COMMENTARY

Legal Perspectives on Telemedicine Part 1: Legal and Regulatory Issues

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ABSTRACT

Telemedicine is defined as the remote delivery of clinical care services through audiovisual conferencing technology. A shortage of care practitioners combined with an aging population with disproportionately increasing care utilization patterns has created a "perfect storm," which since the late 1990s has propelled telemedicine as a potential solution to bridge this supply/demand and access gap. In critical care approximately 20% of nonfederal adult intensive care unit (ICU) beds in the US today are supported by some form of tele-ICU coverage. The literature has shown with increasing clarity during the last decade that correct tele-ICU implementation improves outcomes and has the potential to significantly improve the financial performance of health care systems. As is often the case in technology-driven innovations, the legal and regulatory framework has been moving slower than the clinical adoption of this new care delivery model, which is true not just in critical care, but in other medical specialties as well. This 2-part series focuses on legal perspectives on telemedicine. The first part discusses legal and regulatory challenges of telemedicine in general, with a more in-depth focus on tele-ICU. The second part will discuss the effects of telemedicine implementation on medicolegal risk, using the litigious critical care environment as an example.

INTRODUCTION

Telemedicine is defined as the remote delivery of clinical care services through audiovisual conferencing technology.[1] In the US today, approximately 20% of nonfederal adult intensive care unit (ICU) beds are supported by some form of tele-ICU coverage.[2,3] The literature has shown during the last decade that correct tele-ICU implementation improves outcomes and can significantly improve the financial performance of health care systems.[4-8] This first of a 2-part commentary discusses legal and regulatory challenges of telemedicine in general, with a more in-depth focus on tele-ICU.

THE LEGAL AND REGULATORY LANDSCAPE TODAY

Implementation of telemedicine solutions is being encouraged and assisted by both state and federal government, as well as multiple medical associations, including the American Medical Association. At the federal level, the Department of Health and Human Services, largely through its Health Resources Services Administration and Office for the Advancement of Telehealth, has become increasingly involved in telehealth by administering telehealth grant programs (including a focus on licensure portability), providing technical assistance, developing telehealth policy initiatives to improve access to quality health services, and promoting knowledge exchange about "best telehealth practices."[9]

In 2016, the American Medical Association adopted new guidelines for ethical practice in telemedicine.[10,11] These guidelines advise physicians participating in telehealth/telemedicine to recognize the limitations of the relevant technologies and to take appropriate steps to overcome such limitations, recognizing that a coordinated effort across the profession is necessary to achieve the promise and to avoid the pitfalls of telemedicine. For example, physicians practicing telemedicine must ensure that appropriate protocols are in place to protect the security and integrity of patient information.

Although the government is helping in many ways to stimulate the growth of telemedicine, there is currently no uniform legal approach to telehealth, which continues to be a major challenge to its progress. Telehealth implementation varies widely from state to state in terms of how much service providers will be reimbursed for delivering telehealth services, as well as what sort of *parity* (defined as equivalent treatment of analogous services) is expected between in-person health services reimbursements vs telehealth reimbursements. Currently, 41 jurisdictions have laws that govern private payer reimbursement of telehealth.[12]

Thirty-six states and the District of Columbia have parity laws that cover private insurers and reimbursement for telehealth services.[12] However, many variations exist in how states and private insurers pay reimbursements and what they cover. Twenty-three states and the District of Columbia have full parity, meaning coverage and reimbursement is comparable from in-person to telehealth services. However, the current telehealth coverage laws of 15 states lack parity language, meaning that reimbursement by health plans for telehealth services is not required to be at the same rate as what is paid for in-person services.[12] Without parity, the incentive to provide telehealth services decreases, and telehealth may be prohibitive to adopt and use.

On the federal level, Medicare reimburses for synchronous communications (meaning real-time bilateral audiovisual interactions) and does not cover any store-and-forward services (eg, a radiologic

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image that is taken, digitally forwarded, and stored, to be retrieved and interpreted later) or remote patient monitoring for chronic diseases, except in Alaska and Hawaii. The federal government places numerous limitations on Medicare reimbursement for telehealth services, based on the location of the patient and practitioner as well as the type of distant site facility. For example, patient location must be within an area considered to be a Health Professional Shortage Area or area outside a Metropolitan Statistical Area and be one of the following sites: Hospital, critical access hospital, dialysis center, skilled nursing facility, community mental health center, physician office, rural health clinic, or federally qualified health center.[13]

In 2017, a bipartisan Congressional Telehealth Caucus was formed, and 2 bills were relaunched in an effort to modernize how Medicare reimburses telehealth services and to expand coverage for Medicare beneficiaries. Both bills, the Medicare Telehealth Parity Act of 2017[14] and the Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act of 2017,[15] are under consideration by Congress. On June 1, 2017, the Medicare Telehealth Parity Act was referred to the House Subcommittee on Health. On May 30, 2017, the CONNECT for Health Act was referred to the Senate Committee on Finance. Also being considered by the Senate Committee on Finance is the proposed Creating High-Quality Results and Outcomes Necessary to Improve Chronic Care Act of 2017,[16] which includes a section that would allow greater use of telehealth. In a press release, Representative Mike Thompson (D-CA) stated that "Telehealth saves lives and reduces costs; it's a win-win for both patients and providers."[17]

LEGAL AND REGULATORY CHALLENGES

Professional licensing for telemedicine practitioners is often cited as a barrier to the expanded use of telehealth and telemedicine. In one of the early cases addressing telemedicine, *Hageseth v Superior Court of California*,[18] a California court asserted jurisdiction over Dr Hageseth, then a Colorado-licensed psychiatrist, and criminally charged him with practicing medicine without a license in California. Dr Hageseth had prescribed medication over the Internet to a patient in California, who then committed suicide.[18] After Dr Hageseth's challenge to the court's jurisdiction failed, he pled guilty and was sentenced to 9 months in prison. This case demonstrates the complexity of telemedicine from a legal perspective and the importance of physician education regarding licensure requirements for practicing telemedicine across lines.

