

ARIZONA
TELEMEDICINE
PROGRAM



Legal & Regulatory Considerations for Telehealth

(in the time of COVID-19)

Nancy S. Rowe

Associate Director, Public Policy & Outreach

Arizona Telemedicine Program

Disclosures

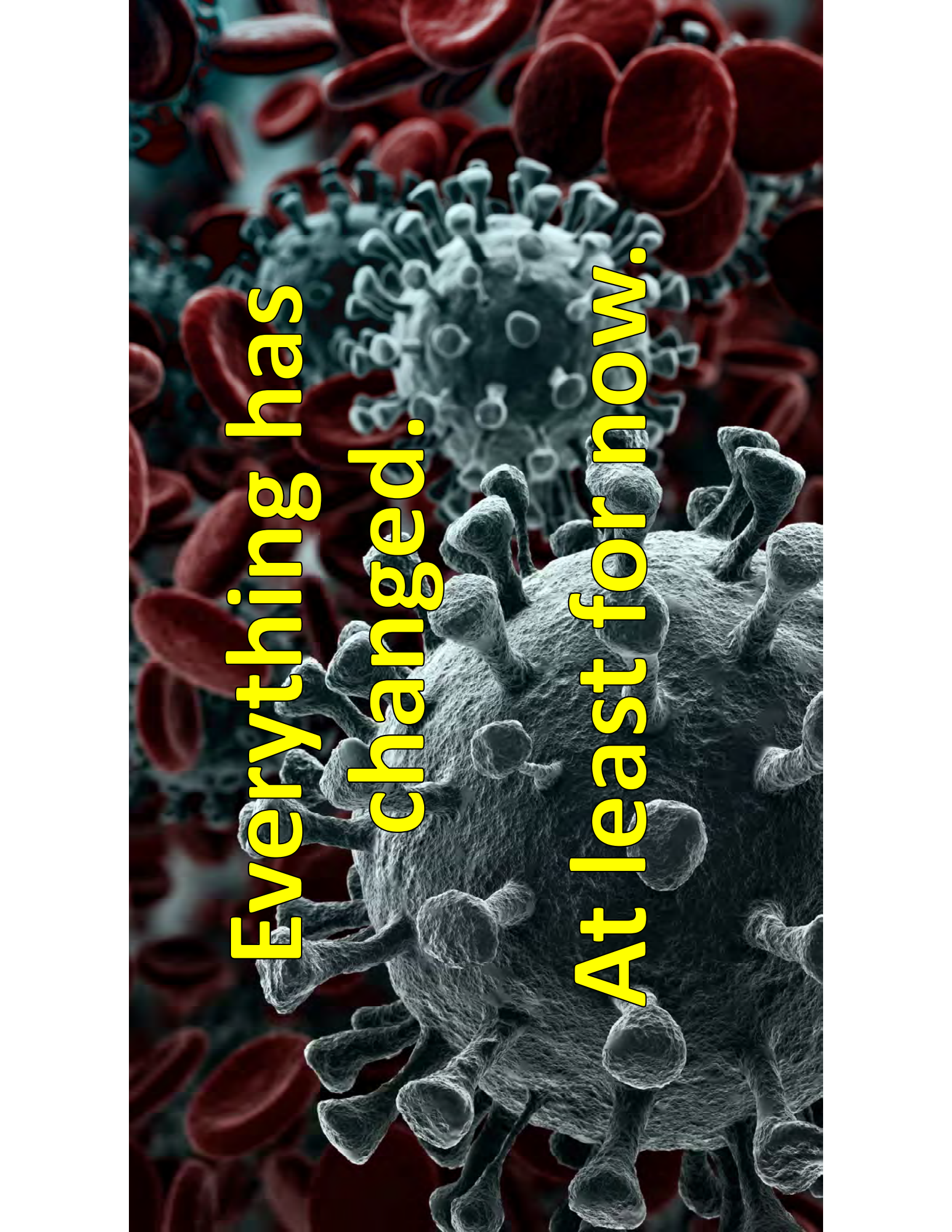
I'm not an attorney.
Consult an
attorney.

This is complicated!

