

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 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

- 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**
- Adopt same quality assurance & peer review practices as with in-person
- Act within scope of licensure
- **Follow pt.-state laws & regs, 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.).



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.



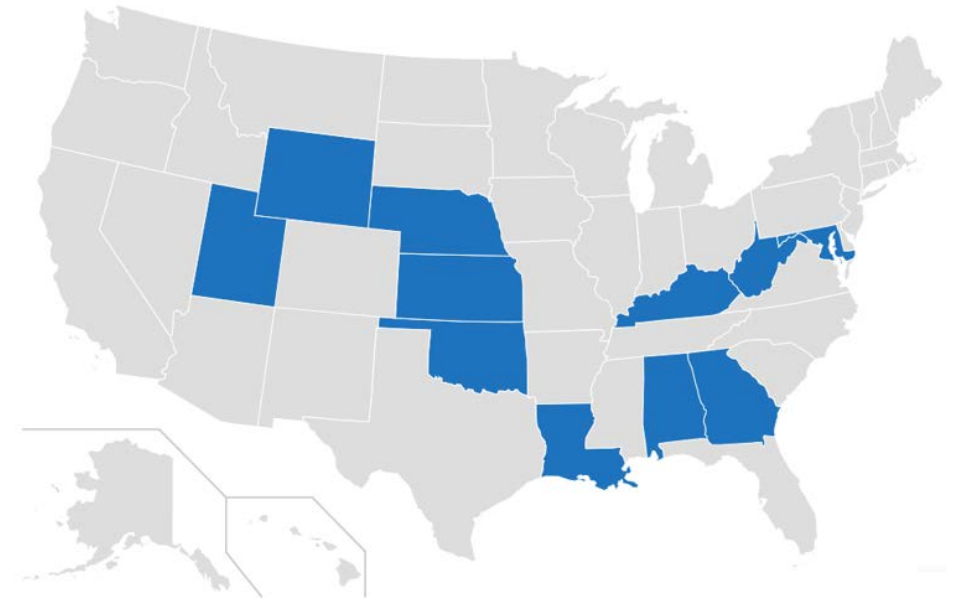
Source: ThinkStock

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

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

17 March 2020 | Blog

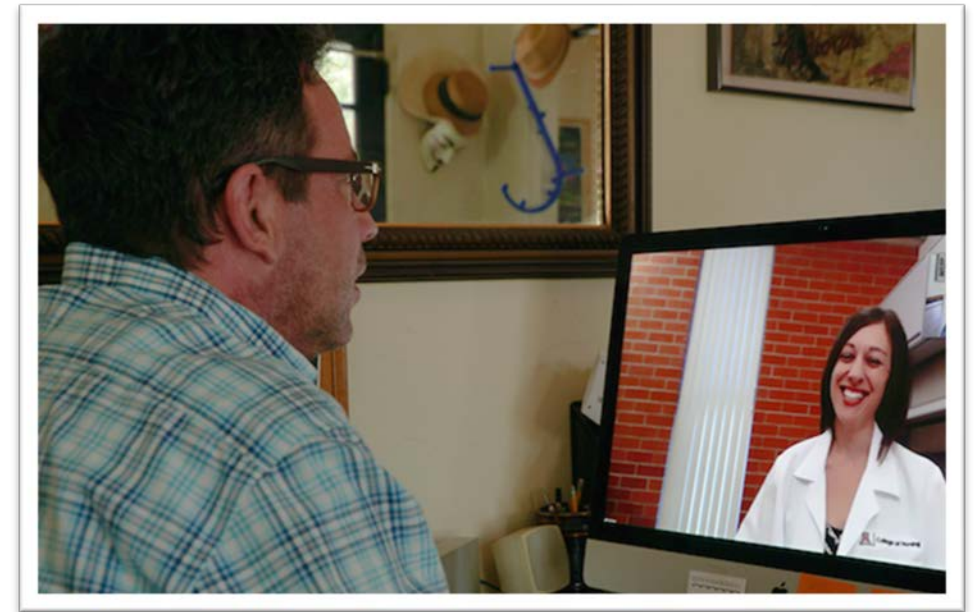
Authors: Emily H. Wein, Rachel B. Goodman, Thomas B. Ferrante

Published To: Health Care Law Today, Coronavirus Resource Center



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)
- **Required** to prescribe



** 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.)

ATTENTION
THIS HAS CHANGED



* 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 regarding the 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 marketers of wearable health monitoring devices have been fined for Medicare fraud 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 used telemedicine platforms to attempt to collect improper

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.

