Healthcare Compliance Webinar Series:

Telehealth

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Health Law Webinar Series

Date	Topic
7/10/2025	Antitrust
7/24/2025	Employment Matters
8/14/2025	HCQIA, NPDB Reporting, and Credentialing Providers
8/28/2025	Discrimination Laws: 1557, Rehab Act, and Others
9/11/2025	Creating, Managing, and Terminating the Patient-Provider Relationship

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Written Resources

- PowerPoint slides
- FSMB, *Telemedicine Policies: Board by Board Overview*, https://www.fsmb.org/siteassets/advocacy/key-issues/telemedicine_policies_by_state.pdf
- 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

If you did not receive them, contact CECobbins@hollandhart.com.

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Overview

- Recent developments
- Licensure
- Scope of practice
- Standard of care
- Remote prescribing
- Credentialing
- Corporate practice of medicine
- HIPAA privacy and security
- Discrimination
- Liability concerns
- Fraud and abuse concerns
- Reimbursement

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Telehealth: Recent Developments

During COVID, CMS and DEA allowed for greater flexibility in receiving care *via* telehealth. Even though public health emergency has ended,

- DEA, jointly with HHS, has extended the current telemedicine flexibilities for controlled substance prescribing through 2025 (*via* a third temporary rule).
  - Allows schedule II-V controlled substances to be prescribed via telemedicine, without an in-person evaluation of patient.
    - Must be for a legitimate medical purpose
    - Must use interactive telecommunications system
    - Practitioner must have DEA registration in state where patient resides and otherwise comply with state law (*e.g.*, state license and controlled substance license/registration).
- CMS has kept certain telehealth coverage in place permanently.

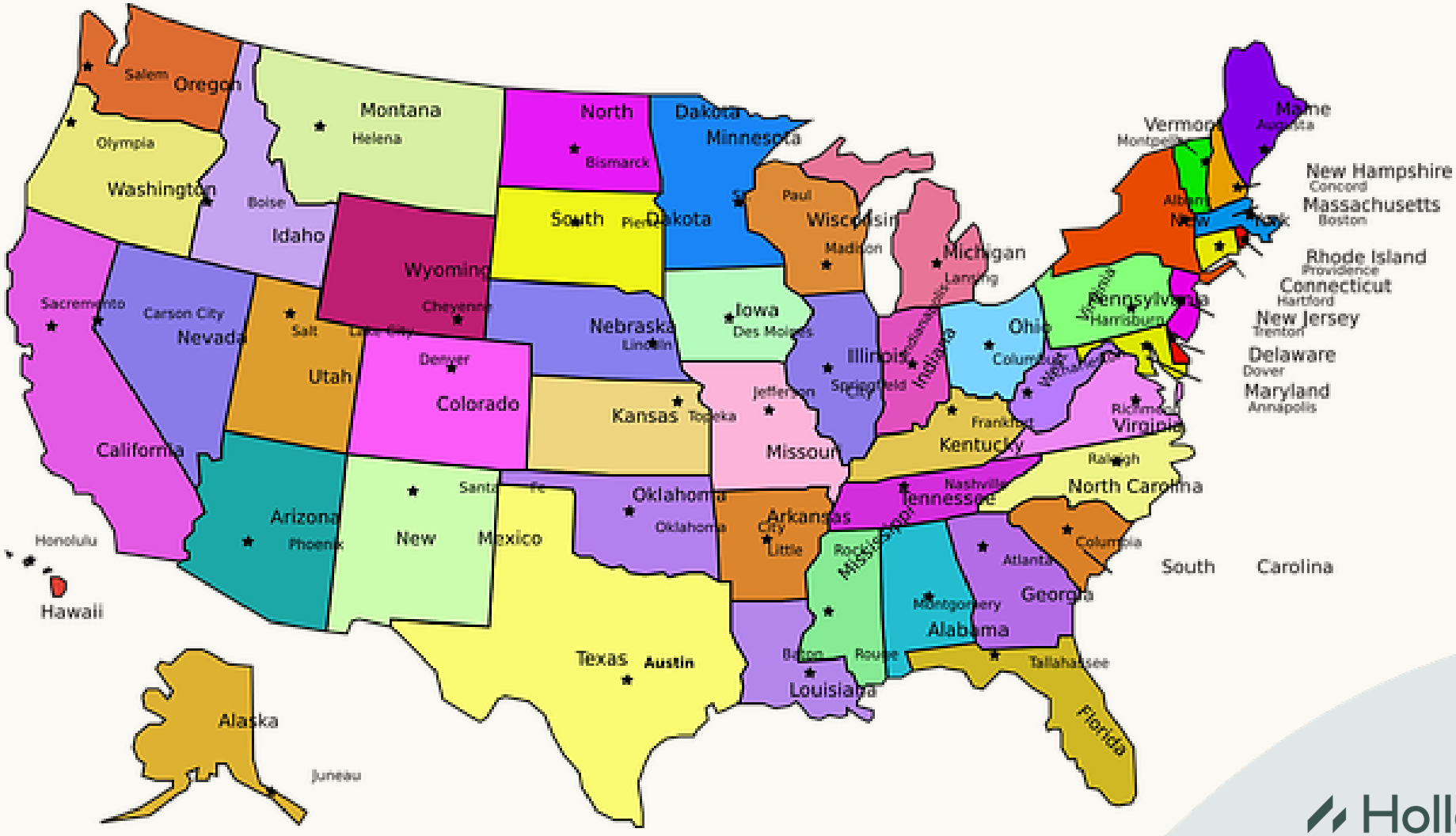
Telehealth: Recent Developments

- OCR guidance concerning:
  - Use of telehealth platforms post-PHE
  - Audio-only telehealth

- DOJ guidance concerning discrimination in telehealth.

- State legislatures and licensing boards addressing telehealth.

Telehealth Rules



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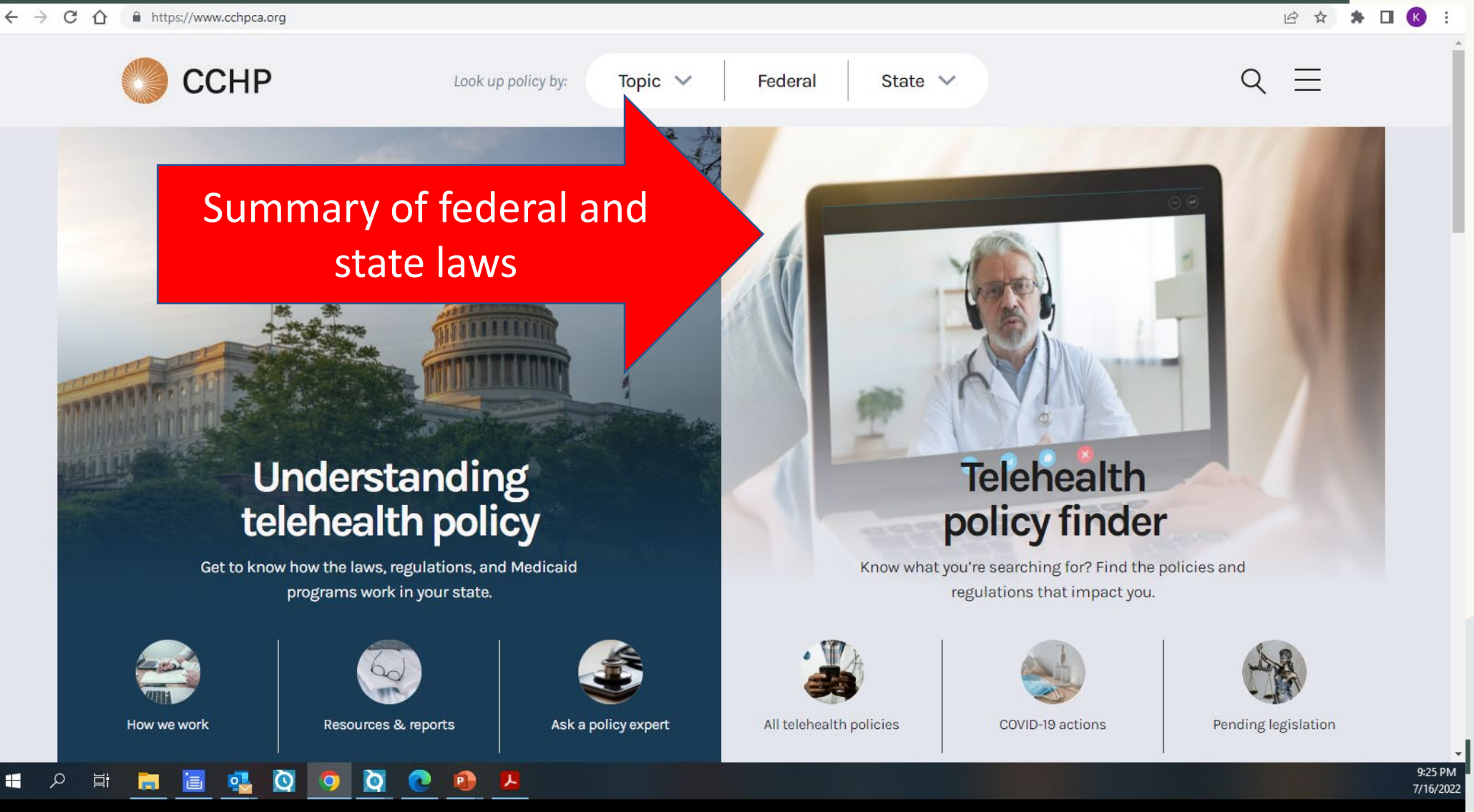
Telehealth Rules

