# TELEHEALTH: LEGAL ISSUES

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November 28, 2017

# Telemedicine/telehealth

Telemedicine/telehealth:  use of telecommunications and information technology to provide clinical health care from a distance

- teleradiology

- ICU remote monitoring

- telepsychiatry

- teledermatology

- tele audiology

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# Pros and cons

Beneficial to

- patients in remote regions, who can receive care without having to travel

- bring in specialty consults from elsewhere

- monitor patients in ICUs

- allow radiology films to be read 24/7

Drawbacks:

- follow-up issues/reduced care continuity

- risk that PHI may be accessed electronically

- risk of error w/o seeing patient

- costs

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# 3 type of telehealth

1) Store and forward (acquire medical data, e.g., images, and transmit data to specialist for assessment at convenient later time)

2) Remote monitoring (allows health professionals to monitor patient remotely using various technology)

3) Real-time interactive (history review, physical exam, psychiatric sessions, assessments)

# Use of telehealth growing

Teladoc, American Well, Doctor on Demand

Remote post-hospitalization care

Preventative care support, e.g., weight loss and smoking cessation

School based telehealth

Assisted living center support

Remote chronic disease management

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# Payers using telehealth

Anthem and United are offering their own direct-to-consumer virtual doctor-visit services

Hopkins and Stanford all offering remote consultation services

Cleveland Clinic is creating "Cleveland Clinic in the Cloud" to allow patients across country to access physicians without going to Ohio

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# Reimbursement for telehealth

Medicare:

Reimburses for telehealth services offered by a provider at a distant site to a patient in a rural area only

Originating site may be:

- practitioner office,

- hospital, SNF, hospital-based dialysis center

- FQHC, rural health clinic, community mental center

Medicare only reimburses for live telemedicine

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# Medicare reimbursement of telehealth

Eligible providers under Medicare:

   - physicians

   - NPs, PAs, clinical nurse specialists

   - nurse midwives

   - clinical psychologists

   - clinical social workers

   - registered dietitians or nutrition professionals

Medicare has a specific list of CPT and HCPCS codes covered under telemedicine

Must use the GT modifier to show service was provided virtually

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# Medicaid reimbursement

46 state Medicaid programs offer physician reimbursement for telemedicine over live video

14 state Medicaid programs covers remote patient monitoring

16 state Medicaid programs cover a facility or transmission fee

Only AK, MN and MS cover all 3 types of telehealth

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# Commercial insurance

24 states and DC have "parity" laws, requiring health insurers to cover and pay for services via telehealth in same way as in-person services

New York: Effective 1-1-2016, commercial health insurers may not exclude from coverage services that are otherwise covered in-person

      - includes MD, NP, social worker, speech language pathologist, diabetes educator, DPM, etc

NJ law:  George Kendall to discuss

# Private pay

Telemedicine visits are often paid by patients directly

- e.g., online services that offer patients 24/7 on-demand access to virtual doctor may charge per-visit fee or monthly or yearly subscription

Example:  Doctors on Demand offers a face-to-face 15 minute online consult through a smart phone, tablet or computer for $50

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# Licensing rules

The location of the patient is considered the "place of service" and the provider must comply with the laws of the state where the patient sits

Practitioner must be licensed in state in which the patient sits

Some exceptions (depending on the state):

- physician-to-physician consultations

- border states

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# Licensing issues

E.g.,at Mayo Clinic, doctors who treat out-of-state patients can follow up via phone, email or web when they return home, but only discuss the conditions treated in person

      - if patient has a new problem, doctor has to be licensed in that state to discuss it

# What counts as practicing a profession?

Some web-based businesses allow customers to consult doctors overseas, who don't have US medical licenses, but post disclaimers that they are providing information and not medical advice

Example:  FirstDerm users upload photos and description of skin issues, and a dermatologist (most in Europe) replies within 24 hours with a possible identification of issue and options

        - says no patient relationship because both physicians and patients are anonymous

# Mid-level providers

If services are provided by mid-level providers, e.g., nurse practitioners or physician's assistants, consider:

  - licensure (in same state where patient sits)

  - scope of practice

  - physician collaboration or supervision

# Credentialing and privileging

Providers practicing at facilities must be credentialed by those facilities

Joint Commission allows hospitals to "privileges by proxy," i.e.., accept a distant site hospital's credentialing and privileging decisions

- so that hospitals need not undergo a separate privileging and credentialing process for each practitioner providing telehealth services from a distant site

Must be allowed by state law and bylaws

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# CMS requirements for hospitals to credential by proxy

