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Analysis
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COVID-19 PHE Policies for AAFP

Overview

Outlined in this document are some impacts the end of the COVID-19 Public Health Emergency (PHE) will have on health-related policies and regulations. This analysis has been updated to reflect the status of policies when the PHE ends on May 11, 2023, as announced by the Biden Administration.[1] While some areas like vaccine and therapeutic availability will not be directly impacted by the end of the PHE declaration, other sectors such as coverage and payment policies, telehealth, and teaching flexibilities will see the significant unwinding of temporary flexibilities and waivers allowed during the COVID-19 PHE. The following includes information on the following policies:

- Vaccine and Therapeutic Emergency Use Authorizations
- COVID-19 Test and Medical Device Availability
- Mask Guidance and Availability
- Coverage and Payment Policies
- HIPAA Flexibilities and Telehealth
- PREP Act Liability Immunity
- Controlled Substance Waivers & Flexibilities
- Substance Use Disorder (SUD) Treatment
- Teaching and Supervision Flexibilities
- Provider Relief Fund (PRF)

Vaccine and Therapeutic Emergency Use Authorizations (EUAs)

Both vaccines and therapeutics fall under the February 4, 2020 Emergency Use Authorization Declaration that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic.[2][3] EUAs will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic is terminated or the EUA is revoked.[4] An EUA declaration by the Secretary is not dependent on the declaration of a public health emergency and operates as a standalone order. While the PHE is slated to end on May 11, 2023, the February 4, 2020 EUA Declaration will not.

Vaccines

The Pfizer-BioNTech (Comirnaty) and Moderna (Spikevax) vaccines have received full FDA approval. Three drug treatments have also received full FDA approval in adults and some pediatric patients: Veklury

[1] Statement of Administration Policy
[2] Notice of Emergency Use Authorization Declaration
[3] See Section 319 of the Public Health Service Act
[4] EUA Expirations

(remdesivir), Actemra (Tocilizumab), and Olumiant (baricitinib).[5] The Secretary can ensure continuous access to COVID-19 vaccines and therapeutics currently authorized under EUA by continuing the EUA declaration until they have achieved full FDA approval.

The monovalent Moderna COVID-19 Vaccine (marketed as Spikevax) is fully approved by the FDA for use in individuals 18 years of age and older. The Moderna COVID-19 Vaccine remains available under EUA as a two-dose primary series for individuals 12 years to 18 years of age, as a third primary series dose for individuals 6 months of age and older who have been determined to have certain kinds of immunocompromise. The bivalent Moderna COVID-19 Vaccine is also authorized for use as a single booster dose to prevent COVID-19, administered at least two months after: (1) Completion of primary vaccination with the monovalent Moderna COVID-19 Vaccine in children 6 months through 5 years of age, (2) Completion of primary vaccination with any authorized or approved COVID-19 vaccine in individuals 6 years of age and older, or (3) Receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine in individuals 6 years of age and older.[6]

The monovalent Pfizer-BioNTech COVID-19 Vaccine (marketed as Comirnaty) is fully approved by the FDA for use in individuals 12 years of age and older. The Pfizer-BioNTech COVID-19 Vaccine remains available under EUA as a two-dose primary series for individuals 5 years of age and older, as a third primary series dose for individuals five years of age and older who have been determined to have certain kinds of immunocompromised, and as the first two doses of the three-dose primary series for children six months through four years of age. The bivalent Pfizer-BioNTech is authorized for emergency use as a third dose of the three-dose primary series following two doses of the monovalent Pfizer vaccine in children 6 months through four years of age, and as a single booster dose at least It is also authorized for use as a heterologous single booster dose two months after completion of either primary vaccination with any authorized or approved COVID-19 vaccine or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine in individuals 5 years of age and older.[7]

The Janssen COVID-19 Vaccine is not fully approved by the FDA but is available under EUA for individuals 18 years of age and older for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and individuals 18 years of age and older who elect to receive the Janssen vaccine because they would otherwise not receive a COVID-19 vaccine. For these individuals, the Janssen vaccine is authorized as a single primary vaccination dose, a single booster dose, and as a heterologous single booster dose following completion of primary vaccination with a different available COVID-19 vaccine.[8]

The Novavax COVID-19 Vaccine, Adjuvanted is not fully approved by the FDA, but is available under EUA for individuals 12 years of age and older. It is authorized for emergency use to provide a two-dose primary series to individuals 12 years of age and older and as a first booster dose to the following individuals at least 6 months after completion of primary vaccination with an authorized or approved COVID-19 vaccine:

- Individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate.