Compliance Department



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

A detailed 3D rendering of a virus particle, likely a coronavirus, with its characteristic spherical shape and numerous spike-like protrusions. The virus is shown in a light grey or white color, contrasting with the dark red, biconcave disc-shaped red blood cells in the background. The lighting creates a sense of depth and texture on the virus's surface.

**Everything has
changed.
At least for now.**

Telemedicine Law

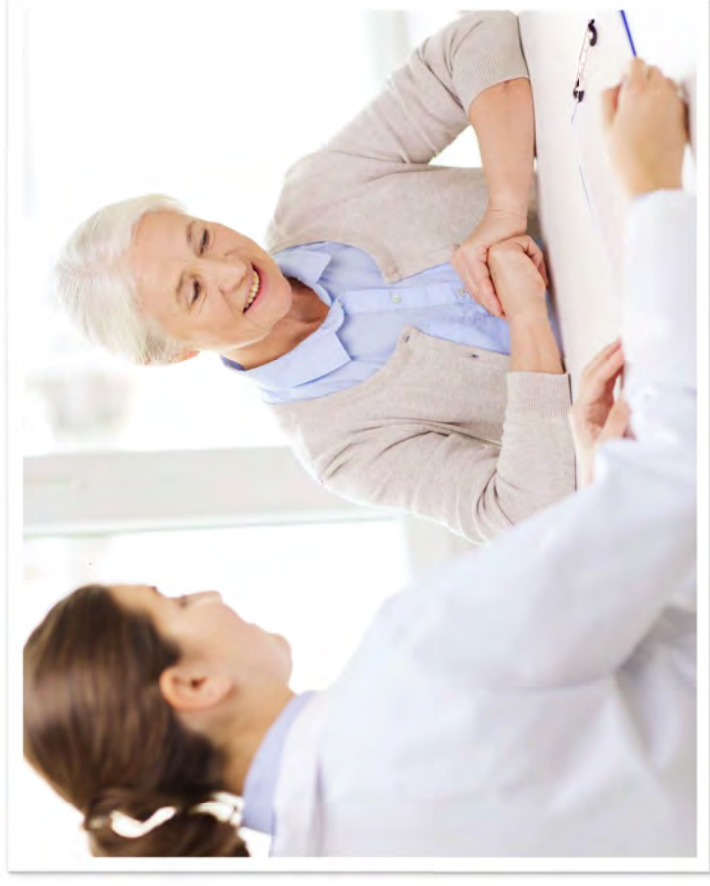
- Healthcare laws & regulations still apply* regardless of whether the healthcare service takes place in person or via telehealth:
 - **Licensing**
 - **Prescribing**
 - **Anti-kickback/Stark**
 - **Other fraud & abuse laws**
 - **Liability**
 - **Standard of care**
 - **HIPAA & HITECH**
 - **Corporate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

**Unless waived or loosened during the national healthcare emergency*



Informed Consent

- 42 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
 - Inform what will happen 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

OIG Report: CMS Paid Practitioners for Telehealth Services That Did Not Meet Medicare Requirements

13 April 2018 | Health Care Law Today | Blog
Authors: Nathaniel M. Lacktman



- **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.).



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**



The screenshot shows a webpage from mHEALTH INTELLIGENCE. The header includes navigation links: Home, News, Features, Inter, Policy, Telehealth, Remote Monitoring, Devices & Hardware, Apps & Software, and Focus on Interoperability. The main article title is "States Move Quickly to Address Coronavirus Pandemic With Telehealth", with a sub-headline: "Eighteen states and Washington DC have enacted emergency". The article is published by FOLEY FOLEY & LARDNER LLP. The article title is "COVID-19: States Waive In-State Licensing Requirements for Health Care Providers". The date is 17 March 2020. The authors are Emily H. Weir, Rachel B. Goodman, and Thomas B. Ferranto. The publisher is Health Care Law Today, Coronavirus Resource Center: Back to Business. The article includes a photo of three healthcare professionals in a clinical setting.

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

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



Source: ThinkStock

By Eric Wicklund



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

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.



