



Realizing the Promise of Telehealth: Understanding the Legal and Regulatory Challenges

As telehealth increasingly becomes an integral component of our health care delivery system, and patients become more accustomed to its convenience, hospitals, health systems and other providers will seek new ways to use the rapidly evolving technology in diverse and innovative ways. From emergency department care to remote patient monitoring for chronic care management, telehealth is changing the way health care is provided – both expanding patient access to routine and specialty care while improving patient satisfaction and outcomes.

As cited in a companion *TrendWatch*, “The Promise of Telehealth for Hospitals, Health Systems and Their Communities,” consumer interest, acceptance and confidence in telehealth are growing as well.¹ Health systems, insurers and private organizations are all responding to increasing consumer pressure for convenient, affordable alternatives to the

traditional doctor’s office visit. Services offered to consumers through private companies, either directly or through their insurer, allow patients to connect with a licensed physician, usually within a few minutes, by smartphone, tablet or computer. During the encounter, a doctor can evaluate symptoms, offer a diagnosis and even provide a prescription, if needed. The predictable costs and convenience of these services are very popular with consumers.²

All indications are that telehealth will continue to permeate the practice of health care as a natural extension and improvement of existing team care models. As telehealth utilization expands, however, myriad significant federal and state legal and regulatory issues will determine whether and how hospitals, health systems and other providers can offer specific telehealth services. In general, the provision of telehealth services requires compliance

with federal and state rules that apply to how most types of health services are provided. This *TrendWatch* focuses on the legal and regulatory challenges that may arise when using telehealth technologies.

Legal and regulatory challenges abound in the following areas:

- Coverage and Payment;
- Health Professional Licensure;
- Credentialing and Privileging;
- Online Prescribing;
- Medical Malpractice and Professional Liability Insurance;
- Privacy and Security; and
- Fraud and Abuse.

In addition, Congress is engaged in legislative efforts to ease the barriers to providing telehealth services, particularly in the Medicare program. States also are undertaking legislative and regulatory reforms to give greater flexibility and access to telehealth services through state Medicaid programs and private insurers.

Coverage and Payment Issues

Few obstacles present greater challenges for providers seeking to improve patient care through telehealth technologies than the issues of coverage and payment. Whether public and private payers cover and adequately reimburse providers for

telehealth services is complex and evolving. Without adequate reimbursement and revenue streams, providers may face obstacles to investing in these technologies. This may be especially detrimental to hospitals that serve areas where the

need for these services is greatest. In contrast, for example, hospitals and health systems with their own health plans may find it easier to deploy telehealth because they make coverage decisions and benefit from any cost savings.

Private Payers

On the private payer side, there has been significant expansion of telehealth services. Twenty-four states and the District of Columbia have enacted “parity” laws, which generally require health insurers to cover and pay for services provided via telehealth the same way they would for services provided in-person.³

Medicaid

With respect to public payers, federal Medicaid law gives states significant flexibility to cover and reimburse providers for telehealth services, including:

- whether to cover telehealth services;
- what types of telehealth services to cover;
- where in the state telehealth services may be covered;
- how services are provided and covered;
- what types of practitioners and providers may be reimbursed for telehealth services; and
- how much to reimburse for telehealth services, as long as payments do not exceed federally designated upper limits.⁴

States also may reimburse providers for facility or transmission fees by incorporating them into the fee-for-service (FFS) rates for the services provided or paying them as separate administrative costs (as long as the fees are linked to a Medicaid-covered service).

As a result of this flexibility, almost every state Medicaid program, both under FFS and Medicaid managed care, has some form of coverage for telehealth services. Live video is the most frequently covered telehealth service, while store-and-forward and remote patient monitoring services are defined and reimbursed by only a handful of state Medicaid programs. State Medicaid programs rarely cover e-mail, telephone and fax consultations, unless they are used in conjunction with some other type of communication. Twenty-four states pay providers at the originating

site either a transmission or a facility fee, or both. A few states have adopted the Medicare policy that restricts coverage of telehealth services to only those provided in rural or underserved areas.⁵

Medicare

Medicare’s policies for coverage and payment for telehealth services lag behind other payers due to the program’s restrictive statutes and regulations, limiting the geographic and practice settings in which beneficiaries may receive services, as well as the types of services that may be provided via telehealth and the types of technology that may be used. Medicare coverage for telehealth services was authorized in 2000 as part of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA). BIPA specified that Medicare covers telehealth only for beneficiaries receiving services in a facility in a rural area, defined as a facility located in a rural health professional shortage area or a county that is not included in a Metropolitan Statistical Area (MSA).⁶ This limits hospitals’ ability to use telehealth to increase Medicare beneficiaries’ access to care, since non-rural areas also may suffer physician shortages, and access to certain specialties (such as psychiatry) can be limited in all geographic areas. In 2014, the Centers for Medicare & Medicaid Services (CMS) slightly expanded the definition of “rural” to include facilities in a rural census tract.⁷ In addition, BIPA listed five types of provider settings that may serve as originating sites:

- hospitals;
- the office of a physician or other practitioner;
- critical access hospitals (CAHs);
- rural health clinics (RHCs); and
- federally qualified health centers (FQHCs).