[5] Coronavirus (COVID-19) | Drugs
[6] Spikevax Moderna COVID-19 Vaccine
[7] Comirnaty Pfizer-BioNTech COVID-19 Vaccine
[8] Janssen COVID-19 Vaccine

- Individuals 18 years of age and older who elect to receive the Novavax COVID-19 Vaccine, Adjuvanted because they would otherwise not receive a booster dose of a COVID-19 vaccine.[9]

Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders[10]

The *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders* details FDA recommendations and procedures for the issuance of EUAs, implementation of emergency use authorities, and reliance on the governmental pre-positioning (stockpiling) authority for medical countermeasures. The guidance is not specific to the COVID-19 pandemic but outlines the process for EUA termination and product disposition.

COVID-19 Test and Medical Device Availability

COVID-19 diagnostic tests fall under the February 4, 2020 Determination of Public Health Emergency that declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for the detection and/or diagnosis of the novel coronavirus.[11] For emergency use purposes, FDA includes in vitro diagnostic tests under the umbrella of "medical devices" along with items like PPE, infusion pumps, remote patient monitoring devices, and ventilators.[12]

In December 2021, FDA released its draft *Transition Plan for Medical Devices Issued Emergency Use Authorizations During the Coronavirus Disease 2019 Public Health Emergency*.[13] The transition plan outlines general recommendations to stakeholders for the transition process from operations adopted during the COVID-19 PHE to normal operations. The guidance is intended to help facilitate continued patient, consumer, and health care provider access to devices needed for the prevention, treatment, and diagnosis of COVID-19.

In the guidance, FDA recommends that manufacturers of devices authorized under EUAs develop plans immediately for their post-EUA regulatory and disposition strategies. The transition plan provides recommendations regarding the preparation and submission of marketing submissions, including the timing of such submissions, for manufacturers who want to keep their products on the market beyond the termination of the EUA. FDA expressly states in the guidance its intent to help facilitate the submission of marketing submissions before the EUA termination date if the manufacturer intends to continue to distribute its device after the EUA for the device is no longer in effect. FDA also provides instructions for manufacturers to initiate discussions with the Agency to develop a plan to address their specific scenario if it is not covered in this guidance.

Section VI of this guidance details several hypothetical examples intended to illustrate the transition policy and exemplify the timeline of the transition plan.

[9] Novavax COVID-19 Vaccine
[10] Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders
[11] Determination of Public Health Emergency
[12] COVID-19 Emergency Use Authorizations for Medical Devices
[13] Transition Plan for Medical Devices Issued Emergency Use Authorizations During the Coronavirus Disease 2019 Public Health Emergency

Alongside the transition plan, FDA also issued the draft *Transition Plan for Medical Devices that Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 Public Health Emergency.*[14] This companion guidance describes FDA's recommendations for transitioning devices that fall within enforcement policies issued during the COVID-19 PHE. The enforcement policy for devices with a marketing submission under review by FDA will be flexible. FDA will allow the continued distribution of devices within the scope of this guidance after the EUA termination date where the manufacturer has submitted a marketing submission to FDA and had it accepted by FDA before the EUA termination date, and FDA has not taken a final action on the marketing submission.

In October 2022, the FDA Center for Devices and Radiological Health (CDRH) published its Proposed Guidances for Fiscal Year 2023.[15] The two transition guidances referenced above appear on the A-list section under "Final Guidance Topics", indicating they are prioritized device guidance documents the FDA intends to publish during FY2023. These documents have not been finalized as of the writing of this document.

