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For Physicians

Legal and Reimbursement Issues of Remote Health Care Delivery

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Use of technology in the clinical practice setting is no longer science fiction but a reality. The global telehealth market is projected to reach $9.35 billion by 2021.[1] Payors, health care providers, and patients are recognizing that telemedicine can expand access to immediate and convenient care and decrease health care costs.

With the transition in administration, push to repeal and replace the Affordable Care Act, and legislative changes affecting the delivery of health care, providers need to keep abreast of the changes to stay competitive. The GOP's A Better Way Plan which outlines the GOP's proposal to repeal and replace the Affordable Care Act includes proposals to promote innovation in health care.[2] The GOP's plan builds on the efforts of the 21st Century Cures Act (H.R.6) which was passed by the House in 2016 and includes various reforms

[1] Cohen, Jessica Kim, *The Growth of Telehealth: 20 Things to Know*, Becker's Health IT & CIO Review (December 22, 2016), *available at* http://www.beckershospitalreview.com/healthcare-information-technology/the-growth-of-telehealth-20-things-to-know.html (last visited on 12/27/16).
[2] *Available at* http://abetterway.speaker.gov/_assets/pdf/ABetterWay-HealthCare-PolicyPaper.pdf

to accelerate discovery, development, and delivery of new treatments and cures (e.g., removing regulatory uncertainty for new technology like mobile apps).[3]

Specifically, the plan seeks to "unleash the power of innovation" by, for example, advancing the use of electronic health records to spur innovation and break down unnecessary legal and regulatory barriers and increase research collaboration through the sharing and analyzing of health data while protecting patient privacy.[4] The GOP's plan is focused, in part, on making sure our regulatory system keeps pace with the state of science. So potential hope for the relaxation of existing regulatory barriers may be on the horizon. However, at the present time, significant challenges still exist for telehealth implementation, including legal and reimbursement barriers, which are generally discussed in this article.

What is Telemedicine?

The terms "telehealth" and "telemedicine" are often used interchangeably but have different meanings.[5] Telehealth is a broader term that encompasses the use of technology beyond the practice of medicine specifically for the traditional clinical diagnostic and remote patient monitoring activities (i.e. telemedicine) and non-clinical activities such as consumer and professional education.

Many states specifically define what constitutes "telemedicine" and/or "telehealth", the types of technologies captured (e.g., audio-visual; store-and-forward technology), and the types of health care providers (e.g., physicians, physician extenders, psychologists) who may provide telemedicine services. "Telemedicine" is generally defined to mean the "practice of medicine using electronic communications, information technology, or other means between a licensee in one location and a patient in another location with or without an intervening health care provider."[6]

Generally, telemedicine can be categorized as two types: (1) asynchronous store-and-forward communications – services that transmit medical data (e.g., x-rays, lab results) to a distant site practitioner for later assessment (e.g., nighthawk radiology services); and (2) synchronous, real-time communications – provision of medical services through use of simultaneous, two-way communications between a patient/provider and a distant site

[3] *Id.* at pg. 29.
[4] *Id.*
[5] For purposes of this article, we have used the term "telemedicine" unless the specific context warrants otherwise.
[6] Federation of State Medical Boards ("FSMB"), *Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine* (April 2014), *available at* https://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/FSMB_Telemedicine_Policy.pdf (last visited on 12/27/16).

provider and/or the use of interactive telecommunication devices (e.g., a/v equipment; e-stethoscopes; remote patient monitoring devices).

How is Telemedicine Used?

Numerous medical specialties provide telemedicine services including, for example, radiology, neurology, psychology, and dermatology.

Telemedicine is being used in a variety of ways, including, for example:

- By physicians and other health care providers –
    - Professional consultations via video conferencing (e.g., rural providers connect with specialists, such as vascular surgeons and neurologists located in metro cities, to immediately diagnose and treat patients in rural areas; patients in ICUs in the U.S. are monitored by intensivists in Australia during the night).
    - Diagnosis and treatment of patients in various settings (e.g., home, rural areas, long-term care facilities) via store-and-forward technologies (e.g., imaging reads), video conferencing, kiosks, mobile platforms, robots, and specially equipped tablets.
    - Education of and communication with patients via video conferencing, remote devices, mobile devices/applications, and patient portals.
- By patients –
    - Transmission of patient health information to health care providers through use of mobile applications/devices such as blood pressure, heart rate, and other vital signs to coordinate and monitor chronic conditions from home (e.g., diabetes, cardiovascular conditions).
    - Convenient and immediate access to care (e.g., pediatric telemedicine consult for pink eye; therapy services from the patient's home).

What are Barriers to Telemedicine?

