TELEHEALTH RISK MANAGEMENT AND INSURANCE CONSIDERATIONS

By Katherine Laws Debes • First Vice President, Client Advocacy

As providers, payers, and patients seek the elusive trinity of healthcare quality, access, and cost, they are increasingly turning to telehealth programs. Global professional services company Towers Watson estimates that a potential maximum savings of $6 billion per year is available through aggressive use of telehealth services.[1]

Although expected growth rate statistics for telehealth vary, the models consistently predict substantial growth in the number of patient visits and related revenue growth. Skip Fleshman with Asset Management Ventures predicts that "telemedicine may just be the biggest trend in digital health in 2015" and notes that "telemedicine is moving like lightning."[2] Providers looking to embrace population health look to telehealth to enhance management of patients with chronic health, to increase access to behavioral healthcare, and to provide a cost-effective point of access for services. This rapid expansion of telehealth warrants an examination of potential risks and insurance issues that should be considered in implementing a program.

A word about the definitions of telehealth and telemedicine: the terms are used interchangeably by some and defined separately by others. The American Telemedicine Association defines telemedicine as "the use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status."[3] The Association uses the terms telemedicine and telehealth interchangeably but acknowledges that some users prefer "telehealth" to describe a broader range of services beyond clinical interactions.

In a given clinical setting, providers should be familiar with the differing definitions of telemedicine from their state statutes, their accrediting bodies, and CMS. CMS defines interactive telecommunications system as "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. Telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system."[4] For purposes of this paper, telemedicine and telehealth are used interchangeably.

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[1] http://www.towerswatson.com/en-US/Press/2014/08/current-telemedicine-technology-could-mean-big-savings

[2] Fleshman, Skip, "Why Telemedicine's Time has Finally Come," *Forbes* Pharma & Healthcare, Jan. 1, 2015

[3] http://www.americantelemed.org/about-telemedicine/what-is-telemedicine

[4] 42 C.F.R. § 410.78(a)(3)

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Additional terms that are critical to a discussion of telehealth relate to the two physical locations that are part of the virtual connection. The "originating site" is the location of the patient receiving the telehealth service, and the "distant site" is the location of the healthcare provider that is providing the telehealth service.