Mask Guidance and Availability

CDC mask guidance is not subject to deadlines or expiration dates associated with the COVID-19 PHE. Mask guidance at the state level beyond that provided by the CDC may coincide with state declarations of a PHE. The National Academy for State Health Policy maintains an interactive database of state-level information on emergency orders and mask requirements.[16]

Coverage and Payment Policies

Medicare, RHCs, and FQHCs

The *Consolidated Appropriations Act, 2023* (CAA) extended several telehealth flexibilities for Medicare patients through December 31, 2024.[17] Specifically, previously waived originating site requirements for telehealth services are to continue through December 31, 2024, along with coverage for audio-only telehealth visits. The omnibus also extends flexibilities that allow federally qualified health centers (FQHCs) and rural health clinics (RHCs) to serve as distant sites, rather than originating sites, for telehealth and delays in-person requirements for mental health services furnished through telehealth.

During the PHE, beneficiaries in traditional Medicare and Medicare Advantage have paid no cost sharing for COVID-19 at-home testing, testing-related services, and certain treatments, including oral antiviral drugs. The end of the PHE will serve as the expiration date for this policy, except for coverage and costs for oral antivirals in accordance with changes made in the CAA.

Several other Medicare flexibilities will come to an end alongside the end of the PHE, including:

- Hospitals receiving a 20% increase in the Medicare payment rate for the treatment of patients diagnosed with COVID-19 through the hospital inpatient prospective payment system (IPPS).
- Waiver of the 3-day prior hospitalization requirement for skilled nursing facility (SNF) stays for those Medicare beneficiaries who need to be transferred because of the effect of a disaster or

[14] Transition Plan for Medical Devices that Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 Public Health Emergency
[15] CDRH Proposed Guidances for Fiscal Year 2023 (FY2023)
[16] States' COVID-19 Public Health Emergency Declarations and Mask Requirements
[17] Consolidated Appropriations Act, 2023

emergency. Beneficiaries who may have recently exhausted their SNF benefits can have renewed SNF coverage without first having to start a new benefit period.

- Requirement that Medicare Part D plans provide up to a 90-day supply of covered Part D drugs to enrollees who request it.
- Section 1135 waivers that allow the Secretary to waive certain program requirements and conditions of participation to ensure that Medicare beneficiaries can obtain access to benefits and services.
    - CMS has issued many blanket waivers[18] and flexibilities for health care providers that are in effect during the COVID-19 PHE to prevent gaps in access to care for beneficiaries impacted by the emergency.[19]

Medicaid Eligibility Redeterminations and Vaccine Coverage

The end of the PHE declaration will not impact the end date of Medicaid's continuous enrollment condition because the *CAA* established the end date for the continuous enrollment policy as March 31, 2023.

In accordance with the *Inflation Reduction Act*, Medicaid and CHIP are required to cover all ACIP-recommended vaccines for adults, including COVID-19 vaccines and vaccine administration, without cost sharing. Medicaid enrollees are eligible to receive coverage of coronavirus testing, including at-home and COVID-19 treatment services without cost sharing through the last day of the first calendar quarter beginning one year after the end of the PHE.[20]

The new eligibility pathway to cover COVID-19 testing and testing-related vaccinations and treatment services for uninsured individuals will expire with the end of the PHE.

Beginning April 1, 2023, the Federal Medical Assistance Percentage (FMAP) implemented through the *Families First Coronavirus Response Act* (FFCRA) will be phased down through December 31, 2023.[21] States that meet the updated conditions to receive the temporary FMAP increase per the *CAA* will be eligible for the following FMAP increases during the unwinding period:

- Q1: January 1 – March 31, 2023: 6.2 percentage points
- Q2: April 1 – June 30, 2023: 5.0 percentage points
- Q3: July 1 – September 30, 2023: 2.5 percentage points
- Q4: October 1 – December 31, 2023: 1.5 percentage points

