TELEMEDICINE: HOW TO ASSESS YOUR RISKS AND DEVELOP A PROGRAM THAT WORKS

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Telemedicine services and activities have been around in the United States for over 40 years. However, it has only been over the last decade that telemedicine, telehealth and "outsourcing," as such terms are sometimes used interchangeably, have risen dramatically. There are a number of reasons for this rise—such as, better reimbursement, increased and better technology, patient demand, cost effectiveness, lifestyle changes for physicians—but challenges remain in setting up a successful, workable telemedicine program. Below is an overview of the major factors to be considered in any telemedicine program or arrangement.[1]

A. What is Telemedicine?

The definition of telemedicine varies based on the source and purpose of the definition, but it generally refers to the use of technology for the delivery of health care services when the health care practitioner and patient are not in the same physical location. Telehealth services are defined more broadly to include any type of health related services, medications or other information that is transmitted electronically. The American Telemedicine Association defines telemedicine as "(t)he use of medical information exchanged from one site to another via electronic communications for the health and education of the patient or health care provider and for the purpose of improving patient care, treatment, and services."

The Federal government and state governments have not yet agreed upon a common definition for telemedicine. For example, the Centers for Medicare and Medicaid Services (CMS) focuses on telehealth services and defines those to include two-way, real-time interactive communication between the patient and distant site physician but *not* via telephone, email, or fax.[2] Many states have chosen to follow CMS's lead in their definition of telemedicine,[3] but other states define telemedicine to *include* telephone calls, emails, or faxes.[4] The Joint Commission (TJC) in its standards refers to the definition used by the American Telemedicine Association.

The definition for telemedicine can also vary within and across states based on the purpose of the statute, such as medical licensure,[5] pharmaceuticals,[6] and private health

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[1] Selected portions of this paper appeared in: a paper entitled "Be Aware of the Nighthawk - Critical Deal Points" presented by Charlene L. McGinty and Lisa D. Taylor for the AHLA 2006 Physicians and Physician Organizations Law Institute; and a book entitled *Telemedicine: Survey and Analysis of Federal and State Laws* (AHLA 2007) by Thomas Wm. Mayo and Tara E. Kepler.

[2] 42 U.S.C. § 1395m(m)(1); 42 C.F.R. § 410.78(a)(3).

[3] *E.g.*, COLO. REV. STAT. § 25.5-5-415(5); NEB. REV. STAT. § 71-8503(4); N.M. STAT. § 24-25-3(C).

[4] *E.g.*, KY. REV. STAT. § 311.550(17); MONT. CODE § 37-3-342; NEB. REV. STAT. § 38-2024; N.M. STAT. § 61-6-6(K).

[5] *E.g.*, COLO. REV. STAT. § 12-36-106(1)(g).

[6] *E.g.*, FLA. ADMIN. CODE § 64B8-9.014(5).

insurance.[7] To further complicate the issue, telemedicine laws and regulations do not always explicitly refer to "telemedicine" and may use other words, such as "telehealth"[8] or "practicing medicine by electronic means."[9]

The most common telemedicine arrangements are found in the radiology arena. In these teleradiology arrangements, off-site physicians credentialed in the United States but either located within the United States or abroad, read or interpret diagnostic tests remotely usually at night and on weekends and holidays. With the rise of publicly-traded companies such as NightHawk Radiology Services and Virtual Radiologic, these teleradiology arrangements have become more common and a relatively successful model. Less successful have been the recent experiments with the use of foreign-credentialed radiologists located abroad to provide professional interpretations. Although teleradiology is by far the most common model, telemedicine arrangements can lend themselves to other disciplines (such as pathology, dermatology, ophthalmology, cardiology, neurology), service lines (such as home health, dentistry), and populations (such as prison inmates).

B. Licensure

1. Multi-State Licensing and Special Telemedicine Permits

Licensing of the physician(s) providing the professional services is one of the key issues in any telemedicine arrangement. This issue can be a challenge as state medical licensing laws have evolved independently of each other, and the lack of state consistency in regulating the practice of medicine presents a significant barrier to any multi-state telemedicine program. One of the initial questions when thinking about multi-state telemedicine activities is whether a license to practice medicine is required in each state or not. Some states explicitly address telemedicine in their state medical licensing laws and define the practice of telemedicine to include telemedicine that reaches into their state.[10] Some states indirectly address telemedicine by including the act of diagnosing or recommending treatment through any "electronic" means as the practice of medicine in their state.[11] Other states use broader language such as "by any means or instrumentality" to subject out-of-state telemedicine physicians to their medical licensing laws.[12] While still other states do not directly or indirectly address telemedicine in their state physician licensing statutes or regulations.

Even for those states that do not directly or indirectly address telemedicine in their medical licensing laws or define the location of the practice of medicine, it is generally assumed that any act of diagnosing or recommending treatment is the practice of medicine in the state the patient is located for the purpose of medical licensing and protection of public health regardless of whether it is accomplished in the physical presence of the patient or through electronic

[7] *E.g.*, HAW. REV. STAT. §§ 431:10A-116.3(b), 432:1-601.5(b), 432D-23.5(b).
[8] *E.g.*, 42 U.S.C. § 1395m(m)(1); NEB. REV. STAT. § 71-8503(4).
[9] *E.g.*, S.D. CODIFIED LAWS § 36-4-41; 22 TEX. ADMIN. CODE § 174.5.
[10] *E.g.*, TEX. OCC. CODE § 151.056(a), (b)(4).
[11] *See, e.g.*, W. VA. CODE § 30-3-13(a).
[12] *See, e.g.*, WIS. STAT. § 448.01(9)(a).

media.[13] Most importantly, all state physician licensing boards explicitly require a license granted by the board to practice medicine in their state. Therefore, in the absence of licensure exceptions for telemedicine, special telemedicine licensure requirements, or simplified license application processes for out-of-state physicians, all states medical boards would likely require a physician to obtain a license to practice medicine in their state before allowing the physician to provide telemedicine services to a patient located in their state.

It is important to note that physicians should reconsider their medical licensing laws even when they only seek to provide telemedicine services within their licensed state. This is because many states have special telemedicine licensing or permitting requirements for currently-licensed physicians seeking to commence telemedicine activities within the state.[14]

2. Licensing Exceptions

Obtaining valid licenses to practice medicine in each state into which a telemedicine project reaches is a cumbersome, costly, and time-demanding process. Many states allow out-of-state licensed physicians to receive an in-state license through abbreviated licensing processes such as endorsement, registration, reciprocity, and bordering states options. This does not necessarily eliminate the administrative and costly burden of obtaining licenses in multiple states, but it may reduce it. However, the physician will still be subject to multiple state medical boards' statutes and regulations upon abbreviated application approval or taking advantage of any out-of-state licensing processes or exceptions.[15]

Another option is the common consultation exception for out-of-state physicians. Most state medical licensing boards offer some form of a consultation exception for those physicians who are duly licensed in another state.[16] The exception exempts out-of-state physicians from the standard licensing requirements of the state. Other exceptions may also apply to a particular telemedicine activity. Thus, identifying the parameters of the applicable exceptions in each state is one way to ease the licensing burden for multi-state telemedicine projects.[17] For example, some states do not require out-of-state physicians to obtain a license to practice medicine from their state if the physician does not practice medicine in their state frequently,[18] is merely providing a second opinion,[19] or does not open a physical practice in the state.[20] Regardless of the nature of the exception, all states require the out-of-state physician to have a full,

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[13] *See, e.g.*, *U.S. v. Quinones*, 536 F.Supp.2d 267, 272 (E.D.N.Y. 2008).

[14] *E.g.,* ALA. CODE §§ 34-24-51, 34-24-501(a)(1), 34-24-502(a); CAL. BUS. & PROF. CODE §§ 2052.5, 2052(a); MINN. STAT. §§ 147.032, 147.081; MONT. CODE §§ 37-3-102(8), 37-3-342, 37-3-343; NEV. REV. STAT. §§ 630.020(3), 630.049, 630.160(1), 630.261(e); N.M. STAT. §§ 61-6-6(K), 61-6-11.1(A), 61-6-20; N.M. ADMIN. CODE §§ 16.10.2.7(E), 16.10.2.11; OHIO REV. CODE §§ 4731.296, 4731.34(A)(3), 4731.41; OR. REV. STAT. §§ 677.135, 677.137, 677.139; TENN. CODE §§ 63-6-201, 63-6-231(b)(21), 63-6-209(b); TENN. COMP. R. & REG. § 0880-2-.16.

[15] *See, e.g., Holzhauser v. State Med. Bd. of Ohio*, No. 06AP-1031, 2007 WL 2773472, at *3 (Ohio Ct. App. Sep. 25, 2007).

[16] *E.g.*, ALASKA STAT. §§ 08.64.326(a)(9), 08.64.240(b), 08.64.370(2).

[17] For a complete survey and analysis of each state's applicable exceptions, see AHLA's *Telemedicine: Survey and Analysis of Federal and State Laws*.

