





Legal & Regulatory Considerations for Telehealth (in the time of COVID-19)

Recorded April 8, 2021

Nancy S. Rowe, Associate Director, Public Policy & Outreach Arizona Telemedicine Program



l'm not an attorney.

Consult an attorney.

This is complicated!

Compliance Department



"I'll be honest ... there are books by James Joyce that are easier to follow than these bad boys."





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Everything has changed.

Mat least for how.

Telemedicine Law

- Healthcare laws & regulations still apply* regardless of whether in person or via telehealth:
 - Licensing
 - Prescribing
 - Anti-kickback/Stark
 - Other fraud & abuse laws
 - Liability
 - Standard of care
 - HIPAA & HITECH
 - Corporate Practice of Medicine

*Unless waived or loosened during the national healthcare emergency







Informed Consent

 Most jurisdictions include some sort of informed consent requirements in statutes, administrative code, and/or Medicaid policies

• Basics:

- Pt. rights, including right to stop or refuse tx via telemed
- Pt responsibilities
- Formal complaint/grievance process
- Potential benefits, constraints, risks
- Discuss plan in case tech fails during session, state contingency plan





Medical Malpractice & Telemedicine

- Telemed coverage may not be included in standard medical malpractice policies: ask your insurer about TM & coverage in other states
- Act within scope of licensure
- Follow pt.-state laws & regs, provider state, federal law, clinical guidelines
- Mitigate risk with strong provider credentialing practices & training specific to telemedicine delivery



• Adopt same quality assurance & peer review practices as in-person





Provider Location – Did You Know?

• Medicare: Distant Site Provider must (still) be physically located within US



1 claim was for services provided by a physician located outside the United States (A physician residing and
practicing psychiatry in Pakistan provided psychiatric counseling services through telehealth technology to a
patient located at a rural medical center in the United States. The service was unallowable because the physician
was located outside the United States.).



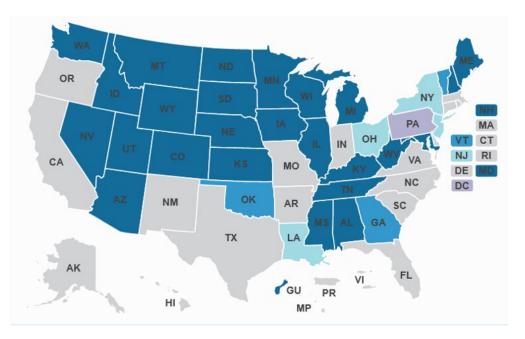




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Licensure: Evolving

- Telemedicine provider must be licensed in pt. state ... or ...
- Interstate licensure compacts:
 - Interstate Medical Licensure Compact (2016)
 - Enhanced Nurse Licensure Compact (2018)
 - PSYPACT (Psychology) (2016)
 - Physical Therapy Compact (2016)
 - REPLICA: Interstate EMS Compact
 - Audiology & Speech-Language Pathology Interstate Compact (in progress)







Licensure Special Cases

- Peer-to-peer consultations
- Provider licensure in home state?
- Federal programs (VA, IHS, tribal)
- Seeing your own established pt. in another state where you are not licensed? (WA says yes)
- Licensure waivers for COVID-19: Medicare & States/Medicaid
- PREP Act: Covered Countermeasures—includes TH providers

IZONA

OGRAM



Laura Dyrda (Twitter) - Friday, December 4th, 2020 Print | Email

in Share 🎔 Tweet 😝 Share 7

HHS will continue to allow clinicians to provide telehealth services across state lines for covered services, including diagnostic tests, to fight the spread of COVID-19.

On Dec. 3, HHS amended the Declaration under the Public Readiness and Emergency Preparedness Act to allow healthcare providers to order or administer "covered countermeasures" to COVID-19, such as diagnostic tests that received emergency use authorization from the FDA across state lines.

Many states now allow healthcare providers to deliver telehealth services from out-of-state during the pandemic, or generally, and the amendment solidifies telehealth coverage for COVID-19 countermeasures, regardless of where the patient and clinician reside.