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

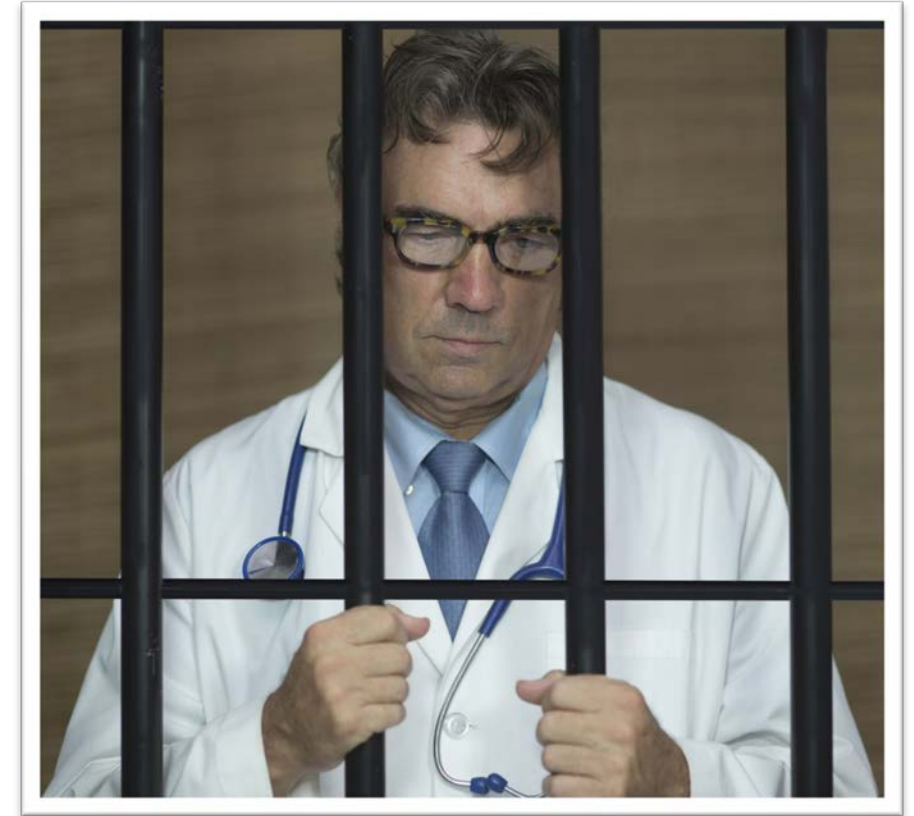
- OK to pay physician above or below FMV
- OK to rent office space or lease equipment below FMV
- OK to loan with interest rate below FMV or on terms unavailable from lender
- Certain referrals OK



Never
Mind?

Anti-Kickback Statute

- Federal healthcare fraud & abuse statute
- 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 – 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 that reinforce the steady progression of, and increasing criminal and civil penalties for, health care fraud enforcement efforts. The article is divided into sections, including "Civil and Criminal Penalty Increases", which details 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



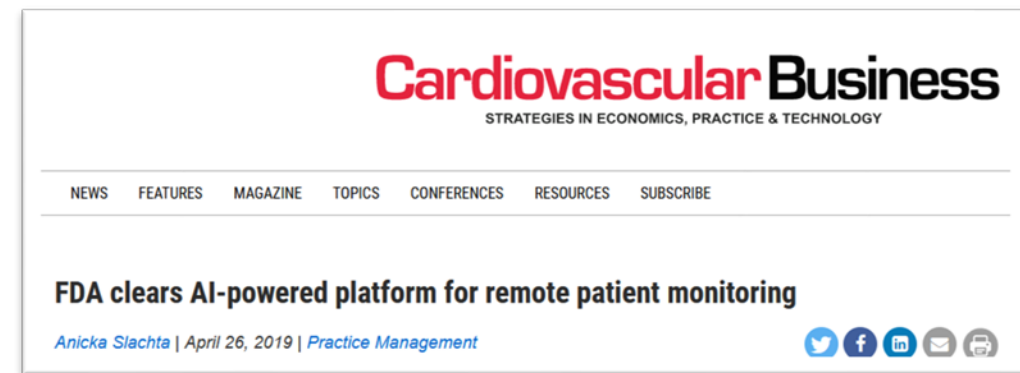
Reverse False Claims Act



- 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”



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FDA clears AI-powered platform for remote patient monitoring

Anicka Slachta | April 26, 2019 | Practice Management

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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.



August 30, 2019

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

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M MINTZ
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?

Lots of Speculation.

No one knows.

Experts Weigh in on Post-COVID-19 Telehealth Rules and Policies

Congress and CMS are being inundated with requests to make permanent telehealth guidelines enacted to expand coverage during the coronavirus pandemic. Here's a rundown of what they're requesting.



Source: ThinkStock

By Eric Wicklund

June 15, 2020 - The ongoing coronavirus stage as healthcare providers of all sizes are navigating the emergency – and the legislative and policy changes that will follow.

Telehealth Advocates Launch Task Force to Lobby for Permanent Policy Changes

The American Telemedicine Association, Alliance for Connected Care and NCQA are spearheading a new task force aimed at lobbying Congress to keep the momentum going to telehealth access and coverage beyond COVID-19.



Source: Getty Images

By Eric Wicklund

June 18, 2020 - Nearly two dozen telehealth advocates, organizations, providers and vendors are joining forces to present a united front in lobbying for long-term connected health access and coverage.

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.



The bill aims to allow providers unfettered use of telehealth during the emergency.

