



Legal, Ethical, and Regulatory Considerations in Telehealth

Presented by:

Tara M. Iacono, PA-C & Hina Mazharuddin, MSPAS, PA-C

DISCLOSURES

No disclosures to report.



DISCLAIMER

The purpose of this presentation is not to offer legal advice or create ethical debate but only to raise awareness of the legal, ethical, and regulatory aspects surrounding the delivery of telehealth services.



OBJECTIVES

At the conclusion of this activity, participants will be able to:

- Explain the main legal and regulatory issues surrounding telehealth and practicing telemedicine
- Explain the telemedicine practice standards
- Describe the unique aspects of informed consent as it pertains to telemedicine
- Describe the ethical concerns surrounding telehealth and telemedicine
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- Explain the Ryan Haight Online Pharmacy Consumer Protection Act of 2008



COMMON LEGAL AND REGULATORY ISSUES SURROUNDING TELEHEALTH

- Provider patient relationship
- Licensure & jurisdiction
- Quality and standard of care
- Informed consent
- Confidentiality, privacy, & data security
- e-prescribing



PROVIDER-PATIENT RELATIONSHIP

All states in the U.S. now allow a provider to establish a physician-patient relationship via telemedicine.

American Medical Association:

- Via telemedicine including videoconferencing e-visits
- A consultation with another provider who already has a relationship with the patient
- By meeting the pre-existing evidence-based practice guidelines for establishing a patient-physician relationship ¹

1. Farouk A. Telemedicine Prompts New Ethical Ground Rules for Physicians. AMA News, Chicago, USA (2016)



PROVIDER-PATIENT RELATIONSHIP

The physician-patient relationship is a fundamental component of high-quality health care delivery that is based in trust and mutual respect.

The lack of an appropriate physician-patient relationship is one of the main concerns regulators face regarding the delivery of telehealth services.

A valid physician-patient relationship must be established prior to delivering services via telemedicine.¹

1. Farouk A. Telemedicine Prompts New Ethical Ground Rules for Physicians. AMA News, Chicago, USA (2016)



LICENSURE AND JURISDICTION

“For telehealth services, licensing rules and applicable state medical practice laws are based not on the location of the physician, but rather the location of the patient at the time of the consult.”²

This applies to all health care professionals as well.

2. Lactman NM. Legal and Regulatory Issues. In: Rheuban KS, Krupinski EA, eds. *Understanding Telehealth*. New York, NY: McGraw-Hill Education.



LICENSURE AND JURISDICTION

State Laws

State laws vary and updated very frequently.

The best resource for the most up to date information on state telemedicine laws is the Center for Connected Policy webpage on Legislation and Regulation Tracking.³

<https://www.cchpca.org/telehealth-policy/current-state-laws-and-reimbursement-policies#>

3. Center for Connected Policy. Legislation and Regulation Tracking. <https://www.cchpca.org/telehealth-policy/legislation-and-regulation-tracking#>. Accessed July 9, 2020.



LICENSURE AND JURISDICTION

Federation of State Medical Board's Interstate Licensing Compact for physicians to practice in multiple states.

Website for Interstate Medical Licensure Compact (physicians): <https://www.imlcc.org/>

Licensing compact available or currently in process for other professions as well.

Physical Therapists: <https://www.fsbpt.org/Free-Resources/Physical-Therapy-Licensure-Compact>

RN's/LPN's: <https://www.nursingworld.org/practice-policy/advocacy/state/interstate-nurse-compact2/>

Advanced Practice Nurses: <https://www.aprncompact.com/index.htm>



LICENSURE AND JURISDICTION

Federation of State Medical Board was awarded a grant in 2019 to support license portability for PA's.⁴

We are hoping that this will come to fruition soon.

4. Fsmb.org. 2020. *FSMB | Federal Grant Awarded To Expand Interstate Medical Licensure Compact; Support License Portability For Pas.* [online] Available at: <<https://www.fsmb.org/advocacy/news-releases/federal-grant-awarded-to-expand-interstate-medical-licensure-compact/>> [Accessed 7 November 2020].



QUALITY AND STANDARD OF CARE

Providers performing telehealth visits should follow the same guideline and standards for quality care as in-person visits.

Clinical practice standards may need to be modified to meet the unique needs of telehealth services.