[18] *E.g.*, IND. CODE §§ 25-22.5-1-1.1(a), (a)(4), 25-22.5-1-2(a)(5).

[19] *E.g.*, 225 ILL. COMP STAT. § 60/49.5(b-c).

[20] *E.g.*, N.J. REV. STAT. § 45:9-21(c).

unencumbered license to practice medicine in the physician's state of residence to qualify for any exceptions.

3. Licensing and Regulation of Non-Physician Practitioners

States regulate more than just physicians involved in telemedicine activities. Many states have statutes that specifically regulate telemedical activities of nurses,[21] and states like Kentucky specifically regulate telemedical activities of chiropractors, dentists, psychologists, optometrists, physical therapists, and occupational therapists.[22] Thus, practitioners and organizations associated with telemedicine activities should be sure to think beyond the medical license issue when reaching across or within state boundaries through telemedicine.

C. Telepharmacies, Internet Pharmacies, and Electronic Prescriptions

1. State Regulation

Telemedicine activities often utilize technologies to facilitate pharmaceutical prescriptions and dispensing. Thus telemedicine coordinators should be aware of the array of state and federal regulation and enforcement efforts aimed at telepharmacies, Internet pharmacies, and electronic prescribing that have burgeoned over the past few years. For example, Alaska,[23] California,[24] Florida,[25] Kentucky,[26] North Dakota,[27] and Texas[28] are a few of the states that specifically regulate remote and Internet prescribing and dispensing activities. States have been aggressive in enforcing these remote prescribing laws and even other laws not specifically aimed at remote prescribing. For example, in August 2008 the Kansas Attorney General announced that charges were filed against a pharmacist for his role in an Internet pharmacy scheme in which the pharmacist allegedly distributed prescription drugs to customers based on Internet questionnaires.[29] The pharmacist was charged with one count Computer Crime, one count Conspiracy to Commit Computer Crime, one count Commercial Bribery, seven counts of violations of the Pharmacy Act of Kansas, and seven counts of violations of the Kansas Food, Drug, and Cosmetic Act. The pharmacist allegedly violated Kansas laws by shipping the drugs without valid prescriptions, not offering counseling to customers, and accepting compensation while violating a duty owed to the customers.

These activities may also result in criminal prosecution of the prescribing physician. For example, in 2006, Dr. Christian Hageseth was charged in California with the felony offense of practicing medicine in California without a license in violation of the California licensing law. Dr. Hageseth lived and worked in Colorado and had a Colorado medical license. The physician

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[21] *E.g.*, ARIZ. REV. STAT. §§ 32-1668 – 1669; IND. CODE. § 25-23.3; VA. CODE §§ 54.1-3030 – 3040.
[22] KY. REV. STAT. §§ 312.220, 313.255, 319.140, 319A.300, 320.390, 327.200.
[23] 12 ALASKA ADMIN. CODE § 40.967(27-28).
[24] CAL. HEALTH & SAFETY CODE § 1261.6; CAL. BUS. & PROF. CODE § 4119.1.
[25] FLA. ADMIN. CODE § 64B8-9.014.
[26] KY. REV. STAT. § 315.310.
[27] N.D. ADMIN. CODE §§ 61-02-08-01 – 09.
[28] TEX. OCC. CODE §§ 562.109 - .110; 22 TEX. ADMIN. CODE §§ 174.4, 291.121.
[29] Press Release, Kansas Attorney General, Attorney General Six Files Charges in Internet Pharmacy Scheme (Aug. 19, 2008), http://www.ksag.org/content/page/id/415.

prescribed drugs over the Internet to a California resident, but neither had direct communications with anyone in California nor was physically present in the state. When an arrest warrant was issued for Dr. Hageseth's arrest, he moved to quash the warrant and dismiss the complaint on the grounds of lack of jurisdiction of the California courts. The case ultimately turned on jurisdictional issues with the California Court of Appeals holding that the state had jurisdiction over the defendant and that it was immaterial to the jurisdictional issue that the alleged offense occurred over the Internet.[30] See further discussion on jurisdictional issues in Section G.6 below.

2. Federal Regulation

Similar to state laws and enforcement, federal laws and enforcement specific to remote prescribing are a top priority and evolving rapidly. Below is an overview of the key recent federal statutes and regulations relevant to remote prescribing and telemedicine: the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, and the U.S. Drug Enforcement Administration's (DEA's) 2008 proposed electronic prescribing regulations.

The MMA requires drug plans that participate in Medicare Part D to support e-prescribing by 2009 through e-prescribing systems that comply with uniform standards.[31] The purpose of the uniform standards are to ensure that e-prescriptions are created and transmitted in an interoperable format that can be read by the receiving pharmacy.

The MIPPA authorizes CMS to promulgate rules for e-prescribing incentive payments under the Medicare physician fee schedule.[32] Under MIPPA, physicians who adopt e-prescribing will qualify for bonus payments between 2009 and 2013. The MIPPA also authorizes a reduction in payments to those physicians who are not "successful" e-prescribers by 2012.

The recently passed Ryan Haight Online Pharmacy Consumer Protection Act of 2008 bans the sale or distribution of prescription drugs over the Internet without a valid prescription.[33] A valid prescriptions requires a practitioner to examine the patient in person, with certain exceptions for telemedicine activities. The law also requires online pharmacies to comply with pharmacy licensing laws in each state in which they do business and requires additional reporting for controlled substance dispensing. The law also increases the penalties for the illegal distribution of certain controlled substances.

The DEA's proposed electronic prescribing regulations would create detailed procedures and system requirements for (1) health care practitioners who create e-prescriptions for controlled substances, (2) the service providers for the e-prescribing software and systems, and (3) the pharmacies that dispense controlled substances pursuant to an e-prescription.[34] The

[30] *See, Hageseth v. The Superior Court of San Mateo, County,* 150 Cal. App.4th 1399, 59 Cal.Rptr.3d 385 (Cal. Ct. App. 2007).
[31] 42 U.S.C. § 1395w–104(e).
[32] *Id*. at § 1395w-4.
[33] 21 U.S.C. §§ 829(e), 802(a)(50-56), 802 (b-d), 830.
[34] Electronic Prescriptions for Controlled Substances, 73 Fed. Reg. 36722-82 (June 27, 2008).

DEA's proposed e-prescribing rules would present new civil and criminal liability risks for physicians, hospitals, and pharmacies participating in e-prescribing or dispensing activities if they fail to comply with the new requirements from the proposed rules. Among other things, the proposed rules would require: (1) practitioners to ensure that they only use e-prescribing systems that comply with the rules; (2) practitioners to ensure the security of their electronic signature tokens; (3) practitioners to monitor and report breaches in the security of their e-prescribing systems on a monthly basis; (4) pharmacies to monitor and report breaches in the security of their e-prescription dispensing systems on a daily basis; and (5) all DEA registrants to maintain records related to e-prescribing of controlled substances for five years.

Even without these new laws specific to remote prescribing, the federal government has used existing laws to target improper use of remote prescribing to divert controlled substances. For example, the Department of Justice recently announced that two physicians pled guilty to conspiracy for their involvement in an international Internet pharmacy business that generated more than $126 million in gross revenues from the illegal sale of prescription pharmaceuticals.[35] The physicians admitted to prescribing medications without conducting physical or mental examinations, having no contact with the customers, and having no physician-patient relationship with the customers.

D. Other Forms of Telemedicine State Regulation

Telemedicine leaders should not stop at state practitioner licensing and telepharmacy laws when researching telemedicine regulation in the specific states into which their telemedicine activity reaches. States have been passing statutes and finalizing rules affecting multiple dimensions of telemedicine practice and the regulations are rapidly evolving. Below is a representative list of the specific aspects of telemedicine that states have chosen to regulate and create heightened requirements:

- *Arizona*—informed consent, medical records, privacy, teleradiology, and hospital licensing;[36]
- *Texas*—informed consent, medical records, privacy, standards of care, quality of care, the physician-patient relationship, advertising, email, conflicts of interest, and physician supervision;[37]
- *California*—informed consent, medical records, and privacy;[38]
- *Florida*—informed consent, medical records, teleradiology, standards of care, and the physician-patient relationship;[39]

[35] Press Release, Department of Justice, Two Physicians Plead Guilty in International Internet Pharmacy Conspiracy (Aug. 1, 2008), http://www.usdoj.gov/criminal/cybercrime/shahPlea.pdf.
[36] ARIZ. REV. STAT. § 36-3602; 9 ARIZ. ADMIN. CODE §§ R9-21-206.01, R9-10-203(C)(2)(i).
[37] TEX. OCC. CODE §§ 111.002, 111.003, 111.004; 22 TEX. ADMIN. CODE §§ 174.3, 174.4, 174.5.
[38] CAL. BUS. & PROF. CODE § 2290.5; CAL. HEALTH & SAFETY CODE § 123149.5(a).
[39] FLA. STAT. § 458.3255; FLA. ADMIN. CODE § 64B8-9.014.