The amendment preempts state laws prohibiting telehealth across state lines. The department said it aims to release more information about how the amendment affects Medicaid and Children's Health

New Telehealth Bill Would Penalize States Who Don't Join Licensure Compact

A bill introduced last month would deny certain federal states who don't join the Interstate Medical Licensure C which aims to improve telehealth expansion by streaml licensure applications.







November 24, 2020 - A group of Congressmen wants to prod states into joining t Medical Licensure Compact, which aims to make it easier for providers to use teld patients in other states.

Congress Gets Another Shot at Easing Telehealth Licensure Restrictions

The TREAT Act, which has the support of dozens of health sy and connected health organizations, would allow providers bypass licensing rules and use telehealth to treat patients in state during the coronavirus pandemic.

mHEALTH

Source: ThinkStock **By Eric Wicklund**

February 08, 2021 - Lawmakers have re-introduced a bill that would allow healthcare to use telehealth to treat anyone in the any state throughout the coronavirus pandemic

f

The Temporary Reciprocity to Ensure Access to Treatment (TREAT) Act, fil the House and Senate this past week aims to allow providers to bypass state and feder

Connected Care Alliance Seeks Support for New Telehealth Licensure Rules

The Alliance for Connected Care is preparing a letter to federal and state lawmakers that would support new policies that allow providers to use telehealth to treat patients in other states.



November 16, 2020 - The Alliance for Connected Care wants to make it easier for health systems and hospitals to use telehealth to treat patients no matter where they live.

Provider-Patient Relationship

- **Medicare** allows video substitute for in-person exam: live, 2-way, real-time, A/V interactive communication
- FSMB guidelines: relationship can be established when physician is remote, with verified pt. ID & disclosure & validation of doc ID & credentials, + appropriate consents
- AZ does not require in-person exam to establish relationship – follows Medicare requirements (no S&F)
- Required to prescribe





Telemedicine Prescribing

- AZ Medical Board Policy Statement: Telemedicine should not be confused with internet prescribing.
 - Established provider-pt. relationship
 - Not just an internet questionnaire
 - Not just a phone call*



* Except for certain uses during PHE





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The DEA & Telemedicine

- Ryan Haight Act (2009):
 - To prevent illegal distribution & dispensing of controlled substances through the Internet
 - Must write a valid prescription for a legit medical purpose
 - Must follow laws of pt. state
 - Must be issued by practitioner who has conducted at least 1 in-person medical eval of pt. <u>OR</u> who meets 1 of 7 telemedicine exceptions ...







DEA Telemedicine Exceptions

- 1. Pt is being treated by & located in a DEA-registered hospital or clinic (or VA practitioner)
- 2. Telemedicine conducted with pt. in physical presence of another practitioner with DEA registration in pt. state (or VA)
- 3. IHS or tribal organization
- 4. Public health emergency
- 5. Special registration for telemedicine
- 6. VA medical emergency with limitations



7. Other circumstances agreed on by HHS & DEA regulation





DEA Updates



Telemedicine

On January 31, 2020, the Secretary of the Department of Health and Human Services issues a public health emergency (HHS Public Health Emergency Declaration).

Question: Can telemedicine now be used under the conditions outlined in Title 21, United States Code (U.S.C.), Section 802(54)(D)?

Answer: Yes

While a prescription for a controlled substance issued by means of the Internet (including telemedicine) must generally be predicated on an in-person medical evaluation (**21 U.S.C. 829(e)**), the Controlled Substances Act contains certain exceptions to this requirement. One such exception occurs when the Secretary of Health and Human Services has declared a public health emergency under 42 U.S.C. 247d (section 319 of the Public Health Service Act), as set forth in 21 U.S.C. 802(54)(D). Secretary Azar declared such a public health emergency with regard to COVID-19 on January 31, 2020 (https://www.hhs.gov/about/news/2020/01/31/secretary-azar-declares-public-health-emergency-us-2019-novel-coronavirus.html). On March 16, 2020, the Secretary, with the concurrence of the Acting DEA Administrator, designated that the telemedicine allowance under section 802(54)(D) applies to all schedule II-V controlled substances in all areas of the United States. Accordingly, as of March 16, 2020, and continuing for as long as the Secretary's designation of a public health emergency remains in effect, DEA-registered practitioners in all areas of the United States may issue prescriptions for all schedule II-V controlled substances to patients for whom they have not conducted an in-person medical evaluation, provided all of the following conditions are met:

