

Telemedicine Overview and Best Practices



What is Telemedicine?

American Telemedicine Association Definition:

- Telemedicine is the “use of medical information exchanged from one site to another via electronic communications to improve patients’ health status.”

Medicaid Definition:

- Telemedicine is the “use of telecommunications and information technology to provide access to health assessment, diagnosis, intervention, consultation, supervision, and information across desistance.”

Medicare Definition

- Telehealth is the “two-way, real time interactive communications between originating site and distant state physicians to deliver health services.”

State Level Definition:

- No two states define and/or regulate telemedicine in the same manner.

What is Telemedicine?

- Common Elements -- Distance & Practice of Medicine
 - Geographic separation during practice of medicine;
 - Use of telecommunications to gather, store, and disseminate clinical-related information; and
 - Use of technologies to assess, diagnose, and treat medical conditions
- **Do not get too caught up in definitions, but rather focus on the relevant definitions specific to the assignment to assess where your exposure exists and what definitions to comply with.**
- Typically, this requires a state-specific review of definitions, both statutory and those within the state professional practice acts.

Telemedicine v. Telehealth

US Federal Government Telehealth Definitions*

	Agency/Office	Definition
1	USDA	Technologies, such as electronic information and telecommunications, that ensure the availability of quality healthcare service, education and healthcare information to rural America.
2	DOC/NIST	Uses ATA's definitions: Telemedicine and telehealth both describe the use of medical information exchanged from one site to another via electronic communications to improve patients' health status...Telemedicine is sometimes associated with direct patient clinical services and telehealth sometimes associated with a broader definition of remote healthcare and is sometimes also perceived to be more focused on other health-related services.
3	DoD	T2: the use of electronic information and telecommunications technologies to support long-distance clinical healthcare, patient and professional health-related education, public health and health administration
4	FCC	Often used as a synonym for e-care, but includes nonclinical practices such as continuing medical education and nursing call centers. E-care is the electronic exchange of information - data, images and video- to aid in the practice of medicine and advanced analysis. Encompasses technologies that enable video consultation, remote monitoring and image transmission ("store and forward") over fixed or mobile networks.
5	NASA	Telemedicine is the interactive transmission of medical images and data to provide better healthcare for people in remote or "medically underserved" locations.
6	VA	"The wider application of care and case management principles to the delivery of healthcare services using health informatics, disease management, and telehealth technologies to facilitate access to care and improve the health of designated individuals and populations with the intent of providing the right care in the right place at the right time."

US Federal Government Telemedicine Definitions*

	Agency/Office	Definition
1	DOC/NIST	Telemedicine is the use of medical information exchanged from one site to another via electronic communications to improve patients' health status.
2	DOD/T2	The use of medical information exchanged from one site to another via electronic communication to improve patients' health status. Telemedicine is a subcategory of telehealth.
3	HHS/CMS	Two-way, real-time interactive communication between the patient and the physician or practitioner at the distant site. This electronic communication means the use of interactive telecommunications equipment that includes, at a minimum, audio and video equipment.
4	HHS/HRSA/NIH	The use of electronic communication and information technologies to provide or support clinical care at a distance. Included in this definition are patient counseling, case management, and supervision/preceptorship of rural medical residents and health professions students when such supervising/precepting involves direct patient care.
5	VA	Telemedicine refers to remote care interactions between patients and providers via closed-circuit TV at their nearest Community Based Outpatient Clinic.

Source (Charles R. Doarn, et al., "Original Research Federal Efforts to Define and Advance Telehealth—A Work in Progress", Telemedicine and e-Health, May 2014, Vol. 20, No. 5: 409-418, available at <http://online.liebertpub.com/doi/pdf/10.1089/tmj.2013.0336> (last visited June 22, 2014).

* These definitions were provided to the author in response to specific queries and should not be considered the formal, legal or comprehensive definitions for each agency....The objective was to illustrate the similarities and differences in telehealth-related definitions across agencies/departments.

Telemedicine v. Telehealth

Telemedicine:

- Use of medical information exchanged from one site to another via electronic communication to provide **direct patient care**. Telemedicine is a subcategory of telehealth.

