COVID-19 Emergency Declarations and Health Care Policy

Introduction

The global COVID-19 pandemic necessitated the implementation of a broad variety of flexibilities in the U.S. health care system. Under U.S. law and regulation, many of these flexibilities were made possible by (1) a declaration of emergency under the National Emergencies Act (NEA), (2) a declaration of emergency under the Stafford Act, and (3) a declaration of a public health emergency (PHE) under the Public Health Service Act (PHSA). These declarations, or a combination thereof, permit agencies to take extraordinary action or to permit actions by payers and providers that would typically be prohibited. In particular, the combination of an emergency declaration and a PHE permit the use of Section 1135 of the Social Security Act, which allows for the waiver of broad sections of the Act with regard to Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).

Department of Health and Human Services (HHS) Secretary Alex Azar declared a PHE on January 31, 2020, retroactive to January 27. President Trump declared a national emergency under both the NEA and the Stafford Act on March 13, 2020, retroactive to March 1. The combination of these declarations empowered the federal government to take action to provide flexibility to the health care system to combat COVID-19 and their continued existence allows for the maintenance of those flexibilities. PHEs last for 90 days, and the COVID-19 PHE is scheduled to expire July 24 without a renewal. The national emergency declaration lasts much longer — one year before requiring renewal. The lapse of either declaration would result in the curtailing of a large number of emergency policies, including those relating to telehealth, Stark Law, and other provider flexibilities.

In addition to the emergency powers already available to the HHS and other agencies, Congress created, in a series of three emergency bills, a range of policies intended to address the pandemic. This included wide latitude to provide, and be reimbursed for, telehealth services during the pandemic. It also included a boost to the federal share of the Medicaid program, an add-on payment for hospitals treating patients with COVID-19, a requirement for payers to cover COVID-19 tests without cost sharing, and provider relief funding during the period of the PHE. These powers are largely tied to the existence of a PHE (and thus, scheduled to sunset on July 24 absent renewal). In addition, HHS and other agencies engaged in emergency rulemaking, granted waivers to states, and are invoking enforcement discretion that are also largely tied to the PHE.

Members of Congress have begun discussions regarding some of the flexibilities outlined below, and more specifically, where it would be appropriate to maintain them beyond the PHE. For instance, Senate HELP Committee Chairman Lamar Alexander (R-TN) called for keeping a policy relaxing originating site rules, thereby expanding telehealth availability, and keeping an expanded list of telehealth services eligible to be reimbursed by Medicare. Additionally, President Trump recently

issued an executive order directing agency heads to examine, among other things, which emergency policies adopted during the pandemic should be kept post-pandemic. HHS last week proposed a regulation that would make one such policy, relating to telehealth services provided in Medicare's home health benefit, permanent. This illustrates that the administration is weighing the extension of some or all of the policies possible to be extended at an administrative level. Letting the declarations expire, in particular the PHE, could result in an abrupt loss of funding and flexibilities for health care providers. As a result, some provider stakeholder groups, such as the American Hospital Association, have begun to call on the administration to extend the PHE.

This memo describes how these three types of emergencies are declared, how they end, and where we stand now. It also explores at a high level the flexibilities that were enabled by the declarations and where those flexibilities depend on the continued existence of one or more emergency declarations.

NATIONAL EMERGENCIES ACT

The National Emergencies Act (NEA) provides for a broad declaration of emergency by the President. To declare an emergency, the President must publish a proclamation of national emergency in the *Federal Register* and specify the emergency authorities that will be invoked. Each chamber of Congress must meet no later than six months after a declaration, and every six months after that, to consider terminating the emergency. Additionally, national emergencies automatically terminate on the anniversary of the declaration, barring a Presidential notice that keeps the emergency active. The President may also declare that an emergency no longer exists. President Trump declared a national emergency under the NEA on March 13, 2020, retroactive to March 1 in Proclamation 9994.

STAFFORD ACT

In contrast to the NEA, the Stafford Act is generally focused on more localized emergencies and authorizes assistance from the Federal Emergency Management Agency (FEMA), among other things. Under the Stafford Act, the President may declare an emergency or a major disaster. Certain emergencies can be declared unilaterally by the President, though major disaster declarations must be requested by state, territorial, or tribal governments.

