

ARIZONA  
TELEMEDICINE  
PROGRAM



# Legal Considerations for Telehealth

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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."**

# 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



# AZ Informed Consent Requirement

- State law: Informed consent required for telemedicine
  - Written or verbal (verbal must be documented on pt. medical record)
  - Exceptions: emergency; transmission of diagnostic images or test results; pt. not physically present
- All medical reports resulting from a telemedicine consult are part of pt. medical record
- No dissemination of images or information identifiable to a specific pt. w/o consent



# 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

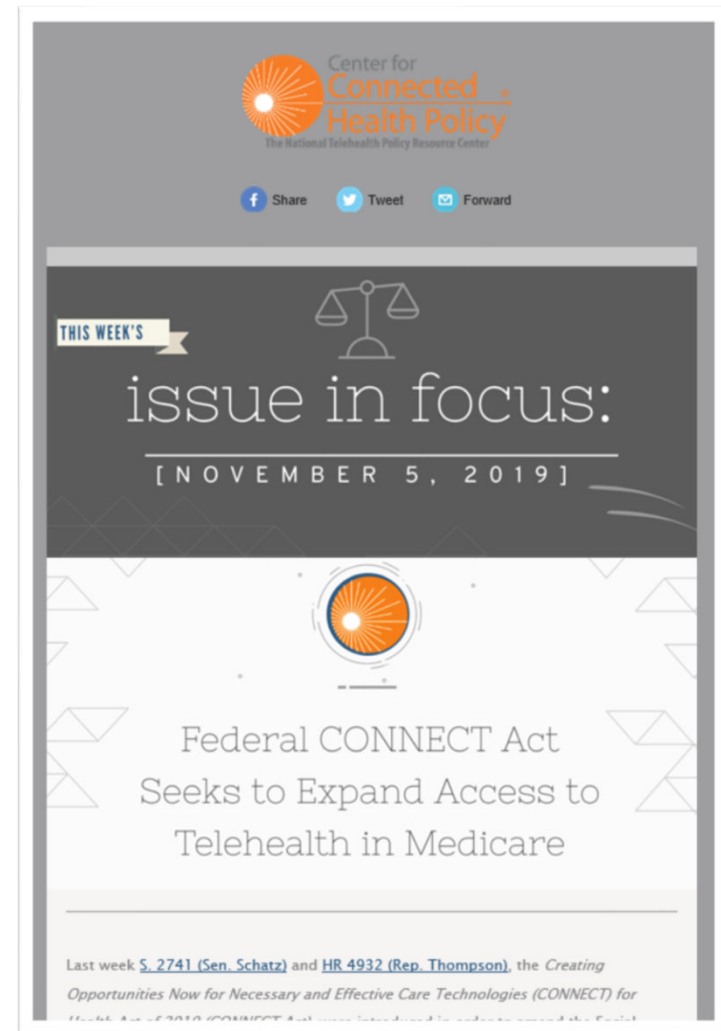


- **1 claim** was for services provided by a physician located outside the United States (A physician residing and practicing psychiatry in Pakistan provided psychiatric counseling services through telehealth technology to a patient located at a rural medical center in the United States. The service 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 3<sup>rd</sup> time the charm?





# 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 (2016)
  - PT Compact (2016)
- Peer-to-peer consultations
- Provider licensure in home state?
- “Universal Licensure” – but must live in AZ



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

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



Republican Arizona Gov. Doug Ducey arrives at Arizona Capitol in a moving van prior to signing into law HB 2569 making Arizona the first state in the nation to provide universal recognition for occupational licenses Wednesday, April 10, 2019, in Phoenix. (AP Photo/Ross D. Franklin)

Gov. Doug Ducey signed legislation Wednesday that will pretty much allow anyone with any professional license to practice in Arizona without further state review.



# Gray Area: People are Mobile

Department of Health  
Medical Quality Assurance Commission

## Policy Statement

Title:	Telemedicine and Continuity of Care	POL2018-01
References:	<a href="#">RCW 18.71.030</a> , <a href="#">RCW 18.71.230</a> , chapter <a href="#">18.71A RCW</a> , <a href="#">RCW 18.71.011</a> , <a href="#">Guideline MD2014-03</a>	
Contact:	Medical Quality Assurance Commission	
Phone:	(360) 236-2750	E-mail: <a href="mailto:medical.commission@doh.wa.gov">medical.commission@doh.wa.gov</a>
Effective Date:	March 2, 2018	
Approved By:	Warren Howe, MD, Chair (signature on file)	

