

HIT News

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Telemedicine: An Interactive Approach to Healthcare in the Wake of Healthcare Reform

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As healthcare providers evaluate many of the new strategies for hospital/physician alignment and provider reimbursement as part of efforts to accomplish healthcare reform initiatives of improved access and affordability, the focus on patient technological capabilities is moving to the forefront. The expanded deployment of telecommunications and remote diagnostic technology, due in large part to the greater accessibility and affordability of such technology for patients and healthcare providers alike, have created more options for how individuals can receive healthcare. Traditionally, the only options available to a patient for the treatment of an illness were either a trip to the emergency room or an in-office visit with a healthcare provider. With the expansion of telemedicine, patients now have a more cost-effective alternative to the traditional face-to-face approach to receiving medical care.

Telemedicine seeks to improve a patient's health by providing two-way, real-time interactive communication between the patient and a physician at a distant site.¹ As the number of newly insured Americans is predicted to increase as a result of the passage of the Affordable Care Act (ACA),² so will the demand for available physicians and other healthcare providers. The use of telemedicine and other innovative healthcare technology will be essential to expanding access to healthcare providers, while lessening the dependence on traditional in-person methods of receiving medical treatment.

The popularity of telemedicine only grows as more patients opt for the ease and convenience of receiving medical care via video conference, mobile phone, or online, as opposed to traveling long distances or enduring long wait times in a physician's office.³ While accessibility to physicians and lower healthcare costs make telemedicine attractive to many patients, there are also several advantages for healthcare practitioners.⁴ For example, overburdened hospital radiology departments use telecommunications and picture archiving technology to send X-rays to remote radiologists after hours. Rural clinics use video conferencing to connect a patient with

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—from a declaration of the American Bar Association

a specialist in a distant town.⁵ Physicians are also using telemedicine technology to continuously track and monitor chronically ill patients in real time, adjust medications, and amend treatment plans without requiring the patient to come into the office.⁶

The results of a recent study predicting that spending on health information technology and healthcare telecommunications will increase to \$14.4 billion over the next five years⁷ suggests that telemedicine will continue to play an important role in the future of the healthcare industry, especially as patients increasingly rely on telecommunication technology to interact with their providers.⁸

Medicare Coverage of Telehealth Services

In response to this surge in health telecommunication technology, the Centers for Medicare & Medicaid Services (CMS) is extending Medicare coverage to additional telehealth services in the Medicare Physician Fee Schedule for the 2013 calendar year.⁹

Currently, Medicare telehealth services may be furnished to an eligible Medicare beneficiary notwithstanding the fact that the healthcare practitioner providing the telehealth services is not located in the same area as the beneficiary.¹⁰ As a condition of payment, telehealth services must be provided through an interactive audio and video telecommunications system that provides for real-time communication between the eligible beneficiary, at the originating site, and the practitioner, at the distant site. Medicare reimbursement for asynchronous “store and forward” technology, such as email, is only permissible for use in the federal telehealth demonstration programs conducted in Alaska and Hawaii.¹¹

CMS defines an “eligible telehealth beneficiary” as an individual enrolled under Medicare Part B, who receives telehealth services furnished at an originating site.¹² Typically, originating sites must be located in a rural health professional shortage area or in a county outside of a metropolitan statistical area and may be physicians’ offices, hospitals, skilled nursing facilities, or federally qualified health centers.¹³ Practitioners at the distant site who may furnish and receive reimbursement from Medicare for covered telehealth services include physicians, nurse practitioners, physician assistants, nurse midwives, and clinical nurse specialists.¹⁴

Currently, Medicare provides coverage for numerous telehealth services including initial and follow-up inpatient consultations, outpatient visits, pharmacologic management, diabetes self-management training, psychiatric diagnostic examinations, kidney disease education, and medical nutrition therapy.¹⁵ CMS has expanded the current list of telehealth services by extending Medicare coverage to the following Healthcare Common Procedure Coding System (HCPCS) codes in the 2013 calendar year:

- G0396 and G0397—Alcohol and/or substance abuse (other than tobacco) structured assessment, brief intervention (fifteen to thirty minutes), and other intervention (more than thirty minutes);
- G0442—Annual alcohol misuse screening (fifteen minutes);
- G0443—Brief face-to-face behavioral counseling for alcohol misuse (fifteen minutes);
- G0444—Annual screening for depression (fifteen minutes);
- G0445—High-intensity behavioral counseling to prevent sexually transmitted infections, face-to-face, individual counseling including—education, skills training, and guidance on ways to change sexual behavior (thirty minutes semi-annually);
- G0446—Annual individual, face-to-face intensive behavioral therapy for cardiovascular disease (fifteen minutes); and
- G0447—Face-to-face intensive behavioral therapy for obesity (fifteen minutes).¹⁶

Medicare will now provide reimbursement for several new services when furnished via telehealth.