Congress expanded this list in 2008 in the Medicare Improvements for

Patients and Providers Act, adding community mental health centers, skilled nursing facilities and hospital-based and CAH-based renal dialysis centers. The statute is silent as to the type of facility that may serve as a distant site, though CMS has excluded RHCs and FQHCs from serving as distant sites.⁸

Medicare beneficiaries’ access to telehealth services is further limited by the restrictive approach taken by CMS toward coverage. BIPA defined telehealth services as professional consultations, office visits, office psychiatry services, and any additional service specified by the Secretary. Through the annual physician fee schedule (PFS) rule, CMS approves new Medicare telehealth services on a case-by-case basis by individual Current Procedural Terminology (CPT) or the Healthcare Common Procedure Coding System (HCPCS) code. In 2015, only 75 individual service codes out of more than 10,000 physician services covered through the Medicare PFS are approved for payment when delivered via telehealth.⁹ This number includes seven codes CMS added in the final 2015 PFS rule.¹⁰

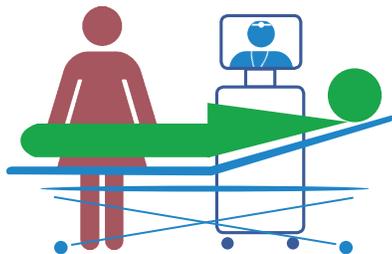
Medicare telehealth coverage also is limited with respect to approved technologies. BIPA provided that Medicare may cover telehealth services furnished only via a real-time video-and-voice telecommunications system. Except in Hawaii and Alaska, Medicare may not pay for telehealth services provided via store-and-forward technologies. And, despite growing evidence of the benefits of remote monitoring technologies for quality of care and improved outcomes for patients, remote monitoring services are not covered by Medicare.¹¹

As private insurers, Medicare Advantage plans have more flexibility and are beginning to provide telehealth benefits that are not covered under Medicare FFS rules. Although this is a positive step toward additional access to telehealth services for Medicare

Medicare provides reimbursement to the originating and distant sites for telehealth services.

Originating Site

Location* of patient receiving the telehealth service.



Originating site receives facility fee from Medicare to cover costs of facilitating a telemedicine visit. The site could be a:

- hospital
- physician's office or other practitioners' office
- critical access hospital
- rural health clinic
- federally qualified health center
- community mental health center
- skilled nursing facility
- hospital-based renal dialysis facility

Note: State Medicaid programs and private insurers may pay a transmission fee instead of, or in addition to, the facility fee.

*Beneficiaries receiving telehealth services must be in a facility in a rural health professional shortage area, a rural census tract, or a county not in a Metropolitan Statistical Area (MSA).

Medicare pays for 75 individual service codes in 2015.

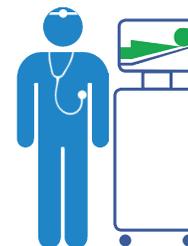


Congress defines telehealth services as:

- professional consultations
- office visits
- office psychiatry services
- others as determined by the Secretary

Distant Site

Location of health care provider providing the telehealth service.



Physician or other practitioner receives professional fee from Medicare for treating the patient.

The Medicare statute does not specify which facilities may serve as distant sites, though CMS has excluded rural health clinics and federally qualified health centers.

Source: Adapted from Center for Connected Health Policy, State Laws and Reimbursement Policies

beneficiaries, it leaves the 70 percent of Medicare beneficiaries utilizing FFS with limited access to these technological advances, unless the current restrictions on geography, practice setting, covered services and approved technologies are lifted. CMS could make progress in expanding telehealth by approving additional telehealth services for Medicare coverage; however, only Congress can lift the geographic and practice setting limitations and approve new technologies.

Delivery System Reform

Telehealth is an important component of delivery system reform. The Affordable Care Act (ACA) created the Center for Medicare & Medicaid Innovation

(CMMI) and tasked the agency with testing innovative payment and delivery models to reduce program expenditures while preserving or enhancing the quality of care. CMMI may test models that support care coordination through the use of technology—including telehealth—for:

- monitoring chronically ill individuals at high risk of hospitalization;
- utilizing telehealth to treat behavioral health issues and stroke; and
- improving the capacity of providers to offer health services for patients with chronic complex conditions, particularly in medically underserved areas and facilities of the Indian Health Service.¹²

The CMMI also has the authority to waive provisions of the Medicare

statute—including limits on the coverage of telehealth services—as necessary to test payment and delivery models. CMMI has waived the geographic limitation on telehealth services for participants in certain Bundled Payments for Care Improvement initiative models.¹³ In March 2015 CMMI announced a new accountable care organization (ACO) model, the Next Generation ACO, which will allow participants to obtain a waiver of the geographic and practice setting restrictions.¹⁴ CMS noted in a December 2014 proposed rule to strengthen the Medicare Shared Savings Program (MSSP) that it is considering a waiver of those same limitations for certain MSSP participants.¹⁵

CMS's Process for Approving Telehealth Services is Cumbersome

Each year, CMS considers requests to add to the list of covered telehealth services through the PFS rulemaking cycle. CMS reviews requests under one of two categories:

Category 1: These services are similar to professional consultations, office visits and office psychiatry services that are currently on the list of covered telehealth services. To determine whether to approve these services, CMS looks for similarities between proposed and existing services in the roles of, and interactions among, the beneficiary and the physician at the distant site, as well as in the telecommunications system used to deliver the proposed service.

Category 2: These services are not similar to services on the current

telehealth list, and thus, CMS undergoes a more rigorous review. Stakeholders must submit evidence indicating that the use of a telecommunications system in furnishing the service produces clinical benefit to the patient, not including minor or incidental benefits. Clinical benefits considered by CMS include:

- the ability to diagnose a medical condition without access to clinically appropriate in-person treatment options;
- provision of a treatment option for a patient population without access to clinically appropriate in-person treatment options;
- reduced rate of complications;
- decreased rate of subsequent diagnostic or therapeutic interventions;

- decreased number of future hospitalizations or physician visits;
- more rapid beneficial resolution of disease treatment;
- decreased pain, bleeding or other quantifiable symptom; or
- reduced recovery time.

Stakeholders must submit requests to CMS by December 31 of each calendar year for inclusion in the subsequent calendar year. For example, requests submitted to CMS by Dec. 31, 2014, will be considered for the calendar year (CY) 2016 proposed rule, which will be released by CMS in July 2015. After considering stakeholder comments, CMS will then finalize the addition of services, if any, in the CY 2016 final rule, which will be released in November 2015.

