



The National Telehealth Webinar Series

Presented by
The National Network of Telehealth Resource
Centers

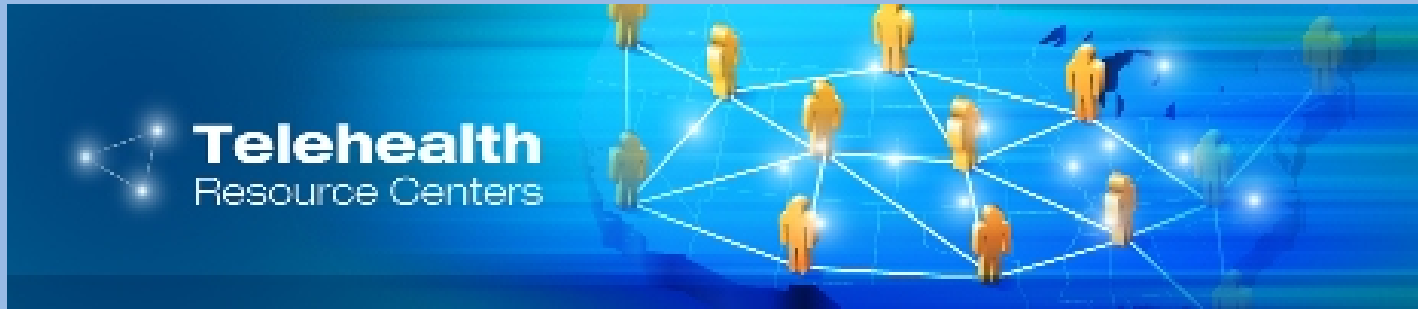
Regional Telehealth Resource Centers

<http://www.telehealthresourcecenters.org>

- California Telemedicine & eHealth Center (CTEC)
- Great Plains Telehealth Resource & Assistance Center (GPTRAC)
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Assisted by:

- Center for Telehealth and eHealth Law (CTeL)
- Telehealth Technology Assessment Center (TTAC)



Your Telehealth Program: Are you following Federal and State Laws and Regulations?

Featured Speaker: Greg Billings
Executive Director,
The Center for Telehealth & e-Health Law (CTeL)

October 20, 2011

(8:00AM HT, 11:00AM PDT, 12:00AM MDT, 1:00PM CDT, 2:00PM EDT)



The National Telehealth Resource Center Webinar Series

Your Telehealth Program: Are you Following Federal and State Laws
and Regulations

Greg Billings, Executive Director, CTeL

October 20, 2011

Objectives:



- Review legal and regulatory issues facing telehealth practitioners in the following areas:
 - Licensure
 - Credentialing and Privileging
 - Prescribing of medication
 - Reimbursement
 - HIPAA, Anti-Kickback and Stark laws

CTeL's History...

- CTeL was founded in 1995 to address the legal and regulatory barriers impacting the utilization of telehealth and related e-health services.
- CTeL, formerly known as the Center for Telemedicine Law, was created under the vision and leadership of:
 - Mayo Foundation
 - Cleveland Clinic
 - Midwest Rural Telemedicine Consortium
 - Texas Children's Hospital

CTeL's Expertise...

- Physician and Nurse Licensure Restrictions
- Credentialing and Privileging of Practitioners
- Telemedicine and Internet Prescribing
- Medicare, Medicaid, and Private Payer Reimbursement
- HIPAA Privacy Compliance
- Referral restrictions and anti-kickback statutes
- International and Maritime Law
- Industrial telemedicine



Definition of Terms:



- Originating site: the location of the patient during a telemedicine encounter.
- Distant Site: the location of the specialist providing service during the telemedicine encounter.

What is Telemedicine, Telehealth, and mHealth?



- **Telehealth:**

- Defined: The use of telecommunications and information technology to provide access to health assessment, diagnosis, intervention, consultation, supervision and information across a distance.
- Includes telephones, fax machines, electronic mail systems, and remote patient monitoring devices which are used to collect and transmit patient data for monitoring and interpretation.
(Source: CMS)

What is Telemedicine, Telehealth, and mHealth?