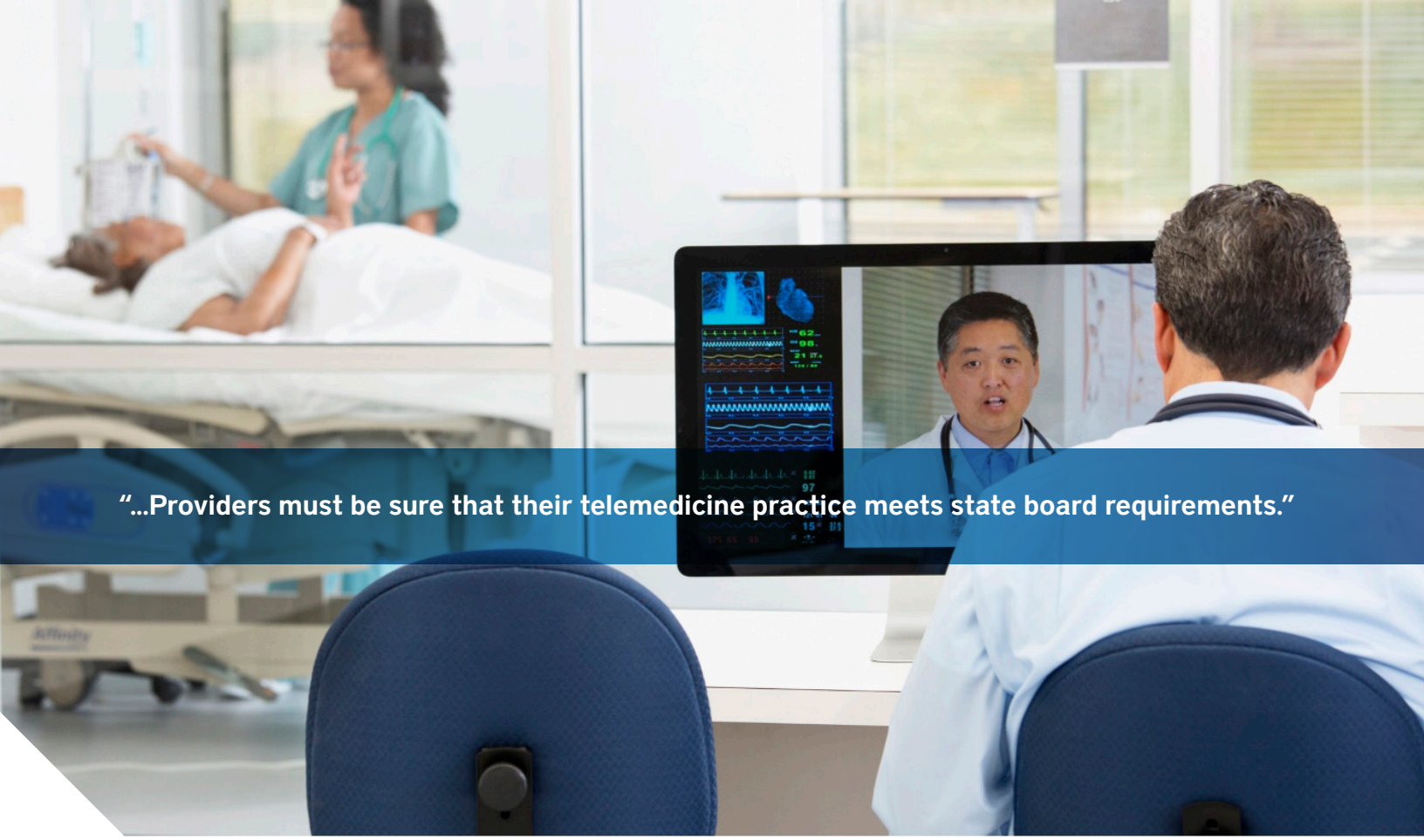
Provider Licensing and Credentialing

The practice of medicine and other healthcare professions is regulated by each state through its state medical board and ancillary agencies. Without a single regulatory authority, physicians and other healthcare providers must have the proper state licenses to provide telehealth services to their patients.

The Federation of State Medical Boards developed the Interstate Medical Licensure Compact in an effort to streamline the multistate licensing issues associated with telemedicine. The compact allows expedited licensing of a compact state physician that meets requirements sets forth in the statute. The physician is still required to be licensed in the state where the patient is located, but the process of obtaining the additional license is much less cumbersome. To date, the compact has been adopted by Alabama, Idaho, Montana, Minnesota, Nevada, South Dakota, Utah, West Virginia, and Wyoming.[5] The compact has been criticized by advocates of a single national medical license as perpetuating the authority of the various state medical boards.

Many states currently offer some kind of medical license reciprocity, but the state statutes and regulations of each state must be carefully reviewed to identify the requirements and scope of that reciprocity. Other states offer a special telemedicine license. For example, the Oregon Medical Board offers an option where an out-of-

[5] Interstate medical licensure compact formed, *Health Day*, June 4, 2015



"...Providers must be sure that their telemedicine practice meets state board requirements."

state physician may be licensed for the practice of medicine to a patient in Oregon when the physician is located in another state. However, that license is restricted to practicing across state lines only and does not authorize the physician to practice while in the State of Oregon.[6]

In addition to understanding the various licensing requirements, providers must be sure that their telemedicine practice meets other medical board requirements, such as when a face-to-face assessment is required and whether such an assessment can be performed via telemedicine.

