Insight

Primer: Public Health Emergencies in the United States

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Executive Summary

- The secretary of the Department of Health and Human Services (HHS) can declare a federal public health emergency (PHE) in response to an occurrence or imminent health threat caused by an infectious disease outbreak, natural disaster, or act of bioterrorism; there is, however, no established threshold of what constitutes a PHE.
- A PHE declaration grants additional authorities to the HHS secretary to address the emergency; if concurrent with a presidential emergency declaration, it also allows the secretary to temporarily waive certain federal requirements in Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and the Health Insurance Portability and Accountability Act (HIPAA).
- States can also be granted additional powers under a PHE declaration, including the ability to temporarily revise various eligibility, enrollment, and cost-sharing provisions in their Medicaid and CHIP plans.
- There are two ongoing national PHEs in the United States; the COVID-19 pandemic PHE has been in effect for more than two years, and the opioid crisis PHE for five years; it is worth considering the usefulness of such extended durations and the appropriate circumstances under which to end them.

Introduction

Most Americans are familiar with the declaration of a public health emergency (PHE) in response to the COVID-19 pandemic. But what exactly is a PHE, what does its designation do, who declares it, and under what circumstances does it end?

While the definition of a PHE varies across federal and state laws, a PHE can be broadly defined as an occurrence or imminent health threat caused by an infectious disease outbreak, natural disaster, or act of bioterrorism that poses a high probability of death or long-term disorder and warrants a response above ordinary measures.[1],[2] As there is no established threshold of urgency or severity that constitutes a PHE, nor a universal legal definition, it is often left to the secretary or respective state governor, in consultation with public health officials, to decide what constitutes a PHE. In most cases, a PHE declaration grants additional powers and releases essential tools to government officials and health care providers to respond swiftly to the emergency and mitigate its long-term effects.

The secretary of the Department of Health and Human Services (HHS) can declare a PHE at either the national or state level; the most common PHE declarations have been at the state level following weather-related events that lead to public health risks. Independent from a declaration by the HHS Secretary, state governors can declare a state-wide PHE or state of emergency. Separately, the president can declare a state of national emergency when an event—not necessarily related to public health— causes severe damages to warrant federal disaster assistance. A PHE declaration expires after 90 days, unless terminated early or renewed by the HHS secretary.

Since 2006, when the Office of the Assistant Secretary for Preparedness and Response (ASPR) was fully implemented within HHS, there have been four PHE declarations at the national level, and roughly 30 weather-related PHE declarations in one or more states. Currently, there are two ongoing national PHE declarations: the COVID-19 pandemic and the opioid crisis. While the two previous national PHEs each lasted around one year, the opioid PHE has been in effect for nearly five years, and the COVID-19 PHE for more than two years. As debate picks up on how and when to end the COVID-19 PHE, this paper reviews the designation's authorities and historic uses. It also considers potential pitfalls of leaving a PHE in place too long, as the longer such flexibilities remain in place, the harder they will be to undo.

Authorities Granted Through PHE Declaration

Section 319 of the PHSA

Under Section 319, which was added to the PHSA in 1983, the HHS secretary can determine that a disease or disorder, including those caused by a bioterrorist attack, presents a PHE. There is no law or rule that specifies a necessary threshold of urgency or severity, or even a definition, under which to declare a PHE, leaving broad authority to the secretary. A PHE declaration expires after 90 days, unless terminated early or renewed by the HHS secretary, and allows the secretary to take additional discretionary actions to respond to the emergency that would otherwise be unavailable.[3] Examples of such powers include accessing reserve funds, deploying the national guard or military trauma response teams, waiving certain federal regulatory and reporting requirements that hinder health care delivery, and supporting advanced research and bio surveillance, in addition to regular authorities.