- **Telemedicine:**
 - Is the use of medical information exchanged from one site to another via electronic communications.
 - Includes, at a minimum, audio and video equipment permitting two-way, real time interactive communication between the patient, and the physician or practitioner at the distant site.

(Source: CMS).



What is Telemedicine, Telehealth, and mHealth?



- mHealth:
 - The practice of medical and public health, supported by mobile devices.
 - The term is most commonly used in reference to using mobile communication devices, such as mobile phones and PDAs, for health services and information.



Sounds Great! What's the Problem?

- Licensure
- Credentialing and Privileging
- Prescribing of medication without an in-person/face-to-face physical exam
- Reimbursement
 - Medicare
 - Medicaid
 - Private payers
- Privacy and Security

Licensure for Telehealth

- Where is the patient located?
- Telehealth practitioners must meet licensing requirements in the state in which they provide services—where the patient is located.
- Licensure requirements are different in each state.

Physician Licensure

- 36 States require full medical licensure.
- 9 States have a telemedicine or special licensure process.
- 43 States require licensure in another locality in order to practice across state lines.

Licensure: Exceptions

- Physician to physician consultation
- Resident in training
- Border states
- U.S. Military/VA physicians
- Public health services
- Medical emergencies/natural disasters

Licensure: Exceptions

- “Infrequent” or “occasional” consultations permitted.
 - 28 states allow this exception
 - 5 states define “occasional” or “infrequent”
 - Delaware: fewer than six consults per year
 - New Mexico: no more than 10 patients per year
 - Wyoming: not more than seven days in any 52 week period.

Special Telemedicine License Procedure/Special Purpose License

1. Alabama
2. Louisiana
3. Montana
4. Nevada
5. New Mexico
6. Ohio
7. Tennessee
8. Texas
9. Wyoming

Special Telemedicine License Procedure/Special Purpose License



- May require other conditions for special license:
 - Maintain a full medical license in another state
 - No ethics violations
 - Must not have an in-state office
 - May only practice telemedicine in emergency situation
 - Limited time or “occasionally”
 - Volunteer services.



Licensure Consultation Requirements



- Montana
 - A physician who is not licensed in Montana may engage in occasional (less than 5 times a year), informal consultation, made without compensation or expectation of compensation, with a physician or other health care provider licensed in Montana.
- North Dakota
 - Licensed physicians from other states may practice in North Dakota to the extent they are called in consultation by a North Dakota-licensed physician.
 - No further restrictions in statute or administrative regulations.



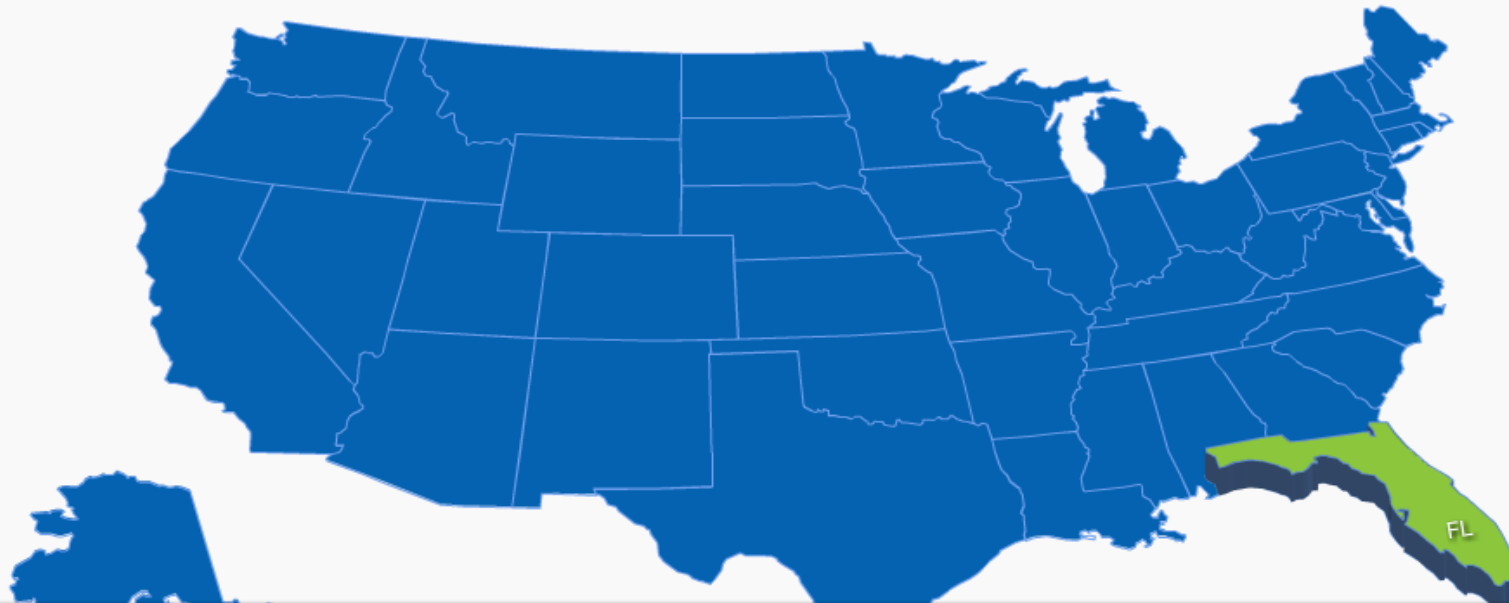
Consultation versus Practicing?