Source: ThinkStock

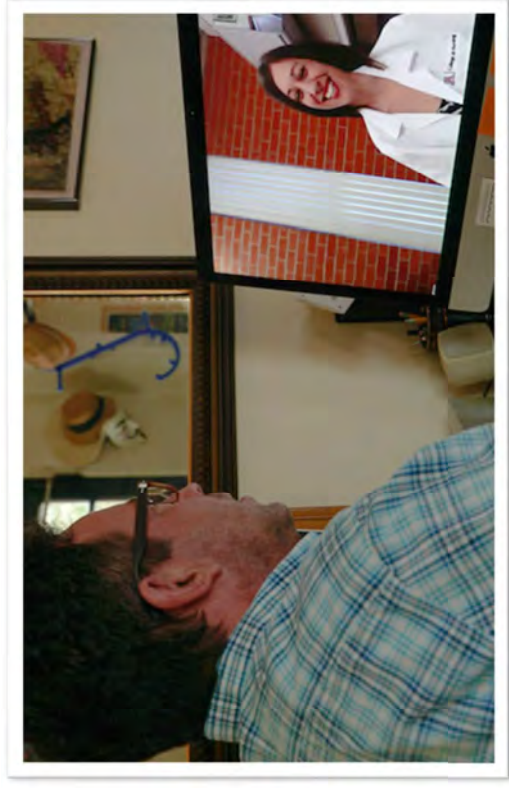
By Eric Wicklund



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.

Establishing the Provider-Patient Relationship

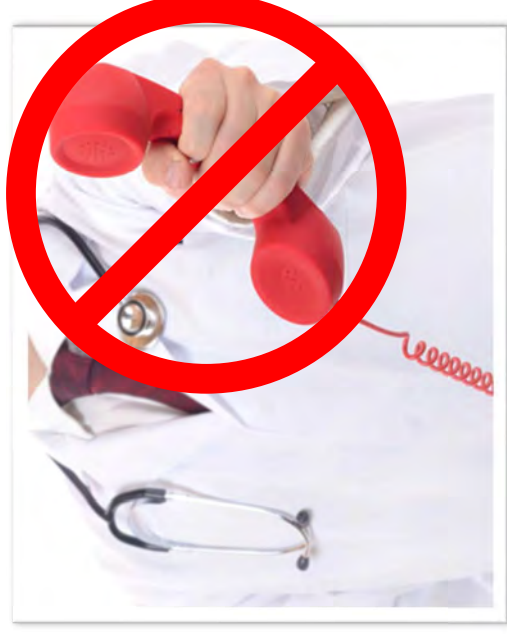
- **Medicare** allows video substitute for in-person exam: live, 2-way, real-time, A/V interactive communication
- **FSMB guidelines:** relationship can be established when physician is remote, with verified pt. ID & disclosure & validation of doc ID & credentials, + appropriate consents
- **AZ** does 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*

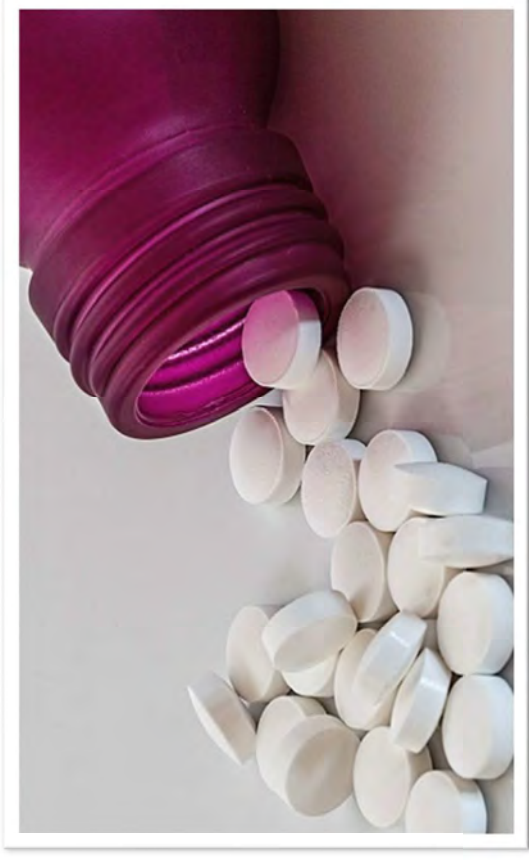
- AZ law prohibits the use of telemedicine in abortions. (~20 other states also do.)