- The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice;
- The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system; and
- The practitioner is acting in accordance with applicable Federal and State laws.

3/31/2020 DEA Letter

- Buprenorphine can be prescribed to new & existing pts with OUD for maintenance or detoxification tx on the basis of a telephone eval.
 - Must ensure Rx is for legit medical purpose
 - Must feel adequate eval can be accomplished via telephone



- For DEA-registered opioid treatment programs: if program physician, PCP, or authorized healthcare professional under supervision of program physician determines adequate eval can be done by phone
- DATA-waivered practitioners complying with applicable standards of care
- State laws override if more strict





OCR HIPAA Enforcement Discretion

- No penalties for noncompliance with HIPAA rules for good faith provision of telehealth
- Can use any non-public-facing audio or video communication products
 - Examples: FaceTime, FB Messenger video chat, Google Hangouts, nonhealthcare Zoom, Skype
- For any medical condition not just COVID-19
- Recommend using HIPAA-compliant
- Notify pts. of potential privacy risks, enable all possible encryption & privacy modes







State Privacy & Security Laws

- You could avoid trouble with the OCR, but could be violating STATE privacy laws
- Also check state requirements re: using a noncompliant platform

- A medical provider that pursuant to this Order offers telehealth services that do not comply with the federal Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936, as amended, or the federal Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, 123 Stat. 226, 467, as amended, shall:
 - a. inform the patient the telehealth service does not comply with those federal acts;
 - b. give the patient an opportunity to decline use of the telehealth service; and
 - c. take reasonable care to ensure security and privacy of the telehealth service.

This Order shall take effect September 26, 2020, and shall remain in effect through September 29, 2020, or until otherwise lawfully modified, amended, rescinded, or superseded.



IN WITNESS WHEREOF, I have hereunto set my hand and caused to be affixed the Great Seal of the State of Utah. Done in Salt Lake City, Utah, on this, the 25th day of September, 2020.

Gary R. Herbert Governor



DOJ arrests 35 in \$2.1B Medicare scam targeting seniors for fraudulent genetic testing

by Heather Landi | Sep 30, 2019 7:45am



Telehealth In the Spotlight as Justice Cracks Down on Medicare Fraud

As federal officials crack down on multi-million-dollar Medicare fraud cases involving telehealth companies, the American Telemedicine Association issues a statement den illegal activities.



Telehealth providers doing 'more visits than humanly possible' in a day draw CMS scrutiny

Twitter) - yesterday Print | Email

mHealth Companies Fined for Medicare Fraud on Wearable Monitors

The makers and markete monitoring have been fir to seek Medicare reimbu services.

Fed Crackdown on Genetic Testing Scam Targets Telemedicine Network

For the second time this month, the Justice Department has announced a crackdown on individuals and companies who have

Telemedicine Providers Charged in Medicare Fraud Investigation

Five telemedicine providers have been charged by federal officials in a massive Medicare fraud scheme that has reportedly cost the agency more than \$1.2 billion.



CMS Administrator Seema Verma reiterated the success of telebaalth during the pandemic and said the adency continues to

Payer

DOJ charges hundreds in connection with \$6B in healthcare fraud in largest takedown ever

by Paige Minemyer | Sep 30, 2020 5:05pm



in

The Department of Justice (DOJ) charged 345 people across 51 federal districts in the largest healthcare fraud takedown in the agency's history.