QUALITY AND STANDARD OF CARE

Examples of practice standards unique to telemedicine include:

- Providing informed consent for telehealth services
- Providing specific disclosures on the provider's website
- Restrictions on the type of telehealth technology/modality that can be used
- Possible requirements for in-person examinations ⁵

5. HealthIT.gov. What is Telehealth? How is Telehealth Different from Telemedicine. Accessed August 16, 2020. <https://www.healthit.gov/fag/what-telehealth-how-telehealth-different-telemedicine#:~:text=The%20Health%20Resources%20Services%20Administration,public%20health%20and%20health%20administration.>



INFORMED CONSENT

The Federation of State Medical Boards and the American Medical Association recommend getting informed consent for services performed via telemedicine.

The written consent should be updated annually and stored in the patient's chart.

It is also recommended that a healthcare provider's visit note make mention of receiving informed consent from the patient prior to starting the visit.



INFORMED CONSENT

The topics covered in the informed consent should include:

- How a telemedicine encounter differs from traditional face-to-face consultation and care
- How data is to be acquired, transmitted, and stored
- What security is in place to ensure that it is not intercepted, who will see it at the other end, and who will have access to it
- How confidentiality will be maintained when others are present during a VC session
- How the patient and health professionals involved will be authenticated
- Patient should also be informed of other options available ⁶



INFORMED CONSENT

29 states include some sort of telemedicine informed consent requirement in their statutes, administrative codes and/or Medicaid policies.

You should always determine in advance what the policies and requirements are for your state.

The Center for Connected Health Policy (CCHP) (<http://www.cchpca.org>) and the American Telemedicine Association (ATA) (<http://www.americantelemed.org/home>) provide overviews of current state policies.⁷

7. Southwest Telehealth Resource Center. How Informed Are You. Accessed August 22, 2020. <https://southwesttrc.org/blog/2017/telemedicine-informed-consent-how-informed-are-you>



CONFIDENTIALITY, PRIVACY, & DATA SECURITY

Though originally created for health insurance companies, HIPAA still applies to telehealth services.



CONFIDENTIALITY, PRIVACY, & DATA SECURITY

Interactive audio video telecommunications/videoconferencing platform should be HIPAA-compliant (i.e., Skype for Business, Updox, VSee, Zoom for Healthcare, Doxy.me, and Google G Suite Hangouts Meet).

HIPAA Business Associate Agreement (BAA) must be signed between provider and platform.



CONFIDENTIALITY, PRIVACY, & DATA SECURITY

What is a Business Associate?

According to HHS, a “business associate” is a person or entity, other than a member of the workforce of a covered entity, who performs functions or activities on behalf of, or provides certain services to, a covered entity that involve access by the business associate to protected health information.”⁸

8. HHS.gov. Health Information Privacy. Accessed August 22, 2020. <https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html>



CONFIDENTIALITY, PRIVACY, & DATA SECURITY

“The HIPAA Rules generally require that covered entities and business associates enter into contracts with their business associates to ensure that the business associates will appropriately safeguard protected health information.”⁸

8. HHS.gov. Health Information Privacy. Accessed August 22, 2020. <https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html>



CONFIDENTIALITY, PRIVACY, & DATA SECURITY

Every provider should also be familiar with their state's own regulations regarding privacy.

This website is a link to each state's regulations:

<http://www.healthinfolaw.org/state>



e-PRESCRIBING CONTROLLED SUBSTANCES

Ryan Haight Online Pharmacy Consumer Protection Act of 2008

- Regulates online internet prescriptions for controlled substances
- Enforced by the DEA
- More restrictive than most state regulations for prescribing controlled substances online



e-PRESCRIBING CONTROLLED SUBSTANCES

The law requires an in person exam prior to prescribing a controlled substance to a patient.

- Seven highly restrictive exceptions to the law
- Changes since COVID-19 – restriction has been lifted during a state of emergency ⁹



TELEMEDICINE MALPRACTICE LIABILITY

- Most malpractice policies cover telemedicine but some do not.
- Clinicians should verify with their carrier that telemedicine is covered and in the state in which they practice.