- *Kentucky*—informed consent, medical records, privacy, and worker's compensation;[40]
- *Nebraska*— informed consent, medical records, privacy, standards of care, and quality of care;[41]
- *Colorado*—medical records, standards of care, hospital licensing, and unprofessional conduct;[42]
- *Oklahoma*—informed consent, medical records, privacy, and the physician-patient relationship;[43]
- *Maine*—hospital licensing, credentialing, and certificate of need;[44]
- *Montana*—medical records;[45]
- *New Mexico*—privacy;[46]
- *Connecticut*—teleradiology;[47]
- *New Hampshire*—teleradiology;[48]
- *Nebraska*—quality of care;[49]
- *Tennessee*—contractual arrangements;[50] and
- *Utah*—hospital licensing.[51]

E. Credentialing and Medical Staff

Credentialing and/or Medical Staff requirements raise important considerations in any telemedicine arrangement. First, call coverage requirements in the Medical Staff Bylaws, rules and regulations, or policies and procedures may create a need for telemedicine services due to the increasing difficulty hospitals face in filling the call schedules in various specialties. However, physicians providing those services must be authorized under the Medical Staff

[40] KY. REV. STAT. §§ 311.5975, 342.315(7); 907 KY. ADMIN. REGS. § 3:170(6-8).
[41] NEB. REV. STAT. §§ 71-8505, 71-8507.
[42] COLO. REV. STAT. §§ 25-1-801, 25-1-802, 12-36-117(1)(jj).
[43] OKLA. STAT. § 36-6804.
[44] 10-144-112 CODE ME. R. § IX.E(4)(c); 10-144-503 CODE ME. R. § 10.E(2).
[45] MONT. CODE. § 37-3-348(2)(b).
[46] N.M. STAT. § 24-25-4.
[47] CONN. GEN. STAT. § 370-20-9(d).
[48] N.H. REV. STAT. § 329:1-b.
[49] NEB. REV. STAT. § 71-8507.
[50] TENN. COMP. R. & REG. § 0880-2-.16(7).
[51] UTAH ADMIN. CODE § R432-100-32.

Bylaws, rules and regulations or applicable policies to provide the services. More often than not, physicians providing telemedicine services may not be able to meet traditional Medical Staff membership requirements, such as seeing attending Medical Staff meetings, or participating on committees or in quality review activities. If the Medical Staff Bylaws are silent on this category of provider, the development of an applicable policy or category of Medical Staff membership or clinical privileges for physicians providing telemedicine services may be warranted, but ultimately may not offer the appropriate long-term solution.

Second, credentialing and recredentialing of a remote physician's credentials and performance both initially and upon reappointment, and at the time of each physician's professional license expiration, is a key concern and hospitals should have policies and procedures in place to handle the credentialing/recredentialing process. Crafting policies and procedures that comply with both TJC requirements and the CMS requirements may prove difficult in that TJC and CMS differ in their approaches and requirements.

Effective January 1, 2009, TJC credentialing standards for telemedicine are found at MS.13.01 and MS.06.01.03[52], and if the telemedicine services are provided through a contractual agreement, LD.04.03.09 applies. While these standards replace the prior TJC standards found at LD.3.50 and MS.4.120, the new standards are virtually identical to the old standards.

Under MS.06.01.03, the hospital must have a clearly defined process for credentialing and privileging its medical staff, with the process outlined in the Medical Staff bylaws. Under LD.04.03.09, consultative services and contractual arrangements that are directly related to patient care, such as telemedicine services, must be defined in writing. Further, licensed independent contractors who provide official readings or interpretations of images or specimens through a telemedicine link must be credentialed and privileged under LD.04.03.09. The contract should either specify that the contracting entity will ensure that all services provided by contracted individuals who are licensed independent practitioners will be within the scope of his or her privileges or verify that all contracted individuals who are licensed independent practitioners and who will be providing patient care, treatment and services have appropriate privileges, by obtaining a copy of the privileges list. Generally, the credentialing and privileging processes of the hospital receiving the telemedicine services (the originating site) will govern how licensed independent practitioners providing services through a contractual arrangement are credentialed and privileged. However, this requirement is not applicable in the following 3 circumstances: (1) where direct care is provided through a telemedicine link (MS.13.01.01 describes several options); (2) interpretive services through a telemedical link (LD.04.03.09, EP 9 permits the originating site to accept credentialing/privileging decisions of a TJC-accredited ambulatory care hospital); and (3) off-site services provided by a TJC-accredited contractor.

Under the new TJC standard in MS 13.01.01, the originating site can fully credential and privilege the practitioner according to its regular medical staff credentialing process. However, this new standard also gives the originating site the option of credentialing and privileging (1) based on information from a distant site if the distant site is a TJC-accredited organization; or (2)

[52] The Joint Commission Comprehensive Accreditation Manual for Hospitals: *The Official Handbook*, Effective January 1, 2009.

using the credentialing and privileging decision from the distant site to make a final decision if all of the following requirements are met: (a) the distant site is a TJC-accredited hospital or ambulatory care organization; (b) the licensed independent practitioner is privileged at the distant site for the services he/she will be providing at the originating site; and (c) the originating site has evidence of an internal review of the licensed practitioner's performance of the privileges, which it sends to the distant site, along with other information useful to assess the practitioner's quality of care, treatment and services for use in privileging and performance improvement; at a minimum, this information must include adverse outcomes from sentinel events resulting from the telemedicine services provided that are considered reviewable by TJC and complaints about the licensed practitioner by patients, staff or other practitioners at the originating site. The latter may be somewhat difficult to evaluate if the physician is not physically present. Although the TJC standards may alleviate some of the originating site's credentialing burdens and give the hospital an ability to circumvent normal Medical Staff Bylaws processes, hospitals should be wary of relying on credentialing and privileging standards of other facilities. If a hospital fails to establish credentialing requirements for this category of provider, or relies entirely on the distant site or the practitioner's employer to perform the credentialing, it increases its exposure on a claim for negligent credentialing.

The specific provisions of a Medical Staff Bylaws, rules and regulations, or policies and procedures depend upon the parameters of the privileges and how they are utilized. Some illustrative examples of provisions that might be included in any such policy are:

- define the scope of "telemedicine" activities with specificity (does it exclude "interpretative services" or "consultations"?)
- privileges and credentialing as an "originating site" and as a "distant site"
- detailed list of information to be provided to hospital and maintained in credentialing file (such as copies of driver's license, current medical license and other certifications, current CV).

CMS takes a different approach to the credentialing and privileging issue. Focusing on the Medicare Conditions of Participation for hospitals relevant to medical staff credentialing[53], CMS requires that each facility (both distant site and originating site) undergo the complete credentialing process applicable at that facility. 42 C.F.R. § 482.12 requires that "[t]he hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws." 42 C.F.R. § 482.22 states that "[t]he medical staff must periodically conduct appraisals of its members" and "[t]he medical staff must examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidates." On November 12, 2004, CMS issued "Centers for Medicare & Medicaid Services (CMS) Requirements for Hospital Medical Staff Privileging" in a letter to state survey agency directors, interpreting the Medicare Conditions of Participation relating to the privileging system found at 42 C.F.R. §§ 482.12 and 482.22. The letter stated that:

> "[a]ll practitioners providing a medical level of care and/or conduct surgical procedures either directly or under supervision, whether employed by the hospital,

[53] See 42 C.F.R. §§ 482.12 and 482.22.

> physician or other entity, or contracted, must be individually evaluated. Board certification, certification, or licensure in and of itself is not recognized as an appropriate basis to bestow or award any or all of the privileges included in a particular practitioner's category."

The language contained in this letter is the basis for the concern that CMS does not share TJC's view that, with respect to providers of telemedicine services, hospitals can accept the credentialing and privileging decisions of the distant site. CMS does not appear to be considering any flexibility in its interpretation and, accordingly, it is likely best to advise hospitals to continue to credential all telemedicine providers through their regular medical staff credentialing process. This, however, can add tremendous cost and time-delay to getting a telemedicine contract in place.

Another wrinkle in this area is that there is a new player in town. DNV Healthcare Inc. (DNV) is a new accrediting organization that has been approved by CMS to provide accreditation as an alternative to TJC accreditation. There are a number of hospitals that now have been accredited under DNV's National Integrated Accreditation for Healthcare Organizations (NIAHO) Interpretative Guidelines and Surveyor Guidance Revision 7. Under the interpretative guidelines to medical imaging standards found at Standard MI.5 regarding supervision is the following statement regarding telemedicine providers:

> "In the event that the hospital contracts for telemedicine to be used including the radiologist who interprets radiology tests, the hospital has a process in place to verify the radiologist interpreting the radiological test is licensed and/or meets the other applicable standards that are required by State or local laws in both the State where the practitioner is located and the State where the patient is located OR is subjected to the credentialing and privileging process through the medical staff to be approved for providing this service at the hospital."