The DOJ said the charges were in connection with cases responsible for more than \$6 billion in losses. Among those charged were more than 100 doctors, nurses and other medical professionals, according to the DOJ.

The billions in false claims were submitted to both public and private insurers, the DOJ said, with

more than \$4.5 billion connected to telemedicine schemes.

4 South Carolina physicians charged in \$100M billing fraud case

Ayla Ellison (Twitter) - Thursday, October 8th, 2020 Print | Er



Four physicians and a nurse in South Carolina were charged conspiracy involving more than \$100 million in fraudulent billir Oct. 7.

The five medical providers allegedly signed prescriptions usin speaking with or meeting the patients. They allegedly wrote the using only information provided by a telemedicine company the *The Post and Courier*.

The five clinicians are among more than 40 people in South 0 for their roles in alleged healthcare fraud schemes. The charg telemedicine fraud takedown.

7 plead guilty in \$931M telemedicine fraud scheme

Ayla Ellison (Twitter) - an hour ago Print | Email

The owner of two pharmacies and a management company in Florida pleaded guilty Jan. 25 to his role in a \$931 million healthcare fraud scheme. He is the seventh defendant to plead guilty in the scheme, according to the U.S. Justice Department.

Larry Smith pleaded guilty to conspiracy to commit healthcare fraud, and his sentencing is set for Oct. 25. In his written plea agreement, Mr. Smith admitted to conspiring with others to defraud pharmacy benefit managers into paying for fraudulent prescriptions. As part of the plea agreement, Mr. Smith agreed to pay restitution of \$24.9 million and forfeit approximately \$3.1 million.

An indictment charged Mr. Smith and others with a nationwide conspiracy to defraud pharmacy benefit managers by submitting \$931.4 million in bills for fraudulent prescriptions purchased from a telemarketing company. After improperly soliciting patient information, the marketing companies received approvals through telemedicine prescribers then sold the prescriptions to pharmacies in exchange for kickbacks, said Derrick Jackson, special agent in charge at HHS' Office of Inspector General in Atlanta.

In September 2018, HealthRight, a telemedicine company, and its CEO Scott Roix pleaded guilty to

FOR IMMEDIATE RELEASE

Wednesday, October 7, 2020

Operation Rubber Stamp: Major health care fraud investigation results in significant new charges

Takedown involves first billion-dollar fraud case in district history



oy, U.S. Attorney, District of South Carolina; Bobby L. Christine, U.S. Attorney, Southern n Kessler, Resident Agent in Charge, U.S. Secret Service Savannah Office; Will ecial Agent, FBI Savannah Office; Douglas Dye, Special Agent, FBI; and Jonathan torney, Southern District of Georgia.

he third in a nationwide series of telemedicine fraud prosecutions includes cases in If Georgia identifying more than \$1.5 billion in fraudulent billings to government rograms.

ed Operation Rubber Stamp, and following two similar nationwide Department of

Stark Law







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Stark Law (Physician Self-Referral Law)

- Prohibits physicians from referring pts. for healthcare service payable by Medicare / Medicaid to an entity with which the physician has a financial relationship
- Goal: protect pts. from being steered to less convenient, lower quality, more expensive services due to physician's financial self-interest
- Severe financial penalties (\$15K per wrongful claim + 3x amount of government overpayment)
- Intent is not required!
- Exceptions include compensation or leases at FMV





Stark Law During COVID-19 PHE

- OK to pay physician above or below FMV
- OK to rent office space or lease equipment below FMV
- OK to loan with interest rate below FMV or on terms unavailable from lender
- Certain referrals OK







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Anti-Kickback Statute (AKS)

- Severe financial penalties (Up to \$100K per wrongful claim) & up to 10 years in prison
- Applies to **anyone**, **all** federal healthcare programs
- Prohibits knowingly offering or soliciting anything of value, directly or indirectly, in return for pt. referrals for Medicare services
- Telehealth space & equipment can be problematic







AKS Safe Harbors

- HHS Office of the Inspector General
- Guidance letters for specific TH arrangements "Safe Harbors"
- Specific to programs that requested
- Costly & lengthy process
- Fit into as many as you can!







