



### Objectives:

- Review legal and regulatory issues facing telehealth practitioners in the following areas:
  - Licensure
  - Credentialing and Privileging
  - Prescribing of medication
  - Reimbursement
  - Accountable Care Organizations

### 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.

### 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:
  - Robert Waters
  - Dr. Yadin David
  - Mayo Foundation
  - Cleveland Clinic
  - Midwest Rural Telemedicine Consortium
  - Texas Children's Hospital

### CTeL and the ... National Telehealth Resource Center...

- From 2006-2011, CTeL has operated the National Telehealth Resource Center (NTRC) through OAT/Health and Human Services.
- The NTRC and CTeL provide information to the telehealth community on legal and regulatory topics, through publications, webinars, speaking engagements, and one-on-one consultations.
- Find us at [www.ctel.org](http://www.ctel.org)

### 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

### 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

### Licensure for Telehealth

- Telehealth practitioners must meet licensing requirements in the state in which they provide services.
- Where is the patient located?
- Licensure requirements are different in each state.
- 36 States require full medical licensure.
- 11 States/Territories have a telemedicine or special licensure exception.

### Special Telemedicine License

1. Alabama
2. Guam
3. Louisiana
4. Minnesota
5. Montana
6. Nevada
7. New Mexico
8. Ohio
9. Oregon
10. Tennessee
11. Texas

### Special Telemedicine License

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

### Licensure: Exceptions

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

### 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.

### Licensure Consultation Requirements

- South Dakota
  - A person licensed to practice any of the healing arts outside of South Dakota may engage in consultation with a South Dakota-licensed practitioner. There are no further restrictions on consultations found in statute or administrative regulations.
- Wyoming
  - Out of state licensed physician may consult with a Wyoming-licensed physician. Wyoming physician must notify the Wyoming Board. Out-of-state physicians are limited to twelve (12) days in any fifty-two (52) week period (more with prior board approval). Established a “temporary” licensure process

## Consultation versus Practicing

- Can the lines be blurred between consultation and practicing?
  - Consulting practitioner to 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...



## 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” 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 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](http://www.ctel.org)

### Internet/Telemedicine Prescribing: Scope of Practice

- Prescribing statutes were written before the widespread use of telemedicine.
- 2/3 of the states still require an "in-person" or "face to face" physical examination.
- Problem: Statutes use vague language.
  - Can a "face to face" examination occur through telemedicine?
    - 34 states require an in-person physical exam.
    - 12 states allow for the examination to take place electronically.

### Telehealth Reimbursement

- Medicare
  - Originating sites in certain locations
  - Covered procedures specified
  - Identified practitioners
  - In 2009, Medicare paid approximately \$2.4 million under the Medicare Physician Fee Schedule
- Medicaid: 39 states cover certain telehealth services.
- 12 state statutes mandate private payer telehealth coverage.

## HIPAA Privacy Rule vs. Security Rule

### Privacy Standard(s)

- Minimum use- payment & operations, not treatment
- Notice of Privacy Practices/Designated Record Set
- Incidental use and disclosure if and only if...
- Verification of requestor
- Sanctions
- Business Associate Contracts

### Security Standard(s)

- Access control
- Authentication
- Network Controls
- Training
- Reasonable safeguards
- Workstation controls: use; location (physical and technical)
- Authentication/ Authorization
- Audit trails
- Chain-of-Trust Agreements

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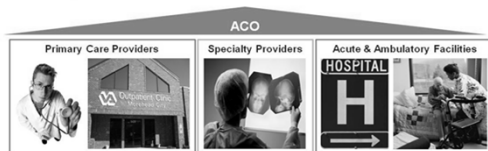
## HIPAA Issues Unique to Telehealth Services

- Security of technology necessary in telemedicine
  - Use of Skype and similar technology to provide telehealth services
- 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
- 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

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## Accountable Care Organizations (ACO)

MedPAC (2009)	"A set of providers associated with a defined population of patients, accountable for the quality and cost of care delivered to that population"
PPACA (2010)	"A group of providers of services and suppliers meeting criteria specified by [HHS] may work together to manage and coordinate care for Medicare fee for service beneficiaries"



Source: Fisher ES et al., *Creating Accountable Care Organizations: The Experience of the Medical Staff*, December 5, 2007, Health Affairs, Vol. 26, pp. 444-451; MedPAC, *Medicare Payment Reform Options*, Committee on Medicare Program Improvements under the Medicare Program of Chapter 2, June 2008, [http://www.medicare.gov/redesign/medpac26\\_chapter02.pdf](http://www.medicare.gov/redesign/medpac26_chapter02.pdf), accessed 2/4/2010

## Why ACOs?

- Current Fee-for-Service System Pays for Volume, not Value
- Current Delivery System is Highly Fragmented, With Little Incentive to:
  - Reduce costs
  - Coordinate care
  - Focus on quality
- To Accomplish Reform of Current System, Need Mechanism to Align Incentives:
  - Pay for quality, not quantity
  - Pay for patient-centric outcomes, not provider outcomes
  - Encourage communication among providers necessary to achieve quality goals
  - Encourage best practices for each episode of care, regardless of provider of services

## Proposed Rule

- Proposed Rule Regarding ACOs Released on April 7, 2011
- Comments Were Due on June 6, 2011
- General Reaction Has Been Largely Negative From all Sectors of the Industry
- HHS has Announced Some Other ACO Initiatives
  - Pioneer ACOs
  - Advanced payment initiative

## Who Can Become an ACO?

- Physician Group Practice
- Network of Independent Physicians (IPA)
- Joint Ventures Between Hospital and Physicians (PHO)
- Hospital with Employed Physicians (IDS)
- Method II Critical Access Hospitals (CAH)
- Others Approved by CMS
- No FQHCs or RHCs, But Shared Savings Incentive Available For Including in Network

## ACOs and Telehealth

- Under Health Care Reform Legislation:
  - ACOs encouraged to use telehealth and remote monitoring to improve quality, reduce cost, and keep patients out of the hospital and other high-cost facilities
  - Part of ACO coordination of care to use telehealth, remote patient monitoring, and other such enabling technologies
  - No specific criteria within proposed rule regarding use of telehealth or remote monitoring
- What are the Benefits?
  - Less Costly Way to Provide Health Services to Many
  - Address Provider/Practitioner Shortages
  - Reduce Disparities to Patient Access
  - Help Improve Patient Outcomes and Quality
  - Help Reduce Reliance on Inpatient Services as Primary Means of Care
  - Improve HIT, Telehealth Deployment and Infrastructure

## Conclusion

- The concrete “black and white” answers may not exist.
- You may think the statute or rule is “stupid”
  - Your opinion doesn’t count! ☹
- 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!!



## Contact Information

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