. Now, if certain requirements are met, the hospital receiving telehealth services may rely on the privileging and credentialing decisions of the hospital providing them. To engage in "credentialing by proxy," the hospitals must have a written agreement that satisfies an array of criteria.²⁸ The agreement must contain provisions requiring the distant-site hospital to use a credentialing and privileging process that meets or exceeds hospitals' Medicare standards.²⁹ The distant-site hospital must provide a list of telemedicine physicians and practitioners privileged there and their current privileges at the distant-site hospital to the hospital or CAH. The hospital must review the services provided to its patients by telemedicine physicians and practitioners covered by the agreement and must provide written feedback to the distant-site hospital addressing at least any adverse events or complaints that relate to the hospital or entity's telemedicine services. The governing board of the distant site hospital must satisfy specified requirements.³⁰ Satisfying all these requirements can be onerous, but this is still preferable to the old approach.

Depending on which jurisdiction's law controls, harm caused by a failure to perform the credentialing and privileging functions for telemedicine services could give rise to a corporate negligence claim that might be difficult to overcome, particularly for a hospital or health care system. Failure to do so also may lead to allegations of the unauthorized practice of medicine, which can result in criminal fines, imprisonment, administrative penalties, and licensure suspension or revocation, with the attendant National Practitioner Data Bank implications. Other risks include payment denials, loss of liability insurance, and Conditions of Participation violations. Thus, those wishing to credential by proxy must do so mindful of the requirements and of the consequences of violations. The practice is nevertheless a significant advance, and reduces the administrative burdens associated with institutional distance care consults.

Privacy Issues

Apart, possibly, from financial data, few types of information are more sensitive to most of us than our health data. One's medical record may document such matters as alcohol or substance abuse, mental illnesses, sexual abuse or sexually transmitted diseases, abortions, child or elder abuse, etc. Highly personal matters all. The law therefore goes to some lengths to protect information such as this from unauthorized dissemination. Its protections extend to virtual care just as they do to conventional, in-person care.

The 800-pound gorilla of American health records privacy law is HIPAA, Public Law 104-191, 110 Stat. 1936, as amended by the Health Information Technology for Economic and Clinical Health ("HITECH") Act. This statute was passed in large part to protect health insurance coverage for employees when they change or lose their jobs. Recognizing, however, that patients might worry about mishandling of their medical data, Congress also wrote HIPAA, and HHS enacted regulations, to provide protections for the privacy and security of what it calls "protected health information," or PHI. Violations can result in fines and penalties, damaging publicity, and even, in egregious cases, criminal prosecution and imprisonment. Violations arise most often from human error, as when a healthcare professional leaves an unencrypted laptop on the train, for example. On the other hand, HIPAA applies

only to covered entities and to their business associates, and not, for example, to the makers of most medical apps. In an era, then, when not all health information is controlled by health care providers and insurers, HIPAA's usefulness is circumscribed. Some argue that the law is outdated.

Long before 1996, when HIPAA was passed, every state in the Union had enacted statutes designed to protect health records as well.³¹ These vary in detail, complexity, and stringency, but they remain good law in the HIPAA era. Indeed, HIPAA itself provides that where, with respect to a given privacy issue, state law is more stringent than federal, state law controls.³² States such as California and New York are example of jurisdictions with particularly exacting requirements. And although under HIPAA there is no private right of action, under state law there often is.

Telemedicine Liability Issues

To date through mid-2019, there have been only a very small number of reported malpractice claims involving telemedicine in a real-time audio-visual encounter or in remote monitoring. Most of the cases filed in the last ten years or more involve teleradiology claims. In the very small remainder of claims, the issue of telemedicine is most always an incidental fact and not the true focus of the case.

Jurisdiction is potentially problematic in telemedicine cases if the encounter occurs across state lines. The courts of the state where the patient was at the time of the encounter will be the most likely place for litigation.

The issue of the appropriate standard of care for telemedicine is evolving. Plaintiffs will argue that that the standard of care in using telemedicine technology is the same as it is when a physical examination is conducted in person. Some state statutes or regulations, in fact, explicitly so provide. There is no case law to date on this point.

Corporate negligence is potentially a major area of exposure. Not credentialing providers, or doing so carelessly, or failing to see that they have the appropriate licenses and credentials to render telemedicine professional services will create hurdles in the defense of any case.

Depending on the rules of evidence in the relevant court,

plaintiffs are apt to invoked state-specific statutes, medical board regulations, American Telemedicine Association guidelines, and specialty-specific guidelines promulgated by specialty societies such as the American College of Emergency Physicians (ACEP) or the American Psychiatric Association (APA) and many others, to attempt to establish the standard of care. The American Society for Healthcare Risk Management (ASHRM), in its "Telemedicine: Risk Management Considerations," points to the Federation of State Medical Boards (FSMB) Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine as not only providing guidance from a risk management perspective, but also representing another form of voluntary guidelines that state medical boards may have adopted. Defendants often take the position that such documentary evidence ought not be used in attacks on defendants. Providers, however, should not merely assume that such arguments will carry the day. In preparing guidelines and the like, then, assuming they feel compelled to do so in the first place, providers should draft their documents with the expectation that their adversaries will try with might and main to use the documents against their drafters and their colleagues.

Telemedicine Claims Scenarios

As noted, telemedicine-related claims have been very few to date. If claims related to teleradiology or the use of remote electronic fetal monitoring are omitted, we are left with only a very few cases to study and learn from. Why is this so?

The numbers of telemedicine encounters to date, while increasing, have remained relatively low. This volume is projected to expand dramatically in the years ahead. Many of the encounters outside teleradiology have been in primary care scenarios where the conditions seen by the physician are mostly benign. But this is changing with rapid adoption of telemedicine technology in many specialties, as for example, to help treat psychiatric patients and stroke patients in remote locations. In the nature of things, broader utilization will, over time, engender more claims.