Telehealth:

- Refers to a broader definition of remote health care that does not always involve clinical services.
 - Includes remote monitoring of chronic health care conditions that don't prompt a need for provider intervention, as well as non-clinical services, such as education programs, administration, and public health that can be provided remotely using communication technologies.

State and Federal Entities that Regulate Telemedicine/Telehealth

- State Legislatures
- State Medical Boards
- State Attorney Generals
- Congress
- Federal Communication Commission (FCC)
- Food and Drug Administration (FDA)
- Federal Trade Commission (FTC)
- Office of Inspector General (OIG)

State and Federal Regulatory Issues

- Licensure
- Credentialing
- Reimbursement
- Informed Consent/Patient Consent
- Stark/Anti-Kickback
- HIPPA
- Broadband and communication devices
- FDA Medical Device Approval Compliance FDA and FTC Mobile Medical App Approval and Compliance
- Electronic Medical Records
- Transmission Security

State and Federal Regulatory Issues

- Though all these issues apply to traditional medicine, as well as telemedicine, the applications may differ.
- Issues that have unique application to Telemedicine:
 - Licensure structure
 - Physician-patient relationship requirements
 - Standard of care obligations
 - Informed Consent/Patient consent rules
 - Prescribing Restrictions
- Traditional regulatory issues that may apply to telemedicine using novel applications:
 - Privacy and security
 - Corporate Practice of Medicine/Fee Splitting
 - Fraud and Abuse
 - Physician Supervision.

Louisiana Telemedicine Regulations

Before addressing the barriers involving the practice of interstate telemedicine (across state lines), the following provides a summary of Louisiana' telemedicine regulatory requirements, as statutorily amended in July of 2016 and pursuant to the Louisiana State Board of Medical Examiners (LSBME) telemedicine rules effective January, 2017:

Telemedicine: the practice of health care delivery, diagnosis, consultation, treatment, and transfer of medical data by a physician using interactive telecommunication technology that enables a physician and a patient at two locations separated by distance to interact via two-way video and audio transmissions simultaneously. Neither an electronic mail message between a physician and a patient, or a true consultation constitutes telemedicine for the purposes of this Part. A physician practicing by telemedicine may utilize interactive audio without the requirement of video if, after access and review of the patient's medical records, the physician determines that he or she is able to meet the same standard of care as if the healthcare services were provided in person.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1262, 1270, 1271, 1275 and 1276.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 35:1533 (August 2009), amended 41:2145 (October 2015), amended by the Department of Health, Board of Medical Examiners, LR 43:317 (February 2017).

Note: the definition of telemedicine has been amended to allow the use of interactive audio (ie. telephone) if, after accessing and reviewing the patients' medical records, the physician determines that he/she is able to meet the same standard of care as if treating the patient in person.

Louisiana Telemedicine Regulations

Licensure: to engage in telemedicine within the state of Louisiana, a physician must hold either 1) an unrestricted license to practice medicine in Louisiana or 2) a limited telemedicine permit.

Note that a physician who practices telemedicine by virtue of a telemedicine permit issued by the board shall not: 1) open an office in this state; 2) meet with patients in this state; 3) receive telephone calls in this state from patients; or 4) engage in the practice of medicine in this state beyond the limited authority conferred by his or her telemedicine permit. Additionally, the physician does not qualified under the MMA because he/she does not hold an unrestricted license in the state of Louisiana.

Patient Relationship; Standard of Care; Location of Participants

A. Physician-Patient Relationship. Telemedicine shall not be utilized by a physician with respect to any individual located in this state in the absence of a physician-patient relationship.

B. Standard of Care. The practice of medicine by telemedicine, including the issuance of any prescription via electronic means shall be held to the same prevailing and usually accepted standards of medical practice as those in traditional (face-to-face) settings. An online, electronic or written mail message does not satisfy the standards of appropriate care.

