

# Telehealth



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(9-28-18)

# Telehealth / Telemedicine

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- “Telemedicine” = provision of clinical services to patients by physicians and practitioners from a distance via electronic communications
  - Simultaneous, synchronous, or “real time” (*e.g.*, tele-ICU)
  - Remote monitoring
  - Non-simultaneous, asynchronous, “store-and-forward” (*e.g.*, teleradiology)

# Telehealth - Generally

Originating or Spoke  
Site:  
Where the patient is  
located



Distant or Hub  
Site:  
Where the remote  
practitioner is located



Telehealth

# Telehealth: Issues for Discussion

- Licensure
- Limits on Remote Prescribing
- Liability Issues
  - Negligent credentialing
  - Malpractice liability
  - Informed consent
  - Establishing patient relationship
  - Patient abandonment
- Privacy and Security
- Reimbursement

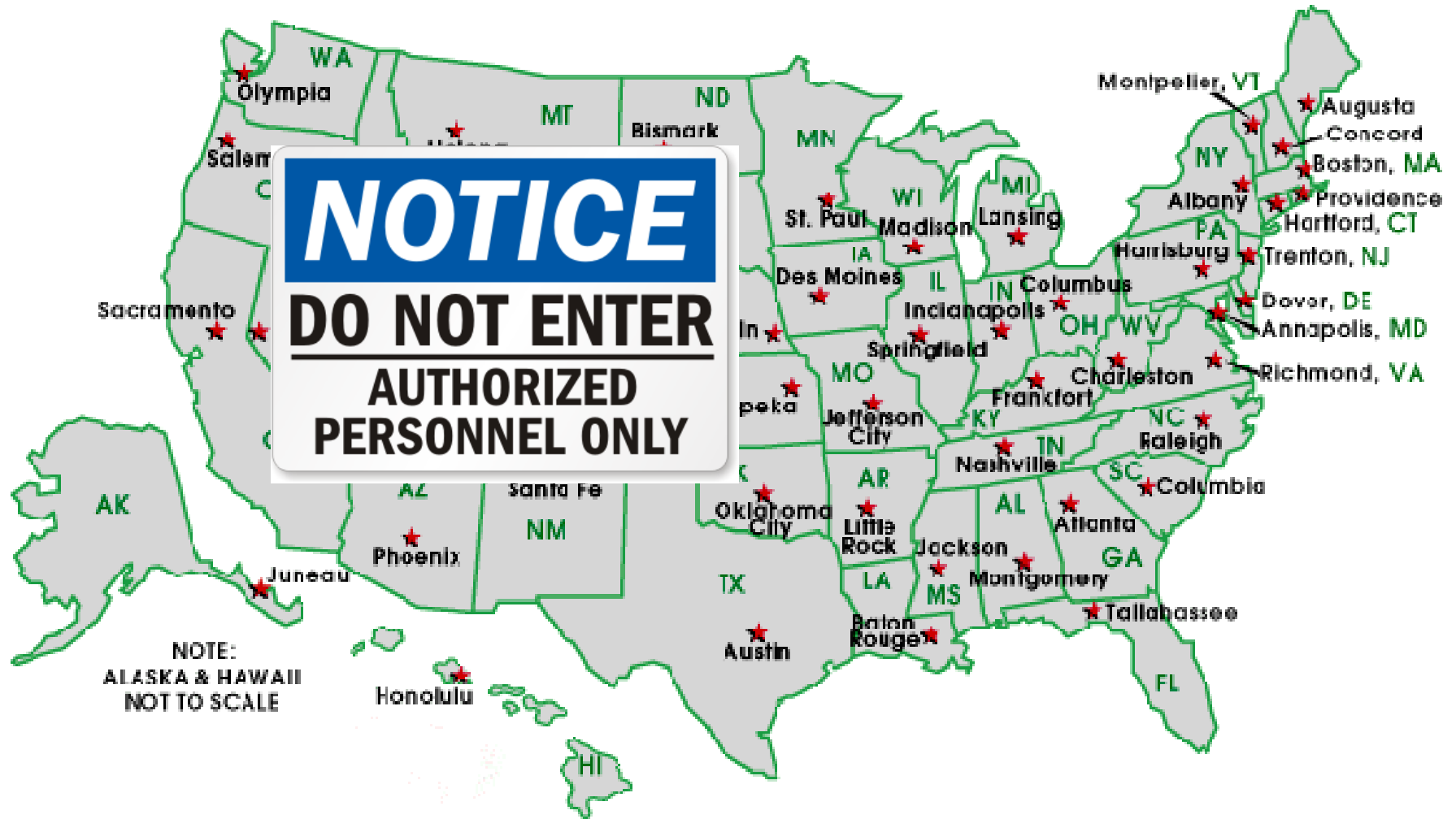


# Preliminaries

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- This is a brief overview of some relevant issues
  - The law has not caught up with technology and practices
    - Statutes and regulations may not address telehealth
    - Relatively few cases
  - The law is changing.
    - New statutes and regulations
  - State laws and regulations differ
    - Telehealth often involves laws from other states because it crosses state boundaries
- **Check applicable laws and regulations when you apply what we discuss**