* Except for certain uses during PHE

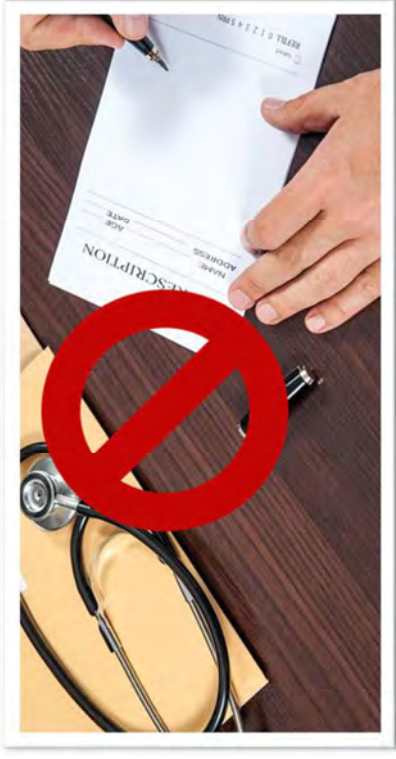
The DEA & Telemedicine

- 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. **OR** who meets 1 of 7 telemedicine exceptions ...

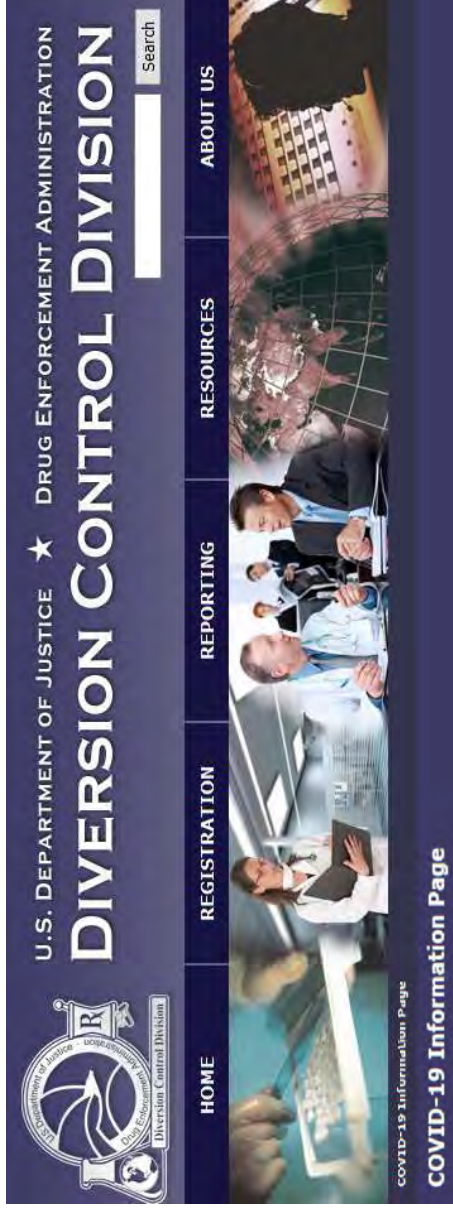


Ryan Haight Act: DEA Telemedicine Exceptions

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.