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/



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Telehealth

- "Telehealth" generally means the provision of clinical services to patients by healthcare professionals from a distance via electronic communications.
  - Simultaneous, synchronous, or "real time" (*e.g.*, tele-ICU)
  - Non-simultaneous, asynchronous, "store-and-forward" (*e.g.*, teleradiology)
  - Remote monitoring
- Usually does not mean communication via phone, e-mail, etc.
- But check applicable state law and payer definitions.

Originating and Distant Site

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

Telehealth

DISTANT SITE:
Where the remote practitioner is located

Beware Applicable Law

As a general rule, telehealth provider must comply with <u>both</u>

- Law of state in which telehealth provider is located,

  <u>and</u>

- 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?

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**

Licensure

States regulate the practice of professions (*e.g.*, medicine, nursing, therapy, counseling, etc.).

- For example, "practice of medicine" may be defined as—
  - "To investigate, diagnose, treat or prescribe for any human disease, ailment, injury, or other condition.
  - "To offer, undertake, attempt or hold oneself out as able to do any of the foregoing."
- Unauthorized practice of medicine is usually a felony.
  - Criminal fines
  - Prison
  - Adverse licensure action
- Similar penalties apply to other professions.

Licensure

States generally require that providers rendering telehealth be licensed or registered in the state where the patient is located.

- Most require full licensure.
- Some permit license from bordering state.
- Some allow a special purpose license, *e.g.*, telehealth.
- Some allow limited practice within state, *e.g.*, consultation or education.
- Some allow for expedited licensure, *e.g.*, Interstate Medical Licensure Compact.

Practitioners in military, VA, Public Health Service may practice within their organization across states.

Federation of State Medical Board Comparison of State Licensure Laws

https://www.fsmb.org/siteassets/advocacy/key-issues/telemedicine_policies_by_state.pdf

	State License Required	Reimbursement Policies				Private Payer Law	Other Rules/Regulations (citation only)
		Medicaid					
		Live Video	Store-and-Forward	Remote Patient Monitoring	Audio-only		
AL	√	√		√			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]	√	√	√	√	√	"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]	√	√	√	√	√^[3]	Ariz. Rev. Stat. § 32-1421 "Issue Brief: Telemedicine" Arizona State Senate, Nov. 2014 AZ HB 2454 (2021)
AZ-O	√+	√	√	√	√	√^	Ariz. Rev. Stat. § 32-1821 Ariz. Rev. Stat. § 32-1854 "Issue Brief: Telemedicine" Arizona State Senate, Nov. 2014 AZ HB 2454 (2021)
AR	√	√		√	√	√	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.
[2] √+ denotes that a state requires physicians to register if they choose to practice medicine across state lines.
[3] √^ denotes that a state has payment parity.

Last updated: March 2023

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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)

Scope of Practice

- **Telehealth provider must comply with scope of practice laws in the state where the patient is located.**

- **In most states, the provider's scope of practice for in-person care also defines their scope of practice for telehealth care.**
  - If they can provide the service in person, they can provide the service through telehealth.
  - Any limits that apply to the scope of practice for in-person care also applies to telehealth.

Scope of Practice

Consider requirements for non-physicians, *e.g.*, PAs, APRNs, RNs, therapists, etc.

- States may limit the applicable scope of practice for telehealth or otherwise.

- States may require appropriate supervision by physician or other provider licensed in the state where the patient is located, *e.g.*,
  - PAs generally need supervising or collaborating physician licensed in the state.
  - APRNs may require supervising or collaborating physician.
  - RNs generally require supervision or direction from a licensed independent practitioner.

Provider-Patient Relationship

- **All states require that telehealth provider establish an appropriate provider-patient relationship.**

- **May differ in the manner in which the relationship may be established, *e.g.*,**
  - In-person encounter.
  - Use of telehealth to establish relationship, *e.g.*,
    - Synchronous v. asynchronous
    - 2-way audio/visual v. audio only
  - Periodic in-person encounters.
  - Other method that satisfies standard of care.

- **May require disclosures to the patient, *e.g.*, licensure, credentials, location, etc.**

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

Doctor fights for her career after Idaho telemedicine sanction

Dr. Ann DeJong

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 including Idaho when she took that call from an Idaho patient through Consult-a-Doctor in 2012.

Idaho House Minority Leader John Rusche, D-Lewiston, a retired physician who sponsored this year's telemedicine legislation, said, "I think the action on the part of the Board of Medicine is excessive. ... It seems to me that this was a statement or an attempt by the members of the Board of Medicine to take on the whole issue of tele-health and telemedicine, and the vehicle that they had was this individual."

Provider-Patient Relationship

Most states have exceptions to requirement for existing provider-patient relationship, *e.g.*,

- Covering for another member of the same group.
- Covering call for another provider with an established provider-patient relationship.
- Initial admissions or necessary care pending first appointment.
- Emergency.
- Consultations without charge.
- Others.

Informed Consent

- **Telehealth provider must generally obtain informed consent from the patient or their personal representative.**
- **Some states have specific requirements for telehealth consents, *e.g.*,**
  - Written documentation of informed consent
  - Information that must be disclosed, *e.g.*,
    - Provider licensure info
    - Risks and benefits of telehealth
    - How to contact provider
    - Others
- **Treating provider usually has the obligation to ensure sufficiently informed consent is obtained.**

Informed Consent

In telehealth context, consider discussing:

- Patient's condition and proposed treatment
- Risks and benefits of treatment
- Alternatives and risks and benefits of alternatives
- Persons/entities providing services
- Limitations of telehealth
  - Limited evaluation or treatment
  - Possible disruption
  - Privacy or security concerns
- Disclaim liability for contractors
- Other relevant facts

Standard of Care

- **In most states, telehealth must be provided consistent with the in-person standard of care.**
  - No special "telehealth" standard of care.
  - Ensure telehealth is appropriate under the circumstances and that you can satisfy the community standard of care.

- **Typically requires:**
  - Appropriate history, evaluation, diagnosis and treatment plan.
    - Online questionnaire is insufficient.
  - Appropriate follow up.
  - Document care rendered and maintain documentation in patient's medical record.
  - Involve or refer to other providers when necessary.