# Licensure



# Licensure: Who Cares?

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- **Telehealth provider**
  - Subject to criminal, civil or administrative sanctions if not properly licensed, *i.e.*, practicing without license
  - No liability insurance
  - No reimbursement for services provided
- **Originating site**
  - No liability insurance for remote practitioner
  - No reimbursement for services provided
  - Facility licensing problems
  - Conditions of Participation problems for hospitals
  - Maybe subject to negligent credentialing liability if bad outcome

# Licensure

- The practice of medicine in Wyoming includes telemedicine:
  - “‘Telemedicine’ means the practice of medicine by electronic communication or other means from a physician in a location to a patient in another location, with or without an intervening health care provider.” Wyo. Stat. § 33-26-102(xxix).
- The unauthorized practice of medicine is a misdemeanor crime:
  - A guilty person “shall be punished by a fine of not more than one thousand dollars (\$1,000.00) or by imprisonment in the county jail for not more than one (1) year, or both.” Wyo. Stat. § 33-26-410(a).
- Wyoming does recognize a physician-to-physician consultation exception from licensure requirements based on the frequency of consultation:
  - No more than 12 days every 52 weeks. Wyo. Stat. § 33-26-103(a)(iv); Wyo. Bd. Med. R. ch. 1, § 7(a).



# Licensure

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- “Practice of medicine” is usually interpreted as occurring where the patient is located
  - Telehealth provider may be subject to law of state where patient is located
- State in which patient is located will usually apply its own medical practices law
  - State wants to protect its own citizens
- Practitioner must generally be authorized to practice in state where patient is located by either:
  - License
  - Exception to license

# Licensure

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States vary re telehealth license

- Most require full medical license for telehealth.
  - No special rules for telehealth providers.
- Some allow special purpose license for telehealth.
  - Relatively new development.
- Some contain exceptions to licensure requirement, e.g.,
  - Education
  - Emergency and “good Samaritan” laws
  - Consultation if local physician involved and remote practitioner does not have office in the state. (*See, e.g.*, IC 54-1804).

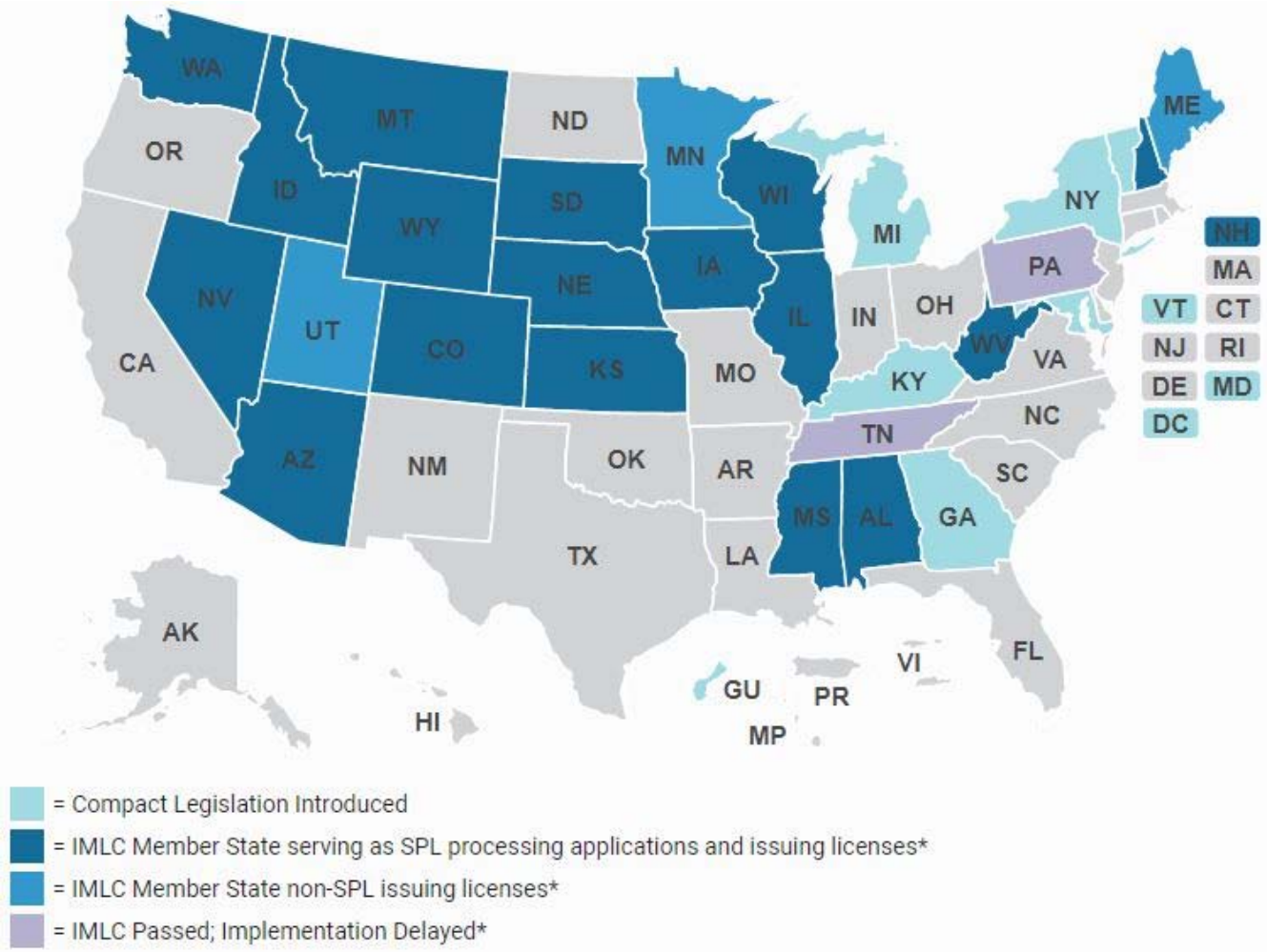
(See [www.fsmb.org/pdf/grpol\\_telehealth\\_licensure.pdf](http://www.fsmb.org/pdf/grpol_telehealth_licensure.pdf))