Medicaid Coverage of Telehealth Services

Unlike Medicare, CMS has not formally mandated coverage for telehealth services under the Medicaid program. States have the option to provide reimbursement for Medicaid-covered services, including those with telehealth applications, provided that the Medicaid-covered services satisfy federal requirements of efficiency, economy, and quality of care. CMS has encouraged states to use this flexibility to create innovative payment methodologies to cover services that incorporate telemedicine technology.¹⁷

For example, states may choose to provide reimbursement for both the healthcare provider at the distant site for the consultation and the provider at the originating site for the office visit. States may also provide reimbursement for additional costs such as technical support, facility fees, transmission charges, and equipment associated with the provision of the covered telehealth services. These additional costs can be incorporated into the fee-for-service rates or billed separately as an administrative cost to the state. However, if the additional costs are billed separately and reimbursed by the state, the costs must be in connection with a covered Medicaid service.¹⁸

Several states currently provide Medicaid reimbursement for some telehealth services. California’s Medi-Cal program provides coverage for certain consultations, office visits, individual psychotherapy, and pharmacologic management delivered via a telecommunications system.¹⁹ Unlike Medicare, Medi-Cal does



not require that the telemedicine service be furnished in a rural or underserved area. However, a telemedicine consultation must meet all of the requirements of the Medi-Cal program and a practitioner must be present at the originating site during the consult in order to receive reimbursement for the originating site service. Medi-Cal does not provide reimbursement for facility fees for the originating site. Additionally, Medi-Cal requires there to be a barrier from receiving the service face to face from the provider. Such barriers may include lack of transportation or the lack of available local providers willing to accept Medi-Cal.²⁰

The State Division of Medicaid & Medical Assistance, which administers the Medicaid program in Delaware, began providing Medicaid reimbursement for telemedicine services on July 1, 2012, in order to improve Medicaid beneficiaries' access to behavioral and general health services. Telemedicine services, such as consultations, office or outpatient visits, psychotherapy, medication management, psychiatric interviews and examinations, substance abuse screenings, and neurobehavioral examinations, are covered by Medicaid when provided by an originating site.²¹ The originating site receives a facility fee for the telemedicine space and equipment, and the consulting services are reimbursed as if furnished to the beneficiary face to face. Both the originating site provider and the distant site provider must be enrolled in the Delaware Medical Assistance Program or in one of the state's managed care organizations. By providing Medicaid reimbursement for telemedicine services, Delaware hopes to produce better health outcomes for patients, improve access to medical care, and reduce hospitalization costs.²²

Telehealth and Healthcare Reform

The U.S. Supreme Court's decision to uphold the ACA is expected to facilitate the widespread adoption of telemedicine as a common method of providing medical care in the United States. Industry observers predict that while the telehealth industry is rapidly expanding and evolving, these advancements may have been halted had the Supreme Court decided to strike down the ACA.²³ The new health reform legislation included several provisions pertaining to telemedicine. Specifically, the ACA created the Center for Medicare & Medicaid Innovation (CMMI), which is designed to "test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to individuals."²⁴ CMMI also provides funding for pilot programs in telemedicine to encourage the development of mechanisms designed to integrate the use of remote health technology in various settings.

To date, more than \$120 million in federal funds have been awarded to telemedicine programs nationwide.²⁵ These programs primarily focus on targeting patients with chronic diseases for medical interventions by a team of healthcare practitioners using telemedicine. The awards range from \$1 million to \$30 million for a three-year period. Each grantee program is monitored for measurable improvements in quality of care and savings generated.²⁶ CMMI is providing a financial incentive for the continuous development of new innovative telehealth systems.

Although telemedicine is being adopted by hospitals and other healthcare entities at a rapid rate, several roadblocks still remain that continue to put a damper on the momentum of the telemedicine industry. CMS provides reimbursement for telehealth services; however, these services are limited and are restricted to Medicare beneficiaries residing in rural areas. Additionally, a number of states severely restrict the ability of an out-of-state healthcare provider to diagnose or treat patients in their state. The ACA provides support for telemedicine, but does not completely resolve some of the critical issues that prevent the expansion of telemedicine into a mainstream method of delivering medical care. While telemedicine has become an increasingly invaluable tool for diagnosing and monitoring illnesses, improving quality of care, and connecting healthcare providers with their patients—regardless of their location—additional legislative reforms are still needed to improve the accessibility and affordability of telemedicine technology for both patients and healthcare providers.

1 Medicaid.gov, "Telemedicine," available at www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Delivery-Systems/Telemedicine.html.

2 Patient Protection and Affordable Care Act of 2010, PL 111-148.

3 Donna Fuscaldo, "TeleHealth: The Doctor Will See You Now, Wherever You Are," FOXBusiness, August 30, 2011, available at <http://foxbusiness.com/personal-finance/2011/08/30/telehealth-doctor-will-see-now-wherever-are/>.

4 *Id.*

5 *Id.*

6 *Id.*

7 *Id.*

8 The Insight Research Corporation, "Executive Summary: Telecom, IT and Healthcare: Wireless Networks, Digital Healthcare, and the Transformation of US Healthcare 2012-2017," May 2012.

9 "2013 Final Medicare Physician Fee Schedule," 77 Fed. Reg. 68891 (November 16, 2012).

10 *Id.*

11 See Centers for Medicare & Medicaid Services, Medicare Learning Network, "Telehealth Services: Rural Health Fact Sheet Series," Feb. 2012.

12 77 Fed. Reg. at 68953.

13 *Id.* (additional originating sites include critical access hospitals, rural health clinics, hospital-based renal dialysis centers, or community mental health centers).

14 Clinical psychologists and clinical social workers can bill for some telehealth services, but may not bill for those psychotherapy services that include medical evaluation and management services.

15 See *supra* note 9 (for a complete list of covered telehealth services).

16 77 Fed. Reg. 68954-5.

17 See *supra* note 1; see also Center for Telehealth and e-Health Law, "Medicaid Reimbursement," available at <http://ctel.org/expertise/reimbursement/medicaid-reimbursement/>.

18 *Id.*

19 California Telemedicine & eHealth Center, "Telemedicine Reimbursement Handbook" at p. 12, available at www.nrtrc.org/wp-content/uploads/Telemedicine-Reimbursement-Handbook1.pdf.

20 *Id.* at 16.

