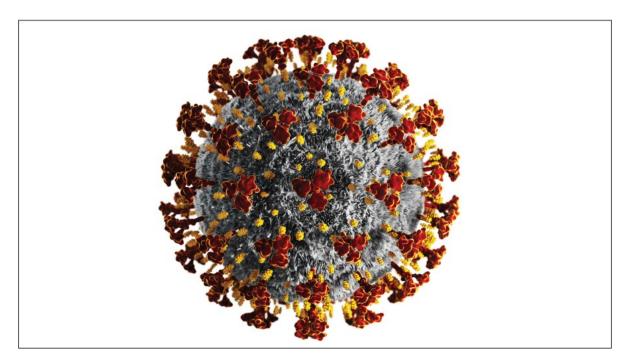
HEALTH LAW WEEKLY

July 22, 2022

HHS Declares That COVID-19 Remains a Public Health Emergency—For Now

Brittney A. Cafero, Reed Smith LLP



On January 31, 2020, then-Department of Health and Human Services (HHS) Secretary Alex Azar declared the COVID-19 pandemic a Public Health Emergency (PHE).[1] Since then, the PHE has been renewed continuously for 90-day extensions, including the latest extension on July 15, 2022, by current HHS Secretary Xavier Becerra that extended the PHE to October 13, 2022.[2]

HHS has not formally communicated how much longer it will maintain the PHE past October, but has reiterated its commitment to state governors to provide a 60-day notice of termination or expiration of the PHE. Therefore, if HHS intends to curtail the PHE before October 13, 2022, it will have to give that notice by August 15, 2022. Providers should prepare for the inevitable end of the PHE.

The Federal Public Health Service Act

By way of background, Section 319 of the federal Public Health Service (PHS) Act, codified at 42 U.S.C. § 247d, is the source of the HHS Secretary's authority to declare a

Copyright 2022, American Health Law Association, Washington, DC. Reprint permission granted.

PHE. A PHE declaration lasts for the duration of the emergency or 90 days, but may be extended by the Secretary.[3] Following a section 319 declaration, the Secretary has the authority to take a variety of actions, including but not limited to: (1) make grants and enter contracts; (2) access "no-year" funds appropriated to the PHE Fund to respond to immediate needs; (3) grant extensions or waive sanctions relating to submission of data reports; (4) modify practice of telemedicine; (5) on a state-by-state basis, grant an extension or waive application deadlines for certain Substance Abuse and Mental Health Services Administration grants and allotments; (6) waive certain requirements of the Drug Supply Chain Security Act; and (7) enable the Department of Labor to issue dislocated worker program grants for disaster relief employment.[4]

COVID-19 PHE Federal Waivers in Effect

There are Blanket Waivers in effect as a direct result of the PHE. For instance, the Blanket Waivers effectuate a waiver of certain sanctions that otherwise apply to violations of the physician self-referral law (Stark Law), if certain conditions are met. [5] Notably, the Office of Inspector General (OIG) incorporated the Blanket Waivers and issued a Policy Statement that the OIG will not impose sanctions related to certain sections of the federal Anti-Kickback Statute. [6] The PHE has also been a means to allow the Office for Civil Rights (OCR) to exercise enforcement discretion to not impose penalties for noncompliance with Health Insurance Portability and Accountability Act (HIPAA) requirements against health care providers in connection with the good faith provision of telehealth during the COVID-19 PHE. [7]

It is imperative for providers to monitor policies at both the state and federal level. At the federal level, many of these waivers and enforcement policies have been maintained since early 2020 as a direct result of the PHE determination. At the state level, however, the waivers and extensions in place have begun to wind down. In California, for instance, Governor Gavin Newsom issued Executive Order N-04-22 on February 25, 2022, to roll back some of the executive orders related to the COVID-19 pandemic.[8] Several COVID-19 policies applicable to California health care providers expired on June 30, 2022.