C. Location of Participants. A physician using telemedicine may be at any location at the time the services are provided. A patient receiving medical services by telemedicine may be in any location in this state at the time that the services are received.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1262, 1270, 1271, 1275 and 1276.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 35:1533 (August 2009), amended 41:2145 (October 2015), amended by the Department of Health, Board of Medical Examiners, LR 43:317 (February 2017).

Louisiana Telemedicine Regulations

Physician-Patient Relationship: to comply with the LSBME's telemedicine rules, a physician utilizing telemedicine must establish a proper physician-patient relationship by satisfying the following criteria:

- a. verifying the identity of the individual requesting treatment. Appropriate contact and identifying information shall be made part of the medical record;
- b. conducting an appropriate examination. The examination does not require an in-person visit if the technology is sufficient to provide the physician the pertinent clinical information reasonably necessary to practice at an acceptable level of skill and safety;
- c. establishing a diagnoses through the use of accepted medical practices e.g., history, mental status, appropriate diagnostic and laboratory testing;
- d. discussing the diagnoses and risks and benefits of various treatment options;
- e. insuring the availability for appropriate follow-up care; and
- f. creating and/or maintaining a medical record.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1262, 1270, 1271, 1275 and 1276.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 35:1533 (August 2009), amended 41:2145 (October 2015), amended by the Department of Health, Board of Medical Examiners, LR 43:317 (February 2017).

Louisiana Telemedicine Regulations

Prerequisite Conditions; Disclosures

A. The practice of medicine is deemed to occur at the location of the patient. Therefore, no physician shall utilize telemedicine to provide medical services to patients located in this state unless the physician:

1. holds an unrestricted Louisiana medical license; or
2. holds a telemedicine permit as provided in §408 of these rules.

B. A physician utilizing telemedicine with respect to patients located in this state shall have:

1. access to the patient's medical record;
2. if required by the standard of care applicable to the diagnosis or treatment of the patient's complaints in a traditional (face-to-face) setting, the ability:
 - a. to utilize peripherals (such as otoscope and stethoscope);
 - b. to obtain diagnostic testing;
 - c. if necessary in the physician's judgment, to access a patient presenter to assist with the telemedicine encounter; and
 - d. to refer the patient to another physician in this state or arrange for follow-up care within this state as may be indicated for that purpose.

Louisiana Telemedicine Regulations

Disclosures. Prior to utilizing telemedicine a physician shall insure that the following disclosures have been made to the patient and documented in the medical record. Such disclosures need not be made or documented more than once, except to update the information provided:

1. the name, Louisiana medical license number and contact information [address, telephone number(s)] of the physician;
2. the physician's specialty or area of practice;
3. how to receive follow-up and emergency care;
4. how to obtain copies of medical records and/or insure transmission to another medical provider;
5. how to receive care in the event of a technology or equipment failure; and
6. notification of privacy practices concerning individually identifiable health information, consistent with state and federal laws and regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1262, 1270, 1271, 1275 and 1276.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 35:1533 (August 2009), amended 41:2145 (October 2015), amended by the Department of Health, Board of Medical Examiners, LR 43:317 (February 2017),

Louisiana Telemedicine Regulations

Patient Records

A. Patient records shall be:

1. created and maintained for every telemedicine visit according to the same standards of care as in an in-person visit. The record shall clearly reflect and state that the patient encounter occurred by telemedicine;
2. confidential and subject to all applicable state and federal laws and regulations relative to privacy and security of health information;
3. accessible by a patient and the physician consistent with all state and federal laws and regulations; and
4. made available to the patient or a physician to whom the patient may be referred within a reasonable period of time; and
5. made available to the board upon request.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1262, 1270, 1271, 1275, and 1276.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 35:1533 (August 2009), amended 41:2146 (October 2015), amended by the Department of Health, Board of Medical Examiners, LR 43:318 (February 2017).

Louisiana Telemedicine Regulations

Informed Consent

- A. In addition to any informed consent and right to privacy and confidentiality that may be required by state or federal law or regulation, a physician shall insure that each patient to whom he or she provides medical services by telemedicine is:
1. informed of the relationship between the physician and patient and the respective role of any other health care provider with respect to management of the patient; and
 2. notified that he or she may decline to receive medical services by telemedicine and may withdraw from such care at any time.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1262, 1270, 1271, 1275 and 1276.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 35:1534 (August 2009).

