



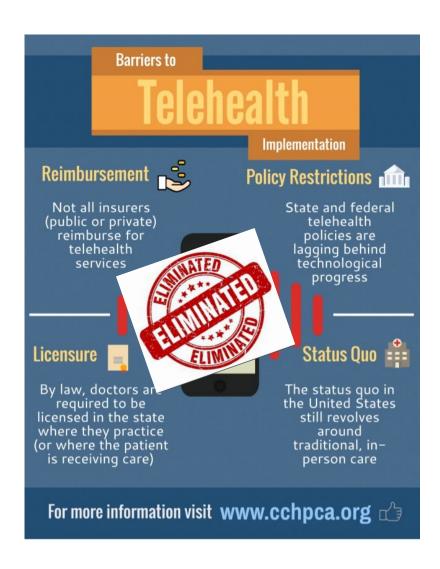
Serving Delaware, Kentucky, Maryland, New Jersey, North Carolina, Pennsylvania, Virginia, Washington DC and West Virginia

National Nurse-Led Care Consortium

May 12, 2023

Telehealth in a Post-PHE World

As A Result of the PHE



Barriers "Temporarily" Removed

- Licensing and Credentialing
- HIPAA
- Ryan Haight and Prescribing of Controlled Substances
- Stark Laws
- Supervision Requirements
- Scope of Practice
- Co-Pays
- Frequency Limitations
- Reimbursement



What Next?

AFTER THE PUBLIC HEALTH EMERGENCY:

Back to Business as Usual?



Status quo has been disrupted.



Temporary
policy changes
are moving
toward
permanency.



Significant investments are being made to expand access to broadband.



Workforce
shortages and
clinician
"burnout" have
been exacerbated
by the pandemic.

Landscape Change Has Taken Place!

What Next?

Preparing for Change: Federal Telehealth **Flexibilities**

Telemedicine Key Dates

Most state waivers expired.

Assume you need licensure in the state where the patient is at the time of the visit. Monitor compact growth!

Omnibus Bill passes Dec. 23. 2022

January 2023 PHE Waiver Extended

February 2023 White House Notification of PHE End

Announced PHE End scheduled for 5.11.23 Future dates below are anticipated

December 2022 CMS releases PFS CY23 Final

Telehealth is still permissible in the home. PHE flexibilities override the PFS CY23 rules regarding telehealth.

Jan. 1. 2023 PFS CY23 Effective

What does this mean? Home is a covered telehealth patient location for all payors under PHE and under the 151day/Omnibus extension. Some billing modifiers may change on the back end but nothing up front.

May 2023 PHE ends -151-Day/Omnibus Flexibilities Begin

Possible Impact:

- Qualifying Providers
- Audio Only Rates

Maga 023 August 2023 HIPAA waiver Ends

DEA 1 November 2023/2024?

covered video platforms & patient communication tools.

Sept 2023 151-Day Only Flexibilities End and **Omnibus** takes effect

PFS CY23 rules now apply but Omnibus flexibilities remain in effect - such as payment for audio only, no originating or geographical site restrictions, and no inperson requirement for behavioral health. Impact: Virtual Supervision

Dec. 31, 2023

Inpatient codes may expire, Stay tuned! PFS CY24 goes live tomorrow.

Dec. 31, 2024

Omnibus telehealth flexibilities expire. PFS CY25 goes live tomorrow.

Moving



Target

The information and tools presented on the National Consortium of Telehealth Resource Center's (NCTRC) website should not be considered as legal advice or interpretation of laws, regulations and policies. NCTRC is providing this for informational and educational purposes only. NCTRC strongly encourages you to check with the appropriate state agency or other applicable authority for further information and direction and to seek the advice of legal counsel if you are in need of a legal opinion.