21 Press Release "Delaware Medicaid Program to Reimburse for Telemedicine-Delivered Services Beginning July 1" (June 27, 2012), available at <http://dhss.delaware.gov/dhss/pressreleases/2012/servicesbeginningjuly1-062712.html>.

22 *Id.*

23 Brian Heaton, "Will the Affordable Care Act Help Telehealth Flourish?" September 10, 2012, available at www.govtech.com/health/Will-the-Affordable-Care-Act-Help-Telehealth-Flourish.html.

24 Patient Protection and Affordable Care Act of 2010, PL 111-148. Section 3021.

25 Rebecca Vesely, "Telehealth to Benefit From SCOTUS Ruling, but Barriers Remain," iHealthBeat, August 6, 2012, available at www.ihealthbeat.org.

26 *Id.* See also the Center for Medicare & Medicaid Innovation HealthCare Innovation Awards.

Negotiating a Telemedicine Agreement on Behalf of a Healthcare Provider: Back to the Basics

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Healthcare providers are implementing telemedicine solutions to improve the quality of care, expand clinician access to colleagues and patients, and more efficiently allocate resources. The definition and scope of telemedicine solutions remains fluid and includes a broad array of equipment and services ranging from clinical consultation to remote patient monitoring and robotic cybersurgery.¹ As telemedicine solutions are further integrated into the daily practice of medicine, both in-house and outside legal counsel will find value in preparing to represent healthcare providers in negotiating telemedicine agreements, maintaining a working knowledge and awareness of applicable regulatory issues, and having the necessary foresight to construct a telemedicine agreement to include performance measures and help avoid adverse events.

Prepare to be Prepared

Successfully negotiating a telemedicine agreement begins prior to counsel receiving the vendor's terms and conditions. As the traditional adage attributed to Abraham Lincoln states, "give me six hours to chop down a tree and I will spend the first four sharpening the axe."² There is no substitute for counsel preparing to be prepared.

Telemedicine equipment and services are part of complex information technology (IT) and clinical systems. Healthcare providers' selection of telemedicine products is anything but effortless. Executives and directors allocate substantial time to meeting with vendors, reviewing features, calculating the return on investment, and performing risk analyses to select the appropriate technology. Project managers design detailed plans to implement it. In order to effectively represent a healthcare provider when negotiating a telemedicine agreement, counsel should understand what led to the healthcare provider and vendor commencing negotiations, and clearly understand the healthcare provider's goals and objectives for the telemedicine agreement. While a concession in license and maintenance fees may be ideal if the purpose is to reduce operating costs and maximize reimbursement, it may prove less valuable if the goal is to improve quality scores and reduce the need for transfers and length of stay across multiple facilities in a specific service line.

Ideally, counsel will be a participant in the healthcare stakeholders' selection process for the telemedicine vendor and its

products. However, it is understandable that resources are limited and that circumstances may not provide counsel immediate access to key stakeholders. If first-hand or in-person access is unreasonable, counsel can offset the absence of immediate access with the following:

Telemedicine Agreement Summary Form

A Telemedicine Agreement Summary Form can assist counsel in obtaining necessary information to negotiate a telemedicine agreement. Also, since telemedicine projects typically involve personnel from several departments, a Telemedicine Agreement Summary Form can facilitate the process of compiling information from multiple stakeholders. Possible Telemedicine Agreement Summary Form topics and questions include:

- What is the strategic purpose of this product/service?
- Why was this vendor/product selected and are there alternatives?
- What is the anticipated life cycle of this product?
- What hardware is being purchased and where will it be located?
- What software will be licensed, and where will it be installed or hosted?
- What data (personal information, protected health information) will be accessed and with whom will it be shared?
- Will the telemedicine product interface with other existing applications or hardware (electronic health record, reimbursement, medical coding)?
- Will this product require training clinical and/or administrative personnel?

Stakeholder and Vendor Materials

For large and mission-critical telemedicine product projects, it is likely that healthcare provider stakeholders have conducted SWOT (strengthen, weakness/limitations, opportunity, threats) analyses regarding the products. Also, the telemedicine vendor may already make available to the healthcare provider stakeholders presentations and sales material regarding the telemedicine product. Access to these materials can reduce the asymmetry of information and provide counsel additional context regarding the parties' relationship and the climate in which negotiations will proceed. Additionally, if a request for information or a request for a quote was issued, the information provided through that process should be reflected in the agreement.

Identify Internal Subject Matter

Telemedicine products draw upon multiple disciplines, including telecommunications, IT, clinical operations, quality improvement, and regulatory compliance. Counsel should work with the healthcare provider to identify which stakeholders are responsible for decision making and identify subject matter experts. These subject matter experts can help "fact check" the negotiations and assist counsel in evaluating options and developing counterproposals.

Regulatory Compliance

The opportunity to review background materials will also assist counsel in determining whether the telemedicine agreement complies with the applicable federal and state regulatory framework. Telemedicine agreements may require that the parties address regulatory issues regarding licensure/credentials, reimbursement, U.S. Food and Drug Administration compliance and guidelines, and data privacy and security. Counsel should give extra attention to assuring Health Insurance Portability and Accountability Act of 1996 compliance for telemedicine agreements, particularly if the telemedicine project will utilize a mobile platform. Recently, Office for Civil Rights Director Leon Rodriguez noted that, “in an age when health information is stored and transported on portable devices such as laptops, tablets, and mobile phones, special attention must be paid to safeguarding the information held on these devices.”³ Also, counsel should be mindful of fraud and abuse issues, including whether the client wants the telemedicine agreement to comply with any applicable Anti-Kickback safe harbors.⁴ Counsel should be aware that guidance on the application of the fraud and abuse programs to telemedicine is less developed than in other health law areas, is particularly fact specific, and may require additional scrutiny. Stark compliance, of course, is equally critical and requires careful analysis. The ability of a healthcare provider to support telemedicine projects can be hindered due to the limitations of Stark exceptions.

