Key Legal and Compliance Issues in Telehealth

Presented by

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Initial Points

• This is a high level summary of key issues – we will not cover every issue today
• This presentation is relatively physician-focused
• Tennessee is a telehealth-friendly state, but there are still many requirements and other state laws vary
• Teleradiology laws and regulations may differ
• The most important thing to keep in mind is this: telehealth laws and policies are changing
Roadmap

- What are telemedicine and telehealth?
- Licensure
- Provider-patient relationship and informed consent
- Technology and format considerations
- E-prescribing
- Payor policies and issues

What Are Telemedicine and Telehealth?

- ATA Definition: Telemedicine is the remote delivery of health care services and clinical information using telecommunications technology. ATA uses the terms “telemedicine” and “telehealth” interchangeably while clarifying telehealth is a broader term not necessarily limited to clinical services.
- In this presentation, telemedicine is specific to physicians. Telehealth refers to physicians plus certain other practitioners.
What Are Telemedicine and Telehealth?

• Tennessee law creates a safe harbor for “telemedicine” practice. The TN definition is key.

• “Telemedicine” includes activities such as secure video conferencing and the use of store-and-forward technology

• “Telemedicine” excludes audio only telephone conversation, e-mail/instant messaging or fax

• The technology involved must replicate the traditional practitioner-patient interaction

What Are Telemedicine and Telehealth?

• Key Terms
  – Originating Site = Patient Site
  – Distant Site = Physician/Practitioner Site
Licensure

- General idea: physician or other practitioner must be licensed where the patient is located at the time of a telehealth encounter
- But don’t assume practitioner need not be licensed in distant state if providing services from outside Tennessee

Licensure

- What telemedicine activities trigger the medical licensure requirement in TN?
  - Practicing medicine in TN (diagnosing and/or treating a patient located in TN) using information transmitted through electronic or “other” means
  - Some exceptions exist, including:
    - TN physician calls a physician licensed in another state to consult/obtain a second opinion
    - US military physicians operating within federal jurisdiction and within applicable regulations
Licensure

- What are licensure categories for medicine?
  - Regular physician license
  - Special telemedicine license
    - TN no longer grants special telemedicine licenses, but existing licenses can be renewed (and could be converted to full license up until October 31, 2018)
    - Must be renewed timely, holders must maintain current ABMS specialty board certification
    - Limited licensees are limited to medical interpretation in their specialty
    - Limited licensees may not prescribe

Provider-Patient Relationship

- Key point:
  - In TN, provider-patient relationship can be established via telehealth without an in-person consultation
  - Other states may require an in-person examination at some point

- Provider-patient relationship is established by:
  - Mutual consent (can be express or implied, but informed consent to treatment should be documented)
  - Mutual communication
Provider-Patient Relationship

- Duties and obligations created by the provider-patient relationship do not arise until provider:
  - Affirmatively undertakes to diagnose and treat the patient; OR
  - Affirmatively participates in diagnosis or treatment

- Generally, TN-licensed providers are held to the same practice standards and rules that apply outside the telemedicine context

- Physician should have access to medical records, must document encounter is via telemedicine and must state the technology used

Provider-Patient Relationship

- Physicians should also take into consideration and observe the principles of AMA Code of Medical Ethics Opinion 1.2.12 (Ethical Practice in Telemedicine), including w/o limitation:
  - Inform patients about the limitations of the format, tailor the informed consent process to the format
  - Establish the patient’s identity and confirm that telemedicine services are appropriate for each patient
  - Advise patients about how to arrange for follow up care
  - Encourage patients to inform their PCPs when they have been treated via telehealth, document care and determine how information will be conveyed to PCP
Provider-Patient Relationship

• Telepresenters/facilitators
  – In TN a facilitator is someone physically present at the patient’s location to facilitate the telemedicine encounter
  – A facilitator is a parent/legal guardian or person affiliated with a local system of care
  – Facilitator is generally required when a patient is under 18
  – If no facilitator is required, applicable requirements differ based upon whether a facilitator is present