CMS, OIG Stark/AKS Final Rule

- New, permanent exceptions for certain Value-Based Arrangements, Care Coord, Cybersecurity Tech & Services, Pt. Engagement & Support Tools (mHealth, TH), etc.
- Guidance on issues like determining FMV
- Clarifications to reduce admin burden
- Effective 1/19/2021

Stark Law Changes Should Benefit Telehealth, Remote Patient Monitoring

The OIG's Final Rule on changes to the Stark Law and Anti-Kickback Statute creates several new safe harbors that will help providers create and expand telehealth platforms and remote patient monitoring programs.







November 24, 2020 - New safe harbors proposed for the Stark Law and Anti-Kickback Statute could help providers expand their telehealth and remote patient monitoring platforms.



Violations lead to more liability

• False Claims Act:

- Liability on persons & companies who defraud gov. programs
- If claim results from kickback or is made in violation of Stark Law, can form basis of FCA litigation - \$\$\$
- Civil Monetary Penalties Law:
 - Prohibits inducements to beneficiaries
 - Authorizes HHS OIG to impose fines for Medicare & Medicaid fraud







OIG Flexibility: AKS & Civil Monetary Penalties Law

- Ordinarily, if practitioners waive costs owed by federal healthcare program beneficiaries (coinsurance, deductibles, copays), implicates AKS & CMP law prohibition on "inducements to beneficiaries"
- Now, flexibility to reduce or waive beneficiary cost-sharing for telehealth visits paid for by federal healthcare programs
- For COVID-19 PHE Only







Reverse False Claims Act



- Recipients of Medicare & Medicaid funds, if overpaid (any funds to which not entitled)
- When you have determined or should have determined, through the exercise of reasonable diligence ...
- After finding error, 60 days to report it & return funds to HHS (MAC) or the state
- Significant financial penalties





State Fraud & Abuse Laws

~	Arizona Attorney General Mark Brnovich Mark Brnovich
	OFFICE - COMPLAINTS - OUTREACH - SENIORS - CONSUMER - CRIMINAL - CIVIL RIGH
1	Seniors / Senior Abuse / Medicaid Fraud Control Unit
	Medicaid Fraud Control Unit
	The Medicaid Fraud Control Unit is a federally funded unit charged with investigating and prosecuting: Medicaid (AHCCCS) fraud; fraud in the administration of the Medicaid program; and abuse, neglect or financial exploitation occurring in Medicaid facilities or committed by Medicaid providers or their employees. The suspect must work for a Medicaid provider, such as a doctor, nursing home, hospital, adult care home, or home health agency. The unit is located in the Attorney General's Office, 2005 N Central Avenue in Phoenix. The unit consists of attorneys, investigators, an auditor, a nurse investigator, paralegal and support staff.
	AHCCCS Fraud can take a variety of forms. Common examples include:
	 Billing for services not rendered Billing for a higher level of service than was performed Billing for unnecessary services Kickbacks Double billing

Embezzlement

If you suspect that AHCCCS fraud has occurred, please contact the Medicaid Fraud Control Unit promptly.

- States may have their own selfreferral laws & other healthcare fraud & abuse laws
- Check with an attorney

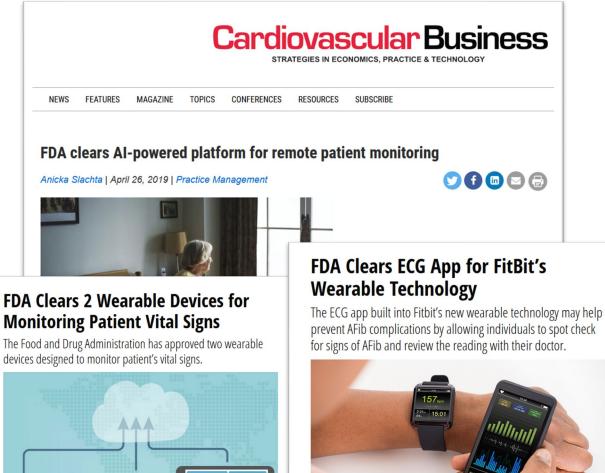




Devices

• FDA Final Guidance (9/2019):