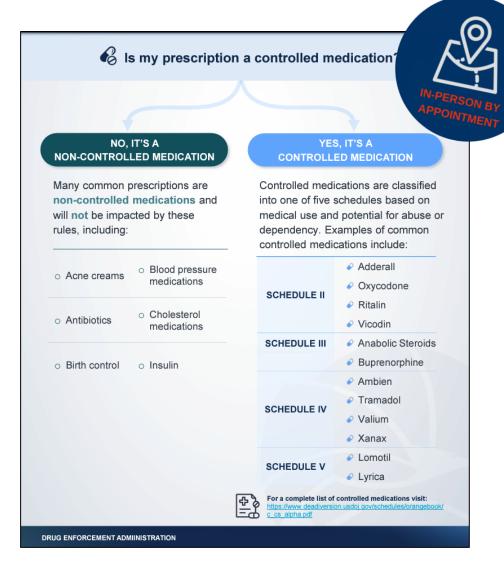
The declaration of a Public Health Emergency (PHE) in March 2020 triggered an allowance in federal law that temporarily allows for the expanded use of telemedicine in prescribing controlled substances for the duration of the PHE. The allowances made for the PHE were set to expire at the end of the PHE – May 11, 2023).



https://www.matrc.org/prescribing/

Under the Ryan Haight Act of 2008, no controlled substance may be delivered, distributed or dispensed without a valid prescription. A valid prescription was one that was issued for legitimate medical purposes by:

- a practitioner who has conducted at least one inperson medical evaluation of the patient; or
- 2) a covering practitioner.



The Ryan Haight Act allowed for several narrowly tailored telemedicine exceptions to the in-person medical evaluation requirement:

- Patient is being treated in a DEA-registered facility (hospital or clinic)
- Patient is being treated in the physical presence of another DEA registered practitioner
- Telemedicine consult is conducted by a DEA registered practitioner for the Indian Health Service (IHS) and is designated as an Internet Eligible Controlled Substances Provider by the DEA
- Telemedicine consult is conducted by a Veterans Health Administration (VHA) practitioner during a medical emergency recognized by the VHA
- During a public health emergency (PHE) declared by the Secretary of the US Dept. of Health and Human Services
- Practitioner has obtained a DEA special registration for telemedicine or under other circumstances specified by future DEA regulations.

On February 24, 2023 the DEA announced proposed rules for permanent telemedicine flexibilities and opened it up for public comment for 30 days:

Proposed Telemedicine Rules Summary

Relationship between prescribing medical practitioner and patient	Prescribing a non-controlled medication	Prescribing Schedule III, IV, or V non-narcotic controlled medications	Prescribing buprenorphine as medication for opioid use disorder	Prescribing Schedule II and/or narcotic controlled medications Permitted Permitted	
Prior in-person medical evaluation by prescribing medical practitioner	Permitted	Permitted	Permitted		
Referral under the proposed rules from medical practitioner who conducted prior in-person medical evaluation	Permitted	Permitted	Permitted		
Telehealth visit without: Prior in-person medical evaluation by prescribing medical practitioner; or Referral from a medical practitioner who conducted prior in-person medical evaluation	Permitted	Up to 30-day initial prescription In-person visit required for additional prescription	Up to 30-day initial prescription In-person visit required for additional prescription	Not permitted	

- The DEA received a record 38,369 public comments
- The DEA filed a draft temporary rule with the OMB last week titled "Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications"
- The proposed "temporary" rule was published in the Federal Register on May 9, 2023! The temporary rule was developed jointly between DEA and SAMHSA



Highlights of the Proposed Temporary Rule

- More time is needed to review all the comments and to educate providers, patients and pharmacists about any upcoming changes.
- The PHE flexibilities will be extended through November 11, 2023
- Any practitioner-patient telemedicine relationships established on/before November 11, 2023 will be permitted to continue under the PHE flexibilities through November 11, 2024

UNCLEAR: What changes the DEA will make to the proposed rule based on the public comments received and when these changes (if any) will be announced



- Providers should use these next few months to at least identify all telehealth patients who require prescriptions or prescription refills of controlled substances and who have never had an inperson appointment.
- Providers should give some thought as to the mechanism by which these patients will be seen in-person (either by the provider or someone who can serve as a referring provider) between now and November 11, 2024).

The declaration of a Public Health Emergency (PHE) in March 2020 triggered waivers to the Stark and other financial arrangement laws. Any financial arrangements with a physician entered in reliance on these exceptions will expire at the end of the PHE - May 11, 2023).