Telemedicine is currently the most important medical regulatory topic to state medical boards[7] in part due to the varying legal requirements and reimbursement challenges faced

[7] *See* Federation of State Medical Boards Press Release, *FSMB Survey Identifies Telemedicine as Most Important Regulatory Topic for State Medical Boards in 2016* (December 15, 2016), *available at* http://www.fsmb.org/Media/Default/PDF/Publications/20161215_annual_state_board_survey_sesults.pdf (last visited on 12/27/16).

by health care providers desiring to provide telemedicine services. However, the regulatory considerations for operational compliance are not limited to state licensure.

(1) Legal Barriers

The FSMB has issued a model policy for the appropriate use of telemedicine technologies in the practice of medicine.[8] However, many states and state medical boards have implemented their own statutes, regulations, and/or policies that impose specific and varying requirements with respect to telemedicine, including, but not limited to, requirements related to: (a) standards of care/establishing a valid physician-patient relationship (e.g., face-to-face history and exam); (b) informed consent; (c) use of a qualified telepresenter; (d) prescribing; and (e) documentation. The challenge for health care providers is that these state laws, policies, and regulations vary widely (ranging from very restrictive to very flexible) and must be carefully analyzed and reviewed particularly if telemedicine services are provided in multiple states.

Licensure

Generally, physicians must be fully licensed in the state (with limited exceptions) in which the patient is located in order to provide telemedicine services. Several states have special purpose or telemedicine licenses (e.g., Alabama, Louisiana, Tennessee, and Texas). Applying for licenses in multiple states with varying requirements imposes immense administrative and financial burdens on physicians. To ease these burdens, the FSMB developed a voluntary interstate licensure compact which, if implemented by a state, allows for a streamlined licensing process for physicians desiring to practice medicine in multiple participating states.[9] However, the states have been slow to adopt the compact. As of December 2016, eighteen (18) states (Alabama, Arizona, Colorado, Idaho, Illinois, Iowa, Kansas, Minnesota, Mississippi, Montana, Nevada, New Hampshire, Pennsylvania, South Dakota, Utah, West Virginia, Wisconsin, Wyoming (with active legislation pending in Michigan)) have adopted the FSMB interstate licensure compact.[10]

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[8] *See Id.*

[9] *See* Federation of State Medical Boards Press Release, *Federation of State Medical Boards Applauds Enactment of Interstate Licensure Compact in Pennsylvania* (October 26, 2016), *available at* *http://www.fsmb.org/Media/Default/PDF/Publications/2016.10.26PACompactEnactment.pdf* (last visited on 12/27/16).

[10] *See* FSMB, *Understanding the Medical Licensure Compact available at* https://www.fsmb.org/policy/advocacy-policy/interstate-model-proposed-medical-lic (last visited 12/27/16).

Standards of Care; Establishment of a Physician-Patient Relationship
Generally, the standards of care applicable to in-person encounters apply to telemedicine services. States vary in terms of how restrictive the laws are with respect to the establishment of a physician-patient relationship and whether such relationship may be established via telemedicine as opposed to a face-to-face encounter (e.g., Louisiana allows physician-patient relationship to be established via telemedicine[11]).

Prescribing Issues
Under the federal Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (the "Act"), it is illegal for a practitioner to issue a prescription for a controlled substance based solely on an online evaluation of a patient. However, the Act exempts providers engaged in the practice of telemedicine (i.e., patient is treated by, and physically located in a hospital or clinic with a valid DEA registration and the telemedicine practitioner is treating the patient in usual course of professional practice)[12] from this requirement.[13]

Additionally, state laws vary as to whether prescriptions (controlled or non-controlled) may be issued without the practitioner first having a face-to-face encounter with the patient (e.g., Michigan's new law which becomes effective on March 21, 2017 allows for prescribing medications via telehealth except for controlled substances[14]; Arkansas law requires a history and in-person exam to be performed by the practitioner except in limited circumstances prior to the issuance of a prescription[15]).

Privacy & Security – HIPAA[16] Compliance
A common misconception among health care providers regarding telemedicine is the use of "HIPAA-compliant" software and technologies will protect health care providers from HIPAA violations. Unfortunately, no such certification exists under law.

HIPAA applies to telemedicine encounters in the same way as in-person encounters. A health care provider may provide telemedicine services through, for example, the use of secure video conferencing and encrypted text messaging if all requisite administrative, physical, and technical safeguards are in place. Ultimately, health care providers must perform risk assessments to determine what additional security risks may arise as a result of their use of new technologies and what controls must be implemented to ensure privacy

[11] L.A.C. 46:XLV.408, §7503.
[12] 21 U.S.C. §802 (54)(A).
[13] 21 U.S.C. §829 (e).
[14] State of Michigan, SB 753 (December 21, 2016).
[15] A.C.A. §17-92-1003(15).
[16] Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, as amended from time to time (collectively, "HIPAA").

and security of patient health information (e.g., documentation and storage of telemedicine encounter records; fully encrypted data transmission; secure network connections; execution of business associate agreements with telemedicine vendors).

