

ARIZONA
TELEMEDICINE
PROGRAM



Legal Considerations for Telehealth

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Arizona Telemedicine Program

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

Telemedicine Law

- All the laws still apply regardless of whether the healthcare service takes place in person or via telemedicine:
 - Licensing
 - Prescribing
 - Anti-kickback/Stark
 - Liability
 - Standard of care
 - Fraud & abuse
 - HIPAA & HITECH
 - Corporate Practice of Medicine



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



Provider Location – Did You Know?

- Medicare: Distant Site Provider must 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.).



Things Keep Evolving

- It would literally take an Act of Congress to change Medicare telehealth coverage restrictions.
- CONNECT for Health Act of 2019:
Is the 3rd time the charm?
- Baby steps, chipping away at restrictions ...
- **Until now!**



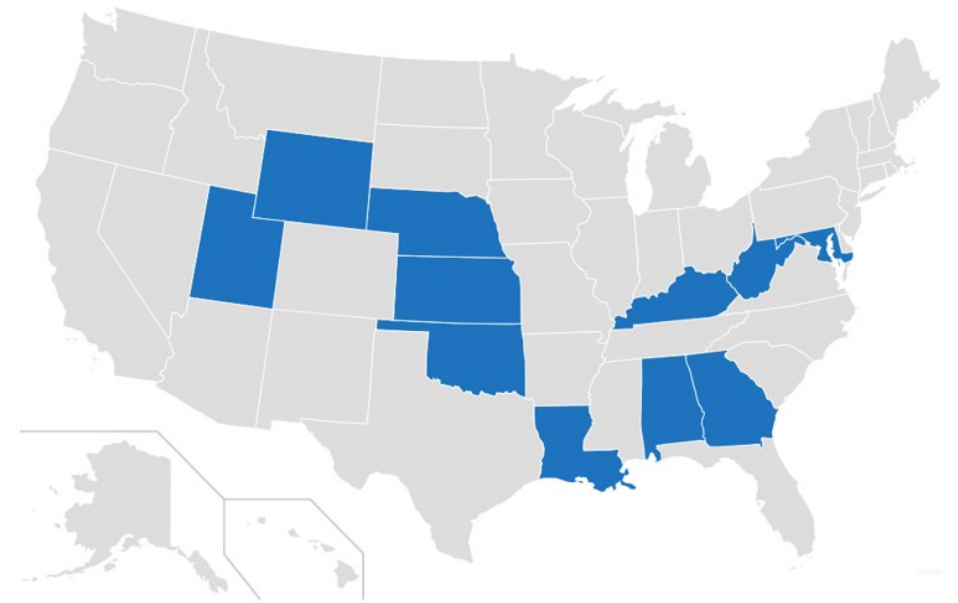
Medical Malpractice & Telemedicine

- 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 models



Licensure

- 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

- 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**

Home / Governor's Office / Ducey signs bill for state to recognize out-of-state license