Health Professional Licensure

State licensure laws for physicians and other health care professionals can be major obstacles for those facilities wanting to provide telehealth services to patients in other states because of the current lack of portability of health professional licenses. Every state and territory has laws in place that govern the practice of medicine. These laws require a person practicing medicine to obtain a full and unrestricted license authorizing that person to engage in the practice of medicine within that state or territory.

A physician could have a restricted license that prevents him/her from performing a particular action. The American

Board of Addiction Medicine notes that a restricted license could be the result of any disciplinary action against the physician or could be as simple as a failure to renew the license before it expires. A license also can be geographically restricted. For example, physicians serving in the military may have licenses that restrict their practice to a military installation.¹⁶

Practice of medicine laws are primarily enforced by state boards of medicine, although in most states other state agencies also play a role in the enforcement of such laws, such as scope of practice provisions for advanced practice nurses. Because current state licensure laws

may not reflect the changing nature of medical practice and the growing use of technology, existing licensure laws could unintentionally present barriers to the opportunities and innovations of telehealth.

While a physician is required to obtain a full and unrestricted license in the state or territory where patients are being treated, many states have some type of physician licensure exceptions to ease some of these regulatory obstacles. Typically, a physician licensed in Idaho also would need to be licensed in Washington State or Wyoming in order to treat patients in those states

via telehealth. But a physician licensed in Idaho who is treating a patient in Idaho via telehealth does not face the same regulatory challenges. Another option for a licensed physician in Idaho is to apply for a special telemedicine license to treat patients in the states with that option, such as Montana or Nevada.

Special Telemedicine Licenses

According to the Center for Connected Health Policy, 10 state medical boards issue special licenses or certificates that allow physicians to treat patients in another state via telehealth services.¹⁷ In these states, an out-of-state provider may render services to a patient via telehealth in another state, while other states permit a clinician to provide services via telehealth in another state if certain conditions are met (such as agreeing not to open an office in that state). States with such licenses are:

- Alabama
- Louisiana
- Montana
- Nevada
- New Mexico
- Ohio
- Oklahoma
- Oregon
- Tennessee (both the medical and osteopathic boards issue such licenses)
- Texas

Consultation Exception

Most states have a consultation exception in their licensure requirements. This exception permits an out-of-state physician who is fully licensed in another state to provide consultations to an in-state licensed physician without requiring the consulting physician to be licensed in the state. Unlike a special telemedicine license, the consultation exception does not involve direct patient care by the out-of-state physician. Some states, such as Nevada, Oklahoma and

Oregon, have both special telemedicine licenses and consultation exceptions.

Given that the exception applies to physician-to-physician consultations, it may have limited appeal to out-of-state telehealth providers who want to consult with patients directly. However, for hospitals and health systems that have telehealth programs in which their physicians directly consult only with other physicians (with no patient interaction), the consultation exception may have appeal. The map below shows those states that permit consultations with few restrictions, and those states that permit consultations on an “infrequent” basis.

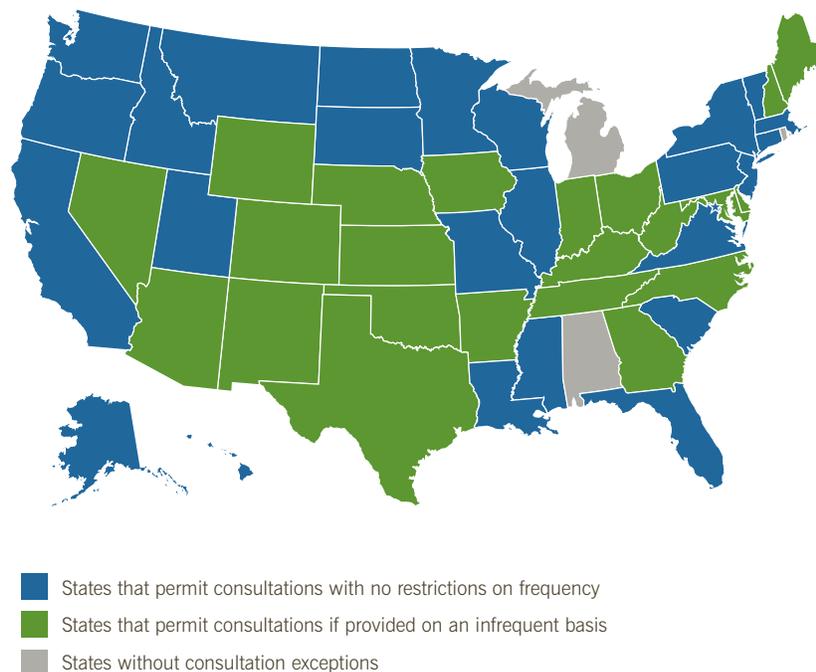
States vary widely on the particulars of the consultation exception. Twenty states permit consultations only if they are provided on an “infrequent” or “occasional” basis, although these terms are not

specifically defined in most state statutes. States do not expect the consultation to be used regularly by out-of-state practitioners to circumvent licensure laws. For example, Delaware limits consultations to 12 per year, while Iowa limits telehealth consultations to no more than 10 consecutive days and no more than 20 days in a year. In other words, the consultations are limited by the number of times a physician consults via telehealth with a physician in another state, not by the number of patients affected by those consultations.

Border State Exception

Under some limited circumstances, there is a licensure exception for a physician lawfully licensed in one state to practice in a border or adjoining state. For example, Ohio allows a duly licensed physician residing near the Ohio border in Indiana

Most states have a consultation exception in their licensure requirements.



Source: Center for Connected Health Policy, February 2015.

The FSMB states that the compact is intended to augment, rather than supersede, existing licensing and regulatory authority of state medical boards.

or West Virginia (contiguous states) to apply for a special certificate in order to treat patients in Ohio. One of the conditions to this exception is that the physician cannot open an office or appoint a place to see patients or receive calls within Ohio.¹⁸

Reciprocity and Endorsement

The least burdensome licensure approach is licensure by reciprocity. States, such as Alabama and Pennsylvania, grant a license to a physician licensed in another state, if that other state reciprocally accepts the original state's license.¹⁹ In Alabama, the State Board of Medical Examiners determines which states or territories have reciprocal licensure requirements meeting Alabama's qualifications. Licensure by reciprocity is very similar to how states grant drivers' licenses by reciprocal agreements.