# Licensure

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- Practitioners in military, VA, Public Health Service
  - May practice within their organization across states.
- Nurse Licensure Compact
  - Allows multistate licensure for nurses.
- Interstate Medical Licensure Compact
  - Developed by Federation of State Medical Boards (“FSMB”).
  - Allows expedited licensure for physicians licensed in another state that is a member of the compact.
  - Several states (including Idaho, Montana, Nevada, Utah, Wyoming, South Dakota, Iowa, West Virginia, and Iowa) have passed laws to participate. (*See IC 54-1842 et seq.*)

<http://www.imlcc.org/>



# Licensure

Hospital conditions of participation (“COPs”).

- “In all cases, healthcare professional must be legally authorized to practice in the state where the hospital is located.”
- “When Telehealth is used and the practitioner and patient are located in different states, the practitioner providing the patient care service must be licensed and/or meet the other applicable standards that are required by the state or local laws in both the state where the practitioner is located and the state where the patient is located.”

(Interpretive Guidelines for 42 CFR 482.11, .12 and .22)

# Licensure

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- Most state Medicaid laws require that practitioner is licensed within the state as condition for reimbursement.
- “Medicaid guidelines require all providers to practice within the scope of their State Practice Act. Some states have enacted legislation that requires providers using telemedicine technology across state lines to have a valid state license in the state where the patient is located. Any such requirements or restrictions placed by the state are binding under current Medicaid rules”  
(<https://www.medicaid.gov/medicaid/benefits/telemed/index.html>)

# Licensure

In short...

- **Distant site practitioner and originating site should ensure that distant site practitioner is licensed in or otherwise authorized to provide the telehealth services in the originating site's state.**



# Restrictions on Remote Prescribing or Treating without In-Person Exam



*No appointments, no prior prescription required, no waiting rooms, no hassle.*

## Online-Pharmacy

- Prescription Medications
- Free Online Medical Consultations
- 24/7 Customer Care Center
- Simple Online Ordering System
- Guaranteed Lowest Prices

**ACCESS DENIED**



# Restrictions on Remote Prescribing/Treatment

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- Early internet pharmacies were prescribing based solely on online questionnaires or similar methods.
- In response, many states or medical boards required an in-person physical exam before allowing the practitioner to prescribe or render treatment.
  - **Medical practices act**
  - **Statement of medical boards**
- Telehealth providers were not amused...

# THE TEXAS TRIBUNE

## Teladoc Files Antitrust Suit Against Medical Board

by [Edgar Walters](#) | April 30, 2015 | [4 Comments](#)

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Photo by Delcia Lopez

In just over a month, a new state rule is set to kick in that could undercut the business model of Dallas-based Teladoc, a rapidly growing telemedicine company that connects patients and doctors over the telephone and internet.

With the clock ticking, the company is brandishing every weapon in its arsenal, deploying teams of lobbyists and lawyers to fight a [Texas Medical Board](#) rule change that it says is more about stifling competition than protecting patient health.