AMA Ethical Practice in Telemedicine

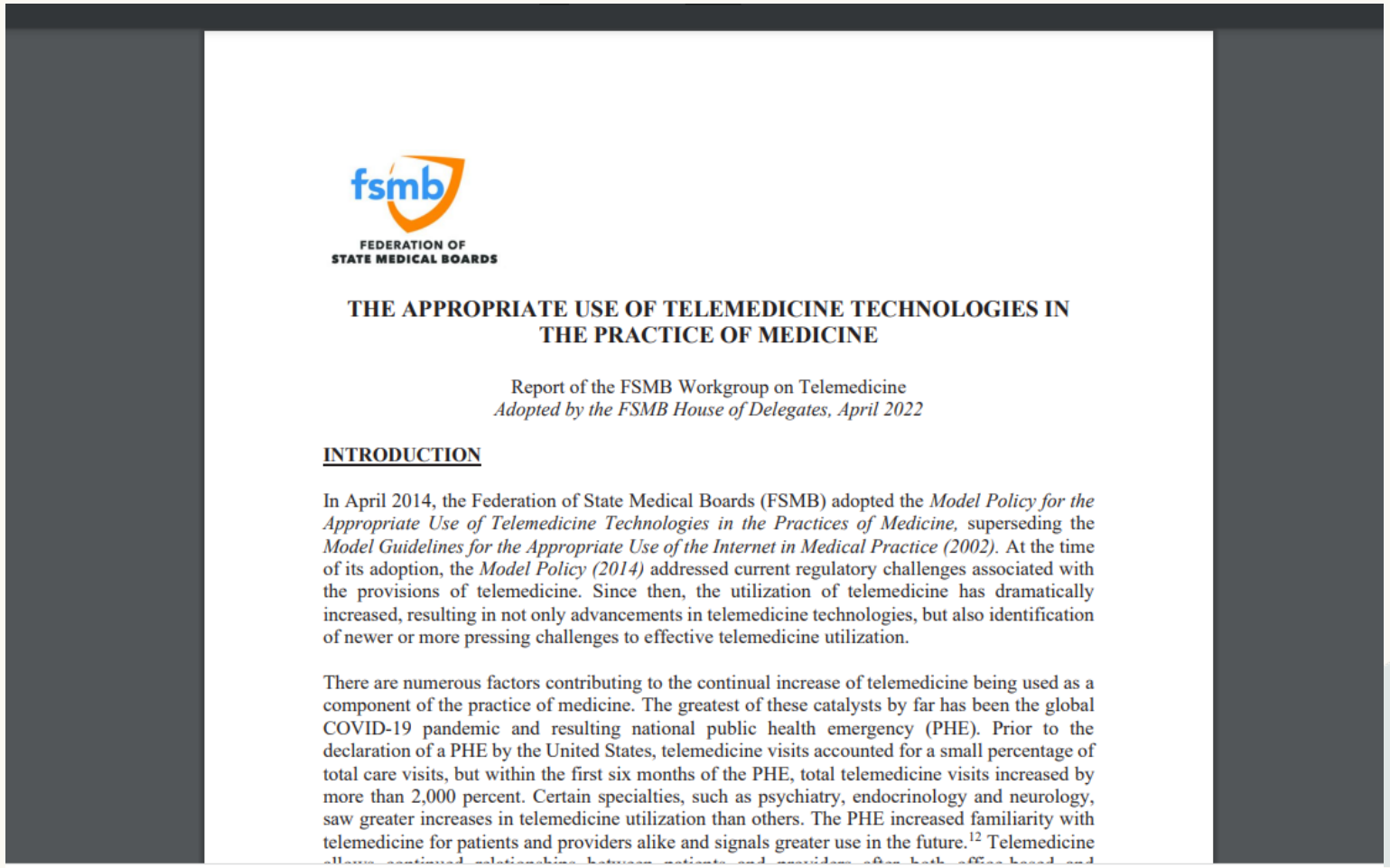
Physicians who provide clinical services through telehealth should:

- 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%20conflicts%20of%20interests)

FSMB Guide re Appropriate Use of Telehealth

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



FEDERATION OF STATE MEDICAL BOARDS

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 declaration of a PHE by the United States, telemedicine visits accounted for a small percentage of total care visits, but within the first six months of the PHE, total telemedicine visits increased by more than 2,000 percent. Certain specialties, such as psychiatry, endocrinology and neurology, saw greater increases in telemedicine utilization than others. The PHE increased familiarity with telemedicine for patients and providers alike and signals greater use in the future.[12] Telemedicine

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Remote Prescribing

- **Many states impose requirements for remote prescribing, *e.g.*,**
  - Require establishment of physician-provider relationship.
    - Historically, required in-person interaction.
    - Now, most if not all states allow provider to establish relationship through telehealth platform.
    - Online questionnaires are insufficient.
  - **Common exceptions for:**
    - Covering for another member of the group.
    - Covering call for a provider with a provider-patient relationship.
    - Emergency.
    - Prescription upon admission.
    - Prescription pending first encounter.
    - Others?

Remote Prescribing: Ryan Haight 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.

    (21 USC 829; 21 CFR 1306.09)
- During COVID-19 emergency, DEA allowed remote prescribing following an evaluation through telephone or interactive audio-visual communications.

Remote Prescribing: Ryan Haight Act

- **DEA has proposed rules to allow for 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)
- **Meanwhile, DEA and HHS, has extended the current telemedicine flexibilities for controlled substance prescribing through 2025 (via a third temporary rule).**
  - Allows schedule II-V controlled substances to be prescribed via telemedicine, without an in-person evaluation of patient.
  - Must be for a legitimate medical purpose
  - Must use interactive telecommunications system
  - Practitioner must have DEA registration in state where patient resides and otherwise comply with state law (e.g., state license and controlled substance license/registration).

Remote Prescribing: 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)

Continuity of Care

- **Once established, provider-patient relationship continues until properly terminated.**
  - Notice + sufficient time to transfer care + necessary care until transferred.

- **Failure to provide continuing care =**
  - Professional misconduct.
  - Patient abandonment.
  - Malpractice.

➢ *Clarify scope of care and confirm expectations for continuing care.*

Credentialing and Privileging

Credentialing Telehealth Providers

- **Hospitals must credential and privilege providers rendering services at the hospital.**
- For telehealth providers, hospital's board may decide whether to credential them:
  - Individually, like other providers; or
  - By proxy if certain conditions are satisfied, i.e., hospital relies on credentialing done by the distant site.
- Credentialing by proxy only applies to those rendering telehealth; it does not apply if telehealth provider renders services personally at the hospital.

Credentialing Telehealth by Proxy

- **Hospital and CAH CoPs allow hospital to rely on credentialing done by remote hospital/entity (credentialing by proxy) if:**
  - Hospital bylaws allow it.
  - Have written credentialing agreement with distant site that contains required terms.
  - Distant site complies with CoP standards.
  - Practitioner privileged at distant site.
  - Practitioner licensed in state where services provided.
  - Hospital reviews practitioner's performance and provides results to distant site.

(42 CFR 482.12 and .22, 485.616 and .635)

Credentialing Telehealth by Proxy

Hospital COP Survey Procedures § 482.12(a)(8) and (a)(9)

- Ask whether hospital uses telemedicine services. If yes:
- Ask to see a copy of the written agreement(s) with the distant-site entities. Does each agreement include the required elements for credentialing and privileging telehealth providers?
- Does the hospital have documentation indicating that it granted privileges to each telehealth provider?
- Does the documentation indicate that for each telemedicine physician and practitioner there is a medical staff recommendation, including an indication of whether the medical staff conducted its own review or relied upon the decisions of the distant-site hospital or telemedicine entity?

(CMS SOM App. A at 482.12(a)(8)-(9))

Credentialing Telehealth Providers

- **Hospitals may need to update medical staff bylaws or policies to address telehealth.**
  - Qualifications for medical staff members.
    - *e.g.*, geographic proximity, admissions, etc.
  - Categories of medical staff members.
    - *e.g.*, add telehealth staff category
  - Privileges.
    - *e.g.*, grant telehealth privileges by proxy consistent with COPs.
  - Credentialing process.
    - *e.g.*, allow credentialing by proxy based on COPs.

Credentialing Telehealth Providers

- "All CAHs must, as a part of their quality assurance program, have an arrangement with an outside entity to review the appropriateness of the diagnosis and treatment provided by each MD/DO providing services to the CAH's patients. This includes MDs and DOs providing telemedicine services to the CAH's patients from a distant-site hospital or distant-site telemedicine entity.

