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CHAMBLISS		
fiercely loyal.	Key Legal and Compliance	
(H)	Issues in Telehealth	-
November 16, 2008		
O HCCA	Presented by	
	Cal Marshall	
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CHAMBLISS	Initial Points	
fiercely loyal.	This is a high level summary of key issues – we will not cover every issue today	
O HCCA	This presentation is relatively physician-focused	
	Tennessee is a telehealth-friendly state, but there are still many	
	requirements and other state laws vary	
	<ul> <li>Teleradiology laws and regulations may differ</li> <li>The most important thing to keep in mind is this: telehealth laws</li> </ul>	
	and policies are changing	
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CHAMBLISS	Roadmap	
fiercely loyal.	What are telemedicine and telehealth?	
O HCCA	• Licensure	
Association	Provider-patient relationship and informed consent	
	Technology and format considerations	
	E-prescribing	
	Payor policies and issues	

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CHAMBLISS	What Are Telemedicine and Telehealth?	
fiercely loyal.		
HCCA matter Constitutes	<ul> <li>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</li> </ul>	
	necessarily limited to clinical services.	
	<ul> <li>In this presentation, telemedicine is specific to physicians.</li> <li>Telehealth refers to physicians plus certain other practitioners.</li> </ul>	
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CHAMBLISS	What Are Telemedicine and Telehealth?	
for a below		
fiercely loyal.	<ul> <li>Tennessee law creates a safe harbor for "telemedicine" practice.</li> <li>The TN definition is key.</li> </ul>	
HCCA	• "Telemedicine" includes activities such as secure video	
	conferencing and the use of store-and-forward technology	
	<ul> <li>"Telemedicine" <u>excludes</u> audio only telephone conversation, e-mail/instant messaging or fax</li> </ul>	
	The technology involved must replicate the traditional	
	practitioner-patient interaction	
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CHAMBEISS	What Are Telemedicine and Telehealth?	
fiercely loyal.		
HCCA	Key Terms     Originating City, Particulation	
	<ul> <li>Originating Site = Patient Site</li> <li>Distant Site = Physician/Practitioner Site</li> </ul>	
	The state of the s	

CHAMBLISS	Licensure	
fiercely loyal.		
O HCCA	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	
	state ii providing services from outside refinessee	
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CHAMBLISS	Licensure	
fiercely loyal.	What telemedicine activities trigger the medical licensure	
O HCCA	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:	
	<ul> <li>TN physician calls a physician licensed in another state to consult/obtain a second opinion</li> </ul>	
	<ul> <li>US military physicians operating within federal jurisdiction and within applicable regulations</li> </ul>	
CHAMBLISS		
	Licensure	
fiercely loyal.	What are licensure categories for medicine?     Regular physician license	
O HCCA	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 <u>may not prescribe</u>	-
	·	<u> </u>

CHAMBLISS	Provider-Patient Relationship
fiercely loyal.	Key point:
O HCCA	– In TN, provider-patient relationship <u>can</u> be established via telehealth
Association	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
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CHAMBLISS	Provider-Patient Relationship
fiercely loyal.	- Duking and abligations assets the table and idea asticut
	<ul> <li>Duties and obligations created by the provider-patient relationship do not arise until provider:</li> </ul>
O HCCA	Affirmatively undertakes to diagnose and treat the patient; OR
	<ul> <li>Affirmatively participates in diagnosis or treatment</li> </ul>
	Generally, TN-licensed providers are held to the same practice
	standards and rules that apply outside the telemedicine context
	<ul> <li>Physician should have access to medical records, must document encounter is via telemedicine and must state the technology used</li> </ul>
	encounter is via telementine and must state the technology used
CHAMP: 105	
CHAMBLISS	Provider-Patient Relationship
fiercely loyal.	Physicians should also take into consideration and observe the
O HCCA	principles of AMA Code of Medical Ethics Opinion 1.2.12 (Ethical Practice in Telemedicine), including w/o limitation:
madit Care Compliance Association	<ul> <li>Inform patients about the limitations of the format, tailor the informed</li> </ul>
	consent process to the format
	<ul> <li>Establish the patient's identity and confirm that telemedicine services are appropriate for each patient</li> </ul>
	<ul> <li>Advise patients about how to arrange for follow up care</li> </ul>
	<ul> <li>Encourage patients to inform their PCPs when they have been treated via telehealth, document care and determine how information will be conveyed to PCP</li> </ul>

