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POLICY UPDATE

Impact of Emergency Declarations on CMS Waivers

Summary: The Centers for Medicare & Medicaid Services (CMS) issued more than 100 waivers during the COVID-19 pandemic, giving providers much-needed flexibility to meet unprecedented demands on the healthcare system. CMS's ability to issue these waivers and the waivers' duration both depend on a complex interplay between long-standing and newly granted statutory and regulatory mechanisms.

Many of these waivers can only continue if either the President's national emergency declaration or the Secretary of Health and Human Services' (HHS's) public health emergency (PHE) declaration remains in effect, or both do so. Under current extensions, the national emergency declaration will expire on **March 1, 2023,** and the PHE declaration will expire on **July 16, 2022.** The Administration has committed to providing a 60-day notice before halting the PHE, and therefore stakeholders should expect to learn about whether the PHE will be renewed by May 16, 2022. The extension of the PHE depends on several factors, including the pandemic's status, hospital and provider need, and whether the Administration believes the flexibilities discussed in this +Insight are still necessary to address the pandemic's changing dynamics.

As policymakers prepare for the potential end of the PHE, stakeholders need to know how and when these flexibilities could end. This article reviews relevant waiver authorities and analyzes what will likely occur when these emergency declarations end, with an emphasis on provider-focused flexibilities, including specific information on telehealth flexibilities. While most CMS flexibilities are tied to the PHE, notable exceptions are highlighted below. If important flexibilities warrant extension beyond the PHE or the national health emergency, providers should work with the Administration and Congress on those efforts now.

HELPFUL LINKS:

- Staying Connected: An Update on Medicare Reimbursement for Telehealth Services After the PHE
- Omnibus Spending Package Extends Select Telehealth Flexibilities
- CMS Releases CY 2022 Physician Fee Schedule Final Rule
- CMS Expands Flexibilities in Response to COVID-19
- CMS Releases Second Round of COVID-19 Flexibilities
- CMS Coronavirus Waivers & Flexibilities
- CMS Request for Information: Regulatory Relief to Support Economic Recovery

BACKGROUND ON FEDERAL EMERGENCY DECLARATIONS

Three sources of statutory authority enable the federal government to issue an emergency declaration: the National Emergencies Act (NEA), the Stafford Act and the Public Health Service Act. As of May 4, 2022, an emergency has been declared under all three acts.

National Emergency Declaration: Stafford Act and National Emergencies Act

The President can declare a national emergency under Section 501(b) of the Stafford Act and under Sections 201 and 301 of the NEA. On March 13, 2020, President Trump first declared an emergency for COVID-19 under both the Stafford Act and the NEA, with an effective date of March 1, 2020. A national emergency declaration is effective until one year from the date the emergency was declared, or until the President issues a proclamation terminating the declaration, whichever comes first. Most recently, President Biden continued the national emergency declaration on February 18, 2022. Unless President Biden terminates the declaration sooner, it will expire on March 1, 2023.

When the President's national emergency declaration ends, many CMS waivers will terminate. Exceptions include certain telehealth waivers; certain policy changes contained in CMS rules; specific policies in the Coronavirus Aid, Relief, and Economic Security (CARES) Act; and specific policies in recently passed legislation.

Public Health Emergency: Public Health Service Act

Section 319 of the Public Health Service Act allows the HHS Secretary to declare a PHE for significant outbreaks of infectious disease. If a presidential declaration under the NEA or the Stafford Act is also in place, then a PHE declaration authorizes the HHS Secretary to exercise authority under Section 1135 of the Social Security Act to temporarily waive or modify certain requirements under Medicare, Medicaid, state Children's Health Insurance Program(s) (CHIP), and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule during the PHE. As noted, the national emergency declaration is in effect until March 1, 2023, unless President Biden terminates it at an earlier date.

A PHE declaration is effective for up to 90 days and can be renewed for additional 90-day increments. The HHS Secretary may terminate the declaration whenever the Secretary determines that it is no longer necessary. Former HHS Secretary Alex Azar first declared the COVID-19 pandemic a PHE on January 27, 2020. Most recently, HHS Secretary Xavier Becerra renewed the PHE declaration on April 12, 2022. The current declaration will expire on July 16, 2022. The Biden Administration has stated that it will provide 60 days' notice before ending the PHE. By May 16, 2022, stakeholders should know whether the PHE will be extended beyond July 16, 2022.