Lawmakers Want a Full Study of Telehealth During the COVID-19 Crisis

A bill before Congress calls on the Health and Human Services Department and the Government Accountability Office to produce separate studies on how telehealth has been used to address the coronavirus pandemic.



FTC Weighs In On Expanding CMS Telehealth Coverage Beyond COVID-19

The Federal Trade Commission has offered its views on several proposals to expand Medicare and Medicaid coverage for telehealth services after the COVID-19 emergency is over.



Source: ThinkStock

By Eric Wicklund



June 05, 2020 - The Fed...

In a letter sent last m... offered the agency's take COVID-19 emergency to

House to Debate Extending CARES Act Telehealth Coverage Indefinitely

The latest in a flurry of bills appearing on Capitol Hill Congress to 'continue the telehealth policies implem... Trump Administration and through the CARES Act.'



Source: ThinkStock

Internists Say Flexibilities for Telehealth and Other Regulatory Waivers Should be Extended

Washington, DC (June 4, 2020) In a letter sent this afternoon to the Centers for Medicare and Medicaid Services (CMS) the American College of Physicians (ACP) said that many of the accommodations that have been put in place to expand the use of telehealth during the COVID-19 pandemic, as well as some of the other regulatory waivers, should remain in place after the period of a public health emergency (PHE) is over.

"It is clear that the policy changes provided by CMS to allow for increased access to and use of telehealth functionality and virtual care have played a pivotal role in mitigating the effects of the COVID-19 pandemic while providing a source of much

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.

Senators Ask HHS, CMS for Telehealth Expansion Timeline, Details

Signed by more than 35 Senators, the letter to HHS and CMS officials asks for 'a written plan and administrative changes to Medicare of telehealth.'



Source: ThinkStock

By Eric Wicklund

July 07, 2020 - Congress is ratcheting up the pressure when and how it will rule on extending telehealth during the pandemic.

In a letter sent last week to leaders at the Health and Human Services Department, the Centers for Medicare & Medicaid Services, more than 35 Senators are addressing the extension of telehealth freedoms during the state of emergency caused by COVID-19.

CMS Moves to Make COVID-19 Home Health Telehealth Expansion Permanent

The Centers for Medicare & Medicaid Services are moving to make telehealth coverage enacted during the pandemic permanent for home health care providers - but they won't be reimbursed.



Source: ThinkStock

By Eric Wicklund

June 26, 2020 - Federal regulators are moving to permanently expand telehealth coverage for home health care services.

New Bill Aims to Make Telehealth Coverage Permanent for FQHCs, RHCs

A bill introduced this week in the House would ensure Medicare coverage for telehealth services provided by FQHCs and RHCs and eliminate originating site facility and location requirements for distant site telehealth services.

JULY NEWSLETTER

Flurry of Telehealth Federal Legislation,

Mounting Pressure for Medicare Telehealth Expansions to be made permanent

JULY 14, 2020

Flurry of Telehealth-Related Bills Introduced in Congress in June

June brought a flurry of newly introduced telehealth-related legislation, each of which takes different approaches to either expand or study telehealth policies during the COVID-19 emergency period or addresses permanent changes in telehealth policies.



to improve telehealth coverage for rural health care providers (RHCs).

Rep. Robert Latta (D-NC), the Helping Families and Workplaces Act of 2020 would, if approved, permanently expand telehealth services and remove originating site requirements for services delivered by them.

'I can't imagine going back': Medicare leader calls for expanded telehealth access after Covid-19

By CASEY ROSS @caseymross / JUNE 9, 2020

Reprints



Seema Verma testifies before the Senate Finance Committee on her nomination to be the administrator of the Centers for Medicare and Medicaid Services.

MANDEL NGAN/AFP/GETTY

President Trump's top Medicare official said Tuesday that expanded access to telemedicine should continue after the coronavirus pandemic recedes and that officials are examining ways to act without waiting for legislation from Congress.

Telehealth now 'embedded' in healthcare system: HHS secretary voices support for expansion

Jackie Drees - Friday, July 10th, 2020 [Print](#) | [Email](#)

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HHS Secretary Alex Azar said during a July 9 virtual *The Hill* event that he supports expanding telehealth provisions that were lifted during the coronavirus pandemic and the agency plans to work with Congress for greater coverage.

"I think we'd have a revolution if anyone tried to go backwards on this," Mr. Azar said, according to [Politico](#). "This is now, I think, an embedded part of our healthcare system."

Since the pandemic began, federal and state governments have lifted various telehealth restrictions to help expand access to care during the public health emergency. CMS expanded telehealth coverage and increased pay rates, generating significant increases in use. CMS Administrator Seema Verma has also been vocal about [supporting](#) permanent telehealth coverage. Prior to the pandemic, CMS [provided](#) 13,000 telehealth visits per week, but by April 25, the number grew to 1.7 million virtual visits per week.

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
- **FSMB & Other Prof'l Associations:** Licensure compacts
- **AHCCCS:** Broadened telehealth coverage – fall 2019
- **AZ Legislature:** SB1089 (2019), HB2536 (2020) to add PTs, OTs, SLPs, etc.



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Thank you!

Questions?

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