CHAMBLISS	Provider-Patient Relationship
fiercely loyal.	Telepresenters/facilitators
O HCCA	<ul> <li>In TN a facilitator is someone physically present at the patient's location to facilitate the telemedicine encounter</li> </ul>
	<ul> <li>A facilitator is a parent/legal guardian or person affiliated with a local system of care</li> </ul>
	<ul> <li>Facilitator is generally <u>required</u> when a patient is under 18</li> </ul>
	<ul> <li>If no facilitator is required, applicable requirements differ based upon whether a facilitator is present</li> </ul>
CHAMBLISS	Provider-Patient Relationship
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CHAMBLISS fiercely loyal.	Provider-Patient Relationship  • No Facilitator Present
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fiercely loyal.	Facilitator Present
HCCA TANKS OF THE PROPERTY OF	<ul> <li>Facilitator verifies the patient's identity and location and facilitates the exchange of information (via secure video conferencing or store-and- forward technology)</li> </ul>
	<ul> <li>Facilitator must identify herself, her role and her title to the patient and the remote physician</li> </ul>
	Physician must disclose name and other information discussed above

Echnology 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 a 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  - 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 cure issue):  - Note a diagnosic based upon the examination and medical tests and basis for the plan and the risks and benefits of various treatment options; and a standard of cure issue):  - But see caveats in the following slides  - Enurure availability of the physicians or coverage for the patient for follow pearse  - But see caveats in the following slides  - Enurure availability of the physicians or coverage for the patient for follow pearse  - But see caveats in the following slides	1		1
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longer than 90 days) through telemedicine		prohibit prescribing of controlled substances for chronic pain (pain lasting	
		longer than 90 days) through telemedicine	

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CHAMBLISS	E-Prescribing	
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fiercely loyal.	Federal caveats for <u>controlled substances</u> PSA varietation provided in each applicable state.	
O HCCA	<ul> <li>DEA registration required in each applicable state</li> <li>Practitioners must also comply with DEA e-prescribing requirements</li> </ul>	
	(systems must comply with rules, system breach reporting obligations and record retention obligations)	
	<ul> <li>Federal DEA regulations require an at least 1 in-person evaluation for prescribing of controlled substances, with limited exceptions</li> </ul>	
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CHAMBLISS	E-Prescribing	
fiercely loyal.	Limited exceptions to in-person requirement, such as (real-time	
HCCA	<ul><li>av system required):</li><li>Prescribing while covering for another practitioner who has seen</li></ul>	
	patient in previous 24 months and is temporarily unavailable	_
	<ul> <li>Patient treated in presence of a DEA-registered treating practitioner</li> </ul>	
	<ul> <li>Patient treated and located at a DEA-registered hospital or clinic during the telemedicine encounter by a DEA-registered practitioner</li> </ul>	
	- Treating practitioner has special registration	
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CHAMBLISS	E-Prescribing	
fiercely loyal.	Special registration	
O HCCA	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	
	<ul> <li>On Oct 3, Congress enacted new opioids crisis response legislation (SUPPORT for Patients and Communities Act), which requires creation of</li> </ul>	
	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	
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CHAMBLISS	Payor Policies and Issues: Medicare Policy	
fiercely loyal.	Three categories of Medicare telehealth services	
O HCCA	• Category 1 – Physician Fee Schedule	
Association	<ul> <li>No "store-and-forward" technology allowed in most locations – interactive "real time" av system is required</li> </ul>	
	<ul> <li>Defined list of services/codes – see CY 2018 Medicare Telehealth Services list</li> </ul>	
	<ul> <li>Eligible distant site practitioners include MDs, NPs, PAs and other practitioners, and they receive the same Medicare rate as for face-to-face services</li> </ul>	
CHAMBLISS	Payor Policies and Issues: Medicare Policy	
fiercely loyal.	Category 1 – Physician Fee Schedule	
HCCA State Constant	<ul> <li>Patient must be located at a valid originating sites, which include physician/practitioner offices, hospitals/CAHs, certain renal dialysis</li> </ul>	
	centers and SNFs  Originating sites <u>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</u>	
	federal telemedicine demonstration project)  - Urban sites do not qualify, so this restriction means Medicare coverage	
	for telemedicine is not available to many patients	
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CHAMBLISS	Payor Policies and Issues: Medicare Policy	
fiercely loyal.	Rural HPSA requirement is a significant compliance issue for	
€ HCCV.	many providers	

