

ARIZONA
TELEMEDICINE
PROGRAM



Legal & Regulatory Considerations for Telehealth

(in the time of COVID-19)



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Disclosures

I am not an attorney.

I don't even play
one on TV.

Consult an attorney.

Compliance Department



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

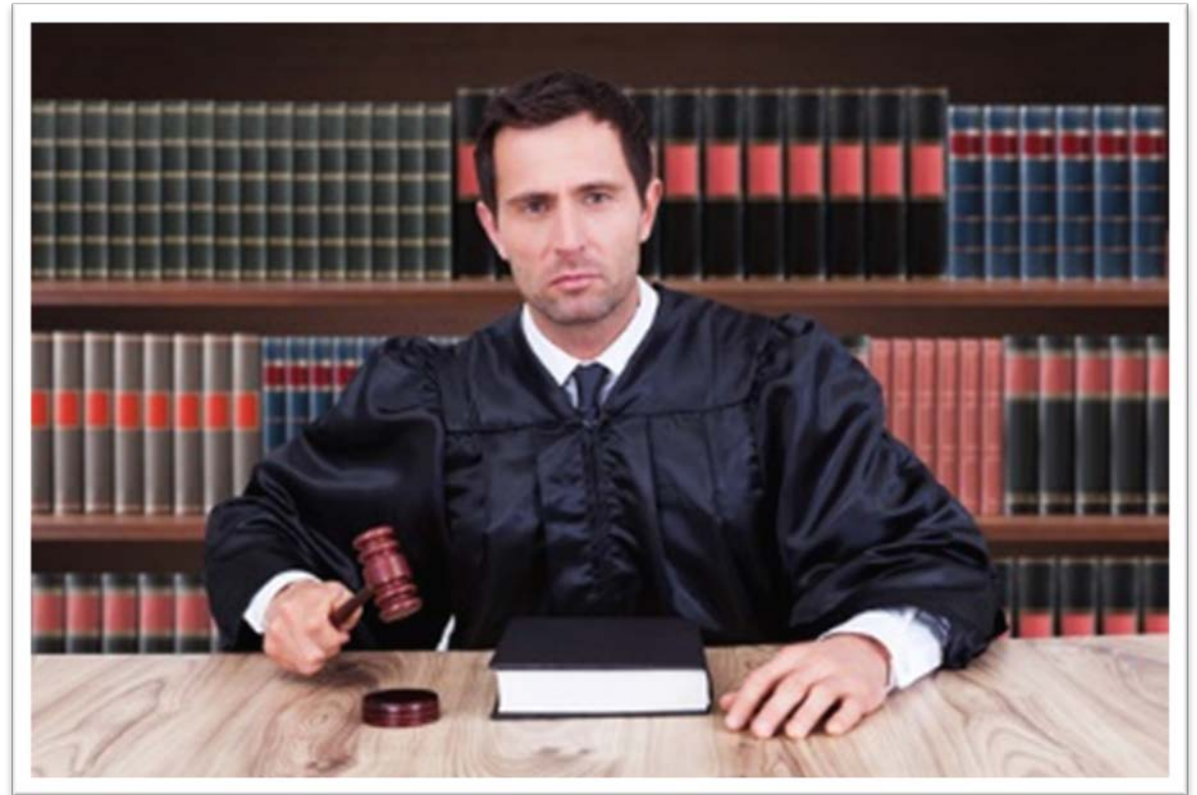
Everything is
changing.

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

- 39 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**
- Mitigate risk with strong provider credentialing practices & **training specific to telemedicine delivery**
- Act within scope of licensure
- **Follow pt.-state laws** & regs, federal law, clinical guidelines
- Adopt same quality assurance & peer review practices as with 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.).



Congress & Telehealth

- It literally takes an Act of Congress to change Medicare telehealth coverage restrictions – SSA
- Baby steps, chipping away at restrictions ...
- **Until now!** CARES Act let HHS Sec. waive Medicare restrictions & other requirements

CARES Act Expands Telehealth Coverage for Medicare, FQHCs and the VA

The Coronavirus relief bill passed by Congress and signed by President Trump last week expands Medicare coverage for telehealth, allows FQHCs and RHCs to qualify for coverage and boosts funding for broadband services.