- •Anti-Kickback Statute: This law prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by Federal health care programs (e.g., Medicare). This practice is often known as "paying for referrals". For telehealth, this could mean "giving away:" software licenses, telehealth equipment, peripheral devices and more.
- •Physician Self-Referral Law (Stark Law): This law prohibits physicians from referring patients to receive "designated health services" payable by Medicare ore Medicaid from entities with which the physician or immediate family member has a financial relationship, unless an exception applies.

https://www.matrc.org/medicare/



Providers need:

- To do their research regarding FMV for telehealth software, equipment, devices, etc.
- To remediate or terminate any noncompliant arrangements / enter into actual contractual agreements where one does not exist
- To ensure appropriate recordkeeping

Preparing For The End Of The PHE And The End Of HIPAA Enforcement Discretion

"Hear No Evil, Speak No Evil, See No Evil" will come to an end!







The PHE ends on May 11, 2023. OCR is providing a 90-calendar day transition period. Therefore, on **August 9, 2023** covered health care providers will once again be subject to penalties for violations of the HIPAA Privacy, Security and Breach Notification Rules that occur in the provision of telehealth!

The Top Ten "Evils" We Have Seen During the PHE

10	(E)	HAVING PHONE CONVERSATIONS WITH PATIENTS IN PUBLIC SPACES AND/OR USING A SPEAKERPHONE
9	2	INITIATING TELEHEALTH VISITS WITH PATIENTS USING SHARED / FAMILY DEVICES
8	(Ô)	COMMUNICATING HEALTH INFORMATION WITH PATIENTS USING UNENCRYPTED EMAIL
7	F	TEXTING WITH PATIENTS USING CONSUMER MESSAGING APPS
6	WI-FI FREE	CONDUCTING TELEHEALTH VISITS ON MOBILE DEVICES OVER VOIP OR A PUBLIC WI-FI NETWORK
5	2 =	HAVING NO MECHANISM FOR VERIFYING PATIENT IDENTITY AND/OR PORTAL ACCOUNT LOG-IN
4		CONDUCTING TELEHEALTH VISITS USING UNENCRYPTED CONSUMER VIDEO PLATFORMS
3		CONDUCTING VISITS ON A TELEHEALTH PLATFORM WITHOUT A BUSINESS ASSOCIATES AGREEMENT
2		NOT ASKING/DOCUMENTING WHO IS IN THE ROOM WITH THE PATIENT DURING A TELEHEALTH VISIT
1		NOT DISCLOSING WHO IS IN THE ROOM WITH THE PROVIDER DURING A TELEHEALTH VISIT

https://www.matrc.org/hipaa/

How To Prepare?

Should I Be Concerned?



DOES HIPAA APPLY TO ME AND MY TELEHEALTH PRACTICE? HIPAA applies to you if you are a healthcare provider that transmits personal health information (PHI) in electronic form. If you do, you ARE a covered entity (CE).



IS THE INFORMATION I AM TRANSMITTING CONSIDERED PHI? Anything that can be used to identify an individual is potentially PHI. There are 18 types of identifiers considered PHI. Examples related to telehealth include names, phone numbers, birthdates, IP addresses, email addresses, device identifiers, and photos/images.



DO I HAVE BUSINESS ASSOCIATES? A business associate is anyone who creates, receives, maintains or transmits PHI on your behalf; or has the ability to come in contact with PHI in your practice. See PHI examples above.



