



COVID-19 Webinars

The Efficacy & Expansion of Telemedicine in Confronting the COVID-19 Pandemic

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WELCOME

The presentation will begin at 1:05 p.m.

Submit questions to the platform during the presentation. Time permitting, questions will be answered at the end of the presentation or in a follow up email.

CLE and CE credits are pending. Email angela.russell@wilsonelsers.com if you wish to be contacted regarding CLE or CE credits for this webinar.



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The Efficacy and Expansion of Telemedicine in Confronting the COVID 19 Pandemic

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Scope of Telemedicine



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TELEMEDICINE: DEFINED – ATA

“The use of medical information exchanged from one site to another via electronic communications for the health and education of the patient or health care provider and for the purposes of improving patient care, treatment and services.”

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TYPES OF TELEMEDICINE

- Physician to physician--often PCP to specialist
- Image transmission--tele-radiology, pathology, cardiology
- Physician (or other health care provider) to patient--prescheduled postop or other follow-up visits
- Patient to physician----simple acute care visits, simple follow-up visits

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TELEMEDICINE TECHNOLOGIES

1. Broadband ---usually occurs between two health care facilities
 - kiosks, telemedicine carts, specialized equipment, uses presenters
 - real time video



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TELEMEDICINE TECHNOLOGIES

2. Cloud based --- any where, any time, any device
 - a. patient initiated
 - b. smart phone, smart watch, Wii
 - c. real time v ideo, buffered video(chat), store and f orward, monitoring



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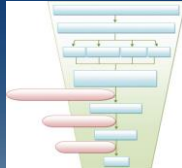
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TELEMEDICINE TECHNOLOGIES

3. Tailored, telemedicine software platforms -

Complete virtual care
which goes beyond
traditional telemedicine
software



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Most common applications of telemedicine to date?

1. TELERADIOLOGY
2. TELEPATHOLOGY
3. TELEDERMATOLOGY
4. TELEOPHTHALMOLOGY
5. TELECARDIOLOGY
7. TELENEUROLOGY
8. TELEPSYCHIATRY

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Telemedicine applications that are becoming more common

Tele-ICU

- “The use of off-site command center where a team of critical care practitioners collaboratively in care of critically ill patients in remote bedside ICU’s through linked and interfaced health information, electronic medical records, data streams and audiovisual connections” (Udeh, Methodist Debaque Cardiovasc J., 2018)



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Tele-ICU Reduces Risk of Medical Errors



CONSTANT & CONTINUOUS EXCHANGE OF PATIENT INFORMATION BETWEEN LOCAL AND TELE-ICU MEDICAL PROFESSIONALS



ENABLES RAPID TREATMENT DECISIONS



SECOND OPINIONS



SURVEILLANCE AND SUPPORT



TRANSFER OF KNOWLEDGE BETWEEN TELE-ICU AND BEDSIDE PHYSICIANS

(Udeh, Methodist Debaque Cardiovasc J., 2018)



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Where is Telemedicine Now ?

In 2016, the American Medical Association adopted new guidelines for ethical practice in telemedicine (Becker, Perm J., 2019)

- Patients to be informed about limitations to telemedicine care
- Use the same professional standards as when treating in-person
- Abide by applicable state/federal law concerning telemedicine
- Uphold standards of obtaining proper informed consent with detailed explanation of telemedicine
- Tailor security needs (HIPAA) to protect patient confidentiality through the use of telemedicine
- Monitor changing telemedicine tools/technology



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New Telemedicine Technologies

- Pandemic drone to detect people with respiratory illnesses – helps to monitor crowds



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New Telemedicine Technologies

- Telemedicine Stations



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New Telemedicine Technologies

- In flight telemedicine systems being unveiled



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Telemedicine – Potentially Liable Duties and Entities

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Potential Liability – Individual Practitioners

MALPRACTICE LIABILITY

Examples:

- Incorrect interpretations of images from home or remote locations – miscommunication of need for “stat” reading (radiology)
- Failure to communicate presenting symptoms to a remote examining practitioner and resulting failure to diagnose (neuro-radiology)
- Incorrect interpretation of remote reading of EFM strips (obstetrics)
- Failed counseling communications (psychiatry)
- Suspected stroke incorrectly diagnosed by a tele-stroke consult (neurology)



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Potential Liability – Individual Practitioners

MALPRACTICE LIABILITY

Examples:

- Suspected stroke incorrectly diagnosed by a tele-stroke consult (neurology)
- Failure to adequately remotely monitor and assess an ICU patient and failure to request an intensivist to perform a more thorough bedside examination (critical care)
- *Niedzwiadek v. Anmuth (NJ)* - \$4.2 million settlement reached in 2019 in a case involving a woman who died of a catastrophic brain injury after elective neck surgery. The post-operative physician as supposed to be monitoring her signals remotely but internet connection was lost.