- Can the lines be blurred between consultation and practicing?
 - Is the relationship between the consulting practitioner and the primary practitioner at the same “level”?
 - Or is the consulting practitioner at different level than the primary practitioner?
- Can the lines be crossed so a consultation is actually practicing medicine without being properly licensed at the originating site?

Where to Find this Information?

CTeL's 50 State Interactive Physician Licensure Map...



FLORIDA



Those wishing to practice medicine in the state of Florida need to obtain a full medical license. Florida does not have specific language within its state statute, nor its administrative regulations, granting physicians a "special/limited" license to enter the state remotely to practice telemedicine.

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Credentialing and Privileging



- Original CMS Policy: Required the originating hospital to fully credential and privilege all practitioners, including telehealth practitioners.
- Joint Commission allowed credentialing / privileging by proxy.
 - 2004: Joint Commission Telemedicine Guidelines
 - JC-accredited facilities could accept credentialing from other JC-accredited facilities
 - System worked unless audited by state or CMS
- CMS and JC were in conflict.
 - JC had “permanent deeming authority”

Credentialing and Privileging



- July 5, 2011 – credentialing and privileging “by proxy” is permitted through CMS Final Regulation.
- Originating Site Hospital can rely on Distant Site for Credentialing and Privileging.
- Distant Site can either be:
 - Medicare Participating Hospital
 - Telemedicine Entity
- Written agreement between hospital and Distant Site.

Credentialing and Privileging



- Hospitals choosing to use this new option for credentialing/privileging must provide for the following:
 - The distant-site hospital is a Medicare-participating hospital.
 - The distant-site practitioner is privileged at the distant-site hospital.
 - The distant-site hospital provides a current list of the practitioner's privileges.

Credentialing and Privileging

- Hospitals choosing to use this new option for privileging must provide for the following:
 - The distant-site practitioner holds a license issued or recognized by the state in which the originating-site hospital is located.
 - The originating-site hospital has an internal review of the distant-site practitioner's performance and provides this information to the distant-site hospital.
 - Information sent from the originating-site to the distant site must include all adverse events and complaints from telemedicine services provided by the distant-site practitioner to the originating-site hospital's patients.
- Fact sheets at www.ctel.org (Credentialing/Privileging Resource Center)

Internet/Telemedicine Prescribing: Scope of Practice



- Prescribing statutes were written before the widespread use of telemedicine.
- 41 states require physical exam or a preexisting physician-patient relationship.
- Problem: Statutes use vague language.
 - Can a “face to face” or “in person” examination occur through telemedicine?

