Outline of Presentation

I. Telemedicine Overview and Trends
II. Bylaws and Credentialing Requirements
III. Telemedicine Agreements
IV. Compliance Considerations
V. Additional liabilities/exposures
Telemedicine Trends

- Global telemedicine market is expected to reach $113.1 billion by 2025, up from $2.78 billion in 2016.
- Increasing incidences of chronic conditions and rising demand for self-care are boosting market growth.
- North America currently dominates the global market, but the Asia-Pacific region is predicted to see significant growth in the future.

Telemedicine Trends

- Hospitals and health systems are at the cutting edge of expanding telehealth. More than 65 percent of hospitals have implemented telehealth in at least one care unit. (AHA, Telehealth: Delivering the Right Care, at the Right Place, at the Right Time)
- In the U.S., a number of factors are driving growth, including rising healthcare costs, a shortage of physicians, and a growing geriatric population. (Beckers Health IT and CIO Review 2016).
- Reimbursement and failure of regulations to keep up with technology changes are still obstacles.

What is telemedicine?

- "Telemedicine" means the practice of medicine using electronic communications, information technology, or other means between a licensee in one location, and a patient in another location with or without an intervening healthcare provider. Generally, telemedicine is not an audio-only, telephone conversation, email/instant messaging conversation, or fax. It typically involves the application of secure videoconferencing or store and forward technology to provide or support healthcare delivery by replicating the interaction of a traditional encounter in person between a provider and a patient.

(Federation of State Medical Boards, Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine)
Terminology

- **Distant Site** = where the clinician is located
- **Originating Site** = where the patient is located

Categories of Telemedicine Providers: Real-time Medicine (Specialties)

- Allergy/Immunology
- Cardiology
- Critical Care
- Dentistry
- Dermatology
- Otolaryngology
- Emergency Medicine
- Endocrinology
- Family/General Practice
- Gastroenterology
- Infectious Diseases
- Internal Medicine
- Maternal/Fetal Medicine
- Mental/Behavioral Health
- Neurology
- Oncology/Hematology
- Ophthalmology/Optometry
- Orthopedics
- Pathology
- Pediatrics
- Psychology
- Pulmonology
- Rehabilitative Medicine
- Rheumatology
- Surgery
- Urology

Categories of Telemedicine Providers: Real-time Medicine (Services)

- Case management
- Correctional telehealth
- Deaf/hearing services
- Dietician services
- Disease management
- Doctor-to-doctor consultation
- Enteroostomal therapy
- Forensic/court services
- Genetic Counseling
- Long-Term Care
- Medication therapy management
- Neonatal/pediatric intensive care unit
- Pain management
- Palliative care
- Pre/post-natal care
- Speech therapy
- Spine Therapy
- Telestroke
- Wound Care
- Adult, Individual and Group, Marital, Family and Sex Therapy
- Behavioral psychology
- Chemical Dependency after care (mood, eating disorders)
- Chemical Dependency therapy (addiction therapy)
- Consultation to Schools
- Psychiatric mediation therapy
- Psychological assessment, testing, and interpretation
- Psychopharmacology
- Stress and health management
Categories of Telemedicine Providers: Store-and-Forward

- Radiology
- Dermatology
- Ophthalmology

Categories of Telemedicine Providers: Remote Patient Monitoring

- Lets healthcare professionals track a patient’s vital signs, activities, and other data from a distance.
- Particularly useful when treating high-risk patients, such as those with cardiovascular problems, or who have recently been released from the hospital.
- Remote patient monitoring can also be used to treat chronic conditions (e.g., diabetes, home health needs)

Bylaws Requirements

- Medical Staff Bylaws should include:
  - Definition of Telemedicine and scope of practice
  - Prerogatives and responsibilities of Telemedicine practitioners
  - Categories of Privileges to be granted to Distant Site practitioners
  - Requirement that Distant site practitioners meet qualifications for Medical Staff appointment
  - Special credentialing procedures for Distant Site practitioners (mandatory)
Definition of Telemedicine

Definition may need to be tailored depending on applicable state licensing statute/regs, e.g.:

- **Florida** - "Telemedicine" means the practice of medicine by a licensed Florida physician or physician assistant where patient care, treatment, or services are provided through the use of medical information exchanged from one site to another via electronic communications. Telemedicine shall not include the provision of health care services only through an audio only telephone, email messages, text messages, facsimile transmission, U.S. Mail, or other parcel service, or any combination thereof. (Fla. Admin. Code Ann. R. 64B-90141;64B15-14.0081)