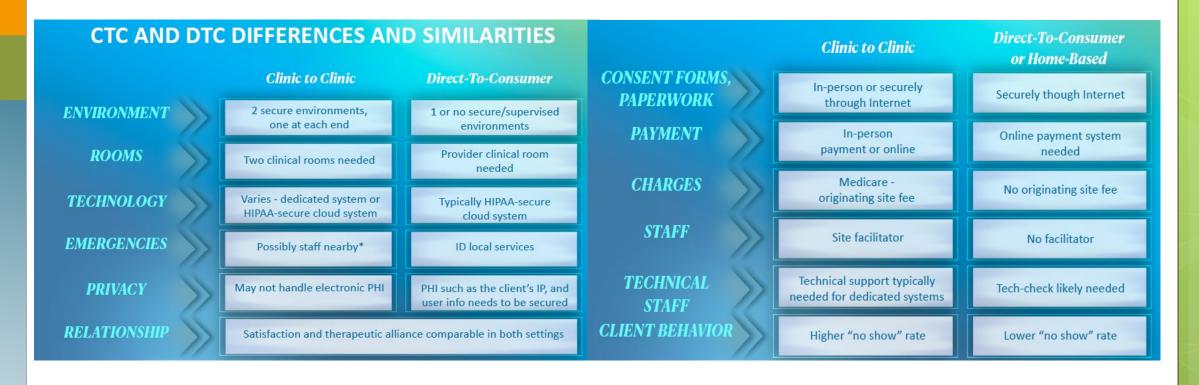


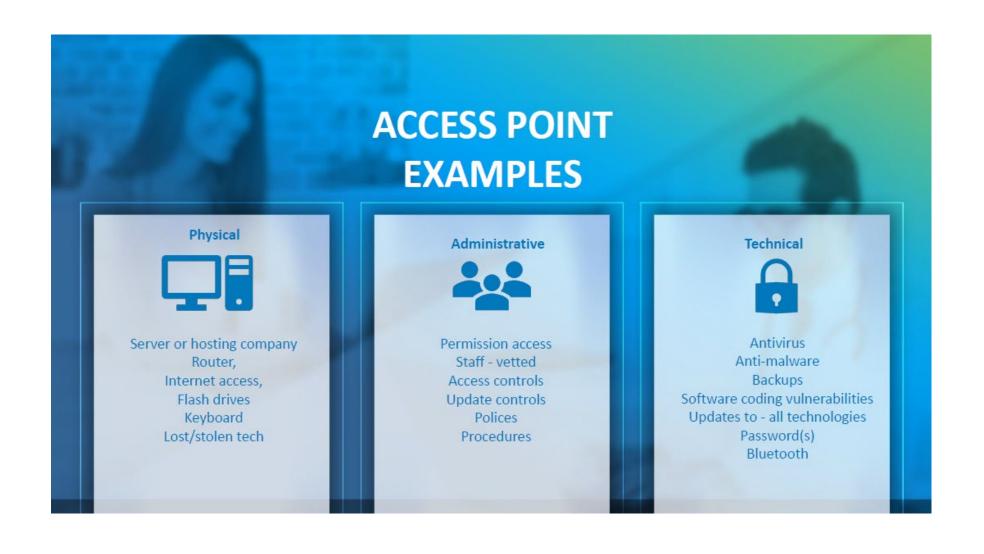
https://telehealthresourcecenter.org/resources/fact-sheets/hipaa-telehealth/



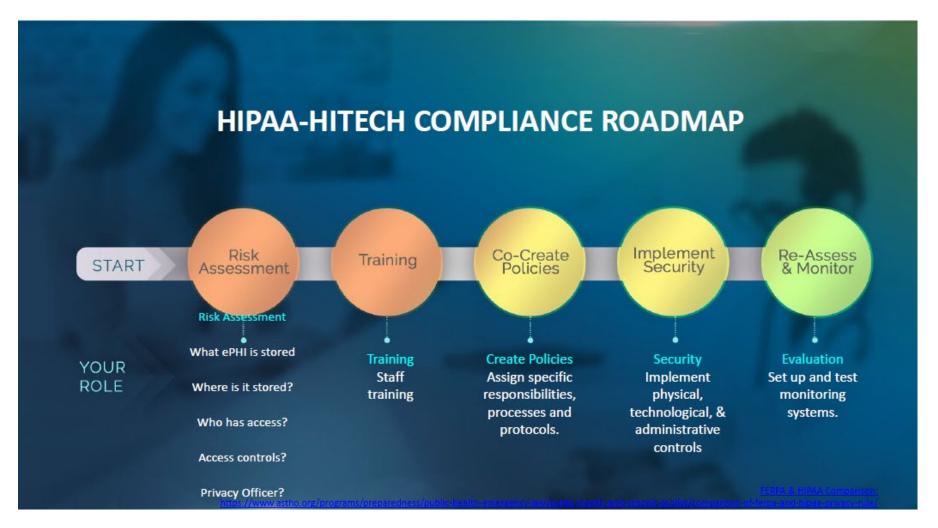
https://www.hhs.gov/hipaa/for-professionals/security/guidance/guidance-risk-analysis/index.html

