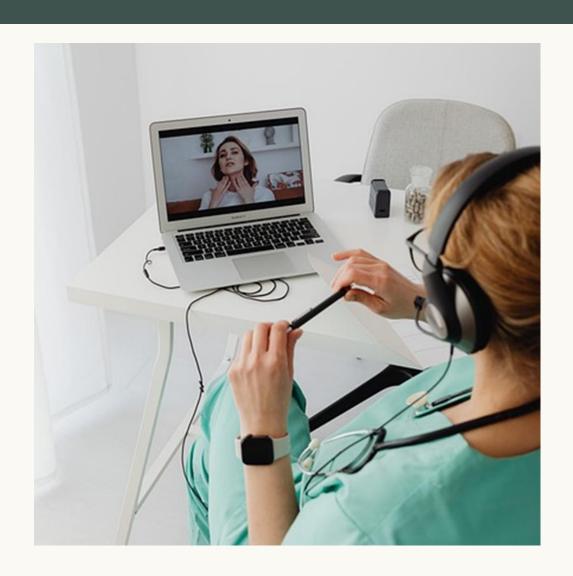
Telehealth



GRAND ROUNDS KIM C. STANGER

(12/23)

/ Holland & Hart

Disclaimer

This presentation is designed to provide general information on pertinent legal topics. The information is provided for educational purposes only. Statements made or information included do not constitute legal or financial advice, nor do they necessarily reflect the views of Holland & Hart LLP or any of its attorneys other than the author.

This information contained in this presentation is not intended to create an attorney-client relationship between you and Holland & Hart LLP. Substantive changes in the law subsequent to the date of this presentation might affect the analysis or commentary.

Similarly, the analysis may differ depending on the jurisdiction or circumstances. If you have specific questions as to the application of the law to your activities, you should seek the advice of your legal counsel.



Written Resources



- .PPT slides
- Idaho Virtual Care Access Act, I.C. § 54-5701 et seq., https://legislature.idaho.gov/wp-content/uploads/statutesrules/idstat/Title54/T54CH57.pdf
- Grajcar, *Idaho Telehealth/Virtual Care Update,* The Report, IBOM (11/23).
- Stanger, *Idaho's New Virtual Care [Telehealth] Access Act*, https://www.hollandhart.com/idahos-new-virtual-care-telehealth-access-act
- Stanger, *Telehealth in Idaho and Elsewhere*, https://www.hollandhart.com/telehealth-in-idaho-and-elsewhere
- FSMB, *Telemedicine Policies: Board by Board Overview*, https://www.fsmb.org/siteassets/advocacy/key-issues/telemedicine_policies_by_state.pdf

Overview

- Recent developments
- Telehealth <u>in</u> Idaho
 - –Idaho Virtual CareAccess Act
- Telehealth <u>outside</u> Idaho
 - –Common legal concerns



Originating and Distant Site

ORIGINATING SITE:
Where the patient is located, including patient's home



DISTANT SITE:
Where the remote
practitioner is located

Telehealth



Potential Penalties for Violations

CIVIL OR ADMINISTRATIVE

- Adverse licensure action
- Denial of reimbursement or repayment
- False Claims Act liability
 - Repayment
 - Civil fines and penalties
 - Qui tam litigation
- Exclusion from payer programs
- Malpractice
 - Violation of state law may constitute negligence per se
- Loss of insurance coverage
- Others?

CRIMINAL

- Practicing without a license
- False claims
- Fraud
- Wire fraud
- Others?
- **≻**Prison
- > Fines
- > Exclusion from Medicare/Medicaid





Virtual Care Access Act: "Virtual Care"

 Provider rendering "virtual care" in Idaho must comply with Idaho laws and rules.

(IC 54-5704, -5713)

 Virtual care is considered to be rendered at the physical location of the patient.

(IC 54-5703)

- "Virtual care" = "technology-enabled health care services in which the patient and provider are not in the same location" such as "telemedicine, telehealth, m-health, e-consults, e-visits, video visits, remote patient monitoring, and similar technologies."
- "Health care services" include "the assessment, diagnosis, consultation, treatment, and remote monitoring of a patient; transfer of medical data; patient and professional health-related education; public health services; and health administration."

(IC 54-5703)

Virtual Care Access Act: Licensure

 Generally, must have Idaho license to render virtual care in Idaho and act within scope of license.

(IC 54-5704, -5713)

- Exceptions: practitioner licensed and in good standing in other state:
 - Has established relationship with patient who is in Idaho temporarily for work, education, vacation, etc.
 - Has established relationship with patient and needs to provide short-term follow-up care.
 - Is employed by or contracted with Idaho facility or hospital to provide care services for which the provider has been privileged or credentialed.
 - Renders care in a disaster.
 - Provides care in preparation for scheduled in-person visit.
 - Consults with or refers patient to Idaho provider.
 - Certain others...

Idaho Medical Practice Act

The following are do not constitute the unlicensed practice of medicine in Idaho:

- Person licensed in another state while rendering care in disaster or at scene of emergency.
- Armed forces medical officer or VA while performing duties.
- Called to consult by a person licensed to practice medicine in Idaho, or provide education (e.g., lecture, clinic or demonstration) so long as he does not open office, appoint a place to meet patients or receive calls in Idaho.
- Testifying in legal proceeding.
- Residents and interns who are properly registered with IBOM and acting in programs.
- Person administering remedy, diagnostic procedure at advice of a physician.
- · Certain others.