Under this same section, the Surveyor Guidance indicates that the hospital must have a verification process in place and that the "radiologist may be required to go through the medical staff credentialing and privileging process of the hospital."

In addition to resolving competing telemedicine credentialing requirements of CMS, TJC, and other accrediting organizations, hospitals must also keep apprised of any new developments in the hospital licensing requirements for each state in which they operate. For example, as a condition for state hospital licensing in Maine and Utah, hospitals must comply with specific credentialing and medical staff requirements for physicians who participate in telemedicine activities in affiliation with the hospital.[54]

F. Reimbursement

1. Medicare Reimbursement

[54] 10-144-112 CODE ME. R. § IX.E(4)(c); UTAH ADMIN. CODE § R432-100-32.

Reimbursement rules create an additional barrier for interstate and intrastate telemedicine programs. The most common telemedicine restriction in federal, state, and private-payor reimbursement contracts is that medical encounters are not considered "medically necessary and appropriate" if the physician was not in face-to-face contact with the patient. Medicare has carved out a few exceptions to this general rule to allow for reimbursement for certain telehealth services, as discussed below.[55] Prior to 1997, with the enactment of the Balanced Budget Act of 1997 (BBA), Medicare did not have an explicit policy to pay for telehealth services. Under the BBA, the scope of telehealth services was limited to consultation services and the implementing regulation prohibited the use of an "asynchronous "store and forward" telecommunications system. Additionally, the professional fee was required to be shared between the referring and consulting practitioners and no facility fees were permitted to be charged. With the enactment of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Medicare payments for telehealth services was expanded effective October 1, 2001.

Currently, telehealth services are only reimbursable by Medicare, to the distant site practitioner, if the services were provided to a Medicare beneficiary at an acceptable "originating site." In addition to the reimbursement of the physician or practitioner at the distant site, qualifying originating sites may also bill Medicare for a facility fee related to the provision of the telemedicine service. Under most circumstances, an originating site must be located in a rural health professional shortage area (HPSA) or in counties located outside a Metropolitan Statistical Area (MSA). The originating site must also be one of the following to qualify: (a) a physician or practitioner office; (b) inpatient or outpatient hospital; (c) critical access hospital (CAH); (d) rural health clinic (RHC); (e) federally qualified health center (FQHC), (f) renal dialysis center, (g) skilled nursing facility, or (h) community mental health center.[56] The following are the current Medicare-reimbursable telehealth services, but the list is reevaluated annually[57]: consultations; office/outpatient visits; individual psychotherapy; pharmacologic management; psychiatric diagnostic interview examinations; and end stage renal disease (ESRD) services.

Medicare reimburses telemedicine services provided in live, real-time situations in which the physician is interacting with the Medicare beneficiary via interactive telecommunications systems. The only exception to the interactive telecommunications requirement is in the case of Federal telemedicine demonstration programs conducted in Alaska and Hawaii. Medicare also requires another physician, or "telepresenter," to be physically present with the Medicare beneficiary if it is medically necessary for the telemedicine service, as determined by the distant physician. The Medicare payment for a telemedicine service is the same amount that Medicare would have paid if the service had not been provided via telecommunications. In order to bill for Medicare reimbursement of telemedicine services, the physician or practitioner must be licensed under state law to provide the telemedicine service and must be one of the following types of health care practitioners: a physician; nurse practitioner; physician assistant; nurse-midwife; clinical nurse specialist; clinical psychologist; clinical social worker; or registered dietitian or nutrition professional.

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[55] See 42 U.S.C. § 1395m(m); 42 C.F.R. §§ 410.78, 414.65; Medicare Claims Processing Manual (chapter 12, § 190).

[56] The last three originating sites were recently added to 42 U.S.C. § 1395(m) in the MIPPA.

[57] Requests to add or delete telehealth services can now be submitted electronically to CMS at its Telehealth Requests resource mailbox at: CMS Telehealth_Review_Process@cms.hhs.gov.

If contracting for teleradiology services, one must also consider the impact of the new anti-markup rules for diagnostic tests on the provision of teleradiology services. The anti-markup rules are designed to prevent physicians or suppliers from profiting from (or "marking up") the technical, and now the professional, component of certain diagnostic tests performed by outside physicians/suppliers (i.e., who does not share a practice with the billing physician/supplier) but billed to Medicare by a different entity/physician. These new rules generally will not impact hospitals or apply to tests for hospital inpatients/outpatients because hospitals do not order tests as well as bill for them. Because the rule only applies to diagnostic tests that an office-based billing physician or supplier orders, the impact of these new rules will likely be felt by group practices who engage other physicians or suppliers to perform and interpret diagnostic tests. In particular, radiologists who interpret studies off-site via teleradiology will feel the impact and may have to restructure their relationships for these services, such as billing the professional component directly rather than reassigning to the practice or supplier.

In the 2009 Medicare Physician Fee Schedule[58], CMS has set up alternative approaches to when the anti-markup rule would not apply. In Alternative 1, CMS took a shared office approach and the anti-markup rule would not apply where the physicians supervising the technical or professional component performs substantially all (at least 75%) of his/her professional services for the billing physician/supplier. The 75% requirement will be satisfied if the billing physician/supplier has a reasonable belief that for the prior 12-month period and for the 12-month period following the provision of the service the performing physician provided substantially all of his/her professional services through the billing physician/supplier. In Alternative 2, CMS took a modified site of service approach in that the anti-markup rule would not apply where the technical component is supervised and conducted in the same office as the billing physician, and the professional component is performed in the same office as the billing physician.

2. State Medicaid and Private Payor Reimbursement

Although CMS encourages states to include telemedicine services in their Medicaid programs, states have great discretion in determining services and coverage under their Medicaid programs. State Medicaid programs and private payors have developed a wide range of reimbursement policies that range from complete denial of telemedicine service reimbursement to full reimbursement of any covered medical service provided through telemedicine. States also tie Medicaid reimbursement of telemedicine services with additional telemedicine-specific requirements, such as privacy, quality of care, and informed consent. For example, California, Colorado, and Kentucky require a range of heightened informed consent, quality of care, and privacy requirements for Medicaid reimbursement of telemedicine services.[59] Thus,

[58] 73 Fed. Reg. 69726 (Nov. 19, 2008). This rule was published as a Final Rule with Comment Period and the comment period ended December 29, 2008.
[59] CAL. WEL. & INST. CODE § 14132.725(e); COLO. REV. STAT. 25.5-5-320(4); KY. REV. STAT. § 205.559(3).

telemedicine program designers should identify the state Medicaid reimbursement policies for telemedicine for each state into which the program will reach.[60]

Private payor reimbursement for telemedicine can only be directly determined on a patient-by-patient, plan-by-plan basis. However, some states have created statutory requirements, to varying degrees, that private payors cannot discriminate between medical services provided via telemedicine and those provided via traditional, in-person encounters.[61] Thus, telemedicine program designers should identify whether the individual states into which their program will reach mandate private health insurance coverage of telemedicine and identify the specific telemedicine reimbursement policies for potential private payors. Practically speaking, health care providers can often negotiate coverage for telemedicine services if the particular service is not explicitly addressed in the payor contract or state Medicaid rules.

G. Malpractice, Liability, and Heightened Standards of Care

Few primary authorities directly address telemedicine malpractice issues. However, existing state malpractice case law, tort law and civil procedure will still govern telemedicine malpractice issues not directly addressed by a specific telemedicine statute or case. Based on the novel jurisdictional issues presented by many telemedicine encounters, telemedicine malpractice risk analyses should begin with the following key questions:

- In what state is the patient located?
- In what state is the physician located?
- To which state medical board(s) has the physician subjected herself in performing the telemedicine act in question?
- Is the physician properly trained to use the telemedicine equipment and did the physician use the equipment properly?
- Did the physician fail to utilize available telemedicine technology which could have prevented injury to the patient?
- What traditional medical encounters are most similar to the telemedicine encounter in question?
- Which state's laws are more favorable for your client (i.e., statutes of limitations, medical malpractice damages caps, medical licensure laws, standards of care, elements of malpractice, and burden of proof)?

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[60] For a more thorough collection of state Medicaid and private payor laws on telemedicine reimbursement, see AHLA's *Telemedicine: Survey and Analysis of Federal and State Laws.*

[61] *E.g.*, CAL. INS. CODE § 10123.85; CAL. HEALTH & SAFETY CODE § 1374.13; COLO. REV. STAT. § 10-16-123; GA. CODE § 33-24-56.4(D); HAW. REV. STAT. §§ 431:10A-116.3(C), 432:1-601.5(C), 432D-23.5(C); KY. REV. STAT. § 304.17A-138; 806 KY. ADMIN. REGS. § 17:270, 17:500(3)(13); LA. REV. STAT. § 22:657; N.M. STAT. § 24-25-5(B); OKLA. STAT. § 36-6803; TEX. INS. CODE § 1455.004.