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Potential Liability – Individual Practitioners

MALPRACTICE LIABILITY

Examples: (across various specialties)

- Power failure resulting in delay/error
- Negligent prescribing based on a video exam
- Negligence in the failure to provide telemedicine support
- Exam should have been performed in-person rather than by video
- Image distortion causing misdiagnosis
- Incomplete telemedicine exam



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Potential Liability – Individual Practitioners

MALPRACTICE LIABILITY

- Jurisdiction can be problematic: across state lines or international
- Standard of care may vary by venue
- Reform laws may differ, e.g. damage caps

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Potential Liability – Individual Practitioners

MALPRACTICE LIABILITY

- Continuity of Care
- Documentation of telemedicine encounters must occur in the medical record
- Choice of the best clinical context for a telemedicine encounter is key: e.g. acute primary care, chronic disease, psy chiatry, but probably not trauma or surgical adv ice where bedside assessment is what is really required

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Potential Liability – Individual Practitioners/Hospitals

LICENSURE ISSUES – BOARD ACTIONS

CMS Rule

- On May 5, 2011 CMS published a rule (effective July 5, 2011) that allows a hospital to grant practice privileges to a telehealth provider by accepting the distant-site facility's credentialing and privileging approvals for that provider.



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Potential Liability – Individual Practitioners/Hospitals

CMS Rule – Requirements

- Applies to arrangements between two Medicare-participating hospitals AND between a Medicare-participating hospital and "distant-site telemedicine entities" such as teleradiology, teleICU, and teleneurology.
- There must be a written agreement that ensures that the medical staff's credentialing and privileging processes and standards at the distant-site "meets or exceeds the [CMS] standards."



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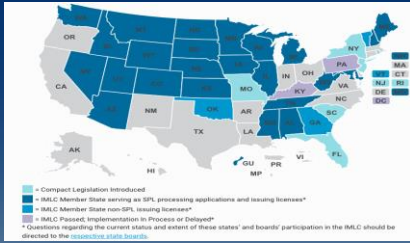
The Interstate Medical Licensure Compact

- The Compact provides a streamlined method for physicians wanting to practice in more than one state to obtain the appropriate licensing. (The IMLC. (n.d.). Retrieved from <https://imlcc.org/>).
- As of January 2019: 26 states & 1 territory included in the Compact (afda, T. (n.d.). Telemedicine Legal Issues You Should Know About. Retrieved from <https://blog.evisit.com/telemedicine-legal-issues-you-should-know-about>)
- 19 Compact member states are the state of principle license (Becker, Perm J., 2019)
- 5 states have passed Compact legislation, but it has yet to be implemented (Becker, Perm J., 2019)
- 29 states have medical and/or osteopathic boards that support the Compact (Becker, Perm J., 2019)



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The Interstate Medical Licensure Compact



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Potential Liability – Examples of Licensing penalties

Massachusetts

Regulations of the Massachusetts Board of Registration in Medicine provide that a Massachusetts physician may be disciplined for “[k]nowingly permitting, aiding or abetting an unlicensed person to perform activities requiring a license.”

Hospitals and HMOs whose providers send biopsies to large national laboratories for interpretation by pathologists may face charges for **aiding and abetting the unlicensed practice of medicine.**

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Potential Liability – Examples of Licensing penalties

New Jersey

- New Jersey enacted the NJ Telemedicine Law in July 2017. The law governs telemedicine practiced in NJ and how providers will be compensated. The standard of care is the same as the care provided in-person. NJ Providers who use telemedicine must be (1) validly licensed, certified or registered in NJ; (2) remain subject to regulation by the appropriate NJ licensing board; (3) maintain liability insurance in NJ. There is a Consultation exception to the NJ Telemedicine Law for those providers who consult with a licensee in NJ but does not provide direct patient care.
- Penalties: NJRS2C:21-20 Unlicensed practice of medicine, surgery, podiatric medicine, crime of third degree.
- 14. A person is guilty of a crime of the third degree if he knowingly does not possess a license or permit to practice medicine and surgery or podiatric medicine, or knowingly has had the license or permit suspended, revoked or otherwise limited by an order entered by the State Board of Medical Examiners, and he: a. engages in that practice; b. exceeds the scope of practice permitted by the board order; c. holds himself out to the public or any person as being eligible to engage in that practice;

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Potential Liability – Hospitals/Healthcare Networks