Additional Recommended Provisions:

- Identification of individuals/specialists, technologies and risks associated with transmission issues (included security breaches)
- Jurisdiction, choice of law, complete understanding of process.
- Patient agreement as to the discretion of the physician to determine whether or not the condition is appropriate for a telemedicine encounter.

Louisiana Telemedicine Regulations

Prohibitions: No physician shall utilize telemedicine:

1. for the treatment of non-cancer related chronic or intractable pain, as set forth in §§6915-6923 of the board's rules;
2. for the treatment of obesity, as set forth in §§6901-6913 of the board's rules
3. to authorize or order the prescription, dispensation or administration of any controlled substance unless;
 - a. the physician has had at least one in-person visit with the patient within the past year; provided, however, the requirement for an in-person visit shall not apply to a physician who holds an unrestricted license to practice medicine in this state and who practices telemedicine upon any patient being treated at a healthcare facility that is required to be licensed pursuant to the laws of this state and which holds a current registration with the U.S. Drug Enforcement Administration;
 - b. the prescription is issued for a legitimate medical purpose;
 - c. the prescription is in conformity with the same standard of care applicable to an in-person visit; and
 - d. the prescription is permitted by and in conformity with all applicable state and federal laws and regulations.

Louisiana Telemedicine Regulations

Exceptions

- A. The following activities shall be exempt from the requirements of this Chapter:
1. furnishing medical assistance in case of a declared emergency or disaster, as defined by the Louisiana Health Emergency Powers Act, R.S. 29:760 et seq., or as otherwise provided in Title 29 of the Louisiana Revised Statutes of 1950, or the board's rules;
 2. issuance of emergency certificates in accordance with the provisions of R.S. 28:53; and
 3. a true consultation, e.g., an informal consultation or second opinion, provided by an individual licensed to practice medicine in a state other than Louisiana, provided that the Louisiana physician receiving the opinion is personally responsible to the patient for the primary diagnosis and any testing and treatment provided.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1262, 1270, 1271, 1275 and 1276.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Medical Examiners, LR 35:1534 (August 2009).

Louisiana Telemedicine Regulations

Remote Prescribing Exception: pursuant to R.S. 37:1271.1, a new statute effective July, 2016, if a telemedicine services are provided to a patient who is being treated in a licensed healthcare facility, a provider can prescribe controlled substances to a hospitalized patient via telemedicine without prior in-person contact with the patient. If the patient is not seeking treatment in a licensed healthcare facility, this prescription disbursement exception does not apply and the telemedicine physician is prohibited from prescribing controlled substances via telemedicine for the treatment of non-cancer related chronic or intractable pain or obesity.

Venue; telehealth and telemedicine: pursuant to R.S. 40:1223.5, effective July 17, 2016, venue shall be proper and instituted before the district court of the judicial district in which **the patient resides** or in the district court having jurisdiction in the parish where the **patient was physically located** during the provision of the telehealth or telemedicine service. The patient is considered physically located at the originating site as defined in R.S. 1223.3 (where the patient is seeking treatment).

- Concerns: what if the patient does not reside in the state of Louisiana?

Barriers to Interstate Telemedicine

- Differing State Laws
 - Licensure
 - Standard of Care
 - Corporate Practice of Medicine Doctrine
- Reimbursement Concerns
- Physician Prescribing Authority Limitations
- Remote Supervision Capabilities Limitations
- Concerns regarding Data Privacy and Security Risks
- Concerns regarding Medical Malpractice Risks and Coverage

Licensure

- **Licensure:** (State-Specific) In general, licensure is required in the state where the healthcare provider is practicing medicine, as well as in the state where the patient is receiving treatment.
- **Determine the following:**
 - Is the healthcare provider engaging in the practice of medicine?
 - If yes, does the healthcare provider fall within a licensure exception:
 - Is the physician engaging in a peer to peer consultation or other form of treatment that constitutes a medical consult that satisfies an exception to the licensure requirements in the state where the patient is receiving treatment?
 - Is the healthcare provider practicing in a neighboring state that has a bordering state exception?
 - Is the healthcare provider providing follow-up care that may be an exception to the state's licensure requirement.

