



Key Legal and Compliance Issues in Telehealth

Presented by

Cal Marshall



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

CHAMBLISS	<h2>Licensure</h2>
fiercely loyal.	
	<ul style="list-style-type: none">• General idea: physician or other practitioner must be licensed where the <u>patient</u> is located at the time of a telehealth encounter• But don't assume practitioner need not be licensed in distant site state if providing services from outside Tennessee

CHAMBLISS	<h2>Licensure</h2>
fiercely loyal.	
	<ul style="list-style-type: none">• What telemedicine activities trigger the medical licensure requirement in TN?<ul style="list-style-type: none">– 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:<ul style="list-style-type: none">• 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

<p>CHAMBLISS</p>	<h2>Licensure</h2>
<p>fiercely loyal.</p>	
	<ul style="list-style-type: none"> • What are licensure categories for medicine? <ul style="list-style-type: none"> – Regular physician license – Special telemedicine license <ul style="list-style-type: none"> • TN no longer grants special telemedicine licenses, but <u>existing</u> 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 <u>may not prescribe</u>

<p>CHAMBLISS</p>	<h2>Provider-Patient Relationship</h2>
<p>fiercely loyal.</p>	
	<ul style="list-style-type: none"> • Key point: <ul style="list-style-type: none"> – In TN, provider-patient relationship <u>can</u> be established via telehealth without an in-person consultation – Other states may require an in-person examination at <u>some point</u> • Provider-patient relationship is established by: <ul style="list-style-type: none"> – 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

CHAMBLISS	Provider-Patient Relationship
fiercely loyal.	
	<ul style="list-style-type: none"> • Telepresenters/facilitators <ul style="list-style-type: none"> – 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 <u>required</u> when a patient is under 18 – If no facilitator is required, applicable requirements differ based upon whether a facilitator is present
	13

CHAMBLISS	Provider-Patient Relationship
fiercely loyal.	
	<ul style="list-style-type: none"> • No Facilitator Present <ul style="list-style-type: none"> – 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 <ul style="list-style-type: none"> • Communicate full name and license (e.g. “Joseph Smith, M.D., Physician”) via visible photo id name tag or communicate same in writing
	14



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

CHAMBLISS	<h2 style="text-align: center;">E-Prescribing</h2>
fiercely loyal.	
	<ul style="list-style-type: none">• Generally, under TN law, physicians may prescribe in connection with telemedicine encounters if they, with limited exceptions:<ul style="list-style-type: none">– 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

17

CHAMBLISS	<h2 style="text-align: center;">E-Prescribing</h2>
fiercely loyal.	
	<ul style="list-style-type: none">• State Caveats:<ul style="list-style-type: none">– 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

18

<p>CHAMBLISS</p>	<h2>E-Prescribing</h2>
<p>fiercely loyal.</p>	<ul style="list-style-type: none"> • Federal caveats for <u>controlled substances</u>
	<ul style="list-style-type: none"> – 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

19

<p>CHAMBLISS</p>	<h2>E-Prescribing</h2>
<p>fiercely loyal.</p>	<ul style="list-style-type: none"> • Limited exceptions to in-person requirement, such as (real-time av system required):
	<ul style="list-style-type: none"> – 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

20

<p>CHAMBLISS</p>	<h2>E-Prescribing</h2>
<p>fiercely loyal.</p>	<ul style="list-style-type: none"> • Special registration
	<ul style="list-style-type: none"> – 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 <ul style="list-style-type: none"> • Calls for US AG to issue regulations specifying the “limited circumstances” for issuance of special registrations, procedure for obtaining same

21

<p>CHAMBLISS</p>	<h2>Payor Policies and Issues: Medicare Policy</h2>
<p>fiercely loyal.</p>	<ul style="list-style-type: none"> • Three categories of Medicare telehealth services
	<ul style="list-style-type: none"> • Category 1 – Physician Fee Schedule <ul style="list-style-type: none"> – 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

22

<p>CHAMBLISS</p>	<h2 style="text-align: center;">Payor Policies and Issues: Medicare Policy</h2>	
<p>fiercely loyal.</p>		<ul style="list-style-type: none"> • Category 1 – Physician Fee Schedule
		<ul style="list-style-type: none"> – Patient must be located at a valid originating sites, which include physician/practitioner offices, hospitals/CAHs, certain renal dialysis centers and SNFs – Originating sites <u>must be</u> 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

23

<p>CHAMBLISS</p>	<h2 style="text-align: center;">Payor Policies and Issues: Medicare Policy</h2>	
<p>fiercely loyal.</p>		<ul style="list-style-type: none"> • Rural HPSA requirement is a significant compliance issue for many providers
		<ul style="list-style-type: none"> – 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

24

<p>CHAMBLISS</p>	<h2 style="text-align: center;">Payor Policies and Issues: Medicare Policy</h2>
<p>fiercely loyal.</p>	
	