The board's rule, set to start June 3, would prevent doctors from treating people over the phone — making a diagnosis or prescribing medicine — unless another medical professional was physically present to examine the patient.

Teladoc's services, used by major insurance companies and state Medicaid patients, among others, offers consultations and prescriptions without an in-person exam.

After years fighting the new rule in court, Teladoc has assembled a top-flight team of more

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# State Telemedicine Statutes or Medical Board Policies

- Many states have enacted or amended statutes or policies to allow telemedicine, e.g.,
    - Allow provider to establish relationship or conduct initial exam through two-way audio and visual interaction.
    - Must be licensed in state where patient located.
    - Must comply with community standard of care.
    - Must obtain informed consent.
    - Must be available for follow-up care.
    - Exceptions for emergencies, covering for other provider, etc.
    - Others?
  - Wyoming guidance for proposed regulations:
    - “Prescribing medications, in-person or via telehealth, is at the professional discretion of the provider.”
    - But: “Treatment, including issuing a prescription, based solely on an online questionnaire does not meet the standard of care.”
- **Check applicable state laws.**

# FSMB Model Policy for Appropriate Use of Telemedicine (4/14)

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- Physician must be licensed in state where patient located.
- Physician-patient relationship may be established using telemedicine technologies.
- Documented medical evaluation and collection of relevant history and other information.
- Same standard of care as in-person treatment.
- Informed consent addressing telemedicine issues.
- Provide for continuity of care.
- Plan for referral for emergency services.
- Maintain appropriate medical records.
- Maintain privacy and security of communications.

([https://www.fsmb.org/globalassets/advocacy/policies/fsmb\\_telemedicine\\_policy.pdf](https://www.fsmb.org/globalassets/advocacy/policies/fsmb_telemedicine_policy.pdf))

# AMA Guidance for Ethical Practice in Telemedicine (6/16)

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Physicians engaging telemedicine should:

- Be proficient in relevant with technologies.
- Recognize and address limitations of relevant technologies.
- Ensure they have info for clinical recommendations when they cannot conduct physical exam, e.g., have another professional on-site conduct the exam.
- Obtain proper informed consent about telemedicine.
- Take steps to provide continuity of care.

(AMA Code of Medical Ethics Opinion 1.2.12)

# Liability Issues

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# Negligent Credentialing

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- In some states, hospitals or other providers may be liable for negligently credentialing those granted privileges:
  - Failed to properly credential a practitioner consistent with applicable standards
  - Patient suffered harm as a result of the negligent credentialing
- It is not clear whether COPs or credentialing by proxy would satisfy tort standards for proper credentialing
  - Negligence per se: failed to satisfy state standards or regulations
  - Community standard of care: failed to credential as similarly situated providers would

# Different Laws

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- If crossing state boundaries, assume that you will be subject to laws of other state:
  - Licensure requirements
  - Professional standards and standard of care
  - Informed consent
  - Statute of limitations
  - Caps on damages
  - Pre-litigation screening
  - Immunities and defenses
  - Reimbursement rules
  - Confidentiality requirements



# Different Procedures

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- If crossing state boundaries, may be sued in other state's court or federal court under different procedures and standards:
  - Pre-litigation screening panel
  - Notice of tort claims
  - Pleading punitive damages
  - Physician-patient privilege
  - Peer review privilege
  - Evidentiary rules re experts or others

# Practitioner-Patient Relationship

- Practitioner-patient relationship may exist even though there is no direct contact
- Test: Would a reasonable patient believe that practitioner-patient relationship exists?
  - Direct contact or communication with patient
  - Contract or agreement to provide care
  - Bills for services
- Some states may have an exception for “consultations” if certain standards are satisfied, *e.g.*,
  - No direct contact with patient
  - No bill for services
- Some states have laws governing establishment of telemedicine relationship

# Malpractice Liability

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- **Applicable standard of care**
  - Different community standards may apply
  - Presumably, a remote practitioner must comply with the same standard of care as a practitioner at the originating site
- **Beware:**
  - Is use of telehealth appropriate for patient's care?
  - Sufficiency of telehealth equipment or technology
  - Training and qualifications of users
  - Effect of other laws
  - Vicarious liability for others, including remote practitioner and originating site personnel

# Informed Consent

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- Informed consent from patient or representative is critical
  - Know the relevant laws for effective, informed consent
  - Informed consent should include:
    - Discussion of risks, benefits, and limitations of telehealth services, including availability of services and provider, technical limitations, etc.
    - Identify persons involved in providing care
    - Whether you will record telehealth sessions
    - Privacy or security of data communications system, especially if use open network
  - Disclaim responsibility for entities that are not your agents