A similar approach is licensure by endorsement. This approach allows an out-of-state licensed physician to obtain an in-state license based on his or her home state's requirements. For example, Connecticut's state medical board accepts the license granted by the physician's home state based on similar licensure standards. Generally, these laws require the physician to be in good standing and have a full and unlimited license to practice medicine in the home state. While physicians who offer telehealth services can use licensure by endorsement to obtain additional licenses in states where they intend to practice, endorsement still requires out-of-state physicians to apply for licenses, although with less burdensome requirements than exist for obtaining a full license.

Given the limited number of states that have reciprocity or endorsement

exceptions, this is not the ultimate solution to the issue of licensure portability for physicians that provide telehealth services in multiple states.

The Federation of State Medical Boards Interstate Medical Licensure Compact

The Federation of State Medical Boards (FSMB), an organization representing the 70 medical and osteopathic boards of the United States and its territories, received a three-year grant in 2012 from the Health Resources and Services Administration (HRSA) to study the issue of physician licensure, including licensure portability. In 2013, the FSMB House of Delegates unanimously passed a resolution to develop an Interstate Compact to expedite physician licensure and facilitate multistate practice. The FSMB assembled a team of state medical board representatives and experts from the Council of State Governments (CSG) to develop and draft a framework for an Interstate Medical Licensure Compact – a new licensing option under which qualified physicians seeking to practice in multiple states would be eligible for expedited licensure in all states that join the compact. State medical board representatives from a diverse collection of states, in terms of population, size, and geographic region, worked in conjunction with compact experts from CSG and FSMB staff to define the component principles to guide the FSMB in developing the compact legislation.

Interstate compacts are formal agreements between states that have the characteristics of both statutory law and contractual agreement. In order for a state to join the Interstate Medical

Licensure Compact, state legislatures must enact the compact into state law. While the compact would make it easier and faster for physicians to obtain a license to practice in those states that belong to the compact, an Interstate Commission would provide oversight and administration of the proposed compact. According to the compact legislation, the commission will create and enforce rules governing the processes outlined in the compact, and promote interstate cooperation, ultimately ensuring that the compact continues to facilitate safe and expedient access to care and physician licensure. Each state participating in the compact would have two representatives to the commission.

Recognizing states' preferences to maintain authority over the licensure process for providers within their own states, the FSMB states that the compact is intended to augment, rather than supersede, existing licensing and regulatory authority of state medical boards.²⁰ Some of the questions states may have about joining the compact involve a state's financial obligation as a member of the compact and how long it will take to develop the compact's bylaws for its governance and operations. A minimum of seven states must enact the Interstate Medical Licensure Compact for the Interstate Commission to begin developing the bylaws and processes needed to operate the compact.

As of April 2015, six states – Idaho, Montana, South Dakota, Utah, West Virginia and Wyoming – have enacted legislation to join the compact. Other state legislatures are considering legislation to join the compact: Alabama,

Illinois, Iowa, Maryland, Minnesota, Nebraska, Nevada, Oklahoma, Rhode Island, Texas and Vermont.

The FSMB compact could be a first step to address the challenge of license

portability. However, even if several states join the FSMB compact, there are still several key challenges associated with multistate physician licensure. These include the varied timetables that states

have for issuing licenses to physicians in states other than their home states—which may add time to the overall efforts by physicians to obtain multistate licensure, even in compact states.

Credentialing and Privileging

Credentialing and privileging are closely related processes undertaken by many types of health care facilities that employ or contract with health care providers. The process of credentialing and privileging occurs after a physician has met the state's licensure requirements. Credentialing is founded on the principle that hospitals and other types of health care facilities are responsible for ensuring the highest quality of care possible for their patients. In efforts to accomplish this goal, steps are taken to verify a health care provider's proficiency through the collection, verification and evaluation of data relevant to the practitioner's professional performance. After the practitioner has met the credentialing requirements, a hospital will further evaluate the practitioner's expertise in a specific practice through the process known as privileging.

In the telehealth context, credentialing and privileging issues may arise because services usually involve two or more health care facilities. For hospitals acting as originating sites, a longstanding problem has been whether they must directly credential and privilege each practitioner providing telehealth services, or may rely on the credentialing and privileging decisions of other hospitals or entities providing telehealth services

(known as “credentialing by proxy”). For several years, Medicare Conditions of Participation (CoPs) required originating site hospitals to credential and privilege distant site practitioners directly, the same way they would if the practitioner was located onsite – a significant burden for smaller facilities serving as originating site hospitals. Standards from The Joint Commission (TJC) allowed hospitals to rely on credentialing by proxy to be deemed in compliance with the CoPs. However, when TJC lost its deeming authority in 2010, it was feared that hospitals would lose the ability to rely on credentialing by proxy.

This issue was largely resolved by changes to the CoPs finalized by CMS in 2011.²¹ The 2011 changes permit originating site hospitals to rely on the credentialing and privileging decisions of the distant site hospital providing the services.²² This eliminates the requirement that hospitals undergo a separate privileging and credentialing process for each practitioner providing telehealth services from a distant site. To use this approach, an originating site hospital must meet several conditions:

- There must be a written agreement between the originating and distant site hospitals.
- The distant site hospital must be a

Medicare-participating hospital.