Understand Setting Differences









 $\frac{https://www.dropbox.com/s/pgok5kbdck61qlf/HIPAA\%20Compliance\%20Roadmap\%20-\%20Summary\%202023\%20-\%20Public\%20\%281\%29.pdf?dl=0$

Some of the Medicare Flexibilities Ending on May 11, 2023:

- Remote evaluations, virtual check-ins, e-visits and remote physiological monitoring will only be reimbursable for ESTABLISHED patients, and not for NEW patients!
- RHCs and FQHCs: Virtual Communication Services (G0071) will no longer include online digital E & M services. G0071 can only be used for G2012 and G2010.
- Waivers of beneficiary co-payments and deductibles associated with telehealth and virtual services

Some of the Medicare Flexibilities Ending on May 11, 2023:

- Hospital Without Walls/Temporary Expansion Sites
 - RHCs and FQHCs: must discontinue using locations outside the location requirements (some clinics created temporary telehealth access point sites that were treated as an extension of the clinic)
 - Hospitals must discontinue temporary expansion sites and off-site locations and provide services in the hospital/original site.

Some of the Medicare Flexibilities Ending on May 11, 2023:

- Hospitals will no longer be able to bill for remote therapy and education services to patients at home (under Medicare OPPS). Patient's homes can no longer be treated as an extension to a hospital outpatient department (this impacts things like PT/OT as a hospital service). This does not impact mental health services or therapy services billed by an independent provider.
- Practitioners providing telehealth services to hospitals must have agreements and be credentialed and privileged.

Some of the Medicare Flexibilities Extended through December 31, 2023:

- Virtual Supervision (telehealth to provide direct supervision)
- Category 3 Telehealth Services (unless made permanent in the Physician Fee Schedule for 2024 – generally published in the Federal Register in November 2023)
- Practitioners working from home as an extension of the office. Effective January 1, 2024 practitioners who render telehealth services from their home will be required to report their home address on their Medicare enrollment.

Some of the Medicare Flexibilities Extended through December 31, 2024:

- Geographic and originating site requirements
- FQHCs and RHCs as distant site providers for telehealth services
- Delay of in-person requirement for mental health services furnished through telehealth
- Audio-only services
- Acute Hospital at Home Initiative

Some of the Medicare Flexibilities Extended through December 31, 2024:

- Use of telehealth to substitute for face-to-face period to recertification for hospice care eligibility
- Expanded list of eligible providers to include PT, OT and SLP

COMMUNICATION IS CRITICAL



Have a plan for letting providers and patients know about these changes! That communication should come from you. Don't hope that they get the information from other sources.

MARCH 2, 2023

Center for Connected Health Policy

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RESOURCE CENTER

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AT-A-GLANCE:

MEDICARE TELEHEALTH/CONNECTED HEALTH WAIVERS POST-PHE

The chart below shows what the status will be for a temporary telehealth-related policy in a post-public health emergency (PHE) landscape. This resource provides an at-a-glance overview of the federal telehealth waivers that were made in response to COVID-19 and is meant to be a summary. Footnotes have also been provided where more explanation may be needed. More detailed information can be found through the <u>Centers for Medicare and Medicaid Services (CMS) fact sheets</u> for each individual provider type. Please note that this at-a-glance chart is divided by provider type, and the page number for each entry refers to that specific CMS fact sheet, which has been hyperlinked in the heading for each section where you can read the full information. The same policy may appear in multiple fact sheets, but the At-A-Giance may only reference it in one fact sheet as the status of that policy post-PHE does not change from fact sheet to fact sheet. The information for this chart was pulled from the CMS fact sheets dated February 24, 2023. Keep in mind that CMS may provide future updates to these documents.