# Patient Abandonment

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- May be liable for abandoning patient if fail to give patient sufficient time to transfer care.
  - Tort liability for patient abandonment
  - Medical Practices Act violation
- To avoid potential abandonment claim:
  - Ensure patient understands scope and limits of practitioner's involvement in care.
    - Informed consent
    - Written agreement or notice
  - Give patient adequate notice and time to transfer care before terminating relationship

# Liability Insurance Coverage

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- Liability insurance may require proper license for coverage
  - Liability insurance policies may exclude:
    - Injuries from unauthorized practice of medicine
    - Legal actions due to unauthorized practice of medicine
      - Administrative or licensure actions
      - Criminal actions
    - Practice medicine in another state
    - Regulatory violations resulting from telehealth, e.g., HIPAA violation, FDA violation
- **Check your malpractice insurance coverage**

# Privacy and Security



# HIPAA

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## Health Insurance Portability and Accountability Act of 1996

- Privacy Rules, 42 CFR 164.500
  - Must protect confidentiality of patient info
  - Gives patients certain rights concerning their protected health info (“PHI”)
- Security Rules, 42 CFR 164.300
  - Must implement specified administrative, technical and physical safeguards to protect e-PHI
  - Designed to protect
    - Confidentiality
    - Integrity
    - Availability



# HIPAA Privacy

- “Does the HIPAA Privacy Rule permit health care practitioners to use e-mail to discuss health issues and treatment with their patients?”
- “Answer: Yes. The Privacy Rule allows covered health care practitioners to communicate electronically, such as through e-mail, with their patients, provided they apply reasonable safeguards when doing so. See 45 C.F.R. § 164.530(c). For example, certain precautions may need to be taken when using e-mail to avoid unintentional disclosures, such as checking the e-mail address for accuracy before sending, or sending an e-mail alert to the patient for address confirmation prior to sending the message. Further, while the Privacy Rule does not prohibit the use of unencrypted e-mail for treatment-related communications between health care practitioners and patients, other safeguards should be applied to reasonably protect privacy, such as limiting the amount or type of info disclosed through the unencrypted e-mail. In addition, covered entities will want to ensure that any transmission of [e-PHI] is in compliance with the HIPAA Security Rule requirements at 45 C.F.R. Part 164, Subpart C.”

(OCR HIPAA Privacy FAQ dated 12/15/08)

# HIPAA Security

- Must implement specified physical, technical, and administrative safeguards for e-PHI, including:
  - *Transmission security*. Implement technical security measures to guard against unauthorized access to [e-PHI] that is being transmitted over an electronic communications network
  - *Integrity controls* (Addressable). Implement security measures to ensure that electronically transmitted [e-PHI] is not improperly modified
  - *Encryption* (Addressable). Implement a mechanism to encrypt [e-PHI] info whenever deemed appropriate

(45 CFR 164.312)

# HIPAA Security

- “Does the Security Rule allow for sending electronic PHI (e-PHI) in an email or over the Internet? If so, what protections must be applied?”
- “Answer: The Security Rule does not expressly prohibit the use of email for sending e-PHI. However, the standards for access control (45 CFR § 164.312(a)), integrity (45 CFR § 164.312(c)(1)), and transmission security (45 CFR § 164.312(e)(1)) require covered entities to implement policies and procedures to restrict access to, protect the integrity of, and guard against unauthorized access to e-PHI. The standard for transmission security (§ 164.312(e)) also includes addressable specifications for integrity controls and encryption. This means that the covered entity must assess its use of open networks, identify the available and appropriate means to protect e-PHI as it is transmitted, select a solution, and document the decision. The Security Rule allows for e-PHI to be sent over an electronic open network as long as it is adequately protected.”

(OCR FAQ [undated])

# HIPAA Security

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From HIPAA omnibus rule commentary:

- “We clarify that covered entities are permitted to send individuals unencrypted emails if they have advised the individual of the risk, and the individual still prefers the unencrypted email.... We do not expect covered entities to educate individuals about encryption technology and the information security. Rather, we merely expect the covered entity to notify the individual that there may be some level of risk that the information in the email could be read by a third party. If individuals are notified of the risks and still prefer unencrypted email, the individual has the right to receive [PHI] in that way, and covered entities are not responsible for unauthorized access of [PHI] while in transmission to the individual based on the individual's request.”

(78 FR 5634 (1/25/13))

# HIPAA Business Associates

- Other treatment providers are not business associates while providing treatment. (45 CFR 160.103)
- May need business associate agreement with vendors or other outsiders who assist with telehealth, including:
  - Entity that transmits PHI and has regular access to PHI, not “conduit”
  - Entity that stores PHI
- Exceptions:
  - Members of workforce
    - You have control over person while onsite
  - Members of organized health care arrangement (“OHCA”)
    - Integrated delivery of patient care

# Additional Regulations

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- FDA regulates medical devices, which may include telehealth equipment and software if used in the diagnosis or treatment of a disease or condition.
- Ryan Haight Online Pharmacy Consumer Protection Act places limits on internet pharmacies.
- Others?