Although not all of the following authorities have been used, other actions the HHS secretary can take after a PHE declaration has been made under Section 319 of the PHSA include:[4]

- Shifting the reimbursement method for certain Medicare Part B drugs from the manufacturer's average sales price (ASP) to the wholesale acquisition cost or other alternative method when there is both a documented inability to access medicines and an increase in the price of a medicine that is not reflected in the manufacturer's ASP for one or more quarters;
- Modifying the practice of telemedicine, in consultation with the Drug Enforcement Administration, by waiving certain requirements of the Ryan Haight Online Pharmacy Consumer Protection Act related to patient locations and the prescription of controlled substances;
- Paying travel expenses of an HHS employee (or family member) assigned to work in an area subject to the PHE declaration who must travel to obtain necessary medical care for an injury or medical condition that cannot be adequately addressed in that location at the time;
- Making temporary appointments to positions that directly respond to the PHE when the urgency of the emergency prohibits examining applicants through the normal process;

- Limiting the liability of health care professionals who are in the Medical Reserve Corps or the Emergency System for Advance Registration of Volunteer Health Professionals so that they are subject only to the state liability laws in which they have been deployed to respond to the PHE;
- Extending or waiving compliance requirements or deadlines for certain Substance Abuse and Mental Health Services Administration grants;
- Waiving requirements of the Ryan White HIV/AIDS grant program related to notification procedures for exposure of emergency responders to infectious diseases and shifting program funds to ensure access to care during the emergency period;
- Temporarily reassigning state and local public health personnel and other public health professionals supported by federal funds;
- Waiving product tracing and wholesale distribution requirements of the Drug Supply Chain Security Act for activities that address the PHE;
- Authorizing the Department of Labor to issue National Dislocated Worker Grants for disaster relief; and
- Providing state and local governments access to the General Services Administration Federal supply schedule when using federal grant funds.

A formal PHE declaration is also one of several possible triggers allowing the HHS secretary to authorize emergency use of unapproved medical countermeasures by the Food and Drug Administration (FDA).[5]

Even without a PHE declaration, however, the HHS secretary has extensive authority to assist states, support disease surveillance, and control outbreaks by, for example, establishing isolation and quarantine, maintaining the Strategic National Stockpile, activating the Public Health Service Commissioned Corps and the National Disaster Medical System, and permitting the dispensing of certain medicines without a prescription. When there is significant potential for a PHE to occur, though before a formal declaration, the HHS secretary can waive Paperwork Reduction Act requirements for the voluntary collection of information and declare that the FDA may authorize medical products intended to prevent, treat, or diagnose a disease or condition for emergency use.[6] When there is significant potential for a PHE to occur, the HHS Secretary is also, in theory, granted access to any "no-year" funds appropriated to the Public Health Emergency Fund (PHEF); the fund was created in 1983 with the enactment of section 319 of the PHSA, and was initially intended to be the main funding source to respond to PHEs, though no appropriations have been made to the fund since a $45 million appropriation in FY2000.[7] The fund had only about $57,000 left in 2016, according to an HHS spokesman at the time.

As an alternative funding mechanism to the empty PHEF, the Centers for Disease Control and Prevention (CDC) created the Infectious Diseases Rapid Response Reserve Fund in 2019. Congress has appropriated money to this fund in each fiscal year since then, which the CDC Director can access when a PHE exists or when there is significant potential for a PHE to occur.

Section 1135 of the Social Security Act

When the HHS secretary has declared a PHE through Section 319 of the PHSA and, at the same time, the president has declared a national emergency under the Stafford Act or the National Emergencies Act, the HHS secretary is authorized to take additional actions under Section 1135 of the Social Security Act (SSA) to meet the needs of individuals in SSA programs and provide flexibilities for health care providers during the emergency period. To that end, the secretary may use Section 1135 waivers, which suspend or modify federal requirements for Medicare, Medicaid, Children's Health Insurance Program (CHIP), the Health Insurance Portability and Accountability Act (HIPAA), and the Emergency Medical Treatment and Labor Act

(EMTALA), including those related to state licensing for health care professionals, participant eligibility, and the supply of health care items and services as necessary. These waivers may be retroactive to the start of the joint emergency period (or any subsequent date) and—at the HHS secretary's discretion—can last up to 60 days after the waiver was published, unless renewed by the HHS secretary, or until the end of the emergency period.