Provider-Patient Relationship

• No Facilitator Present
  – Technology used by patient must be adequate for physician to verify patient’s identity (ask for government-issued photo id) and location (location is key) (consider video conference)
  – Patient must transmit all relevant health information via secure video conferencing or via store-and-forward technology
  – Provider must disclose (1) name, (2) current and primary practice location and (3) medical degree and recognized specialty area
    • Communicate full name and license (e.g. “Joseph Smith, M.D., Physician”) via visible photo id name tag or communicate same in writing
Provider-Patient Relationship

• Facilitator Present
  – Facilitator verifies the patient’s identity and location and facilitates the exchange of information (via secure video conferencing or store-and-forward technology)
  – Facilitator must identify herself, her role and her title to the patient and the remote physician
  – Physician must disclose name and other information discussed above

Technology and Format Considerations

• Ensuring HIPAA compliance of any software used (particularly encryption of ePHI) is important
• Consider integration of telehealth software with your EMR solution
• If the information a physician receives is not adequate or not of sufficient quality to form an opinion, physician must say so and must request additional information or recommend an in-person visit
• FDA is minimally involved with most basic telemedicine software platforms, but stay tuned
E-Prescribing

• Generally, under TN law, physicians may prescribe in connection with telemedicine encounters if they, with limited exceptions:
  – Perform an appropriate history and physical examination (presents a standard of care issue);
  – Make a diagnosis based upon the examination and medical tests and consistent with good medical care;
  – Formulate and discuss a therapeutic plan with the patient, as well as the basis for the plan and the risks and benefits of various treatment options; and
  – Ensure availability of the physician or coverage for the patient for follow-up care
• But see caveats in the following slides

E-Prescribing

• State Caveats:
  – Physicians with a special TN telemedicine license may not prescribe
  – The TN DoH’s Chronic Pain Guidelines (for outpatient settings) expressly prohibit prescribing of controlled substances for chronic pain (pain lasting longer than 90 days) through telemedicine
E-Prescribing

- Federal caveats for controlled substances
  - DEA registration required in each applicable state
  - Practitioners must also comply with DEA e-prescribing requirements (systems must comply with rules, system breach reporting obligations and record retention obligations)
  - Federal DEA regulations require an at least 1 in-person evaluation for prescribing of controlled substances, with limited exceptions

- Limited exceptions to in-person requirement, such as (real-time av system required):
  - Prescribing while covering for another practitioner who has seen patient in previous 24 months and is temporarily unavailable
  - Patient treated in presence of a DEA-registered treating practitioner
  - Patient treated and located at a DEA-registered hospital or clinic during the telemedicine encounter by a DEA-registered practitioner
  - Treating practitioner has special registration
E-Prescribing

• Special registration
  – Concept was enacted over 10 years ago but never made available by the DEA
  – In 2016, DEA announced its intention to issue regulations but has not acted since
  – On Oct 3, Congress enacted new opioids crisis response legislation (SUPPORT for Patients and Communities Act), which requires creation of the special telemedicine registration within 1 year
    • Calls for US AG to issue regulations specifying the “limited circumstances” for issuance of special registrations, procedure for obtaining same

Payor Policies and Issues: Medicare Policy

• Three categories of Medicare telehealth services

• Category 1 – Physician Fee Schedule
  – No “store-and-forward” technology allowed in most locations – interactive “real time” av system is required
  – Defined list of services/codes – see CY 2018 Medicare Telehealth Services list
  – Eligible distant site practitioners include MDs, NPs, PAs and other practitioners, and they receive the same Medicare rate as for face-to-face services
Payor Policies and Issues: Medicare Policy

• Category 1 – Physician Fee Schedule
  – Patient must be located at a valid originating sites, which include physician/practitioner offices, hospitals/CAHs, certain renal dialysis centers and SNFs
  – Originating sites must be in a rural HPSA located in a rural census tract or in a county not included in an MSA (or be participating in an approved federal telemedicine demonstration project)
  – Urban sites do not qualify, so this restriction means Medicare coverage for telemedicine is not available to many patients

