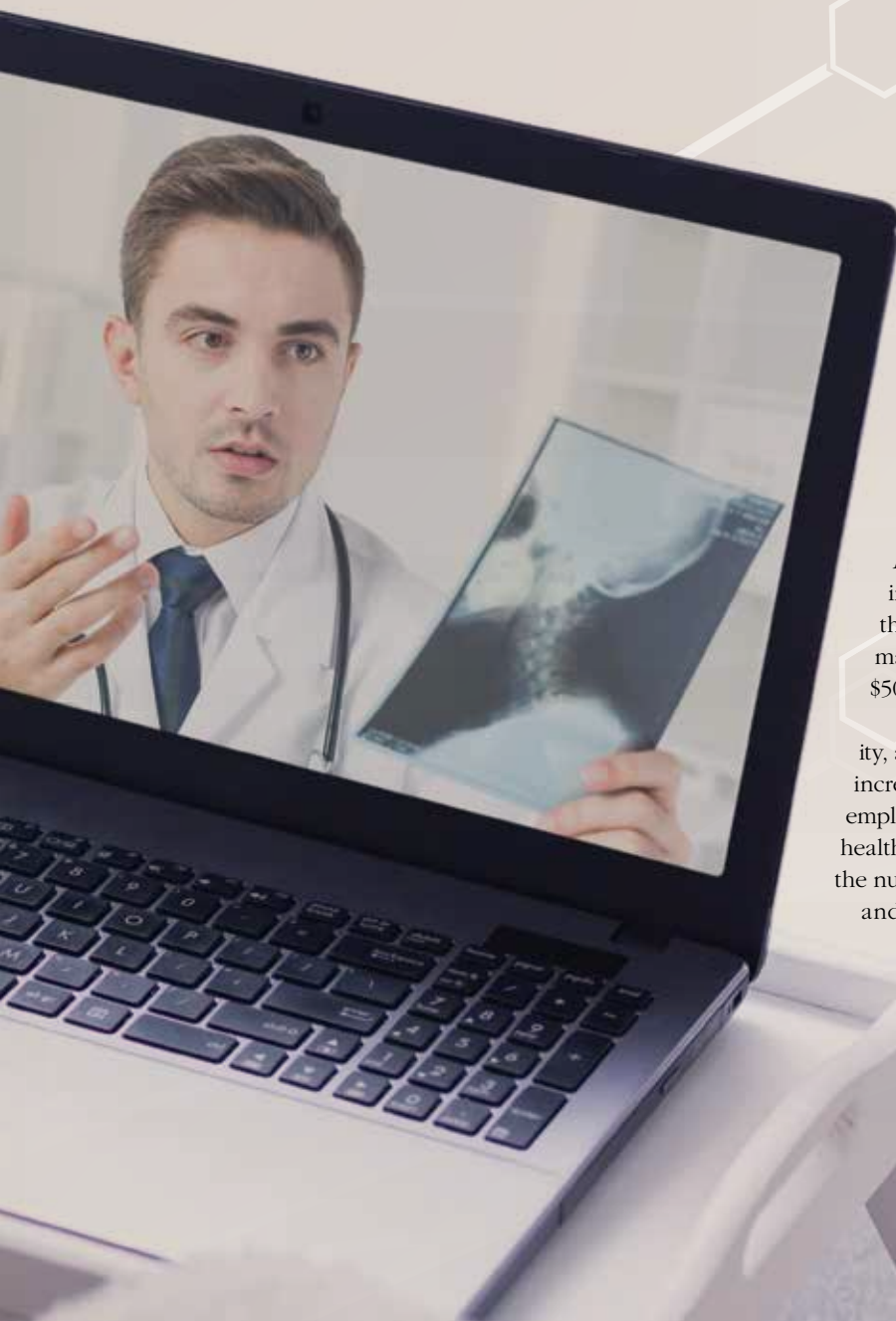


The Promise of Telemedicine

Current Landscape and Future Directions

By Dr. Kimberly Lovett Rockwell



Telemedicine—“[t]he delivery of healthcare services, where distance is a critical factor... using information and communication technologies for the... diagnosis, treatment and prevention of disease...”¹—is a growing industry in the healthcare sector. As of late 2012, 42 percent of U.S. hospitals had adopted telemedicine, which included just fewer than 50 percent of Michigan hospitals surveyed.² Approximately 71 percent of employers say they will offer telemedicine through their health plans by 2017.³ A major health system serving the Silicon Valley projected that it would conduct more telemedicine visits with patients than face-to-face visits in 2016.⁴ And the largest care provider for patients with stroke in the country is now a telemedicine company.⁵ With this growth, the projected value of the telemedicine market in 2020 is approximately \$13 billion (up from \$500 million in 2014).⁶