- The distant site practitioner must be privileged at the distant site hospital.
- The distant site hospital must provide a current list of the practitioner's privileges to the originating site hospital.
- The distant site practitioner must hold a license issued or recognized by the state in which the originating site hospital is located.
- The originating site hospital must review the distant site practitioner's performance and provide feedback to the distant site hospital, including information regarding any adverse events and complaints related to services provided by the distant site practitioner to the originating site hospital's patients.²³

Since reliance on credentialing by proxy may not completely protect an originating site hospital – for example, it may not provide a defense against potential claims for negligent credentialing – each hospital should assess for itself whether to use this approach or conduct its own credentialing process for distant site practitioners. In addition, hospitals should review their bylaws to ensure that telehealth services, such as remote monitoring, are allowed to be provided by physicians to whom they issue credentials and grant privileges.

CMS's 2011 changes to the CoPs allow the originating site hospital to rely on the credentialing and privileging decisions of the distant site hospital that provides medical services.

Online Prescribing

Even assuming hospitals have appropriately licensed physicians to provide services via telehealth, the issue of prescribing medication is another significant barrier to wider adoption of telehealth services by hospitals and other health care providers. States regulate online prescribing to guard against fraud and abuse by providers and patients. However, providers must be able to prescribe medications to patients they treat via telehealth to achieve the full efficacy of telehealth technology. Generally, and unless one of a very limited number of exceptions applies, state laws require that a physician first establish a valid physician-patient relationship before he/she may prescribe for the patient. The varying state approaches to online prescribing have led to a patchwork of inconsistent state laws with which hospitals operating telehealth programs in multiple states must contend.

In most states a physical examination or evaluation of the patient must be performed *prior* to issuance of a prescription by the prescribing physician.²⁴ But, the definition of a valid “physical examination” varies from state to state. In the case of telehealth, what constitutes a “physical examination” is critical, given that many telehealth physicians will be unable to physically examine or evaluate a patient in-person if the patient has not been seen previously by the telehealth physician.

Twenty states explicitly allow physical examinations or evaluations to be performed by electronic means or via telehealth technologies. For example, in Maryland, if no prior in-person, face-to-face interaction with a patient has occurred, a physician may “incorporate real-time auditory communications or real-time visual and auditory communications to allow a free exchange of information between the patient and

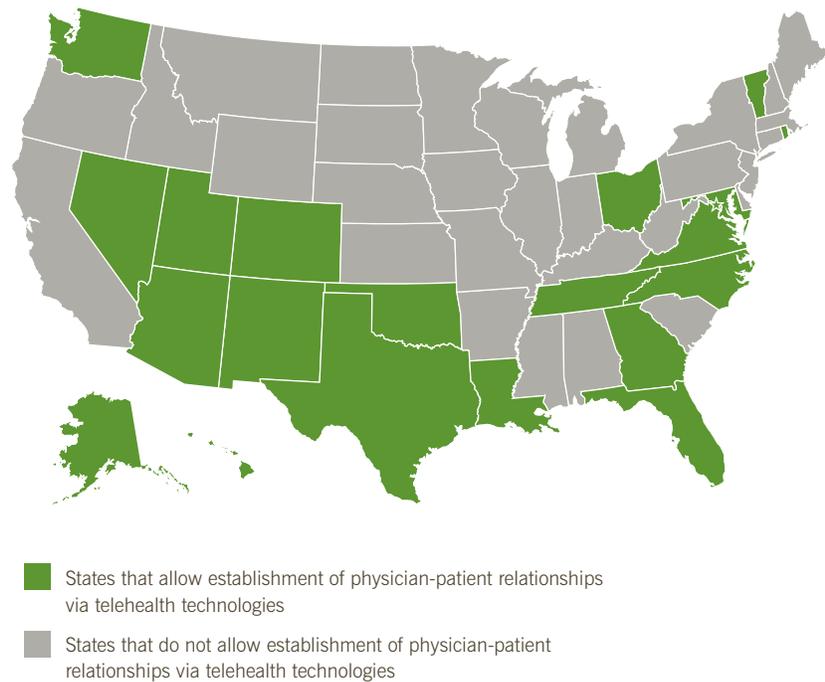
the physician performing the patient evaluation.”²⁵ States that allow physical examinations to occur by electronic means or via telehealth technologies tend to be more progressive overall regarding their approach to regulating the practice of telehealth. Hospitals in these states may find it easier to operate their telehealth programs with fewer restrictions than exist in many other states.²⁶

Other states broadly interpret the requirement and offer flexibility in determining how a physical examination or evaluation is conducted to establish a physician-patient relationship before the physician may prescribe online. Despite such varied approaches by states regarding the nature of physical examinations and evaluations, many states uniformly

prohibit prescribing based solely on information about a patient that the physician has gathered from an online questionnaire.

Some states have taken steps to regulate online prescribing through state pharmacy laws, which generally address issues related to when prescriptions are considered “valid.” These states’ laws place importance on the validity of the associated physician-patient relationship (including the physical examination/evaluation) that must be in place before a pharmacist will be allowed to dispense. In the District of Columbia, for example, a pharmacist cannot “dispense a prescription if the pharmacist knows that the prescription was issued without a valid patient-practitioner relationship.”²⁷ Under Colorado law, a pharmacist

Twenty states allow physician-patient relationships to be established via telehealth technologies.



Source: Center for Connected Health Policy, February 2015.

cannot dispense a prescription drug if the pharmacist knows or should have known that the order for such drug was issued on the basis of an internet-based questionnaire, an internet-based consultation or a telephonic consultation, all without a valid pre-existing patient-practitioner relationship.²⁸

The FSMB, as part of its *Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine*, proposed an innovative approach to online prescribing that would leave much of the discretion to the physician. This approach would give hospitals and physicians greater flexibility in how to implement telehealth programs that involve prescriptions. The model policy provides, in part, that:

telemedicine technologies, where prescribing may be contemplated, must implement measures to uphold patient safety in the absence of traditional physical examination. Such measures should guarantee

that the identity of the patient and provider is clearly established and that detailed documentation for the clinical evaluation and resulting prescription is both enforced and independently kept. . . . Prescribing medications, in-person or via telemedicine, is at the professional discretion of the physician.²⁹