- Telehealth products & tech are mobile medical apps if intended for use either as accessories to other regulated medical devices or to transform mobile tech platforms into regulated apps.
- If HIT is intended for use in diagnosis or treatment = medical device





Fitbit's new electrocardiogram (ECG) app for assessing heart rhythm for atrial fibrillation (AFib) through the company's latest wearable technology has been cleared for used in the US and Europe.

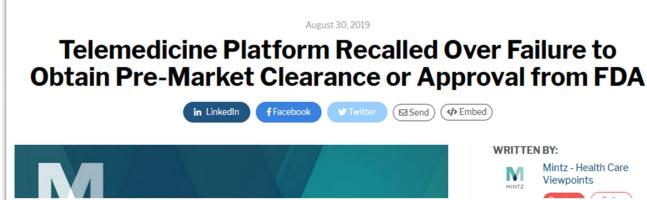
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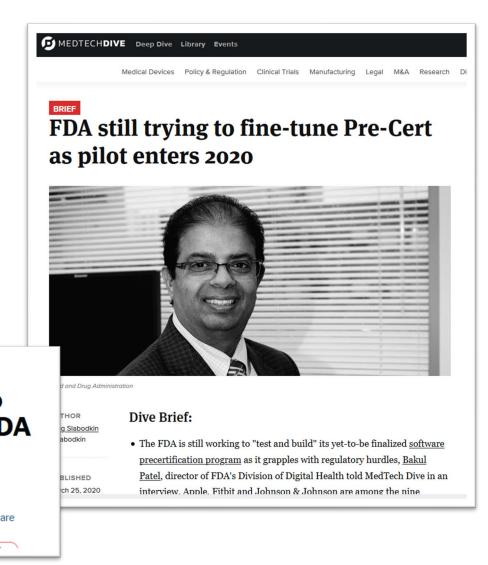
By Samantha McGrai

April 25, 2019 - The Food and Drug Administration (FDA) has approved two wearable devices designed to monitor patient's vital signs.

Devices

- FDA Final Guidance 9/2019: If poses "minimal risk," FDA won't enforce
- FDA "Pre-Cert" program for companies w/ "culture of quality," "organizational excellence" - still in pilot stage









FDA Guidance – PHE

- Most apps & software for public health surveillance & communication are not medical devices regulated by FDA, including contact & location trackers, educational info, video platforms
- Expanded use of certain FDA-approved, non-invasive vital-sign measuring devices to be used by healthcare providers for RPM
- Relaxed certification on some Rx-only connected health tools designed to treat depression & other mental health conditions
- Won't enforce requirements for lower risk devices like screening & preventative recommendations, checklist of symptoms, questionnaire

FDA Eases Guidelines for New mHealth, Telemental Health Treatments

The US Food and Drug Administration is easing pre-market certification requirements for new mHealth apps and telehealth tools designed to help patients and providers access mental health resources during the COVID-19 emergency.



What About the Future?

The COVID-19 Telehealth Expansion Bills Are Starting to Pile Up

Congress is very interested in expanding Medicare's telehea coverage beyond the COVID-19 emergency, as the growing number of bills would attest.

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Source: ThinkStock By Eric Wicklund	MHEALTH INTELLIGENCE xtelligent Healthcare media	F

 $\rm July$ 31, 2020 - Senator Lamar Alexander has added another telehealth bill to the rapidl list of efforts to expand connected health coverage in the wake of the coronavirus pande

The Tennessee Republican and chair of the Senate Committee on Health, Education, La Pensions this week introduced the **Telehealth Modernization Act (S. 4375)**, which aims to

2 More Telehealth Bills Return to Congress For Another Try

Both the TREATS Act and the Telehealth Modernization Act are being re-submitted this week, as telehealth advocates look to set the agenda for post-COVID-19 connected health coverage.