Negligent credentialing/privileging

- Hospitals have a corporate legal duty to credential all providers at originating site; also CMS and Joint Commission require, by laws should take into account
- Networks, ACOS, have a credentialing obligation
- Ostensible agency liability

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Potential Liability – Telehealth Provider

- Equipment malfunction/software failure
- Telehealth providers may have to defend against charges in other state's medical Board licensure proceedings for the unlicensed practice of law

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Potential Liability – Practitioners and Hospitals

- To date - no indication of rise in telemedicine malpractice cases even as field grows.
- Telemedicine does not present many unique challenges in the area of medical malpractice.
 - Many negligence cases involve actors from multiple states – this is not unique to telemedicine.
- Some commentators note that telemedicine may be safer because of multiple "eyes" on patient and more advanced systems in place.
- Still – practitioners and hospitals should draft specific telemedicine guidelines, informed consent forms and focus on privacy concerns that are be specific to telemedicine.

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Telemedicine: Duties of Care



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Healthcare: Standard of Care

"The prevailing standard of care governing the conduct of medical professionals has been a fixed part of our common law for more than a century (see generally *Pike v. Honsinger*, 155 N.Y. 201 (1898)). The Pike standard demands that a doctor exercise "that reasonable degree of learning and skill that is ordinarily possessed by physicians and surgeons in the locality where the doctor practices." (*id.* at 209)

A doctor is charged with the duty to exercise due care, as measured against the conduct of his or her own peers – the reasonably prudent doctor standard." See *Nestorowich v. Ricotta*, 97 N.Y.2d 393, 398 (N.Y. App. Div. 2002).



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Telemedicine: Standard of Care

- Telemedicine is no longer viewed as a secondary option for care—it is an enhanced standard of care that is both expected by patients and popular with providers. Care continues to improve as patients have greater access to nationwide physicians and as new technology
- **Key: Health standards in telemedicine are the same as traditional delivery systems.**



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White v. Harris, 36 A.3d 203 (V.T. Sup. Ct. 2011)

Holding: A duty applies to the service provided (90 min video consult), as a professional consultation may arise in many different circumstances, and is supported by the facts which bears on the scope of the professional relationship from which defendant's duty arose and it helps to frame the applicable standard of care. Through the 90 min consult, the doctor assumed a duty to act in a manner consistent w/ the applicable standard of care so as to not harm decedent through the consult services provided.

See White v. Harris, 36 A.3d 203 (V.T. Sup. Ct. 2011)

2011 VT 115
Terrence WHITE, Individually, and as Administrator of Estate of Krystine White, and Pauline Searles
v.
Mark S. HARRIS, M.D., Nancy Foote, Susan Farrell, Upper Valley Pediatrics, Northeast Kingdom Human Services, Inc., Rita M. Gelsomini Gruber, M.D., Fletcher Allen Health Care, Inc., and Gail Paolo Bentivoglio, M.D.
No. 10-216.
Supreme Court of Vermont.
Sept. 29, 2011.



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White v. Harris, 36 A.3d 203 (V.T. Sup. Ct. 2011)

In determining whether a duty exists, the question is whether the relationship of the parties was such that the defendant was under an obligation to use some care to avoid or prevent injury to the plaintiff.



RELATIONSHIP BETWEEN PARTIES



NATURE OF THE RISK (INCLUDING FORESEEABILITY)



PUBLIC POLICY IMPLICATIONS OF IMPOSING DUTY ON DEFENDANT



WHETHER THE DOCTOR WAS IN UNIQUE POSITION TO PREVENT HARM



BURDEN OF PREVENTING HARM



WHETHER THE PLAINTIFF RELIED ON DOCTOR'S DIAGNOSIS OR INTERPRETATION



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West, et al. v. Harris, et al.

(Thomas R. Kline, West vs. Teleradiology, et al, CCP Lehigh County No. 2007-C-2369 Pre Trial Memorandum)

- Images taken at a Pennsylvania hospital were read by teleradiologists in India
- Studies read by the teleradiologists in India were "finalized" the following business day by the hospital radiologists in PA
- Testimony by defendant radiologists, both in India and at the PA hospital, established that no one believed it was their responsibility to prepare a final report
- One of the defendant teleradiologists in India admitted liability and that they misread the images

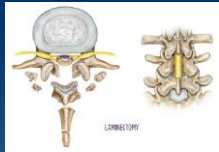


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West, et al. v. Harris, et al.

Who was responsible/liable to prepare a final report?

How can the standard of care be met when dealing with a nine and a half plus hour time difference between when the films were initially read and then when they were finalized?



