ARIZONA TELEMEDICINE PROGRAM

SOUTHWEST TRC TELEHEALTH RESOURCE · CENTER™

Legal & Regulatory Considerations for Telehealth

(in the time of COVID-19)

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Arizona Telemedicine Program

Disclosures

No relevant financial relationships/COI.

I’m not an attorney.

Consult an attorney.


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

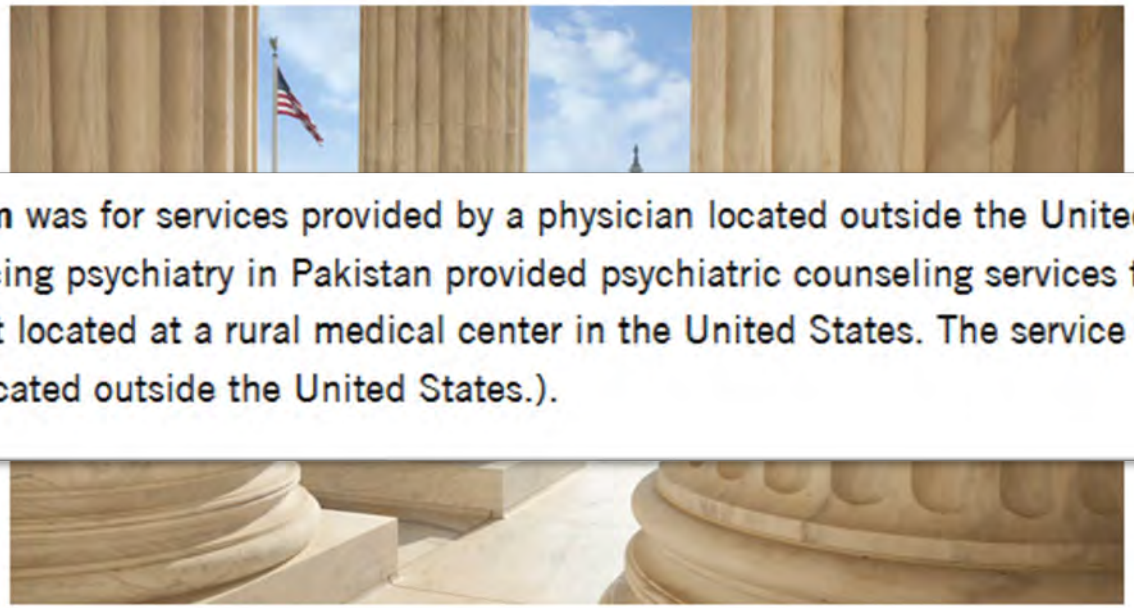
Provider Location – Did You Know?

- 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

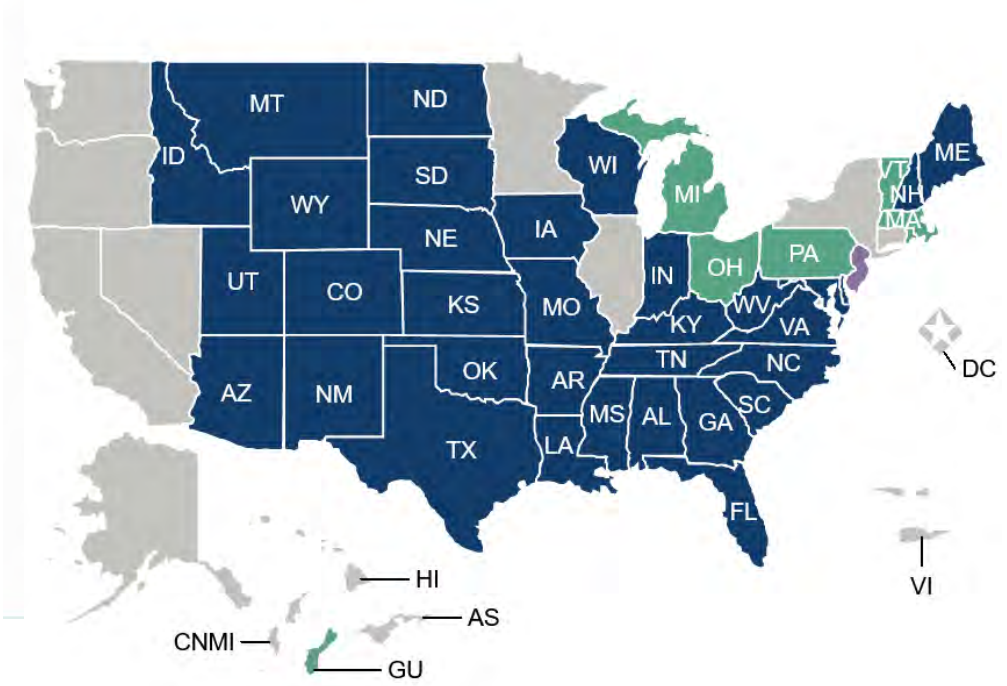
Authors: Nathaniel M. Lacktman



- **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)



