



**MUCH MORE
THAN A BROKER**



Telemedicine 101: Risks, Challenges, & Solutions

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Learning Objectives

- Define and identify benefits of eHealth, telehealth, telemedicine and mHealth
- Understand how telemedicine is regulated
- Address the challenges to practicing via telemedicine

Definitions

eHealth

- Use of electronic information and communication technologies (ICT) for health-related services
- Not a specialty in and of itself!

Definitions

Telehealth

- Delivery of patient care, consultations and education supported by telecommunications technologies, including live interactive video-conferencing, store and forward technologies, remote patient monitoring, and mHealth
- Not a specialty in and of itself!

Definitions

Telemedicine

- Use of technology for the delivery of health care services when the health care practitioner and patient are not in the same physical location
- American Telemedicine Association definition:
 - “the use of medical information exchanged from one site to another via electronic communications to improve a patient’s clinical health status.”
- Not a specialty in and of itself!



Definitions

mHealth



- Mobile health
- Practice of medicine and public health supported by mobile devices
- Not a specialty in and of itself!

Models

- Health system (including academic) classic hub and spoke models, many also extending to the home
- Veterans Health Administration
- Telemedicine services companies
 - Specialty care
 - Remote patient monitoring
- Retail clinics
- Workplace clinics
- Aging in place models
- Direct to consumer market
 - Within systems
 - Payer developed

There's an App for That!

ECG/EKG Device



Glucose Meter



Ultrasound Device



Blood Pressure Monitor



Benefits

Helping...

- Patients
- Health Professionals
- Hospital Systems
- Communities

Overcome...

- Time & Distance
- Health Care Workforce Shortages
- Cost of Care
- Limited Choice of Providers

How is Telemedicine Regulated?

- Food and Drug Administration (“FDA”)
- Centers for Medicare & Medicaid Services (“CMS”)
- State health codes, medical boards, etc.
 - If more stringent, will override CMS



How Does the FDA Regulate Telemedicine?

- When equipment or software is intended for use in the diagnosis or treatment of a disease or other condition, the FDA considers the equipment or software to be a medical device.
 - Remote Holter Monitoring
- FDA regulates the software used in *telehealth* systems.
 - Software that “reads” and “interprets” the Holter data; software that transmits the remote retinal images, etc.

FDA Oversees Mobile Medical Apps

As of September 25, 2013, the FDA regulates mobile medical apps that:

- Are used as an accessory to an FDA-regulated medical device.
- Transform a mobile platform into a regulated medical device.



How Does CMS Regulate Telemedicine?

- Requires hospitals receiving telemedicine services to privilege each physician or practitioner providing services to its patients, as if the practitioner worked on site.
- While current regulations permit use of third-party credentialing verification organizations, the hospital's governing body retains responsibility for all privileging decisions.

Challenges

- Licensure
- Credentialing and Privileging
- Prescribing
- Privacy and Security/HIPAA Compliance
- Reimbursement
- Malpractice Coverage



Licensure

- The practice of medicine occurs in the state the *patient* is located for the purpose of medical licensing, regardless of whether it is in the physical presence of the patient or through electronic media.



Conditional/Telemedicine License States

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

Licensure: Exceptions

- 45 states and DC permit “infrequent” or “occasional” provider-to-provider consultations
 - Some states define “infrequent” or “occasional”
 - **Delaware:** fewer than 12 consults per year
 - **Rhode Island:** on a singular occasion... for a period not to exceed seven (7) days
 - **Tennessee:** less than once a month or involves fewer than ten patients on an annual basis
 - **West Virginia:** less than once a month or less than twelve times in a calendar year

Federation of State Medical Boards Compact

1. Alabama
2. Arizona
3. Colorado
4. Idaho
5. Illinois
6. Iowa
7. Kansas
8. Minnesota
9. Mississippi
10. Montana
11. Nevada
12. New Hampshire
13. South Dakota
14. Utah
15. West Virginia
16. Wisconsin
17. Wyoming

Reciprocity States

1. Maryland
2. DC
3. Virginia
4. NY

Credentialing & Privileging

- 2011 – CMS Final Regulation
 - Permits credentialing and privileging “by proxy”
 - Originating site (o-s) hospital can rely on distant site (d-s) for credentialing and privileging
 - Distant site can either be:
 - Medicare Participating Hospital
 - Telemedicine Entity
 - Must have written agreement between o-s hospital and d-s

Credentialing & Privileging “by Proxy” Checklist

Distant Site Hospital

- Medicare-participating hospital or entity that can ensure Medicare-compliance.
- Provides a current list of the practitioner’s privileges.

Distant Site Practitioner

- Privileged at the d-s hospital or entity.
- Holds a license issued or recognized by the state in which the o-s hospital is located.

Credentialing & Privileging “by Proxy” Checklist

- The o-s hospital has an internal review of the d-s practitioner’s performance and provides this information to the d-s hospital.
- Information sent from the o-s to the d-s must include all adverse events and complaints from telemedicine services provided by the d-s practitioner to the o-s hospital’s patients.

