Compliance TODAY

July 2016

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

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by Cybil Roehrenbeck, JD and Emily Shaw, JD

Telemental health: Key compliance considerations

- » Telemental healthcare providers should be aware of the state laws, rules, and regulations that may affect the lawful provision of telemental health.
- » A chief compliance concern for telemental healthcare providers is prescribing of controlled substances; many states have specific rules on what may and may not be prescribed via telehealth.
- » State licensing for healthcare professionals continues to be a challenge. Telehealth providers should ensure that they are properly licensed in states in which their patients are located.
- » Hospital counsel should be familiar with Medicare regulations concerning credentialing and privileging of telehealth providers in distant-site hospitals.
- » The establishment of a valid patient relationship between the telemental healthcare provider and the patient is a significant compliance consideration and may differ from state to state.

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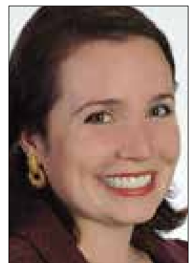
To understand what is meant by "telemental health," it is helpful to first understand what the terms "telemedicine" and "telehealth" refer to. According to the American Telemedicine Association (ATA), telemedicine is the use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status. Telemedicine includes a growing variety of applications and services using two-way video, email, smartphones, wireless tools, and other forms of telecommunications technology. Telehealth is a somewhat broader term, which also includes the use of remote patient monitoring and non-medical services.

Telemental health is a subset of telehealth and refers to the provision of mental health and substance abuse services from a distance. Because mental health and substance abuse counseling are unique in that they do not always require a "hands-on" clinician interaction, telemental health has been a trailblazer in this area, with earlier adoption than many other medical specialty areas. Telemental health can improve access to mental health and substance abuse counseling services in remote, rural, and underserved populations, as well as help healthcare providers reach homebound patients, such as those with limited mobility or chronic illness.



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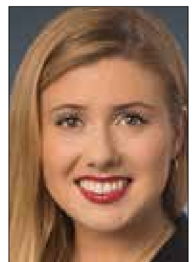

Shaw

Legal and regulatory challenges

The healthcare industry is no stranger to complex regulatory schemes. These complexities are only compounded when health services are delivered by telehealth modalities, particularly if the patient and provider communicate across state lines. Significant issues implicated by telemental health include internet prescribing, state licensure, privileging and credentialing, establishment of the physician-patient relationship, and reimbursement.

Internet prescribing

Telemental health providers may encounter significant obstacles in the prescribing authority space. First, federal law imposes significant restrictions on the ability to remotely prescribe controlled substances. The Ryan Haight Act, signed into law in 2008, prohibits the prescribing of controlled substances without at least one in-person consultation. A narrow exception is made for when the patient is located at a facility registered with the Drug Enforcement Administration (DEA) and is being treated by a DEA-registered provider; however, this model eliminates many otherwise workable telemental health models. Further, state laws are inconsistent and generally disfavor prescribing remotely without a prior physician-patient relationship and, in many states, without a physical examination.[1]

Internet prescribing statutory schemes may vary widely by state. Some states, such as Missouri, regulate internet prescribing through physician disciplinary statutes, defining certain practices as constituting unprofessional conduct. Others, such as North Carolina, prohibit pharmacists from filling prescriptions obtained without proper physician-patient relationship. The District of Columbia requires a physical examination, but only for controlled substances to treat pain. Fourteen states explicitly prohibit prescribing based solely on internet questionnaires. Various states require an "in-person exam," a "physical exam," a "face-to-face exam," a "patient evaluation," or a "physician-patient relationship." Each of these terms requires state-specific inquiry into statutory definitions, judicial glosses, and administrative interpretations; a physical examination doesn't always mean "in-person." To complicate matters further, the state's interpretive authority may not have kept pace with technological advances in telehealth. Providers must be familiar the laws of their state and the patient's state in order to avoid potential liability.

State licensure

States generally require that healthcare providers be licensed in the state in which they care for patients. In the case of telehealth and telemental health, this often means that providers must be licensed in the state in which the patient is located, even if the provider is located in another state. This policy has been supported by concerns about patient safety and the need for states to exercise control over the provision of healthcare to patients located in their state. Many telehealth advocates, however, agree that the state-based licensure system may need additional flexibility to allow for telehealth services to take place and reach their full potential.

States have responded to this issue in a variety of ways. Some states maintain full licensure requirements, which may impose significant costs and complications on healthcare providers who wish to provide care remotely. Some states explicitly carve out telemedicine from general licensing requirements. Alabama, Louisiana, Minnesota, Nevada, New Mexico, Ohio, Oregon, Tennessee, and Texas are the only states that extend a conditional or telemedicine license to out-of-state physicians.[2] Other states address the issue through reciprocity arrangements or consulting exceptions applicable to telemedicine. In response to licensure challenges, some states have adopted the Interstate Medical License Compact, promulgated by the Federation of State Medical Boards, which seeks to create an expedited process for obtaining physician licensure.[3]

Privileging and credentialing

For hospital counsel, it is notable that the Centers for Medicare & Medicaid Services (CMS) promulgated changes to the Medicare Conditions of Participation (CoP) for hospitals regarding credentialing and privileging for telemedicine services, and that The Joint Commission (TJC) has also issued standards

on this topic. In the past, Medicare's CoP required hospitals and critical access hospitals to engage in full privileging and credentialing for telemedicine providers. The Medicare rules now allow originating-site hospitals and critical access hospitals to rely on the credentialing and privileging information of the distant-site Medicare-participating hospital or the distant-site telemedicine entity. TJC made changes to their telemedicine standards to align with the revised Medicare CoP in an effort to eliminate inconsistencies between providers complying with Medicare's rules and providers operating under "deemed status" through TJC accreditation.