LONG-TERM USE OF WAIVERS AND FLEXIBILITIES BY CMS UNDER EMERGENCY DECLARATIONS

These emergency declarations authorize CMS and other agencies to issue waivers and increased flexibility for the duration of the PHE. They do not, however, mandate that such waivers and flexibilities remain in place for the duration of the PHE. While the broader PHE remains in effect at least through July 16, 2022, CMS may examine specific waivers and flexibilities that it believes are no longer improving the health and safety of Medicare beneficiaries and providers.

For example, CMS recently analyzed the necessity of waivers initially granted during the PHE related to certain long-term care facilities, and decided to phase out some of these waivers. This change was

targeted and not necessarily indicative of a broader trend to phase out pandemic-related flexibilities. In its announcement of its decision, CMS clarified that it believes these specific flexibilities no longer effectively and safely served Medicare patients and providers in certain long-term care facilities. CMS detailed its reasons for phasing specific flexibilities out, including its belief that the facilities in question had developed policies or other practices that mitigated the need for targeted waivers. Other than this change, broader waivers and flexibilities continue to remain in place.

EMERGENCY DECLARATIONS AND SPECIFIC CMS WAIVERS (Section 1135)

As noted, Section 1135 of the Social Security Act provides the HHS Secretary authority to grant certain Medicare, Medicaid, CHIP and HIPAA Privacy Rule waivers when two conditions are met: the President has declared a national emergency under the NEA or the Stafford Act, and the HHS Secretary has declared a PHE under the Public Health Service Act. When both the national emergency declaration and the PHE declaration are active (as is currently the case), the HHS Secretary can use Section 1135 waiver authority to waive several requirements:

- Conditions of participation or other certification requirements for individual healthcare providers or types of providers, program participation and similar requirements for individual healthcare providers or types of providers, and pre-approval requirements
- Requirements that physicians and other healthcare professionals be licensed in the state in which they provide services, if they have equivalent licensing in another state and are not affirmatively excluded from practice in that state or in any state that is included, in whole or in part, in the emergency area
- Actions under Section 1867 relating to examination and treatment for emergency medical conditions and women in labor (*i.e.*, the Emergency Medical Treatment and Labor Act (EMTALA))
- Sanctions under Section 1877(g) relating to limitations on physician self-referral
- Deadlines and timetables for performance of required activities, except that such deadlines and timetables may only be modified, not waived
- Limitations on payments under Section 1851(i) for healthcare items and services furnished to individuals enrolled in a Medicare Advantage plan by healthcare professionals or facilities not included under such plan
- Sanctions and penalties that arise from noncompliance with certain provisions under HIPAA.

During the COVID-19 pandemic, CMS has used Section 1135 waiver authority to issue numerous waivers not only to help providers address the emerging challenges of treating patients with COVID-19, but also to ensure providers' ability to deliver ongoing care to patients in non-COVID-19 situations. Nearly all Section 1135 waivers are tied to the existence of both the PHE and the national emergency declaration. If one or both declarations were to end, the flexibilities currently provided under Section 1135 waiver authority would also end.

CMS USED EXISTING REGULATORY AUTHORITY TO PROVIDE FLEXIBILITIES

CMS issued two interim final rules (one on March 30, 2020, and one on April 30, 2020) that broadly relaxed certain regulations through changes to specific requirements and through enforcement discretion. These rules permitted hospitals to expand their capacity, increased telehealth services, added codes to CMS's telehealth list, increased payment for office-based telehealth visits, waived certain licensing requirements for the purposes of reimbursement, eased supervision rules, reduced face-to-face requirements for a range of services, and suspended audits and other administrative requirements.

Unlike CMS's authority to issue Section 1135 waivers, the authority for the policy changes included in these two interim final rules did not necessarily require an existing PHE declaration. However, CMS chose to tie the interim final rules' flexibilities to the duration of the PHE. As a result, the flexibilities contained in these rules will terminate when the PHE terminates, unless extended via additional CMS rulemaking (with the exception of certain telehealth policies, described below.)