Prescribing via Telemedicine: Scope of Practice

- 41 states and DC have a policy or statement on Internet prescribing.
- Many require a “face to face” exam or pre-existing physician-patient relationship.
- 12 States allow virtual “face to face” exams:
 - California
 - Hawaii
 - Kansas
 - Louisiana
 - Maryland
 - Nevada
 - New Mexico
 - North Carolina
 - South Dakota
 - Texas
 - Vermont
 - Virginia

Hageseth v. The Superior Court of San Mateo County



San Mateo County Sheriff / Courtesy to The Chronicle



McKay Family / Courtesy to The Chronicle

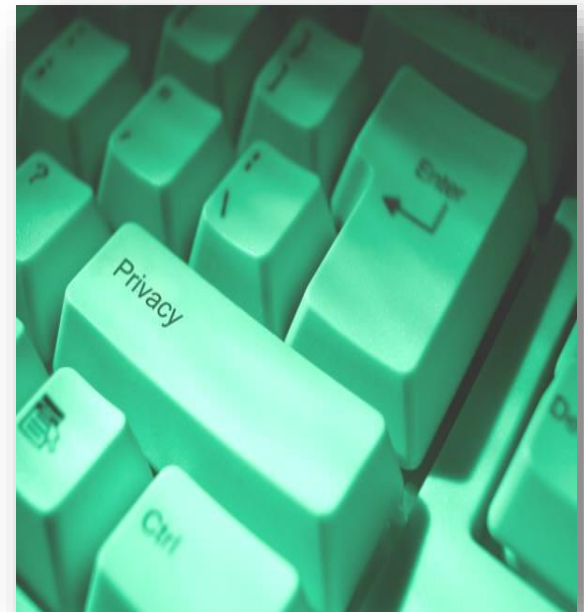
Ann DeJong, MD



- Sanctioned by Idaho's medical licensing board for prescribing a common antibiotic over the phone
- Board certification threatened
- Idaho Board of Medicine sanction triggered reviews of her licensing in all 9 states in which she is licensed
- Sanctioned with license restriction, preventing her from consulting with patients by telephone or telecommunications, and ordered to pay almost \$10,000 in fines and costs and take a medical ethics course

Privacy & Security in Telemedicine

- Health Information Portability and Accountability Act (“HIPAA”)
- HIPAA Administrative Simplification provisions
 - Outline the national standards for privacy and security regarding electronic health care transactions
- State level regulations
 - More stringent overrules



You must know the privacy laws

in the state where you practice

&

**in the state or country where
the patient is located!**

CONFIDENTIAL

Privacy & Security Issues

- Individual Device Security
 - Provider
 - Patient
- Patient Identification
- Access Security
 - Secure logins for both patient and provider
 - Multi-factor authentication
- BAAs & PHI use
 - Review vendor contracts



Is Your Organization Ready for Telemedicine?

- **Assess & Define**
 - Assess Service Needs and Environment
 - Define Program Model
 - Develop Business Case

- **Develop & Plan**
 - Develop and Plan Program and Technology
 - Develop Performance Monitoring Plan

- **Implement & Monitor**
 - Implement Telemedicine Program
 - Monitor and Improve Program (Ongoing)

Crafting a Compliant Telemedicine Program

- Informed Consent
- Privacy and Data Transmission
- Systems Security
- Physician-Patient Relationship
- Patient Abandonment
- Continuity of Care
- Medical Records
- Contractual Arrangements
- Peer Review

Informed Consent

- Informed Consent document should include acknowledgement that the patient understands and agrees that despite best efforts to protect privacy and confidentiality:
 - use of communication mediums entail a risk of inadvertent or intentional disclosure by and to third parties
 - patient information may be accessible to operators of the medium
 - complete security cannot be assured

Informed Consent Dos

- Know the legal requirements in relevant jurisdictions
- Check with insurance carrier regarding recommendations/rules
- Understand that the form is mere evidence
- Verify identity of the signer
- Add “the unknown” to risks
- Point out limitations of the technology used
- Consider video as part of the process
- Assert that all blanks are filled in at time of signing and that patient could ask questions and is satisfied with answers

Informed Consent Don'ts

- Re-purpose a form developed for in-person care
- Overstate benefits
- Understate risks
- Allow patient to sign without discussing and asserting his/her understanding of the associated risks

Peer Review

- Tele-providers should regularly participate in an established quality assurance program, including formal peer review, to ensure patient safety.
- Programs should address physician education and error reduction, enable longitudinal follow-up, provide an opportunity for a second opinion when the local caregivers raise concern, and include a process of remediation for low-performing tele-providers.

Malpractice Insurance

- Some carriers may only cover “face to face” encounters within the State in which the doctor practices and is licensed
- Obligations of malpractice insurance carriers must be examined on a state-by-state basis
- Separate policies may exist for clinicians who provide interpretive telemedicine services, i.e. teleradiology
- Obtain written assurance from an insurer that the medical malpractice liability policy covers telemedicine malpractice
- If providing services across state lines, obtain written assurance that coverage extends to multiple states

Available Resources

- American Telemedicine Association (“ATA”)
 - Standards & Guidelines
 - Core Standards for Telemedicine Operations
 - Practice Guidelines by Specialty
- Regional Telehealth Resource Centers
- Center for Telehealth and e-Health Law
- Center for Connected Health Policy
- CTRC Telehealth Program Developer Kit

Key Takeaways

- Comply with telemedicine regulations that apply in the locations where BOTH the practitioner and the patient are located.
- Address key challenges before implementing a telemedicine program.
- Telemedicine + Telehealth + mHealth = the future of healthcare – weigh the benefits and risks!

Questions? Comments?

**Thank you for your time
and attention!**

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