Section 1135 also allows the HHS secretary to waive insurance pre-approvals, Stark laws limiting physician referrals, performance deadlines and timetables, and limitations on beneficiary payments to permit Medicare Advantage enrollees to use out-of-network providers in an emergency situation without additional cost-sharing.[8] The HHS secretary may decide to waive certain federal requirements on a blanket basis or in response to individual provider requests, and states may also request Section 1135 waivers to adjust state-level requirements in their Medicaid and CHIP programs.[9]

Additionally, the HHS secretary may decide to waive sanctions and penalties for HIPAA noncompliance. Sanctions may be waived for noncompliance related to obtaining a patient's consent to speak with family or friends, honoring a patient's request to opt out of the facility directory, distributing a notice of privacy practices, or a patient's right to request privacy restrictions or confidential communications. Waivers for HIPAA requirements apply only to hospitals within the designated emergency area that have disaster protocols in place.

The EMTALA typically ensures access to emergency services regardless of one's ability to pay and requires that a patient who presents to the emergency room must receive an appropriate medical screening to determine whether they have an emergent medical condition. If the patient has an emergent medical condition, the hospital is obligated to stabilize the patient before transferring them to another facility or face strict penalties through monetary fines or reduced Medicare reimbursement. Under joint emergency declarations from the HHS secretary and the president, however, hospitals would not be required to stabilize the patient before transferring them if the transfer was necessitated by circumstances of the PHE.[10] Section 1135 waivers for EMTALA sanctions—as well as HIPAA sanctions—only apply if the actions of the waiver are not based solely on the patient's source of payment or ability to pay.

In the case of a PHE not involving a pandemic disease, however, waivers of HIPAA and EMTALA are limited to only a 72-hour period following implementation of hospital disaster protocol.[11]

Of note, Section 1135 waivers apply only to federal requirements. For example, waiving or modifying requirements that physicians and health care professionals hold licenses in the state in which they provide services if they have an equivalent and active license from another state applies only to Medicare, Medicaid, or CHIP reimbursement— state law still determines whether a non-federal provider is authorized to provide services in the state without state licensure.[12]

Past PHEs

PHEs were not formally declared by the HHS secretary until ASPR was fully implemented within HHS in 2006.

Before the creation of ASPR, the public health response in the United States was fragmented and lacked clear mechanisms for coordination between federal and state governments or access to emergency funds.[13] For example, to mobilize federal funds following the West Nile outbreaks in New York and New Jersey in 2000, President Clinton declared a national emergency under the Stafford Act though it's unclear whether an infectious disease outbreak is included in that Act's definition of a "major disaster."[14] In addition to the presidential emergency declaration, some reports indicate a national PHE was declared in response to the

September 11, 2001, attacks in New York City, though there is limited information available about this PHE declaration and it is not included in ASPR's record of all previous PHE declarations and renewals.

Following the September 11 terrorist attacks and subsequent anthrax threats in 2001, Congress created the Department of Homeland Security (DHS) as the focal point for "natural and manmade crises and emergency planning," and granted new authorities to HHS and the CDC through the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.[15] There were still widespread coordination failures in the public health response coordinated by the DHS after Hurricane Katrina in 2005, however, which subsequently led to the Pandemic and All-Hazards Preparedness Act in 2006. The act created ASPR within HHS to move away from the "all-hazards" emergency response previously coordinated through the DHS. Since the transition, ASPR has become the central coordinator of federal emergency public health response and specifically helps provide funding and technical assistance to states when needed.