Internet/Telemedicine Prescribing: Scope of Practice



- 12 states allow for the physical examination to take place electronically.
 - California
 - Kansas
 - Maryland
 - New Mexico
 - South Dakota
 - Virginia
 - Hawaii**
 - Louisiana
 - Nevada
 - North Carolina
 - Texas
 - Vermont

Internet/Telemedicine Prescribing: Scope of Practice



- 29 States require a Patient Medical History before prescribing.
- 17 States require physician to establish appropriate follow up medical care.
- 14 States allow for emergency prescribing.
- 30 States specifically prohibit medical questionnaires and/or patient supplied history as sole basis for prescription.



Telehealth Reimbursement



- Medicare Statute
 - Originating sites in certain locations
 - Covered procedures specified
 - Specific practitioners eligible
 - In 2009, Medicare reimbursed approximately \$2.4 million under the Medicare Physician Fee Schedule
- Medicaid
 - 39 states cover certain telehealth services.

Telehealth Reimbursement



- 12 States mandate private payer telehealth coverage.
 - California
 - Georgia
 - Kentucky
 - Maine
 - Oklahoma
 - Texas
 - Colorado
 - Hawaii
 - Louisiana
 - New Hampshire
 - Oregon
 - Virginia

HIPAA Generally

- Health Insurance Portability and Accountability Act of 1996
- The Privacy Regulations govern the use and disclosure of health information held by Covered Entities.
- The Security Regulations protect health information from access by unauthorized people.

HIPAA Privacy Rule vs Security Rule

A blue stethoscope is positioned in the top right corner of the slide, partially overlapping the title area.

- Privacy Standards
 - Minimum use—payment and operations, not treatment
 - Notice of Privacy Practices
 - Designated Record Set
 - Incidental use and disclosure
 - Sanctions
 - Business Associate contracts

HIPAA Privacy Rule vs Security Rule

A blue stethoscope is positioned in the top right corner of the slide, partially overlapping the title area.

- Security Standards
 - Access control
 - Authentication
 - Network Controls
 - Reasonable safeguards
 - Workstation controls
 - Authentication
 - Audit trails
 - Chain-of-Trust Agreements

Privacy Rule: Protected Health Information

- Privacy Rule applies to protected health information (PHI) which is information:
 - in any form of medium, oral or recorded (not just electronic)
 - that relates to the individual's health, healthcare, treatment, or payment
 - that identifies the individual in any way



Privacy Rule: Covered Entity Requirements

- Obtain authorization for special additional uses of PHI
- Designate a privacy official
- Develop policies and procedures; and sanctions for employees violating policies
- Provide privacy training to their workforce
- Implement appropriate administrative, technical, & physical safeguards to protect privacy

Security Rule Requirements



- 3 types of safeguards:
 - Administrative
 - How to deactivate access
 - When is activity logged
 - Physical
 - Where are devices located
 - How is physical access to systems and/or ePHI accomplished
 - Technical
 - Encryption

Security Rule: Electronic Protected Health Information



- Security Rule applies only to electronic protected health information (ePHI):
 - PHI that is created, received, maintained or transmitted in electronic format
 - Does not include paper-to-paper faxes or video teleconferencing or messages left on voice mail
- Information being exchanged did not exist in electronic form before the transmission.

Breach Notification Rule

- Requires covered entities to report breaches of protected health information
 - Impermissible uses or disclosures that create a significant risk of financial, reputational, or other harm to the individual
- Covered entities are expected to report breaches that they discover, or through reasonable diligence would have discovered

State Privacy Laws

- If the provision of State law relates to the privacy of health information and is “more stringent” than the privacy rule, state law prevails
- Examples:
 - California
 - Florida
 - New York
 - Illinois

HIPAA Issues Unique to Telehealth



- Security of technology necessary in mHealth
 - Use of Skype and similar technology to provide services
 - Authentication
- Distribution of the *Notice of Privacy Practice* to patient, if the health care provider is not a member of the patient site workforce
- HIPAA privacy training/education if the health care provider is a member of the patient site workforce
- Use of videoconferencing

HIPAA Issues Unique to Telehealth

- Business associate agreements with technical providers (non-covered entities) who assist with the delivery of healthcare by telemedicine
- Telehealth consultations may require additional non-clinical personnel, such as technicians and camera operators, who do not participate in traditional medical care