(SOM App. for 586.641(b))

Corporate Practice of Medicine ("CPOM")

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Corporate Practice of Medicine

- **In some states, physicians may not be employed by corporations.**
  - Concern that non-physicians may influence physician conduct.
  - Medical practices acts interpreted to prohibit corporations from "practicing medicine" through employed physicians.
  - Statutes prohibit physicians from practicing medicine as an employee of corporation.

  E.g., California, Washington, New York, Texas, etc.

- Penalties may include fines, criminal penalties for "aiding and abetting" the unauthorized practice of medicine, adverse licensure actions, or injunctions to stop practice.

Corporate Practice of Medicine

- **CPOM is usually subject to exceptions.**
  - Statutes expressly allow or contemplate that certain entities may employ physicians (e.g., hospitals, managed care organizations, other licensed entities).
  - Professional corporations, professional limited liability companies, etc.
- CPOM usually does not apply to independent contractors.
- CPOM usually does not apply to advanced practice professionals.

➢ Physicians and corporations employing physicians must beware CPOM when practicing across state boundaries.

Privacy and Security

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
- **Ensure you are using a secure platform.**
- Technical, including encryption
- Execute business associate agreements.

(45 CFR 164.300 *et seq.*)

Protect ePHI:

- Confidentiality
- Integrity
- Availability

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)

Communicating by E-mail or Text

General rule: PHI must be secure, *i.e.*, encrypted.

- **To patients:** may communicate *via* unsecure e-mail or text if warned patient and they choose to receive unsecure. (45 CFR 164.522(b); 78 FR 5634)

- **To providers, staff or other third parties:** 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)

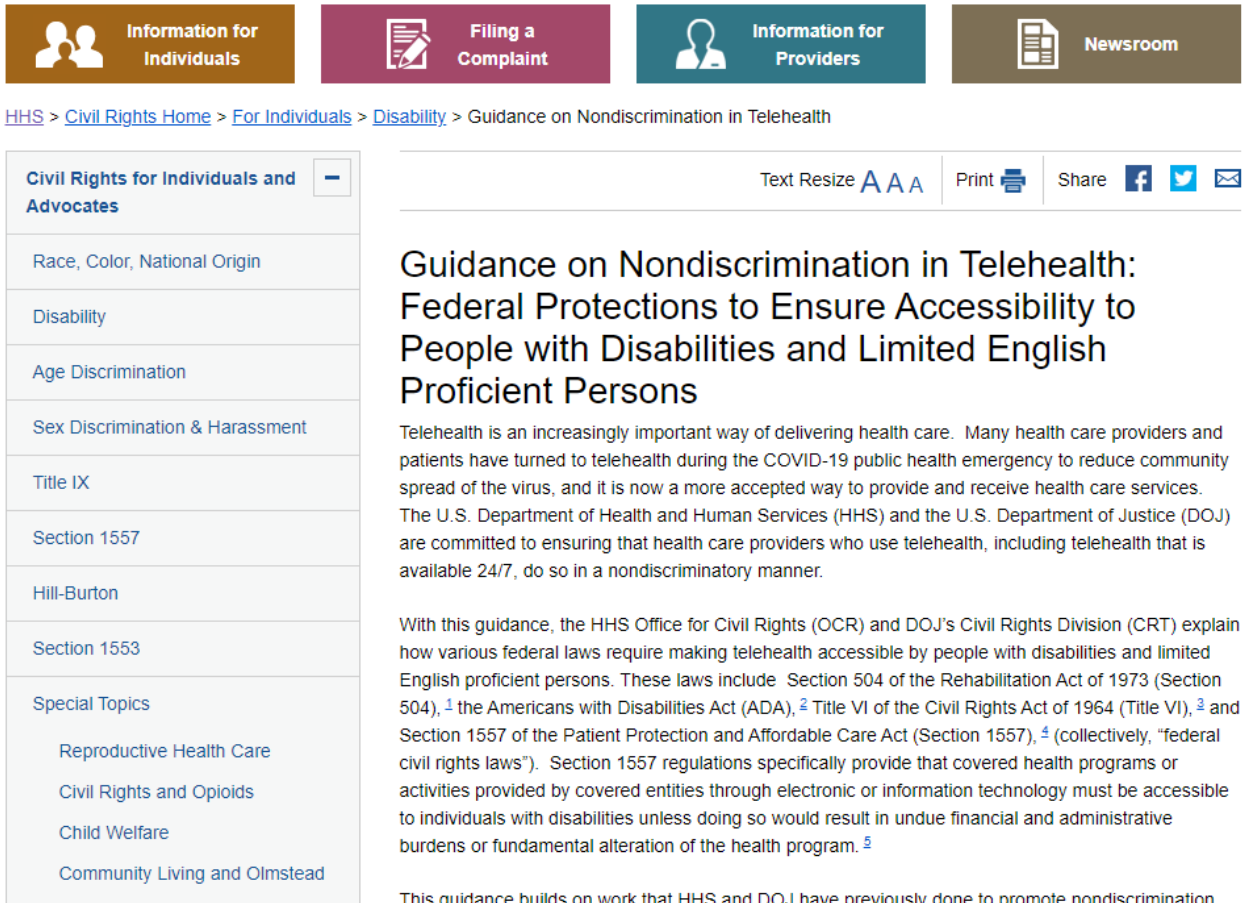
Business Associates

- **Other treating providers are <u>not</u> business associates while providing treatment.**
- **May need business associate agreement (BAA) with vendors or others who assist with telehealth,** *e.g.*,
  - Entity that maintains or transmits ePHI and has regular access to ePHI, not "conduit."
  - Entity that stores PHI.
- **Exceptions:**
  - Members of workforce.
  - Members of organized healthcare arrangement ("OHCA").

(45 CFR 164.314, -502, and .504)

Discrimination in Telehealth

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



Information for Individuals | Filing a Complaint | Information for Providers | Newsroom

HHS > Civil Rights Home > For Individuals > Disability > Guidance on Nondiscrimination in Telehealth

Civil Rights for Individuals and Advocates

- Race, Color, National Origin
- Disability
- Age Discrimination
- Sex Discrimination & Harassment
- Title IX
- Section 1557
- Hill-Burton
- Section 1553
- Special Topics
  - Reproductive Health Care
  - Civil Rights and Opioids
  - Child Welfare
  - Community Living and Olmstead

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Guidance on Nondiscrimination in Telehealth: Federal Protections to Ensure Accessibility to People with Disabilities and Limited English Proficient Persons

Telehealth is an increasingly important way of delivering health care. Many health care providers and patients have turned to telehealth during the COVID-19 public health emergency to reduce community spread of the virus, and it is now a more accepted way to provide and receive health care services. The U.S. Department of Health and Human Services (HHS) and the U.S. Department of Justice (DOJ) are committed to ensuring that health care providers who use telehealth, including telehealth that is available 24/7, do so in a nondiscriminatory manner.

With this guidance, the HHS Office for Civil Rights (OCR) and DOJ's Civil Rights Division (CRT) explain how various federal laws require making telehealth accessible by people with disabilities and limited English proficient persons. These laws include Section 504 of the Rehabilitation Act of 1973 (Section 504), [1] the Americans with Disabilities Act (ADA), [2] Title VI of the Civil Rights Act of 1964 (Title VI), [3] and Section 1557 of the Patient Protection and Affordable Care Act (Section 1557), [4] (collectively, "federal civil rights laws"). Section 1557 regulations specifically provide that covered health programs or activities provided by covered entities through electronic or information technology must be accessible to individuals with disabilities unless doing so would result in undue financial and administrative burdens or fundamental alteration of the health program. [5]

This guidance builds on work that HHS and DOJ have previously done to promote nondiscrimination

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Discrimination in Telehealth

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.

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)

Discrimination in Telehealth

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?

Different Procedures

- **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 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.*

Negligent Credentialing

- **In some states, hospitals or other providers may be liable for negligently credentialing those granted privileges, *i.e.*,**
  - Failed to properly credential a practitioner consistent with applicable standards, and
  - 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 other similarly situated providers would.

