

ARIZONA
TELEMEDICINE
PROGRAM



Telehealth Regulation: What Now?

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***Arizona Telemedicine Program / Southwest
Telehealth Resource Center***



COVID-19 Telehealth Changes: Recap

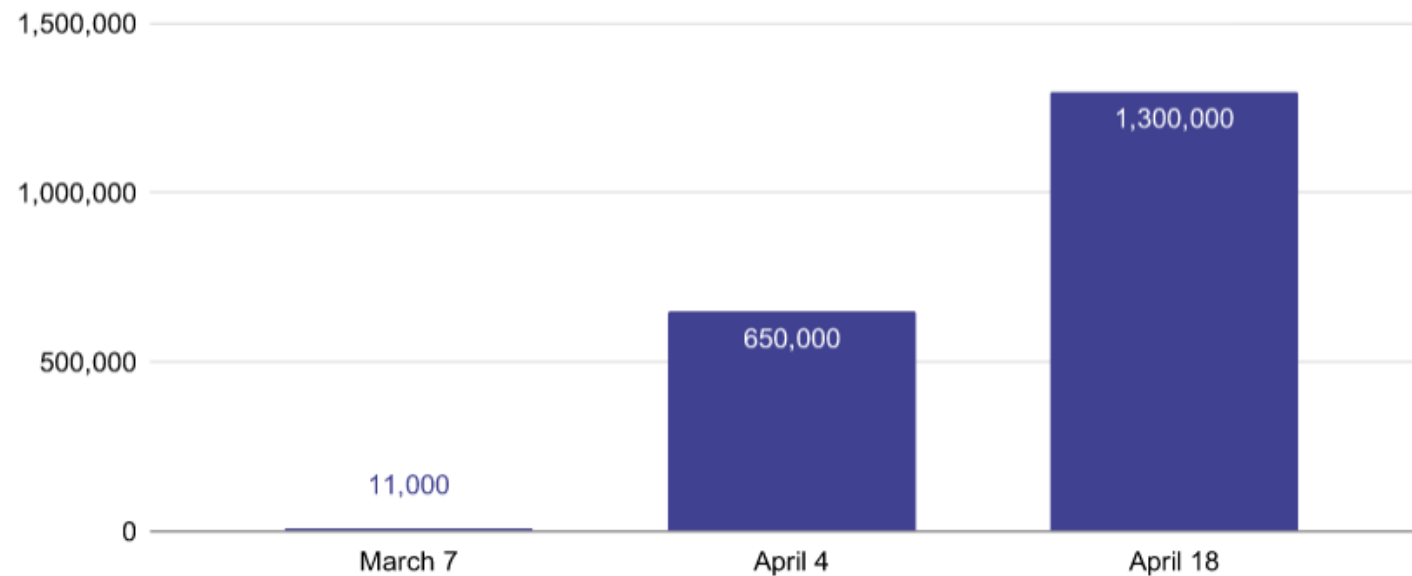
- Congress – CARES Act
- HHS – Multiple waivers
- CMS – Medicare & other restrictions lifted, CMMI flex
- OCR – HIPAA enforcement discretion
- OIG – AKS & CMP flexibilities
- DEA – PHE Telemedicine Exception
- FDA – relaxed certain device enforcement
- FCC – grants, more \$ for Rural Health Care Program
- DOD – TRICARE: audio-only, no cost-sharing, internat'l

Medicare Telehealth Services During the PHE

- 11,718% increase in 1.5 months

The number of seniors in Medicare using telehealth has shot up as CMS relaxed regulations amid the pandemic

Medicare beneficiaries receiving telehealth services in the weeks ending March 7, April 4 and April 18



Rebecca Pifer/Healthcare Dive, data from CMS

From Healthcare Dive

When Will the COVID-19 PHE End?

- A. October 24, 2020
- B. When the HHS Secretary says it's over – no notice required
- C. No one knows
- D. All of the above



When Will the PHE End?

January 2022?