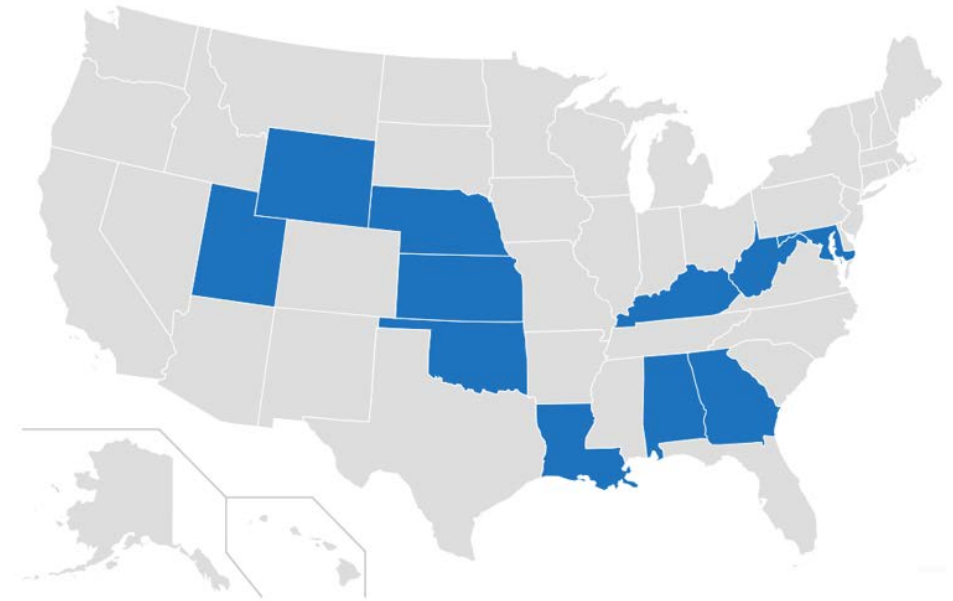
Source: ThinkStock

By Eric Wicklund



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?
- Universal licensure (AZ)
- Seeing your own established pt. in another state where you are not licensed? (WA says yes)
- **Licensure waivers for COVID-19**
 - Medicare
 - States/Medicaid

States Move Quickly to Address Coronavirus Pandemic With Telehealth

Eighteen states and Washington DC have enacted emergency regulations to increase the use of telehealth to tackle the Coronavirus epidemic, including in some cases allowing doctors and patients to collaborate by phone.