(i) Distant site hospital must participate in Medicare or be a telemedicine entity

(ii) Provider is privileged at the distant site hospital

(iii) A current list of the telehealth provider's privileges is given to the originating site hospital

(iv) Written agreement between the parties

(v) Telehealth provider licensed in originating site hospital's state

(vi) Originating site hospital reviews provider and shares info with distant site hospital

(vii) Sites aware of all adverse events

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# Medical staff bylaws

- Ensure that the medical staff bylaws allow privileging of telemedicine providers
  - e.g., nothing in the bylaws that require a certain number of admissions
  - Have specific provision for telehealth providers

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# Prescribing often requires patient relationship

Patient relationship established when:

- patient exam performed

- patient condition diagnosed

- patient condition treated

- follow-up care plan created

Some states require at least one in-person consult to establish a patient relationship

Many states: can't prescribe based on internet questionnaire, consult, call or email

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# Prescribing often requires physical exam

A physical exam should be performed BEFORE a prescription

Question:  can an exam be done via telehealth?

    - twenty states allow physical exams or evaluations to be performed by electronic means or via telehealth technologies

Some states regulate through what pharmacists can fill

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# Prescribing narcotics

- Ryan Haight Act: no controlled substance may be delivered, distributed, or dispensed by means of the internet without a valid prescription.  A valid prescription is one issued for a legitimate medical purpose in the usual course of professional practice by: 1) a practitioner who has conducted at least one in-person medical evaluation of the patient; or 2) a covering practitioner.

# Controlled substances

Ryan Haight exceptions

**(1) Treatment in a hospital or clinic.** Telemedicine conducted while the patient is being treated by, and physically located in, a hospital or clinic by a practitioner w/DEA registration

**(2) Treatment in practitioner physical presence**

**(3) Indian Health Service or tribal organization.**

**(4) Public health emergency declared by HHS**

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# Ryan Haight exceptions cont.

(5) **Special registration.** Telemedicine by a practitioner with a special registration under section 311(h) of the Act (21 U.S.C. 831(h));

(6) **Veterans Affairs medical emergency.**
(7) **Other circumstances specified by regulation.** Telemedicine under circumstances that the Administrator and the Secretary of Health and Human Services have jointly, by regulation, determined to be consistent with effective controls against diversion and consistent with public health and safety.

# HIPAA

Providers may or may not be HIPAA-covered entities and REQUIRED to be HIPAA compliant

Providers must comply with same HIPAA requirements whether services are in-person or through telehealth

HIPAA privacy rules:  policies, procedures, maintaining privacy of PHI

   - apply to both originating and distant site

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# HIPAA security

Storage of electronic files, images, etc.

Technology used for telehealth needs to ensure high-level security and prevent breaches of patient personal health

Encryption to protect data hacking

Do risk assessment with respect to data transmission as required by HIPAA

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# HIPAA sharing of information

Technical providers who can access PHI and work on behalf of provider is a business associate, and need a business associate agreement

Telehealth involves sharing of information with more than one organization

- so address questions about shared responsibility for managing and securing patient informing generated through a telehealth encounter

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# HIPAA and mobile apps

An app developer is typically NOT a covered entity subject to HIPAA, or a business associate

- Simply because app collects health related data doesn't make it subject to HIPAA

- A wearable health app by a consumer is not subject to HIPAA, or a medication-adherence health app for patient self-use

But consider state law, e.g., CA's Confidentiality of Medical Info Act, which requires health app developers & PHR vendors to maintain same standards as hc provider re medical information

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# HIPAA to-do's

Ensure secure communications channels

Implement business associate agreements and other confidentiality and privacy agreements

Provide education re appropriate use of telehealth technologies

Understand how and what patient information is being collected and stored

Do security risk analysis

All subcontractors with access to PHI must comply with HIPAA requirements

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# Malpractice liability

Four elements of a malpractice/negligence suit:

- duty of care

- breach of that duty (i.e., provider didn't act like a reasonably prudent person in that situation)

- damage to the patient

- the provider's breach of duty caused the damage

Lawsuits in telehealth not common.  Most common: radiology

- failure to diagnose properly

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# Malpractice insurance

Must ensure that malpractice insurer covers telehealth

Malpractice carrier may require submission of a questionnaire regarding location, frequency and type of service provided via telehealth, or pre-approval

May also have to pay a surcharge on malpractice premium - depending on risk, venue, whether other state in which service is provided has higher risk, whether service increase exposure

Malpractice carrier may cover telehealth only within the State in which the provider practices

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# Informed consent

Consider what type of informed consent patient must provide before telehealth used

- explain: purpose, risks, benefits, alternatives

Also consider:

- what documentation exists of consent

- where patient signs

- where documentation is maintained

# Federation of State Medical Boards: Informed Consent

Informed consent for telemedicine should include:

- Identification of physician and credentials;

- Types of transmissions permitted, e.g. prescription refills, appointment, scheduling, etc.