- Zika pandemic 2016-2017: 260 days
- H1N1 pandemic 2009-2010: 360 days
- Each renewed multiple times

The Telehealth Cliff



CTeL – Congressional Staffers’ Discussion

CTEL SUMMIT AGENDA | FRIDAY, JUNE 19, 2020

ALL TIMES ARE IN EASTERN STANDARD

General Session | The Home Stretch: Last Chance to Pass Telehealth Legislation in the 116th Congress

René Quashie, Esq.

Vice President, Policy & Regulatory Affairs, Digital Health | Consumer Technology Association

Crozer Connor

Senior Legislative Assistant | Representative Mike Thompson (D-CA)

Elizabeth Henry

Health Policy Advisor | Senator Hyde-Smith (R-MS)

Danielle Janowski

Legislative Assistant | Senator John Thune (R-SD)

Lauren Jee, JD

Health Policy Counsel | Senator Ben Cardin (D-MD)

Meghan O’Toole, MA

Health Policy Advisor | Senator Brian Schatz (D-HI)

Priorities:

- FQHCs & RHCs
- Keep HHS Sec 1135 authority on the books
- Telephone-only
- CARES Act changes permanent
- Can’t wait until 2024 for a report
- Cliff: Can’t be abrupt
- Need aggregate data re: cost, access

What Would Have to Happen to Avoid the Telehealth Cliff?

The list below represents what actions would be necessary to maintain or extend telehealth flexibilities that were implemented during the COVID-19 public health emergency.

Legislation

Telehealth Flexibility	Detail
Provider/patient location	
Geographic and originating site requirements. During the PHE, providers may deliver telehealth services to patients in their homes and other locations and in any area of the country (waiver of the geographic and originating site requirements).	Section 1834(m) of the Social Security Act (the Act) restricts the delivery of telehealth services to certain rural areas of the country (geographic site restrictions) and certain physical locations such as hospitals and physicians' offices (originating site restrictions). Section 3703 of the CARES Act (H.R. 748) gave the Secretary the authority to waive this and all other requirements of Sec. 1834(m) during the PHE. Legislation would be required to permanently remove these restrictions from statute.
Eligible providers and facilities	
RHCs and FQHCs. During the PHE, Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) may serve as distant sites for the provision of telehealth services.	This flexibility was established in Section 3704 of the CARES Act (H.R. 748), which added a paragraph to Section 1834(m) instructing the Secretary to pay for telehealth services that are furnished via a telecommunications system by an FQHC or an RHC, subject to certain requirements. Legislation would be required to permanently retain the ability of RHCs and FQHCs to serve as distant sites for the provision of telehealth services.
Additional practitioners. During the PHE, all health care professionals who are eligible to bill Medicare for their professional services (including physical therapists, occupational therapists, speech language pathologists, and others) may deliver and bill for services provided via telehealth.	Section 1834(m)(4)(E) limits payment for telehealth services to physicians and a limited set of non-physician practitioners under the Medicare physician fee schedule. In its general waiver document, CMS used its authority under the CARES Act to waive this limitation so as to expand the types of health care professionals that can furnish distant site telehealth services. A change in legislation would be necessary to permanently allow this expanded list of providers to deliver and bill for telehealth services or to give the Secretary authority to determine

What Would Have to Happen?



FEDERAL COVID-19 EMERGENCY ACTIONS

The following details the temporary actions taken in reaction to COVID-19, basis of those actions, expiration date and what action could be taken to preserve such policy change after the public health emergency (PHE) is over. These actions should not be considered legal recommendations.