The American Medical Association (AMA) has developed a series of model bills for consideration in state legislatures, one of which provides guidelines for establishment of a patient-physician relationship via telemedicine. The bill includes the requirement that telemedicine providers conduct a “face-to-face” examination (e.g., videoconferencing using interactive two-way audio and visual technology) to establish a patient-physician relationship, if the same would be required to provide treatment to a new patient in-person. For example, teleradiology or teleneurology might not require such technology. The model legislation

also provides an option for state legislatures to prohibit prescribing of medication to new patients based solely in response to an online questionnaire or telephone consultation. According to the AMA, legislatures in at least 21 states are considering measures based on this model bill.³⁰

The Federal Drug Enforcement Administration (DEA) laws pose barriers to providers of telehealth services. The 2008 Ryan Haight Act regulates those who deliver, distribute or dispense medication via the Internet. To prevent fraud and drug abuse, it prohibits the dispensing of controlled substances using the Internet without a valid prescription involving at least one in-person medical evaluation. The specific restrictions on the “practice of telemedicine” with respect to prescribing controlled substances may cause hospitals to limit or discourage their employed physicians from prescribing controlled substances via telehealth, which could hamper important services such as telepsychiatry.³¹

Medical Malpractice and Professional Liability Insurance

It is premature to judge whether existing principles of malpractice liability will need to be adapted for telehealth encounters. There are many unresolved issues and questions regarding malpractice liability as it relates to practicing in the telehealth setting, including the nature of physician-patient relationships, informed consent, practice standards and protocols, supervision and provision of professional liability insurance coverage.

Principles of liability are traditionally based upon in-person interactions between providers and patients, and there is an extremely limited body of case law from which to develop

assumptions about whether there are unique legal risks associated with providing telehealth services. Further, much of the case law associated with telehealth involves litigation against providers who prescribed medication over the Internet, rather than claims brought against providers for negligent care administered via telehealth technologies.

It is unclear whether the professional liability insurance industry will treat the provision of telehealth services differently than other types of practice. The professional liability insurance industry may require different premium rates and/or other additional types of

insurance coverage for providers practicing telehealth services. Insurers will likely assess issues such as:

- *Quality* – whether provision of care via telehealth technologies when the provider cannot see or touch the patient in person, improves or lessens the quality of care;
- *Effectiveness* – whether the quality of technology used during a telehealth encounter provides the same level of detail compared to viewing patients’ symptoms and conditions in person; and
- *Training* – how, and how well, providers are trained before engaging in telehealth encounters.

Key Questions Regarding State Professional Liability Laws

Some issues to consider regarding a state's laws before engaging in telehealth services include:

- When the timing of a physician-patient relationship is established and whether there are any unique considerations when services are provided using telehealth;
- Whether state laws require informed consent specifically for the use of telehealth that differs from the informed consent requirements for services provided in-person;
- Whether an existing standard of care is affected if the service is provided using telehealth and, if so, in what ways;
- Who bears the responsibility for the failure of telehealth equipment; and
- How the use of telehealth affects existing liability coverage.

Privacy and Security Considerations

Hospitals must understand how the existing legal and regulatory requirements for safeguarding the privacy and security of a patient's medical information and other data extend to the operation of telehealth programs. Telehealth technologies can facilitate the generation, transmission, and storage of tremendous volumes of new electronic health information and as a result, create some additional operational challenges for hospitals in meeting their existing privacy and security obligations under the Health Insurance Portability and Accountability Act (HIPAA), the Health Information Technology for Economic and Clinical Health Act (HITECH), as well as any relevant state privacy laws.

Hospitals may need to update their security risk analyses as well as modify and adapt their data privacy and security practices to respond to the specific risks and compliance challenges of using telehealth technologies. Telehealth patient interactions, by definition, involve voice, video and electronic communications with patients who are not physically present in the same location as the provider of the services. As a result, these interactions

heighten risks of, for example, an unauthorized disclosure of a patient's information (i.e., disclosure to someone who is not the patient or to a provider who is not responsible for that patient's treatment) in violation of HIPAA's privacy requirements. Consequently, existing hospital policies and practices should be reviewed carefully, and may need to be modified or adapted to ensure effective and reliable verification and authentication of the identities of patients and providers involved in a telehealth encounter.

Hospitals operating telehealth programs must address these vulnerabilities to adequately maintain the integrity and availability of protected health information as the HIPAA security regulations require. In addition, telehealth interactions typically involve providers from multiple organizations (e.g., mental health services are provided by Hospital A while mental health professionals are at Hospital B). As a result, hospitals operating telehealth programs will need to address questions like shared responsibility for securing and managing the health information generated through a telehealth encounter – including responsibilities

related to data breach notification and reporting—to confirm compliance with privacy and security requirements. Telehealth interactions rely on multiple information systems and communication technologies and platforms to generate and transmit electronic health information. Such circumstances can make it difficult, for example, to verify the security of data transmission or, even worse, to know when a breach of information has occurred that may implicate policies and practices for compliance with privacy and security requirements. Telehealth transmissions also may be vulnerable to interference, signal errors or transmission outages that can result in interrupted communications and the alteration or loss of important clinical information. The additional risks of telehealth programs require a health care organization's privacy and security professionals to participate from the start in the design and implementation of telehealth programs, and assume responsibility for actively monitoring operations.

When reviewing the types of electronic health information that are generated through telehealth encounters, hospitals should consider certain issues:

- Whether the data should be maintained as part of the “medical record.” This may pertain to whether video sessions should be recorded or if remote patient monitoring data should be saved.
- Whether relevant state laws require that the data be maintained or included in the medical record or HIPAA-designated record set. For instance,

HIPAA regulations serve as a “floor.” Some states, such as New York and California, have more restrictive requirements.

- Where data that are included as part of a patient’s medical record, or maintained for other reasons, are secured and maintained.