# Reimbursement



# Reimbursement

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- Reimbursement for telehealth is expanding ...
  - Medicare expanded coverage for FY2018, but still limited
  - Medicare Advantage will provide some coverage beginning 2020
  - ACO coverage expanding in 2020
  - Medicaid programs generally provide some coverage, but depends on states
  - Private payers
    - Some payers expanding services to reduce other costs
    - Most states have some form of telehealth parity laws



# Reimbursement: Medicare

- Part A: CMS pays for telehealth if satisfy conditions of payment.
- Part B: CMS pays for “telehealth” if—
  - Use interactive audio and video telecommunications permitting real-time communication practitioner at distant site and beneficiary at originating site
    - NOT asynchronous, store-and-forward technology except under demonstration project in Hawaii and Alaska
  - Patient must be present and participating in telehealth
  - Another physician or “telepresenter” is not required at originating site unless it is medically necessary as determined by distant physician

(45 USC 1395m(m); 42 CFR 410.78 and 414.65; Medicare Claims Processing Manual, Ch. 12, Sect. 190)

# Reimbursement: Medicare

- **Originating site must be:**
    - **In rural HPSA or county outside a MSA county, and**
    - **Proper type of facility**
      - **Physician or practitioner office**
      - **Hospital**
      - **Critical Access Hospital (“CAH”)**
      - **Rural Health Clinic (“RHC”)**
      - **Federally Qualified Health Center (“FQHC”)**
      - **Skilled Nursing Facility (“SNF”)**
      - **Hospital- or CAH-based Renal Dialysis Center**
      - **Community Mental Health Center**
      - **Participating in demonstration project**
- (42 USC 1395m(m); 42 CFR 410.78)

# Reimbursement: Medicare

- Distant site practitioner must be—
  - Licensed under state law to provide the telehealth service (i.e., within scope of practice), and
  - One of following:
    - Physician
    - Nurse practitioner (“NP”)
    - Physician assistant (“PA”)
    - Nurse midwife
    - Clinical nurse specialist (“CNS”)
    - Certified registered nurse anesthetist (“CRNA”)
    - Clinical psychologist and clinical social worker, but may not bill for certain codes
    - Registered dietician or nutrition professional

# Reimbursement: Medicare

- Covered services include:
  - Consultations, emergency department or initial inpatient
  - Follow-up inpatient telehealth consultations furnished in hospital or SNFs
  - Office or other outpatient visits
  - Subsequent hospital care services limited to 1 telehealth visit every 3 days
  - Individual and group kidney disease education and diabetes self-management training
  - Individual and group health and behavior assessment and intervention
  - Individual psychotherapy
  - Telehealth pharmacologic management
  - Psychiatric diagnostic interview exams
  - ESRD services
  - Individual and group medical nutrition therapy
  - Neurobehavioral status exams
  - Smoking cessation services
  - Certain types of alcohol and substance abuse treatment

<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/telehealthsvcsfctsht.pdf>

# Reimbursement: Medicare

- Covered services (cont.):
  - Annual depression screening
  - Face-to-face behavioral therapy for cardiovascular disease
  - Face-to-face behavioral therapy counseling for obesity
  - Certain transitional care management services
  - Certain advance care planning
  - Psychoanalysis
  - Family psychotherapy
  - Prolonged service in office or other outpatient setting requiring direct patient contact beyond usual service
  - Prolonged service in inpatient or observation setting beyond usual service
  - Annual wellness visits
  - Critical care services
  - Others

<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/telehealthsrvcfsctst.pdf>

➤ **Check specific requirements**

# Reimbursement: Medicare

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- Facility fee to originating site:
  - No facility fee to distant site.
- Payment to provider at distant site:
  - Must use appropriate code + telehealth modifier.
  - No payment to practitioner or “telepresenter” at originating site.
  - Physician/practitioner at distant site may not share payments with referring physician or telepresenter.