TELEMEDICINE MALPRACTICE LIABILITY

An April 2019 JAMA article discussed reported cases of medical malpractice in direct to consumer medicine. The study showed zero cases of malpractice for telemedicine visits that were following the standard of care.¹⁰

10. Fogel AL, Kvedar JC. Reported Cases of Medical Malpractice in Direct-to-Consumer Telemedicine. *JAMA*. 2019;321(13):1309–1310. doi:10.1001/jama.2019.0395



TELEMEDICINE MALPRACTICE LIABILITY

Malpractice companies are still trying to determine if telemedicine visits should be categorized as “high risk.”

PAVMT has partnered with a large malpractice company endorsed by the AAPA as a resource for our members. We were successful in being able to bring it down from a P3, high risk category, to a P1.



ETHICAL PRACTICE IN TELEMEDICINE

American Medical Association has a Code of Ethics unique to providing care via telemedicine.¹¹

There are ethical differences between in person visits and telemedicine visits.

11. AMA. Ethical Practice in Telemedicine. Accessed August 16, 2020. <https://www.ama-assn.org/delivering-care/ethics/ethical-practice-telemedicine>



ETHICAL PRACTICE IN TELEMEDICINE

AMA Code of Ethics¹¹

- Healthcare providers have ethical obligations to patients to provide them with confidentiality and privacy.
- A valid patient-provider relationship must be established for a telemedicine visit to take place.



ETHICAL PRACTICE IN TELEMEDICINE

AMA Code of Ethics:

Healthcare providers have an “ethical responsibility to uphold fundamental fiduciary obligations by disclosing any financial or other interests the physician has in the telehealth/telemedicine application or service and taking steps to manage or eliminate conflicts of interests.”¹¹



ETHICAL PRACTICE IN TELEMEDICINE

AMA Code of Ethics:

Healthcare providers have an ethical responsibility that their “telemedicine services have appropriate protocols to prevent unauthorized access and to protect the security and integrity of patient information.” ¹¹



ETHICAL PRACTICE IN TELEMEDICINE

AMA Code of Ethics:

Healthcare providers have an ethical responsibility to:

- Establish the patient's identity
- “Be prudent in carrying out a diagnostic evaluation or prescribing medication”¹¹
- Ensure the telemedicine services are appropriate for the patient's needs
- Take steps to ensure continuity of care



COURSE EXAM

Must obtain 70% to pass and receive credit for the course.



COURSE EXAM

QUESTION 1:

True or False.

Providers performing telehealth visits should follow the same guideline and standards for quality care as in-person visits.



COURSE EXAM

QUESTION 2:

True or False.

The lack of an appropriate physician-patient relationship is one of the main concerns regulators face regarding the delivery of telehealth services.



COURSE EXAM

QUESTION 3:

True or False.

All states in the U.S. allow a provider to establish a physician-patient relationship via telemedicine.



COURSE EXAM

QUESTION 4:

Healthcare providers must be licensed to practice telemedicine:

- A. In the state in which the patient is located.
- B. In the state in which the healthcare provider is located.
- C. In both the state in which the healthcare provider is located and where the patient is located.
- D. Healthcare providers don't need a license to practice.



COURSE EXAM

QUESTION 5:

Informed Consent is unique to telemedicine in that it should inform the patient as to:

- A. The reasons why the telemedicine visit differs from a traditional in person visit.
- B. How the patient's data is acquired, transmitted, and stored.
- C. Security measures in place to keep their data private.
- D. All of the above.



COURSE EXAM

QUESTION 6:

True or False.

Informed consent should be written and saved to the patient's record as well as a copy given to the patient.



COURSE EXAM

QUESTION 7:

True or False.

Interactive audio video platforms must sign a Business Associate Agreement (BAA) with the healthcare provider in order to comply with HIPAA regulations.



COURSE EXAM

QUESTION 8:

The Ryan Haight Act of 2008:

- A. Regulates internet prescribing of controlled substances.
- B. Is enforced by the DEA.
- C. Requires an in-person exam prior to prescribing a controlled substance.
- D. All of the above.



COURSE EXAM

QUESTION 9:

True or False.

The Ryan Haight Act requirement of an in-person exam prior to prescribing a controlled substance has been lifted during the COVID-19 state of emergency.



COURSE EXAM

QUESTION 10:

True or False.

All malpractice carriers cover telemedicine visits.

██████████ Healthcare providers should verify with their malpractice carrier that they are covered for telemedicine visits prior to practicing telemedicine.



COURSE SURVEY



QUESTIONS

Please e-mail us at:
info@pavmt.org
or visit our website:
pavmt.org