President Trump declared an emergency under the Stafford Act on March 13, 2020. This is the first time that the Stafford Act has been invoked for an infectious disease event. It also the first time that an emergency was declared under the Stafford Act simultaneously with a national emergency declaration under the NEA, as well as the first time that the Stafford Act has been invoked for a nationwide emergency declaration. This declaration authorized only public assistance emergency protective measures from FEMA.

As the Stafford Act primarily serves to provide disaster relief assistance in active emergencies, the Act does not provide for a date-certain termination of emergency declarations. Thus, it does not require renewal.

PUBLIC HEALTH SERVICE ACT

Section 319 of the Public Health Service Act (PHSA) gives the HHS Secretary the authority to determine that a public health emergency (PHE) exists and to exercise certain emergency authorities. These authorities include making grants, providing awards for expenses, allowing deviations from current good manufacturing practices, and conducting and supporting investigations into the cause, treatment, and prevention of the disease for which a PHE exists. It also allows for emergency use authorizations (EUA) for drugs, devices, and biologics, though there are other circumstances under which EUAs may be issued. The Strategic National Stockpile (SNS) is also deployed at the discretion of the HHS Secretary to respond to an actual or potential PHE. Furthermore, a PHE can be justification for a declaration under the Public Readiness and Emergency Preparedness (PREP) Act, though the use of the PREP Act does not require a PHE declaration. The PREP Act provides liability immunity to certain individuals and entities from claims resulting from medical countermeasures to combat a threat.

PHEs last for a 90-day period or until the Secretary determines that an emergency no longer exists. PHEs are renewable for additional 90-day periods. The current PHE was declared on January 31, 2020 and was retroactive to January 27, 2020. It was renewed effective April 26. The current PHE will expire July 24, 2020 and would need to be renewed effective July 25. There is currently one other PHE in effect which relates to the opioid crisis and was initially declared on October 26, 2017.

New health-related authorities created under the CARES Act pursuant to the PHE include:

- Allowing the Secretary to require disclosures from medical device manufacturers on interruption or discontinuance of manufacturing that is likely to lead to a disruption in supply of the device in the United States. This applies to drugs that are needed during or in advance of a PHE.
- Allowing the Secretary to require drug manufacturers to report the amounts of drugs manufactured at the time a PHE is declared. This provision is effective September 23, 2020.

In addition, temporary rulemaking issued by HHS references the PHE declaration and its continued effect is largely dependent on the existence of a PHE.

SECTION 1135

Section 1135 of the Social Security Act allows the HHS Secretary to waive portions of the Act to ensure the continued provision of health care to individuals during an emergency period. The invocation of Section 1135 requires the existence of (1) an emergency declaration under the NEA *or* an emergency declaration under the Stafford Act *and* (2) a declared PHE under the PHSA. Additionally, when one of those two conditions are not met, Section 1135 authority is terminated. 1135 waivers last for 60 days and are renewable for additional 60-day periods as long as the emergency declaration conditions are met.

When HHS Secretary Alex Azar invoked Section 1135 on March 13, 2020, he did so pursuant to the PHE and President Trump's declaration under the NEA. The 1135 waivers he announced were retroactive to March 1, 2020.

Under Section 1135, the HHS Secretary may issue waivers of Social Security Act Titles XVIII (Medicare), XIX (Medicaid), and XXI (CHIP) or ensuing regulations for provisions pertaining to:

- Provider conditions of participation;
- State licensure requirements;
- Certain requirements for the examination and treatment for emergency medical conditions and women in labor;
- Physician referral limitations;
- The timeline for required reporting and other activities; and
- Sanctions from certain HIPAA requirements.

Additionally, in Sec. 3703 of the CARES Act and Sec. 102 of the Coronavirus Response Supplemental Appropriations Act, Congress added the ability for the HHS Secretary to waive telehealth requirements under Sec. 1834(m). Importantly, this includes originating site requirements for telehealth visits. This authority also carries an exception to the usage criteria. For the purposes of the current COVID-19 PHE, the Secretary may use this authority as of the beginning of the PHE and may continue to use it until the end of the PHE; that is, it is not tied to a Stafford Act or NEA declaration, unlike the rest of the authorities under Sec. 1135. This gave HHS the authority to relax telehealth restrictions prior to an emergency declaration.