/ Holland & Hart

Virtual Care Access Act: Standard of Care

- A provider delivering health care services via virtual care must:
 - Practice in a manner consistent with the provider's scope of practice and
 - Comply with the Idaho community standard of care that applies in an in-person setting.
- Treatment based solely on a static online questionnaire does not constitute an acceptable standard of care.

(IC 54-5706)

➤ Ensure telehealth complies with standard of care for inperson visits!

Virtual Care Access Act: Provider-Patient Relationship

Twitt ×

oise/2015/aug/21/doctor-fights-her-career-after-idaho-telemedicine-sanction/

Blogs / Eye On Boise / Doctor fights for her career after Idaho telemedicine sanction



By Betsy Z. Russell bzrussell@gmail.com (208) 336-2854

Betsy Russell covers Idaho news from the state capitol in Boise and writes the Eye on Boise blog.

Follow Betsy online:

Twitter

■ Newsletter

Recent Eye On Boise posts

FRIDAY, AUG. 21, 2015, 3:30 P.M.

Doctor fights for her career after Idaho telemedicine sanction

y Twitter

f Facebook

⊕ Reddit

Dr. Ann DeJong has had to sell her house in Wisconsin and is \$200,000 in debt. Now her medical career is in jeopardy, all because she was sanctioned by Idaho for prescribing a common antibiotic over the phone.

At the time, Idaho law required a face-to-face exam for a prescription. This year, lawmakers changed that to allow for consultations through telemedicine. DeJong was working for such a company, Consult-a-Doctor, when she prescribed the medication; it subsequently pulled out of Idaho. DeJong says if Idaho doesn't modify its order by October, she'll lose her board certification in family practice, and thus her job and livelihood. "It would keep me from practicing anywhere," said DeJong, who was licensed to practice medicine in eight states



Virtual Care Access Act: Provider-Patent Relationship

- Must first establish provider-patient relationship.
 - May establish by virtual care technology if the applicable Idaho community standard of care is satisfied.
- Exceptions:
 - Patient has provider-patient relationship with other provider in the group.
 - Provider is covering call for provider with established relationship.
 - Provider is writing initial hospital admission orders.
 - Provider is writing prescription as permitted by IC 54-1733 (discussed below)

(IC 54-5705)

Virtual Care Access Act: Evaluation and Treatment

Providers rendering virtual care (including prescription or ordering device) must:

- Obtain and document patient's relevant clinical history and current symptoms to diagnose and identify underlying conditions and contraindications to treatment.
 - -Remember: static online questionnaire is not sufficient.
- Obtain proper informed consent.
 - -"Informed" consent may require disclosure of risks associated with telehealth.
- Be available for follow-up care or provide info.
- Refer when medically indicated, including emergencies. (IC 54-5706, 5708)

Virtual Care Access Act: Prescriptions

- A provider may issue prescription drug orders using telehealth services if:
 - -Have an established provider-patient relationship,
 - –Prescribing authority is within the scope of the provider's license; and
 - -Comply with applicable laws, rules and regulations, including the Idaho community standard of care;
 - NOT a controlled substance unless prescribed in compliance with title 21 U.S.C.

(IC 54-5707(1))

• Still subject to limits on prescriptive authority imposed by law or the provider's licensing board.

(IC 54-5707(2))

Idaho Prescription Drug Order Law

- A prescription drug order for a legend drug is valid only if:
 - Issued by prescriber who is licensed and acting within scope of license to prescribe;
 - –Issued from prescriber-patient relationship;
 - -For legitimate medical purpose; and
 - Documented patient evaluation adequate to establish diagnoses, if applicable, and identify underlying conditions and/or contraindications to the treatment.
- May establish prescriber-patient relationship through virtual care if Idaho community standard of care met.
- Treatment, including issuing a prescription drug order, based solely on an online questionnaire or consultation outside of an ongoing clinical relationship does not constitute a legitimate medical purpose.

(IC 54-1733)

Prescriptions: Exceptions to Provider-Patient Relationship

- Generally, must have established prescriber-patient relationship to prescribe drugs.
- Exceptions: No prior prescriber-patient relationship needed to prescribe in following situations:
 - Writing initial admission orders for a newly hospitalized patient;
 - For a patient of another prescriber for whom the prescriber is taking call;
 - For a patient examined by a physician assistant, advanced practice registered nurse or other licensed practitioner with whom the prescriber has a supervisory or collaborative relationship;
 - Medication on a short-term basis for a new patient prior to the patient's first appointment;

(IC 54-1733)

Prescriptions: Exceptions to Provider-Patient Relationship

- Exceptions (cont.): No prior prescriber-patient relationship needed to prescribe in following situations:
 - -For an opioid antagonist pursuant to IC 54-1733B;
 - -In emergency situations where the life or health of the patient is in imminent danger;
 - -İn emergencies that constitute an immediate threat to public health including, e.g., prophylaxis to prevent or control an infectious disease outbreak;
 - -If a prescriber makes a diagnosis of an infectious disease in a patient, prescribe or dispense antimicrobials to an individual who has been exposed to the infectious person in accordance with clinical guidelines.

(IC 54-1733)

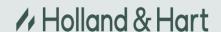
Ryan Haight Online Pharmacy Consumer Protection Act

- Prohibits providers from prescribing controlled substances via the internet without having previously performed an in-person medical evaluation of the patient.
- Exceptions:
 - Prescribing provider is temporarily covering for another provider with a treatment relationship; or
 - –Patient being treated in DEA-registered facility, provider has DEA registration in state in which patient is located, and provider renders telehealth through 2-way interactive audio and video communication system.