Fraud and Abuse Concerns

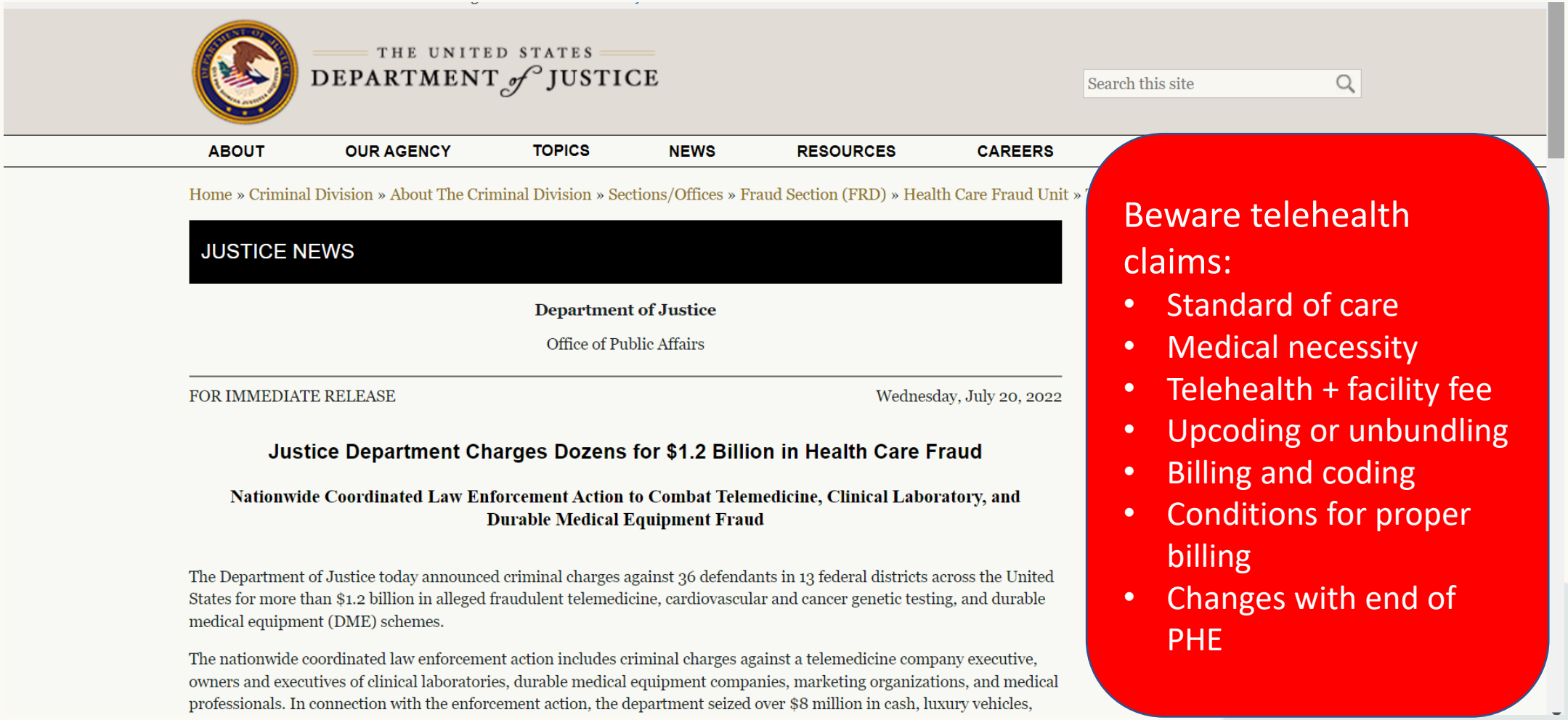
- **False Claims Act or Fraud claims based on failure to comply with telehealth billing rules.**
- **Financial relationships with telehealth providers may trigger Stark, Anti-Kickback Statute, and Civil Monetary Penalties, *e.g.*,**
  - Contracts for services.
  - Use of space, equipment, or personnel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



THE UNITED STATES DEPARTMENT of JUSTICE

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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

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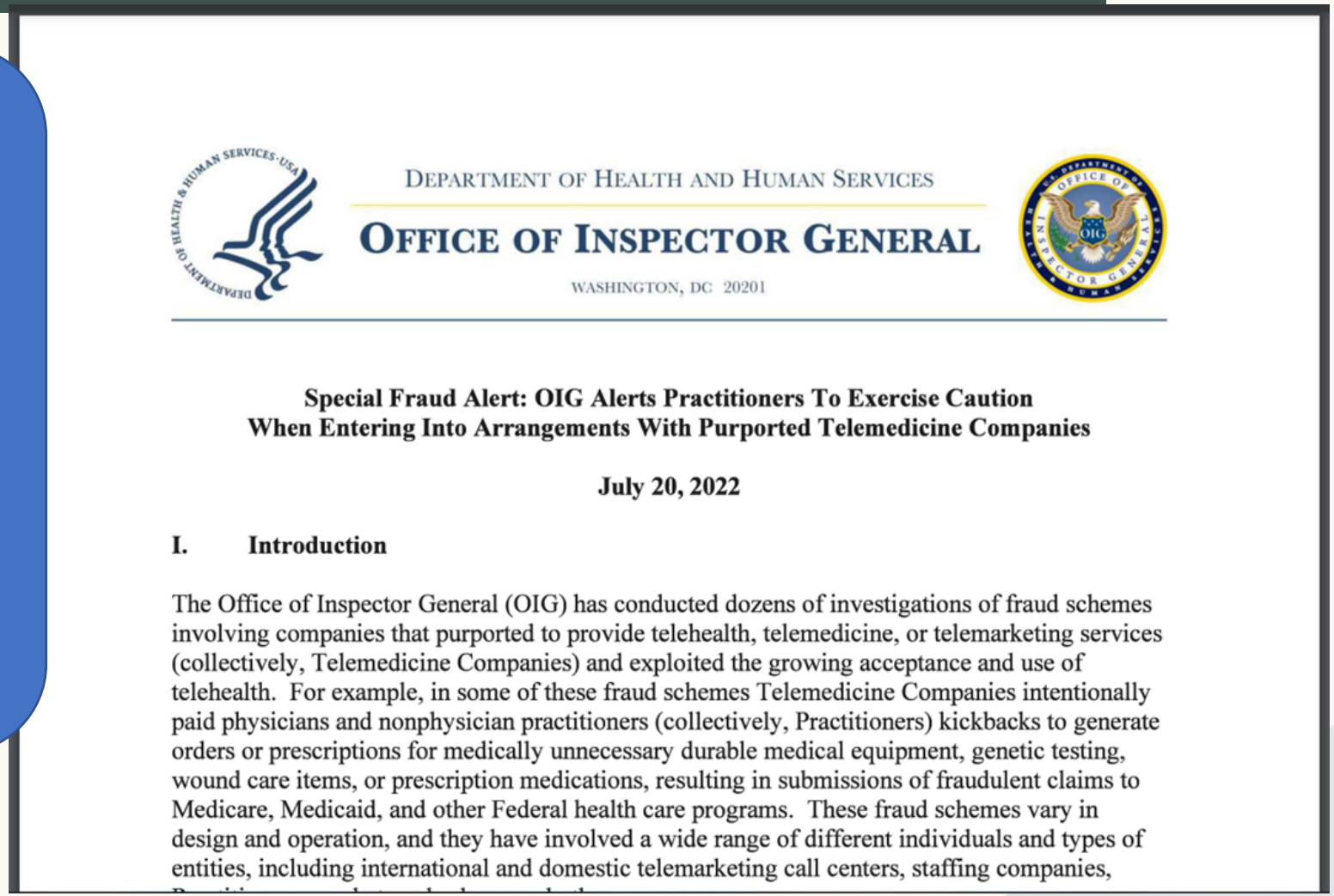
OIG Special Fraud Alert

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: Disclaimer

- I am not a billing expert.
- Reimbursement varies by state and payer.
- Check with the payer and/or your billing experts to confirm reimbursement issues….

