Monday, June 22, 2020

The Centers for Medicare and Medicaid Services (CMS) has issued more than 100 waivers giving healthcare providers the flexibility to meet the demands presented by the Coronavirus (COVID-19) pandemic.

These waiver flexibilities are temporary, however. The authority to grant public health emergency-based waivers under §1135 of the Social Security Act is provided to the Secretary of Health and Human Services (HHS) when two things are true: the Secretary declares a public health emergency (PHE), and the President declares a national emergency under the National Emergencies Act (NEA) or the Robert T. Stafford Disaster Relief and Emergency Assistance Act. Currently, both of these declarations are active.

Should the national emergency declaration end, most of the waivers would terminate. There are notable exceptions, however, including telehealth waivers, policy changes contained in two interim final rules, and specific policies in the Coronavirus Aid, Relief, and Economic Security (CARES) Act. Should both the national emergency declaration and the PHE end, all waiver authority would cease.

BACKGROUND ON FEDERAL EMERGENCY DECLARATIONS
There are three sources of statutory authority for the federal government to issue an emergency declaration: the Public Health Service Act, the Stafford Act, and the National Emergencies Act. As of March 13, 2020, emergencies were declared under all three acts.

**Public Health Service Act**

Section 319 of the Public Health Service Act allows the Secretary of HHS to declare a PHE for significant outbreaks of infectious diseases. Similar to the declaration under the NEA, this emergency declaration allows the Secretary of HHS to exercise authority under §1135 of the Social Security Act to temporarily waive or modify certain requirements of the Medicare, Medicaid and State Children’s Health Insurance programs and the HIPAA Privacy Rule throughout the duration of the PHE. In order for the Secretary to exercise the §1135 waiver flexibility, however, a presidential declaration under the NEA or the Stafford Act also must be in place in addition to the PHE.

HHS Secretary Alex Azar declared the Coronavirus pandemic PHE on January 27, 2020. A PHE declaration is effective for 90 days and can be renewed in additional 90-day increments. On April 26, 2020, the Secretary renewed the PHE for an additional 90 days. The current PHE ends near the end of July. The Secretary may also terminate the declaration whenever the Secretary determines that the PHE has ceased to exist.

**Stafford Act and National Emergencies Act**

On March 13, 2020, President Trump declared an emergency for COVID-19 under Section 501(b) of the Stafford Act and an emergency under Sections 201 and 301 of the NEA. These sections of the NEA allow the Secretary of HHS to exercise the authority under §1135 of the Social Security Act to temporarily waive or modify certain requirements of the Medicare, Medicaid and State Children’s Health Insurance programs and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule throughout the duration of the emergency declaration. Under the statute, this 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.

**IMPACT OF DECLARATIONS ON CMS WAIVERS UNDER §1135 AUTHORITY**

With both the national emergency declaration and the PHE are active, the Secretary can use §1135 authority to waive the following:

- 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., 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.

CMS has used the §1135 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. Providers and other stakeholders have widely appreciated CMS’s actions. Almost all of these §1135 waivers are tied to the existence of both the PHE and the national emergency declaration. Should one or both of these declarations end, barring other Administrative action, the waiver flexibilities would no longer be in effect.

**IMPACT OF DECLARATIONS ON INTERIM FINAL RULES**

In addition to the waivers under §1135, CMS issued two interim final rules. These rules, issued **March 30, 2020**, and **April 30, 2020**, relaxed regulations in a broad range of areas, including the following:

- Enabled hospitals to expand their capacity
- Promoted 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
- Suspended audits and other administrative requirements.

Unlike §1135 waivers, the policy changes included in these two rules do not require a PHE per se, but in issuing them, CMS tied their duration to the duration of the PHE. They are not affected by the existence of a national emergency declaration. These flexibilities therefore would continue to exist even if the national emergency declaration ended, as long as the PHE remained in effect. But they would self-terminate if HHS ended the PHE. CMS could, however, extend them further in the absence of a PHE, if the agency undertook another rulemaking specifically to extend these flexibilities beyond the PHE.

**IMPACT OF DECLARATIONS ON TELEHEALTH WAIVERS**

The Secretary’s ability to waive telehealth requirements is distinct from the §1135
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 stimulus bill) gave the Secretary authority to waive two specific requirements for telehealth services under 1834(m): the “originating site” requirements and restrictions on the type of telecommunication used for providing telehealth services. The CARES Act subsequently expanded the telehealth waiver authority to include all provisions in 1834(m). CARES also authorized the following waivers:

- 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 Secretary of HHS 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 a 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. Greater reliance on virtual care and administration is intended to limit patient travel and exposure to COVID-19 and reduce the spread of the virus, in adherence to other federal guidelines. At the same time, telehealth gives providers an opportunity to provide some healthcare services to their patients without a face-to-face encounter, preserving revenue during the crisis.

The two stimulus laws specified that these authorities and waivers are permitted for the duration of the PHE, but they are not tied to the existence of a national
emergency declaration. This means that the telehealth waivers, along with the CARES Act policies noted above, could continue to exist if the national declaration ended, as long as the PHE remained in effect.

**IMPACT OF ENDING THE NATIONAL DECLARATION AND PHE**

Through a series of recent fact sheets and guidance documents, as well as public statements, the President has encouraged healthcare providers to move toward re-opening healthcare facilities and practices for non-emergent care. There is a possibility that the Administration may end the national emergency declaration and the PHE soon. The declarations may not, however, end at the same time.

What happens if the national emergency declaration ends, but the PHE does not?

If the national declaration ends, one of the two required conditions for §1135 waiver authority would no longer be met, and therefore all of the §1135 waiver flexibility provided would end and no further §1135 waivers could be granted. There is no requirement or statutory basis that provides a roadmap for a phased approach. Barring other Administrative action, these §1135 waivers would terminate the day the national emergency ends.

Telehealth is one exception, however, because the telehealth waiver authority is authorized under a separate law, and is tied only to existence of the PHE. If the national declaration ends but the PHE stands, CMS could continue to offer flexibility for telehealth services until the end of the PHE, if no further action provides a mechanism for a phased approach.

The other exceptions are the policy changes included in the CMS interim final rules, as the agency specified these also were tied to the PHE. If the national declaration ends but the PHE stands, these policies would continue until the end of the PHE. The previously described policies included in CARES would also remain in effect until the end of the PHE.

**What happens if both the national emergency and the PHE end?**

If both the national emergency and the PHE end, all waived policies also would end, barring other Administrative action. This includes all §1135 waiver authority, telehealth flexibilities, the interim final rules, and the provisions specified in CARES.

**CONCLUSION**

The CMS waivers continue to provide important flexibility for providers and patients. Stakeholders widely agree that there is an ongoing need for these waivers, even as parts of the country gradually re-open. The needs of providers vary widely, and without this authority, CMS would not have the necessary tools to support patients and providers. CMS may begin proposing to make some of these waivers permanent in forthcoming proposed payment update rules. Stakeholders should consider which waivers are necessary for short- and long-term durations, and should communicate with the Administration and congressional allies accordingly.