Ryan Haight Act: Remote Prescribing

- DEA has issued temporary rules extending COVID-19 PHE flexibilities through 12/31/24.
 - Registered practitioner may prescribe schedule II–V controlled substances via telemedicine to a patient without having inperson medical evaluation if:
 - The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice;
 - The prescription is issued pursuant to a communication between a practitioner and a patient using an interactive telecommunications system satisfying certain conditions;
 - The prescription is consistent with all other requirements of 21 CFR part 1306.

(21 CFR 1307.41; 88 FR 69879 (10/10/23))



Ryan Haight Act: Remote Prescribing

- DEA proposed rule would allow telehealth prescription without in-person evaluation for:
 - –30-day supply of Schedule III-V non-narcotic controlled medications; and
 - –30-day supply of buprenorphine for treatment of opioid use disorder.

(88 FR 12875; https://www.dea.gov/press-releases/2023/02/24/dea-announces-proposed-rules-permanent-telemedicine-flexibilities)

SUPPORT Act

- Facilitates telehealth for substance use disorders (SUD) by:
 - DEA required to establish a telehealth registration process to facilitate prescriptions for SUD.
 - See new proposed rule
 - –State Medicaid programs required to allow for prescription of controlled substances to SUD patients via telehealth.
 - –Medicare beneficiaries allowed to receive telehealth in their home.
 - Home is an approved "originating site".

(21 USC 831(h)(2) and 42 USC 1395m and 1396a)

Virtual Care Access Act: Records

- Must document services rendered via virtual care in medical record to same standard as for in-person care.
- Records must be maintained in compliance with state and federal laws, including HIPAA and HITECH.
- Records must be accessible to:
 - -The patient per applicable law, and
 - Other providers if the patient has given permission.
 - But what about HIPAA and Information Blocking Rule?

(IC 54-5711)

Virtual Care Access Act: Mental Health

- Mental and healthcare providers rendering virtual health in Idaho do not need to be licensed in Idaho if:
 - They are licensed or registered in another U.S. state, district, or territory to practice mental or behavioral health care.
 - Not subject to any past or pending disciplinary proceedings.
 - Comply with all Idaho laws and regulations.
 - Maintain liability insurance to extent required by Idaho law.
 - Register biennially with relevant Idaho licensing board to provide telehealth services. Registration is not licensure and does not allow in-person treatment.
- Idaho community standard of care applies.
- Subject to Idaho jurisdiction and penalties.

Virtual Care Access Act: Enforcement

- Providers prohibited from rendering virtual unless comply with applicable law and Idaho community standard of care.
- State licensing board may take action for violations.
- Healthcare services deemed to occur where patient is located.
- By rendering virtual care in Idaho, provider consents to jurisdiction in Idaho and action by relevant Idaho licensing board, e.g.,
 - Injunction
 - Civil penalties
 - Fines
- Civil or administrative action by licensing agency or patient from out-of-state provider may be located in patient's county or another county as deemed proper by court.

(IC 54-5712 and -5713)

Virtual Care Access Act: Enforcement

 May also be liable for practicing without a license under applicable criminal statutes, e.g.,

"[I]t shall constitute a felony for any person to practice medicine in this state without a license and upon conviction thereof shall be imprisoned in the state prison for a period not to exceed five (5) years, or shall be fined no more than ten thousand dollars (\$10,000), or shall be punished by both such fine and imprisonment.

(IC 54-1804)



Telehealth Outside Idaho

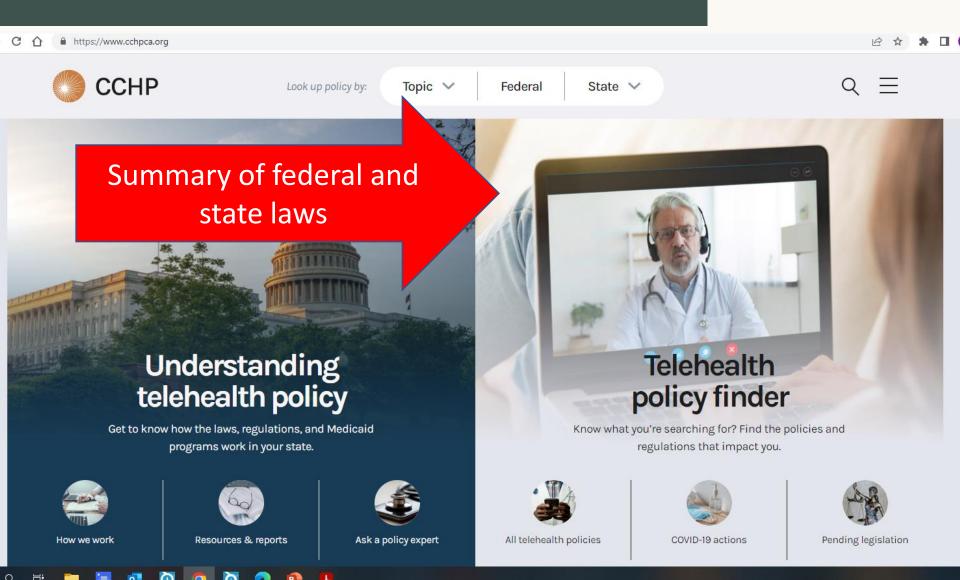


Telehealth Rules

No comprehensive or coordinated national law.