- That the physician determines if the condition is appropriate for a telemedicine encounter;

- Security measures, e.g., encryption, password protected screen savers, authentication,

- Hold harmless if info lost with technical failures;

- Express consent to forward information

# Federal Communications Commission & telehealth

FCC regulates devices that use electromagnetic spectrum, or broadcast devices (regulate devices as communications devices, not as a medical device)

FCC in 2012 approved its mobile body area network (MBAN), allocating electromagnetic spectrum for personal medical devices

- to allow for faster & more reliable transmission of data from monitoring devices to practitioners

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# Medical devices

FDA regulates medical devices

FDA and FCC entered into MOU to collaborate with each other

Center for Devices & Radiological Health (CDRH) in FDA lead agency: ensures safety and effectiveness of medical devices used in telehealth

- premarket review, post-market surveillance, quality systems, standards, & science relating to telehealth

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# Medical devices

When equipment or software is intended for use in the diagnosis or treatment of a disease or other condition, FDA considers it to be a medical device

- requires registration and listing, premarket notification or approval, good manufacturing practices, and post-market surveillance

2015: FDA has low enforcement priority for mobile medical apps that pose a low risk to patient safety

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# FDA Guidance on Mobile Medical Applications

9/25/2013 Guidance: 3 categories of medical apps:

1. Mobile apps considered medical devices and subject to FDA regs (assist with diagnosis or treatment recommendations).

2. Help manage health, organize and track information, help document or communicate information, or perform simple calculations (FDA does not intend to regulate)

3. Not medical devices: reference materials, educational tools, automate office operations

# Fraud and abuse statute

Beware of relationships with others that provide incentives for referrals or healthcare business - eg, lease of equipment from referring docs

Federal anti-kickback law: cannot offer, pay, solicit or receive remuneration to induce referral of items or services covered by Medicare, Medicaid or any other federally funded healthcare program

- various "safe harbors," e.g., employment, personal services, leases

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# Application of anti-kickback law

2011 OIG Advisory Opinion: health system proposed to provide neuro-emergency clinical protocols & immediate consults with stroke neurologists via telemedicine to certain community hospitals

- OIG: no sanctions given safeguards to reduce risks of improper payment for referrals

    - e.g., stroke patients could be referred anywhere

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# Peer review is important

Important to develop policies and procedures for monitoring telehealth practitioners and sharing internal review information so that privacy of patient information and peer review protected, while information to make appropriate credentialing decisions is shared

- include adverse events that result from telemedicine, complaints

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# AMA Telemedicine Policy

1. Establish patient relationship before provision of telemedicine services, through:

   - Face to face exam, if this would be required w/o tele.

   - Consult with a physician with an ongoing patient relationship who agrees to supervise patient's care

   - Meeting evidence-based clinical practice guidelines developed by specialty societies, e.g., radiology

   Exceptions: on-call, cross-coverage, emergencies

2. Abide by state licensure laws and practice laws

3. Patients must have choice of provider

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# AMA Telemedicine policy

4. Patients must have access to qualifications of providers in advance of visit.

5. Standards and scope of telemedicine services are consistent with in-person services.

6. Follow evidence-based guidelines

7. Patients must know costs and any limitations, e.g, in meds available

8. Medical history must be collected.

9. Services must be properly documented.

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# AMA Telemedicine policy

10. Care coordination with patient's existing treating physicians

11. Protocols for referrals for emergencies.

12. Abide by laws for privacy and security of patient medical information

13. Physicians are responsible for supervision of nonphysician providers, including:

      - protocols, conferencing & record review

      - visit sites & know competence of providers

      - conform to state practice acts

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# Telehealth resource centers

US has 14 Telehealth Resource Centers, funded by US Health Resources and Services Administration (HRSA) Office of Advancement of Telehealth

- provide information and research re telehealth, with focus on increasing access for underserved

Mid-Atlantic Telehealth Resource Center

- 855-628-7248, 434-906-4960

- state-specific resources for VA, WV, KY, MD, DE, NC, PA, DC and NJ

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- Questions ?

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