- Does either state have telemedicine laws that heighten physician requirements and standards when performing telemedicine acts (i.e., informed consent, medical records, Internet advertising, quality of care, or prescribing medication)?

- Does the physician's malpractice insurance cover the telemedicine act in question? and

- Does the physician or telemedicine provider have sufficient assets in the state (or in the United States in the case of international telemedicine activities) in which the patient and hospital are located?

1. The Physician-Patient Relationship

As a general rule in medical malpractice, a physician does not owe a duty to a patient unless a physician-patient relationship has been established. In traditional medical encounters, the creation and termination of the physician-patient relationship is usually clearly defined and based on simple contract principles. The existence of the relationship becomes more questionable in common telemedicine encounters in which the patient and physician never meet each other, never have a conversation, and the remote physician merely interprets an x-ray or other diagnostic tool that later impacts the patient's subsequent treatment by another physician.

The boundaries of the physician-patient relationship created by these virtual encounters are not yet well-established in case law. However, courts have reviewed other indirect encounters and have developed applicable guidelines for determining whether a physician-patient relationship has been formed pursuant to a remote telemedicine encounter.[62] For example, physicians have been using telephones for many years to offer consultations, advice, and referrals directly and indirectly to patients. As these encounters have resulted in various medical malpractice claims over the years, some courts have held that direct contact is not required to establish a physician-patient relationship.[63] These courts have used the following types of guidelines for determining if a physician-patient relationship existed:

- A physician-patient relationship may exist even though the physician and patient have never had direct contact;

- A physician-patient relationship may exist where others have contracted with the physician on the patient's behalf;

- A physician-patient relationship exists if the relationship was contracted for or with the express or implied consent of the patient or for the patient's benefit; and

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[62] *See e.g., Lopez v. Aziz*, 852 S.W.2d 303, 305-7 (Tex. App.—San Antonio 1993, no writ); *Walters v. Rinker,* 520 N.E.2d 468, 472 (Ind. Ct. App. 1988); *Dougherty v. Gifford*, 826 S.W.2d 668, 673-75 (Tex. App.—Texarkana 1992, no writ).

[63] *See e.g., id.*

- A physician-patient relationship exists when health care services are rendered on behalf of the patient and are done for the patient's benefit.[64]

2. Multiple Physicians

Telemedicine encounters also make it difficult to determine which physicians involved in the encounter are creating a physician-patient relationship during the encounter. Often, more than one physician can be involved in a given telemedicine encounter. Telemedicine equipment on either or both sites of the telemedicine encounter may be operated by one or more physicians or supervised assistants. Operation of the telemedicine equipment by one physician may affect the treatment or diagnosis provided by the other physician involved in the encounter.

The question of who actually has control over the care of the patient and liability for negligence in such care is not as clear as in traditional medical encounters in which one doctor diagnoses or treats the patient in a face-to-face encounter. Traditional rules on joint and several liability will apply to telemedicine encounters in which more than one physician is involved and is found to be responsible for an indivisible injury to a patient during a single encounter.

3. Standard of Care

Assuming a physician-patient relationship is established, the standard of care to which the physician's care is compared to determine negligence is not always clear, even in traditional medical encounters. Some courts prefer using a local or community standard of care, while others use a national standard of care.

If a community standard is used, multi-state telemedicine encounters complicate the analysis. Which community should the court use as the reference point—the patient's or the physician's? It would be onerous to assume that the physician should be knowledgeable of multiple community standards of care. Alternatively, using the standard of care in the patient's community would also be reasonable because standards of medical care are primarily regulated by states to protect the patients located within the state. State regulation of medicine is rarely a tool for accommodating to the professional preferences of physicians located in the state. Obviously, a national standard of care simplifies the analysis for multi-state telemedicine encounters. However, international telemedicine encounters create the same type of dilemma when using a national standard of care. Which nation's standards should the court use, that of the patient or the physician?

In addition to pre-existing standards of care based on the type of treating physician or disorder being treated, states and private organizations have taken proactive steps to create standards of care specific to telemedicine encounters. For example, some states have created telemedicine-specific informed consents standards, privacy standards and general telemedicine standards of care, as discussed above. This creates an additional, heightened standard of care to which the physician's actions might be compared in a telemedicine negligence or malpractice dispute. Finally, private organizations have created standards of care for various types of

[64] *Walters,* 520 N.E.2d at 472.

telemedicine encounters, such as the Society of American Gastrointestinal and Endoscopic Surgeons' Guidelines for the Surgical Practice of Telemedicine;[65] the American Academy of Dermatology Association's Position Statement on Telemedicine;[66] the American Psychological Association's Statement on Services by Telephone, Teleconferencing, and Internet;[67] the National Electrical Manufacturers Association's (NEMA) Digital Imaging and Communications in Medicine (DICOM) Standard;[68] and the TJC Sentinel Event Alert 42, "Safely Implementing Health Information and Converging Technologies."[69]

Another complicating malpractice issue for telemedicine is whether a physician will be held liable for *not* utilizing available telemedicine technologies. Further, physicians may be liable for improper use and lack of training to use telemedicine equipment properly.

4. Patient Abandonment

Physicians can be held liable for patient abandonment if the physician unilaterally severs the relationship with the patient without reasonable notice or without providing adequate alternative medical care at a time when there is a necessity of continuing medical attention. Telemedicine encounters are often one-time encounters for a specific purpose. Failed communication between the consulting or referring physician's role in the ongoing care of the patient could result in an unintentional patient abandonment case in which both physicians assumed the other was responsible for the ongoing care of the patient. Therefore, physicians involved in telemedicine encounters should establish policies and procedures to ensure proper communication to the patient and among the involved physicians regarding the ongoing care of the patient after the encounter.

5. Malpractice Insurance Coverage

The parties involved in a telemedicine arrangement should ensure that a professional liability insurance policy is in place and actually affords coverage for telemedicine services. A careful review of their respective professional liability insurance policies' descriptions of coverage and exclusions is warranted and the lack of an exclusion for telemedicine services or a broad definition of professional medical services does not mean that the policy provides coverage for the telemedicine services. Therefore, the parties should seek written confirmation of coverage for these services from the insurer and affirmatively disclose the provision or use of telemedicine services as part of the insurance underwriting process. Some insurers, aware of this issue, explicitly request information regarding telemedicine services in their application.

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[65] Available at http://www.sages.org/sagespublication.php?doc=21 (last accessed Dec. 12, 2008).
[66] Available at http://www.aad.org/Forms/Policies/Uploads/PS/PS-Telemedicine%206-15-07.pdf (last accessed Dec. 12, 2008).
[67] Available at http://www.sages.org/sagespublication.php?doc=21 (last accessed Dec. 12, 2008).
[68] Available at http://medical.nema.org (last accessed Dec. 12, 2008).
[69] Available at http://www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_42.html (last accessed Dec. 18, 2008) ("As health information technology (HIT) and 'converging technologies'—the interrelationship between medical devices and HIT—are increasingly adopted by health care organizations, users must be mindful of the safety risks and preventable adverse events that these implementations can create or perpetuate.")

In the same way that the physician providing telemedicine services may need to be licensed both in the jurisdiction where he or she resides and the patient's home state, so may the insurance carrier. Few companies write malpractice coverage for broad geographic areas in the United States. Therefore, it may be necessary to obtain insurance in more than one jurisdiction to cover the telemedicine services if the multi-jurisdictional services cannot be covered under one policy. This need for multi-jurisdictional policies may avoid disclaimers of liability under an argument that the services were not rendered within the jurisdiction for which the policy affords coverage.

Another area of concern is that state insurance licensure requirements may prohibit coverage for telemedicine services due to requirements that the insurance carrier be licensed where the services are rendered, which can depend on the patient's location, the physician's location or both. In jurisdictions where government administered funds have been set up for basic or excess professional liability, those funds are often limited to coverage for services rendered in the state and often exclude coverage for telemedicine services. Coverage for services rendered outside the United States is an entirely separate issue, which must be addressed if services are provided or obtained in foreign countries. In sum, the challenge of obtaining comprehensive professional liability insurance for telemedicine arrangements may warrant the parties' consideration of alternative risk vehicles, such as the formation of a captive insurance company, in connection with the provision of services.

6. Jurisdiction and Choice of Law

For each state into which a multi-state telemedicine program reaches, the number of possible medical malpractice conflicts of law issues multiplies. The forum shopping possibilities for telemedicine malpractice claims should capture the attention of any national or multi-state telemedicine program's risk manager. Currently, the inability to predict how courts will allocate loss related to a given telemedicine encounter is a formidable barrier to multi-state telemedicine programs, and a complete analysis of telemedicine malpractice conflicts of law issues and forum shopping possibilities is beyond the scope of this paper.

However, telemedicine risk managers can begin by identifying the following:

- The possible states into which the telemedicine program and physicians are reaching; and
- The similarities and differences in medical malpractice law for the identified states.