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Laminectomy Decompression Surgery

File(s) of <http://www.summitortho.com/services/back-neck-spine/treatments/lumbar-surgery/laminectomy-decompression-surgery/>

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Medical Care Provided in PA, Radiology Read by Teleradiologist Located in and Working for OH company



INITIAL CT OF THE ABDOMEN AND PELVIS WITH CONTRAST REVEALED "NO ACUTE PROCESS"



REPEAT CT WITHOUT CONTRAST READ BY TELERADIOLOGIST REVEALED "DIFFUSE SMALL BOWEL DISTENSION, LIKELY REFLECTING GENERALIZED ILEUS"



STANDARD OF CARE WHEN THERE IS NO MEANINGFUL COMMUNICATION BETWEEN ALL RADIOLOGISTS INCLUDING TELERADIOLOGISTS



DOES TELEMEDICINE LEAD TO DELAYED DIAGNOSIS AND TREATMENT

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In re Division of Mental Health Service's, 2009 WL 1675502 (N.J. Super. Ct. App. Div. June 17, 2009)

Telepsychiatry was approved by the American Psychiatric Association in 1995. Under that approval, the Guidance Center of Warren County made the argument for implementation of the waiver alleging that video communication "very closely replicates physically being present" and outlined the video conferencing process:

1. Consultation with the Guidance Center screening clinician and telepsychiatrist
2. Screener faxes the required screening consumer documentation to the telepsychiatrist
3. Screener then calls the psychiatrist via the telepsychiatry system so the consumer is interviewed face to face
4. Telepsychiatrist consults again with the screener to determine disposition
5. Telepsychiatrist completes all medical commitment forms and progress notes and faxes them back to the screener

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Golob v. Arizona Med. Bd. of State, 176 P.3d 703 (Ariz. Ct. App. 2008)

Dr. Golob, a physician licensed in Arizona, worked for Secure Medi-cal, Inc., issued prescriptions over the internet without establishing a physician-patient relationship or ever physically examining the patient for whom the prescription was being made out to.

The Board of Pharmacy believed Dr. Golob was violating the state statute, A.R.S. 32-1401(27)(ss), defining unprofessional conduct, which includes:

- Prescribing, dispensing or furnishing a prescription medication... to a person unless the licensee first conducts a physical examination of that person or has previously established a doctor-patient relationship. *Id.* at 706.



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Golob v. Arizona Med. Bd. of State, 176 P.3d 703 (Ariz. Ct. App. 2008)

The Court held, Arizona statute A.R.S. 32-1401(27)(ss) did "not discriminate against physicians who prescribe over the internet; to the contrary, it holds them to the very same standard of care that is required of all physicians." *Id.* at 712

"A relationship is clearly established when the physician agrees to undertake diagnosis and treatment of the patient and the patient agrees, whether or not there has been a personal encounter between the physician... and the patient." *Id.* at 709. Further, "treatment, including issuing a prescription, based solely on an online questionnaire or consultation does not constitute an acceptable standard of care." *Id.*



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Golob v. Arizona Med. Bd. of State, 176 P.3d 703 (Ariz. Ct. App. 2008)

"Physicians who prescribe medications via the Internet shall establish, or have established, a valid patient-physician relationship, including, but not limited to, the following components. The physician shall:

1. Obtain a reliable medical history and perform a physical examination of the patient, adequate to establish the diagnosis for which the drug is being prescribed and to identify underlying conditions and/or contraindications to the treatment recommended/provided;
2. Have sufficient dialogue with the patient regarding treatment options and the risks and benefits of treatment(s);
3. As appropriate, follow up with the patient to assess the therapeutic outcome;
4. Maintain a contemporaneous medical record that is readily available to the patient and subject to the patient's consent, to his or her other health care professionals; and
5. Include the electronic prescription information as part of the patient medical record. *Id.*



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Duties of Care specific to COVID-19

- Adequate training
- Appropriate use of telemedicine platforms
- Duty to conduct comprehensive exams
- Duty to plan/ staffing/ equipment / prevent transmission

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Crisis Standard of Care???

- Substantial change in usual healthcare operations and the level of care it is possible to deliver, which is made necessary by a pervasive (e.g. pandemic influenza) or catastrophic disaster. This change in the level of care is justified by specific circumstances
- The formal declaration enables specific legal/regulatory powers and protections for healthcare providers in the necessary tasks of allocating and using scarce medical resources.