COVID-19: States Waive In-State Licensing Requirements for Health Care Providers

17 March 2020 | Blog

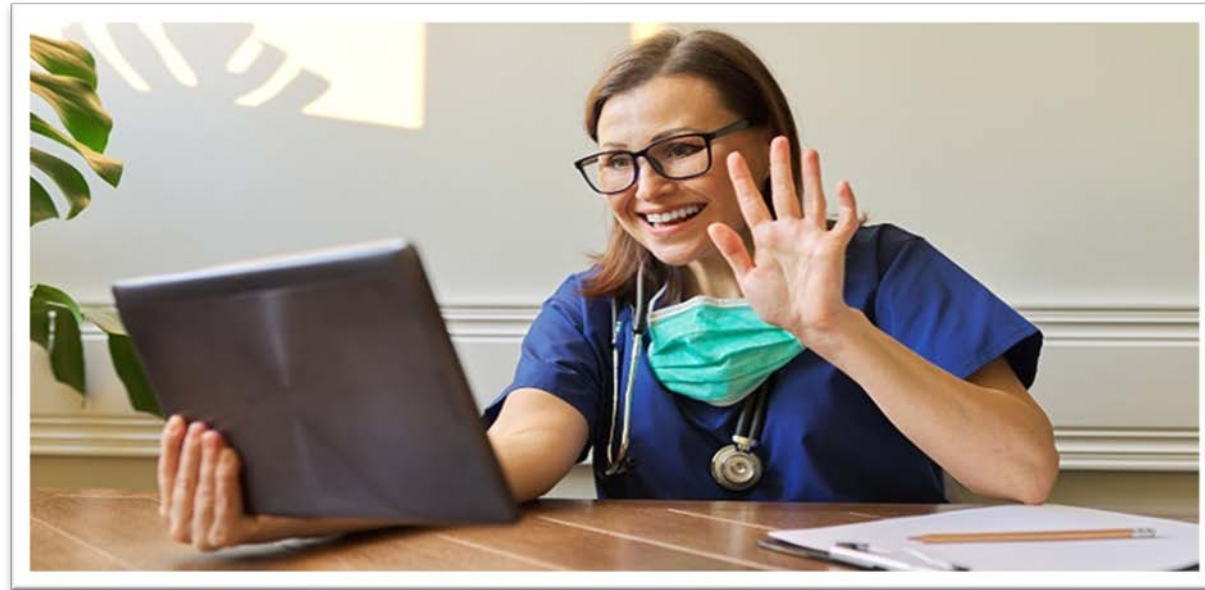
Authors: Emily H. Wein, Rachel B. Goodman, Thomas B. Ferrante

Published To: Health Care Law Today, Coronavirus Resource Center



The Physician-Patient Relationship

- Generally, once a physician affirmatively acts in a pt.'s case by examining, diagnosing, treating, or agreeing to do so, & pt. accepts, a relationship exists
- Must establish physician-pt. relationship in order to prescribe



Establishing the Physician-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)



** some telephonic services allowed for new pts. for PHE*

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: 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
- Notify pts. of potential privacy risks, enable all possible encryption & privacy modes
- Recommend using HIPAA-compliant
- For any medical condition – not just COVID-19
- For PHE only – doesn't impact state laws



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 denouncing the illegal activities.

mHealth Companies Fined for Medicare Fraud on Wearable Monitors

The makers and marketers of an mHealth wearable for cardiac monitoring have been fined \$13.45 million for compelling doctors to seek Medicare reimbursement for more expensive RPM services.

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.

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 used telemedicine platforms in an attempt to collect improper reimbursements from Medicare.

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

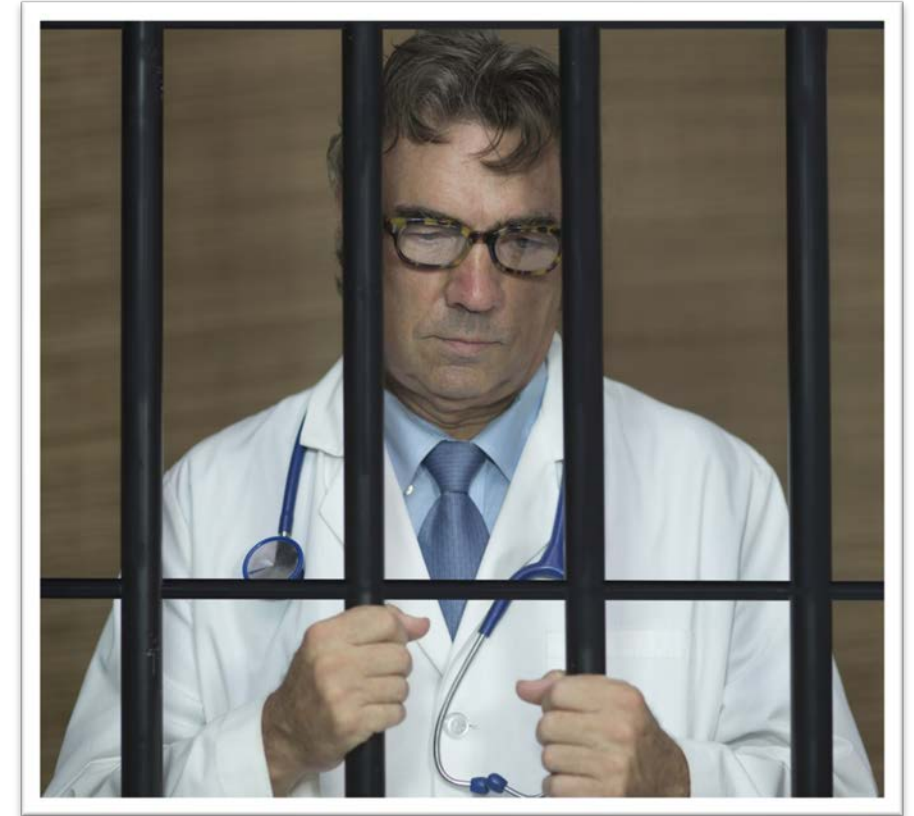
- OK to pay physician above or below FMV
- OK to rent office space or lease equipment below FMV
- OK to loan with interest rate below FMV or on terms unavailable from lender
- Certain referrals OK