State PHE Declarations

The HHS secretary can declare PHEs following weather-related events or natural disasters that result in significant health risk for the affected and surrounding areas. Such declarations by HHS under Section 319 of the PHSA are separate from, and may apply alongside, emergency declarations from the state governor or a local health official. For weather-related emergencies in the past, the secretary has declared a PHE in the state(s) in which the disaster happened, and sometimes in affected surrounding states. Since 2005, the HHS secretary has declared a PHE in one or more states following roughly 30 separate weather events, including hurricanes, tornadoes, flooding, and wildfires.[16]

National PHE Declarations

Since 2005, the HHS secretary has declared four national PHEs, three of which were for infectious disease outbreaks. Two of the national PHEs—for the H1N1 Flu Outbreak (April 2009–June 2010) and the Zika Virus Outbreak (August 2016–July 2017)— lasted roughly one year each, while the other two—for the opioid crisis (first declared in October 2017) and the COVID-19 pandemic (first declared in January 2020)—are ongoing.

Ongoing PHEs

Opioid Crisis

Before 2017, PHEs were traditionally declared in response to natural disasters resulting in public health risk or infectious disease outbreaks requiring emergency response. On October 26, 2017, however, the acting HHS secretary declared the opioid crisis a national PHE to underscore the urgency of the response, reduce administrative burdens for providers, and increase support for state and local governments. According to HHS officials at the time, the decision to declare the opioid crisis a PHE was based on increasing rates of opioid-related overdose deaths, especially related to synthetic opioids such as fentanyl, and an increase in emergency department visits due to opioid overdoses.[17] Subsequent decisions to renew the PHE declaration were based on sustained increases.

Since declaring this PHE, the HHS secretary has mainly relied on three authorities granted under Section 319 of the PHSA to address the opioid crisis. The secretary waived requirements in the Paperwork Reduction Act, allowing HHS to quickly assess prescribing trends for medication and inquire about any barriers to prescribing by bypassing review by the Office of Management and Budget. Additionally, as authorized by Section 319 of

the PHSA, the secretary expedited support for research on opioid use disorder and development of treatments by launching the Helping to End Addiction Long-term Initiative within the National Institutes of Health in April 2018.[18] Further, the secretary waived the public notice period typically required for the approval of Medicaid demonstration projects to speed up implementation of projects related to substance use disorder (SUD) treatment in two states—Louisiana and New Hampshire.

The PHE declaration for the opioid crisis is ongoing; it has been renewed 17 times since the initial declaration, most recently on January 3, 2022. The opioid PHE will reach the five-year mark this fall, raising questions about its overall efficacy.

COVID-19 Pandemic

The first case of COVID-19 was identified in the United States on January 18, 2020, and on January 31, 2020, the HHS secretary declared a PHE retroactive to January 27, 2020, as a result of rising cases. Subsequently, on March 13, 2020, the president issued simultaneous emergency declarations under the National Emergencies Act and the Stafford Act as a result of the severity and magnitude of the pandemic. The PHE declaration for COVID-19 is still in place and was most recently extended until April 15, 2022. Given that in January 2021 the HHS promised to provide a 60-day notice prior to lifting the declaration—which would have been required by February 15 but was not issued—the declaration is likely to be extended until at least July 2022.

Together, the PHE and national emergency declarations provide broad authority to the HHS secretary to waive various reporting requirements and federal regulations to reduce barriers to care and help hospitals and health care facilities manage patient surges. Many of the authorities granted under Section 319 of the PHSA have been leveraged in response to the COVID-19 PHE; the most pronounced changes have affected telehealth flexibilities and program requirements for Medicaid, CHIP, and Medicare. In March 2020, the Centers for Medicare and Medicaid Services (CMS) issued hundreds of blanket Section 1135 waivers for Medicare provisions and a variety of regulatory changes made outside of the notice-and-comment rulemaking process as allowed by the PHE.[19] These waivers affect a vast range of requirements, including the number of residents allowed per room in long-term care facilities, onsite nurse visits required for home health aides, the delivery of dialysis treatment at a certified facility, and many more. CMS has also issued blanket Medicare waivers to relax requirements on practitioner locations and Stark laws.[20]

For Medicaid and CHIP provisions, states submitted their own Section 1135 waiver applications to CMS. All 50 states and the District of Columbia have Section 1135 waivers in place for certain provider qualifications and enrollment requirements in Medicaid and CHIP, including allowing out-of-state providers with equivalent licensing to deliver care and postponing deadlines for revalidation of providers. Additionally, a majority of states have waivers in place that suspend prior authorization requirements or pre-admission screening for long-term services and supports.[21]