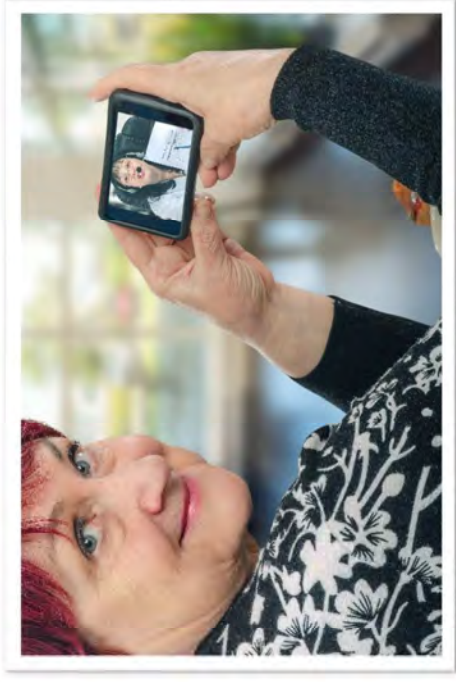
DEA Letter

- March 31: Buprenorphine can be prescribed to new & existing pts with OUD for maintenance or detoxification tx on the basis of a **telephone eval**.
 - Must meet obligation to ensure Rx is for a legit medical purpose
 - Must feel adequate eval can be accomplished via telephone
 - DEA-registered as 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



HHS OCR Enforcement Discretion: HIPAA

- 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, non-healthcare 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



HHS OCR Enforcement Discretion: HIPAA

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

2. 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.

Handwritten signature of Gary R. Herbert in black ink.

Gary R. Herbert
Governor

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

by Heather Landl | 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 regarding the illegal activities.

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

(Twitter) - yesterday Print | Email



Tweet



Share 14

mHealth Companies Fined for Medicare Fraud on Wearable Monitors

The makers and marketers of wearable health monitoring devices have been fined for seeking Medicare reimbursement for 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 engaged in illegal activities related to the collection and use of genetic information for improper purposes.

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 telehealth during the pandemic and said the agency 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



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.**

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**



USAO-SDGA

From left: Peter M. McCoy, U.S. Attorney, District of South Carolina; Bobby L. Christline, U.S. Attorney, Southern District of Georgia; Glen Kessler, Resident Agent in Charge, U.S. Secret Service Savannah Office; Will Clarke, Supervisory Special Agent, FBI Savannah Office; Douglas Dye, Special Agent, FBI, and Jonathan Porter, Assistant U.S. Attorney, Southern District of Georgia.

SAVANNAH, Ga. The third in a nationwide series of telemedicine fraud prosecutions includes cases in the Southern District of Georgia **identifying more than \$4.5 billion in fraudulent billings to government healthcare insurance programs.**

The takedown – dubbed Operation Rubber Stamp, and following two similar nationwide Department of

Legal & Regulatory Issues

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

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



Four physicians and a nurse in South Carolina were charged in a healthcare fraud and kickback conspiracy involving more than \$100 million in fraudulent billings, the Department of Justice announced Oct. 7.

The five medical providers allegedly signed prescriptions using a web-based platform, often without speaking with or meeting the patients. They allegedly wrote the prescriptions for Medicare beneficiaries using only information provided by a telemedicine company they were doing business with, according to *The Post and Courier*.

The five clinicians are among more than 40 people in South Carolina and Georgia facing federal charges for their roles in **alleged healthcare fraud schemes.** The charges were brought as part of a nationwide telemedicine fraud takedown.

Stark Law



"Winter is coming."

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

Never
Mind?



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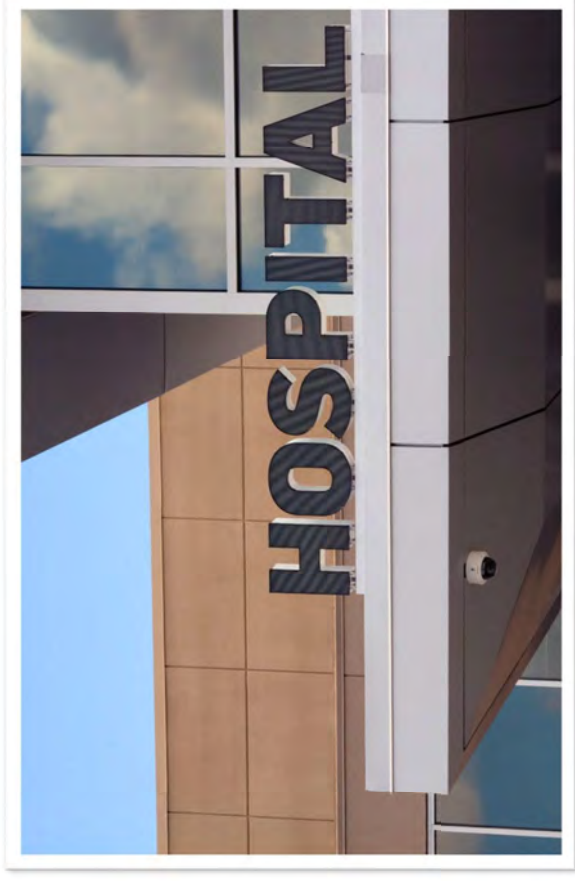
Anti-Kickback Statute (AKS)