(42 USC 1395m(m); 42 CFR 414.65)

# Reimbursement: Medicaid

- States have flexibility in covering telehealth so long as it furthers “efficiency, economy and quality of care”
- Most states provide coverage for some telehealth services
  - Usually cover live-video conferencing, not “store and forward” technology
  - Often cover professional fee + facility fee; a few pay for transmission fee
  - May limit based on type of provider, facility, service or geographic location
- **Check relevant state laws and Medicaid regulations and policies**

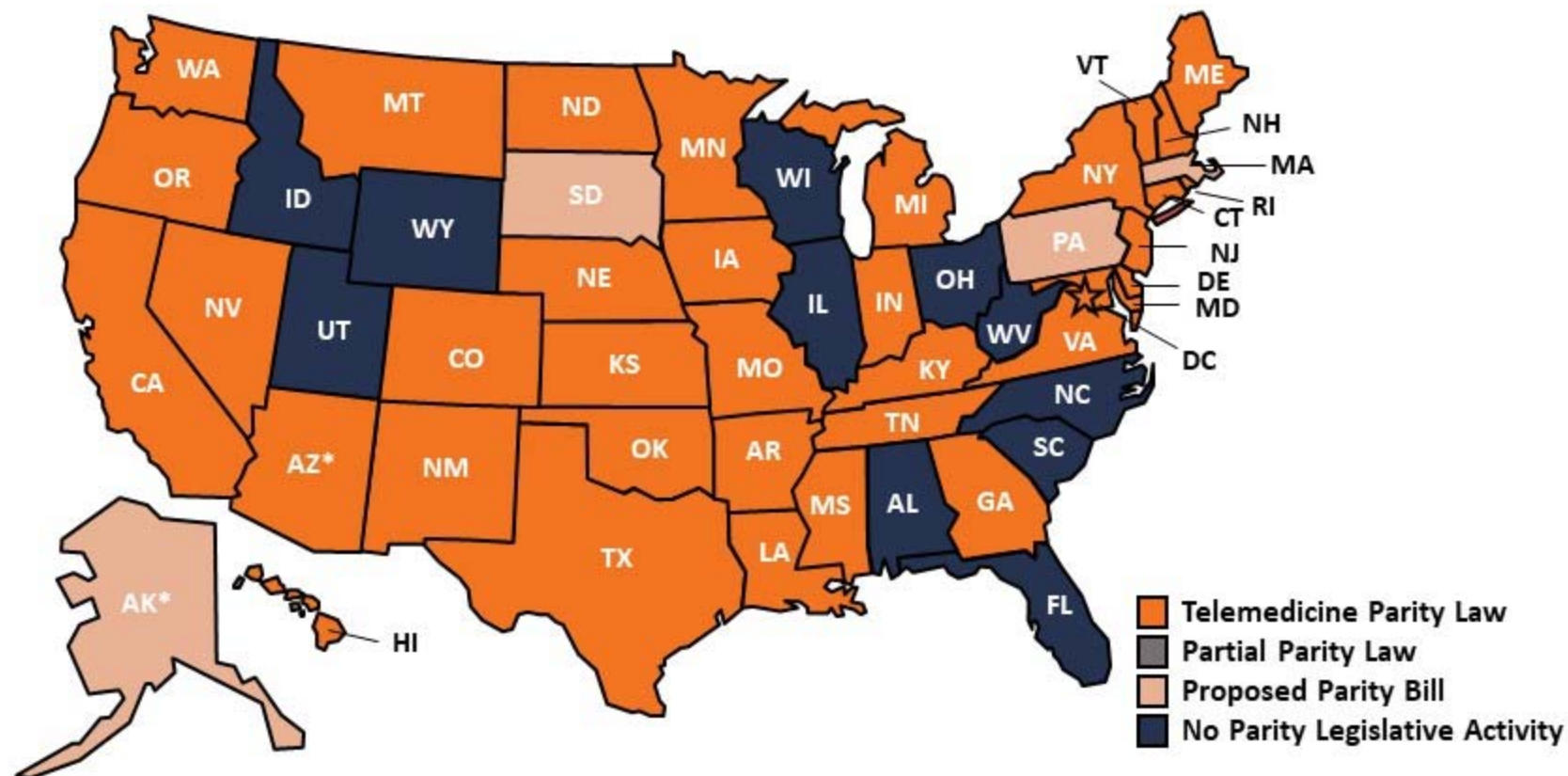
# Reimbursement: Private Payers

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- Most states have some kind of parity law
  - Often require private insurers to cover telehealth service to the same extent as face-to-face consultations so long as it meets same standard of care
  - May place limits on parity
  - May not require same level of reimbursement as in-person care



# States with Parity Laws for Private Insurance Coverage of Telemedicine (2018)



States with the year of enactment: Alaska (2016)\*, Arizona (2013)\*, Arkansas (2015), California (1996), Colorado (2001), Connecticut (2015), Delaware (2015), Georgia (2006), Hawaii (1999), Indiana (2015), Iowa (2018), Kentucky (2000), Louisiana (1995), Maine (2009), Maryland (2012), Michigan (2012), Minnesota (2015), Mississippi (2013), Missouri (2013), Montana (2013), **Nebraska (2017)**, Nevada (2015), New Hampshire (2009), **New Jersey (2017)**, New Mexico (2013), New York (2014), **North Dakota (2017)**, Oklahoma (1997), Oregon (2009), Rhode Island (2016), Tennessee (2014), Texas (1997), Vermont (2012), Virginia (2010), Washington (2015) and the District of Columbia (2013)

States with proposed legislation: In 2018, Alaska, Massachusetts, Pennsylvania, and South Dakota

\*Coverage applies to certain health services.

