Telemedicine Risk Exposures and Mitigation Strategies

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Objectives

To describe key clinical and enterprise risk exposures in telemedicine.

2. To examine potential risk exposure outcomes stemming from telemedicine.

3. To discuss practical strategies to mitigate telemedicine risk management exposures.
What is Telemedicine, Anyway?

“...the use of medical information exchanged from one site to another via electronic communications to improve a patient’s clinical health status.

Telemedicine includes a growing variety of applications and services using two-way video, email, smart phones, wireless tools and other forms of telecommunications technology.”

American Telemedicine Association
http://www.americantelemed.org/about-telemedicine/what-is-telemedicine#.VXH82-en5nc
What is Telehealth

“Telehealth is the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health and health administration.”

HRSA, http://www.hrsa.gov/ruralhealth/about/telehealth/
Do You See A Distinction?

Telemedicine: Two-way electronic communications to improve a patient’s clinical health status.

Telehealth: Long-distance support for clinical health care, patient and professional health-related education, public health and health administration.
CMS Weighs in on the Definition

Telehealth includes such technologies as telephones, facsimile machines, electronic mail systems, and remote patient monitoring devices, which are used to collect and transmit patient data for monitoring and interpretation.

While they do not meet the Medicaid definition of telemedicine they are often considered under the broad umbrella of telehealth services. Even though such technologies are not considered "telemedicine," they may nevertheless be covered and reimbursed as part of a Medicaid coverable service, such as laboratory service, x-ray service or physician services (under section 1905(a) of the Social Security Act).
Are We Just Splitting Hairs?

• ATA says that it uses the terms interchangeably.

• But look closely at laws and regulations. This may not be the case.

• Splitting the definitional hairs may be important in terms of regulatory risk, reimbursement, and more.

Something to keep in mind beyond public policy. Quite relevant for all healthcare entities along the continuum of care.
Key Telemedicine Risk Exposures
Key Clinical Telemedicine Risk Exposures

- Licensure
- Standard of Care/Negligence
- Consent
- Scope of Practice
- Credentialing & Recredentialing
Alabama became the seventh state to enact the Interstate Medical Licensure Compact after Governor Robert Bentley signed the legislation into law today, triggering the formation of the Interstate Medical Licensure Compact Commission. The Commission will administer a new streamlined process for qualified physicians seeking to obtain licensure in multiple states and jurisdictions participating in the Compact.”
“A state's existing Medical Practice Act and related regulatory laws apply once a physician obtains state licensure through the Compact. Therefore, a physician licensed by a state via the Compact pathway MUST abide by all of the laws, rules, and regulations of that state where the patient is located and the practice of medicine occurs.

FSMB. http://licenseportability.org/#panel7

Interstate Medical Licensure Compact
A Teleradiology Negligence Case

Radiologist was working from home. She interpreted one set of images sent to her electronically. Radiologist was unaware that there was a second set of images to read.

Radiologist took time off to attend a wake. Did not advise the hospital. When she returned she found the second set of images. Realized the patient had a significant problem, but it was too late. Patient unstable for transport. Died on the operating room table.

- Duty of Care.
- Breach of the Duty of Care.
- Causal link with the breach resulting in foreseeable harm.

And how about professional discipline?
Example: Clinical Risk

67 year-old patient at a critical access hospital (CAH) needs an MRI with contrast dye of a part of the abdomen. Remote radiologist is “doing” the study that was ordered by the local PCP. Rad tech is unavailable at the CAH. However, an RN is available who has completed some in-service programs on using the MRI machine.

Remote radiologist located in another state assumed that the PCP and RN had obtained appropriate patient history to identify risks that would rule out the MRI and contrast dye.

Intravenous gadolinium was administered as the contrast media for the MRI. The patient experienced an adverse reaction called nephrogenic systemic fibrosis (NSF). Only after he was transferred to a tertiary hospital for treatment did the remote radiologist learn that the patient had a major contraindication for the contrast media: impaired renal function.
Clinical Example, Continued

Carrying out the MRI was beyond the RNs job description and it exceeded her scope of practice.

PCP failed to meet the applicable standard of care in screening the patient for contraindications to contrast media.

Patient was in a state that required the remote telemedicine provider to be physically located in the same jurisdiction.
Consent and Telemedicine

- Indications for telemedicine.
- Explanation of the process.
- Probable benefits, probable risks.
- Alternatives and related probable benefits, probable risks.
- Consequences of declining recommended and alternate diagnostic or therapeutic measures.
- Answer questions in an understandable manner.
- Teach-back affirmation.
- Document.