- **Arkansas** - "Telemedicine" means the medium of delivering clinical health care services by means of real time two-way electronic audio-visual communications, including without limitation the application of secure video conferencing, to provide or support healthcare delivery that facilitates the assessment, diagnosis, consultation, or treatment of a patient’s health care while the patient is at an originating site and the healthcare professional is at a distant site. (Ark. Code Ann. 17-80-118)

Prerogatives

Bylaws should address whether telemedicine providers:

- Are appointed to the Medical Staff
- Exercise clinical privileges in Hospital
- May admit/be attending of record for patients
- Attend meetings of the Medical Staff and/or Department
- Vote or hold office
- Be appointed to serve on Committees
- Pay dues

Sample Bylaws Language

TELEMEDICINE MEDICAL STAFF CATEGORIES

- AFFILIATE STAFF

  The Telemedicine Affiliate Staff shall consist of Physicians who meet the basic and particular qualifications for Medical Staff membership and who provide diagnostic or treatment services to Hospital patients via Telemedicine devices (i.e., interactive [involving a real time (synchronous) or near real time (asynchronous) two-way transfer of medical data and information] audio, video, or data communications [but not solely telephone or electronic mail communications]) between Physician and patient.
Sample Bylaws Language

AFFILIATE STAFF Cont’d

- Prerogatives
  - (a) Telemedicine Affiliate Staff Members may not admit patients to the Hospital or exercise Clinical Privileges in the Hospital. Members of this staff category may only provide patient care services from a Distant Site.
  - (b) Telemedicine Affiliate Staff members may attend meetings of the Medical Staff and Department meetings. However, they may not vote at Department or general Medical Staff meetings, or hold any office in the Medical Staff organization. Telemedicine Affiliate Staff Members may, however, be appointed by the Medical Executive Committee to serve on committees, and they may vote in those committees if the right to vote is specified at the time of appointment.
  - (c) Telemedicine Affiliate Staff Members shall pay dues.

Bylaws Requirements (COPs)

- Medical Staff Bylaws must include:
  - Criteria for determining the privileges to be granted to individual practitioners;
  - Procedure for applying the criteria to individuals requesting privileges;
  - For distant-site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the hospital, that the criteria for determining privileges and procedure for applying the criteria are subject to the requirements in 482.12(a)(8) and (a)(9), and 482.22(a)(3) and (a)(4)

Bylaws Requirements (COPs)

- 42 CFR 482.12(a)(8): Contracting requirements for Telemedicine services acquired through a Medicare-certified hospital
- 42 CFR 482.12(a)(9): Contracting requirements for Telemedicine services acquired through a non-Medicare certified hospital or other entity
- 42 CFR 482.22(a)(3): Proxy credentialing for Telemedicine providers acquired through a Medicare-certified Hospital
- 42 CFR 482.22(a)(4): Proxy credentialing for Telemedicine providers acquired through a non-Medicare certified hospital or other entity.
Credentialing Procedures

- Hospitals and some other facilities must credential licensed independent practitioners before allowing them to provide or order services.
- Required by Medicare Conditions of Participation ("COPs"), TJC or other accreditation standards, state statutes or licensing regs, common law tort duty, risk management.

Options for facilities: individual credentialing or credentialing by proxy

- Individual credentialing – the facility reviews each practitioner’s credentials to determine privileges, which can be burdensome. There may be many providers, as in teleradiology. The originating site may also lack expertise to effectively review teleproviders.
- Credentialing by proxy – facility relies on credentialing done by another facility. This can be more efficient for teleproviders, who are already credentialed by their own entities.

Review state law!

- State statutes or licensing regulations may still require individual credentialing, e.g.:
  - Massachusetts has not endorsed credentialing by proxy, leaving only the traditional "primary source credentialing" approach available (legislation pending)
  - Proxy Credentialing may not reflect local standard of care (potential negligent credentialing liability).
Credentialing Procedures (COPs)

- Medicare Governing Body COPs:
  - Hospital governing board may require medical staff to individually credential each telehealth provider.
  - If the governing body permits the medical staff to rely on credentialing done by distant-site Medicare participating hospital or other entity, then:
    - The hospital must have a detailed written agreement, which specifies the responsibilities of the distant site to (i) comply with the COPs (if a participating hospital) or (ii) enable the originating site to comply with the COPs (if another type of entity).
    - The hospital must then monitor the distant-site telemedicine practitioners and provide quality data to the distant-site for credentialing and quality oversight purposes.