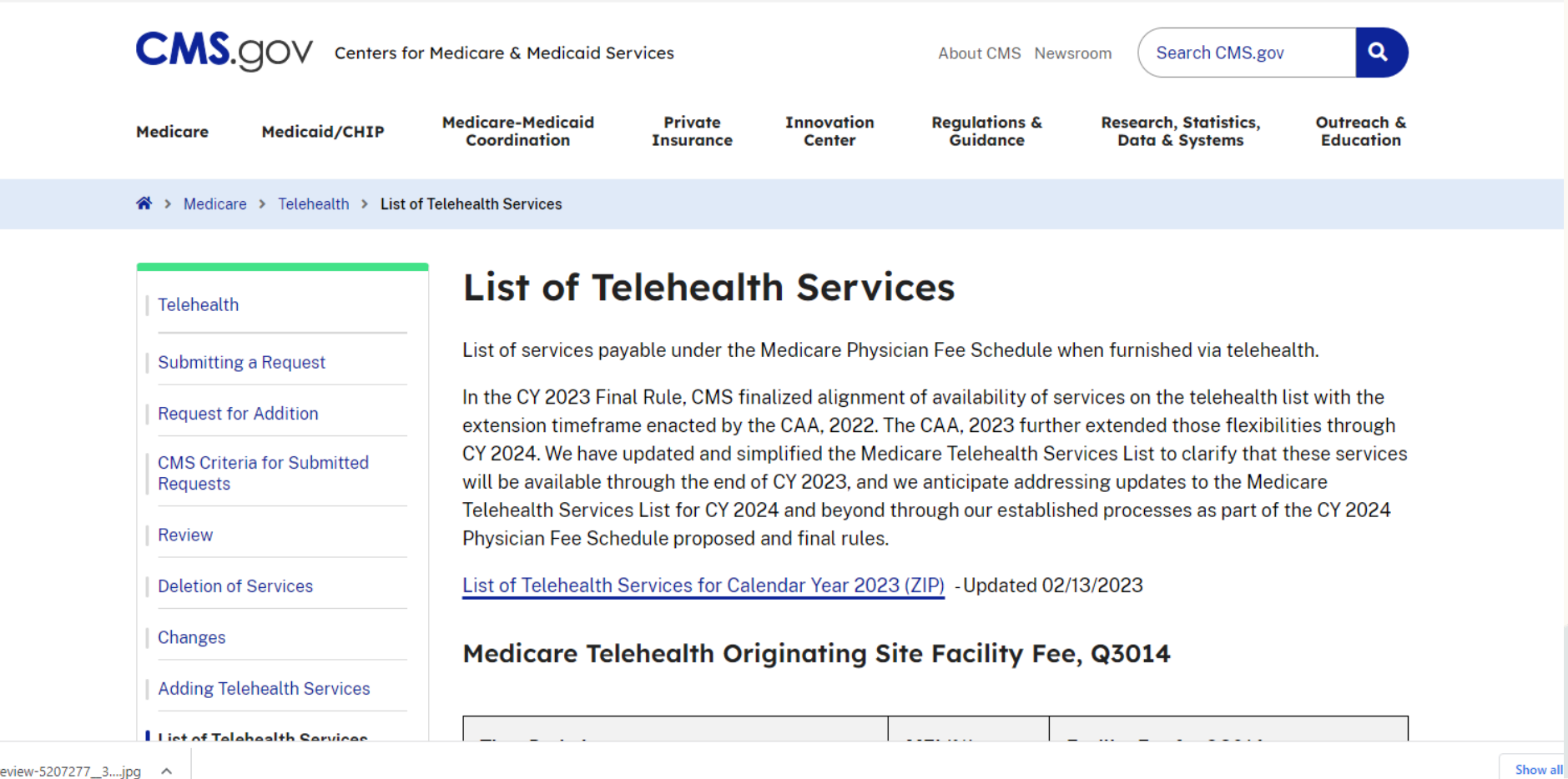
Reimbursement: Medicare

- Part A: CMS pays for telehealth if satisfy conditions of payment.
- Part B: CMS pays for certain telehealth services if use interactive audio and video telecommunications permitting real-time communication between practitioner at distant site and patient at originating site.
  - NOT asynchronous, store-and-forward technology except in demonstration projects.

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

List of Currently Covered Telehealth Services

https://www.cms.gov/medicare/medicare-general-information/telehealth/telehealth-codes



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Reimbursement: Medicare

- **In general, outside of COVID-19, 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
    - Renal Dialysis Facility
    - Community Mental Health Center
    - Participating in demonstration project
    - Patients with ESRD getting home dialysis
    - Mobile stroke units

(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)
  - Certified nurse midwife (CNM)
  - 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

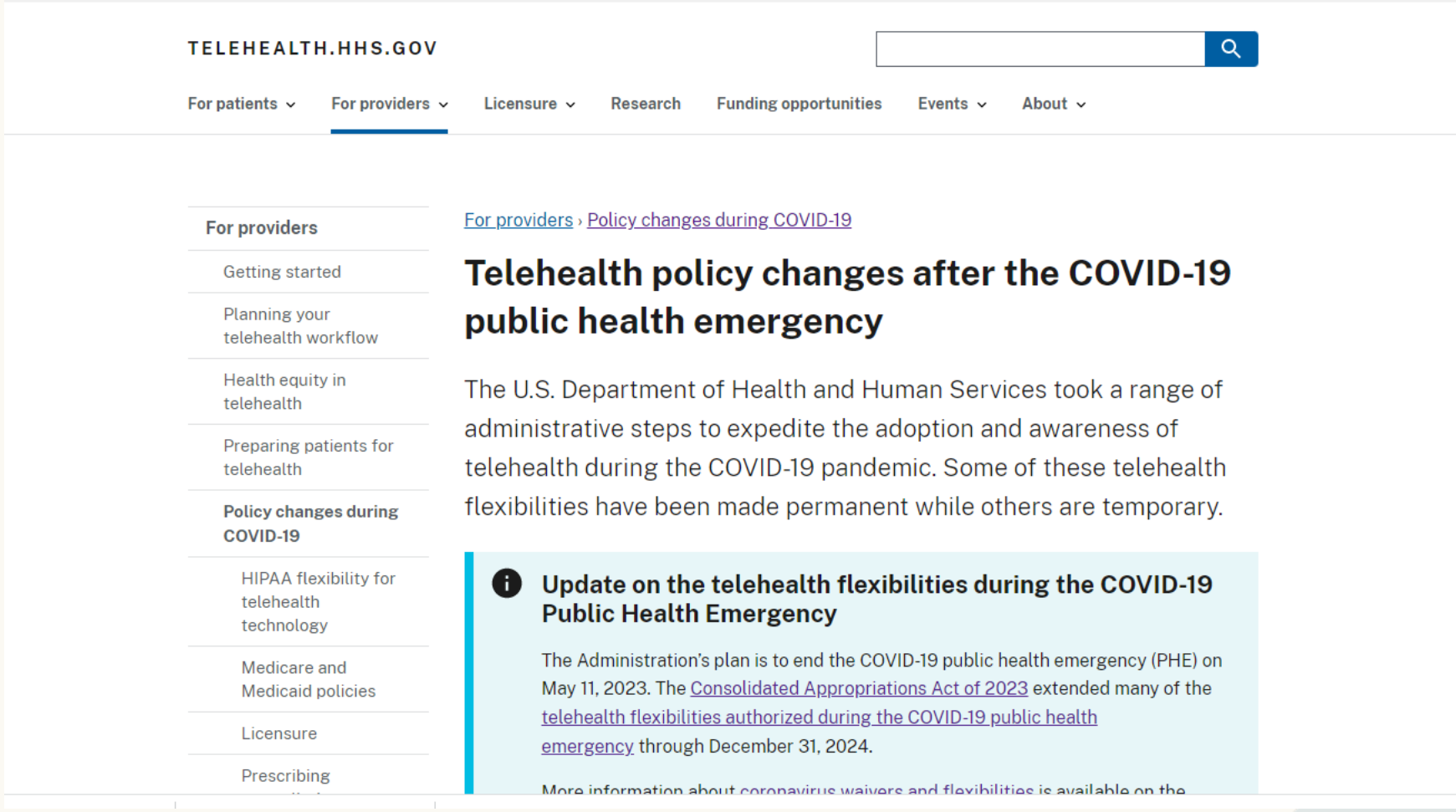
(MLN901705 (6/21))

Reimbursement: Medicare

- During COVID-19 emergency, many of the restrictions were waived and there were more flexibilities. Some of these have ended, but some remain.
- Visit https://telehealth.hhs.gov/providers/billing-and-reimbursement/medicare-payment-policies#permanent-telehealth-policy to read latest on CMS's payment policies for telehealth.