Ducey signs bill for state to recognize out-of-state license

By: Howard Fischer, Capitol Media Services April 10, 2019



FOLEY
FOLEY & LARDNER LLP

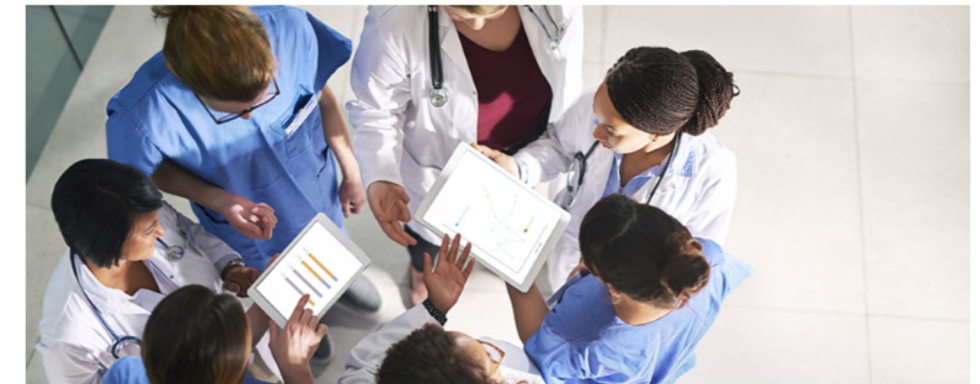
Practice Areas Industry Teams People

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

17 March 2020 | Blog

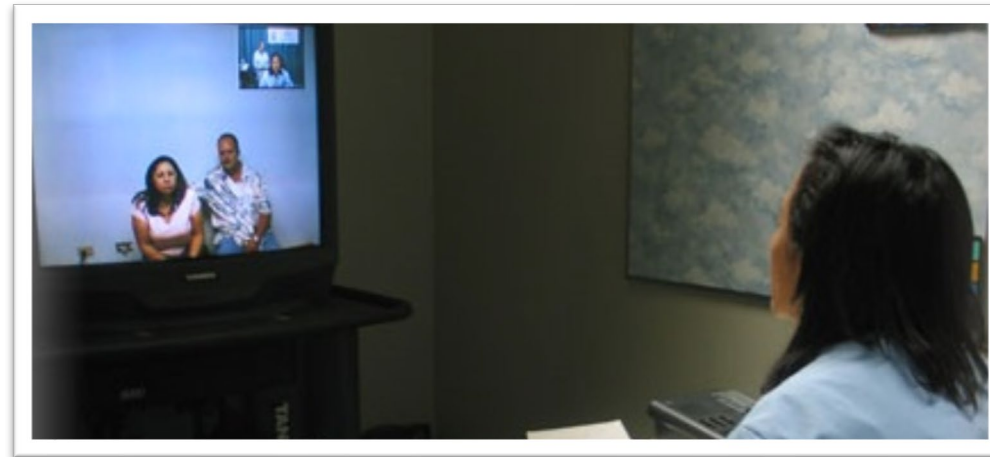
Authors: Emily H. Wein, Rachel B. Goodman, Thomas B. Ferrante

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

**for “telehealth” services*



Telemedicine Prescribing

- AZ Medical Board Policy Statement: Telemedicine should not be confused with internet prescribing.
 - Not just an internet questionnaire
 - Not just a phone call
- AZ law prohibits the use of telemedicine in abortions. (~20 other states also do.)



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 Special Registration for Telemedicine ... ?

- Practitioner w/ special registration may prescribe controlled substances via telemed w/o in-person exam or meeting 1 of 7 exceptions
- Still waiting ...



Nathaniel Lacktman @Lacktman · 20h

Many #telehealth companies awaiting the forthcoming @DEAHQ rule allowing #telemedicine prescribing of controlled substances without an in-person exam. President set an Oct 24, 2019 deadline ⌚ More at



The Special Registration

CTeL has submitted a letter urging the DEA to develop the special registration for telemedicine prescribing without an in-person exam requirement. You can read that letter [here](#).

Last year's SUPPORT for Patients and Communities Act tasked the DEA with developing regulations and procedures for the special registration. This registration could expand telemedicine prescribing considerably, saving lives and slashing morbidity in non-clinical settings—especially in areas with provider shortages.

DEA Updates

MARK R. WARNER
VIRGINIA

United States Senate

WASHINGTON, DC 20510-4606

January 17, 2020

Mr. Uttam Dhillon
Acting Administrator
Drug Enforcement Administration (DEA)
U.S. Department of Justice
800 K Street NW Suite 500
Washington, D.C. 20001

Dear Acting Administrator Dhillon,

I am writing regarding the Drug Enforcement Agency's (DEA) implementation of critical provisions in the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act) (Public Law 91-513) and the recently passed SUPPORT for Patients and Communities Act (SUPPORT Act) (Public Law 115-271) that ensure individuals with substance use disorders can successfully access medical treatment via telehealth.

As you likely know – the Ryan Haight Act prohibits the delivery, distribution, or dispensing of a controlled substance online without first conducting an in-person exam. The intent of this law is to prevent illegitimate entities from selling dangerous controlled substances online while maintaining the ability for legitimate healthcare providers to treat patients in need.

The Ryan Haight Act has directed the DEA to promulgate rules exempting certain health care

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POLICY NEWS

Warner Tells DEA to Launch Registration for Telehealth Prescriptions

Senator Mark Warner is taking the DEA to task for failing to launch a promised - and mandated - special registration process for care providers who want to use telehealth to prescribe controlled substances.



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Congresswoman Kuster, Senators Murray and Warren Press Drug Enforcement Administration on Long-Overdue Steps to Expand Access to Opioid Addiction Treatment

Jan 21, 2020 | Press Release

Kuster, Murray and Warren send letter to Drug Enforcement Administration over delay in action to help people struggling with opioid addiction

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.