The *CAA* amended the FFCRA to end continuous Medicaid enrollment as a condition for claiming the temporary FMAP increase beginning on March 31, 2023. Thus, any state that claims the temporary FMAP increase during Q2, Q3, or Q4 will no longer be required to maintain the enrollment of a Medicaid beneficiary for whom the state completes a renewal and who no longer meets Medicaid eligibility requirements.[22]

[18] COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers
[19] What Happens When COVID-19 Emergency Declarations End? Implications for Coverage, Costs, and Access
[20] Inflation Reduction Act of 2022
[21] Medicaid Continuous Enrollment Condition Changes, Conditions for Receiving the FFCRA Temporary FMAP Increase, Reporting Requirements, and Enforcement Provisions in the Consolidated Appropriations Act, 2023
[22] Ibid.

States must continue to meet three of the requirements outlined in the FFCRA during each quarter in which they claim the FMAP increase. These are:

- **Section 6008(b)(1):** States may not claim the temporary FMAP increase for a quarter if, during that quarter, they impose eligibility standards, methodologies, or procedures that are more restrictive than those in effect on January 1, 2020.
- **Section 6008(b)(2):** States could not claim the temporary FMAP increase if they imposed any premium "with respect to an individual" enrolled under the state plan (or a waiver of the plan) that exceeded the amount of such premium as of January 1, 2020. CMS interpreted this condition to mean that a state claiming the temporary FMAP increase could not increase the amount of any premium charged to an individual enrollee (even if that person's income increased).[23]
    - Beginning April 1, 2023, section 5131 of the CAA amends the FFCRA to remove "with respect to an individual enrolled under such plan (or waiver)." This means states claiming the temporary FMAP increase must continue to ensure that the amounts in their Medicaid premium schedule do not exceed the amounts that were in place under the state plan or any waiver of the plan as of January 1, 2020, but may increase the premium amount that is imposed on a given individual without jeopardizing the state's ability to claim the temporary FMAP increase, subject to the following three conditions:
        - The increase must be consistent with the state's Medicaid premium schedule.
        - The premium schedule amounts must not have increased over the amounts in effect as of January 1, 2020.
        - The state must comply with redetermination requirements prior to resumption of Medicaid premiums, as discussed in response to Q24-25 of the COVID-19 Public Health Emergency Unwinding Frequently Asked Questions for State Medicaid and CHIP Agencies.
- **Section 6008(b)(4):** The state must provide coverage, without cost sharing, for any testing services and treatments for COVID-19, including vaccines, specialized equipment, and therapies.[24]

CMS has published several guidance documents in its series of resources about the issues facing state Medicaid programs at the end of the COVID-19 Public Health Emergency (PHE).[25]

According to our HMA colleagues, these guidance documents focus on states' responsibilities and actions once the freeze on Medicaid eligibility standards and maintenance of continuous coverage for individuals enrolled in Medicaid during the COVID-19 PHE ends. The FFCRA made these eligibility and coverage policies a requirement for states that wished to receive higher federal Medicaid matching rates during the COVID-19 PHE declaration.[26] However, once the PHE declaration ends, states will resume normal eligibility redetermination reviews and must prepare for the end of enhanced federal funding.

Since early 2021, CMS and states have been building out state plans for resuming normal operations to address pending applications, verifications, renewals, and to improve the overall eligibility determination process going forward. The resources provide clarity on options and strategies available to states during

[23] COVID-19 FAQs for State Medicaid and CHIP Agencies
[24] Medicaid Continuous Enrollment Condition Changes, Conditions for Receiving the FFCRA Temporary FMAP Increase, Reporting Requirements, and Enforcement Provisions in the Consolidated Appropriations Act, 2023
[25] Unwinding and Returning to Regular Operations after COVID-19
[26] Families First Coronavirus Response Act

the unwinding period. CMS also articulates its expectations for states, for example by requiring that states must complete a post-PHE redetermination for each member before ending coverage.