Check out the FSMB consent recommendations, too!
FSMB_Telemedicine_Policy.pdf April 2014
Telemedicine Consent Risks

- Failure to meet state consent requirements for telemedicine
- Using telemedicine when in-person consent process is required. (Abortion)
- Not providing key information: Alternatives. Cost information.
CREDENTIALING/REREDENTIALING FOR

TELEMEDICINE


Telemedicine Credentialing Risks

Who is conducting the work for your patients?

Consent: Did the patient authorize the contracted telemedicine provider?

There is a one-way route for Quality & Adverse Event Data

When was the list last updated?

Are there providers on the list who have been debarred by Medicare or Medicaid?

As a compliant organization, can you utilize the services of a debarred provider?
Key Legal-Regulatory Telemedicine Risks

Who is in control: the states or the federal government?

Who is collecting the data?

Who is using the data?

What evidentiary protections are in place?

Is telemedicine data addressed in the e-Discovery Plan?
“Payment may not be made for a medical service (or a portion of it) that was subcontracted to another provider or supplier located outside the United States. For example, if a radiologist who practices in India analyzes imaging tests that were performed on a beneficiary in the United States, Medicare would not pay the radiologist or the U.S. facility that performed the imaging test for any of the services that were performed by the radiologist in India.”

Medicare Beneficiary Policy Manual, *(Rev. 198, 11-06-14)*
60 - Services Not Provided Within United States
(Rev. 102; Issued: 02-13-09; Effective/Implementation Date: 03-13-09)
But Medicare Pays for Many Telehealth Services

Section 223 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) - Revision of Medicare Reimbursement for Telehealth Services amended §1834 of the Act to provide for an expansion of Medicare payment for telehealth services.

Effective October 1, 2001, coverage and payment for Medicare telehealth includes consultation, office visits, individual psychotherapy, and pharmacologic management delivered via a telecommunications system. Eligible geographic areas include rural health professional shortage areas (HPSA) and counties not classified as a metropolitan statistical area (MSA). Additionally, Federal telemedicine demonstration projects as of December 31, 2000, may serve as the originating site regardless of geographic location.

An interactive telecommunications system is required as a condition of payment; however, BIPA does allow the use of asynchronous “store and forward” technology in delivering these services when the originating site is a Federal telemedicine demonstration program in Alaska or Hawaii. BIPA does not require that a practitioner present the patient for interactive telehealth services.

With regard to payment amount, BIPA specified that payment for the professional service performed by the distant site practitioner (i.e., where the expert physician or practitioner is physically located at time of telemedicine encounter) is equal to what would have been paid without the use of telemedicine. Distant site practitioners include only a physician as described in §1861(r) of the Act and a medical practitioner as described in...
Medicare Access and CHIP Reauthorization Act of 2015

Public Law 114–10, April 16, 2015

- How the definition of telehealth across various Federal programs and Federal efforts can inform the use of telehealth in the Medicare program.

- Issues that can facilitate or inhibit the use of telehealth under the Medicare program...including oversight and professional licensure, changing technology, privacy and security, infrastructure requirements, and varying needs across urban and rural areas.

- Implications of greater use of telehealth regarding payment and delivery system transformations under Medicare.

- How CMS monitors payments made under the Medicare to providers for telehealth services.
Risks and Public Law 114–10

Requires the Comptroller General to Study & Report Recommendations within 24 months to Congress.

It is not the ONLY “Act” in town – more Congressional changes that seem like overlap are under consideration now.

What does this mean for the healthcare industry?

• Greater interest/encouragement in use of telehealth.
• The “John Wayne” Syndrome: get the process now in control out of the way. But will that increase risk.
• Be ready for rigorous financial accountability scrutiny for fraud & abuse.
Potential Changes in Federal Control

21st Century Cures Act
H.R. 6

TITLE III—DELIVERY
Subtitle B—Telehealth

Sec. 3021. Telehealth services under the Medicare program.

05/19/2015 approved by House Energy & Commerce Committee

Looking at population health data involving telehealth

Activities by CMMI examining uses of telehealth services in models, projects, or initiatives funded through the Social Security Act

The types of high volume procedures codes or diagnoses suitable to the furnishing of services via telehealth.

Identify barriers that might prevent the expansion of telehealth services
“physical examination that must be performed by either a face-to-face visit or in-person evaluation as defined in § 174.2(3) and (4) of this title (relating to Definitions). The requirement for a face-to-face or in-person evaluation does not apply to mental health services, except in cases of behavioral emergencies.”

“An online questionnaire or questions and answers exchanged through email, electronic text, or chat or telephonic evaluation of or consultation with a patient are inadequate to establish a defined physician-patient relationship.”