Availability and Performance

The telemedicine solution “availability” is a critical component of a telemedicine agreement. In this context, availability refers to the ability of a provider to conduct a clinical encounter remotely using the telemedicine system. A loss of service or software can immediately impact patient health and safety. When counsel negotiates a telemedicine agreement, it is important to keep in mind that an ounce of prevention is worth a pound of cure. Remedies for a loss of availability are important, but it is better to focus on ensuring that the vendor has appropriate policies and procedures in place to make certain that the services or software remain available throughout the telemedicine agreement. To this end, counsel should ensure that the following sections sufficiently protect the healthcare provider: service levels, force majeure, warranties of performance, warranties against time locks, and subcontractors.

Service Levels

The telemedicine agreement should provide both clear service levels and an explanation of the vendor penalties and obligations in the event that the service levels are not met. Financial incentives for the vendor to maintain the system and/or services can be powerful tools in avoiding risk. Service levels can address several aspects of service and software, such as uptime, software performance, data security, etc.

In telemedicine, uptime commitment is particularly important. By its nature, some component of the telemedicine solution will be remotely located. Because it is remotely located, the healthcare provider’s internal IT personnel may have little control over fixing

a problem that arises. When negotiating the uptime commitment, counsel should make sure that any excused downtime for maintenance is clearly established. The best outcome here is to limit scheduled downtime to specific hours that the healthcare provider foresees as being “off-peak.” Counsel will need to work closely with the healthcare provider’s IT department to ensure that scheduled downtimes are acceptable. If access is truly critical twenty-four hours a day, seven days a week, 365 days a year, consider rolling downtimes through which the production environment is transferred to a backup facility while the primary facility is down for maintenance; once the primary facility is again available, the secondary facility can be taken down for maintenance.

Force Majeure

Force majeure events may be unavoidable, but the telemedicine agreement should contain appropriate protections for the healthcare provider in the event that the vendor is unable to perform its obligations. Most telemedicine vendors will argue that they need a force majeure provision in the telemedicine agreement to enable performance to be delayed or suspended due to a natural disaster or act of God. However, suspension of telemedicine services can have dangerous consequences for patients. If a vendor has robust disaster recovery and continuity of operations plans, the impact of a force majeure event should be minimal. Effective disaster recovery and continuity of operations plans will transfer operations from the affected data center to an unaffected secondary or tertiary data center. While response times may be delayed, and there may be a brief downtime as the systems failover, the impact should be minimal. Another important consideration is to define the force majeure event as a closed list of events. To provide some flexibility, the healthcare provider may wish to include language that permits a termination of the telemedicine agreement if the force majeure event lasts more than a set period of time. Additionally, counsel should ensure that the healthcare provider’s payment obligations are suspended during any delay of services and/or software performance.

A unique consideration in the telemedicine field is priority of service reinstatement. The force majeure provision should include language that the healthcare provider is first priority for reinstatement when the vendor restores services and/or software. This obligation will enhance the ability of the healthcare provider to assist patients as soon as possible.

Once a force majeure event occurs, the vendor will rely on its disaster recovery procedures. The healthcare provider should review the vendor’s disaster recovery plan (DRP) as part of the contract negotiation. A robust DRP should contain three control measures: prevention (prevent the disaster), detection (detect the disaster), and correction (correct the disaster). The DRP should be reasonable, and should be tested to provide adequate assurances to the healthcare provider that the vendor is equipped and ready to respond to disaster. Recovery time and recovery points should be defined.

Warranties of Performance

A warranty of performance will allow the healthcare provider to claim a breach of the telemedicine agreement in the event that

the services or software do not perform in accordance with the technical documentation provided by the vendor. Performance metrics can be included in the definition of “documentation” and be tied to performance warranty, acceptance testing, and uptime provisions. By tying the documentation to these provisions, counsel can create an objective standard by which the products’ performance can be measured. This process can free up the healthcare provider to find another vendor, instead of having to navigate other contractual remedies with a troubled vendor.

Warranties Against Time Locks

Software often includes various time locks or other functions that serve to restrict access. Often, these are included as a security feature to prevent unauthorized use. However, the telemedicine agreement should include language that obligates the vendor to inform the healthcare provider of all such restrictions, and provide instructions to override these restrictions in the event of an emergency. Otherwise, when an emergency occurs, the healthcare provider may waste valuable time with back-and-forth communications with the vendor’s support services personnel.

Accepted Subcontractor

Prior to negotiating the telemedicine agreement, the healthcare provider will have reviewed the Telemedicine Agreement Summary Form discussed earlier. This serves as a vetting of the vendor to ensure that it is a company that can be trusted to provide software or services. However, IT vendors often utilize subcontractors in providing services. Because the subcontractor may play a crucial role, the healthcare provider could be placing its fate in the hands of an unknown party. To avoid this risk, the telemedicine agreement should include language that limits the vendor to using subcontractors that have been approved in writing by the healthcare provider. This requirement allows the healthcare provider to properly vet all parties that will be responsible for maintaining the telemedicine services.