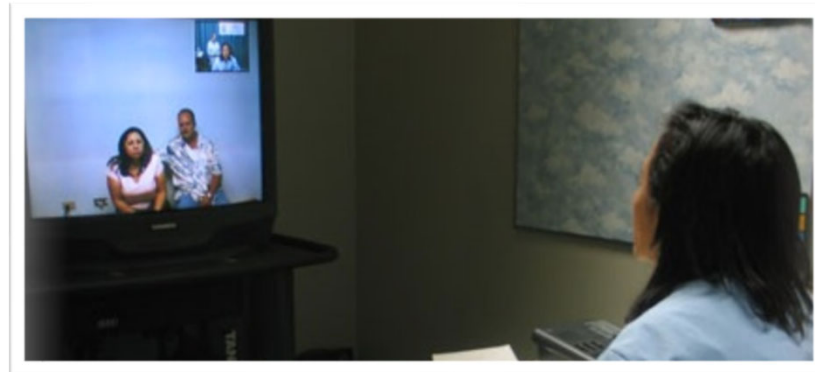
### Policy

The Medical Quality Assurance Commission (Commission) supports the use of telemedicine as a tool that has the potential to increase access, lower costs, and improve the quality of healthcare. Because of rapid changes in telemedicine technology, the practice of medicine is occurring more frequently across state lines, raising regulatory challenges for state medical boards. The Commission issues this policy statement on the role of telemedicine to promote and facilitate continuity of care.

The Commission interprets current law to permit, under certain circumstances, non-Washington-licensed practitioners to use telemedicine to provide follow-up care to established patients in Washington. The Commission also interprets current law to allow Washington-licensed practitioners to use telemedicine to consult with non-Washington-licensed practitioners in other states. This policy statement is consistent with current law, and strikes the appropriate balance between enhancing access to care and ensuring patient safety.

# 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 ... ?

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



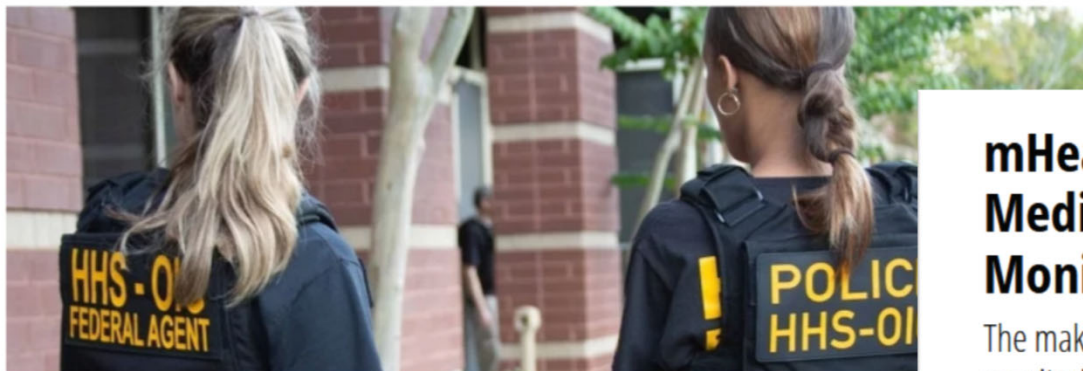
## The Special Registration

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.

## 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

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 Stark Law. It also mentions that the BBA amped up penalties under the AKS and CPML, and that the AKS prohibits willful payment or receipt of remuneration to induce referrals of federal health care program business. The article notes that 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. The CPML is described as a catch-all statute that authorizes the Department of Health and Human Services to impose civil monetary penalties for health care fraud.



Healthcare Practice Advisor

## 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):**

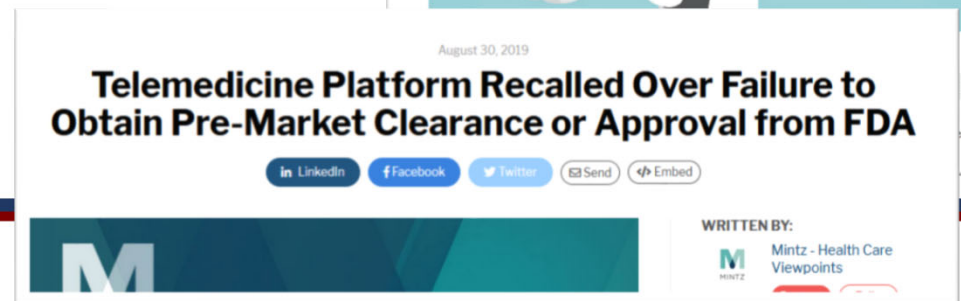
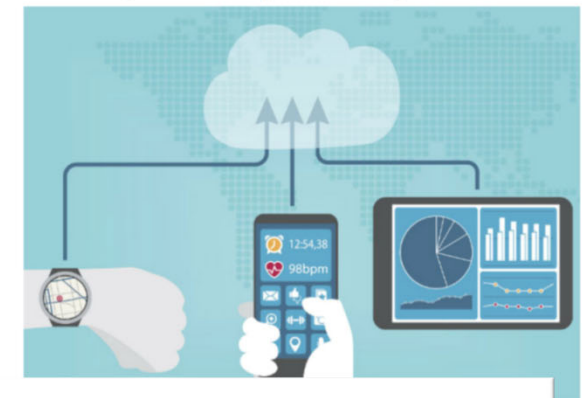
- Telehealth products & tech are mobile medical apps if intended for use either as accessories to other regulated medical devices or to transform mobile tech platforms into regulated apps.
- If app/device is intended for use in **diagnosis or treatment** = medical device
- If poses “minimal risk,” FDA 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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