Anti-Kickback Statute

- Prohibits the offering, paying, soliciting or receiving any remuneration in return for
 - Business for which payment may be made under a federal health care program
 - Inducing purchases, leases, orders or arranging for any good, service, or item paid for by a federal health care program
- Remuneration includes:
 - Kickbacks
 - Bribes
 - Rebates
 - Cash or in kind, direct or indirect

Safe Harbor

- Immunize certain payment and business practices that are implicated by the anti-kickback statute from criminal and civil prosecution under the statute
- Most common safe harbors for telehealth
 - Space Rental Safe Harbor
 - Equipment Rental Safe Harbor
 - Personal Services and Management Contracts Safe Harbor
 - Bona Fide Employees' Safe Harbor

Common Anti-Kickback Issue

- The provision of subsidized or free equipment
 - Does an originating site's subsidization of the capital and/or operating costs result in referrals (directly or indirectly)?

Anti-Kickback Analysis/Questions

- Did something of value get offered, requested, exchange hands?
- If so, was the conduct willful?
- Did the provider's treatment pattern change?
- Were patients switched because of the kickback?
- If yes, were they consulted and told about the inducement?
- Did the parties know about the Anti-Kickback Statute?
- If so, is there a safe harbor?
- If so, was some or all of the expected/desired business paid for by a federal health care program?

Stark Law

- The federal Stark physician self-referral law generally prohibits a physician from making referrals to an entity for any of eleven (11) designated health services if the physician (or an immediate family member) has a “financial relationship” with the entity
 - Some exceptions
 - Ownership, investment interests
 - Compensation arrangements

Conclusion

- The concrete “black and white” answers may not exist.
- You may think the statute or rule is “stupid”
 - Your opinion doesn’t count! (that’s not really true 😊)
- Incorporate the legal and regulatory questions into your business model at the beginning, not the end.
 - The legal and regulatory problems won’t just go away if you don’t address them.
 - They only get worse.

Friend CTeL!!



CTeL
CENTER FOR TELEHEALTH
& e-HEALTH LAW

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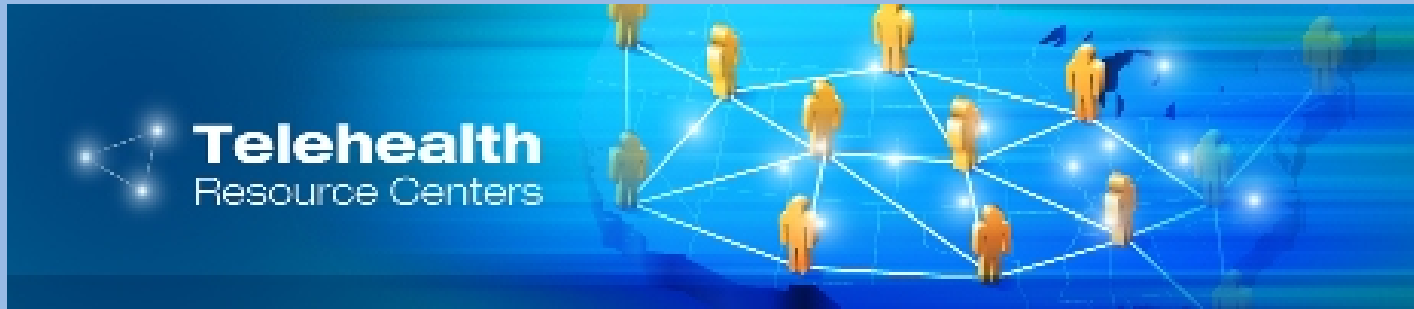
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The National Telehealth Resource Center Webinar Series

3rd Thursday of every month

Next Webinar:

Topic: Enabling State Licensure through Key Portability Initiatives

Presenter: Federation of State Medical Boards

Sponsor: Northwest Regional Telehealth Resource Center

Date: Thursday, November 17, 2011

Times: 2:00 PM Eastern Time / 1:00 PM Central Time

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Your Telehealth Program: Are You Following Federal & State Laws & Regulations

We value your opinion on this presentation.

Please complete the brief survey found at:

<http://www.surveymonkey.com/s/NationalTRCWebinars-2>

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