1115 Demonstration

Section 1115 of the Social Security Act also affords the Secretary broad, but not unlimited, authority to approve a state's or territory's request to waive compliance with certain provisions of federal Medicaid law and authorize expenditures not otherwise permitted by law. To receive a section 1115 demonstration, states must submit a demonstration request and agree on Special Terms and Conditions. States that have a federally declared disaster are deemed to meet budget neutrality. States may be exempt from the normal public notice process in emergent situations provided they meet 42 CFR § 431.416(g)(2). Disaster-related demonstrations can be retroactive to the date of the Secretary declared public health emergency. A list of the 1115 waivers issued under the PHE may be found here.

Emergency Policies

HHS and other agencies have exercised emergency powers to create flexibilities in the health care system to help address the emergency. In addition, agencies have used rulemaking authority to put temporary rules in place that are tied to the continuance of the emergency. The following policies have been put in place as a result of the COVID-19 pandemic and continuation of the authority is tied

to at least one of the federal emergency declarations. The table below focuses on the areas of greatest impact and is not exhaustive. A full list of 1135 waivers may be found here and a list of the state Medicaid and/or CHIP 1135 waivers is posted here.

Policy	Description	Authority	Expiration
Expanded Originating Sites	Congress allowed CMS to temporarily waive originating site requirements for telehealth services. This allows telehealth services to be provided to patients in their homes or at any other setting.	CARES Act (H.R. 748) Sec. 3703 (Amends Sec. 1135)	End of PHE
FQHCs and RHCs as Distant Sites	Congress directed HHS to pay for telehealth services provided by FQHCs and RHCs. Payment would be based on the national average of payment rates for comparable telehealth services in the physician fee schedule.	CARES Act (H.R. 748) Sec. 3704	End of PHE
Telehealth-Eligible Providers	Sec. 3703 of the CARES Act added 1135 waiver authority to expand the universe of providers eligible to provide telehealth services and to waive certain other restrictions. The use of this waiver authority permits coverage of telehealth services by physical therapists, occupational therapists, speech language pathologists, and more.	CARES Act (H.R. 748) Sec. 3703 (Amends Sec. 1135)	End of PHE
Face-to-Face Encounters	CMS is allowing some face-to-face services, such as for home dialysis and home health certification, to be conducted via telemedicine.	CARES Act (H.R. 748)	End of PHE
Telehealth Payment	CMS is modifying a number of telehealth payment policies, including frequency limits, payments, and technology requirements.	IFR (RIN: CMS-1744-IFC), IFR (RIN: CMS-5531-IFC)	End of PHE
Out-of-State Licenses	HHS waived requirements for physicians or other health care professionals to hold licenses in the state in which they provide services with respect to Medicare and Medicaid services for the duration of the public health emergency. This does not pre-empt state-specific requirements.	Sec. 1135	End of declared emergency or PHE
Remote Patient Monitoring	CMS clarified that RPM can be used for patients with both chronic and acute conditions. On a temporary basis, CMS will	IFR (RIN: CMS-1744-IFC); IFR	End of PHE

Policy	Description	Authority	Expiration
	allow remote patient monitoring services to be provided to both a physician's new and established patients with consent provided once annually. In addition, CMS is broadening the availability of remote evaluation services. Remote patient monitoring services may not substitute for in-person visits.	(RIN: CMS-5531-IFC)	
FQHC/RHC Telehealth Eligibility	Congress directed HHS to pay for telehealth services provided by FQHCs and RHCs. Payment would be based on the national average of payment rates for comparable telehealth services in the physician fee schedule.	CARES Act (H.R. 748) Sec. 3703	End of PHE
Stark Law and Anti-Kickback Statute	A waiver of certain sections of the Stark Law and enforcement discretion on the anti-kickback statute allows for provision of services in good faith that would otherwise violate the physician self-referral law and anti-kickback statute.	Sec. 1135	End of declared emergency or PHE
EMTALA	A blanket waiver of section 1867(a) of the Emergency Medical Treatment and Labor Act (EMTALA) will allow hospitals to screen patients at offsite locations during the emergency to inhibit the spread of COVID-19.	Sec. 1135	End of declared emergency or PHE
Controlled Substance Prescription	The Controlled Substances Act contains exceptions to the requirement that prescriptions for controlled substances issued over the internet must be predicated on an in-person evaluation. One such exception is a PHE. The Secretary and the Acting DEA Administrator designated that the exception applies to all schedule II-V controlled substances in all areas of the U.S. for the duration of the PHE.	Controlled Substances Act (21 USC 802(54)(D))	End of PHE
DEA State Reciprocity	DEA-registered practitioners are not required to obtain additional DEA registrations for additional states where they prescribe for the duration of the public health emergency. DEA-registered practitioners therefore can prescribe in any state if they are registered with DEA in at	21 CFR 1307.03	End of PHE