Physician-patient relationship

Many states have statutes which govern what constitutes a valid physician-patient relationship for purposes of a telehealth or telemental health visit. Some states, such as North Carolina, are fairly permissive, allowing telemedicine to establish a physician-patient relationship in lieu of an in-person examination. Other states have more restrictive requirements; for example, Arkansas requires either an in-person examination, personal knowledge of the patient and their health status, or consultation or referral from a provider with an established physician-patient relationship. Texas's telehealth regulations regarding establishment of the physician-patient relationship are currently the subject of controversy; the Texas Medical Board is embroiled in ongoing litigation with Teladoc over the Board's rule requiring a physical examination to establish the physician-patient relationship. The federal district court recently denied the Board's motion to dismiss the case, citing antitrust concerns and basing the opinion largely on the recent United States Supreme Court ruling in *North Carolina Board of Dental Examiners v. Federal Trade Commission*,[4] which held that state licensing boards made of active members of their profession are not immune from antitrust laws unless they are actively supervised by the state.

Industry associations have developed guidelines that address the formation of the physician-patient relationship. The Model Policy promulgated by the Federation of State Medical Boards (FSMB) states that a physician-patient relationship is established when the physician agrees to undertake diagnosis and treatment of the patient, and the patient agrees to be treated, whether or not there has been an encounter in person between the physician and patient. The FSMB policy goes on to emphasize the importance of verifying and authenticating the location and identity of the patient, disclosing and validating the provider's identity and credentials, and obtaining appropriate consents. The ATA suggests that telehealth providers should be cognizant of establishment of a provider-patient relationship and should proceed accordingly with an evidence-based standard of care. The ATA further recommends referring to existing specialty guidelines to determine whether specific definitions of "patient-provider relationship" and/or "encounter" exist.

Finally, the American Medical Association (AMA) has developed principles which state that a valid patient-physician relationship must be established before the provision of telemedicine services through:

- a face-to-face examination, if a face-to-face encounter would otherwise be required in the provision of the same service not delivered via telemedicine;
- consultation with another physician who has an ongoing patient-physician relationship with the patient and who agrees to supervise the patient's care; or
- meeting standards of establishing a patient-physician relationship included as part of evidence-based clinical practice guidelines on telemedicine developed by major medical specialty societies, such as those of radiology and pathology.

Under this AMA policy, exceptions to the foregoing include on-call, cross coverage situations, emergency medical treatment, and other exceptions that become recognized as meeting or improving the standard of care.

Reimbursement

Payment and coverage for telehealth services can be complicated by arbitrary insurance requirements and disparate payment streams that present obstacles to full implementation of a telemedicine model. Because many payers have heretofore declined to cover many telehealth services, the proliferation of telehealth has been slow. The increasing patient demand for telemedicine, as well as efforts by large employers to offer telehealth services within their employer-sponsored benefits, is pushing the payers to integrate telemedicine coverage. Further, just over half of states now have telehealth parity laws, which generally require telemedicine services to be reimbursed at the same rate as in-person services. The ATA provides a 50-state survey of reimbursement policy on their website, where more state-specific information can be found.[5]

Medicare reimburses for telehealth services only when the originating site (patient's location) is in a Health Professional Shortage Area (HPSA) or in a county that is outside of any Metropolitan Statistical Area (MSA).[6] Further, the definition of a qualifying originating site precludes in-home services. Telemental health has been one of the few medical specialty areas to be covered, however, and Medicare does cover individual and group health and behavior assessments and interventions, individual psychotherapy, psychiatric diagnostic interview examinations, neurobehavioral status examinations, alcohol and substance abuse-related screenings and assessments, annual depression screenings, psychoanalysis, and family psychotherapy.

A number of telehealth bills have been introduced in the U.S. Congress; however, many of these bills have never made it out of committee, partly due to concerns about increased utilization and additional costs to the Medicare program. Most recently, in February of 2016, the CONNECT Act[7] was introduced. This bicameral, bipartisan legislation removes restrictions around reimbursement for telehealth and includes additional provisions to encourage the use of remote patient monitoring. Studies indicate that this bill would modernize Medicare's approach to telehealth while saving $1.8 billion over ten years. The bill has received broad industry support, including endorsements by the AMA, AARP, and Kaiser Permanente. Many industry stakeholders are optimistic that this legislation may fare well going forward.

Conclusion

Telemental healthcare providers should be aware of potential compliance concerns related to prescribing of controlled substances, state licensure, credentialing and privileging, the establishment of a valid physician-patient relationship, and reimbursement. Additionally, pending modifications to Medicare reimbursement of telehealth may significantly change the landscape for telemental health service models, and counsel should stay abreast of developments in this area.

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4. Supreme Court Opinions: *North Carolina State Board of Dental Examiners v. Federal Trade Commission*. Decided February 25, 2015. Available at http://1.usa.gov/25KrnCC
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7. CONNECT for Health Act (S. 2484/H.R. 4442). Available at http://1.usa.gov/1ZaGqOq