Of course, while HIPAA and its state equivalents continue to be the focus

of information privacy and security compliance concerns, hospitals also should pay attention to the Federal Trade Commission (FTC) as another significant, but perhaps lesser known, regulator of information privacy. The FTC regulates privacy under its consumer protection authority and could be applicable based on its jurisdiction over privacy issues.³²

Hospitals may need to update their security risk analyses as well as modify and adapt their data privacy and security practices to respond to the specific risks and compliance challenges of using telehealth technologies.

Fraud and Abuse

As is the case with other types of arrangements among providers in the health care field, telehealth relationships must comply with applicable federal and relevant state health care fraud and abuse laws, such as the federal False Claims Act.³³ Arrangements between independent providers (e.g., physician collaborations with institutional providers and/or technology companies) may be subject to federal and state anti-kickback statutes and/or federal and state physician self-referral prohibitions. As telehealth utilization and coverage for these services by Medicare, Medicaid and private carriers continues to grow, the potential for exposure to liability under various federal and state fraud and abuse laws will only increase.

One significant law is the federal Anti-Kickback Statute (AKS)³⁴ which prohibits a person from knowingly and willfully offering, paying, soliciting, or receiving remuneration, whether directly or indirectly, to induce referrals

of items or services covered by Medicare, Medicaid, or any other federally funded health care program. While telehealth arrangements are subject to the same scrutiny as other arrangements, they also benefit from the protection of applicable “safe harbor” regulations (e.g., personal service arrangements, space and equipment leases, and employment).

In 2011 guidance, the U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) concluded that a not-for-profit health system with a nationally ranked neurology and stroke center could cover certain program expenses, including the technology expenses that an outlying community hospital would have to incur in order to participate in the health system’s telestroke program without warranting sanctions under the AKS.³⁵ This conclusion was reached even though the OIG found that the telestroke program likely would result in transfers of some patients from the

community hospital to the health system’s stroke center.

Although this opinion is limited to this particular arrangement, the OIG noted that several factors adequately reduced the risk that the proposed arrangement could be an improper payment for referrals:

- the community hospital would not be pressured to refer patients to the health system;
- the telestroke program likely would result in a reduction of the number of transfers of simple stroke cases received by the health system’s stroke center; and
- physicians at hospitals participating in the telestroke program would not be restricted from referring stroke patients to hospitals other than the health system.

Another important federal statute is the Physician Self-Referral Law (“Stark Law”), which prohibits a physician from referring patients to an entity with which the physician or an immediate

Scenarios that could raise potential fraud and abuse concerns:

- Providing free or discounted telehealth equipment or software to individuals who may become patients or consumers of telehealth services;
- Providing or offering telehealth-related funding or equipment to organizations that are actual or potential referral sources;
- Offering telehealth services to organizations that are potential or actual referral sources and agreeing to refer telehealth patients preferentially to providers within these organizations for non-telehealth services;
- Billing private or government payers for telehealth services that were not rendered in compliance with state laws relating to licensure and/or scope of practice;
- Providing physicians who are potential or actual referral sources (or users of the product) with cash gifts, airline tickets, free lodging or meals.

family member of the physician has a “financial relationship” (meaning an ownership or compensation arrangement) for certain types of services.³⁶ The types of services include hospital services and radiology services that are paid by Medicare. However, the statute creates exceptions to the restrictions, many similar to those for AKS.

As with the AKS, there are many different ways in which a telehealth services arrangement could implicate the Stark Law. Two of the most common scenarios would be:

- referrals to organizations that provide physicians with free or discounted access to telehealth equipment or services (e.g., a hospital that provides physicians on its medical staff with free access to telehealth technologies of significant value) or
- referrals to organizations by physicians who are financially connected to the organization other than as employees

(e.g., a physician who refers a patient for health services to a telehealth provider that has engaged the physician as an independent contractor).

As mentioned, hospitals should be mindful of the federal False Claims Act (FCA), which provides that persons and companies that submit false or fraudulent claims for payment to any of the federal health care programs are subject to a civil penalty of between \$5,500 and \$11,000 for each false claim (those amounts are adjusted from time to time) and treble the amount of the government’s damages. If a person self-reports a violation of the FCA, the FCA provides that the person shall be liable for not less than double damages under certain conditions. While there are many potential pitfalls that could lead to violations of the FCA for all providers submitting claims to the federal health care programs, several create some unique liability risks for

telehealth providers. For example, telehealth providers may face heightened risk under the FCA with respect to services that are supervised but not directly performed by a physician or other supervising practitioner.

The Medicare program has specific requirements relating to supervision of non-physician personnel that providers must meet in order to bill appropriately for supervised services.³⁷ The supervision requirements raise various questions regarding whether claims submitted for reimbursement for services where supervision is provided via telehealth technologies could potentially be subject to FCA liability. In one case, the president of an Atlanta-based teleradiology company, and one of its principal radiologists, were found guilty of perpetrating a scheme to defraud various hospitals by signing and submitting tens of thousands of radiology reports performed by non-physician practitioners.³⁸

As telehealth utilization and coverage for these services continues to grow, the potential for exposure to liability under various federal and state fraud and abuse laws will only increase.

Federal and State Telehealth Legislative and Regulatory Efforts

Several federal agencies already are adopting or promoting the use of telehealth technologies to improve access to quality health care. In December 2014, HHS released a draft of a five-year strategic plan encouraging health care providers to adopt new technologies. The included strategies involve reforming public sector payment systems, including Medicare, to accommodate more widespread utilization of telehealth services, ensuring that different facilities can exchange information, and promoting the use of remote technology to monitor patients. The draft was issued in partnership with approximately 35 other agencies, including HHS's Office of the National Coordinator, CMS and HRSA, as well as the Departments of Agriculture, Defense and Veterans Affairs.³⁹ For instance, HRSA provides resources to support telehealth, including regional telehealth resource centers that provide technical assistance.