Several factors contribute to the promise, popularity, and growth of telemedicine. Telemedicine facilitates increased convenience and access to care for full-time employees, homebound patients, and patients located in healthcare professional shortage areas.⁷ It also increases the number of providers able to serve a given population and is quickly accessible; patients can wait several weeks for a physician appointment, but can immediately access telemedicine services via certain platforms that staff healthcare providers around the clock.⁸ Further, mobile and Internet technologies are continuously expanding. Ninety percent of the world population is projected

to have a smartphone by 2020.⁹ And as electronic health records mature, more providers adopt these platforms to receive increased reimbursement under the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009.¹⁰ Finally, telemedicine promises to reduce healthcare costs.¹¹ Indeed, one study projected that large employers could save up to \$6 billion per year if their employees routinely engaged in remote consults instead of visiting emergency rooms, urgent care centers, and physicians' offices.¹²

Currently, telemedicine primarily connotes conversational audiovisual clinical visits with remote providers. As telemedicine services evolve, however, the industry will also be associated with routine data transfer from remote monitoring devices that sense vital signs, clinical symptoms, and cardiac activity.¹³ As the telemedicine industry grows, attorneys must be aware of the rapidly evolving legal, regulatory, and reimbursement landscape. This article broadly reviews the current legal and regulatory landscape and pending federal and Michigan legislation affecting the telemedicine industry.

Telemedicine device technology, the FDA, and safety

Telemedicine delivery requires technology and hardware. Accordingly, alongside telemedicine services expansion, the industry has witnessed growth in the development, manufacture, and use of mobile medical applications and devices to facilitate service delivery and remote patient monitoring.¹⁴ This includes monitoring devices such as blood pressure cuffs and electrocardiography devices that transmit readings over an information network. The Food and Drug Administration (FDA) regulates such devices pursuant to the Food, Drug, and Cosmetic Act of 1938 and the Medical Device Amendments of 1976. The FDA's role is to ensure device efficacy and patient safety.

In September 2013, the FDA issued broad regulatory guidance regarding mobile medical devices used for patient monitoring and data transfer in telemedicine.¹⁵ The FDA requires these device manufacturers to implement "general controls," such as registering with the agency and providing a list of devices they produce or market.¹⁶ Manufacturers may also need pre-market approval from the FDA, requiring clinical data demonstrating device safety and efficacy.¹⁷ Regulated manufacturers must also adhere to the agency's definition of "current good manufacturing practices" as well as other aspects of the agency's quality framework.¹⁸ And finally, manufacturers may be required to track and report adverse events and issue recalls when patient safety issues are uncovered.¹⁹

Healthcare providers who employ such medical device technology on behalf of their patients must demand assurances from device manufacturers that each has honored the

FDA process.²⁰ And hospitals and healthcare systems are advised to develop internal policies and procedures for monitoring and reporting adverse patient safety events.²¹

Federal data security and privacy laws

The telemedicine industry is especially vulnerable to exposing private patient health information given its reliance on electronic data collection and storage and frequent distant data transfer. Since its enactment in 1996, the Health Insurance Portability and Accountability Act (HIPAA) dictates the privacy and security regulatory framework to protect identifiable patient health information when it is collected and shared by "covered entities" such as healthcare providers and health plans. HIPAA's Privacy Rule establishes limits on the use and disclosure of identifiable health information while its Security Rule imposes technical, physical, and administrative safeguards that must be implemented to protect the integrity and confidentiality of electronic identifiable health information. The Security Rule safeguards include, for example, password protection and encryption of data at rest and in transit. Every healthcare provider and entity providing direct telemedicine services must ensure strict compliance with HIPAA as it relates to all telemedicine devices and data transmission and storage sites under its control to avoid fines, penalties, and other sanctions.

Furthermore, the HITECH Act of 2009 extends several HIPAA privacy and security requirements to certain "business associates" that "create, receive, maintain, or transmit" identifiable health information while performing a service or function on behalf of a covered entity. Whether a patient-facing telemedicine technology vendor is a HIPAA business associate subject to these regulations is a complex question depending on multiple variables. Electronic health records, video storage devices, telemedicine devices, and any other data-generating or receiving device involved in the telemedicine interaction

FAST FACTS

Telemedicine is a rapidly growing, quickly evolving, and exciting area of the healthcare industry.