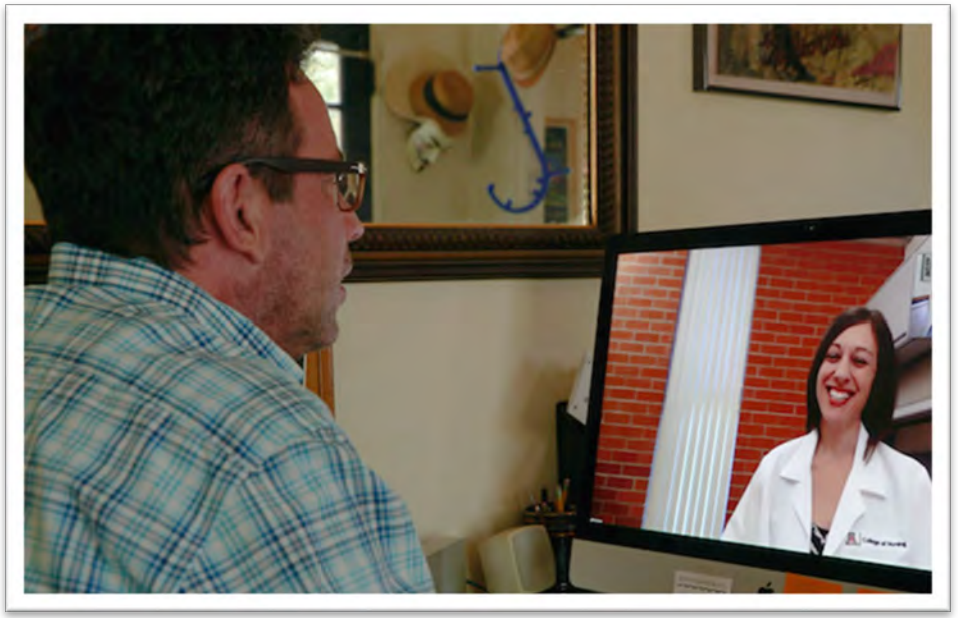
Licensure Special Cases

- 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

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
- **NM:** interactive encounter w/ history, physical &/or mental exam to make diagnosis & Tx, medical record



Telemedicine Prescribing: New Mexico

- Established provider-pt. relationship required to prescribe
- Not just an online questionnaire
- Not just a phone call*

** Except for certain exceptions 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

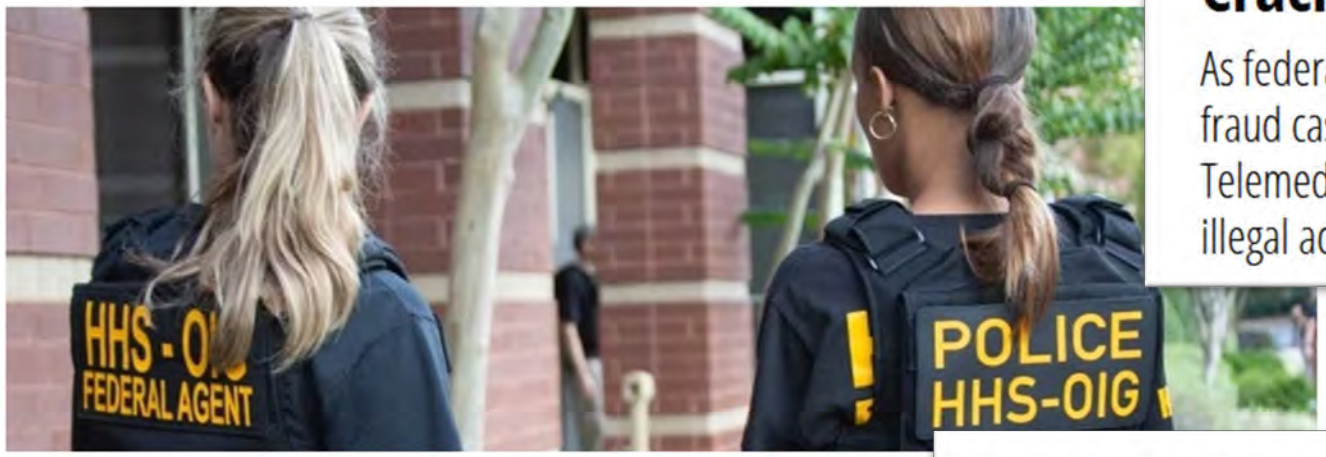
- March 31: Buprenorphine can be prescribed to new & existing pts with OUD for maintenance or detoxification tx on the basis of a **telephone eval.**
  - Must meet obligation to ensure Rx is for a legit medical purpose
  - Must feel adequate eval can be accomplished via telephone
  - DEA-registered as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

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
illegal activities.