MEDICARE			
POLICY ISSUE	COVID CHANGE	EXPIRATION DATE	CHANGE TO MAKE PERMANENT
Removed geographic & facility/site limitation	HR 6074	When PHE is over/expires	Statutory change needed. However, “rural” is not defined in statute and CMS could use a broader definition. Precedent for this administrative action taken in 2014. Allowing the “home” to be an eligible originating site for other services beyond ESRD & treatment for OUD with a co-occurring mental health diagnosis would require statutory change. This limitation would also mean ability for hospitals to bill outpatient services when the patient is at home would not be able to continue.
Added additional providers to eligibility list (Including FQHCs/RHCs & Allied Health Professionals)	CARES Act – HR 748/1135 Waiver	When PHE is over/expires	Statutory change needed
Allowed audio-only phone for telehealth services/Increased payment amount	CARES Act – HR 748/1135 Waiver	When PHE is over/expires	Administrative action can be used as “telecommunication system” not defined in statute
Expansion of services eligible for reimbursement	Existing law	When PHE is over/expires	Existing power for CMS to determine what services can be reimbursed if provided via telehealth
In-person requirement for renewal/check-in of certain services such as for home dialysis patients, hospice.	1135 Waiver	When PHE is over/expires	Most appear to be CMS requirements which would allow for changes to be made Administratively
Frequency limitations	1135 Waiver	When PHE is over/expires	Most appear to be CMS requirements which would allow for changes to be made Administratively



Supervision requirements	1135 Waiver	When PHE is over/expires	Most appear to be CMS requirements which would allow for changes to be made Administratively. May still encounter state level policy issues.
Temporary waiver of licensing requirement (must be licensed in patient’s state)	1135 Waiver	When PHE is over/expires	Would require statutory change
PRESCRIBING CONTROLLED SUBSTANCES			
POLICY ISSUE	COVID CHANGE	EXPIRATION DATE	CHANGE TO MAKE PERMANENT
Allowing use of live video to prescribe without falling into one of the other exceptions	Existing law – activates when a PHE is declared	When PHE is over/expires	Already existing exception
Allowing audio-only phone to prescribe buprenorphine for opioid use disorder treatment	Current DEA authority	When PHE is over or unless otherwise specified by DEA	DEA authority to continue
HIPAA			
POLICY ISSUE	COVID CHANGE	EXPIRATION DATE	CHANGE TO MAKE PERMANENT
OCR to not fine for violations during PHE	Current OCR authority	When PHE is over/expires	Legislation and/or regulations likely needed
STARK LAWS			
POLICY ISSUE	COVID CHANGE	EXPIRATION DATE	CHANGE TO MAKE PERMANENT
Waiver of certain requirements	1135 Waiver	When PHE is over/expires	Legislation likely needed

**What Is Being Done
to Avoid the Cliff?**

Testimony Before Congress

U.S. SENATE COMMITTEE ON
Health, Education
Labor & Pensions

CHAIRMAN

RANKING MEMBER

HEARINGS

COMMITTEE ACTIONS

ABOUT

FULL COMMITTEE HEARING

Telehealth: Lessons from the COVID-19 Pandemic

Date: Wednesday, June 17, 2020

Time: 10:00 AM

Location: 430 Dirksen Senate Office Building



- 4 prominent TH leaders
- Importance of TH during PHE, broad acceptance
- Pts will lose access if expansions not made permanent
- Make originating site expansion permanent
- Allow any Medicare eligible healthcare provider
- Digital divide / telephone-only reimbursement s/be permanent
- Private payer reimbursement

June 9: Seema Verma of CMS: “I can’t imagine going back”

STAT+ CONVERSATIONS

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

By CASEY ROSS @caseymross / JUNE 9, 2020



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 telemedicine should continue after the coronavirus pandemic recedes, and that officials are examining ways to act without waiting for legislation from Congress.

“I can’t imagine going back,” said Seema Verma, administrator of the Center

June 11: Helping to Ensure Access to Local Telehealth (HEALTH) Act of 2020: would keep FQHC & RHC TH payments

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.



Source: ThinkStock



By Eric Wicklund

June 12, 2020 - A bill introduced in Congress this week aims to improve telehealth coverage for federally qualified health centers (FQHCs) and rural health clinics (RHCs).

Introduced by US Reps. Glenn Thompson (R-PA) and George Butterfield (D-NC), the **Helping to Ensure Access to Local TeleHealth (HEALTH) Act of 2020** would, if approved, mandate Medicare coverage for telehealth services at these clinics and remove originating site facility and location requirements for distant site telehealth services delivered by them.