Avoidance of Adverse Events

Too often, contract negotiations are reduced to how to allocate liability between the parties in the event of undesirable consequences. Telemedicine agreements are no different in that each party routinely seeks to address exposure to warranty breaches (failed performance); bad acts (rogue employee or subcontractor); indemnification obligations (intellectual property infringement, malpractice, regulatory fines); and other unexpected consequences. Typically these risks are memorialized in the limitation of liability and indemnification provisions. While indemnification and limitation of liability provisions provide the stage for addressing the consequences of risk events, such terms and conditions do little to reduce the probability of an adverse action.⁵ The best limitation of liability provision is the one that is never needed. An effective negotiation aims to reduce the probability that adverse events arise and that the business relationship fails.⁶ In a telemedicine agreement, counsel should focus on developing clear and robust terms and conditions that include the following.

Technical Specifications and Interoperability Standards

The telemedicine agreement should clearly identify the telemedicine products’ technical specifications and interoperability standards. This process includes looking prospectively toward anticipated technical standards and market trends. Parties should also consider negotiating provisions that allow for the healthcare provider, or its contractor, to develop interfaces with the telemedicine products.

Detailed Implementation Plan

Negotiating a telemedicine agreement should include developing a clear plan for implementing the telemedicine products and services. Ideally the implementation plan will include defined milestones, performance measurements, and include sufficient time and opportunities for the provider to address the unforeseen interconnectivity and operational issues that can arise during implementation, as well as test the telemedicine products in an environment that will simulate anticipated use. Also, the implementation plan should include mechanisms and remedies to address a partial or completely failed implementation.

Governance Model

For large-scale and mission-critical telemedicine products and services implementation, counsel should consider including in the telemedicine agreement a governance model. A governance model can provide structure to the business relationship by identifying roles and responsibilities and the opportunity and process for dispute resolution. Also, a governance model can include creating a group comprised of representatives from both the vendor and the healthcare provider to identify problems and perform root cause analysis, as well as to assess the functionality of the telemedicine products and services. Typically, the governance model is attached as an exhibit to the telemedicine agreement.

Successful negotiation of a telemedicine agreement will require adequate preparation, as well as consideration of the unique aspects of a telemedicine solution. While this article serves as a useful starting point for considering various aspects of a telemedicine agreement, counsel should be vigilant about staying up to date with relevant regulations, as well as any technological advancements that will alter the way telemedicine is provided in the future.

- 1 See TARA KEPLER & CHARLENE L. MCGINTY, *Telemedicine: How to Assess Your Risks and Develop a Program That Works* (2006), available at www.healthlawyers.org/Events/Programs/Materials/Documents/HHS09/kepler_mcginty.pdf.
- 2 O. RUSSEL MURRAY, *THE MEDIATION HANDBOOK; EFFECTIVE STRATEGIES FOR LITIGATORS* 43 (Bradford Publishing Company 2010) (2006).
- 3 Press Release, U.S. Department of Health and Human Services, Massachusetts provider settles HIPAA case for \$1.5 million (September 17, 2012, available at www.hhs.gov/news/press/2012pres/09/20120917a.html).
- 4 See *OIG Advisory Opinion No. 11-12*, Op. OFF. INSPECTOR. GEN. (August 29, 2011) (available at <http://oig.hhs.gov/fraud/docs/advisoryopinions/2011/AdvOp11-12.pdf>).
- 5 See INTERNATIONAL ASSOCIATION FOR CONTRACT & COMMERCIAL MANAGEMENT, *2011 TOP TERMS IN NEGOTIATION* (2011).
- 6 *Id.*

Telemedicine Legal Hurdles—An Overview of Lesser Known Challenges

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When it comes to legal issues arising from telemedicine, most providers and companies seeking to participate in this business model think first and foremost about licensure and credentialing obligations that may impact the business. Lesser-discussed legal topics, like supervision obligations from a remote location, in-person requirements to establish a doctor-patient relationship, and the corporate practice of medicine, should also receive significant consideration for each telemedicine program or entity.

Telemedicine is merely the remote delivery of healthcare services; said another way, practicing medicine using some means of technology to connect with a patient or other providers for the delivery of medical care. Regulators, at the state and federal level, continue to evaluate how this delivery model for healthcare services may or may not require new or different regulatory requirements. Some states have adopted laws and regulations specific to certain telemedicine-related topics (later revised in some instances),¹ while others remain silent on telemedicine-specific requirements. Regardless of the path taken by regulators, providers using telemedicine to deliver care must often deal with the challenge of interpreting regulations intended for the current “in-person” delivery models, especially with respect to topics such as: (1) supervision; (2) establishing a doctor-patient relationship; and (3) the corporate practice of medicine.

Supervision and Telemedicine

Many regulators, both at the state and federal level, require physician supervision of certain licensed and unlicensed personnel for the provision of particular healthcare services, tasks, or procedures. Such supervision requirements are typically based around physical location; thus, the application of telemedicine models necessitates a close review as the supervising physician may not be at the same physical location as the patient or the personnel that he or she is supervising. Further, the application of supervision requirements within telemedicine is generally an area where, to date, regulators are largely silent, leaving telemedicine providers and entities with little specific guidance on the topic.

At the federal level, the Social Security Act and Medicare Benefit Policy Manual provide three distinct levels of physician supervision for the performance of certain diagnostic tests, and require that different supervision thresholds be met depending on the type

of diagnostic test. “General Supervision” means the procedure is furnished under the physician’s overall direction and control, but the physician’s presence is not required during the performance of the procedure. “Direct Supervision” means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed. “Personal Supervision” means a physician must be in attendance in the room during the performance of the procedure.²

What is unclear within the context of telemedicine is whether or not the supervising physician’s presence, via remote synchronous video conferencing, is ever capable of meeting the direct supervision or personal supervision levels given that the supervising physician is, by definition, at a physical location separate from where the procedure is being performed. Arguably, within many telemedicine models, the supervising physician may have a more direct engagement with the location where the procedure is performed as the physician is “in the room virtually” even where only direct supervision is required in traditional “face-to-face” settings; yet, strictly speaking, the supervising physician may not be in compliance with supervision requirements, as his or her physical location is remote from the facility where the procedure is conducted.