- Federal agencies may have certain requirements
 - −e.g., Medicare, VA, DEA, FDA
- Each state has its own requirements,
 - –e.g., licensing, telehealth standards, remote prescribing, reimbursement, etc.
- Different licensing agencies may have differing requirements.
 - –e.g., physicians and PAs, nurses, psychologists, social workers, etc.
- Each payer may have their own requirements for reimbursement.
- > Check the law in the states where you intend to provide services.

Center for Connected Health Policy, https://www.cchpca.org/



Beware Applicable Law

As a general rule, telehealth provider must comply with both

 Law of state in which telehealth provider is located,

Beware!

and

- Law of state in which patient is located.
 - States want to protect patients.
 - Likely sufficient contacts to establish jurisdiction over telehealth provider

- Licensure
- Permissible telehealth methods
- Provider-patient relationship
- Scope of practice
- Standard of care
- Informed consent
- Remote prescribing
- Credentialing telehealth providers
- Reimbursement
- Malpractice liability and insurance
- Corporate practice of medicine
- Others?



Federation of State Medical Board Comparison of State Licensure Laws

https://www.fsmb.org/siteassets/advocacy/keyissues/telemedicine_policies_by_state.pdf

	State License Required	Reimbursement Policies Medicaid				Deliver	
		Live Video	Store- and- Forward	Remote Patient Monitoring	Audio- only	Private Payer Law	Other Rules/Regulations (citation only)
AL	V	V		V			Ala. Admin. Code § 540-x-16 ALBME Special Purpose License (Abolished 5/26/22) AL Medicaid Management Information System Provider Manual, Primary Care Physician
AK	√ *1	√	√	V	√	1	"Telehealth Statutes, Regulations & Policy" Alaska Dept. of Health and Social Services SB 74 of 2016, Chapter 25 SLA 16 "Board Issued Guidelines: Telemedicine", AMB, Nov. 2014 Alaska Courtesy License AK HB 265 (2022) re: out-of-state referrals
AZ-M	√+ ²	V	√	√	√	√^3	Ariz. Rev. Stat. § 32-1421 "Issue Brief: Telemedicine" Arizona State Senate, Nov. 2014 AZ HB 2454 (2021)
AZ-O	√+	V	V	V	V	√ ^	Ariz. Rev. Stat. § 32-1821 Ariz. Rev. Stat. § 32-1854 "Issue Brief: Telemedicine" Arizona State Senate, Nov. 2014 AZ HB 2454 (2021)
AR	V	٧		V	V	V	AR Code § 17-95-206 AR Stat. 10-3-1702(10) "When Does Telemedicine or Internet- Based Patient Healthcare Violate Regulation 2.8?" AR State Med. Board Newsletter Fall 2012

¹ Alaska allows individuals with suspected or diagnosed life-threatening conditions, to be treated by an out-of-state physician as long as they have a referral from their Alaska-licensed physician, among other requirements.

3 1/2 denotes that a state has payment parity

^{2 √+} denotes that a state requires physicians to register if they choose to practice medicine across state lines.

Licensure: Hospital CoPs

- **Hospital COPs:** "When telemedicine 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 State or local laws in both the state where the practitioner is located and the state where the patient is located." (SOM App. A for 42 CFR 482.11(c))
- CAH COPs: "[E]ach physician or practitioner who provides telemedicine services to the CAH's patients [must] hold a license issued or recognized by the State where the CAH is located...."

(SOM App. W for 485.616(c))

Licensure: Medicaid

- Most state Medicaid programs require that the provider is licensed within the state as condition for reimbursement.
- "Medicaid guidelines require all providers to practice within the scope of their State Practice Act. States should follow their state plan regarding payment to qualified Medicaid providers for telehealth services."

(https://www.medicaid.gov/medicaid/benefits/downloads/medicaid-telehealth-services-doc.pdf)

AMA Ethical Practice in Telemedicine

Physicians who provide clinical services through telehealth should:

- Be proficient in the use of the relevant technologies.
- Recognize the limits of the relevant technologies and take appropriate steps to overcome those limits, e.g., by involving other on-site practitioner or ensuring technology allows proper evaluation.
- Ensure telehealth is appropriate under the circumstances.
- Conduct and document an appropriate evaluation and any prescription.
- When obtaining informed consent, ensure patient understands distinctive features of telehealth.
- Promote continuity of care.

(https://code-medical-ethics.ama-assn.org/ethics-opinions/ethical-practice-telemedicine#:~:text=All%20physicians%20who%20participate%20in,or%20eliminate%20conflcts%20of%20interests)

// Holland & Hart

FSMB Guide re Appropriate Use of Telehealth

https://www.fsmb.org/siteassets/advocacy/policies/fsmb-workgroup-on-telemedicineapril-2022-final.pdf