Governing Body/Medical Oversight Requirements

- Hospital must have medical staff bylaws
- Medical staff bylaws rules and regulations are approved by the governing body.
- Governing body:
  - Determines which practitioners are eligible for privileges
  - Appoints practitioners, after review by the medical staff
  - Ensures that the medical staff is accountable to it for quality of care
  - Ensures that the criteria used for credentialing are individual character, competence, training, experience, judgment, and
  - Ensures that privileges are not conditioned solely on certification or membership in a specialty body or society.

Credentialing Procedures (TJC)

- In general, TJC permits credentialing by proxy if the distant site is a Joint Commission accredited organization, and the distant-site practitioner has a license that is issued or recognized by the state in which the patient is receiving telemedicine services.
- There must be a written agreement
- The governing body of the distant site is responsible for having a credentialing and privileging process that is consistent with the credentialing and privileging requirements in the "Medical Staff" (MS) chapter
- The governing body of the originating site grants privileges to a distant-site licensed independent practitioner based on the originating site's medical staff recommendations, which rely on information provided by the distant site.
- LD.04.03.09 (Contracted Services).
Credentialing Procedures (TJC/CMS)
- TJC worked with CMS to align its telemedicine requirements for hospitals that use Joint Commission accreditation for deemed status.
- Distant site must be TJC-accredited
- There must be a written agreement in place that specifies:
  - The distant site is a contractor of services to the hospital
  - The distant site furnishes services in a manner that permits the originating site to comply with Medicare COPs
  - The originating site ensures through a written agreement that all distant site telemedicine providers’ credentialing and privileging processes meet the applicable Medicare COPs

Credentialing Procedures (TJC)
- MS.13.01.01 specifies the detailed standards for telemedicine proxy credentialing, particularly for hospitals with deemed status:
  - The distant site is a Joint Commission-accredited hospital or ambulatory care organization
  - The practitioner is privileged at the distant site for the services to be provided at the originating site
  - The distant-site practitioner has a license that is issued or recognized by the state in which the patient is receiving telemedicine services
  - For hospitals that use Joint Commission accreditation for deemed purposes:
    - The distant site provides the originating site with a current list of the practitioner’s privileges
    - The distant site’s credentialing must comply with Medicare COPs
  - After appointment, the originating site maintains evidence of an internal review of the practitioner’s performance of these privileges and sends to the distant site information that is useful to assess the practitioner’s quality of care, treatment and services for use in privileging and performance improvement. At a minimum this includes all (1) adverse outcomes related to sentinel events considered reviewable by The Joint Commission that result from telemedicine services provided, and (2) complaints

Elements of Hospital Telemedicine Contracts
Distant Site - Medicare-certified Hospital

- Written agreement confirms:
  - Distant-site hospital participates in Medicare
  - Distant-site practitioner is privileged at the distant-site hospital for the services to be provided at the originating site
  - Distant-site entity maintains and provides to originating site a current list of practitioner’s privileges
  - Distant-site practitioner is licensed, or license is recognized, in state where originating site is located
  - When distant-site practitioner has privileges at originating site, it:
    - Conducts internal review of practitioner's performance
    - Sends performance information to distant-site hospital for use in periodic review of practitioner, including all adverse events and complaints

Distant Site - Medicare-certified Hospital

- Written agreement confirms distant site hospital board is responsible for:
  - Determining which categories of practitioners are eligible for medical staff;
  - Appointing members of the medical staff after considering recommendations of the existing medical staff;
  - Assuring that the medical staff has bylaws;
  - Approving medical staff bylaws, rules, and regulations;
  - Ensuring that medical staff is accountable for quality of care;
  - Ensuring members are selected per individual character, competence, training, experience, and judgment; and
  - Ensuring that under no circumstances medical staff membership or privileges depending solely upon certification, fellowship, or membership in a specialty body or society

Distant Site - Other Telemedicine Provider

- Written agreement confirms:
  - Distant-site entity is a contractor and provides services in a manner that allows hospital to comply with COPs
  - Distant-site practitioner is privileged at the distant-site entity
  - Distant-site entity maintains and provides to originating site a current list of practitioner’s privileges
  - Distant-site practitioner is licensed, or license is recognized, in state where originating site is located
  - When distant-site practitioner has privileges at originating site, it:
    - Conducts internal review of practitioner’s performance
    - Sends performance information to distant-site provider for use in periodic review of practitioner, including all adverse events and complaints

42 CFR 482.22(a)(3)

42 CFR 482.22(a)(4)
Distant Site - Other Telemedicine Providers

- Contract ensures that credentialing is done in a manner that enables Originating Site Governing Body to fulfill its obligations under COPs to:
  - Determine which categories of practitioners are eligible for medical staff;
  - Appoint members of the medical staff after considering the recommendations of the existing medical staff;
  - Ensure that medical staff is accountable for quality of care;
  - Ensure that members are selected per individual character, competence, training, experience, and judgment; and
  - Ensure that under no circumstances medical staff membership or privileges depending solely upon certification, fellowship, or membership in a specialty body or society.