June 15: 30 Senators Ask Congressional Leadership for permanent Medicare TH expansions

United States Senate

June 15, 2020

The Honorable Mitch McConnell
Majority Leader
United States Senate
Washington, DC 20510

The Honorable Charles Schumer
Minority Leader
United States Senate
Washington, DC 20510

Dear Majority Leader McConnell and Minority Leader Schumer:

As you continue your work on critical legislation to respond to the COVID-19 crisis, we write to ask that you make permanent the provisions from our bipartisan CONNECT for Health Act that were included in previous COVID-19 legislation. These provisions have resulted in an important expansion of access to telehealth services for Medicare beneficiaries during the pandemic.

We have long advocated for increasing access to telehealth because of its potential to expand access to health care, reduce costs, and improve health outcomes.¹ Telehealth has proven to be pivotal for many patients during the current pandemic, ensuring they receive the care they need while reducing the risk of infection and the further spread of COVID-19. We have all heard from our constituents about how effective and convenient it is. Expanded Medicare coverage of telehealth services on a permanent basis—where clinically appropriate and with appropriate guardrails and beneficiary protections in place—would ensure that telehealth continues to be an option for all Medicare beneficiaries after the pandemic ends.

As you know, the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 and the Coronavirus Aid Relief and Economic Security Act included provisions from the CONNECT for Health Act to increase access to telehealth services for Medicare beneficiaries during the COVID-19 pandemic. Specifically, these laws provide the Secretary of Health and Human Services the authority to waive telehealth requirements under Section 1834(m) of the Social Security Act, allow Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) to provide distant site telehealth services, and allow for the use of telehealth to conduct the face-to-face visit required to recertify a patient’s eligibility for hospice care.

Because of these new authorities provided by Congress, Medicare has expanded coverage of telehealth services for the duration of the pandemic to include all areas of the country—as well as allowing a patient’s home to serve as an originating site for telehealth. In addition, more types of health care providers—including FQHCs and RHCs that provide primary care in rural and underserved areas—are able to furnish and bill Medicare for telehealth services. These changes have already contributed to a dramatic increase in the use of telehealth services in Medicare. Available data show that the number of Medicare beneficiaries using telehealth services during the pandemic increased 11,718 percent in just a month and a half.²

¹ For example: https://www.cchpca.org/sites/default/files/2018-09/HRSA_Cost_Efficiency_Studies.pdf and <https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/ceer-216-telehealth-final-report.pdf>

² <https://www.healthcaredive.com/news/medicare-seniors-telehealth-covid-coronavirus-cms-trump/578685/>

June 18: >20 organizations announce TH policy task force

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.

June 18: KEEP Telehealth Options Act – would require HHS & GAO TH studies

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.



Source: ThinkStock



By Eric Wicklund



June 22, 2020 - While Congress is under mounting pressure to extend telehealth coverage past the coronavirus pandemic, some lawmakers want to make sure the evidence is there to support those moves.

A bill introduced in the House last week calls on both the Health and Human Services Department and the Government Accountability Office to conduct separate studies of telehealth use and outcomes during the ongoing emergency. Known as the **KEEP Telehealth Options Act**, the bill aims to give lawmakers a detailed accounting of the connected health landscape.

June 19: Equal Access to Care Act – would let TH providers see pts. anywhere up to 6 months after PHE

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.

June 25: Advancing Telehealth Beyond COVID-19 Act – would continue TH policies from PHE

House to Debate Extending CARES Act Telehealth Coverage Indefinitely

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



Source: ThinkStock

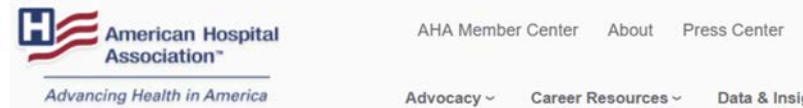
By **Eric Wicklund**



June 29, 2020 - The House of Representatives is setting the stage for discussion on extending telehealth freedoms enacted over the past few months by the Health and Human Services Department to address the coronavirus pandemic.

A bill introduced this past week in the House aims to make those freedoms permanent. Called **the Advancing Telehealth Beyond COVID-19 Act**, it would "continue the telehealth policies implemented by the Trump Administration and through the CARES Act, while advancing access to emerging technology for seniors especially in rural areas."