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

(Twitter) - yesterday Print | Email

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CMS Administrator Seema Verma reiterated the success of telehealth during the pandemic and said the agency continues to

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
mproper

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.

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.

Legal & Regulatory Issues

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

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

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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.

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. Christine, 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 $1.5 billion in fraudulent billings to government healthcare insurance programs.

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

Stark Law

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

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!

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

Bloomberg Law

Health Law & Business News

Bipartisan Budget Act of 2018: Fraud Penalties Up, Stark Law Clarified

June 4, 2018, 9:41 AM

The Bipartisan Budget Act of 2018 (BBA), enacted on Feb. 9, 2018, increased the criminal and civil penalties that can be imposed 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 changes to the Anti-Kickback Statute (AKS), Civil Monetary Penalties Law (CMPL), and Stark Law have important implications for health-care organizations and their counsel because they appear to reflect a broader congressional intent to focus on health-care fraud deterrence. Congress increased the penalties and enacted statutory clarifications that reinforce the steady progression of, and increasing criminal and civil penalties for, health care fraud enforcement efforts.

Civil and Criminal Penalty Increases

The BBA, in Section 50412, amps 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 CPML, 42 U.S.C. § 1320a-7a, is a catch-all statute that authorizes the Department

Gejaa Gobena
Hogan Lovells

Sarah Marberg
Hogan Lovells

OIG AKS & Civil Monetary Penalty Flexibility

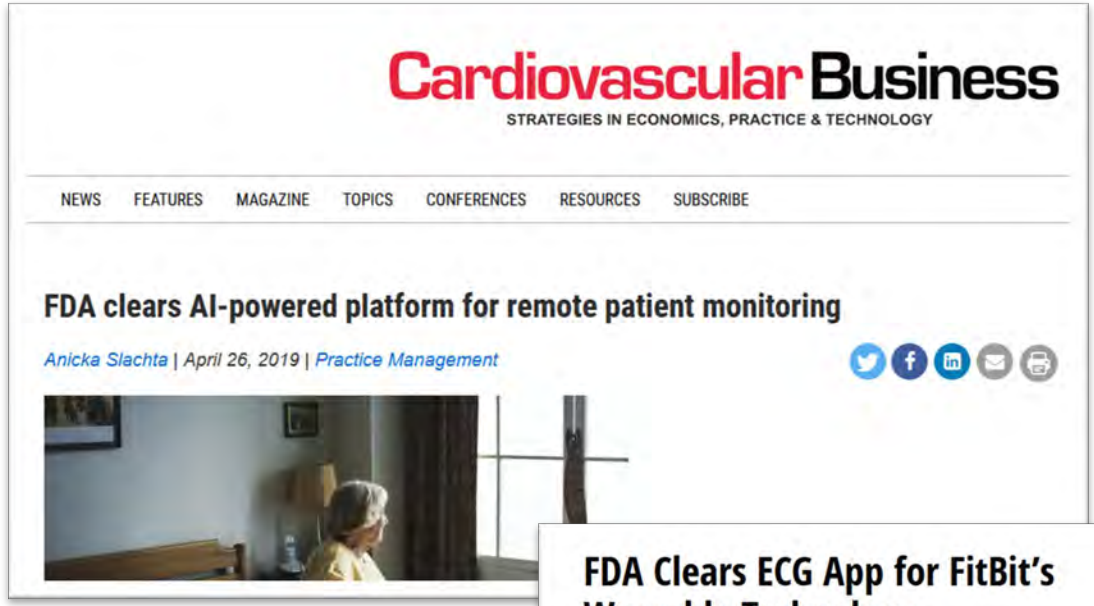
- Ordinarily, if practitioners waive costs owed by federal healthcare program beneficiaries (coinsurance, deductibles, copays), implicates AKS & CMP law prohibition on “inducements to beneficiaries”
- Now, flexibility to reduce or waive beneficiary cost-sharing for telehealth visits paid for by federal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