Licensure

- Typical licensure exceptions include (vary greatly by state):
 - physician to physician consultation
 - border-state reciprocity
 - Maryland, D.C., New York, and Virginia are the only states that facilitate licensure reciprocity from bordering states
 - registries permitting qualified out-of-state physicians to practice in-state
 - Florida, Maine and New Mexico are the only states that currently offer this alternative
 - emergencies
- Intended for rare and extraordinary circumstances, not as a safe harbor for a business model focused on the provision of ongoing services
- Not a reliable strategy for an interstate telemedicine offering

Licensure Variations

- Nine states offer a conditional registration or telemedicine license to out-of-state physicians in lieu of full licensure to practice in the jurisdiction
 - Louisiana, Minnesota, Nevada, New Mexico, Ohio, Oregon, Tennessee and Texas
- Limited to practice telemedicine and often require that the provider
 - I. hold a full license to practice in another state
 - II. not open an office in the state or meet or receive calls from patients while in the state
 - III. submit to jurisdiction and compliance with the laws of the state providing the registration

Note: In Louisiana, a conditional telemedicine license does not allow participation in and/or protection under the MMA. The MMA defines physician as one holding an unrestricted license in the state of Louisiana

Interstate Compact for Physician Licensure

- The Federation of State Medical Boards Spearheaded the Interstate Compact for Physician Licensure
- As of June 28, 2017, 22 states have joined the Compact

Alabama, Arizona, Colorado, Idaho, Illinois, Iowa, Kansas, Maine, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Hampshire, Pennsylvania, South Dakota, Tennessee, Utah, Washington, West Virginia, Wisconsin and Wyoming

 - Key Elements:
 - Participation voluntary for both physicians and state boards of medicine
 - Does not change a state's existing *Medical Practice Act*
 - Regulatory authority remains with the participating state medical boards
 - Practice of medicine occurs where the patient is located
 - Improved sharing of complaint and investigative information between medical boards
 - The license may be revoked by member state once issued
 - Ability of boards to assess fees will not be compromised

Standards of Care

- **Standard of Care:** (State-Specific) Ordinarily, the standard of care is the same whether the patient is seen in-person or via a telemedicine encounter, however the patient's state law governs and must be reviewed to assure compliance.
- Standard of care is a concept that constantly evolves as new research, teaching standards, and procedures make the case for change to advance positive patient outcomes
 - No specific definition
 - A principle from more than 100 years of legal cases
- Some state-specific regulations attempt to establish a different standard of care when a physician engages by means of telemedicine (limiting available medications, the type of technology utilized, and how often a provider must “see” the patient in person) regardless of the patient situation.
- From a medical malpractice perspective, the absence of telemedicine may violate the standard of care (i.e., teleradiology, telestroke, telecardiology).

Informed Consent/Patient Consent

- Twenty states and D.C. have informed consent requirements, with Texas and Washington requiring written acknowledgment from the patient.
- Consent requirements vary by state, type of service (e.g., teleneurology versus tele-ICU), and delivery model (e.g., physician-to-physician care versus direct-to-consumer)
- Specific forms and processes should be developed depending on a telemedicine provider's practice area and geographic scope of practice
- Regardless of state regulatory requirements, some payers (both government and private) require telemedicine consent and have specific process and recording rules to meet payer guidelines for reimbursement of the telemedicine-provided service

Corporate Practice of Medicine Doctrine

- **Prohibits** the practice of medicine through a **business corporation, LLC, or partnership** that is not wholly owned by medical professionals, licensed in the jurisdiction, where the entity is providing telemedicine services. The Corporate Practice of Medicine Doctrine also prohibits medical professionals from sharing revenue with non-licensed individuals and entities (fee-splitting doctrine)
 - For example, California prohibits the corporate practice of medicine, requiring that business or management decisions and activities resulting in control over a physician's practice be made by a licensed California physician.
- **Penalties:**
 - Physicians may face professional discipline and other penalties.
 - Institutions contracting for telemedicine services may have exposure under state statute, regulation or case law.