EMERGENCY DECLARATIONS AND CERTAIN TELEHEALTH FLEXIBILITIES

A broad range of stakeholders are highly interested in how the end of the national emergency and/or the PHE will impact telehealth flexibilities. The HHS Secretary's ability to waive telehealth requirements is distinct from Section 1135 authority. Congress provided specific telehealth waiver authority through two of the COVID-19 stimulus bills. The Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (the first pandemic stimulus bill) gave the HHS Secretary authority to waive two specific requirements for telehealth services under Section 1834(m) of the Social Security Act: the Medicare "originating site" requirements, and restrictions on the type of telecommunication used for telehealth services. The CARES Act subsequently expanded the telehealth flexibility authority to include all provisions in Section 1834(m).

The CARES Act

The CARES Act implemented the following flexibilities:

- Allowed federally qualified health centers and rural health clinics to provide telehealth services to Medicare beneficiaries
- Eliminated the requirement that Medicare beneficiaries with end-stage renal disease receiving home dialysis have a face-to-face clinical assessment at least once every three months
- Allowed Medicare beneficiaries receiving hospice care to have a face-to-face encounter via telehealth with a hospice physician or nurse practitioner to recertify continued eligibility for hospice care
- Required the HHS Secretary to issue clarifying guidance regarding the use of telecommunications systems for home health services, including remote patient monitoring
- Increased reimbursement to hospitals by providing a 20% add-on payment for inpatient hospital discharges related to COVID-19
- Waived the requirement that patients of an inpatient rehabilitation facility receive at least 15 hours of therapy per week (three hours of therapy per day, five days per week)

- Adjusted transition rules for payment reductions for durable medical equipment
- Required Medicare prescription drug plans and Medicare Advantage drug plans to permit Part D plan enrollees to obtain a 90-day supply of a covered Part D drug (even if the drug is subject to cost and utilization management, medication therapy management or other such programs)
- Expanded the type of hospitals eligible for the Medicare hospital accelerated payment program.

Under these CARES Act provisions, CMS took significant action to increase access to and use of telehealth services, and to provide flexibilities for providers to complete certain administrative requirements virtually. The statute specified that these authorities and flexibilities are tied to the PHE.

Additional Legislation

The Consolidated Appropriation Act, 2022 (CAA)[1] enacted on March 15, 2022, extended certain telehealth flexibilities for 151 days (approximately five months) after the PHE ends. During that period, the law maintains the following measures:

- Extends an expanded list of qualifying Medicare telehealth providers (including occupational therapists, physical therapists, speech language pathologists and audiologists)
- Extends the waiver of originating site and geographic restrictions (so Medicare beneficiaries can still receive telehealth services from any site, including their homes)
- Delays implementation of in-person visit requirements[2] for Medicare mental telehealth services
- Provides for continued Medicare coverage of and payment for telehealth services furnished through audio-only telecommunications systems
- Extends the flexibilities applied to federally qualified health centers and rural health clinics as providers of telehealth services
- Permits pre-deductible coverage of telehealth services in high-deductible health plans with health savings accounts between April 1, 2022, and December 31, 2022.

Although the CAA extended these telehealth flexibilities for five months beyond the end of the PHE, the law did not address some important flexibilities. For example, the CAA did not extend the increased payment rates for office-based telehealth services and did not address licensure flexibilities, among other things. It also did not extend critical access hospitals' ability to serve as distant site providers for telehealth and offer telehealth services the same way they do in-person care. Some stakeholders are concerned that without this flexibility, many critical access hospitals will limit or end telehealth options at the end of the PHE. For a detailed overview of the telehealth provisions in the CAA, including the flexibilities left out of the law, see our additional analysis here.

[1] Public Law No: 117-103

[2] The Consolidated Appropriations Act, 2021 (Public Law No: 116-260) imposes an in-person visit requirement for Medicare beneficiaries receiving mental telehealth services (other than substance use and co-occurring mental health disorders) from an expanded list of originating sites, including the home. Under the requirement, the beneficiary must generally have an in-person visit with her provider in the six-month period before starting the telemental health treatment.