- 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



Anti-Kickback Statute – 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!



New! 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.



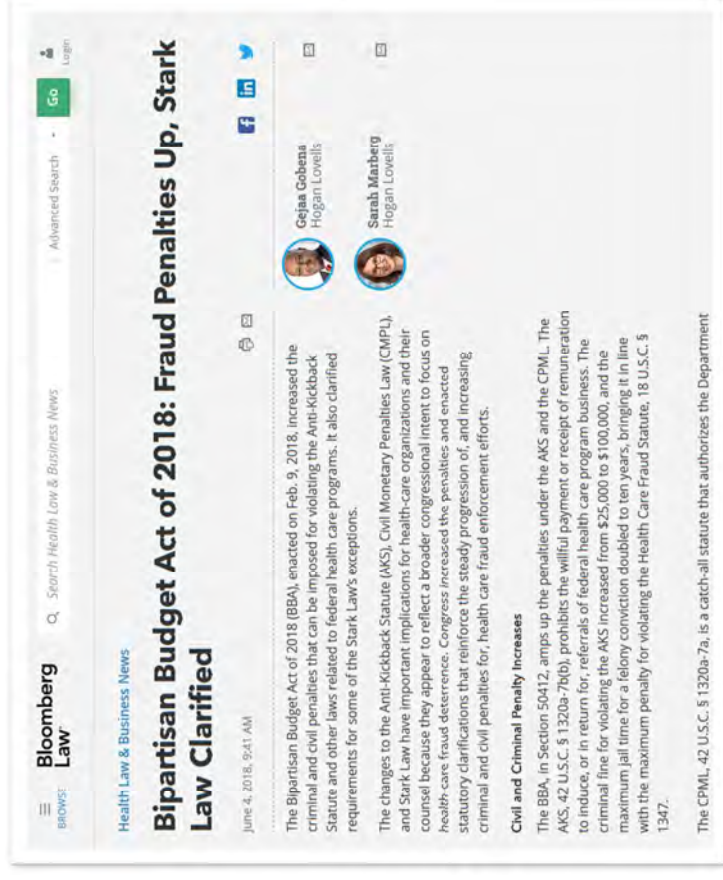
Source: ThinkStock

By Eric Wicklund



Violations can 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 AKS & Civil Monetary Penalty Flexibility

- 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

States

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

The screenshot shows the Arizona Attorney General's website. At the top, it says "Arizona Attorney General Mark Brnovich". Below this is a navigation menu with options: OFFICE, COMPLAINTS, OUTREACH, SENIORS, CONSUMER, CRIMINAL, CIVIL RIGHTS. The "SENIORS" menu item is selected, leading to a page titled "Medicaid Fraud Control Unit". The page content includes a search bar, a description of the unit's role in investigating and prosecuting Medicaid fraud, and a list of common examples of fraud such as billing for services not rendered, billing for a higher level of service, kickbacks, double billing, denial of necessary services, and embezzlement. It concludes with a statement: "If you suspect that AHCCCS fraud has occurred, please contact the Medicaid Fraud Control Unit promptly."

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

Cardiovascular Business
STRATEGIES IN ECONOMICS, PRACTICE & TECHNOLOGY

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FDA clears AI-powered platform for remote patient monitoring
Anicka Slachta | April 26, 2019 | Practice Management

FDA Clears ECG App for FitBit's Wearable Technology
The ECG app built into Fitbit's new wearable technology may help prevent AFib complications by allowing individuals to spot check for signs of AFib and review the reading with their doctor.