June 26: AHA urges CMS to extend waivers



CMS Urged to Extend Certain COVID-19 Flexibilities

Advocacy / Letter/Comment

AHA today urged the Centers for Medicare & Medicaid Services to temporarily extend certain COVID-19 public health emergency flexibilities to allow hospitals to continue to provide better and more cost effective care to their patients and communities. For example, AHA recommends CMS continue to temporarily expand the services that can be provided via telehealth and via audio-only; the locations where these services can be delivered; and the practitioners and providers, such as outpatient departments, that can bill for these services. It also recommends CMS continue to temporarily increase bed capacity in rural areas in an emergency, optional quality measurement reporting requirements during the pandemic and delaying certain reporting requirements to focus clinical resources solely on patient care.

June 29: 340 healthcare organizations ask Congress to make expansions permanent, give HHS more authority

Healthcare IT News

[Global Edition](#) [Telehealth](#)

Hundreds of industry groups call on Congress to advance permanent telehealth reform

Medical associations, health systems, vendors and other stakeholders are asking Senate and House leaders to prioritize four areas when enshrining permanent changes to telemedicine regs.

By **Kat Jercich** | June 30, 2020 | 10:06 AM



Three hundred and forty healthcare organizations published an [open letter](#) Monday asking Senate and House leaders to permanently enshrine changes to policies that

July 7: >35 Senators ask HHS & CMS for plan & timeline for making TH changes permanent

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 timeline for permanent administrative changes to Medicare rules governing the provision of telehealth.'



Source: ThinkStock



By Eric Wicklund



July 07, 2020 - Congress is ratcheting up the pressure on the federal government to explain when and how it will rule on extending telehealth access and coverage past the coronavirus pandemic.

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

July 9: HHS Secretary: "We'd have a revolution if anyone tried to go backwards on this"

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.

Flurry of Telehealth Federal Legislation,

Mounting Pressure for Medicare
Telehealth Expansions to be
made permanent

JULY 14, 2020



At least nine TH bills introduced
in Congress in June alone!

More at CCHP's legislative &
regulatory tracker:

<https://www.cchpca.org>

Flurry of Telehealth–Related Bills Introduced in Congress in June

June brought a flurry of newly introduced telehealth–related legislation, each of which take different approaches to either expand or study telehealth policies during the COVID–19 emergency period or addresses permanent changes in telehealth policies that would apply once the emergency ends.

*From the Center for
Connected Health Policy*

Action in the States

Idaho

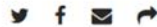
Idaho Statesman

STATE POLITICS

Idaho Gov. Little signs executive order easing telehealth restrictions permanently

BY RUTH BROWN

JUNE 22, 2020 01:30 PM , UPDATED JUNE 22, 2020 06:25 PM



June 22: Gov. Brad Little signs an executive order permanently easing restrictions on access and affordability to Idahoans. BY KATHERINE JONES



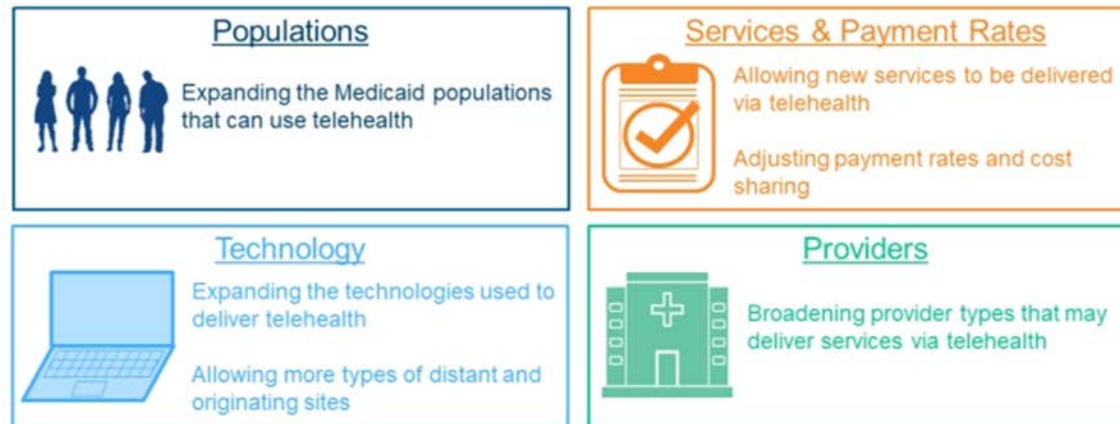
Listen to this article now
01:52 Powered by Trinity Audio