Action Steps

1. 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. (Example, LLC, PC)
2. If entity is authorized, confirm that the entity is qualified to do business in the jurisdiction (as a foreign domiciled entity, if necessary).
3. Ensure that the owners of the entity are properly licensed in all jurisdictions in which the entity does business.

Model State Regulatory Guideline

(Must always rely on state specific regulations)

- **Licensure**
 - Physician is under the jurisdiction and subject to licensure laws where the patient is located
 - Practice of medicine is defined by state where patient is located at the time telemedicine technologies are used
- **Evaluation and Treatment**
 - Telemedicine physician must collect relevant clinical history
 - Telemedicine physician held to same standards as face to face
- **Diagnosing**
 - Held to same standards as other treatments
 - Sole use of online questionnaire is not acceptable

Model State Regulatory Guideline

(Must always rely on state specific regulations)

- **Informed Consent**
 - Identification of individuals/specialists, technologies and risks associated with transmission issues (included security breaches)
 - Jurisdiction, choice of law, complete understanding of process.
 - Patient agreement as to the discretion of the physician to determine whether or not the condition is appropriate for a telemedicine encounter.
- **Continuity of Care**
 - Patient access to follow up care or information from the provider of telemedicine services
- **Referral for emergency services**
 - Written protocol appropriate to services rendered

Telemedicine and CMS' Credentialing and Privileging Reliance Rule

- In 2011, the Center for Medicare & Medicaid Services (CMS) issued its final rule for telemedicine credentialing and privileging for hospitals and critical access hospitals (CAH). The Final Rule amends the conditions of participation (CoPs) for hospitals and CAHs, creating a more streamlined process for credentialing and privileging of telemedicine physicians.
- Prior to the Final Rule, regulations required hospitals and CAHs to apply the credentialing and privileging requirements as if all practitioners were onsite.
- Now, under the Final Rule, a hospital that provides telemedicine services to its patients pursuant to a written agreement with a “distant-site” hospital can rely upon information furnished by the distant-site hospital in making credentialing and privileging decisions for the distant-site hospital’s physicians and practitioners providing telemedicine services.
- The Final Rule reduces the burden and duplicative nature of the traditional privileging process for Medicare-participating hospitals and CAHs engages in telemedicine agreements, while still assuring accountability to the process.

42 CFR § 482.12(a)(8)-(9); 485.616(c)(2), (4); Effective date July 5, 2011.

Breaking Down CMS' Telemedicine Credentialing and Privileging Reliance Rule

Definitions:

- **Distant-Site Hospital:** a Medicare-participating hospital that provides the practitioner who is providing the telemedicine services. (i.e., Ochsner is distal-site when treating tele-stroke patients at a remote location).
- **Distant-Site Telemedicine Entity:** a non-Medicare participating hospital or entity that provides contracted services in a manner that enables a hospital or a CAH (critical access hospital) using telemedicine services to meet all applicable Conditions of Participation (CoPs). These entities often more established telemedicine service providers.

Required Provisions Under CMS' Telemedicine Credentialing and Privileging Reliance Rule:

The governing body of the hospital or CAH using telemedicine services is responsible for ensuring that the distant-site hospital or entity meets CMS credentialing and privileging standards.

One way of ensuring this is the Final Rules clarification that an agreement for the provision of telemedicine services be in writing. The written agreements must be provided, upon request, when a hospital or CAH is surveyed.