THE APPROPRIATE USE OF TELEMEDICINE TECHNOLOGIES IN THE PRACTICE OF MEDICINE

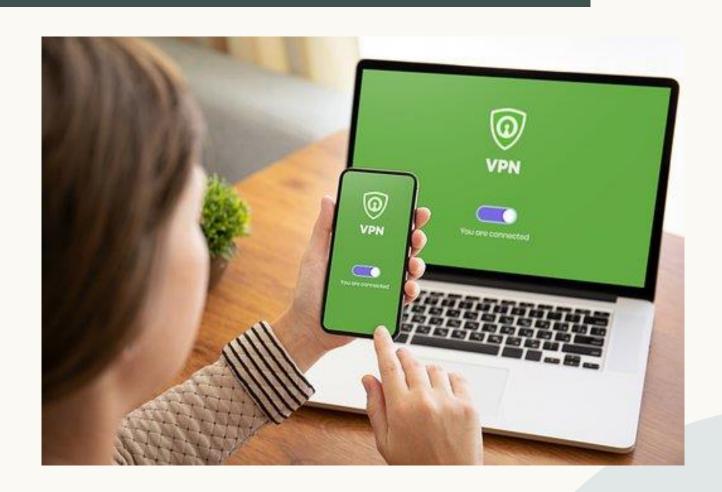
Report of the FSMB Workgroup on Telemedicine Adopted by the FSMB House of Delegates, April 2022

INTRODUCTION

In April 2014, the Federation of State Medical Boards (FSMB) adopted the *Model Policy for the Appropriate Use of Telemedicine Technologies in the Practices of Medicine*, superseding the *Model Guidelines for the Appropriate Use of the Internet in Medical Practice (2002)*. At the time of its adoption, the *Model Policy (2014)* addressed current regulatory challenges associated with the provisions of telemedicine. Since then, the utilization of telemedicine has dramatically increased, resulting in not only advancements in telemedicine technologies, but also identification of newer or more pressing challenges to effective telemedicine utilization.

There are numerous factors contributing to the continual increase of telemedicine being used as a component of the practice of medicine. The greatest of these catalysts by far has been the global COVID-19 pandemic and resulting national public health emergency (PHE). Prior to the

Privacy and Security



HIPAA and Telehealth

OCR has emphasized privacy and security in telehealth

- In 10/22, OCR published guidance concerning HIPAA concerns in audio-only telehealth.
- On 8/9/23, relaxed security standards for telehealth platforms ended.
- In 10/23, OCR published guidance for providers and patients concerning privacy and security risks in telehealth.

(See https://www.hhs.gov/hipaa/for-professionals/special-topics/telehealth/index.html)

Telehealth Privacy Tips for Providers





What are the data privacy and security risks in telehealth?

- Privacy risk is when an individual lacks control over the collection, use, and sharing of their health data.
- Security risk is when there is unauthorized access to an individual's health data during the collection, transmission, or storage.
- These risks can affect trust between the patient and provider and contribute negatively to adherence and continuity of care.



How do I fulfill privacy obligations during a telehealth session?

- Privacy and security risks are present for in-person, remote monitoring, and virtual visits. Electronic transmission of data means greater privacy and security risks.
- Make sure you are up-to-date on security and protections requirements for <u>HIPAA compliance</u> and are aware of other <u>legal considerations</u>.
- Providers have an ethical obligation to discuss privacy and security risks. These discussions can be part of a patient-centered care plan to help ensure confidentiality.



How do I communicate privacy protections to patients?

- Make privacy part of the workflow by confirming identities of everyone present at each telehealth session and communicate how any third-parties may be involved.
- Set up and communicate the below safeguards to your patients:
 - Create unique user identification numbers
 - Use password protected platforms
 - Establish automatic logoff



How do I protect my own privacy and reduce risk of breaches?

- Health data breaches are costly and can involve investigations, notifying patients, and recovering data, so providers need to be familiar with their security features.
- Establish the below processes:
 - Routinely review your telehealth privacy and security policies.
 - Schedule regular deletion of files on mobile devices.
 - Utilize data back-up and recovery processes in case of breach.
- Conduct a security evaluation from an independent party on your telehealth system to verify security features such as authentication, encryption, authorization, and data management.
- Check out more security tips from the Office of the National Coordinator for Health Information Technology.

HIPAA Privacy Rule

- Provide notice of privacy practices.
 - Do not need to specify telehealth.
- Verify identity of participants.
- Implement reasonable safeguards to minimize risk of improper access or disclosures, e.g.,
 - -Private rooms, if reasonably available.
 - Conduct discussions in manner to avoid others overhearing.
 - -Safeguard records.
- "Incidental disclosures" are not violations or breaches.

(45 CFR 164.501 et seq.)

HIPAA Security Rule

- Risk assessment.
- Implement safeguards.
 - -Administrative
 - –Physical
 - –Technical, including encryption
 - ➤ Ensure you are using a secure platform.
- Execute business associate agreements.

(45 CFR 164.300 et seq.)

Protect ePHI:

- Confidentiality
- Integrity
- Availability

HIPAA Security Rule

• During PHE, providers were allowed to use non-compliant technologies (e.g., FaceTime, Messenger, Zoom, Skype, etc.).

(https://www.hhs.gov/sites/default/files/telehealth-faqs-508.pdf)

 OCR confirmed that relaxed security standards ended August 9, 2023.

(https://www.hhs.gov/about/news/2023/04/11/hhs-office-for-civil-rights-announces-expiration-covid-19-public-health-emergency-hipaa-notifications-enforcement-discretion.html)

Audio-Only Telehealth

On 6/13/22, OCR issued Guidance re Audio-Only Telehealth:

- Must comply with HIPAA rules, e.g.,
 - -Implement reasonable safeguards (e.g., use private setting; avoid overhearing, etc.).
 - -Verify identity of individual.
 - -Comply with security rule if applicable (not landline but will apply to voice over internet protocol (VoIP), cellular messaging, record and store tech, etc.).
 - -Obtain BAAs if required (e.g., platforms that are not merely conduits for PHI).