Medicare Physician Fee Schedule

CMS has also allowed for certain exceptions related to telehealth policies through rulemaking. In the CY 2021 Medicare Physician Fee Schedule (PFS) final rule, for example, CMS provided coverage for more than 100 services added (on an interim basis) to the Medicare Telehealth List through the end of the PHE.[3] In the CY 2022 PFS final rule, CMS extended coverage for those telehealth services through the end of CY 2023, regardless of the PHE's status.

For additional details on the telehealth policies contained in the CY 2022 PFS final rule, see our analysis here. For a detailed overview of Medicare telehealth flexibilities and the level of authority (*e.g.*, congressional or regulatory) required to extend those flexibilities beyond the PHE or make them permanent, see our analysis here.

IMPACT OF TERMINATING THE EMERGENCY DECLARATIONS

Whether CMS flexibilities can exist after the PHE or national emergency declarations terminate depends upon the authority under which the flexibility was issued. For example, flexibilities provided under Section 1135 waiver authority would terminate when either the national emergency declaration terminates or the PHE declaration terminates. Under currently projected end-dates, this would mean that these waivers could terminate as soon as **July 16, 2022.** Other flexibilities, unrelated to Section 1135 waivers, have already been extended via regulation or statute for a specific period of time beyond the end of the pandemic.

What Happens If the PHE Declaration Ends?

Most flexibilities will end when the PHE ends. This includes all Section 1135 waivers (because both conditions for Section 1135 waiver authority would no longer be met), all telehealth flexibilities tied to the PHE, the CMS interim final rule changes tied to the PHE, and the provisions specified in the CARES Act. Notable exceptions are the coverage extensions for certain added telehealth services (under the CY 2022 PFS final rule) and the telehealth flexibility extensions included in CAA—because these are implemented by statute and are not tied to the PHE, they will remain in place post-PHE.

Vaccines, Therapies and Devices Granted Emergency Use Authorization

The termination of the PHE will not directly impact products and devices granted emergency use authorization (EUA). The US Food and Drug Administration's (FDA's) authority to issue EUAs for covered countermeasures (*e.g.*, vaccines, therapies, devices) is not dependent on a PHE declaration under Section 319 of the Public Health Service Act, but instead derives from a separate EUA declaration under Section 564 of the Federal Food, Drug, and Cosmetic Act. On February 4, 2020, the HHS Secretary issued a separate and distinct declaration finding that the spread of COVID-19 constituted a PHE for the purposes of allowing FDA to issue EUAs for covered countermeasures. The EUAs for approved products and devices will remain in effect until the HHS Secretary terminates the EUA declaration. Agencies have indicated their intention to provide 12 months for the disposition of unapproved products before terminating the EUA declaration.

[3] These were added on a Category 3 basis. Categories 1 and 2 represent the long-term criteria for additions to the telehealth list; CMS created Category 3 to allow additions not clearly fitting under Categories 1 and 2. Category 3 codes are temporary.

The below table summarizes the conditions necessary for the flexibilities to remain in effect, based on their source of issuing authority.

Source of Flexibility	Conditions Required to Remain in Effect
Section 1135 Waivers	National emergency declaration *and* PHE declaration
Policies Contained in CMS Rules	PHE declaration *or* potential additional rulemaking
CARES Act Policies	PHE declaration
CAA	None. The law expressly extended certain telehealth flexibilities for approximately five months after the PHE ends

CONCLUSION

Many CMS flexibilities put in place during the COVID-19 pandemic will continue to be essential for providers and patients even after the pandemic abates. As policymakers prepare for the potential transition out of an official PHE, stakeholders should examine which flexibilities have been implemented in their organizations and identify when and how operations will transition away from using such flexibilities. While most flexibilities will terminate when the HHS Secretary's PHE declaration and/or the President's national emergency declaration terminates, certain flexibilities could be extended through existing regulatory processes or through new legislation. Stakeholders should engage accordingly with regulators and Congress to advocate for a smooth post-PHE transition.

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