Telehealth providers must be properly credentialed in advance of providing telehealth services. In 2011, CMS implemented a new credentialing and privileging process for physicians providing telemedicine services.[7] The rule change acknowledged that the process of requiring the originating site to credential and privilege providers at a remote site presented a barrier to the effective use of telemedicine. In an effort to provide flexibility to rural and small hospitals using telehealth to enhance delivery of care, the rule revised the conditions of participation for hospitals and critical access hospitals by allowing the governing body of the originating hospital to rely on the credentialing performed by the distance hospital or telemedicine entity if certain conditions are met. Originating hospitals relying on the credentialing of the distant hospital should carefully review these credentialing requirements as part of establishing a telemedicine program.

Both the originating site and the distant site need insurance coverage for patient claims arising from allegations of negligent credentialing. Such coverage is typically included as part of a professional liability policy, but policies should be carefully reviewed to confirm coverage. A second potential exposure is a claim by a physician

[6] ORS 677.139

[7] 76 Fed. Reg. 25550

arising from an adverse credentialing or peer review decision. Coverage for these actions is typically part of the directors and officers insurance policy. Even when the originating site has essentially adopted or relied upon the credentialing performed by the distant site, that site may still be sued in a credentialing-related matter and will want to be sure they have appropriate coverage. The contract governing the parties may specify the amounts of insurance coverage each party is required to carry and may also require that the entity be named as an additional insured on the other party's insurance.

- Verify and document that each telemedicine provider is properly licensed in all applicable states.
- Determine legal requirements for credentialing and regularly review process to determine compliance.
- Confirm proper insurance coverage at both sites for credentialing claims arising from the telemedicine program.

Billing and Regulatory

To date, private payers have been leading the way in reimbursing providers of telehealth services. UnitedHealth Group recently announced a sweeping increase in telehealth options, including online physician access 24 hours a day.[8] The program is expected to provide video-based office visits to patients in 47 states and the District of Columbia.[9]

CMS has been criticized by some for being too slow to implement reimbursement guidelines for telemedicine. Those against the expansion of telehealth for Medicare argue that giving seniors online access to doctors will simply encourage seniors to use more services and will not decrease costs.[10] Telehealth reimbursement by Medicare originally covered only beneficiaries in rural areas, and in order to qualify, the beneficiary had to be seen at an authorized originating site. Authorized sites include offices of physicians or practitioners, hospitals, rural health clinics, skilled nursing facilities, or community mental health centers.[11] In March, CMS announced that it would extend reimbursement for telehealth services further by waiving the rural and health facility requirements for beneficiaries under a Next Generation Accountable Care Organization.[12]

Providers participating in and billing CMS for telehealth programs as either originating or distant sites are subject to many of the same regulatory statutes as traditional clinical settings. Legal review of any potential regulatory exposures is advised. The OIG has provided some guidance in the form of advisory opinions regarding specific telemedicine affiliation agreements.[13]

DEFINITION

Originating Site: The location of the patient receiving the telehealth service.

Distant Site: The location of the healthcare provider that is providing the telehealth service.

[8] http://www.unitedhealthgroup.com/Newsroom/Articles/Feed/UnitedHealthcare/2015/0430VirtualCarePhysicians.aspx

[9] Id.

[10] http://www.daytondailynews.com/feed/lifestyles/medicare-slow-to-adopt-telemedicine-due-to-cost/fCDX7D/

[11] http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/TelehealthSrvcsfctsht.pdf

[12] http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/TelehealthSrvcsfctsht.pdf

[13] See generally https://oig.hhs.gov/compliance/advisory-opinions/

Many insurance carriers now provide regulatory insurance coverage specifically designed to respond to claims arising out of billing issues related to regulatory violations. Such coverage does not typically carry an exclusion for treatment provided via telemedicine and, as such, should be considered in connection with a telehealth program.

- Seek legal advice regarding program compliance with Stark, Anti-kickback, and other state and federal regulations.
- Regularly audit the billing process to ensure compliance for billing of telehealth care.
- Review available insurance options for regulatory/billing specific coverage.

Privacy and Security

Protecting patient health information in the telemedicine setting presents many of the same challenges as a traditional clinical setting, along with unique challenges. Telemedicine includes the use of electronic voice and video communications with the patient, which presents additional opportunities for a breach. In addition, consideration must be given to whether electronic voice and video data is required to be maintained as part of the medical record. When such data is maintained, HIPAA and state equivalent rules must be followed.