It is unlikely that either of these tasks can be completed in accordance with clear legal guidance given the current embryonic state of telemedicine case law. The virtual nature of multi-state telemedicine encounters makes it difficult to determine where the injury actually occurred and what contacts the patient and physician have established within the multiple states involved that might dictate the law that will be used to resolve the dispute.[70]

[70] *See, e.g.*, *Hageseth*, 59 Cal.Rptr.3d at 399.

Further, just as advances in technology and transportation required state variances in commercial law to be standardized in the Uniform Commercial Code, telemedicine is challenging the traditional, independent state control over medical malpractice. States have significant variances in statutory and common law authority governing the elements of medical malpractice, standards of care, statutes of limitations, informed consent requirements, arbitration requirements, burden of proof, immunities and damages caps. These variances allow for creativity and increased opportunities for telemedicine malpractice claims but also limit the predictability of loss allocation and the effectiveness of telemedicine risk management.

In an attempt to address some of the legal ambiguities inherent to the virtual nature of telemedicine encounters, some states have crafted telemedicine-specific statutes that affect medical malpractice analyses.[71] Some states have statutorily defined the location of the telemedicine act as the physical location of the patient.[72] Some states have statutorily subjected out-of-state physicians to the laws of their state if the physician practices medicine in their state through telemedicine or utilizes a licensure exception to provide temporary or consultative services to in-state patients.[73] Some state even have new caselaw on the issue.[74] Thus, telemedicine risk managers should identify whether the states into which their programs are reaching have similar statutes or cases that offer a degree of clarity or an additional level of complexity to the risk analysis process.

Further, when drafting any telemedicine-related agreements, the drafting parties should take advantage of choice of law provision opportunities to avoid some of these ambiguities. Choice of law provisions allow the parties to decide how the terms of the agreement will be construed should a question arise. If the parties are in different states, or even different countries, as is common in these arrangements, deciding the law under which the terms will be construed provides certainty to the parties' liabilities outlined above. The default rules used by courts throughout the United States in deciding what law to apply to a contract are varied, with no definite rule applied, creating a great deal of uncertainty as to how the telemedicine agreement will be construed. International agreements without a choice of law provision are even more uncertain. To be safe, parties to these arrangements should take the time to review the laws of the states or countries involved in the transaction and draft a choice of law provision accordingly.

H. Fraud and Abuse

As with any method for practicing medicine in the United States, a physician undertaking a telemedicine endeavor is subject to a multitude of complex federal and state health care fraud and abuse statutes, regulations, and case law. In general, the majority of fraud and abuse issues unique to telemedicine relate to the infrastructure, equipment, and support necessary to implement any effective telemedicine endeavor. This section provides an overview of the key issues and arrangements unique to telemedicine that pose particular health care fraud and abuse

[71] *E.g.*, FLA. ADMIN. CODE § 64B8-9.014(1).
[72] *E.g.*, NEV. REV. STAT. § 630.049.
[73] *E.g.*, 225 ILL. COMP. STAT. § 60/49.5(e); MONT. CODE §§ 37-3-349, 27-6-103.
[74] *Hageseth*, 59 Cal.Rptr.3d at 399.

risks, but is beyond the scope of this paper to address the full range of possible fraud and abuse risks presented by telemedicine arrangements.

1. Anti-Kickback Risks

Under the anti-kickback statute, it is a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by any federal health care program.[75] If an arrangement that would otherwise implicate the anti-kickback statute meets the requirements of all applicable anti-kickback safe harbors, then the arrangement would not implicate the statute.[76] Two relatively new anti-kickback safe harbors relevant to telemedicine have been finalized. The safe harbors apply to situations in which a physician receives free electronic prescribing technology or training or free electronic health records software, information technology or training.[77]

It is important to note that Medicare's limited reimbursement for telemedicine services does not necessarily reduce anti-kickback risks. Even though Medicare limits the type and nature of reimbursable telemedicine services, a telemedicine arrangement could implicate the anti-kickback statute by inducing any other referrals beyond the telemedicine services involved. For example, if the necessary intent were present, the anti-kickback statute would be implicated by a telemedicine arrangement in which a cardiologist provided free telemedicine equipment to a general practitioner and offered free telemedicine consultations to the general practitioner's patients in return for the general practitioner's referral of patients to the cardiologist for Medicare-covered cardiology services.

2. OIG Guidance on Anti-Kickback

The Office of the Inspector General (OIG) has published two advisory opinions and one special fraud alert addressing telemedicine-related fraud issues. The OIG is responsible for enforcing the anti-kickback statute and publishes various guidance documents to assist health care entities in determining whether a certain arrangement would implicate the anti-kickback statute. In 1994, the OIG issued a relevant special fraud alert regarding clinical laboratory services which stated that the provision of free computers or fax machines to physicians by clinical laboratories could constitute illegal remuneration under the anti-kickback statute unless the physician: (1) used such equipment exclusively for coordinating laboratory services; and (2) the equipment was integral to the physician's use of the laboratory's services.[78]

This guidance could be applicable beyond computer and fax machine equipment for laboratory services and could be extended to any telemedicine-related equipment provided to physicians to facilitate a telemedicine encounter. For example, physician access to hospital telemedicine equipment for remote consultations could implicate the anti-kickback statute unless the hospital takes necessary precautions to make sure the equipment and services are only used

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[75] 42 U.S.C. § 1320a-7b.
[76] 42 C.F.R. § 1001.952.
[77] *Id*. at § 1001.952(x), (y).
[78] OFFICE OF THE INSPECTOR GENERAL, SPECIAL FRAUD ALERT: ARRANGEMENTS FOR THE PROVISION OF CLINICAL LAB SERVICE, 59 Fed. Reg. 65,372, 65,377 (Dec. 19, 1994).

for the benefit of hospital patients or any additional use is charged to the physician in accordance with the fair-market value (FMV) of the access to the equipment.

In 1998, the OIG issued another relevant advisory opinion regarding an arrangement between an ophthalmologist and an optometrist for telemedicine consultations provided by the ophthalmologist to the patients of the optometrist.[79] The ophthalmologist leased equipment to the optometrist that was necessary to facilitate the telemedicine consultations. The optometrist could also use the equipment to provide other services to her patients independent of the consultations by the ophthalmologist. The telemedicine consultations were offered to the patients for free. However, the OIG determined that the arrangement did not implicate the anti-kickback statute because: (1)the lease agreement for the equipment complied with the equipment lease safe harbor requirements; (2) patients referred for ophthalmologist services pursuant to the free telemedicine consultation were allowed the opportunity to choose any ophthalmologist to provide the recommended services; and (3) the ophthalmologist's free telemedicine consultations only resulted in minimal and incidental business benefits for the optometrist.

It is important to note that any telemedicine arrangement must be analyzed from each party's perspective and what benefits either party may receive in return for inducing referrals. Also, a safe harbor is remuneration-specific and does not globally protect an arrangement. As demonstrated in the arrangement between the ophthalmologist and the optometrist above, compliance with the equipment rental safe harbor only protected the remuneration directly related to the lease of the equipment. It did not protect the possibly valuable increase in the optometrist's business due to the additional telemedicine services being provided in the optometrist's office.

In 1999, the OIG issued an opinion related to the possible fraud exposure upon the expiration of a federal grant supporting a rural telemedicine network.[80] The OIG found that the health system's ongoing financial support of telemedicine equipment provided to rural health care providers would not violate the anti-kickback statute primarily because of the clear Congressional intent that network support was expected to continue beyond the term of the grant to establish much-needed telemedicine infrastructure in rural areas across the United States.

Given the unique facts of this opinion, it is unlikely that it will be useful fraud and abuse guidance for other telemedicine programs other than those that have received direct state or federal grant funding for the programs. However, the OIG was clear in stating that even with the Congressional intent, any health care provider that stood to profit from the telemedicine network should share the appropriate costs born by the health system to maintain the telemedicine infrastructure so as not to violate the anti-kickback statute. This is consistent with the previous opinion and the special fraud alert indicating that health care providers should not expect to profit from telemedicine equipment or services provided free-of-charge by an entity to which the health care provider can make referrals.

[79] 98 Op. Off. Inspector Gen. 18 (1998).
[80] 99 Op. Off. Inspector Gen. 14 (1999).

In summary, telemedicine arrangements in which free telemedicine equipment or services are provided should be analyzed for possible anti-kickback risks. Volume discounts and "per-click" arrangements in which an entity is reimbursed based on the number of Medicare referrals that are generated by the arrangement raise anti-kickback concerns. Further, secondary technology issues, such as physician websites that provide advertisements for on-line pharmacies, create anti-kickback risks. Applicable safe harbors should be examined to protect a telemedicine arrangement that would otherwise violate the anti-kickback statute.