States have several flexibilities they can retain and newly adopt, some of which may require new state plan amendments, waivers, and changes to systems. States' responses will have far-reaching implications on state coverage programs and budgets, health plan and provider workloads, enrollee/patient panels, and the experiences of consumers. States, health plans, providers, and advocates will need to continue to assess federal agency guidance. All partners and stakeholders should consider appropriate strategies and activities to adapt to state-specific landscapes to avoid the loss of coverage by large numbers of eligible individuals and to help individuals transition to other coverage programs when appropriate.

HIPAA Flexibilities and Telehealth

During the COVID-19 PHE, the Office for Civil Rights (OCR) at HHS elected to refrain from imposing penalties for non-compliance with regulatory requirements under the HIPAA Rules against covered health care providers in connection with the good faith provision of telehealth.[27]

OCR maintains a compendium of resources and guidance related to HIPAA and the COVID-19 PHE on the HHS website.[28] From the OCR FAQs on the Notification of Enforcement Discretion: "The Notification of Enforcement Discretion will remain in effect until the Secretary of HHS declares that the public health emergency no longer exists, or upon the expiration date of the declared public health emergency, including any extensions, whichever occurs first. OCR will issue a notice to the public when it is no longer exercising its enforcement discretion based upon the latest facts and circumstances."[29]

On June 13, 2022, OCR issued additional guidance for covered health care providers and health plans on using remote communication technologies to provide audio-only telehealth services in compliance with HIPAA Rules.[30] This document provides guidance in an FAQ format on audio-only telehealth use when the Notification of Enforcement Discretion for Telehealth is no longer in effect.[31]

PREP Act Liability Immunity

The Public Readiness and Emergency Preparedness Act[32] (PREP Act) provides that, absent willful misconduct, "…a covered person[33] shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the

[27] Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency
[28] HIPAA and COVID-19
[29] FAQ on Telehealth and HIPAA during the COVID-19 nationwide public health emergency
[30] HHS Issues Guidance on HIPAA and Audio-Only Telehealth
[31] Guidance on How the HIPAA Rules Permit Covered Health Care Providers and Health Plans to Use Remote Communication Technologies for Audio-Only Telehealth
[32] 42 USC 247d-6d
[33] A "covered person" includes, (a) the United States; or (b) a person or entity that is, (i) a manufacturer of such countermeasure; (ii) a distributor of such countermeasure; (iii) a program planner of such countermeasure; (iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or (v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).

administration to or the use by an individual of a covered countermeasure if a declaration[34] under…this section has been issued with respect to such countermeasure."[35]

Effective February 4, 2020, the Secretary of HHS made a PREP Act declaration triggering immunity from loss caused by administration or use of "any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product."

The Secretary is authorized to determine an effective period of declaration that is different for various covered persons or countermeasures in order to address logistical, practical, or other differences in responsibilities. Immunity under the PREP Act clearly applies if the countermeasure was administered or used during the effective period of the declaration. There is however some variation in the status of immunity after the declaration expires.

For COVID-19, the effective period of the PREP Act declaration as currently issued is essentially the same for all covered persons and lasts through (1) the final day the declaration is in effect, or (2) October 1, 2024, whichever occurs first. The Secretary may amend any section of the declaration including the effective period expiration date, except that immunity may not be limited retroactively or in ways contrary to the statute.

While each immunity claim may be highly fact-specific, the following table gives a very high-level summary of how we believe these immunity provisions will be interpreted or applied.[36]

	Physicians, HCPs, etc.	"Program planners"	Manufacturer
Use of countermeasure during the declaration	Extensive immunity	Extensive immunity	Extensive immunity
Use of a non-SNS countermeasure after the declaration	Narrow immunity for purposes of limiting administration and use	Narrow immunity for purposes of limiting administration and use	Limited immunity for disposition and for purposes of limiting administration and use
Use of a SNS countermeasure after the declaration	1. Broad immunity for countermeasures "in the stockpile" 2. Good argument that there is little immunity for countermeasures not in the stockpile at	1. Broad immunity for countermeasures "in the stockpile" 2. Good argument that there is little immunity for countermeasures not in the stockpile at	1. Broad immunity for countermeasures "in the stockpile" 2. Good argument that there is little immunity for countermeasures not in the stockpile at