Payor Policies and Issues: Medicare Policy

• Rural HPSA requirement is a significant compliance issue for many providers
  – MedPAC’s 2016 report to Congress cited to data that suggests a large volume of telemedicine claims are coming from invalid (urban) originating sites
  – In Summer and Fall 2017, the HHS OIG added Medicare (FY18) and Medicaid (FY19) audits to its Work Plan
Payor Policies and Issues: Medicare Policy

- Category 2 – Medicare Advantage Plans
  - MA plans can cover additional supplemental telehealth benefits with CMS approval

- Category 3 – Medicare also pays for telehealth services through payment models being tested under CMS’s Center for Medicare and Medicaid Innovation
  - CMS has authority to waive certain Medicare requirements to test these models

Payor Policies and Issues: Medicare Policy

- Recent policy changes in Bipartisan Budget Act of 2018 (the “Continuing Resolution”) include:
  - ESRD patients receiving home dialysis can receive certain monthly ESRD-related clinical assessments via telehealth (incl. at home) – Jan 1, 2019
  - Geographic and certain originating site limitations for acute stroke telehealth services removed – Jan 1, 2019
  - MA plans permitted to include TBD telehealth services in basic plan benefits in 2020
  - Certain ACOs will have the ability to expand the use of telehealth services (originating site will include the patient’s home beginning in 2020)
**Payor Policies and Issues: Medicare Policy**

- An additional notable change from the SUPPORT for Patients and Communities Act:
  - Beginning July 1, 2019, the Act eliminates the geographic requirement for telehealth services provided to Medicare patients with a substance use disorder diagnosis for purposes of treating the disorder or a co-occurring mental health disorder.

- 2019 MPFS Proposed Rule and HH PPS Proposed Rule includes some potential expansions (most not Medicare telehealth services):
  - Category 1 - Interactions via remote communication technology (i.e., not Medicare telehealth services):
    - Brief virtual patient check-ins used to evaluate whether an office visit is warranted (HCPCS GVC11):
      - Separate reimbursement only available if patient does not seek an office visit
      - Consent required, only available in existing physician-patient relationship
Payor Policies and Issues: Medicare Policy

• Category 1 - Interactions via remote communication technology (i.e., not Medicare telehealth services)
  – Evaluation of pre-recorded, patient-created videos or images to determine whether office visit warranted (HCPCS GRAS1) (store and forward)
  
  • Separate reimbursement only available if no office visit, non-established patients a possibility
  
  – Interprofessional consultations undertaken for the benefit of treating a patient (CPT 994X6, 994X0, 99446-9) – advance verbal consent required

Payor Policies and Issues: Medicare Policy

• Category 2 – Notable Proposed Changes to Medicare Telehealth Services List
  – Two codes (HCPCS G0513-4) for prolonged preventative services beyond the typical service time of the primary procedure (these are additions to the Medicare telehealth services list)

• Additional proposed change from HH PPS Proposed Rule:
  – Allow HHAs to report costs of remote patient monitoring on cost reports if used to augment the care planning process
Payor Policies and Issues: TN Telehealth Parity Law

- CMS does not impose telehealth restrictions under Medicaid – states determine Medicaid telehealth policies
- Many private payors cover telehealth services, although the requirements vary

Payor Policies and Issues: TN Telehealth Parity Law

- TN’s telehealth “parity” law applies to private health insurers, with limited exceptions, and Medicaid managed care plans (i.e., TennCare)
  - Provider licensure and standard of care parity
  - Provider requirement/contractual terms parity
  - Coverage parity
    - Cover telehealth services consistent w/ in-person coverage for same services; cannot refuse to cover solely b/c a service is provided through telehealth
    - Reimburse telehealth without geographic distinctions
    - Reimburse out-of-network telehealth services under same reimbursement policies as other out-of-network services
Payor Policies and Issues: 
TN Telehealth Parity Law

- Provider must be located at a specific site, including a provider office, licensed mental health facility or licensed hospital
- Patient must be located at one of the above sites or a properly equipped and staffed public school or school clinic
- Applicable telehealth technology includes real-time video/audio or store-and-forward technology but not audio-only conversation, e-mail or fax
- But check reimbursement rules and policies
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