To assure compliance with the rule, the hospital or CAH must have a **written agreement** that establishes the following:

1. The distant-site hospital is a Medicare-participating hospital.
2. The distant-site physician/practitioner is privileged at the distant-site hospital providing the telemedicine services, as evidenced by a current list of the practitioner's privileges provided by the distant-site hospital.
3. The physician/practitioner holds a license issued or recognized by the state in which the hospital or CAH whose patients are receiving telemedicine services is located.
4. The hospital has evidence of an internal review of the distant-site practitioner's performance of these privileges and sends the distant-site hospital performance information for use in the periodic appraisal of the distant-site practitioner (**shared performance review information**)

(42 CFR § 482.22(a)(3); 485.616(c)(2))

Additional Safeguards when Utilizing CMS' Telemedicine Credentialing and Privileging Reliance Rule:

- Written agreements should also include:
 - Any additional standard with which a distant site's credentialing and privileging process should comply
 - Adequate **representations and warranties** regarding the quality of services and credentialing/privileging processes provided by the distant site **and** any entity with which the distant site subcontracts
- Remember: Physician Credentialing and Privileging Agreements often supplement and exist along with other agreements.
 - Provider Service Agreements
 - Equipment Agreements

CMS requires that Relying Hospital Monitor Performance

- Relying hospitals **are required** to monitor distant-site telemedicine practitioners.
- **CMS' Reliance Rule:** Hospitals using telemedicine services of distant-site practitioners must maintain evidence of an internal review of the distant-site practitioner's performance of privileges and send information to the distant site for use in the periodic appraisal of the practitioner.
- The law requires, **at a minimum**, that the monitored and shared information include:
 1. All adverse events that result from telemedicine services provided by practitioner to patients, and
 2. All complaints the hospital has received about the practitioner

(42 CFR § 482.22(a)(3)(iv), (a)(4)(iv))

Required Provisions Under CMS' Telemedicine Credentialing and Privileging Reliance Rule:

If a Hospital or CAH enters into a telemedicine agreement with a distant-site telemedicine entity (as opposed to a Medicare-participating hospital), the governing body of the hospital or CAH must ensure, through its written agreement, that the distant-site telemedicine entity, acting as a contractor of services, furnishes its services in a manner that enables the hospital or CAH to comply with all applicable CoPs and standards. The final three requirements identified in the prior slide should also be included in the written agreement.

From a risk management perspective, because the written agreement requires the sharing of privileged peer review information between the hospital or CAH and the distant-site hospital or telemedicine entity, the written agreements should include language that will assure **ongoing protection of this peer review information**. Additionally, hospitals and CAHs that choose to use this streamlined proxy credentialing approach should ensure that their **medical staff bylaws permit credentialing for telemedicine privileges consistent with the Final Rule**.

Monitoring Performance of Telemedicine Providers

To Minimize Risk:

- Educate Hospital Staff on the following:
 - What “papered” information, if any, to collect as part of the monitoring process.
 - What information to share – less is better
 - Only share and disclose information in a manner that preserves **all peer review privileges under state law.**

Important Consideration:

- A telemedicine entity may not be recognized as a peer review body under state law and thus not subject to any peer review privilege. (i.e., sharing the data waives the privilege)

Health Information Technology for Economic and Clinical Health (HITECH) Act.

Providers billing for telemedicine services are responsible for:

- Complying with HIPAA and State-Specific Confidentiality and Privacy Rules for protection and protected health information (PHI).
- Ensuring policies and procedures are in place to prevent a breach in privacy or exposure of PHI (whether oral or recorded in any form or medium) to unauthorized persons.

Providers must maintain:

- Business Associate Agreements
- Patient Consent Forms
- Patient Rights and Consent to engage in Telehealth Encounters

Security Compliance Risk Minimization

- Use of telemedicine services and technologies expands the number of people who have potential access to patients' medical information.
- Develop policies and procedures that comply with federal and state privacy laws:
 - Administrative (45CFR 164.308)
 - Physical (45 CFR 164.310)
 - Technical (45 CFR 164.312)
- Parties must understand how distant-site telemedicine practitioners will use, store and maintain electronic health records (EHR) for patient care and liability purposes.
 - Role-Based Access Control (RBAC) to limit user access
 - Data Encryption
 - De-identification of PHI

Business Associate Agreements (BAAs)

- Because telemedicine consultations involve disclosure of PHI, a BAA between the remote site and the provider organization is required to properly protect the confidentiality of patient clinical information.
- The BAA may be incorporated into an affiliation agreement if the remote site is already affiliated with the provider organization.