COVID POLICY	PERMANENT ¹	ENDS WITH PHE	ACTIVE THROUGH 2023 ²	EXPIRES 12/31/24 ³	FACT SHEET PAGE			
FACT SHEET: PHYSICIAN & OTHER CLINICIANS								
Allowing all eligible Medicare providers to provide services via telehealth.				х	5			
Temporarily continue to allow the use of audio-only to provide certain services.				х	5, 8			
Temporarily waive site requirements such as patient needing to be in a rural area or in a specified health care site when receiving services via telehealth.				х	5			
Temporarily suspend in-person visit requirement for delivery of mental health services via telehealth when patient is not located in a geographically and/or site eligible location.				Х	5			

¹ Source of change: Physician Fee Schedule

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https://www.cchpca.org/2023/03/MEDIC ARE-TELEHEALTH-POLICIES-POST-PHE-AT-A-GLANCE-FINAL-MAR-2023.pdf

https://www.cchpca.org/

² Source of change: Physician Fee Schedule

³ Source of Change: Consolidated Appropriations Act of 2023.

PYA End of the PHE Compliance Checklist

READ ME: The end of the COVID-19 public health emergency (PHE) means the end of federal regulatory waivers and flexibilities. Providers must now roll back policies and practices implemented in reliance on those waivers and flexibilities. Unless stated otherwise, return to normal operations must be completed before May 12, 2023.

PYA has prepared this checklist to help providers identify the work to be done by that date. Rather than summarizing each waiver and flexibility (e.g., "CMS changed the timeline from 5 to 21 days"), the checklist states the rule that will be in effect following the end of the PHE (e.g., "The timeline is 5 days"). For each item, we cite the relevant regulation, as applicable.

This checklist focuses primarily on waivers and flexibilities relating to the Medicare program. It does not address the following:

- · Waivers and flexibilities made permanent or terminated prior to
- · Reimbursement for COVID-19 vaccinations, testing, and
- · Modifications to Medicare value-based purchasing programs
- · CMS-approved state Medicaid program waivers and flexibilities
- · State and local waivers and flexibilities

Note the following are not impacted by the end of the PHE. Any changes to or discontinuation of these requirements will be the subject of separate

- · FDA emergency use authorization for COVID-19 vaccines, tests, and
- · Hospital and long-term care facility COVID-19-related reporting requirements
- Health care provider vaccine mandates
- · OSHA's Healthcare Emergency Temporary Standard
- · Duties and obligations relating to Provider Relief Fund payments

We have categorized the waivers and flexibilities by the type of provider most directly impacted. Because a waiver or flexibility may impact more than one provider type, one should review each section to identify all relevant post-PHE changes.

This checklist is current as of April 13, 2023. PYA will update the checklist as additional guidance becomes available. This checklist does not constitute and cannot be relied upon as legal, tax, accounting, banking, financial, or any other form of professional or other advice. We have made a reasonable effort to address all waivers and flexibilities, but we do not and cannot warrant the completeness of this checklist.

1. Applicable to Multiple Provider Types

- A. Medicare Provider Enrollment
 - 1. CMS will resume normal application processing timelines
 - 2. Practitioners who have opted out of the Medicare program will no longer be permitted to cancel their opt-out status earlier than allowed by regulation (42 CFR 405.445)
 - 3. Effective January 1, 2024, practitioners who render telehealth services from their home will be required to report their home address on their Medicare enrollment
- B. Medicare Appeals

All regulatory flexibilities relating to Medicare appeals (e.g., extended timeframes) will terminate

C. COVID-19 Diagnostic Testing and Reporting

Providers of COVID-19 diagnostic tests will no longer be required to post cash prices for those tests; however, all hospital price transparency rules will remain in effect

D. State licensure requirements

CMS will defer to state law on issues regarding licensure requirements

- E. Fraud and abuse
 - 1. Any financial arrangement with a physician entered into in reliance on the Stark Law blanket waivers must be brought into compliance with a Stark Law exception (including fair market value) or be terminated, except appropriate repayment terms agreed to prior to the end of the PHE may continue beyond that date
 - 2. Any financial arrangements entered into in reliance on OIG's FAQs regarding the application of its administrative enforcement authorities to arrangements directly connected to the PHE must be brought into compliance with the fraud and abuse laws or terminated (https://oig.hhs.gov/ coronavirus/authorities-faq.asp)

Continued on next page.