Since *Hageseth* was decided in 2007, there has been considerable progress in the area of cross-state licensing for the practice of telemedicine. That said, current licensure requirements for practicing telemedicine across state lines vary widely from state to state. A detailed explanation of each state's current laws and reimbursement policies for telehealth can be found at www.cchpca.org.[12] Most states still require a physician to be licensed in the state in which the patient is located. Nine state medical (or osteopathic) boards issue special licenses or certificates related to telehealth, which could allow out-of-state practitioners to render services via telemedicine in a state where they are not located or allow clinicians to provide services via telehealth in a state if certain conditions are met, such as agreeing that they will not open an office in that state. Those states are Alabama, Louisiana, Maine, Minnesota, New Mexico, Ohio, Oregon, Tennessee (osteopathic board only), and Texas. Some states have laws that do not specifically address telehealth and/or telemedicine licensing but make allowances for contiguous states or for certain situations where a temporary license might be issued, provided the specific state's licensing conditions are met. The most common licensure exceptions include physician-to-physician consultations, public health services, medical emergencies ("Good Samaritan"), or natural disasters.

Although attempts at federal legislation to address the cross-state licensure barrier to telemedicine have not yet succeeded, the issue has been addressed by the Federation of State Medical Boards in the Interstate Medical Licensure Compact (IMLC), which is expected to help streamline the licensure process by offering a voluntary expedited pathway to licensure for qualified physicians who wish to practice in multiple states. Nineteen IMLC member states currently serve as the state of principal license, processing applications and issuing licenses. Five states have passed IMLC legislation, but implementation is in process or delayed.[19] Twenty-nine state medical and osteopathic boards have endorsed the IMLC.

In addition to regulatory challenges, the move toward providing more telehealth-based services across state borders has raised legal concerns.[20] For example, whereas some malpractice liability policies cover multiple states, most specify that coverage is available only for claims occurring in a specific jurisdiction. A telehealth physician sued in a state other than the jurisdiction in which s/he is covered might find that no coverage is available. Practitioners also need to confirm that their policies include coverage for telemedicine.

RECOMMENDATIONS

As more studies demonstrate increased quality of care and patient satisfaction and the institutional cost savings resulting from telemedicine,[5-8,21] the health care industry should embrace it in multiple disciplines. Given practitioner shortages throughout the US, in both rural and urban areas, telemedicine has a unique capacity to increase and improve service to millions of new patients. However, there are important steps that must be taken in the regulatory and legal contexts, to maximize the impact of telemedicine:

- A uniform standard and/or a streamlined process to obtain medical licenses for physicians who practice telemedicine in multiple jurisdictions should be established
- Congress should provide clarity on reimbursement rates so that practitioners understand which telemedicine services private and public insurance policies will reimburse
- Medicare coverage of telehealth services, including remote patient monitoring, should be expanded beyond rural areas

- Universal parity laws should be enacted to reduce barriers to entry for hospital systems and providers to implement these services
- State legislatures should consider codifying a heightened standard of care in malpractice cases against health care providers with telemedicine in place
- Research funding for telemedicine should increase, to advance the field by supporting important research on implementation, resource utilization, quality improvement, and clinical outcomes.

Additionally, health care institutions, schools, and practitioners should take the following actions to promote telemedicine:

- Professional associations should increase education regarding the resources available to support and encourage telemedicine development, including the existence of policies and protocols for telehealth, should be easily accessible to health care practitioners
- All health care entities should explore the utility of forming or partnering with Departments or Centers for Telemedicine, to increase access to central telemedicine expertise to clinicians and to take advantage of synergies in organization, implementation, coordination, and support of telemedicine projects across the spectrum of care (similar to how information technology has evolved as an entity in modern medicine)
- Telemedicine must become an integral part of graduate and postgraduate medical education for physicians and nurses. Medical schools and nursing schools should develop comprehensive telehealth curricula, including lecture series, clinical clerkships, and rotations. The next generation of health care practitioners must be well educated on how to incorporate telemedicine into their clinical practices
- Health care practitioners should stay informed of pending legislative and regulatory developments in telehealth, especially those relating to reimbursement and license portability.

CONCLUSION

To expand a care delivery model that improves patient care, increases access for patients, and enhances the capabilities of practitioners, while at the same time having the potential to greatly lower health care costs in multiple sectors, it is essential to establish a uniform standard for licensing physicians who practice telemedicine, to provide clarity on reimbursement rates, and to educate the health care industry regarding the many resources available to support and encourage telemedicine development. ❖

Disclosure Statement

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