Significant Impact When COVID-19 PHE Ends

Providers must prepare for the inevitable end of the PHE, as it will have significant effects on all aspects of the health care system, and in particular, Medicaid enrollments. The Families First Coronavirus Response Act of 2020 (FFCRA) required states to implement a continuous coverage requirement to ensure that workers who lost their jobs or employer-provided coverage would have insurance through Medicaid or some other source. [9] The law allowed states to maintain continuous Medicaid enrollment by providing a temporary increase of 6.2% in federal Medicaid payments. [10] Before the pandemic and enactment of the FFCRA, states reviewed the income, age, or disability

Copyright 2022, American Health Law Association, Washington, DC. Reprint permission granted.

status of those enrolled to see if they continued to qualify for the state and federal safety net program. That review was suspended during the PHE; but when the PHE ends, state Medicaid officials must reinstate their policies prior to the pandemic and reassess Medicaid eligibility for each individual.[11]

Notably, patients could potentially lose their Medicaid coverage when the PHE ends, as the states will no longer have the funding through the PHE. The Centers for Medicare & Medicaid Services (CMS) has issued guidance to assist states in restoring routine eligibility and enrollment of operations, while recognizing that states will need time to work in a systematic way that maintains coverage for eligible beneficiaries and reestablishes a renewal schedule that is sustainable for the state agency.[12]

The end of the PHE will also impact telehealth, although not as immediately as the effects on Medicaid coverage and enrollment. Waivers as to who can use telehealth and from where that were based on the existence of a PHE will expire. However, in the Consolidated Appropriations Act, 2022, which it passed in March 2022, Congress extended telehealth flexibilities, including removal of geographic requirements, expansion of originating sites, expansion of types of practitioners who can provide telehealth, expanding use of telehealth in rural health clinics and federally qualified health centers, as well as delaying the in-person requirements for coverage of telehealth under Medicare. This extension will last for 150 days after the declared end of the PHE. So, assuming that the declaration lasts until October 13, 2022 at the earliest, these flexibilities would continue until March 12, 2023.[13]

Moreover, once the PHE ends, hospitals will not receive the 20% increase in payments for treating inpatient Medicare COVID-19 cases that was part of the Coronavirus Aid, Relief, and Economic Security Act funding. The impact on providers, particularly hospitals, will be significant.[14]

State officials, hospitals, and health care systems should take steps to prepare for the end of the PHE and implement effective policies and operations that will mitigate damages to providers and patients during a time of transition.

Brittney A. Cafero is an associate attorney in the Life Sciences and Health Industry group at Reed Smith, LLP.

Copyright 2022, American Health Law Association, Washington, DC. Reprint permission granted.

^[1] U.S. Dep't of Health & Human Servs., Public Health Emergency, https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.

^[2] HHS Office of the Assistant Secretary for Preparedness and Response (ASPR), https://aspr.hhs.gov/legal/PHE/Pages/covid19-15jul2022.aspx.

[3] U.S. Dep't of Health & Human Servs., Public Health Emergency, https://www.phe.gov/Preparedness/legal/Pages/phedeclaration.aspx.

[4] *Id*.

[5] Ctrs. for Medicare & Medicaid Servs., https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Spotlight.

[6] U.S. Dep't of Health & Human Servs., Office of Inspector Gen., OIG Policy Statement Regarding Application of Certain Administrator Enforcement Authorities Due to Declaration of Coronavirus Disease 2019 (COVID-19) Outbreak in the United States as a National Emergency, (Apr. 3, 2020).

[7] U.S. Dep't of Health & Human Servs., *Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency*, https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html.

[8] Executive Department State of California, Executive Order N-04-22 (Feb. 25, 2022).

[9] Pub. L. No: 116-127; see also J. Burns, *Medicaid Directors Prepare for the End of the Public Health Emergency*, MHE Publication (June 20, 2022), https://www.managedhealthcareexecutive.com/view/medicaid-directors-prepare-for-the-end-of-the-public-health-emergency.

[10] *Id*

[11] *Id*.

[12] CMS letter to state health officials, SHO# 22-001, *Promoting Continuity of Coverage and Distributing Eligibility and Enrollment Workload in Medicaid* (Mar. 3, 2022).

[13] Consolidated Appropriations Act, 2022, Pub. L. No. 117-103 (March 15, 2022), Div. P., tit III, subtit. A "Telehealth Flexibility Extensions."

[14] G. Gonzalex, How Hospitals Should Prepare for the End of the Public Health Emergency, Beckers Hospital Review (June 28, 2022), available at, https://www.beckershospitalreview.com/strategy/how-hospitals-should-prepare-for-the-end-of-the-public-health-emergency.html.