Attorneys must be prepared to advise telemedicine clients on medical device compliance, HIPAA/HITECH compliance, interstate licensure and credentialing issues, state scope of practice restrictions, unique malpractice issues, and reimbursement restrictions.

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carries the potential to collect and store protected health information. Collection and storage of that information as well as any use or disclosure are subject to federal HIPAA and HITECH laws. Attorneys must consider whether their clients and the services they provide to healthcare entities qualify them as business associates under the HITECH Act to ensure compliance with these federal regulations.

State requirements for providers engaging in telemedicine

Each state restricts the scope of permitted telemedicine services within state boundaries. First, states define “telehealth” and “telemedicine” differently to include or exclude various services or practice situations.²² For example, Michigan defines “telemedicine” as “the use of an electronic media to link patients with health care professionals in different locations.”²³ To be considered telemedicine in Michigan, “the health care professional must be able to examine the patient via a real-time, interactive audio or video, or both, telecommunications system and the patient must be able to interact with the off-site health care professional at the same time the services are provided.”²⁴

States also differ on whether and when a provider must physically see a patient to engage in telemedicine services. Georgia and Texas, for example, require an in-person follow-up with the provider after a telemedicine encounter²⁵ while Michigan has no such physical encounter restriction.

Further, some states—including Texas, Alaska, and Hawaii—require that a healthcare provider, known as a telepresenter, be present with the patient at the time of the telemedicine encounter.²⁶ Michigan does not require a telepresenter.

Finally, nearly every state restricts online prescribing in some form. Most states require the provider to directly engage the patient via video or telephone to prescribe *any* medications online (i.e., mere review of a patient-completed questionnaire cannot serve as the basis for a prescription). Michigan,

for example, requires that telemedicine providers have an “existing patient-physician relationship” to prescribe online.²⁷ And Idaho’s 2015 legislation explicitly indicates that treatment based solely on an online questionnaire does not constitute an acceptable standard of care.²⁸ Many states, including Michigan, also do not permit online prescribing of abortion-inducing medications.²⁹ And while the federal Drug Enforcement Administration has jurisdiction over online prescribing of controlled substances and permits telemedicine providers to prescribe controlled substances online under a limited set of circumstances,³⁰ some states do not permit any online controlled substance prescribing. Pending legislation in Michigan, for example, would restrict online prescribing to non-controlled substances only.³¹

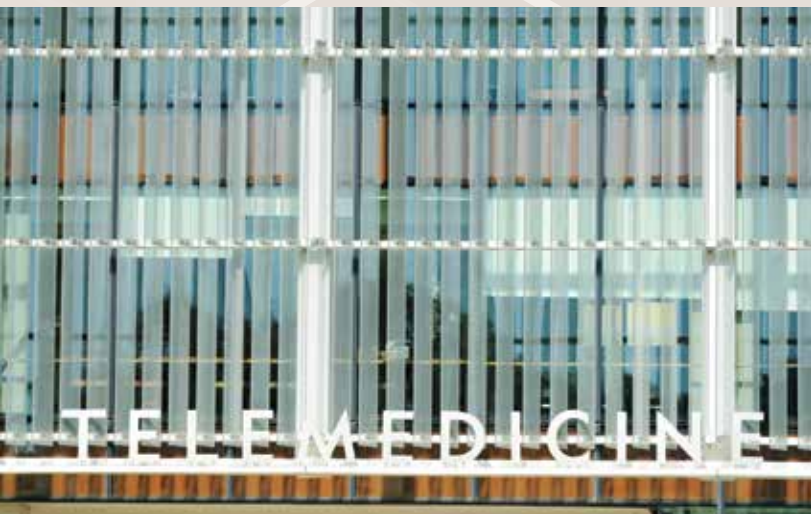
Attorneys must be familiar with the scope-limiting restrictions in each state in which patients may receive telemedicine services from a client. The American Telemedicine Association’s State Policy Resource Center, found at <http://www.americantelemed.org/main/policy-page/state-policy-resource-center>, is a great place to start when evaluating state-by-state policies.