From a risk management perspective, authentication protocols should be used to limit access to telehealth records to approved personnel. Encryption and other security measures should be fully tested before operating a new telehealth program, and policies and procedures governing the use of data on portable devices should be in place and regularly audited for compliance.

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The provision of telehealth services typically involves multiple parties, including technology vendors. Telehealth providers should consider indemnification clauses, as well as requiring any party to the transaction with the potential to cause a breach to carry insurance with limits sufficient to address a breach. Telehealth necessarily requires that the equipment used in the interaction function appropriately, or care cannot be provided. Although a traditional clinical setting may respond to a computer-related outage by using a paper medical record as a short-term fix, telehealth service may be completely interrupted. Before implementing a telehealth program, complete contingency planning for both short-term and long-term outages of service. In addition, before a program goes live, business interruption risk and insurance coverage for same should be considered.

- Design a program using state-of-the-art encryption and authentication procedures.
- Draft contract language to include indemnification for data breaches caused by other parties.
- Insure the program under a privacy and security liability insurance policy.

Professional Liability

In most states, professional liability is based on the question of whether a provider violated the standard of care by doing, or not doing, what a similarly situated healthcare provider would have done under the same or similar circumstances.

As telemedicine evolves, this legal standard will be examined in the context of remote delivery of healthcare. Other issues that may arise include formation of the patient–physician relationship, obtaining informed consent, and recognizing the need for referral to an elevated level of care. Consider potential choice of law issues where the physician and patient are located in separate states. For example, a physician based in a state with tort reform treating a patient in a state without tort reform may likely be subject to the laws of the state where the patient is located.

In the rush to look at risk management issues unique to telemedicine, it is important to not abandon traditional risk management principles. Education and training around documentation of telehealth visits and communication between the team providers remains very important. Risk management of telehealth should include identification and analysis of adverse events in a system similar to that used in the traditional clinical setting.

The structure of the telemedicine setting requires establishing processes to accomplish tasks such as ordering of labs or other tests, reporting results to the provider and then to the patient, making specialist referrals, and prescribing medication. As with any new process, provider education, process testing, and real-time error analysis and correction will be essential.

At present, professional liability insurance policies do not typically distinguish between coverage provided for in-person care versus telehealth care. However, as telemedicine develops, it will be important to monitor policies to be sure that there are no restrictions on coverage for telemedicine activities. Policies may restrict coverage only to care provided at a scheduled location or within the United States. Certain states require providers to carry minimum limits of insurance. Providers or those contracting with telemedicine providers should carefully review the professional liability policies to determine that they apply the proper scope of coverage.

Telehealth programs often include an increased use of advanced practice clinicians. This raises the question of whether the limits of insurance for these individuals should be separate from the entity limit of insurance or in addition to those limits. Statutory requirements, the experience of the jurisdiction, and individual exposure data should all be assessed in determining limits of coverage.

- Integrate traditional risk management concepts into the telehealth program.
- Research choice of law issues to understand the potential scope of risk in advance of implementing a program.
- Structure professional liability coverage to fully cover the telemedicine program.

CONCLUSION

Telemedicine presents great opportunities to enhance the delivery of healthcare, and the success of these programs will depend on a disciplined approach to their planning and implementation. Part of that planning should include a review of existing insurance coverage and steps to fill in potential gaps in coverage that may be created by a telehealth model.

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CONTACT

K. Todd Hagemeier
Executive Vice President
and Managing Director
214 273 3162
thagemeier@alliant.com

Freddie Nutt
Executive Vice President
and Managing Director
832 485 4065
fnutt@alliant.com

Philip E. Reischman
Executive Vice President
and Managing Director
713 470 4197
preischman@alliant.com

THE AUTHOR

Katherine Laws Debes
First Vice President,
Client Advocacy
703 547 6295
kdebes@alliant.com