Institute of Medicine Committee for Guidance for Establishing Standards of care for use in disaster situations, per HHS - 2010

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PREP Act

- The Public Readiness and Emergency Preparedness Act (PREP Act) provides immunity from tort liability claims (except willful misconduct) to individuals or organizations involved in the manufacture, distribution, or dispensing of medical countermeasures. Activation of the Act requires a declaration by the Secretary of HHS after a determination that a disease constitutes a public health emergency.

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PREP Act

- Secretary Alex Azar issued his Declaration on March 17, 2020, but the Declaration was backdated to be effective as of February 4, 2020.
- The term “Covered Persons” is defined in the PREP Act to include manufacturers, distributors, program planners, and qualified persons, licensed health care professionals or other individuals authorized to prescribe, administer or dispense Covered Countermeasures under the law of the state in which the Covered Countermeasure was prescribe



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Telemedicine: Duties to Patients and Cross State Practice

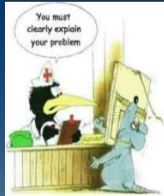


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Duties to Patients

INFORMED CONSENT ISSUES

- Should disclose the risks of a telemedicine consult (i.e. delays, equipment failures, security breaches)
- Should be discussed with patient before signing consent form
- Proof should be maintained in the medical record
- Practitioners are responsible for making their services accessible to clients in a manner that facilitates their ability to make an informed choice
- Should provide a clear description of what patient can expect in regards to treatment, testing, follow up, etc
- Should provide sufficient information to patient to address the limitations of computer technology



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Duties to Patients

INFORMED CONSENT ISSUES – ADVANCES IN TECHNOLOGY

- To address issues of remote access, travel and management of staff at remote sites, innovative solutions (such as Teleconsent) have been developed which embed the informed consent process into a telemedicine session. Teleconsent allows a provider to remotely video conference with a patient, display and interactively guide patients in real-time through a consent form.
- Electronic consent technologies (such as eConsent) help overcome challenges related to readability, comprehension and consent management.



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Duties to Patients – Cross State Practice

- Licensure of the physician providing services is essential
- Lack of state consistency here is a huge challenge but one must know the laws before proceeding
- Not all states' laws address telemedicine but many do
- Some states have special telemedicine licensing even for in-state functions; others require full medical licensure



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Duties to Patients – Cross State Practice

Most states' medical boards offer a "common consultation exception" (exempting from licensure) that may apply to telemedicine scenarios

Other types of licensing exemptions that may apply across all the states;

- Emergency exceptions (e.g. patient coding)
- Consultation exceptions (scope varies)
- Special/temporary telemedicine license
- License endorsement (reciprocity from other state medical boards)

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Duties to Patients – Cross State Practice

- The vast majority of states require out-of-state physicians who provide medical services to individuals in that state via telemedicine to obtain a full, unrestricted license (inc. MD)
- Most states have "consultation exception" for physician to physician communication
- Twenty-nine States, including the District of Columbia and Guam, have adopted the Federation of State Medical Boards (FSMB)'s Interstate Medical License Compact (IMLC). The Compact allows for an Interstate Commission to form an expedited licensure process for licensed physicians to apply for licenses in other states.

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Duties to Patients – Cross State Practice

- To treat COVID-19, administration announced plans to relax physician licensing 3/18 - no regulation yet from HHS

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Duties to Patients – Privacy, Security and Confidentiality

- All standard laws and regulations still apply with telemedicine i.e. HIPAA
- Confidentiality confirmed as part of informed consent process
- Hospital must verify the security of vendor's systems
- Patients should be informed of potential for security breaches, use of unencrypted platforms, e.g. Skype



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Duties to Patients – Privacy, Security and Confidentiality

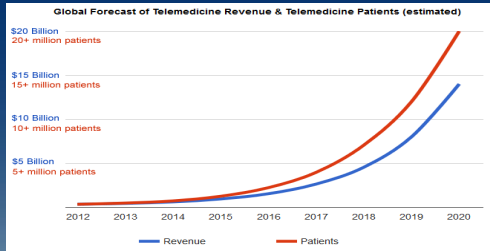
- Most States require that a telehealth provider comply with all laws concerning confidentiality of health care information and patient's rights to medical information.
- Some State Medicaid programs have begun incorporating specific documentation and confidentiality. Privacy and security guidelines within their manuals for telehealth specifically. Two States passing new telehealth private payer laws in 2019 took very different approaches with regard to payment parity: Georgia requiring payment parity and Florida allowing plans and providers to negotiate rates.

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TELEMEDICINE GROWTH



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Expanded Use Amid the Coronavirus Pandemic

- Screening and Triage
- Patient Monitoring and Management
- Expanded coverage for Telehealth services in Medicare
- Waiver of co-pays
- Volume Challenges
- Online resources



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