Informal polling of medical professional liability insurance carriers over the last few years revealed these actual, but minimally described, claims scenarios:

- Incorrect interpretations of images from a home setting (radiology)
- Miscommunication of the timeline for a “stat” reading of a (radiology) film from a home setting
- Failure to communicate presenting symptoms to a remote examining neuro-radiologist and allegedly resulting failure to diagnose a spinal abscess
- Failed telepsychiatry examination communications
- Incorrect diagnosis of a bacterial meningitis from a patient seen in a kiosk in a retail setting
- Suspected stroke incorrectly diagnosed by a telestroke consult
- Failure to adequately monitor remotely and assess an ICU patient for blood loss and hypotension, allegedly resulting in severe brain damage; failure to summon a intensivist for a more thorough bedside examination
- Telemedicine exam should have been performed in-person rather than by video

Telemedicine: Managing the Risk

Despite the paucity of claims to date, the potential for malpractice liability exists as the use of telemedicine expands rapidly. Perhaps the most important actions to be taken to prevent malpractice claims are to obtain good legal advice that thoroughly reviews all applicable state and federal laws and regulations, especially those of state medical board. Telemedicine-specific guidelines promulgated by accrediting organizations, such as the Joint Commission, should also be reviewed, even if only because of their likely use as foundations for arguments by plaintiff’s counsel.

Physician extenders must practice within their state’s licensure laws and defined scope. Credentialing of all providers for their competency and verification of licensure consistent with all state laws and regulations are essential. Staff training and clear definition of roles and documentation for a telemedicine encounter will reduce potential liability. Many organizations have internal telemedicine encounter protocols. These may offer some

insights, but providers must remember they are highly likely to also offer ammunition to plaintiffs’ attorneys. Many medical specialties have created telemedicine-specific guidelines; these can be considered if an entity insists on creating practice or facility protocols.

As mentioned above, ASHRM (the American Society for Health Care Risk Management) has published an excellent, comprehensive monograph on managing telemedicine risk. The document is titled “Telemedicine: Risk Management Considerations” and was published in 2018.

In general, providers should generally not be the very earliest adopters of some new technological advance, but neither should they be the last to sign on. They should build in redundancy and secure good IT support for their distance care services, and should not permit midlevels (NPs and PAs), no matter how talented, to exceed the scopes of their licenses. Providers should educate patients about the limitations of telemedicine and remain astute to decline to use the technology to care for patients whose symptoms suggest that in-person evaluation is indicated. Even where no specific authority compels it, providers offering distance care should obtain and document consent. They should also be cautious in describing the benefits of telemedicine, allowing enthusiasm to overtake reality. Plaintiffs will not hesitate to base contract or warranty claims on overly bullish descriptions even though their authors never intended to make any promises. At each encounter, providers must identify all in attendance and verify their physical location. Providers using telemedicine to care for children should insist that parent or guardian be present, except in cases (adolescents with sexual or substance use problems, for example) where they may not lawfully do so.

Underwriting Telemedicine: Medical Professional Liability

Owing to telemedicine’s explosive growth underwriting medical professional liability insurance for patient-provider telemedicine and the wide range of telehealth technologies encounters is becoming more common. Some insurers have specific policies developed for this service.

But the exposures for telemedicine go beyond medical professional liability, and thus buyers, brokers and underwriters should recognize other significant related

and insurable risks and tailor insurance coverages appropriately. These might include general liability, cyber liability, product liability, and tech errors and omissions liability, depending on the nature of the telemedicine/telehealth products and services.

Here are a few key considerations for insuring or placing coverage for telemedicine:

- Is there intrastate or interstate exposure? How rapidly is the entity expanding across state lines?
- Numbers of patient encounters in the past/projected and numbers by location/territory?
- Is there any international exposure? For example, physicians in a foreign country reading studies or seeing patients through video visits.
- Verification of provider compliance with all applicable licensure laws: statutory or regulatory.
- What portion of the provider's practice is dedicated to distance care?

Conclusion

Telemedicine and telehealth are revolutionizing care delivery not just in the United States but across the globe. The demand for patient-provider video encounters is growing as is their sheer numbers. The technology can help address the shortage of primary care and specialist physicians and mental health professionals outside urban settings.

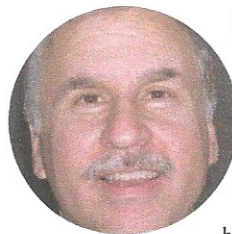
Telemedicine and telehealth can lower costs, especially by redirecting appropriate patient care from more costly settings, whether it is urgent care, emergency departments, the acute care hospital or a long term care settings to cheaper ones, thereby also increasing access and convenience for patients and families.

The number of tort claims to date is very low and this is likely a function of the relatively low numbers of patient encounters so far. It may also be attributable to the fact that providers are simply providing good, thoughtful care.

Telemedicine/telehealth risk is insurable, as its risks are manageable with attention to how insureds comply with state and federal laws and the customs of their peers, to

licensure, and to the other issues considered here. There is great opportunity for the property/casualty insurance industry to grow premium and meet the needs of organizations and providers engaged in telemedicine and telehealth. This extends beyond medical professional liability to coverage for cyber risks, tech E&O, life sciences coverage, and potentially other areas as well.

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End Notes

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- ³¹ e.g., Va. Code § 32.1-127.1:03, the Virginia Health Records Privacy Act, <https://law.lis.virginia.gov/vacode/title32.1/chapter5/section32.1-127.1:03/>.
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