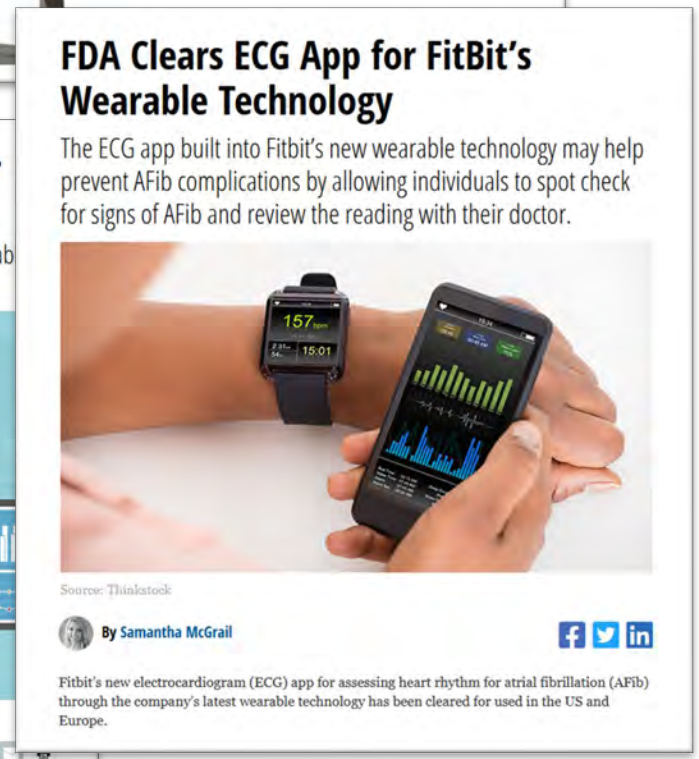
Reverse False Claims Act

- 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

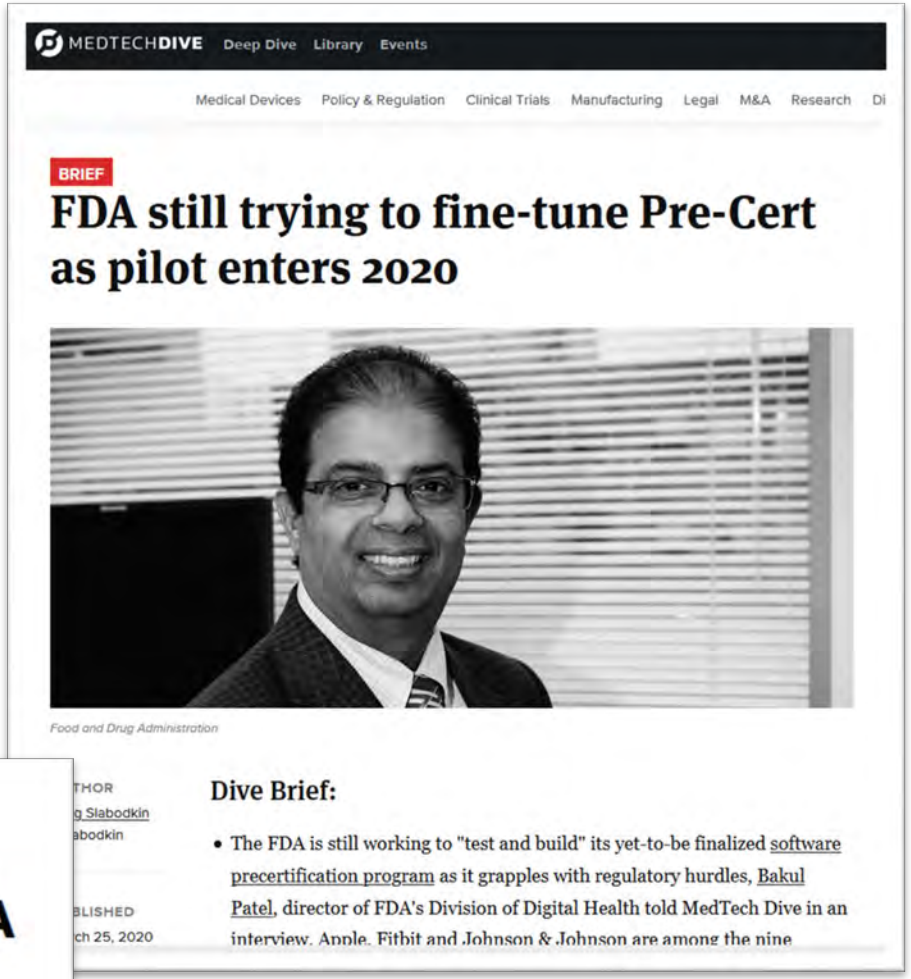
- **FDA Final Guidance (9/2019):**
- Telehealth products & tech are mobile medical apps if intended for use either as accessories to other regulated medical devices or to transform mobile tech platforms into regulated apps.
- If HIT is intended for use in **diagnosis or treatment =** medical device





