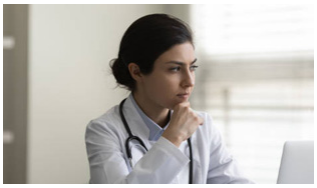

Feds signal a PHE cease. Expect some waivers, like Stark Law, to go when it does.

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COVID-19

Signs are emerging that the national public health emergency (PHE) related to COVID-19 is entering an end phase, and practices should start planning for a halt to some of their PHE-based flexibilities, such as referral arrangements, that likely are not going to survive it.

The initial PHE declaration, made by then-HHS Secretary Alex Azar on Jan. 31, 2020, led to a series of changes in CMS policy that have affected Medicare and other federal health care payment programs. Since then, HHS has renewed the PHE every three months, using its 1135 waiver authority to expand coverage terms and loosen billing requirements, among other actions. The next renewal is required by July 15, 2022.

Yet in the third year of COVID-19, there are signs that HHS, CMS and states are retreating from COVID policies. On March 22, HHS' Health Resources and Services Administration (HRSA) announced it was suspending its Uninsured Program that paid for COVID-related services to Americans without health care coverage. On April 7, CMS announced it was "returning to certain pre-COVID-19 policies in long-term care and other facilities."

According to the National Academy for State Health Policy, 14 states have ended their COVID emergency provisions, and there are currently no statewide mask mandates, with the exception of certain settings, in any state at present.

Review the flexibilities in place

Over the past two years, HHS has "waived dozens of Medicare payment and coverage requirements for a wide variety of providers, providing greater flexibility across a range of matters, such as verbal orders, medical staff credentialing, various location-based requirements, and various requirements relating to direct physician involvement in care," says Joseph B. Keillor, a health care transactional and regulatory attorney with Baker Donelson in Baltimore.

One of the most consequential changes CMS made was to allow telehealth services to be performed and paid for without regard to the normal distant, originating site and eligible physician restrictions; also, the HHS Office for Civil Rights (OCR) announced that it would not enforce telehealth rules regarding the use of non-HIPAA-compliant technologies to conduct such encounters, and OIG announced that it would allow co-pays for telehealth encounters to be waived (*PBN 3/17/20*). By April 6, 2020, CMS had codified these and other telehealth changes in its "Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency" interim final rule (*PBN blog 4/1/20*).

CMS has since added several more changes, and Congress recently addressed some of them in its Consolidated Appropriations Act (CAA) (*PBN 4/4/22*). But that only extends the key provisions for 151 days past the end of the PHE — at which time most of them could be revoked, as the laws that the waivers temporarily amended have not changed.

Telehealth isn't the only policy affected by the waivers. For example, CMS has used 1135 waivers to allow providers to obtain same-day Medicare enrollment and billing privileges and for hospitals to extend physician privileges that were set to expire (*PBN blog 3/23/20*). Dozens of other changes have also been made, though some have been rescinded or set for rescission (*see resources, below*). Practices should review the slate of policies to see which will have an impact on them when revoked.

While the recent CAA has made provision to extend some telehealth flexibilities, "the vast majority of other Medicare payment and coverage waivers are presently set to expire at the end of the public health emergency," Keillor says.

Keep an eye on timelines, declarations

Even when the PHE ends, you'll probably have plenty of heads-up. The Biden administration has promised to give 60 days' notice before it pulls the plug (*PBN 3/1/21*).

Paul Johnson, CEO and founder of Redirect Health in Scottsdale, Ariz., and former mayor of Phoenix, believes some of the popular COVID-era flexibilities, particularly in telehealth, will be saved. "Given the growing popularity of telehealth

outside of just pandemic safety precautions, I believe Medicare will end up retaining these telehealth protections even after the PHE ends," Johnson says.

But he acknowledges that a permanent telehealth expansion is no sure thing. While it has broad support in the industry, entrenching telehealth flexibilities would still require Congressional action. (*Stay tuned to future issues of* Part B News *for complete telehealth coverage as lawmakers consider extending it further.*)

Some administrative changes are more or less guaranteed to come with the end of the PHE. For example, the use of modifiers **CR** (Catastrophe/disaster related) and **DR** (Disaster related) on services allowed under 1135 waivers are likely to go (*PBN 5/4/2020*). You can expect the generous COVID extreme and uncontrollable circumstances exemption to the Quality Payment Program/Merit Incentive Payment System (QPP/MIPS) to be altered as well (*PBN 3/28/22*).

Keillor says the blanket waivers of the physician self-referral law, commonly referred to as the Stark Law, are set to automatically expire at the end of the PHE, and he does not foresee their extension (*PBN 7/6/20*).

"Prior to the termination of the public health emergency, physicians will need to ensure that their arrangements with 'designated health services' entities like hospital and laboratories fully comply with all traditional elements of the Stark Law, including requirements relating to fair market value and written agreements that were temporarily waived," Keillor says.

And if your state still has COVID restrictions of its own, you can expect them to go away, according to Keillor. "Even where state public health emergency declarations are not expressly tied to the federal public health emergency declaration, the end of the federal public health emergency declaration will likely result in significant additional political pressure on states to wind down their emergency declarations," he says.

Monitor PREP progress

A related factor to consider is the Public Readiness and Emergency Preparedness (PREP) Act, which HHS invoked on March 17, 2020, and has repeatedly amended since. Its authority has been used to expand delivery of care during the pandemic — for example, by authorizing pharmacists to order and administer COVID vaccines. It also offers "liability immunity" to those providing "medical countermeasures" in a pandemic, barring "actions or failures to act that constitute willful misconduct," according to the government's PHE website.

The current PREP Act declaration says its liability immunity is "administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction begins with a Declaration and lasts through (1) the final day the emergency Declaration is in effect, or (2) October 1, 2024, whichever occurs first."

Sandra Mekita Cianflone, a partner with Hall Booth Smith P.C. in Atlanta, thinks this may lead to controversy and even litigation in states that have their own PHE declarations and keep them after the federal government drops theirs, as those states may argue they are the "Authority Having Jurisdiction" and their health care providers are still protected with respect to covered countermeasures. It's worth noting that some states have extended their existing COVID emergencies, Johnson points out.

Whatever confusion or chaos the end of the emergency portends, Cianflone expects that the feds are already working on ways to smooth the transition.

"Even if they pull the rug out," she says, "they're going to have to issue some kind of guidance in the interim to get you back to stasis, or we would hope they would do so given that particular portions of legislation are contingent on the PHE being in place."

Resources

HHS, "Determination that a Public Health Emergency Exists," January 31, 2020: *www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx*HHS/CMS. "Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency," April 6, 2020: *www.federalregister.gov/documents/2020/04/06/2020-06990/medicare-and-medicaid-programs-policy-and-regulatory-revisions-in-response-to-the-covid-19-public*HHS, "Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19": *www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures*National Academy for State Health Policy, "States' COVID-19 Public Health Emergency Declarations and Mask Requirements": *www.nashp.org/governors-prioritize-health-for-all/*HRSA, "COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration for the Uninsured," March 22, 2022: *www.hrsa.gov/CovidUninsuredClaim*
CMS, "CMS Returning to Certain Pre-COVID-19 Policies in Long-term Care and Other Facilities," April 7, 2022: *www.cms.gov/newsroom/press-releases/cms-returning-certain-pre-covid-19-policies-long-term-care-and-other-facilities*
CMS, "COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers": *www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf*
PHE.gov, "PREP Act Q&As": *www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx#immune2*