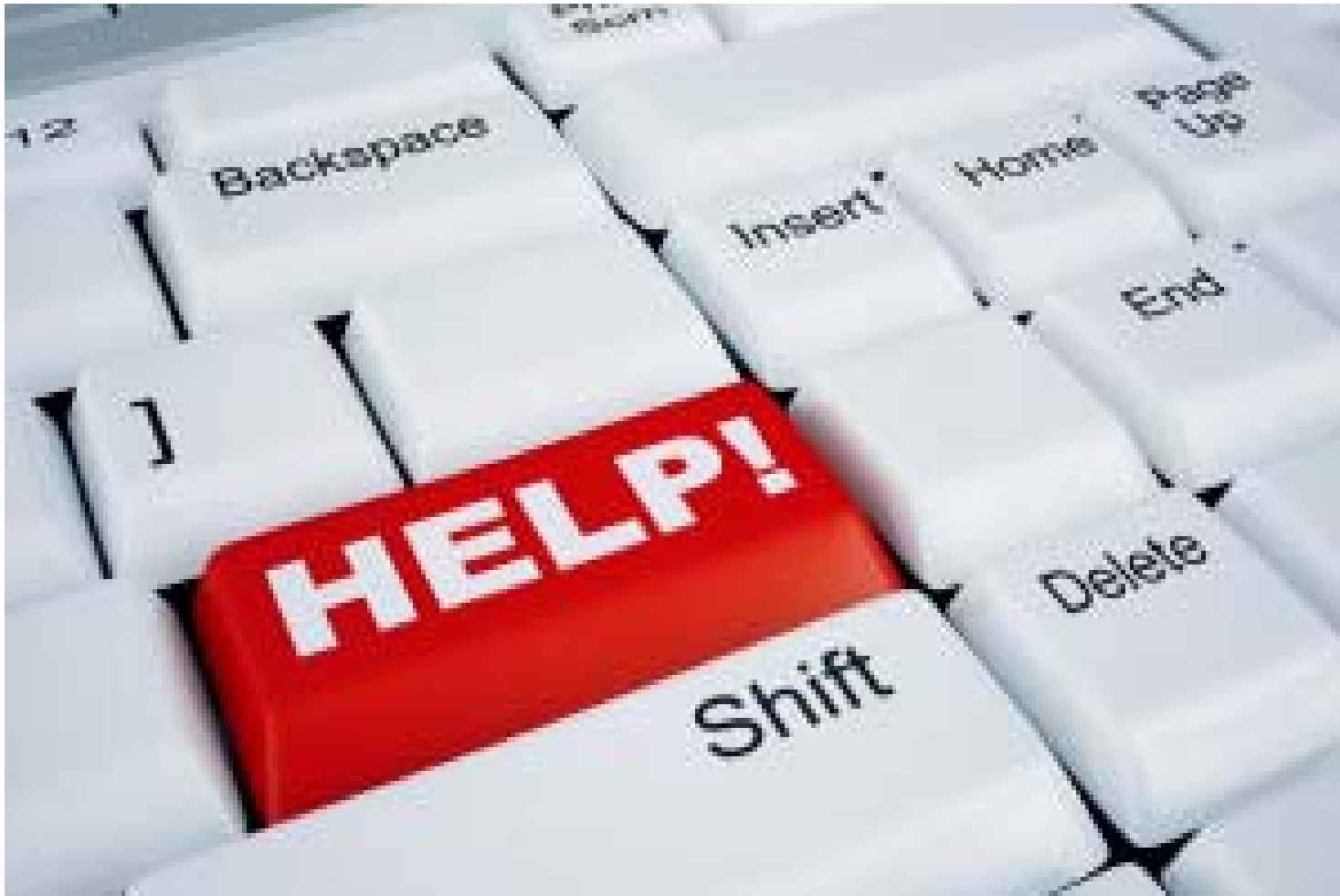


# Reimbursement

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- Private payers
  - Check your state laws for parity requirements
  - Check payer contracts
  - Ensure you use correct “site of service” or other modifiers

# Additional Resources



# Additional Resources

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- Federation of State Medical Boards
  - Summaries of state laws governing telehealth.
  - Legislative update.
- Center for Telehealth & e-Health Law (“CTel”)
  - Publications and guides.
  - News and information.
- American Telehealth Ass’n,
  - Practice standards and guides.
  - News and information.
- Center for Connected Health Policy
  - 50-state survey of telehealth laws and policies

# Questions?

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