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

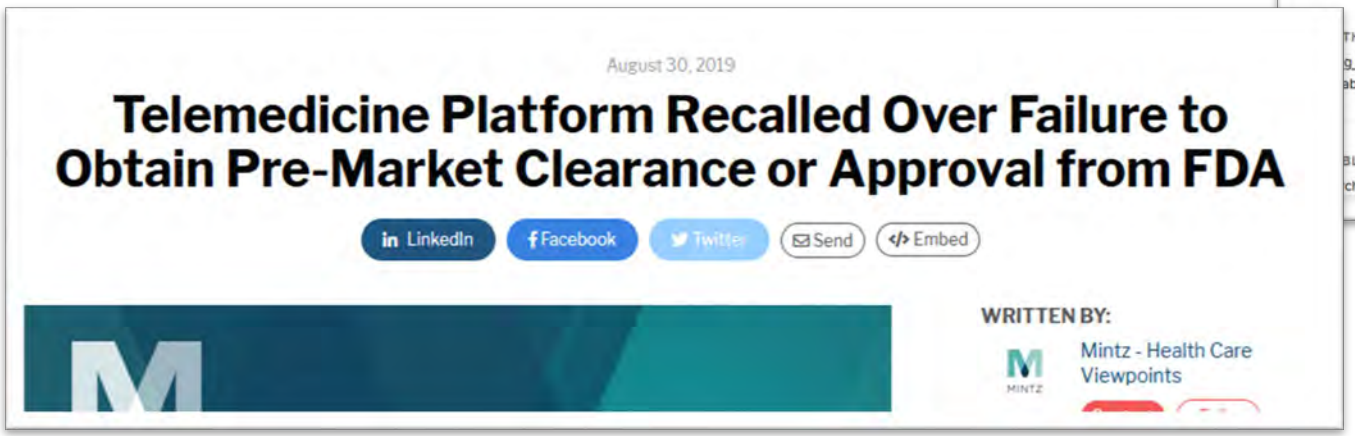
Food and Drug Administration

THOR
g Slabodkin
abodkin

BLISHED
ch 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, Bakul Patel, director of FDA's Division of Digital Health told MedTech Dive in an interview. Apple, 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

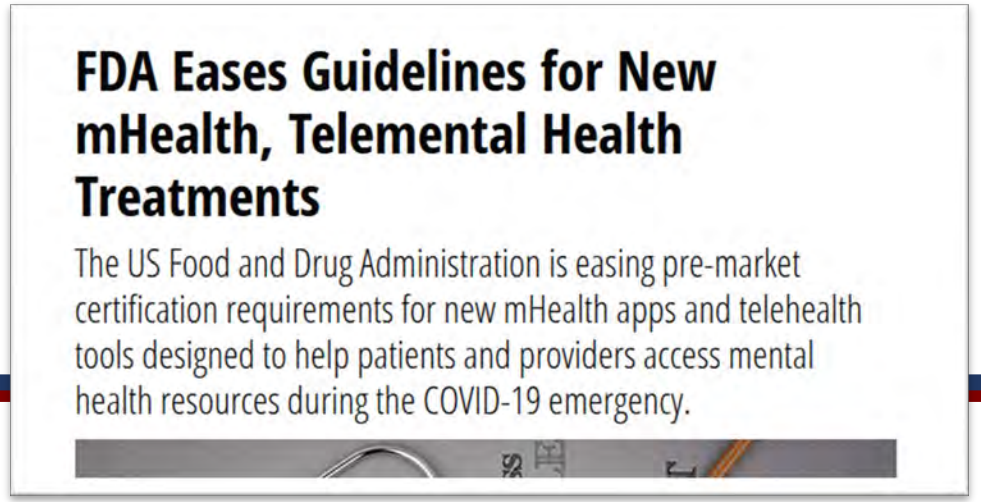
in LinkedIn | Facebook | Twitter | Send | </> Embed

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?

Movement Was Already Occurring

- **DEA:** Special Reg. for Telemedicine due Oct. 2019
- **FDA:** Risk-based enforcement system – fall 2019
- **FSMB & Other Prof'l Associations:** interstate licensure compacts
- **OIG:** Proposed AKS changes – fall 2019
- **CMS:** Proposed permanent exceptions to Stark Law for Value-based Care – fall 2019

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

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Thank you!

Questions?

nrowe@telemedicine.arizona.edu

https://southwesttrc.org/resources/covid19