Idaho Gov. Brad Little on Monday signed an executive order easing restrictions around telemedicine permanent.

Multiple State Medicaid Expansions

Figure 1

In response to COVID-19, states are expanding telehealth in Medicaid by making adjustments to key areas:



SOURCE: Centers for Medicare and Medicaid Services (CMS), [State Medicaid & CHIP Telehealth Toolkit](#), April 2020, as well as KFF analysis of Medicaid telehealth guidance posted to state websites.

KFF
HENRY J. KAUFMAN
FAMILY FOUNDATION

Figure 1: In response to COVID-19, states are expanding telehealth in Medicaid by making adjustments to key areas:

New Jersey



Assembly Committee Passes Bill to Improve Accessibility of Telehealth and Telemedicine Services

June 23, 2020, 4:00 pm | in

Assembly Committee Passes Bill to Improve Accessibility of Telehealth and Telemedicine

Conaway, Houghtaling, Benson & Karabinchak

and affordability of care delivered remotely, Assembly Conaway, Eric Houghtaling, Daniel Benson and Robert to provide expanded coverage for telemedicine and telehealth services by the Assembly Health Committee on Tuesday.

0) would require New Jersey health benefits plans, Medicaid and Health Benefits Programs and School Employees' Health Benefits providers for telehealth and telemedicine services at the same rate

Massachusetts & Pennsylvania

After Past Failures, 2 States Push Ahead With New Telehealth Rules

Massachusetts' medical board has issued its first-ever telehealth policy, while Pennsylvania lawmakers are poised to review a telehealth bill that replaces the one vetoed by their governor 2 months ago.



Source: ThinkStock



By Eric Wicklund



July 02, 2020 - Two states with troubled histories of telehealth support are pushing ahead with plans that would improve the connected health landscape.

In Massachusetts – long considered one of the least telehealth-friendly states – the Board of Registration in Medicine **recently approved its first permanent policy on telemedicine**. The one-paragraph policy states that an in-person visit between a provider and patient is not

Colorado

Gov. Jared Polis signs bill protecting telehealth

SB20-212: Reimbursement for telehealth services



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Photo by: Nick Chamberlin

SB20-212.



By: Colette Bordonon

Posted at 11:42 PM, Jul 06, 2020 and last updated 2:12 PM, Jul 07, 2020

SOUTHERN COLORADO — Gov. Jared Polis signed four new bills into law Monday to protect and expand a variety of health care services for Coloradans.

Rhode Island

Rhode Island Lawmakers Look to Make Telehealth Coverage Permanent

A bill making its way through the State Senate would require payers in the state to permanently cover telehealth services - including audio-only phone calls and care delivered to the patient's home.



CMS Regulatory Authority

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

The Centers for Medicare & Medicaid Services is proposing to make telehealth coverage enacted during the COVID-19 crisis permanent for home health care providers - though providers still 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.

*Proposed rule –
June 30, 2020*

Proposed PFS

Mid-July

- Look for it
- Telehealth coverage expansions made permanent?!
- Comment – send experiences
- Stay tuned!

Practices

CMS: Upcoming Medicare payment rule to include permanent telehealth expansions

by Heather Landi | Jun 25, 2020 4:30pm



Under Administrator Seema Verma, the Centers for Medicare & Medicaid Services has made sweeping, temporary changes to telehealth reimbursement policies. (HIMSS)

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Thank you!

For questions or more info:

nrowe@telemedicine.arizona.edu

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