Changes to Texas Administrative Code 22 § 190.8 Disciplinary Guidelines
State Grip on Control Eroding?

Is it possible that Texas style board requirements violate antitrust laws?

Follow the Teledoc case argument:

North Carolina Board of Dental Examiners v. FTC (February 2015) US Supreme ruled that when a controlling number of the [Dental] Board’s “decision makers are active market participants in the occupation the Board regulates, the Board can invoke state-action antitrust immunity only if it was subject to active supervision by the State.”

Teledoc asserts the Texas “in person” rule violates antitrust laws – gets preliminary injunction.

Insurance Coverages Risk

- Professional Liability Coverage
- Cyber-Risk Coverage
- Tech Error & Omissions Coverage
- Business Continuity
- Property Coverage (Telehealth Providers)
Telemedicine Infrastructure Risks

Note: Some states have requirements for technology & telemedicine

Potential Vulnerabilities:

- Interoperability
- HIPAA Privacy
- HIPAA Security
- HIPAA HITECH
- Encryption standards
- mHealth devices
- Store and Forward requirements
- Beware software Upgrades”
- Response time with rollover to back-up
- Time and Date conventions
- Report format conventions
Telemedicine Contracting Risks

• One-sided agreements.
• Overly broad terms and conditions.
• No block on subcontracting to third parties.
• No “right of first refusal” on contract being picked up as part of a merger or acquisition.
• No opportunity to cure deficiencies.
• No opportunity to terminate if provider is debarred by Medicare or Medicaid.

Beware: the “missing” schedule, exhibits or addendum.
Billing and Code Risk Issues

- Private Payer Parity Issues
- Medicaid
- Medicare

- Coding issues
- Appropriate level of reimbursement
- Upcoding
- Fraud and Abuse
- Delay in Payments
Practical Strategies to Mitigate Telemedicine Risk Exposures
Strategy One: Identify Risk Tolerance

- Articulate your organization’s “appetite for risk” in telemedicine and telehealth.
- Quantify what is your organization’s “total cost of risk” (TCOR) in telemedicine and telehealth.
Strategy Two: Use an Enterprise Risk Approach

Complete a Risk Inventory for your organization in telemedicine

- Strengths
- Opportunities
- Weaknesses
- Threats

Action Plan:
- Accept Risk
- Eliminate Risk
- Adjust Risk
- Transfer Risk
Strategy Three: Applied ERM

- Contracting
- Credentialing
- Consent

- Financial & Regulatory Monitoring
- Require Two-Way Quality and Adverse Event Reporting
- Monitor and Act on Legal and Market Trends
Example: Telemedicine Contracts

- Content experts participate
- Team effort looking at organizational impact
- Use your own standard terms
- Close the loopholes
- Build in requirements for contingencies
- Proof of insurance in specified amounts
- No subcontracting
- Set reporting conventions
- Breach notification
- Curing deficiencies
- Termination

Monitor for contractual compliance!
Example: Telemedicine Credentialing

Governing Body should set the policy:

✓ Local credentialing
✓ Taking advantage of the CMS rule for “proxy credentialing”
✓ Consider costs
✓ Consider control of data and evidentiary protection
✓ Consider data access
✓ Be consistent in credentialing
Example: Telemedicine Consents

- Not just a piece of paper
- Medical history
- The consent “process”
- Compliant with state law
- Consistent with FSMB Policy
- Document authorization
Example: Financial & Regulatory Monitoring

• Internal audit for billing and coding private and public payers

• Monitor for HIPAA – HITECH compliance

• Monitor for Medicare – Medicaid Debarment

• Follow-up promptly on variances
Example: Two-way Quality Monitoring

- Leverage contract terms – make certain to get complete information on quality, patient satisfaction, adverse events, adverse credentialing actions and potential compensatory events.

- Work with legal counsel to design procedures for leveraging evidentiary protection requirements.

- Start with a legal-HIM agreed upon approach for data e-Discovery and legal hold.
Strategy Four: Internal & External Scans

- Laws
- Regulations
- Judicial Decisions
- Interpretive Guidelines
- Market trends
- Market share
- Technology changes
- Payment models
Conclusion
Telemedicine Take-Aways

• Dynamic not static.
• New models emerging.
• New payment approaches.
• Relaxing of some federal requirements; expect tightening of others linked to funding controls.
• Avoid a silo-approach. Use an enterprise risk approach.
• Involve the content experts on the telemedicine – telehealth team.
## Resources - I

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| Federation of State Medical Boards (FSMB) |
| http://www.fsmb.org/ |

| National Association for Medical Staff Services (NAMSS) |
| http://www.namss.org/ |
Resources


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Thank you!