Never
Mind?

Anti-Kickback Statute

- Federal healthcare fraud & abuse statute
- 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 – need “**safe harbors**”
- Severe financial penalties (Up to \$100K per wrongful claim) & up to 10 years in prison



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

The screenshot shows a Bloomberg Law article from June 4, 2018. The article title is "Bipartisan Budget Act of 2018: Fraud Penalties Up, Stark Law Clarified". The authors listed are Gejaa Gobena and Sarah Marberg, both associated with Hogan Lovells. The article text discusses the Bipartisan Budget Act of 2018 (BBA), enacted on Feb. 9, 2018, which increased criminal and civil penalties for violating the Anti-Kickback Statute and other laws related to federal health care programs. It also clarified requirements for some of the Stark Law's exceptions. The article mentions that the changes to the Anti-Kickback Statute (AKS), Civil Monetary Penalties Law (CPML), and Stark Law have important implications for health-care organizations and their counsel. It notes that Congress increased the penalties and enacted statutory clarifications to reinforce the steady progression of, and increasing criminal and civil penalties for, health care fraud enforcement efforts. A section titled "Civil and Criminal Penalty Increases" states that the BBA, in Section 50412, amped up the penalties under the AKS and the CPML. The AKS, 42 U.S.C. § 1320a-7b(b), prohibits the willful payment or receipt of remuneration to induce, or in return for, referrals of federal health care program business. The criminal fine for violating the AKS increased from \$25,000 to \$100,000, and the maximum jail time for a felony conviction doubled to ten years, bringing it in line with the maximum penalty for violating the Health Care Fraud Statute, 18 U.S.C. § 1347. The article also mentions that the CPML, 42 U.S.C. § 1320a-7a, is a catch-all statute that authorizes the Department