Special Considerations for Contracted Providers

- Does the contract permit the distant-site provider to provide services through a subcontractor? If so:
  - Verify and confirm that the distant-site provider’s contracts and arrangements with its subcontractors ensure compliance with COPs, state laws and accrediting standards
  - Determine whether originating site should have a direct written contract with subcontractors under state law

Additional Contract Considerations

- Representations and warranties regarding the quality of services and compliance with applicable law/regulation by the distant-site provider
- Equipment and software needed
- Indemnification
- Requirement that distant-site telemedicine entity has liability insurance
- Termination of Provider’s Services
- Termination of Contract
Quality/Peer Review P&Ps
- Under CMS' Telemedicine Rule, Originating Hospitals are required to monitor distant-site telemedicine practitioners:
  - At a minimum, monitored and shared information must include (1) adverse events, and (2) complaints
  - What additional information is shared may depend on state peer review law
  - P&Ps should be structured to maximize peer review privilege protections
- Consider mechanisms for informal/formal remediation:
  - Contractual versus medical staff processes for addressing quality issues
  - OPPE/FPPE of telemedicine providers?
  - Corrective action by originating hospitals?
  - Hearing and appeal rights at originating hospitals?
- Make sure contracts and bylaws are clear and consistent.

- No liability, but illustrates pitfalls arising from lack of good communication
  - Radiologist providing services through Imaging on Call had quality issues at Hospital.
  - Hospital complained to Imaging for 4 years, which never advised Radiologist.
  - Hospital started its own investigation, then asked Imaging to ask Radiologist to resign her medical staff privileges with Hospital.
  - Imaging asked her to resign, and she did, not knowing of the Hospital investigation.
  - Hospital filed adverse action report with NPDB stating that the Radiologist resigned her privileges while under investigation.
  - Plaintiff rescinded her resignation and Hospital reported the rescission to NPDB.
  - Hospital then moved to revoke privileges by ultimately, after hearing, the revocation was reversed.
  - Hospital's actions protected under HCQIA.
  - Radiologist sued Imaging in a 7-count complaint in federal court.
  - Court granted Motion to Dismiss.

Telehealth Compliance Checklist: Contracts, Bylaws, P&Ps
- Is there a surrogate credentialing agreement in place that contains all the required elements?
- Does the hospital relying on surrogate credentialing have the appropriate authority under its bylaws?
- Does the hospital engage in periodic re-credentialing assessments?
- Does the hospital conduct routine quality/peer review and report the results to the Distant Site Provider?
- Have the peer review procedures and reporting been structured to comply with and maximize state law privilege protections?
- Have the peer review laws of the originating and distant sites been taken into account?
Additional Compliance issues

- Licensure
- Scope of practice
- Prescribing
- Informed Consent
- Standard of Care
- Patient Abandonment
- Insurance

State Licensure Issues

- COPs and TJC require that the provider be licensed in the state where the patient is located (“Originating Site”)
- Interstate Medical Licensure Compact is helping
  - 22 states participate; legislation is pending in 4 states
  - Under the Compact, licensed physicians can qualify to practice medicine across state lines within the Compact if they meet the eligibility requirements
  - Offers a voluntary expedited pathway to licensure in Compact Member States by leveraging the physician’s existing information previously submitted in their state of principal license

Interstate Medical Licensure Compact

Source: www.imlcc.org
State Licensure Issues

- For non-IMLCC States:
- Check state licensing statute/regulations regarding cross-border practice via telemedicine
  - Some states have special telemedicine licenses. See Ohio Rev. Code Ann. 4731.296 and 4731.294 (discussing requirements for telemedicine and special activity certificates)
  - Some states have exceptions for de minimis telemedicine practice. See, Minn. Stat. 147.032 (2) (exemptions from registration)
  - Some states require full licensure to practice in the state, via telemedicine or otherwise, but provide an exception for physician consultation (E.g., Hawaii)