Reimbursement

Like state rules, different payers also construct nuanced rules that significantly restrict the scope and types of reimbursable services. Medicare, like most other payers, will only reimburse for live audio-video telemedicine services and will not reimburse for remote monitoring services.³² Michigan Medicaid also reimburses live video services for a number of clinical situations, but is silent on remote monitoring services.³³

Most payers will not reimburse for telemedicine services delivered to a patient at the patient’s home or from a non-clinical location via a personal mobile device³⁴—scenarios vitally important for increasing access to and convenience of telemedicine services. Medicare and Michigan Medicaid will only reimburse telemedicine services for which a patient receives care at a designated subset of healthcare facilities.³⁵ Medicare goes further by narrowly restricting the geographic areas that are eligible for telemedicine reimbursement to extremely rural areas or known health professional shortage areas.³⁶

Twenty-nine states now have variously structured “telemedicine parity laws” that require private insurers to reimburse telemedicine services similarly to in-person care.³⁷ Michigan dictates, for example, that payer-provider contracts not require face-to-face contact between a provider and patient for services appropriately rendered through telemedicine.³⁸ Despite these parity laws, however, states leave significant discretion with private payers, and telemedicine reimbursement often mirrors Medicare reimbursement.³⁹



Given the barriers of obtaining reimbursement from public and private payers, many telemedicine companies instead contract directly with employers to provide relatively low-cost telemedicine services to employees. These telemedicine providers typically charge a flat fee per visit or a capitated annual fee per employee.⁴⁰ Attorneys should be aware of reimbursement difficulties and ready to support clients looking to creatively monetize telemedicine services.

Interstate licensure

For providers to practice telemedicine across state lines, they must be licensed in every state in which patients receive their services. Michigan law, for example, provides that private

payors and Michigan Medicaid need not reimburse telemedicine services not furnished by a Michigan-licensed provider.⁴¹ And though physicians are required to pass national accreditation examinations to qualify for both medical licensure and board certification, each state licenses physicians separately.⁴² The requirements for any given state can be onerous, including high annual fees, criminal background checks, in-person interviews, and certified copies of medical school and residency diplomas.⁴³ Such varied requirements make it difficult and unappealing for physicians to maintain licenses in multiple states.

There exist some solutions to this interstate licensing problem. For example, nine states—Louisiana, Maine, New Mexico, Oklahoma, Oregon, Tennessee, Texas, and Minnesota—issue special telemedicine licenses or certificates.⁴⁴ Such licenses could allow an out-of-state provider to render telemedicine services if certain conditions are met (e.g., the provider cannot open a physical office in the state).⁴⁵ Other states, including Maryland, New York, and Virginia, have reciprocity statutes that permit physicians licensed in bordering states to practice within the participating states without obtaining a separate state license.⁴⁶ Additionally, 17 states—Alabama, Arizona, Colorado, Idaho, Illinois, Iowa, Kansas, Minnesota, Mississippi, Montana, Nevada, New Hampshire, South Dakota, Utah, West Virginia, Wisconsin, and Wyoming—have adopted some version of the Federation of State Medical Board's Interstate Licensure Compact, which permits an expedited process for licensed physicians to apply for other state licenses.⁴⁷ The specific details of how the compact will operate in each state are not yet known, but this expedited process will ostensibly mitigate the otherwise onerous and divergent licensing requirements of each participating state.⁴⁸ Michigan and Pennsylvania also have pending legislation to adopt the compact.⁴⁹

Medical malpractice coverage

Related to interstate licensure issues, medical malpractice coverage for physicians rendering telemedicine services in several states can pose significant difficulties as well. The scope of medical malpractice coverage is dictated by contract, not statutory law. And while some malpractice insurers provide special riders for telemedicine coverage, many will only cover claims for face-to-face encounters for which the insurer agreed to cover the provider. Malpractice insurers may not even be licensed in states where patients are receiving telemedicine services from the provider. Attorneys and providers must ensure that the provider's malpractice insurer is licensed in the same states where patients are served and check the insurance contract to verify the telemedicine claims are covered. It is also important to advise providers that personal

jurisdiction and choice-of-law issues are complicated in malpractice actions given the interstate nature of providing telemedicine services.

Conclusion

For clients looking to establish or expand an existing telemedicine program, an attorney must examine federal and state laws and regulations to determine the types of services that may be offered in various states and help clients navigate the many privacy, security, medical device, reimbursement, licensing, and credentialing issues facing the telemedicine industry. Telemedicine laws are changing rapidly with new legislation being evaluated at the state and federal levels every year. Attorneys must stay apprised of the changing legal and regulatory landscape to advise healthcare clients who are interested in engaging in this expanding and exciting healthcare industry. ■



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