3. Anti-Kickback Case Law

There have been two anti-kickback cases associated with telemedicine activities demonstrating that telemedicine arrangements are not immune from anti-kickback enforcement efforts. In *United States v. Greber*, an osteopathic physician was convicted of Medicare fraud for paying illegal remuneration to other physicians in return for referring patients for diagnostic services performed by his company, Cardio-Med, Inc.[81] One of the services provided by Cardio-Med was cardiac monitoring in which the data was stored in the device while the patient was wearing it, later uploaded to a computer, and the data was interpreted by the osteopathic physician at the Cardio-Med facility. This is a type of telemedicine service called "store-and-forward" and is different from other types of telemedicine services that occur in "real time." Remote interpretation of x-rays is another example of "store-and-forward" telemedicine.

In a similar case, *United States v. Polin*, a physician was convicted of Medicare fraud for paying illegal remuneration to a cardiac devices sales representative in return for referring patients to the physician's cardiac monitoring company, CVS.[82] In the opinion, the judge explicitly addressed the telemedicine component of the arrangement and explained that the monitoring services could be performed by the monitoring physician while in direct contact with the patient or remotely using appropriate technology.

4. Stark

The federal Stark self-referral law prohibits physicians from referring Medicare beneficiaries to an entity in which the physician has a financial interest for designated health services (DHS) reimbursable by Medicare.[83] The Stark self-referral prohibition is more narrow in its scope than the anti-kickback statute, but it is a strict liability offense that does not require intent. Similar to the anti-kickback safe harbors, compliance with a Stark exception protects a physician from violating the self-referral prohibition.[84]

The Stark definition for "financial interest" provides numerous financial interest exceptions, but the definition otherwise includes almost any arrangement in which a physician receives something of value from an entity to which she makes referrals.[85] So, similar to the anti-kickback statute, telemedicine arrangements that involve free telemedicine equipment or

[81] *United States v. Greber*, 760 F.2d 68, 69-70 (3rd Cir. 1985).
[82] *United States v. Polin*, 194 F.3d 863, 864 (7th Cir. 1999).
[83] 42 U.S.C. § 1395nn.
[84] *Id.*; 42 C.F.R. §§ 411.355 – 411.357.
[85] 42 C.F.R. §§ 411.354-411.357.

services, volume discounts, "per-click" payments, or advertisements on physician websites should be analyzed for possible self-referral risks and self-referral exceptions.

Similar to the new anti-kickback safe harbors discussed above, two new self-referral exceptions relevant to telemedicine apply to financial arrangements in which a physician receives free electronic prescribing technology or training or free electronic health records software, information technology or training.[86] Many of the other self-referral exceptions would also work well with common telemedicine programs. For example, one of the exceptions is for community-wide health information systems.[87] This exception permits physicians to refer Medicare patients to entities from which the physician has received information technology equipment or services that allow physician access to and sharing of electronic health care records for patients served by community providers, if certain conditions are met. The terms of this regulatory exception are similar to the OIG Advisory Opinion 99-14 and Special Fraud Alert in 1994 for clinical laboratory services addressed in the anti-kickback discussion above.

Another exception permits physicians to refer Medicare patients to a rural provider in which the physician has a financial interest.[88] A rural provider is defined as any entity that furnishes at least 75% of the DHS that it furnishes to residents of a rural area. Many telemedicine programs are used to provide remote medical services to patients in rural areas. Therefore, a physician might utilize this exception to invest in and refer patients to a telemedicine program that primarily served rural patients.

5. False Claims Act and Civil Monetary Penalties

Specific health care fraud and abuse violations, such as anti-kickback and Stark, are often coupled with more general federal sanctions under the False Claim Act (FCA) and the Civil Monetary Penalties (CMP) authority of the OIG.[89] The FCA prohibits knowingly submitting or causing to be submitted false or fraudulent claims for payment or false statements or certifications to the government.[90] CMP are applicable if a person knowingly presents, or causes to be presented, to a state or federal government employee or agent any false or improper claims.[91] Claims submitted to the Medicare program usually require the submitter to certify that the services were provided in accordance with all applicable federal and state laws and regulations.[92] Therefore, any telemedicine project that involves violation of federal anti-kickback or self-referral laws could be subject to additional sanctions under FCA and CMP, depending on the express and implied certification caselaw of the particular jurisdiction.

Independent of anti-kickback and Stark violations, FCA and CMP sanctions could be applicable to certain telemedicine projects that reach across state lines if appropriate licensure precautions are not taken. Medicare regulations explicitly require that the health care

[86] *Id*. at § 411.357(v), (w).
[87] *Id*. at § 411.357(u).
[88] *Id*. at § 411.356(c)(1).
[89] *See, e.g. United States v. Am. Healthcorp, Inc*., 914 F. Supp. 1507 (M.D. Tenn. 1996).
[90] 31 U.S.C. § 3729.
[91] 42 U.S.C. § 1320a-7a(a).
[92] 42 C.F.R. § 410.12.

practitioner who provided the services submitted on the claim be licensed to provide the services by the applicable state entity.[93] This requirement presents a unique fraud and abuse risk for physicians providing telemedicine services across state lines because the practice of medicine is defined by the location of the patient, not the location of the physician, and licensure laws vary by state. Therefore, if a physician provides telemedicine services for a patient physically located in another state without obtaining a license to practice medicine in that state or without qualifying for a particular exception to the licensure requirement, then, depending on the certifications made regarding licensure, the physician could be subject to FCA and CMP sanctions in billing Medicare or Medicaid for the telemedicine service.

6. State Fraud and Abuse Laws

The federal Stark and anti-kickback statutes and regulations are only the starting point for a telemedicine program fraud and abuse analysis. Any telemedicine program will also be subject to any state versions of the federal Stark and anti-kickback laws for the states into which the telemedicine program may reach. Some states have chosen to establish health care fraud and abuse laws that are much more expansive than the federal laws, while other states have chosen not to regulate the area at all. Certain states have chosen to integrate the federal fraud and abuse statutes into their state Medicaid statutes even though the federal anti-kickback and Stark statutes already apply to all state Medicaid programs as federally-subsidized health care programs. Some states have explicitly adopted certain aspects of the federal statutes but have failed to incorporate the related safe harbors and exceptions. Therefore, an arrangement that complies with a federal exception may still be subject to state fraud and abuse sanctions. In addition, a state may create telemedicine-specific fraud and abuse laws.[94]

I. Corporate Practice of Medicine

A jurisdiction's corporate practice of medicine requirements, if any, also need to be taken into account. To the extent that a jurisdiction prohibits the practice of medicine through a business corporation or a limited liability corporation or partnership that is not wholly owned by professionals licensed in the jurisdiction and the entity is providing telemedicine services (i.e. the corporate practice of medicine), the entity and the physicians providing services may be subject to professional discipline and other penalties for violation of the corporate practice of medicine doctrine. Depending on the state's statute, regulations, and case law, the institution contracting for the telemedicine services may also have some exposure.

Accordingly, parties considering a telemedicine arrangement should first confirm that the jurisdiction in which the telemedicine services are to be rendered allows the provision of professional medical services through the type of entity utilized. For example, although the use of professional limited liability companies for the provision of medical services is allowed in many jurisdictions, in some jurisdictions the provision of medical services by or through a limited liability company violates the corporate practice of medicine. Next, if the entity providing the telemedicine services is authorized under applicable state law to provide those

[93] *Id*. at § 410.20(b).
[94] *E.g*., KY. REV. STAT. § 311.5975(2)(a); TEX. OCC. CODE §§ 153.004, 111.004; TEX. GOV'T CODE § 531.02161; 22 TEX. ADMIN. CODE § 174.3.

services, confirm that the entity is qualified to do business in the jurisdiction (as a foreign domiciled entity, if necessary) and that the owners of the entity are properly licensed in all jurisdictions in which the entity does business.

J. International Issues

1. Fraud and Abuse

The practice of telemedicine across national boundaries presents additional fraud and abuse risks. As with many industries in this growing global economy, the health care industry has begun taking advantage of lower-cost, easily accessible physician services from overseas, particularly with radiology. The cost of transmitting radiological films overseas electronically is minimal, and the same is true for transmitting the foreign radiologist's interpretation of the films back to the originating location. State medical licensure laws are less accommodating to foreign-licensed physicians than to out-of-state licensed physicians, and the burden of complying with the necessary state licensure requirements for foreign physicians is greater.[95] This practice of telemedicine across national boundaries obviously presents an even more complicated licensure fraud and abuse issue than simply practicing telemedicine across state lines.

2. Medicare Reimbursement Limitations

Medicare currently places a ban on payment for services provided outside the United States. This ban can be problematic, particularly in teleradiology arrangements where the professional interpretations are provided overseas. But this prohibition has been sidestepped by labeling the professional interpretations provided by these physicians as preliminary and considering the subsequent follow-up reads by the regular staff the next day as the final interpretation.

3. Immigration

To the extent that services are rendered by physicians outside the United States or for the benefit of patients outside the United States, immigration issues must not be overlooked. These issues are especially crucial if telemedicine services are to be provided by resident alien physicians (permanent non-citizen residents of the United States holding green cards) since relocation outside the United States will invalidate eligibility for a green card if there is no longer an intention to permanently and indefinitely reside in the United States. Similarly, United States citizen physicians living in foreign countries providing telemedicine services may have immigration issues that should be considered by the parties.