Additionally, many states have privacy and security laws that are more stringent than HIPAA and must be reviewed and analyzed prior to providing telemedicine services to ensure compliance.

Further, careful review of contractual and other considerations when negotiating telemedicine vendor agreements is key to ensure the vendors are complying with and have the appropriate security protocols in place to comply with federal and state privacy and security laws.

Other Applicable Federal and State Laws

A myriad of other federal and state laws must be reviewed and considered if you are considering expanding your practice to include telemedicine. For example: (a) credentialing issues may arise for hospital-based physicians (e.g., The Joint Commission policy allows the hospital receiving the telehealth services to accept the distant site hospital's (where the telehealth provider is located) credentialing and privileging decision); (b) if mobile medical applications are developed, Federal Trade Commission policies regulating the truth in advertising and data privacy may be implicated; (c) U.S. Food and Drug Administration guidelines may be triggered if mobile health devices are utilized; (c) if services are provided to minors, the Children's Online Privacy Protection Act of 1999 may be implicated; (d) federal and state fraud and abuse laws (e.g., Physician Self-Referral Law; Anti-Kickback Statute; False Claims Act; Civil Monetary Penalties Law) may be implicated depending on the particular telemedicine arrangement; and (e) state corporate practice of medicine and fee-splitting prohibitions depending on the particular telemedicine arrangement.

(2) <u>Private and Public Payor Reimbursement Barriers</u>

To date, federal and state reimbursement laws and regulations related to telemedicine have not kept up with the pace of technology advancement. A majority of states have laws requiring private payors to provide coverage and reimbursement for telemedicine services (e.g., Texas).[17] However, Medicare, Medicaid, and private payors have different policies governing coverage and reimbursement for telemedicine services and vary with respect to: (a) reimbursement levels for telemedicine services; (b) patient location requirements (e.g.,

[17] *See* Texas Ins. Code §1455.004(b).

patient's home or qualifying originating site as Medicare requires); (c) reimbursable services; and (d) eligible providers.

Medicare

Medicare restricts telehealth payment to extremely narrow circumstances – the originating site (where the patient is located) must be located in a county outside of a Metropolitan Statistical Area ("MSA"), a Health Professional Shortage Area located outside of an MSA, or in a rural census tract, as determined by the Office of Rural Health policy within the Health Resources and services administration.[18] Additionally, as a condition of payment, the provider must use an interactive audio and video telecommunications system that permits real-time communication between the provider, the distant site, and the beneficiary. On July 27, 2017, the U.S. Attorney's Office for the District of Connecticut announced a settlement with a Connecticut psychiatrist and his mental health practice to settle False Claims Act allegations that the mental health practice improperly billed Medicare for telehealth services for failing to meet the foregoing requirements.[19]

In the 2017 Physician Fee Schedule Medicare added advance planning and critical care consultations in to the list of reimbursed telehealth services and continues to add new codes each year.

Medicaid

Medicaid coverage varies by state but almost all states provide some form of coverage for telehealth services. Many states limit the types of service that may be delivered via telehealth, providers who may receive reimbursement for telehealth services, and many requires specific patient settings or locations as a condition of payment.

Private Payors

As noted above, many states have private payor parity laws in place that require private payors to reimburse telemedicine services in the same way as in-person services. However, private payors have differing policies and, thus, such agreements, policies, and manuals should be reviewed to ensure coverage and reimbursement for telemedicine services.

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[18] *See generally* Department of health and Human Services Centers for Medicare and Medicaid Services, Medicare Learning Network, *Telehealth Services* (December 2015), *available at* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/TelehealthSrvcsfctsht.pdf (last visited on 12/27/16).

[19] *See* Department of Justice U.S. Attorney's Office District of Connecticut, *Danbury Physician and Mental Health Practice Pay $36,000 to Settle False Claims Act Allegations* (July 27, 2016), *available at* https://www.justice.gov/usao-ct/pr/danbury-physician-and-mental-health-practice-pay-36000-settle-false-claims-act (last visited on 1/19/17).

Conclusion

Telemedicine has numerous benefits for health care providers and their patients. However, prior to expanding your practice to include telemedicine services, we recommend you carefully navigate through (with experienced legal counsel) the potential challenges outlined above. Further, as the health care climate continues to change and uncertainty remains high, providers should ensure they are engaging appropriate advisors (including legal advisors) before delving into new practice modalities.

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