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

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



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.

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.

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.”

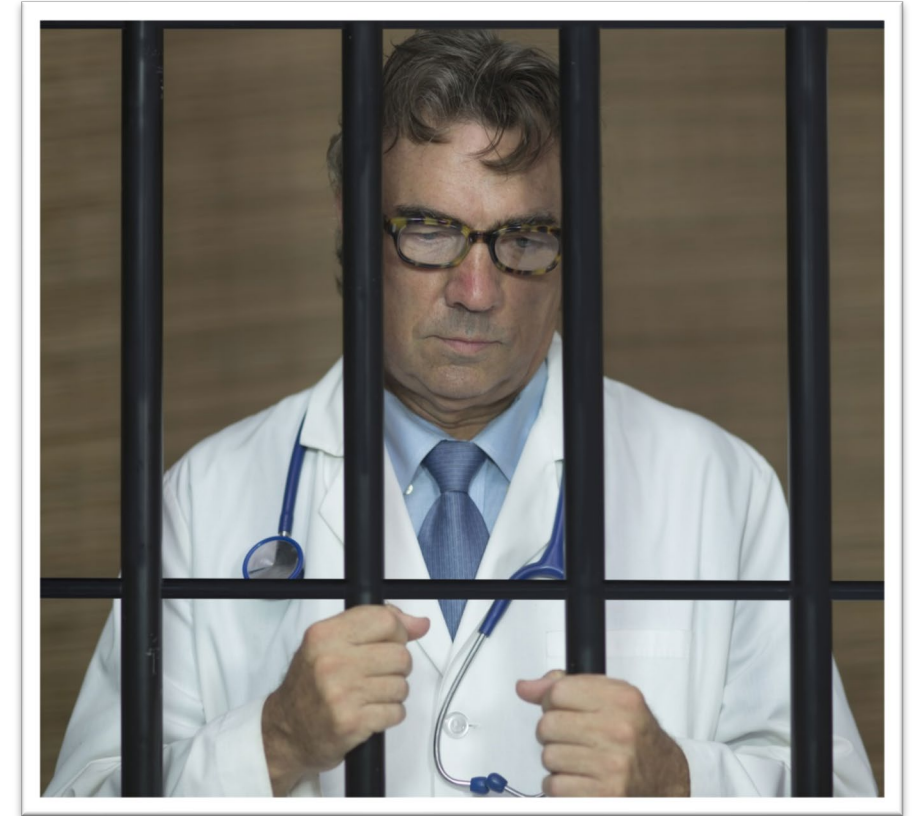
Stark Law – Physician Self-Referral Law

- 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)
- Intent is not required!
- “Safe harbors” include space leases at FMV



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



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

CMS New Rule: Stark Law Promotes Care Over Self-Referral

Posted October 30, 2019

Share:    

The 80's are back, but it's not fashion you should worry about. First enacted in 1989, the Stark Law is getting significant updates from CMS that benefit patient care, according to a proposed rule issued in October 2019. Comply with these new regulations that open the door to areas previously restricted as conflicts of interest.



The Stark Law has been revised several times in the past, but it's complicated. And many physicians remain in the dark about exactly what is or isn't okay under Stark.

Not only that, there are a myriad of exceptions that physicians must navigate to stay in compliance. That's a problem because the penalties for violating this complex regulation — including heavy fines and exclusion from Medicare/Medicaid — are serious.

CMS Proposed Stark Rule (10/2019)

- 1989 Stark Law has not evolved to keep pace with transition to VBC
- Reduces unnecessary regulatory burden
- New, permanent exceptions for value-based arrangements
- Spurs innovation to coordinate/improve care & lower costs
- Additional guidance & clarification

Telemedicine and Digital Health Companies Will Benefit from Newly-Proposed Fraud and Abuse Waivers

28 October 2019 | Health Care Law Today | Blog

Authors: Emily H. Wein, Nathaniel M. Lacktman



The OIG recently [released proposed revisions](#) to the Anti-Kickback Statute (AKS) and Civil Monetary Penalties (CMP) Law. Several of these changes, if finalized, will directly benefit companies offering telemedicine and digital health items or services, remote patient monitoring (RPM), and Chronic Care Management (CCM) services. The key changes relevant to