The immigration laws are also commonly implicated in situations where a foreign physician is to provide telemedicine services in the United States on a work visa since the rules regarding the type of work that may be performed by the foreign physician are quite specific. Therefore, when contracting to provide, or contracting for the provision of telemedicine services, the parties to the arrangement must assure that the physician providing services is legally eligible

[95] *See* AMERICAN MEDICAL ASSOCIATION, STATE MEDICAL LICENSURE REQUIREMENTS AND STATISTICS 16-18 (2006).

to do so under the immigration laws and that, by providing such services, will not violate the immigration laws or jeopardize the physician's immigration status.

4. Tax Consequences

Tax consequences need to be taken into consideration by qualified U.S. and foreign tax counsel early on by parties contemplating an international telemedicine arrangement, especially if services are to be rendered overseas by a United States-based company, affiliate, or subsidiary. For example, if a United States-based company or practice decides to directly acquire professional medical services overseas (such as by directly hiring overseas physicians to perform interpretative services) such an arrangement could subject the entire company to foreign income taxation depending upon the laws of the foreign jurisdiction.

One theoretical option to try to avoid foreign taxation of non-foreign income is to create a foreign subsidiary. However, this approach gives rise to other issues. Depending on the jurisdiction, a corporate practice of medicine doctrine may prevent the use of subsidiary entities altogether because the operating entity must be solely and wholly owned by licensed physicians (see discussion above). Another theoretical option to avoid this undesirable tax implication involves creating a foreign affiliate, which operates parallel to the United States-based practice. However, depending upon the applicable laws, this structure could subject the owners of the parallel affiliate to a panoply of requirements of the foreign jurisdiction. These requirements could be extraordinarily burdensome or costly, especially if the United States-based owner has little or no involvement with the foreign jurisdiction. Foreign income will also have to be repatriated (brought back into the United States), resulting in tax consequences under the laws of this country—both federal and state.

Parties to a telemedicine arrangement with an overseas component need to take into account the separate, but related, matter of currency fluctuation. Purchasing the telemedicine services in United States currency will avoid currency fluctuation or exchange issues, but purchase or sale of dollar denominated services can in some instances have its own foreign tax consequences.

5. GATS National Treatment Provisions

In addition to state and international practitioner licensing requirements, telemedicine project developers should also be aware of any implications of the National Treatment provision of the World Trade Organization's (WTO's) General Agreement on Trade in Services (GATS). The WTO administers international agreements, such as GATS, that govern disputes in international trade of goods and services. The GATS National Treatment provision essentially prevents member countries from favoring their own services and service suppliers over services and service suppliers from other member countries.[96] As applied to telemedicine, a foreign telemedicine provider who is barred from providing telemedicine services in a particular country due to the country's medical licensing laws may be able to invoke the GATS National Treatment provisions to preempt the licensing restriction. The provider would need to show that the

[96] Matthew S. Yeo, Distance Health Services Under the General Agreement on Trade in Services, 35 JOURNAL OF HEALTH LAW 83, 90 (2002).

licensing restriction results in the favoring of *local* telemedicine providers over *foreign* telemedicine providers.[97] The applicability of the GATS National Treatment provision would need to be determined on a case-by-case basis depending on the GATS commitments of the two countries in question and the specific licensing law in question.

K. Ethical Considerations

As with the traditional practice of medicine, physicians participating in telemedicine activities should be aware of applicable ethical guidelines that may establish higher standards with which the physician is expected to comply, in additional to those standards established by statutes, regulations, and clinical practice guidelines. In 2002, the Federation of State Medical Boards' Special Committee on Professional Conduct and Ethics published *Model Guidelines for the Appropriate Use of the Internet in Medical Practice*.[98]

Many state medical organizations model their ethical guidelines on those of the American Medical Association (AMA), and the AMA has numerous ethical guidelines applicable to telemedicine,[99] such as H-480.968—Telemedicine, H-160.937—The Promotion of Quality Telemedicine, H-225.962—Medical Staff Membership Category for Physicians Providing Telemedicine, E-5.025—Physician Advisory or Referral Services by Telecommunication, E-5.027—Use of Health-Related Online Sites, and H-478.997 (and E-5.026)—Guidelines for Patient-Physician Electronic Mail. Thus, telemedicine program developers should be aware of any ethical guidelines from medical profession organizations that may apply to the particular telemedicine activity.

L. Practical Tips

While the possible legal issues presented by telemedicine activities might seem endless, counsel could reasonably identify and address the key risk areas for a particular telemedicine activity by asking the following questions.

In what states and/or countries will the involved health care practitioners, patients, and any related technologies be located? The laws of each of these jurisdictions will likely apply. Initially designing a telemedicine program that complies with the laws of the most rigorously regulated jurisdiction will likely make compliance with the other jurisdictions more manageable or at least allow decision makers to tailor the program in a way that will minimize multi-jurisdiction compliance burdens.

What types of health care practitioners will be participating in the activity at both the practitioner's location and the patient's location? Make sure you have checked the licensing laws applicable to each type of state-licensed practitioner and, specifically, for any heightened telemedicine standards or licensing exceptions or requirements that may apply. Unless a specific

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[97] DAVID P. FIDLER, DRAFT LEGAL REVIEW OF THE GENERAL AGREEMENT ON TRADE IN SERVICES (GATS) FROM A HEALTH POLICY PERSPECTIVE 232-33 (World Health Organization 2005).

[98] *See* the Federation of State Medical Boards website, http://www.fsmb.org/pdf/2002_grpol_Use_of_Internet.pdf (last visited on Nov. 19, 2008).

[99] See the AMA's website, http://www.ama-assn.org/apps/pf_new/pf_online (last visited on Nov. 19, 2008).

exception is identified, assume all practitioners will need to be licensed in each jurisdiction and will be subject to discipline by each licensing agency. Also be sure to check for possible heightened telemedicine standards or ethical guidelines from any private professional organizations that may apply to one of the participating practitioners or to the type of medical activity involved (i.e., teleradiology, teledermatology, telepsychiatry, etc.). In light of how rapidly telemedicine laws are currently evolving, compliance managers could craft a more proactive compliance program by being aware of the most common heightened telemedicine requirements in the areas of informed consent, privacy and data transmission, systems security, email and websites, the physician-patient relationship, patient abandonment, continuity of care, medical records, and contractual arrangements.

What types of facilities will be involved in the activity? Again, make sure you have checked the licensing laws and certificate of need laws for each type of state-licensed facility and for any heightened telemedicine standards that may apply. Also be sure to check for possible heightened telemedicine standards from private facility accrediting organizations that may apply.

What type of reimbursement will be sought for the services? Medicare, state Medicaid, state health insurance regulation, and private payor contract requirements for telemedicine must be independently scrutinized in light of other licensing or accreditation requirements that may complement or conflict with each other. Again, initially designing the telemedicine program to comply with the most rigorous reimbursement or accreditation standards will help counsel and decision makers define the parameters of the telemedicine program and choose reimbursement options that are in the best interest of the involved practitioner(s) and facility(s).

Does the activity involve any type of remote prescribing or dispensing of pharmaceuticals? This is one area of telemedicine that state and federal agencies have not only been regulating but also aggressively enforcing. Become familiar with all the federal DEA and CMS statutes, regulations, and case law (i.e., the MMA's Medicare Part D participation requirements, the MIPPA's Medicare e-prescribing incentive payments, the Ryan Haight Online Pharmacy Consumer Protection Act, and the DEA's e-prescribing regulations) and any heightened state requirements that may apply. Any activity that involves remote prescribing: (a) based solely on Internet questionnaires; or (b) situations in which the physician has never had a face-to-face interaction with the patient should be re-evaluated and closely scrutinized.

How can malpractice, liability, and fraud and abuse risks be minimized? Make sure the practitioners and staff are properly trained to use any involved telemedicine equipment, technology, or software. Become familiar with the established malpractice issues for traditional medical encounters that are most similar to the particular telemedicine activity in question. Create procedures at the onset of the telemedicine project that ensure proper creation and termination of the physician-patient relationship, continuity of care, coordination of care, and ultimate responsibility over the patient among multiple health care practitioners and facilities. Keep a list of the relevant state laws or professional standards of care that create heighten requirements for your particular telemedicine activity. Verify that your malpractice insurance covers the telemedicine act in question. Be critical of any arrangement in which telemedicine equipment, software, or services are provided free of charge. Do not assume that the federal anti-kickback and Stark laws are more rigorous than any similar, applicable state laws prohibiting patient solicitation or referral conflicts of interest. This is a hot area for state

regulation and enforcement in the current state of affairs with unanticipated budget shortfalls and unprecedented health care fraud recoveries. States have shown a willingness to enforce their health care fraud and abuse laws across state lines against those practitioners and business entities that reach into their state through telemedicine.