

## St. Louis Regional Healthcare Compliance Conference

### Key Legal Issues that Health Care Providers Should Consider When Providing Telehealth and Telemedicine

*Jayme R. Matchinski*

*March 1, 2019*

*St. Louis, Missouri*

This presentation and outline are limited to a discussion of general principles and should not be interpreted to express legal advice applicable in specific circumstances.

## What is Telemedicine?

The Health Resources & Services Administration (HRSA) of the U.S. Department of Health and Human Services defines telehealth as:

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

## What is Telemedicine (cont'd)

- Telehealth and telemedicine are sometimes used interchangeably.
- The HRSA distinguishes telehealth from telemedicine in its scope.
- According to the HRSA, telemedicine only describes remote clinical services such as diagnosis and monitoring, while telehealth includes preventive, promotive, and curative delivery.

## What is Telemedicine?

- Federation of State Medical Boards
- Telemedicine is 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.

## Three Main Types of Telemedicine

- American Medical Association (AMA) breaks telemedicine into three types:
  - Store-and-forward telemedicine transmits medical data to a physician for assessment.
  - Remote monitoring allows physicians to monitor a patient remotely.
  - Interactive telemedicine services provide real-time, face-to-face interaction between patient and physician.

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## AMA

- The American Medical Association (AMA) report in June 2014, notes that telehealth is being used to “improve access to care, care coordination and quality, as well as reduce the rate of growth in health spending.”
- AMA. Report of the Council on Medical Service. Coverage of and payment for telemedicine. CMS Report 7-A-14. June 11, 2014.

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## Examples of Telemedicine

- Clinics and Sleep Disorder Centers with site presenters
- Remote monitoring
- Kiosks
- Teleradiology
- Mental Health assessments and referrals
- Neuro services for stroke identification and treatment in emergency departments

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## Telemedicine Varies from State to State

Each state decides issues of:

- › Establishment of physician/patient relationship
- › Scope of practice
- › Licensure
- › Patient consent and disclosures

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# Telemedicine Varies from State to State

Each state decides issues of:

- › Recordkeeping and information access
- › Clinical standards
- › Payment practices
- › Coordination of care
- › Prescription standards

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# Regulatory Landscape

## Federal Law:

Social Security Act Section 1834 (m) defines the conditions for payment for telehealth service under Medicare.

- The Statute requires that a patient must present at a rural, clinical originating site in order to receive care via telehealth.
- Medicare reimbursement for telehealth is only available at clinical sites in rural areas, and patients seeking care in metropolitan areas are unable to access these services.

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# Medicare Regulations

- For 2015, CMS added additional telemedicine coverage. The final rule released October 31, 2014 added seven telemedicine billing codes, including for psychotherapy, prolonged office visits, and annual wellness visits.
- CMS also added language to pay for remote patient monitoring for chronic conditions.
- Prior to this, Medicare did not pay separately for these services and bundled them into “evaluation and management” codes. However, Medicare reimbursement for telehealth is still only available at clinical sites in rural areas.

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# Medicare Coverage for Telemedicine

- Remote patient face-to-face services via live video conferencing requirements
  - Eligible beneficiary in originating site located outside of a Metropolitan Statistical Area
  - Eligible medical service

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## Medicare Coverage for Telemedicine (cont'd)

- Eligible providers – physicians, NPs, PAs, etc.
- Eligible facility
- If requirements are met, practitioner delivering service will be reimbursed for medical service the same as current fee schedule and non-metro facility eligible for facility fee

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## What Medicare Does Not Cover

- Home health services
  - Not permitted for any covered home health services paid under home health prospective payment system.
- Remote non face-to-face.
  - Not considered telemedicine.
  - Covered as on-site services.
  - Example: interpretation of an electrocardiogram that has been transmitted via telephone.

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# Medicaid Coverage for Telehealth

- OIG announced a new project, the *Medicaid Services Delivered Using Telecommunications Systems*, which was added to OIG Work Plan update in November 2017.
- OIG noted the “significant increase in [Medicaid] claims” for telehealth, telemedicine and telemonitoring services, and indicated that the OIG expects the trend to continue.”

# Medicaid Coverage for Telehealth (cont'd)

OIG's description of the telemedicine project:

“Medicaid pays for telemedicine, telehealth, and telemonitoring services delivered through a range of interactive video, audio or data transmission (telecommunications). Medicaid programs are seeing a significant increase in claims for these services and it is anticipated that this trend will continue. We will determine whether selected State Medicaid payments for services delivered using telecommunication systems were allowable in accord with Medicaid requirements.”