In response to a PHE or disaster declaration, states are allowed to temporarily revise various eligibility, enrollment, and cost-sharing provisions in their Medicaid and CHIP state plans through Medicaid Disaster Relief State Plan Amendments (SPAs) or CHIP SPAs for those living in disaster areas.[22] In response to the COVID-19 PHE, many states elected to use such powers. The flexibilities last until the end of the PHE and span a variety of changes, including suspending cost-sharing for COVID-19-related testing and treatments, lifting restrictions on prior authorizations and emergency ambulance services, and increasing payment rates for nursing facilities and SUD treatment facilities.[23]

Regarding changes to Medicaid and CHIP eligibility, Congress also required states to suspend eligibility determinations for the duration of the PHE in order to receive the 6.2 percent increase in the federal share of Medicaid costs provided in the Families First Coronavirus Response Act.[24] Without states' ability to remove ineligible beneficiaries from Medicaid, overall enrollment numbers soared 19 percent from February 2020 to September 2021, meaning Medicaid now covers nearly a quarter of the U.S. population. Following the end of the PHE declaration, states may begin disenrolling ineligible beneficiaries at the start of the subsequent month and will have 12 months to initiate all renewals and outstanding eligibility determinations for Medicaid and CHIP beneficiaries and two additional months to complete the process.[25]

Following the initial PHE declaration, HHS also made several changes to Medicare's telehealth policies for the duration of the PHE, building on the Section 1135 waiver authorities granted through the joint emergency declarations. The changes include reimbursing providers for virtual visits at the same rate as in-person visits, waiving the requirement that the patient and provider must have a pre-existing relationship prior to a telehealth visit, allowing patients to receive virtual care from their homes rather than a designated site, and waiving penalties for HIPAA violations to allow calls over free technologies such as FaceTime or Skype.[26] Of note, the Coronavirus Preparedness and Response Supplemental Appropriations Act in 2020 amended Section 1135 of the SSA to permit Section 1135 telehealth waivers when only a PHE declaration is in place, without the need for a concurrent presidential emergency declaration.[27] While many of the COVID-19-related changes to telemedicine were widely used and increased access to care throughout the pandemic, questions remain about the value of telehealth compared to in-person care, and thus the payment parity between such visits, and privacy concerns about permanently waiving HIPAA protections.

Many of these flexibilities expire with the PHE, leading lawmakers to request temporary extensions. Senators Cortez Masto and Young introduced bipartisan legislation to extend most Medicare telehealth flexibilities for two years following the end of the PHE, as well as require the Medicare Payment Advisory Commission (MedPAC) to conduct studies regarding the utilization, cost, and value of telehealth. The omnibus spending bill that recently passed in March 2022, however, included this MedPAC study requirement, but extended Medicare telehealth flexibilities for five months following the end of the PHE. Some groups have called for additional COVID-19-related waivers and flexibilities to be made permanent and others have used the pending expiration of the PHE as an opportunity to promote extended Affordable Care Act Marketplace subsidies.

Now, more than two years after the initial PHE declaration, COVID-19 cases have leveled off following the rapid spread of the Omicron variant, nearly 70 percent of the U.S. population above the age of five is fully vaccinated, and a large portion of the population has recovered from at least one COVID infection. In February of this year, 70 Republican members of Congress wrote a letter requesting an unwinding of pandemic policies, including surviving vaccine mandates, citing widespread access to vaccines and effective treatments and natural immunity. Unwinding such policies, however, will be a lengthy process; doing so will first require an inventory of all the intertwined regulatory actions and emergency measures enacted during the PHE, as well as identification of measures that could become permanent, such as certain telehealth flexibilities. The longer such flexibilities remain in place, and the longer people rely on what were supposed to be "temporary" flexibilities, the harder they will be to eventually undo. At this point, there is still broad disagreement about ending the COVID-19 PHE, though the decision ultimately lies with the HHS secretary.

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