Telemedicine Contracts

- In contracts for telemedicine services, make sure to identify:
 - Equipment needed to provide telemedicine services
 - Who is responsible for providing and maintaining the equipment.
 - What staff and technical support is needed to service and maintain the equipment.
 - Who is authorized to use telemedicine technologies.
 - How patient interaction/consultation/visit will continue if there is a technology problem, how to respond to emergencies.
- In contracts with telemedicine technology vendors:
 - Protect against liability for equipment failure.
 - Ensure appropriate secure communication channels are in place.
 - Ensure access to continued support services, technology updates.
 - Have vendor represent and warrant technology's compliance with regulatory requirements.

Telemedicine Education and Training

- **Identify**
 - What education and training is needed to use telemedicine technology and provide telemedicine services.
 - Cost of training and who will be responsible for training.
 - How education, training, and competence will be assessed.
 - The importance of written protocols and procedures.
- **Practical Considerations:**
 - Educate/train all administrators, employees, and medical staff members regarding appropriate use of telemedicine technologies and distant-site telemedicine practitioners.
 - Develop a quality improvement process to identify needed improvements and react to changes.

Establishing Telemedicine Roll-out -- Implement Best Practices

- If ATA has Best Practice Guidelines for telemedicine specialty, strictly comply.
- If not, follow ATA Best Practice Guidelines for similar telemedicine specialty.
- Communicate and address oversight concerns that arise when contracting with a distant-site telemedicine entity rather than a licensed, distant-site hospital.
- Require additional assurances if a distant site subcontracts with a telemedicine entity or provider.
- Avoid relying solely on representations and warranties.
- Include tight, protective indemnification and risk-sharing provisions.
- Require distant-site telemedicine entities to have sufficient liability insurance.

Telemedicine Roll-out Recommendations

- Communicate regularly with distant-site hospitals and telemedicine entities and other practitioners involved in patient's care.
- Be knowledgeable of the roles and responsibilities of all parties involved in the delivery of health care services.
- Understand the purposes and boundaries of all technologies or potential technologies.
- Regularly monitor state and federal laws and regulatory guidance.

Steps To Maximize Telemedicine Benefits

- Incorporate and integrate the core elements of healthcare reform, namely, EMR [electronic medical record], MU [meaningful use], HIE [health information exchange] and ACO [accountable care organization] into the health care facility's telemedicine system.
 - Establish policies, protocols and procedures specific to telemedicine.
 - Integrate telemedicine into QA/AC and Peer Review Protocol, per JCAHO accreditation criteria.
 - Educate medical staff and physicians in areas regarding documentation and interaction with telemedicine providers, to maximize patient care and minimize institutional malpractice liability.

Medical Malpractice Issues

Issues specific to telemedicine include:

- (1) Jurisdiction
- (2) Choice of law
- (3) Applicable standard of care
- (4) Informed consent
- (5) Security breaches
- (6) Failure of telemedicine equipment or internet connection
- (7) Adequate insurance coverage
- (8) Applicability of State Medical Malpractice Acts/Caps

Medical Malpractice Issues

- Physicians engaging in telemedicine encounters have the same responsibilities and obligations of care to their patient as in-person encounters.
- Although no significant rise in medical malpractice cases involving telemedicine providers, with the increased use of telemedicine/telehealth, it is expected that malpractice claims against telemedicine providers will increase
- Though the same elements of a traditional medical malpractice claim apply, cases involving telemedicine providers complicate the claim from a procedural perspective.
- Some traditional medical malpractice cases allege the lack of telemedicine services (particularly in rural areas with physician shortages) constituted a breach in the standard of care and malpractice.

Conclusion

Telemedicine is a key component in future integrated care. Today's segregated telemedicine applications require linking into more comprehensive healthcare strategies, in which clinical pathways and service delivery processes are fully coordinated and patient data safely shared.

Healthcare providers must work across sectors as a team with common goals and resources to deliver a coordinated response to each individual's care requirements. Advanced communications technology provides telemedicine the opportunity to maximize care integration.