HHS Telehealth Website

https://telehealth.hhs.gov/providers



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Reimbursement: Medicare

Permanent Medicare changes:

- FQHCs and RHCs can serve as a distant site provider for behavioral/mental telehealth services.
- Medicare patients can receive telehealth services for behavioral/mental health care in their home.
- There are no geographic restrictions for originating site for behavioral/mental telehealth services.
- Behavioral/mental telehealth services can be delivered using audio-only communication platforms.
- Rural hospital emergency department are accepted as an originating site.

(https://telehealth.hhs.gov/providers/policy-changes-during-the-covid-19-public-health-emergency/policy-changes-after-the-covid-19-public-health-emergency#:~:text=The%20Consolidated%20Appropriations%20Act%20of,Medicaid%20Services%20(CMS)%20website)

Reimbursement: Medicare

Temporary Medicare changes through September 30, 2025

- Medicare patients can receive telehealth services for non-behavioral/mental health care in their home.
- There are no geographic restrictions for originating site for Medicare non-behavioral/mental telehealth services.
- Telehealth services can be provided by all eligible Medicare providers.
- FQHC/RHC can be a distant site provider for non-behavioral/mental telehealth.
- No requirement for in-person visit for behavioral/mental telehealth service
- Some non-behavioral/mental telehealth services can be delivered using audio-only communication platforms.

https://telehealth.hhs.gov/providers/telehealth-policy/telehealth-policy-updates#:~:text=The%20Consolidated%20Appropriations%20Act%20of,Medicaid%20Services%20(CMS)%20website

Reimbursement: Medicare

Permanent Medicare changes:

- Interactive telecommunications system may include two-way, real-time audio-only communication technology for any telehealth service furnished to a patient in their home if the distant site physician or practitioner is technically capable of using an interactive telecommunications, but the patient is not capable of, or does not consent to, the use of video technology.
- FQHCs and RHCs can serve as a Medicare distant site provider for behavioral/mental telehealth services.
- Medicare patients can receive telehealth services for behavioral/mental health care in their home.
- Behavioral/mental telehealth services can be delivered using audio-only communication platforms.
- There are no geographic restrictions for originating site for Medicare behavioral/mental telehealth services.
- Marriage and family therapists and mental health counselors can serve as Medicare distant site providers.

https://telehealth.hhs.gov/providers/telehealth-policy/telehealth-policy-updates#:~:text=The%20Consolidated%20Appropriations%20Act%20of,Medicaid%20Services%20(CMS)%20website

Reimbursement: Medicaid

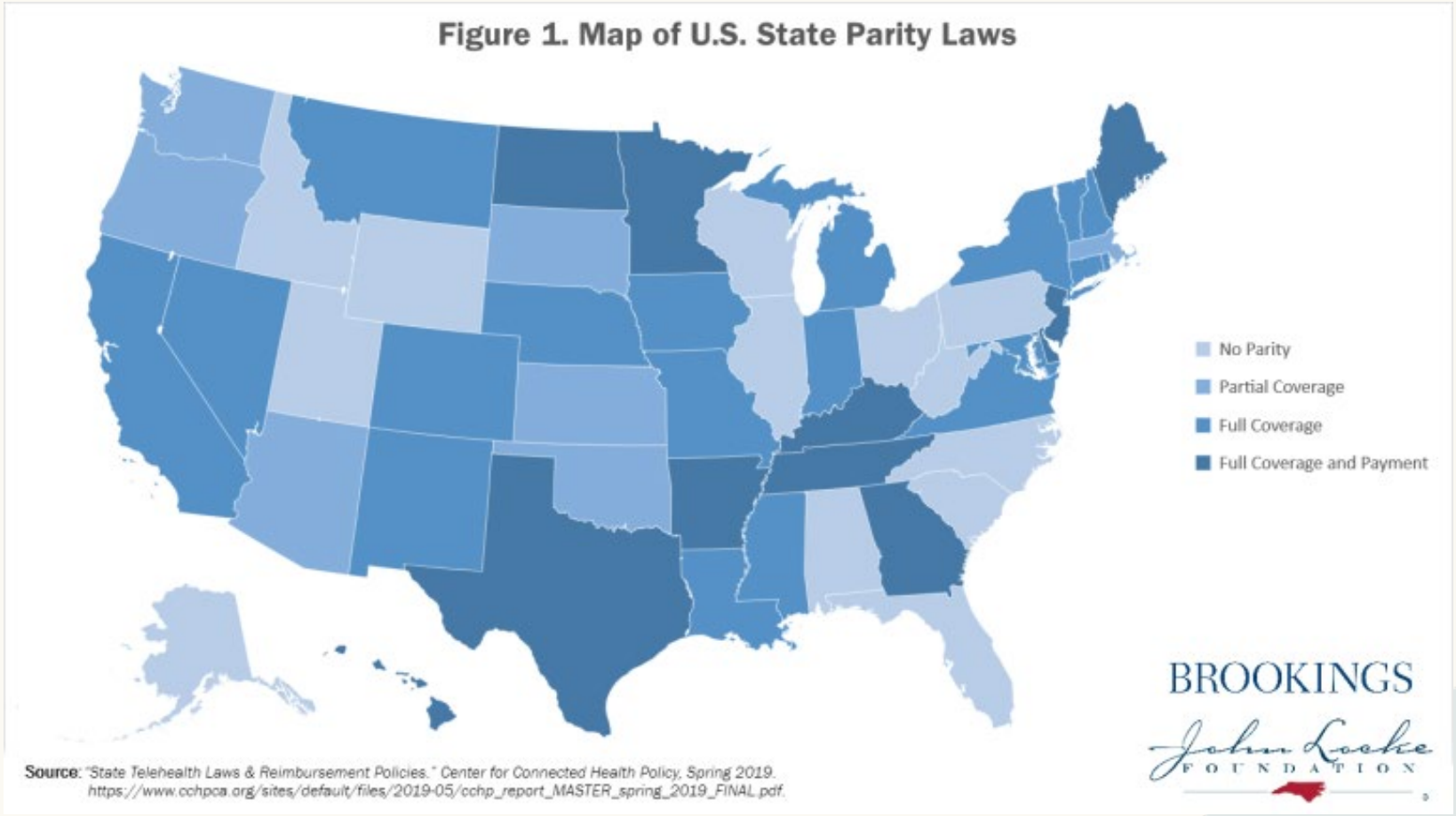
- **States have flexibility in covering telehealth so long as it furthers "efficiency, economy and quality of care."**
- **Most states provide coverage for some telehealth services.**
  - Usually cover live-video conferencing, not "store and forward" technology.
  - Often cover professional fee + facility 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