Some states use the Medicare definitions of supervision noted above, while other states utilize a unique definition for distinct levels of supervision. Still other states maintain a general requirement that services performed by certain individuals be “performed under the supervision of a physician” but fail to place any specific criteria around “supervision” in the laws or regulations.

Consider, as a hypothetical, a telemedicine business designed around in-person evaluations performed by a medical assistant in the homes of patients residing in rural areas of Arizona followed by an assessment by a family medicine physician through a synchronous videoconferencing connection with the patient. A medical assistant is typically an unlicensed individual who performs certain data-gathering and clinical tasks under the license and supervision of a physician. States differ in the level of supervision required for medical assistants and also in the range of services that a medical assistant may perform, but, in Arizona, medical assistants can only perform certain delineated tasks under the direct supervision of a physician.³ Arizona defines direct supervision as requiring the supervising physician, physician assistant, or nurse practitioner to be present “within the same room or office suite as the medical assistant in order to be available for consultation regarding those tasks the medical assistant performs.”⁴ As such, under Arizona law the hypothetical telemedicine program may need to be restructured to meet state supervision requirements. In contrast, this same telemedicine model may not be specifically prohibited in Nevada, as Nevada requires medical assistants to perform clinical tasks under the supervision of a physician or physician assistant, but does not define supervision, thus physical in-person presence may not be required.⁵

Many feel, especially given the shortage of physician resources, that a strong advantage of telemedicine lies in its ability to provide a delivery method for non-physician practitioners (nurses, technicians, nurse practitioners, and physician assistants) to conduct healthcare services under the remote supervision of and consultation with a physician.⁶ The traditional constructs of supervision require modification and adaptation to care models providing significant physician involvement and supervision (perhaps even more so than in the traditional office setting), albeit from a location remote from the patient.

Establishing the Doctor-Patient Relationship in Telemedicine

Primarily in reaction to the issues surrounding online pharmacies, regulators adopted various requirements to establish an appropriate doctor-patient relationship prior to prescribing medications. As such, practitioners providing healthcare services through the use of telehealth technology must be cognizant of the doctor-patient relationship requirements for prescribing in a particular state and, also, any requirements that an in-person examination must be performed prior to the use of telemedicine to provide care and treatment.

Some states require an “in-person” (face-to-face) consultation between a physician and a patient, depending on the location of the patient (i.e., healthcare facility versus home environment), before a doctor-patient relationship is established for purposes of delivering healthcare services, including prescribing medicines. As an illustration, Texas differentiates between the use of telemedicine in a healthcare facility setting and the use of telemedicine in a patient’s home. Treatment of a patient in an institutional setting through telemedicine does not require a prior in-person examination. However, before a practitioner can provide treatment or other health services to a patient using telemedicine to a patient’s home, the practitioner must have a pre-existing doctor-patient relationship with the patient. Once that initial diagnosis is made, in person or at a facility, the patient may receive follow-up care for that pre-existing condition via telemedicine at home.⁷

Others states make exceptions for telemedicine services separate from prescribing medications. For example, Ohio law does not require an in-person examination of a patient prior to using telemedicine; however, an in-person examination may be required prior to prescribing medication.⁸

Still other states, like California and North Carolina,⁹ provide that a medical history may be conducted remotely if more than just a questionnaire is obtained. For instance, California also requires an appropriate prior examination before a physician may prescribe to a patient through telemedicine; however, this examination need not be in person if the technology is sufficient to provide the same information to the physician as if the exam was performed face to face.¹⁰

States requiring a face-to-face consultation to establish a doctor-physician relationship must be reviewed carefully in developing a telemedicine model, especially in the context of a direct doctor-

to-patient model where the patient is accessing the services from the patient’s home as compared with a doctor-to-doctor care consultation model where the services are provided in the setting of a healthcare facility. Doctor-to-consumer models may consider utilizing an on-site allied professional or primary care physician to conduct an exam under the supervision of the remote physician (see prior comments regarding supervision) to meet the in-person requirement, but it remains unclear as to whether such adapted structures satisfy the in-person requirement in some jurisdictions.

Corporate Practice of Medicine

A long-standing doctrine restricting non-professionals and non-professional entities from practicing medicine or employing professionals to practice medicine, the corporate practice doctrine presents a barrier to general corporations providing telemedicine services. Founded in state legislation and case law, the “rationale for prohibiting employment of physicians . . . is derived from the concept that individual physicians should be licensed to practice medicine, not corporations.”¹¹

Many states with a corporate practice doctrine provide exemptions for hospitals and other healthcare facilities to directly employ or contract with professionals to provide healthcare services on behalf of such facilities. However, as many telemedicine entities and providers are not structured or licensed as healthcare facilities, they are often subject to corporate practice prohibitions pertaining to general corporations. This can significantly limit the options of a general corporation from engaging in telemedicine within many jurisdictions.

Where the corporate practice doctrine limits the direct provision of healthcare by a general corporation, the general corporation may assist providers or professional entities controlled by providers with a telemedicine business by serving as its manager. Commonly known as a “friendly PC/MSO structure,” the general corporation may provide technology and management of scheduling functions, in addition to other administrative activities, while the professionals focus on the practice of medicine.¹²

Stay Tuned—Evolving Activities Likely Mean an Unstable Regulatory Environment

As with any evolving business model, regulators will undoubtedly continue to adapt, modify, and establish rules and requirements that impact telemedicine. As such, it is important for any telemedicine provider or entity to stay abreast of the latest activities of state medical boards as they relate to topics such as those discussed in this article in addition to the known telemedicine-specific topics of licensure and credentialing.