Policy	Description	Authority	Expiration
	least one state and have permission *under state law* to prescribe controlled substances in the state where dispensing occurs. This applies to the prescription of controlled substances via telemedicine.		
HIPAA	HHS' Office of Civil Rights (OCR) announced that it would not impose penalties for noncompliance with HIPAA requirements for providers engaging in the good faith provision of telemedicine during the PHE. Thus, providers may use consumer video chat applications such as FaceTime or Zoom for telehealth services.	Enforcement discretion, though the HIPAA privacy rule can be waived through Sec. 1135	End of PHE
FEMA Funding	States may request 75 percent federal cost-sharing for expenses relating to the outbreak, including tests, supplies, vaccinations, and emergency workers.	No	None
COVID-19 Inpatient Add-On	Provides for a 20 percent add-on payment for discharges of patients with COVID-19.	CARES Act (H.R. 748) Sec. 3710	End of PHE
FMAP Increase	Provides for a 6.2 percentage point increase to most FMAP.	Families First Coronavirus Response Act (H.R. 6201) Sec. 6008	End of the calendar quarter in which the last day of the PHE occurs
Testing Coverage	Payers, including private insurance, Medicare, Medicare Advantage, Medicaid, CHIP, VA, etc., must provide COVID-19 diagnostic test coverage without cost sharing.	Families First Coronavirus Response Act (H.R. 6201) Secs. 6001-6004 and 6006-6007	End of PHE
Cost Sharing	Cost-sharing for telehealth services may be reduced or waived.	OIG Policy Statement	End of PHE
State-Specific 1135 Waivers	HHS approved 1135 waivers requested by states covering a variety of topics.	Sec. 1135	End of PHE or Emergency Declaration
Take-Home Supplies in OTPs	States may request blanket exceptions for all stable patients in an OTP to receive 28 days of Take-Home doses of the patient's	42 CFR 8.11(h)	End of Emergency Declaration

Policy	Description	Authority	Expiration
	medication for opioid use disorder. States may request up to 14 days of Take-Home medication for those patients who are less stable but who the OTP believes can safely handle this level of Take-Home medication.		
Testing by Pharmacists	Pharmacists may order and conduct COVID-19 diagnostic tests.	IFR (RIN: CMS-5531-IFC)	End of PHE
National and Local Coverage Determinations	CMS removed certain requirements, including requirements for face-to-face encounters, in national and local coverage determinations.	IFR (RIN: CMS-1744-IFC)	End of PHE
Hospital Facility Flexibility	Hospitals will be allowed to transfer patients to outside facilities, including ambulatory surgery centers (ASC), hotels, and dormitories while still receiving Medicare hospital payments. In addition, ASCs may enroll in Medicare and bill as hospitals during the emergency.	Sec. 1135	End of PHE
Waivers for Providers	CMS waived several requirements that apply to a broad cross section of providers. Requirements waived include facility requirements, training requirements, supervision requirements, and inspections.	Sec. 1135	End of PHE or Emergency Declaration
Ambulances	Part B will reimburse ambulance transportation to any destination that may be equipped to treat the condition of the patient.	IFR (RIN: CMS-1744-IFC)	End of PHE

CONCLUSION

Since the beginning of the pandemic, Congress and the administration have put several emergency policies related to the provision of health care into place. These policies are largely tied to the existence of an HHS-declared PHE or to one of two emergency declarations made by President Trump. The first of these declarations is the PHE, which will expire in late July unless it is renewed. That expiration would result in the end of a large number of the emergency policies, including those related to coverage of testing and treatment, Stark Law and the Anti-Kickback Statute, and the federal share of Medicaid funding. Stakeholders whose response to the COVID-19 pandemic depends in large part on these flexibilities will want to monitor a possible expiration closely.