FDA Clears 2 Wearable Devices for Monitoring Patient Vital Signs
The Food and Drug Administration has approved two wearable devices designed to monitor patient's vital signs.

Source: Thinkstock

By **Samantha McGrail**

Source: Thinkstock

By **Fred Donovan**

April 23, 2019 - The Food and Drug Administration (FDA) has approved two wearable devices designed to monitor patient's vital signs.

Source: Thinkstock

By **Samantha McGrail**

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 use in the US and Europe.

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

MEDTECHDIVE Deep Dive Library Events
Medical Devices Policy & Regulation Clinical Trials Manufacturing Legal M&A Research DI

BRIEF **FDA still trying to fine-tune Pre-Cert as pilot enters 2020**

Food and Drug Administration

THOR
Raj Subodhin
Booker

BLISHED
Feb 25, 2020

Dive Brief:

- The FDA is still working to “test and build” its yet-to-be finalized software precertification program as it grapples with regulatory hurdles, **Rajul Patel**, director of FDA’s Division of Digital Health told MedTech Dive in an interview. **Annie, Fitbit and Johnson & Johnson are among the nine**

August 30, 2019

Telemedicine Platform Recalled Over Failure to Obtain Pre-Market Clearance or Approval from FDA

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WRITTEN BY:
 Mintz - Health Care Viewpoints

FDA Guidance on Digital Health Policies – PHE

- Most apps & software for public health surveillance & communication are not medical devices regulated by FDA, including contact & location trackers, educational info, videoconferencing 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 of Telehealth Regulation?

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

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



Source: ThinkStock

By Eric Wicklund



July 31, 2020 - Senator Lamar Alexander has added another telehealth bill to the rapidly growing list of efforts to expand connected health coverage in the wake of the coronavirus pandemic. The Tennessee Republican and chair of the Senate Committee on Health, Education, Labor and Pensions this week introduced the **Telehealth Modernization Act (S. 4375)**, which aims

Congresswoman's Telehealth Bill Combines 9 Other Pieces of Legislation

US Rep. Ann Wagner's Telehealth Act pulls together nine telehealth bills introduced over the past year - all by Republicans in a bid to give lawmakers one overarching piece of connected health legislation



Source: ThinkStock

By Eric Wicklund



August 18, 2020 - A Missouri Congresswoman has introduced a telehealth bill that combines nine other connected health bills into one piece of legislation.

The Telehealth Act (HR 7092), sponsored by US Rep. Ann Wagner (R-MO), aims to give

New Bill Would OK Telehealth Anywhere For 6 Months After COVID-19 Emergency

A bill introduced this week would enable providers to use telehealth to treat patients in any location up to 180 days after the emergency, bypassing site restriction and interstate licensing guidelines.



Source: ThinkStock

By Eric Wicklund



June 19, 2020 - A new bill before Congress aims to allow providers unfettered use of telehealth for six months after the end of the COVID-19 emergency.

Telehealth Policy Resources

- ATP/SWTRC Telemedicine COVID-19 Resources web pages:

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

- Center for Connected Health Policy (CCHP):

<https://www.cchpca.org/>

- **NEW** as of Oct. 20! Fall 2020 50-state report



The screenshot displays the website for the Southwest Telehealth Resource Center (SWTRC), which is a subsidiary of the Arizona Telemedicine Program. The page features a navigation menu with links for Home, About Us, Region, Blog, Online Education, Resources, Events, Training, and Contact Us. A search bar is located in the top right corner. The main content area is titled "Telemedicine COVID-19 Resources" and includes a welcome message and a list of resource categories: FOR HEALTHCARE PROVIDERS, STATE-SPECIFIC INFORMATION, CONSUMER RESOURCES, and COVID-19 NEWSLETTERS. A "COVID-19 Resource Partner" logo for ADHS is also visible. The footer contains contact information for the Southwest Telehealth Resource Center, including its address in Tucson, AZ, and a note that the website was made possible by grant number 02261400560 from the Office for the Advancement of Telehealth, Health Resources and Services Administration, DHHS.

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Thank you!

Questions?

nrowe@telemedicine.arizona.edu

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