As telemedicine is just a delivery model for healthcare providers, it is always important to keep in mind all compliance and regulatory requirements normally applicable to the provision of healthcare services. Just be ready to adapt and interpret those requirements in the context of a remote environment where you are sometimes asked to fit a square peg into a round hole.

- 1 The Texas Medical Board continues to refine the telemedicine-specific rules included as part of Texas Medical Board, Board Rules, Texas Administrative Code, Title 22, Part 9, Chapter 174.
- 2 See 42 U.S.C. § 1861(s)(3); see also Centers for Medicare & Medicaid Services, U.S. Department of Health & Human Services, Medicare Benefit Policy Manual, Pub. No. 100-02, ch. 15, § 80.
- 3 See Ariz. Rev. Stat. Ann. § 32-1456 and Ariz. Admin. Code R4-16-401 to -403 (February 23, 2006).
- 4 See Ariz. Rev. Stat. Ann. § 32-1401(8) (September 24, 2012).
- 5 See Nev. Rev. Stat. § 630.0129 (January 1, 2012).
- 6 In fact, predicted healthcare provider shortages are not limited to physicians and include an anticipated nursing shortage of one million nurses by 2020—a crisis that may be tempered through widespread use of telehealth technology. See *What Works: Healing the Healthcare Staffing Shortage*, PricewaterhouseCoopers Health Research Institute, at 3 (2007).
- 7 See Texas Medical Board, *TMB Telemedicine FAQs* (last accessed Sept. 24, 2012, 12:15 pm), available at www.tmb.state.tx.us/professionals/physicians/licensed/telemedicineFAQs.php.
- 8 See State Medical Board of Ohio, *Position Statement on Telemedicine* (approved May 10, 2012) (last accessed Sept. 24, 2012, 12:17 pm), available at www.med.ohio.gov/pdf/NEWS/Position%20Statement%20on%20Telemedicine_Approved%20May%2010,%202012.pdf.
- 9 North Carolina Medical Board, *Policy Committee offers new position statement on telemedicine* (last accessed Sept. 24, 2012, 12:20 pm), available at www.ncmedboard.org/notices/detail/policy_committee_offers_new_position_statement_on_telemedicine/.
- 10 See Cal. Bus. & Prof. Code §§ 2242, 2242.1 (last accessed September 24, 2012).
- 11 Charles F. Kaiser III & Marvin Friedlander, *Corporate Practice of Medicine* 56, 60 (2010) (last accessed Sept. 24, 2012, 12:33 pm), available at www.irs.gov/Charities-&-Non-Profits/CPE-for-FY-2000.
- 12 Michael McArthur & Jim Owens, *Merger and Acquisition Activity for Hospital and Health Systems: Post-Reform Priorities and Trends* (Feb. 2011) (last accessed Sept. 24, 2012 12:44 pm) available at www.google.com/url?sa=t&src=1&esrc=s&frm=1&source=web&cd=2&ved=0CCoQFjAB&url=http%3A%2F%2Fwww.healthlawyers.org%2FEvents%2FPrograms%2FMaterials%2FDocuments%2FPHYHHS11%2Fmcarthur_owens_slides.pdf&ei=1alFUNnFDNSPQQG6_oFw&usq=AFQjCNEBsOmD2m8UJ3dG7BCPKf4Y_8HryA&sig2=RrUQsXknw_dA_boSAMLznNg.

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Accountability in Cross-Jurisdictional Telemedicine and mHealth

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As both clinical professionals and their patients increasingly adopt mobile telecommunications technology¹ that might serve as platforms for innovative medical applications (medical apps), it seems increasingly reasonable to envision a near future when there is no technological barrier to doctors diagnosing and treating patients from anywhere—their offices, homes, or the bleachers of their kids' after-school sports activity. This technological revolution also raises legal concerns related to the accountability of physicians performing remote medical diagnosis and individuals who develop these applications. Although some telemedicine services, such as telesurgery, will continue to require access to specialized technology and the participation of licensed clinicians at the site of care, a wide variety of care not requiring direct physical contact is currently technically feasible via apps running on smartphones and tablets across a continent or an ocean.² As physicians and others strive to fulfill patients' wishes for convenient access to healthcare services over the phone or Internet, without ever meeting the physician or other licensed professional providing the diagnosis, treatment, or other professional advice, it seems likely that legal practitioners and courts will increasingly need to consider complex questions raised by this new model of care delivery.

Traditionally, technology and the unwillingness of payors to pay for telemedicine were the chief limiting factors holding physicians back from widespread adoption. In order to provide telemedicine services, a provider traditionally had to invest in large, expensive equipment and had to have a special broadband connection. These technological and infrastructure barriers fixed the site of service to a particular geographic location. Accountability was accomplished through state medical boards that could enforce state law relating to the practice of medicine, and payors, who would not pay for such services. This paradigm shifted with the widespread availability of broadband Internet and the decreasing costs of technology. The introduction of smartphones allowed individuals to have high-speed processing power and portable broadband Internet connection in the palm of their hand. In addition, states, the federal government, and payors started to see the benefits of telemedicine and started to pay for such services.

In parallel to widespread adoption of versatile mobile technology and increasing availability of mobile medical apps, payment

system innovations that offer opportunities for increased direct financial contracting between patient and physician, such as high-deductible health plans, may also help to accelerate the emergence of service delivery models that are less tied to geographic proximity of provider and patient, and that cannot rely on payors' provider credentialing and prior in-person-visit requirements, which may have previously reduced the probability that insured persons would seek medical care from any provider willing to treat them in cyberspace.