Challenges remain to ensure that federal policies can be applied seamlessly and uniformly to health care systems throughout the country. For instance, some rural communities in Alabama and Vermont do not have sufficient and reliable broadband access, which significantly hinders their ability to utilize these rapidly changing technologies. The Federal Communications Commission

(FCC) is taking a large role in telehealth to address some of these inequities. Among other things, in 2013, the FCC allocated \$400 million through the Healthcare Connect Fund to help rural providers access broadband services.⁴⁰ The Connect Fund is essentially an update to the FCC's Rural Health Care Pilot program, which provided an 85 percent rate subsidy to fund regional and statewide health broadband networks in 38 states. It will allow patients of rural hospitals and clinics to access specialists at major health centers through telehealth while supporting the exchange of electronic health records. More recently, the FCC announced the formation of a new task force, the Connect2Health Task Force that "will bring together the expertise of the FCC on the critical intersection of broadband, advanced technology, and health."⁴¹ The Connect2Health Task Force is considering ways to increase adoption of health care technology, including telehealth, by "identifying regulatory barriers and incentives and building stronger partnerships with stakeholders in the areas of telehealth, mobile applications, and telemedicine."⁴²

Congress is showing great interest in facilitating telehealth innovation and adoption. More than 50 bills dealing with some aspect of telehealth were

introduced during the 113th Congress. In January 2015, the U.S. House of Representatives Energy and Commerce Committee drafted the Advancing Telehealth Opportunities in Medicare Act and sought stakeholder input on ways to modernize Medicare's approach to telehealth. In response to this request, the AHA urged the committee to address several Medicare statutory restrictions in order to expand Medicare coverage for telehealth services and make Medicare reimbursement more consistent with state Medicaid programs and private payers.⁴⁴

The U.S. Senate also continues to explore a broad range of telehealth issues. In September 2014, the Senate Select Committee on Aging held a roundtable titled, "Harnessing the Power of Telehealth: Promises and Challenges?" that involved CMS, FCC, FTC and several stakeholder groups discussing licensure, reimbursement and how to define telehealth.

The recent Medicare Access and CHIP Reauthorization Act called for a General Accounting Office (GAO) study by 2017 with legislative and administrative recommendations on a number of telehealth issues, including issues that facilitate or inhibit the use of telehealth under Medicare (i.e., oversight and professional licensure;

"Our Colorado Telehealth Network has participated in the Rural Health Care program for many years, and combined those funds with state efforts to build a strong telehealth network. Our experience has shown us that the FCC still has much to learn about the obstacles that states face in creating robust broadband networks in order to facilitate meaningful telehealth utilization. The formation of the FCC task force is certainly a step in

the right direction, and we will work with the FCC and the Connect2Health Task Force in any way we can to help them understand what is needed at the state level to increase access to health care services that robust broadband networks will facilitate."

— *Ed Bostick, executive director,
Colorado Telehealth Network, March 2015*⁴³

changing technology; privacy and security; infrastructure requirements; and varying needs across urban and rural areas).

State governments are very active in the telehealth policy arena. More than 40 states have pending legislative or regulatory proposals concerning various aspects of expanding access to telehealth services.⁴⁵ The state proposals address a number of issues, including coverage and reimbursement, licensure, scope of practice and online prescribing.

Several state medical boards are actively reviewing their licensure and standards of practice to accommodate the increasing use of telehealth services and the rapidly developing technologies that will be available to increase access. Some medical boards are considering

the policies included in the 2014 FSMB *Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine*. The model policy was developed in recognition that state medical boards face complex regulatory challenges and patient safety concerns in adapting regulations and standards historically intended for the in-person provision of medical care to new delivery models involving telemedicine technologies.⁴⁶ As previously discussed, the FSMB model policy proposes to give hospitals and physicians greater flexibility to implement telehealth programs involving prescriptions.

Most recently, the AMA circulated three model bills to state medical and specialty societies to be considered during the 2015 state legislative sessions.⁴⁷

As mentioned earlier, one of the AMA model bills addresses requirements for establishing patient-physician relationships. The other two model bills reflect current trends in state policies. The model bill on reimbursement would require health plans to pay for telehealth services at the same rate they reimburse in-person care, as currently required in 24 states. The other bill would prohibit health plans from denying coverage because a service was delivered via telemedicine.

Most of these efforts illustrate that federal and state governments, as well as the private sector, are trying to find ways to reduce the barriers in order to implement innovative health policy reforms that give better access for patients and improve health outcomes.

Policy Considerations to Ease the Barriers to Telehealth

The next few years have the potential to bring about significant changes that will make it easier for hospitals and health systems to provide telehealth services. As hospitals and health systems work with policymakers to adopt telehealth policies, they should remember that telehealth is a rapidly developing field, so broad policies should be adopted in order to promote future growth and innovation. Policy discussions should focus on increasing patients' access to existing health care services by means of technology while remaining mindful of providing high-quality care and appropriate patient safety, privacy and fraud and abuse constraints.

To that end, several critical policy considerations need to be addressed by federal and state policymakers, including:

- More comprehensive Medicare coverage and payment policies for telehealth services that increase patient access to services in more convenient and efficient ways:
 - Eliminate geographic and setting location requirements;
 - Expand the types of covered services;
 - Simplify the process to expand the list of covered services by type instead of CPT codes; and
- Include store-and-forward and remote patient monitoring as covered services.
- Harmonization of state laws to foster:
 - Increased physician licensure portability;
 - Greater licensure portability for nurse practitioners, physician assistants and other health professionals;
 - Increased flexibility of the physical examination requirement for online prescribing; and
 - Clarification of medical malpractice insurance rules for telehealth encounters.
- Broader adoption of state telehealth parity statutes that require health insurers to cover and pay for services provided via telehealth the same way they pay for services provided in-person.
- Consistent standards to guide development of telehealth clinical guidelines and protocols, such as the definition of a physician-patient encounter and the ability for nurses and other licensed practitioners to provide telehealth services.
- More uniformity among federal and state privacy and fraud and abuse standards.

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