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



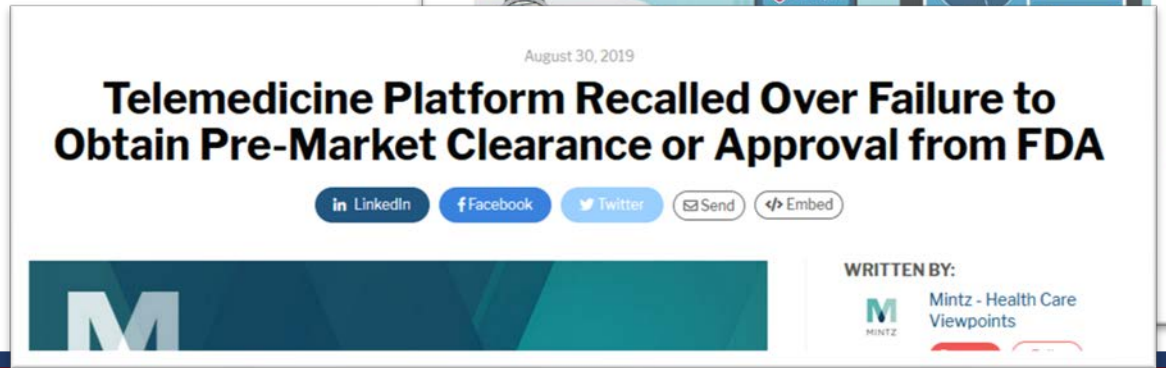
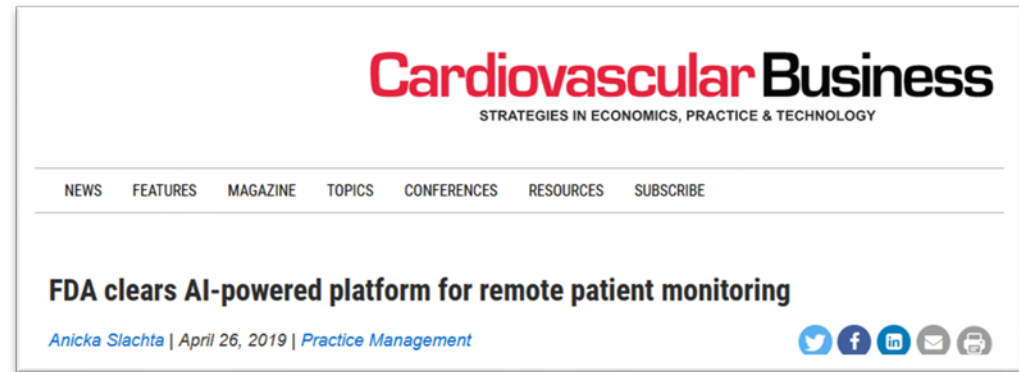
Reverse False Claims Act



- 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

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
 - If poses “minimal risk,” FDA won’t enforce
- FDA “Pre-Cert” program for companies w/ “culture of quality,” “organizational excellence”



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?

Lots of Speculation.

No one knows.

Movement Was Already Occurring

- **DEA:** Special Reg. for Telemedicine due Oct. 2019
- **FDA:** Risk-based enforcement system – fall 2019
- **OIG:** Proposed AKS changes – fall 2019
- **CMS:** Proposed permanent exceptions to Stark Law for VBC – fall 2019
- **Congress & CMS:** Chipping away at 1834 Restrictions since 2018
- **AHCCCS:** Broadened telehealth coverage – fall 2019
- **AZ Legislature:** SB1089 (2019), HB2536 (2020) to add PTs, OTs, SLPs, etc.



COVID-19 Gives Providers a Blueprint for New Telehealth Strategies

The lessons learned in applying telehealth and mHealth to a pandemic will help health systems and hospitals shape their connected health strategies far beyond this crisis.



Source: Getty Images



May 18, 2020 - It's been said, rightly and tragically so, that it took a pandemic of telehealth to the American healthcare system.

Lawmakers Push to Extend Telehealth Freedoms Past the COVID-19 Emergency

More than 30 members of Congress are asking Congressional leadership to extend regulatory freedoms for telehealth in mental health settings past the COVID-19 emergency.

BECKER'S HOSPITAL REVIEW

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'The genie's out of the bottle on this one': Seema Verma hints at the future of telehealth for CMS beneficiaries

Laura Dyrda (Twitter) - Tuesday, April 28th, 2020 Print | Email

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When the COVID-19 pandemic began and it became clear telehealth would be necessary for physicians and nurses to treat patients remotely, CMS boosted rates for telehealth visits so they matched rates for in-clinic visits and would sustain providers during the pandemic.

ATP/SWTRC Telemed COVID-19 Web Page

- <https://southwesttrc.org/resources/covid19>
- **Resources for Healthcare Providers:** Starting/expanding telehealth, general info, CMS updates & billing, regulatory updates, private payer info, grants
- **State-Specific Info:** telehealth reg. & licensure changes, Medicaid & CHIP changes, SWTRC state-specific links
- **Consumer Resources:** Telehealth info for pts., broadband & equipment resources, COVID-19 info, finding online medical care, distance ed. info



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Thank you!

Questions?

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