[34] Note that there are several different types of public health emergency declarations. These can have different terms and apply to different activities. This section focuses only on the declaration under the PREP Act and is separate from the declaration made by the Secretary on January 31, 2020 under Section 319 of the Public Health Service Act that a public health emergency exists.
[35] Covered Countermeasures must be "qualified pandemic or epidemic products," or "security countermeasures," or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.
[36] This table is a simple summary and assumes that the specific provisions of the PREP Act have been met. Some exceptions do apply such as the exception for willful misconduct.

	the time of termination of the declaration	the time of termination of the declaration	the time of termination of the declaration

From this chart, it is evident that the date of declaration expiration may have a serious impact on the broad immunity provided by the PREP Act. Indeed, the important and costly consequences of terminating the PREP Act declaration may be a factor in HHS' decision to not do so too quickly.

While the application of immunity is straightforward during the declaration effective period, the statutory language that provides for additional periods of immunity for both SNS and non-SNS countermeasures is much more ambiguous and may depend on the individual facts of each case.

Controlled Substance Waivers & Flexibilities

DEA has made changes related to prescribing controlled substances during the COVID-19 PHE that allow for flexibility in prescribing via telehealth.[37] [38] During the PHE, DEA-registered practitioners may prescribe controlled substances without having to interact in person with their patients. These policies were effective beginning March 31, 2020, and will remain in effect for the duration of the PHE unless DEA specifies an earlier date. DEA has not published transitional guidance for this prescribing flexibility. HHS has also issued guidance on prescribing controlled substances via telehealth.[39]

In January 2023, DEA officials indicated that the agency will propose regulations shortly that allow telehealth providers to continue prescribing controlled substances after the COVID-19 PHE ends.[40] Flexibilities currently in effect are permitted by a waiver of the *Ryan Haight Act*[41] rules during the COVID-19 public health emergency, including waiving the required initial in-person visit prior to prescribing controlled substances via telehealth and allowing the use of telephone evaluations to initiate buprenorphine prescribing.

Unlike other telehealth policies, Congress did not make these particular flexibilities permanent in the legislative package approved in December 2022.

The DEA rules currently in the final stages of review are:

- Special Registration to Engage in the Practice of Telemedicine[42]
- Expansion of Induction of Buprenorphine via Telemedicine Encounter[43]

Substance Use Disorder (SUD) Treatment

SUD treatment during the COVID-19 pandemic has benefited from HIPAA flexibilities, telehealth expansion, and controlled substance flexibilities discussed above that allow for creativity in care provision. In June of 2020, CMS and SAMHSA released a document on leveraging existing health and

[37] How to Prescribe Controlled Substances to Patients During the COVID-19 Public Health Emergency
[38] DEA COVID-19 Page
[39] HHS: Prescribing Controlled Substances via Telehealth
[40] Official end of covid emergency injects uncertainty into telehealth
[41] Public Law 110-425
[42] Special Registration to Engage in the Practice of Telemedicine
[43] Expansion of Induction of Buprenorphine via Telehealth Encounter

disease management programs to provide behavioral health resources during the COVID-19 PHE.[44] In this document, the agencies encourage health insurance issuers to expand coverage for SUD services delivered via telehealth platforms, providing SUD resources through online health and disease management programs, connecting enrollees to community resources for SUDs, and leveraging technology like apps to provide resources during the PHE.

SAMHSA also issued Guidance on 42 CFR Part 2 compliance during the COVID-19 PHE in 2020.[45] The guidance dictates that the prohibition on use and disclosure of patient identifying information under 42 CFR Part 2 would not apply in situations where providers may not be able to obtain written patient consent for disclosure of SUD records to the extent that, as determined by the provider(s), a medical emergency exists. SAMHSA emphasizes that under this medical emergency exception, providers may make their own determinations whether a bona fide medical emergency exists for purposes of providing needed treatment to patients. This guidance is not a waiver or temporary flexibility and therefore will still apply beyond the PHE.