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

Telehealth Parity Laws



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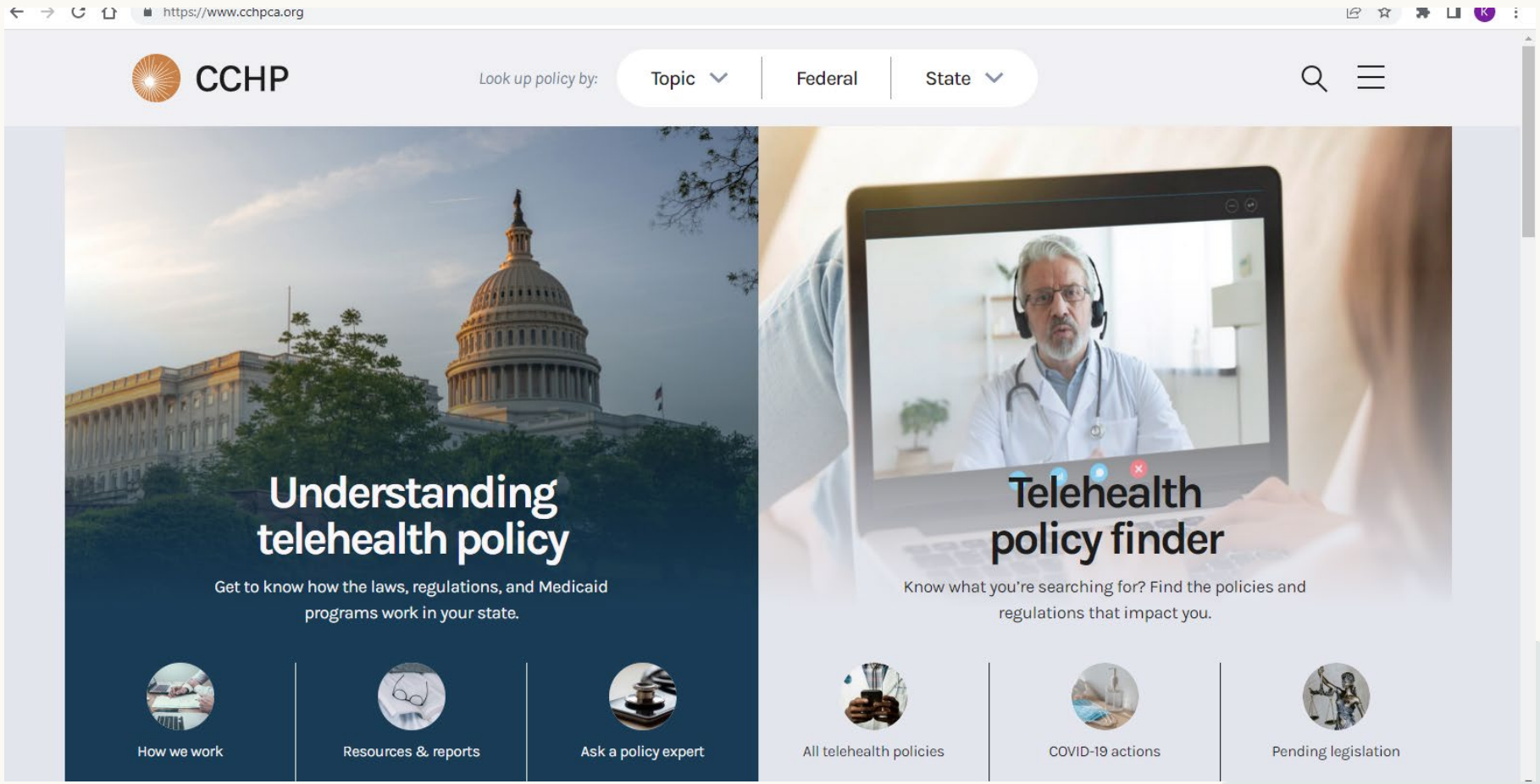
Reimbursement

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

Additional Resources

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



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HHS, https://telehealth.hhs.gov

TELEHEALTH.HHS.GOV

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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.

Preparing patients for telehealth

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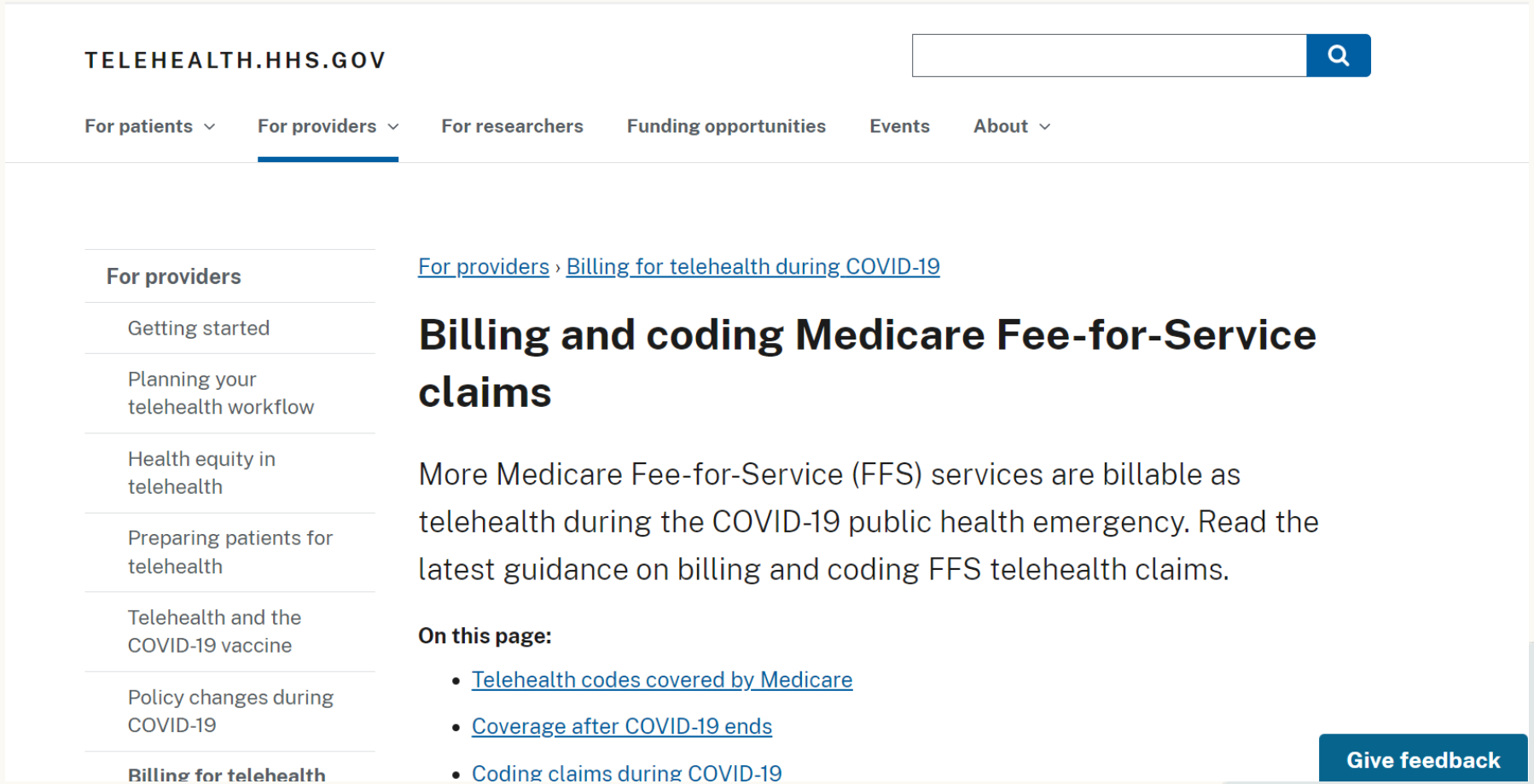
https://telehealth.hhs.gov/providers/billing-and-reimbursement/billing-and-coding-medicare-fee-for-service-claims/



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Additional Resources

- Federation of State Medical Boards,
  - 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

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Our team provides holistic guidance on regulatory issues, including Stark, Anti-Kickback Statute, HIPAA, Medicare/Medicaid, and similar state laws. We handle provider and payor contracting; mergers, acquisitions, and joint ventures; data privacy and security; licensing, credentialing and medical staff issues; government investigations and False Claim Act litigation; antitrust and trade regulation; employment; real estate; tax; employee benefits; and administrative or civil litigation. Given our combined experience, there is not much our healthcare clients face that we haven't seen and successfully handled before.

Innovations in healthcare delivery and device and pharmaceutical design are also often top priorities for our clients. Our intellectual property and life sciences groups combine legal expertise in patent, trademark, and IP licensing, with sophisticated scientific knowledge to protect and monetize innovations and emerging technologies.

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