The market for remote-delivered healthcare, particularly professional services furnished via newer mobile apps, is only beginning its development, and case law remains relatively rare. However, relevant cases, some legal literature, and guidelines and commentaries related to furnishing remote care to patients a physician has never met in person suggest a number of themes will be relevant in considering physician accountability for care delivered remotely via information and communications technology.

Licensure requirements apply when communicating with a patient in cyberspace, but licenses remain largely limited to specific geographic jurisdiction. Physicians seeking to treat, via the Internet or mobile health modalities, patients who are located outside the state(s) in which the physician is currently licensed will want to consider carefully their potential risk of being found to have practiced medicine in violation of applicable licensure laws, such as those of the state where the patient resides or is located when the treatment is delivered. Other clinical professionals may also need to consider, and seek legal counsel on, the potential differences in scopes of practice between states, and the resultant potential risk that furnishing care outside the state(s) where they are currently licensed may risk furnishing care they would not be authorized to provide if they did hold an equivalent license in that state.

The communication may occur in cyberspace, but any benefits or harms will accrue to the patient where the patient is located. Within the United States, current prevailing doctrines of jurisdiction suggest that clinicians furnishing services across jurisdictional boundaries via telephone, Internet, or mobile app may be found to have directed enough activity to the state where their patients reside, or where they knew the patients were located when care occurred, to subject themselves to that state's jurisdiction for at least the purposes of any contract or torts actions that might arise from the interaction with that patient. Determining where care occurred or mistakes occurred for purposes of choosing law to apply may be quite difficult even with the use of contractual choice-of-law provisions, which in some jurisdictions may be upheld only for contractual purposes and not for any potential medical negligence issues arising out of or incident to the performance of the physician-patient contract.

An interesting, and not yet adjudicated, question is whether a physician-patient contract provision stipulating choice of applicable standard(s) of care would be found to be valid under state laws. This suggests that physicians seeking to deliver care remotely should consider familiarizing themselves with the applicable standards of care (community or national) that might apply to remote patients' jurisdictions, and how those standards may differ with the standards of care the physicians are accustomed to referencing in their daily practice. This may be an even more crucial consid-

eration if a physician contemplates furnishing services to patients residing outside the United States. Other countries' professional practice guidelines applicable to care furnished by providers within their borders may differ to at least some degree from what would be considered national standards of care within the United States for the same condition rendered by a physician in the same specialty. Some of these standards may be mandatory for providers furnishing services to patients residing in that country.

The degree to which healthcare providers may be held accountable for hardware or software malfunctions or for availability failures of necessary Internet or other communications services is not yet clear. While the U.S. Food and Drug Administration has announced draft guidance in 2011 and plans to issue further guidance in 2012, pending later issuance of a more-complete regulatory framework, this guidance is limited to the specific medical apps that would qualify for regulation as medical devices or accessories to medical devices. Where care is at least partially dependent on technology that is more than simple text email or voice phone call, but still falls outside the definition of a medical device—say, for example, a smartphone's video-chat capability or camera—who is responsible if the patient is harmed as a result of an undetected malfunction in the technology? This is a question for which it is difficult to speculate what the answer might or should be. In the meanwhile, it would seem prudent to avoid purchase or service contracts whereby the physician agrees to indemnify the technology vendor or service provider for issues and events that are better predicted and managed by the technology professionals than by the physicians.

In conclusion, as technology evolves to meet challenges of new delivery and payment models, health professionals and supporting service providers may be increasingly interested in marketing services across jurisdictional boundaries both within the United States and internationally. To keep pace with this evolution, the law will need to develop constructs for predictably addressing issues of accountability for professional services delivered across jurisdictional boundaries via these technologies. While statutory, regulatory, and case law develops with the evolving market, prudent physicians and their counsel may be well advised to specifically research and analyze the potential licensure requirements and liability exposures applicable to each additional jurisdiction in which they would like to furnish care via technology.

Consideration of the potential benefits and limitations of such risk-mitigation tools as contract provisions may be indicated, and physicians may be well advised to consider identifying, and seeking patients' advance informed consent to accept, limitations on the types and complexities of symptoms the physician is willing to diagnose and treat without benefit of direct physical examination and under specific limitations of the available technology.

1 A survey in May 2011 found that 83% of adults in the United States owned a cell phone of some type, and 35% of all United States adults owned a smartphone—a handheld mobile device capable of accessing the Internet as well as making voice (and potentially video) calls. Aaron Smith, *35% of American Adults Own a Smartphone*, Pew Internet & American Life Project, 2011. Available at http://pewinternet.org/~media/Files/Reports/2011/PIP_Smartphones.pdf (last accessed September 23, 2012). A phone survey of approximately 3,000 adults living in the United States in January 2012 found 44% owning

smart phones and 18% owning tablets, with tablet ownership up 50% since the summer of 2011. Amy Mitchell, Tom Rosenstiel, and Leah Christian, *Mobile Devices and News Consumption: Some Good Signs For Journalism*, The State of News Media 2012, An Annual Report on American Journalism, Pew Research Center's Project for Excellence in Journalism, March 2012. Available at <http://stateofthemedias.org/2012/mobile-devices-and-news-consumption-some-good-signs-for-journalism/> (last accessed September 24, 2012).

2 While medical professional organizations have identified concerns about the quality of a physician-patient relationship, and about the extent of diagnosis that is ethical to perform without direct physical examination of the patient, these are outside the scope of this article.

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