(https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/hipaa-audio-telehealth/index.html)

/ Holland & Hart

Communicating by E-mail or Text

- ➤ General rule: PHI must be secure, i.e., encrypted.
- To patients: may communicate via unsecure email or text if warned patient and they choose to receive unsecure.

(45 CFR 164.522(b); 78 FR 5634)

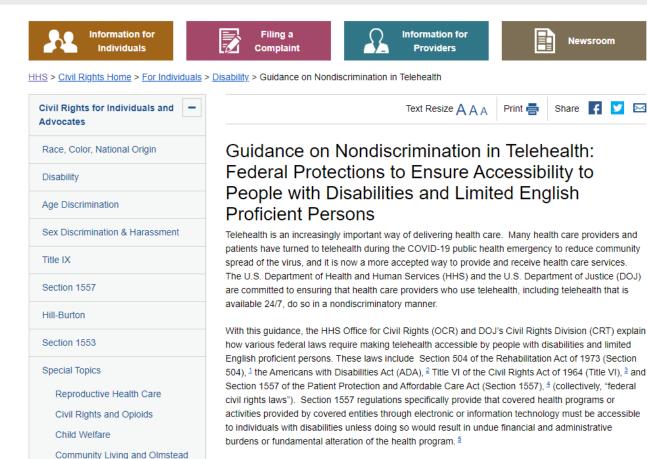
• <u>To providers, staff or other third parties</u>: must use secure platform.

(45 CFR 164.312; CMS letter dated 12/28/17)

 Orders: Medicare Conditions of Participation and Conditions for Coverage generally prohibit texting orders.

(CMS letter dated 12/28/17)

https://www.hhs.gov/civil-rights/for-individuals/disability/guidance-on-nondiscrimination-in-telehealth/index.html



This guidance builds on work that HHS and DO. I have previously done to promote pondiscrimination

On 7/29/22, OCR and DOJ issued Guidance on Nondiscrimination in Telehealth (Section 504, ADA, Title VI, and Section 1557)

Persons with Disabilities

- Nondiscrimination
- Reasonable modifications
- Effective communication

Limited English Proficiency

 Meaningful access, e.g., language assistance services

(https://www.hhs.gov/civil-rights/for-individuals/disability/guidance-on-nondiscrimination-in-telehealth/index.html)

 Proposed 1557 rule would add a provision expressly prohibiting discrimination in telehealth.



Per OCR/DOJ Guidance, examples of necessary accommodations might include:

- Intellectual disability:
 - Offer more time for patient and provide support person to assist during encounter.
- Deaf or hard of hearing:
 - -Provide sign language interpreter during encounter.
 - -Use platform that provides real-time captioning.
- Blind or visual disability.
 - -Ensure recommendations are screen-reader capable.
 - –Use video with audio descriptions.

(https://www.hhs.gov/civil-rights/for-individuals/disability/guidance-on-nondiscrimination-in-telehealth/index.html)



Per OCR/DOJ Guidance, examples of necessary accommodations might include:

- Limited English proficiency
 - -In e-mails or social media posts about telehealth opportunities, include short non-English statement that explains how LEP person may obtain info in their language.
 - Provide qualified language interpreter; don't rely on patient to bring their own interpreter.
 - Ensure telehealth platform may accommodate an interpreter or video remote interpreter.

(https://www.hhs.gov/civil-rights/for-individuals/disability/guidance-on-nondiscrimination-in-telehealth/index.html)



Liability Issues



Different Laws

- 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

Do you know these and are you prepared to comply?

Practitioner-Patient Relationship

- Practitioner-patient relationship may exist even though there is no direct contact.
- Test: would 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 may have laws governing establishment of telemedicine relationship.

Patient Abandonment

- 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.

Malpractice Liability

- Applicable standard of care
 - Different community standard may apply.
 - Presumably, 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.

Liability Insurance Coverage

- Liability insurance may require proper license for coverage.
- Liability insurance policies may not cover:
 - -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.

Fraud and Abuse Concerns

- False Claims Act or Fraud claims based on failure to comply with telehealth billing rules.
- Financial relationships with telehealth providers may trigger Stark, Anti-Kickback Statute, and Civil Monetary Penalties, e.g.,
 - Contracts for services.
 - Use of space, equipment, or personnel for free or at a discount.
 - Provision of free or discounted telehealth equipment to patients.

(42 CFR 411.357 and -1001.952)

- ➤ Make sure you are compliant with post-PHE rules.
- ➤ Check with Compliance Officer.

DOJ Targeting Telehealth



Search this site

2

ABOUT

OUR AGENCY

TOPICS

NEWS

RESOURCES

CAREERS

Home » Criminal Division » About The Criminal Division » Sections/Offices » Fraud Section (FRD) » Health Care Fraud Unit » 7

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Wednesday, July 20, 2022

Justice Department Charges Dozens for \$1.2 Billion in Health Care Fraud

Nationwide Coordinated Law Enforcement Action to Combat Telemedicine, Clinical Laboratory, and Durable Medical Equipment Fraud

The Department of Justice today announced criminal charges against 36 defendants in 13 federal districts across the United States for more than \$1.2 billion in alleged fraudulent telemedicine, cardiovascular and cancer genetic testing, and durable medical equipment (DME) schemes.