# Illinois Regulations

- Legislation was passed in 2015 in Illinois that amended the Illinois Insurance Code to provide that if an insurance company provides coverage for telehealth services, then it must comply with certain prohibition, including:
- Under 215 ILCS 5/356z.22 (effective January 1, 2015), an insurer may not:
  - a) require that an in-person contact occur between a provider and patient;
  - b) require the provider to document a barrier to an in-person consultation;

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# Illinois Regulations (cont'd)

- a) require the use of telehealth if provider has determined it is not appropriate; or
  - b) require the use of telehealth if the patient chooses an in-person consultation.
- Additionally, under the new law, deductibles, copays, or coinsurance cannot exceed that required for the same services provided through an in-person consultation.

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## Telehealth: The Numbers

- In the 113<sup>th</sup> Congress, there were 57 bills introduced that relate to telehealth.
- More than 20 million Americans received some type of remote medical care in 2017, and that number is projected to keep increasing. (American Telemedicine Association (ATA))

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## Telehealth: The Numbers (cont'd)

- Three-Fourths of the 100 million electronic visits that were expected to occur in 2014, would occur in North America.
- It is estimated that telehealth could deliver more than \$6 billion a year in health care savings to U.S. companies and that it yields an 87% satisfaction rate.

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# Compliance Officers Should Consider the Following Telemedicine Issues

- ❖ Credentialing and Privileging
- ❖ Documentation
- ❖ Security of Data Systems
- ❖ Medicare/Medicaid Requirements
- ❖ State Licensure and Regulatory Issues
- ❖ Third Party Payors - Commercial Insurance, Medicare, and Medicaid
- ❖ Regulatory Compliance - Fraud and Abuse Consideration

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# Key Risk Factors to Consider

## Health Care Provider Issues and Risks - A Checklist for Compliance Officers:

- Business terms and transactional considerations, including compensation;
- Intellectual property;
- FDA compliance;
- Data access;
- Scope of practice and licensure;

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## Key Risk Factors to Consider (cont'd)

### A Checklist for Compliance Officers:

- Patient privacy and information security;
- Fraud and abuse concerns;
- Cybersecurity insurance;
- Reimbursement; and
- Regulatory compliance, including HIPAA and state privacy regulations.

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## Examples of Telehealth/Telemedicine Models and Provider Arrangements

- **Online patient access/portals/technical support** - A sleep disorder center provides patients with online access to view results from the polysomnography (sleep study), and offers patients options regarding the treatment of sleep disorders.
- **Clinician-to-Clinician** - A primary care physician practice group provides peer consulting services regarding various areas of telemedicine to consult on challenging cases.
- **Direct-to-Patient Urgent Care Access** - Patients contract with health care providers for on-demand telemedicine services.

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## Examples of Telehealth/Telemedicine Models and Provider Arrangements (cont'd)

- **Health Care Institute-to-Health Care Institution** - Rural health clinic contracts with a regional hospital and health system to provide teleradiology services with full coverage and availability.
- **Chronic Care Management** - Pain management clinic contracts with a physician practice group for chronic care management and follow-up services.
- **eHealth, mHealth, and Medical Apps** - Self-tracking apps for diagnostics, care support, and monitoring that may include weight loss, smoking cessation, medication compliance, and durable medical equipment compliance.

## Telehealth/Telemedicine Goals

- Enhance patient care and outcomes.
- Retain local care by providing specialist expertise and support.
- Offer care and services in markets where availability of specialists and specialty services is limited.
- Seamless patient care model.

# Health Information Exchange (HIE)

HIE = transmission of clinical data from one health care delivery organization to another.

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# HIE Risk Exposures

- Patient Privacy Exposures
  - Cybersecurity → loss of patient information
  - Hackers accessing patient data
  - Consent issues
  - User access

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## HIE Risk Exposures (cont'd)

- Infrastructure Exposures
  - D & O for:
    - failures of the system
    - incorrect data sent from HIE
    - late or untimely data sent

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## HIE Risk Exposures (cont'd)

- Clinical Issues
  - Responsiveness
  - Email coverage
- Directors and Officers' exposure
  - Government issues and oversight of the policies and procedures

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**Jayme R. Matchinski**  
**Greensfelder, Hemker & Gale, P.C.**  
**[jmatchinski@greensfelder.com](mailto:jmatchinski@greensfelder.com)**  
**(312) 345-5014**  
**[Linkedin.com/in/jaymematchinski](https://www.linkedin.com/in/jaymematchinski)**