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How to Prepare?



https://www.pyapc.com/wpcontent/uploads/2023/03/PYA-End-of-the-PHE-Compliance-Checklist-Final-031323-PRESS.pdf



Federal PHE Ending May 11, 2023
Telehealth Compliance Audit Checklist

Extended Flexibilities

What Federal Medicare PHE Flexibilities Have Been Extended?

On Thursday, December 29, President Biden signed the Fiscal Year 2023 Consolidated Appropriations Act. This legislative package extends most of the pandemic-era Medicare telehealth flexibilities for two years, through December 31, 2024.

The following Medicare telehealth flexibilities have been extended through December 31, 2024:

- a. Removing Geographic Requirements and Expanding Originating Sites for Telehealth. This will continue to allow all Medicare beneficiaries, regardless of geographic location, to be able to utilize telehealth services. Medicare beneficiaries will also be able to continue to utilize telehealth services in the comforts of their home.
- Extending Telehealth Services for Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs).
- c. Delaying the In-Person Requirements Under Medicare for Mental Health Services Furnished Through Telehealth and Tele-Communications Technology. FQHC and RHCs will also be able to furnish telehealth services for mental health patients without an inperson requirement through January 1, 2025.
- d. Allowing for the Furnishing of Audio-Only Telehealth Services for Medicare Beneficiaries.
- Allowing for the Use of Telehealth to Conduct Face-to-Face Encounters Prior to Recertification of Eligibility for Hospice Care.
- f. Expanding Practitioners Eligible to Furnish Telehealth Services. This provision will continue to allow physical therapists, occupational therapists, and speech-language pathologists to furnish telehealth services to Medicare beneficiaries.
- g. Requiring the Secretary of the Department of Health and Human Services to Conduct a Study on Telehealth and Medicare Program Integrity by October 1, 2024.
- h. Extending the Acute Hospital Care at Home Initiative.
- *Virtual Supervision has been extended under the Medicare Physician Fee Schedule through December 31, 2023. It is unclear at this time if Virtual Supervision flexibilities will be extended again into fiscal year 2024.



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End Of The Public Health Emergency (PHE)

We are pleased to to provide a central site for end of Public Health Emergency (PHE) telehealth flexibility planning, which will include blog posts, trusted resource links, tips and tricks, and downloadable tools.

Explore collection \rightarrow



https://telehealthresourcecenter.org/ /collections/

What May Change?

The Consolidated Appropriations Act of 2022 temporarily added qualified OTs, PTs, SLPs and Audiologists as eligible providers for telehealth services for Medicare (will end on December 31, 2024). It is unclear what State Medicaid programs or private payers will do with this.

What May Change?

The Consolidated Appropriations Act of 2022 temporarily extended the waiver allowing audio-only telephone E&M services and behavioral health counseling and educational services through December 31, 2024. It did not mandate parity in reimbursement with in-person care. It is unclear whether rates for audio-only services will change.

The Emerging Challenge

Several recent population-based studies have shown that Medicaid beneficiaries, including patients who are older; black, Hispanic or Asian; who have limited English proficiency; and have lower incomes all have lower rates of telehealth visits during COVID-19 than other populations, **especially telehealth visits by video**.



Telehealth relies on existing infrastructures of <u>healthcare</u> and <u>technology</u> that are

fundamentally

inequitably

distributed.

Poor access is poor access.

A Deeper Dive

THERANDBLOG

Rethinking the Impact of Audio-Only Visits on Health Equity

COMMENTARY (Health Affairs)



Photo by shapecharge/Getty Images

by Lori Uscher-Pines and Lucy Schulson
December 17, 2021

https://www.rand.org/blog/2021/12/rethinking-the-impact-of-audio-only-visits-on-health.html

Ongoing delivery of audioonly visits can reduce the quality of care among lowincome populations and contribute to health disparities.

Generous parity
reimbursement for audioonly visits may be
creating perverse
incentives to deliver
substandard care to the
most underserved.

Contact

For More Information:



Kathy Hsu Wibberly, PhD

Director, Mid-Atlantic Telehealth Resource Center UVA Center for Telehealth

Email: Kathy.Wibberly@virginia.edu

Phone: 434.906.4960





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