O HCCA

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 CHAMBLISS fiercely loyal. • Category 2 - Medicare Advantage Plans O HCCA - MA plans can cover additional supplemental telehealth benefits with CMS • 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 Payor Policies and Issues: Medicare Policy CHAMBLISS • Recent policy changes in Bipartisan Budget Act of 2018 (the "Continuing Resolution") include: O HCCA - ESRD patients receiving home dialysis can receive certain monthly ESRDrelated 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 CHAMBLISS

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# 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 discover diagnosis for purposes of treating the disorder or a co-occurring mental health disorder

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#### Payor Policies and Issues: Medicare Policy

- 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 GVCI1)
    - Separate reimbursement only available if patient does not seek an office visit
    - Consent required, only available in existing physician-patient relationship

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### 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, nonestablished patients a possibility
  - Interprofessional consultations undertaken for the benefit of treating a patient (CPT 994X6, 994X0, 99446-9) – advance verbal consent required

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## 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

state	TN Telehealth Parity Law
state	
	does not impose telehealth restrictions under Medicaid – es determine Medicaid telehealth policies
	ry private payors cover telehealth services, although the irements vary
CHAMBLISS	Pavor Policies and Issues:
HAMBLISS	Payor Policies and Issues: TN Telehealth Parity Law
• TN's	Payor Policies and Issues: TN Telehealth Parity Law telehealth "parity" law applies to private health insurers, with ed exceptions, and Medicaid managed care plans (i.e., TennCare
• TN's limite	TN Telehealth Parity Law telehealth "parity" law applies to private health insurers, with ed exceptions, and Medicaid managed care plans (i.e., TennCare ovider licensure and standard of care parity
• TN's limite  HCCA  - Pr  - Pr	TN Telehealth Parity Law telehealth "parity" law applies to private health insurers, with ed exceptions, and Medicaid managed care plans (i.e., TennCare ovider licensure and standard of care parity ovider requirement/contractual terms parity
TN's limite     Pr     Pr     Cc	TN Telehealth Parity Law  telehealth "parity" law applies to private health insurers, with ed exceptions, and Medicaid managed care plans (i.e., TennCare ovider licensure and standard of care parity ovider requirement/contractual terms parity overage parity  Cover telehealth services consistent w/ in-person coverage for same services; cannot refuse to cover solely b/c a service is provided
TN's limite     HCCA     Pr     Pr     Cc     •	TN Telehealth Parity Law  telehealth "parity" law applies to private health insurers, with ed exceptions, and Medicaid managed care plans (i.e., TennCare ovider licensure and standard of care parity ovider requirement/contractual terms parity overage parity  Cover telehealth services consistent w/ in-person coverage for same

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# 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 <u>not</u> audio-only conversation, e-mail or fax
- But check reimbursement rules and policies

CHAMBLISS fiercely loyal. O HCCA Cal Marshall 423.757.0214 cmarshall@chamblisslaw.com CHAMBLISS Cal Marshall fiercely loval. 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. O HCCA http://www.chamblisslaw.com/People/Calvin-Marshall CHAMBLISS Disclaimer fiercely loyal. 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  $\bigoplus_{i \in \mathcal{I}}$ this presentation. Do not act upon this information without seeking the advice of an attorney. 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.