Scope of Practice

- State licensure laws, Board of Medicine regulations, Medicare/Medicaid regulations, and Medical Staff Bylaws may all limit the types of services that may be provided, or may be paid for, through telemedicine, or the type of technology that may be used, e.g.:
  - Arkansas requires telemedicine to be delivered via real-time two-way electronic audio-visual communications
  - Some states prohibit physicians from prescribing drugs, or more specifically prescribing controlled substances, without an in-person physical exam
  - Several states that have legalized medical marijuana prohibit a physician from issuing a certification without examining the patient in person
  - Medicare does not pay for in-home services (but see H.R. 2550, Medicare Telehealth Parity Act of 2017)
Prescribing

- Limits imposed by federal law (Ryan Haight Act) and state law
- Consider Indiana:
  - Providers may prescribe non-controlled substances if:
    - The provider has satisfied the applicable standard of care in the treatment of the patient.
    - The issuance of the prescription by the provider is within the provider's scope of practice and certification.
    - The prescription is not for a controlled substance.
    - The prescription is not for an abortion inducing drug.
- The prescription is not for an ophthalmic device, including: (1) glasses; (2) contact lenses; or (3) low vision devices.

A 2016 law included a blanket ban on prescribing controlled substances via telemedicine, but a 2017 amendment softened the rules.

Prescribing

- Indiana Providers may now prescribe controlled substances via telemedicine if:
  - The prescription is not for an opioid, unless the opioid is a partial agonist.
  - The prescriber maintains a valid controlled substance registration.
  - The prescriber meets the conditions set forth in the federal Ryan Haight Act.
  - The patient has been examined in-person by a licensed Indiana health care provider and the licensed health care provider has established a treatment plan to assist the prescriber in the diagnosis of the patient.
  - The prescriber has reviewed and approved that treatment plan and is prescribing for the patient pursuant to that treatment plan.
  - The prescriber complies with Indiana's INSPECT prescription drug monitoring program.
  - The prescription for a controlled substance is prescribed and dispensed in accordance with Indiana Code 35-48-7.

Informed Consent

- Check laws applicable to originating site for effective informed consent.
  - There may be specific requirements for telehealth, e.g.:
    - Connecticut Public Act No. 15-88 ("At the time of the telehealth provider's first telehealth interaction with a patient, the provider shall inform the patient concerning the treatment methods and limitations of treatment using a telehealth platform, and after providing the patient with such information, obtain the patient's consent to provide telehealth services. The provider shall document such notice and consent in the patient's health record.")
  - In the absence of clear guidelines, see FSMB and AMA guidance.
Informed Consent

- Discussion of risks, benefits, and limitations of telemedicine services, including risk that data may be intercepted by third parties, there may be interruptions or unauthorized access to technology
- Discussion of alternatives to using telemedicine
- That users should arrange for follow-up care with primary care physician or appropriate specialist, if necessary
- Telemedicine encounter may be terminated at any time at the request of the patient
- Types of electronic transmissions the patient is consenting to
- A hold harmless clause for information lost due to technical failures
- Requirement for express consent to forward PHI to a third party
- Disclosure of any financial or other interests the physician has in the telemedicine application or equipment (AMA)

Liability Insurance Coverage

- Medical professionals are required to maintain professional liability insurance to offset risks and costs of lawsuits based on medical malpractice, which is governed by state law
- Liability insurance may require proper license for coverage
- Liability insurance policies may exclude:
  - Injuries from services other than in-person encounter
  - Injuries from unauthorized practice of medicine
  - Legal actions due to unauthorized practice of medicine
  - Practice of medicine in another state
  - Regulatory violations resulting from telemedicine (HIPAA, FDA)

Other State Regulatory Issues

- In the absence of clear guidance from state medical board/legislature, consult:
  - Federation of State Medical Boards “Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine” (www.fsmb.org)
  - American Medical Association Code of Medical Ethics (www.ama-assn.org)
Telehealth Compliance Checklist: Providers

- Are the telehealth professionals licensed in the state where the patient is located?
- Are there practice standards for patient examinations and remote prescribing?
- Are professionals documenting and maintaining patient records of the encounters?
- Does insurance policy cover telehealth services?
- Is the insurance carrier licensed in every state where services are provided?
- Does the informed consent form and policy account for services provided via telehealth?

Telehealth Compliance: Additional Considerations

- Fraud & Abuse
- Privacy & Security
- Reimbursement

Appendix of Resources

- AHLA, Telehealth: A 50 State Survey (2d Edition) (for purchase)
- Interstate Medical Licensure Compact, http://www.imlcc.org