February 23, 2021 - Two popular telehealth bills that failed to make it through last year's Legislature are being reintroduced this week on Capitol Hill, adding to a growing number of connected health bills aimed at continuing the momentum for telehealth beyond the coronavirus pandemic.

Lawmakers Resubmit Telehealth Bills Targeting Kids' Health, COVID-19 Effects

Two more telehealth bills have returned to Capitol Hill after failing to make it through last year's session. One takes on kids' health and other calls for an HHS study of how telehealth has effected care delivery.





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March 01, 2021 - Two more telehealth bills have resurfaced on Capitol Hill, joining a growing package of legislation aimed at improving connected health coverage and access after the coronavirus pandemic.





Telehealth Policy Resources

Telehealth Legislative Trackers

• States:

Center for Connected Health Policy (CCHP) <u>https://track.govhawk.com/</u> <u>reports/24PKO/public</u>

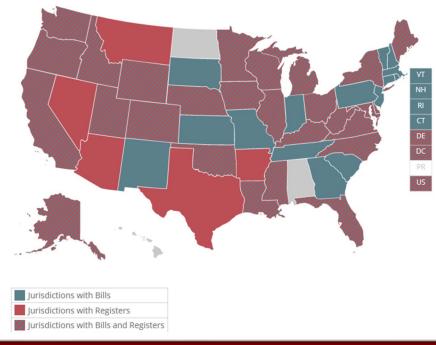
• Federal:

Alliance for Connected Care <u>http://connectwithcare.org/</u>telehealth-legislation/



Telehealth Legislation & Regulation

Utilize the interactive 50 state legislation and regulatory tracking tool, located below, to browse telehealth legislation and regulation across the nation for the current legislative session. RETURN TO THE CENTER FOR CONNECTED HEALTH POLICY BY VISITING WWW.CCHPCA.ORG.

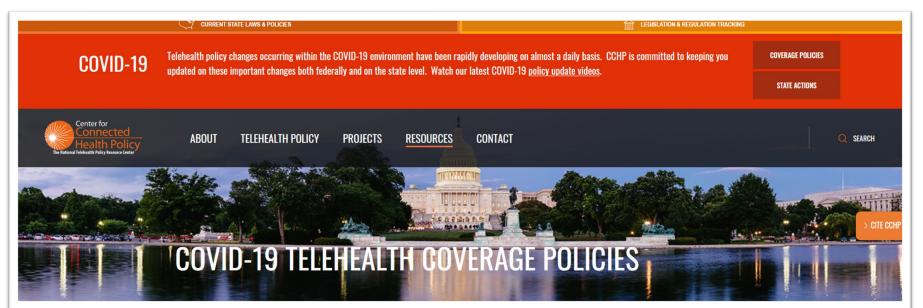






Center for Connected Health Policy

https://www.cchpca.org/



TELEHEALTH COVERAGE POLICIES IN THE TIME OF COVID-19

TO VIEW RECENT STATE ACTIONS AS A RESULT OF COVID-19 CLICK HERE!

Timestamp: September 15, 2020 - 3 pm PT

Most of the changes discussed below will end when the federal Public Health Emergency expires. In January 2021, the Dept. of Health and Human Services released a letter addressed to all Governors stating that the PHE will likely remain in place for the entirety of 2021. For more details on the PHE extension letter, read the full text.

As things rapidly develop regarding what we know about COVID-19, policies around telehealth have also been developing alongside of it. Below is a summary of what is covered by various public and private payers with the information that has been released. Keep in mind that events are evolving and to consider this a living document that could change frequently as new information and new policies become

ATP/SWTRC COVID & Telehealth Site

<u>https://southwesttrc.org/resources/covid19</u>

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Thank you!

Questions?

https://telemedicine.arizona.edu/contact

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