Teaching and Supervision Flexibilities

On March 1, 2020, CPT codes for physicians and residents with the GE modifier under 42 CFR 415.174 were expanded for the duration of the PHE.[46] The expansions allow residents to provide expanded offerings to patients at primary care centers, including levels 4-5 of an office/outpatient Evaluation and Management (E/M) visit, telephone E/M, care management, and some communication technology-based services.[47]

For the duration of the COVID-19 PHE, CMS has authorized teaching physicians to use audio/visual real-time communications technology to interact virtually with residents to meet the requirement that they are present for the key portion of the service, including when the teaching physician involves the resident in furnishing Medicare telehealth services. These flexibilities do not apply in the case of surgical, high-risk, interventional, or other complex procedures, services performed through an endoscope, and anesthesia services.[48]

In addition, teaching hospitals that send residents to other hospitals for purposes of providing COVID-19 medical services can continue to claim those residents as Indirect Medical Education (IME) and Direct Graduate Medical Education (DGME) full time equivalent (FTE) resident counts provided (1) the residents are sent in response to the COVID-19 pandemic, (2) resident training at other hospitals is a substitute for training at the sending hospital; and 3) resident training immediately before or after the COVID-19 PHE is included in the FTE count for the sending hospital. This practice ceases upon expiration of the COVID-19 PHE. Note, sending residents to non-teaching hospitals does not trigger IME and/or DGME FTE resident caps until expiration of the COVID-19 PHE at which point the cap count reinstates.[49]

[44] CMS and SAMHSA: Leveraging Existing Health and Disease Management Programs to Provide Mental Health and Substance Use Disorder Resources During the COVID-19 Public Health Emergency (PHE)
[45] SAMHSA: COVID-19 Public Health Emergency Response and 42 CFR Part 2 Guidance
[46] 42 CFR 415.174
[47] Medicare FFS Response to the PHE on COVID-19
[48] Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency
[49] Teaching Hospitals, Teaching Physicians and Medical Residents: CMS Flexibilities to Fight COVID-19

After the COVID-19 PHE ends, CMS will allow payment for virtual supervision of residents by teaching physicians only when the patient and resident are located in a rural area. When telehealth services are provided by residents, virtual supervision by the teaching physician will only be allowed in rural areas.

The primary care exception detailed above will be limited to services of lower and mid-level complexity once the COVID-19 PHE ends. Services under this exception are expanded permanently to include online digital E/M services, interprofessional telephone, internet, and electronic health record consultation, remote evaluation of recorded video and/or images submitted by an established patient, and brief communication technology-based service.[50]

The Association of American Medical Colleges (AAMC) advocates for virtual supervision payment without restriction based on rural location and other medically underserved communities. They assert that ensuring patients receive high-quality care is the responsibility of the supervising physician, and they should determine when virtual supervision of residents is appropriate. The organization sees telehealth training for residents as a vital tool to promote personal and effective care and supports using three-way calling to allow teaching physicians to supervise telehealth visits.[51]

Provider Relief Fund (PRF)[52]

As of February 6, 2023, HRSA has processed 99% of Phase 4 PRF applications distributing approximately $15.4 billion in funding to more than 90,000 providers.[53]

While HRSA has not distributed all the PRF funds for Phases 2, 3, and 4, it does not appear that this program will be impacted by the end of the PHE.

On March 22, 2022, the HRSA COVID-19 Uninsured Program (UIP) stopped accepting claims for testing and treatment and on April 5, 2022, stopped accepting vaccination claims due to a lack of sufficient funds.

[50] AAMC Regulatory Resource: Resident Supervision Requirements Under Medicare
[51] AAMC Regulatory Resource: Resident Supervision Requirements Under Medicare

[52] Provider Relief Fund

[53] HRSA: Phase 4 and ARP Rural Distributions – Payment Status