The nationwide coordinated law enforcement action includes criminal charges against a telemedicine company executive, owners and executives of clinical laboratories, durable medical equipment companies, marketing organizations, and medical professionals. In connection with the enforcement action, the department seized over \$8 million in cash, luxury vehicles,

Beware telehealth claims:

- Standard of care
- Medical necessity
- Telehealth + facility fee
- Upcoding or unbundling
- Billing and coding
- Conditions for proper billing
- Changes with end of PHE



OIG Special Fraud Alert

Key concerns:

- Telehealth company recruits patients.
- Services not medically necessary.
- Provider has little to no interaction with patient.
- Provider paid based on volume or value of services ordered.
- No follow up with patients.



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



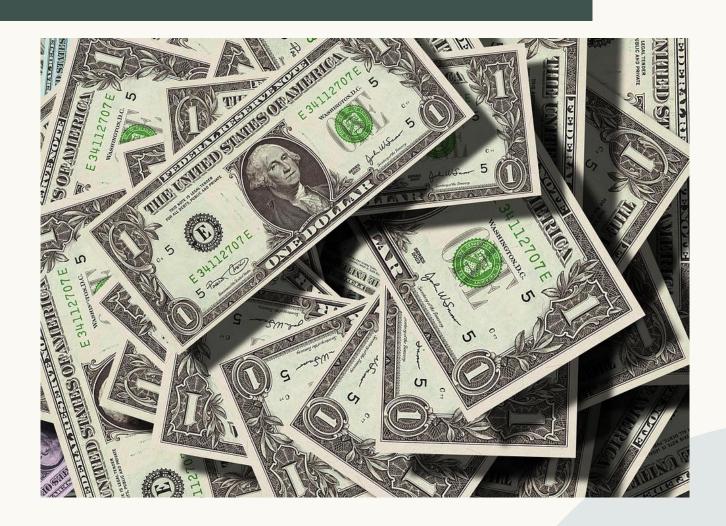
Special Fraud Alert: OIG Alerts Practitioners To Exercise Caution When Entering Into Arrangements With Purported Telemedicine Companies

July 20, 2022

I. Introduction

The Office of Inspector General (OIG) has conducted dozens of investigations of fraud schemes involving companies that purported to provide telehealth, telemedicine, or telemarketing services (collectively, Telemedicine Companies) and exploited the growing acceptance and use of telehealth. For example, in some of these fraud schemes Telemedicine Companies intentionally paid physicians and nonphysician practitioners (collectively, Practitioners) kickbacks to generate orders or prescriptions for medically unnecessary durable medical equipment, genetic testing, wound care items, or prescription medications, resulting in submissions of fraudulent claims to Medicare, Medicaid, and other Federal health care programs. These fraud schemes vary in design and operation, and they have involved a wide range of different individuals and types of entities, including international and domestic telemarketing call centers, staffing companies,

Reimbursement

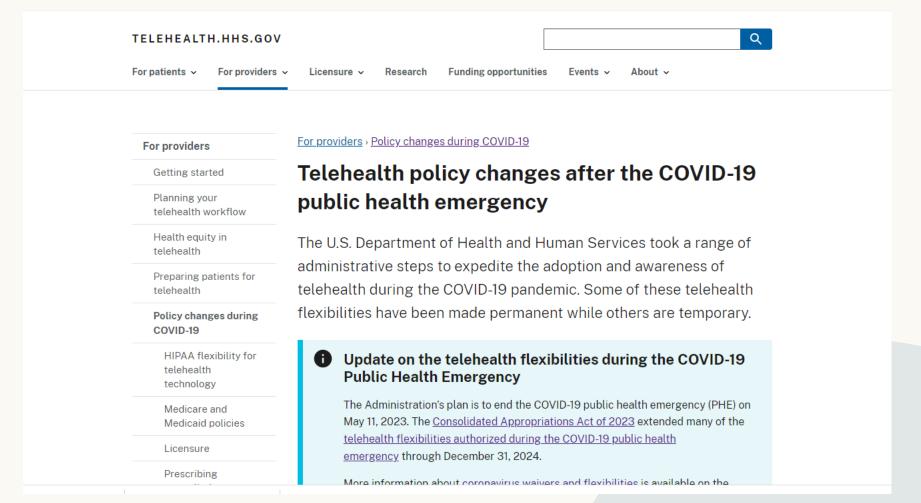


Reimbursement

- COVID-19 flexibilities have changed.
 - –Many ended.
 - -Some have extended.
 - -Some have been changed permanently.
- ➤ Be sure to confirm reimbursement rules!

HHS Telehealth Website

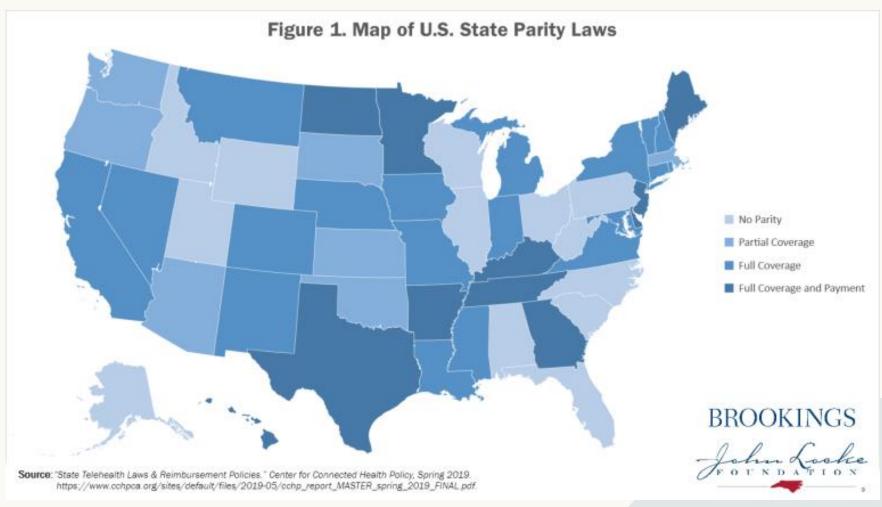
https://telehealth.hhs.gov/providers



Reimbursement: Private Payers

- 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 inperson care.
- Absent law to the contrary, payers are generally able to establish the conditions on which they will cover telehealth.