<ul style="list-style-type: none"> • Category 2 – Medicare Advantage Plans <ul style="list-style-type: none"> – 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 <ul style="list-style-type: none"> – CMS has authority to waive certain Medicare requirements to test these models 	

25

<p>CHAMBLISS</p>	<h2 style="text-align: center;">Payor Policies and Issues: Medicare Policy</h2>
<p>fiercely loyal.</p>	
	
<ul style="list-style-type: none"> • Recent policy changes in Bipartisan Budget Act of 2018 (the “Continuing Resolution”) include: <ul style="list-style-type: none"> – 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) 	

26

<p>CHAMBLISS</p> <hr/> <p>fiercely loyal.</p> <hr/> 	<h2 style="margin: 0;">Payor Policies and Issues: Medicare Policy</h2>
	<ul style="list-style-type: none"> • An additional notable change from the SUPPORT for Patients and Communities Act: <ul style="list-style-type: none"> – 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

27

<p>CHAMBLISS</p> <hr/> <p>fiercely loyal.</p> <hr/> 	<h2 style="margin: 0;">Payor Policies and Issues: Medicare Policy</h2>
	<ul style="list-style-type: none"> • 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) <ul style="list-style-type: none"> – Brief virtual patient check-ins used to evaluate whether an office visit is warranted (HCPCS GVC11) <ul style="list-style-type: none"> • Separate reimbursement only available if patient does not seek an office visit • Consent required, only available in existing physician-patient relationship

28

<p>CHAMBLISS</p>	<h2 style="text-align: center;">Payor Policies and Issues: Medicare Policy</h2>
<p>fiercely loyal.</p>	
	
<ul style="list-style-type: none"> • Category 1 - Interactions via remote communication technology (i.e., not Medicare telehealth services) <ul style="list-style-type: none"> – Evaluation of pre-recorded, patient-created videos or images to determine whether office visit warranted (HCPCS GRAS1) (store and forward) <ul style="list-style-type: none"> • 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 	

29

<p>CHAMBLISS</p>	<h2 style="text-align: center;">Payor Policies and Issues: Medicare Policy</h2>
<p>fiercely loyal.</p>	
	
<ul style="list-style-type: none"> • Category 2 – Notable Proposed Changes to Medicare Telehealth Services List <ul style="list-style-type: none"> – 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: <ul style="list-style-type: none"> – Allow HHAs to report costs of remote patient monitoring on cost reports if used to augment the care planning process 	

30

<p>CHAMBLISS</p> <hr/> <p>fiercely loyal.</p> <hr/> 	<h2 style="margin: 0;">Payor Policies and Issues: TN Telehealth Parity Law</h2>
	<ul style="list-style-type: none"> • CMS does not impose telehealth restrictions under Medicaid – states determine Medicaid telehealth policies • Many private payors cover telehealth services, although the requirements vary

<p>CHAMBLISS</p> <hr/> <p>fiercely loyal.</p> <hr/> 	<h2 style="margin: 0;">Payor Policies and Issues: TN Telehealth Parity Law</h2>
	<ul style="list-style-type: none"> • TN’s telehealth “parity” law applies to private health insurers, with limited exceptions, <u>and</u> Medicaid managed care plans (i.e., TennCare) <ul style="list-style-type: none"> – Provider licensure and standard of care parity – Provider requirement/contractual terms parity – Coverage parity <ul style="list-style-type: none"> • 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



Cal Marshall
423.757.0214
cmarshall@chamblisslaw.com

<p>CHAMBLISS</p>	
<p>fiercely loyal.</p>	
	<div style="text-align: right;">  </div> <h2 style="text-align: right;">Cal Marshall</h2> <p>Cal is an attorney in the Health Care and Business Practice Groups at Chambliss. He works with clients on a variety of health care and business matters, including medical practice contracting and compliance issues, HIPAA/HITECH compliance, data breach response, telehealth issues, fraud and abuse law, Medicare enrollment and payment issues, and compliance with state laws and regulations. Prior to practicing law, Cal served as an aide to several members of the U.S. House of Representatives, working on health care policy and government oversight matters, among others. Cal writes and speaks on health care legal issues and serves in multiple leadership roles within the American Bar Association's Health Law Section.</p> <p>http://www.chamblisslaw.com/People/Calvin-Marshall</p>

<p>CHAMBLISS ATTORNEYS AT LAW</p>	<h2 style="text-align: center;">Disclaimer</h2>
<p>fiercely loyal.</p> 	<p>This presentation is provided with the understanding that the presenter is not rendering legal advice or services. Laws are constantly changing, and each federal law, state law, and regulation should be checked by legal counsel for the most current version. We make no claims, promises, or guarantees about the accuracy, completeness, or adequacy of the information contained in this presentation. Do not act upon this information without seeking the advice of an attorney.</p>
	<p>This outline is intended to be informational. It does not provide legal advice. Neither your attendance nor the presenter answering a specific audience member question creates an attorney-client relationship.</p>