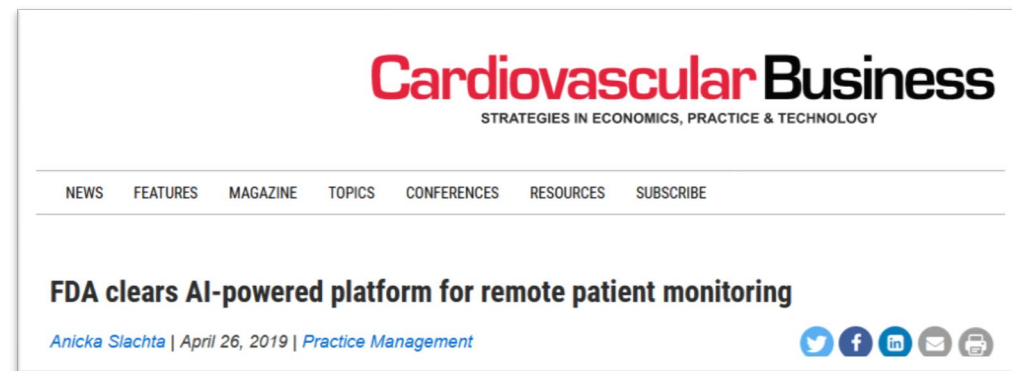
HHS OIG Proposed AKS Changes (10/2019):

- OIG proposal: extend safe harbor for free tech to pts. for value-based enterprises
- Seeking comment: Extend outside VBEs?
- Considering limited waiver of pt. copays for CCM & RPM
- Safe harbor for smart phones for ESRD services to pt. homes with limits – seeking comment

Devices

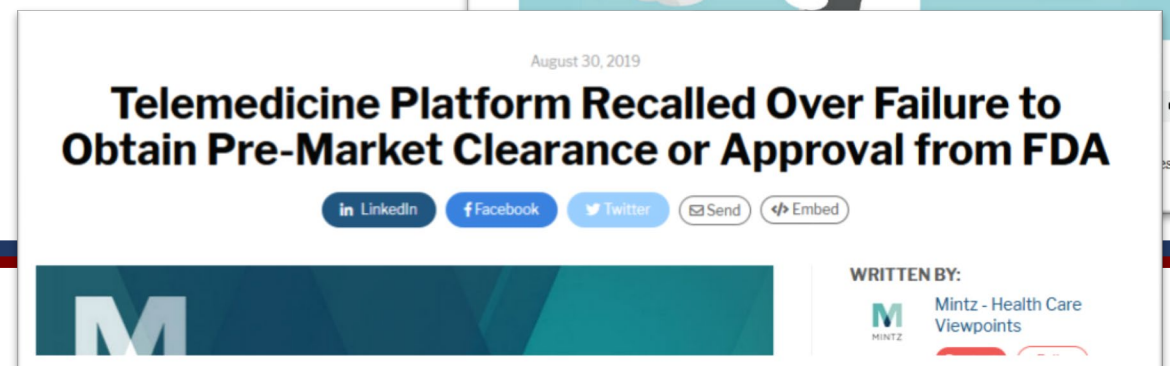
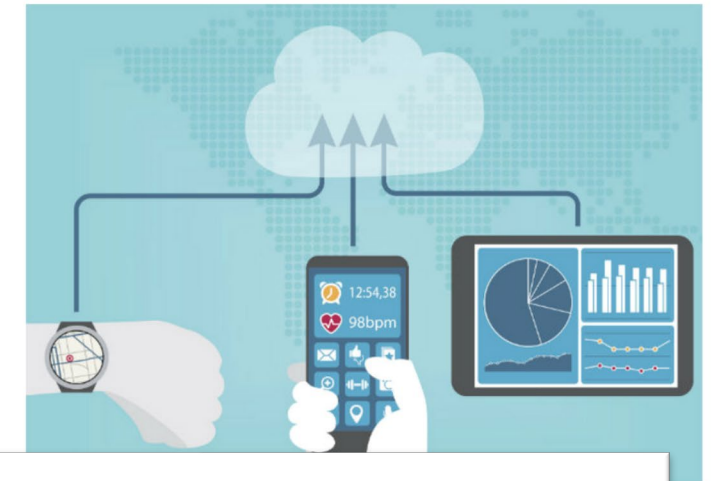
- **FDA Final Guidance (9/2019):**

- 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 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.



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Thank you!

Questions?

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