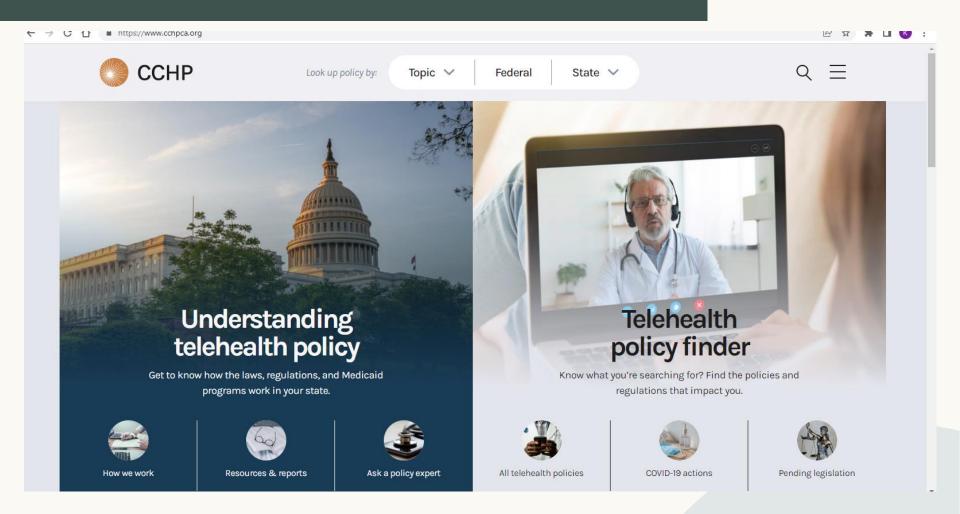
Telehealth Parity Laws



Additional Resources



Center for Connected Health Policy, https://www.cchpca.org/



HHS, https://telehealth.hhs.gov

TELEHEALTH.HHS.GOV

Q

For patients ~

For providers ~

For researchers

Funding opportunities

Events

About ~

For providers

Telehealth resources for health care providers, including doctors, practitioners, and hospital staff.





Getting started with telehealth

How to evaluate telehealth vendors and begin offering care through telemedicine.



Planning your telehealth workflow

How to set up and manage a workflow for virtual visits.



Health equity in telehealth

How health care providers can improve access to telehealth for all populations.



Drangring nationts for talahaalth

https://telehealth.hhs.gov/providers/billing-and-reimbursement/billing-and-coding-medicare-fee-for-service-claims/

TELEHEALTH.HHS.GOV

For patients
For providers
For researchers Funding opportunities Events About
For patients
For providers
For researchers Funding opportunities Events Funding Opportunities Funding

For providers

Getting started

Planning your telehealth workflow

Health equity in telehealth

Preparing patients for telehealth

Telehealth and the COVID-19 vaccine

Policy changes during COVID-19

Billing for telehealth

For providers > Billing for telehealth during COVID-19

Billing and coding Medicare Fee-for-Service claims

More Medicare Fee-for-Service (FFS) services are billable as telehealth during the COVID-19 public health emergency. Read the latest guidance on billing and coding FFS telehealth claims.

On this page:

- <u>Telehealth codes covered by Medicare</u>
- Coverage after COVID-19 ends
- Coding claims during COVID-19

Give f

Additional Resources

- Federation of State Medical Boards, http://www.fsmb.org/grpol_telemedicine.html.
 - Summaries of state laws governing telemedicine.
 - Legislative update.
- Center for Telehealth & e-Health Law ("CTel"), https://ctel.org/policy-issues/.
 - Publications and guides.
 - News and information.
- American Telemedicine Ass'n, http://www.americantelemed.org/
 - Practice standards and guides.
 - News and information.

www.hollandhart.com/healthcare



Search by Keyword

OVERVIEW >

PEOPLE
PRACTICES/INDUSTRIES
NEWS AND INSIGHTS

CONTACTS

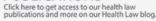


Kim Stanger Partner Boise



Blaine Benard
Partner
Salt Lake City





CLICK HERE FOR COVID-19 RESOURCES FOR HEALTHCARE PROFESSIONALS

The Healthcare Industry is poised to continue its rapid evolution. With this sector now making up close to 20 percent of GDP, our lawyers stand ready to help as changes unfold.

Issues such as rising healthcare costs, healthcare reform, data and privacy security, and innovations in healthcare delivery, device and pharmaceutical designs are forefront in the minds of many of our clients. We are here to guide our clients through the challenges and opportunities that arise in this dynamic industry.

Clients We Serve

- Hospitals
- Individual medical providers
- ical groups aged care organizations (MCOs)

Webinars and Publications

ers of healthcare assets

- ging centers
- An oulatory surgery centers
- Medical device and life science companies
- Rehabilitation centers

Questions?



Kim C. Stanger

Office: (208) 383-3913

Cell: (208) 409-7907

kcstanger@hollandhart.com