Cruising Through Key Legal Compliance Issues in Telemedicine

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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 physician-focused and group practice-oriented
- Tennessee is a telemedicine-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: telemedicine laws and policies are changing
Roadmap

- What is telemedicine?
- Licensure
- Provider-patient relationship
- Telepresenters/facilitators
- Technology/format considerations
- E-prescribing
- Medicare policy
- TN Telehealth “Parity” Law

What is Telemedicine?

ATA Definition:
The use of medical information exchanged from one site to another via electronic communications to improve patients’ health status. Closely associated with telemedicine is the term “telehealth,” which is often used to encompass a broader definition of remote healthcare that does not always involve clinical services.
What is Telemedicine?

- 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 is Telemedicine?

- 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 telemedicine encounter
- But don’t assume practitioner need not be licensed in distant site state if providing services from outside Tennessee

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**Licensure**

- What telemedicine activities trigger the 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 converted to full license (until October 31, 2018) or renewed
    - 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 telemedicine 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 physician:
  - Affirmatively undertakes to diagnose and treat the patient; OR
  - Affirmatively participates in diagnosis or treatment
- Generally, physicians 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

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
Telepresenters/Facilitators

• 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. “Joe Smith, M.D., Physician”) via visible photo id or communicate same in writing

• 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/Format Considerations

- Ensuring HIPAA compliance of any software used (particularly encryption of data transmissions) is important
- Consider integration of telemedicine 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
E-Prescribing

- 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 provider has special telemedicine registration

E-Prescribing

- Special telemedicine 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
  - The “Special Registration for Telemedicine Clarification Act,” which is pending in Congress, would require implementation within 30 days
- At the moment, many practical obstacles to telemedicine prescribing of controlled substances remain
Medicare Policy

- Three categories of Medicare telemedicine 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 – see CY 2018 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

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

- Category 3 – Medicare also pays for telemedicine 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
Medicare Policy

- **Category 1 – Physician Fee Schedule**
  - Valid originating sites, which include physician/practitioner offices
  - Originating sites must be in a rural HPSA (use CMS eligibility analyzer to determine)
  - Few sites qualify, so this restriction means Medicare coverage for telemedicine is not available to many patients – Congress is considering this issue
  - This is a significant compliance issue for many providers
    - MedPAC reports suggest a large volume of telemedicine claims come from invalid originating sites

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
Medicare Policy

- Recent policy changes in Bipartisan Budget Act of 2018 (the “Continuing Resolution”) include:
  - Some loosening of telestroke and dialysis-related requirements
  - MA plans can now include telehealth services in basic plan benefits
  - Certain ACOs now have the ability to expand the use of telehealth services (originating site includes the patient’s home beginning in 2020)
- Other changes have been proposed, including the Medicare Telehealth Parity Act of 2017

Tennessee Telehealth “Parity” Law

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

Tennessee Telehealth “Parity” Law

- Physician must be located at a specific site, including a physician 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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