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IN FOCUS

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Pandemic and All-Hazards Preparedness Act: An Overview

In 2006, Congress enacted the Pandemic and All-Hazards Preparedness Act (PAHPA; P.L. 109-417), which authorized a suite of programs and authorities within the Department of Health and Human Services (HHS) to focus on public health emergency preparedness and response. Congress has reauthorized PAHPA twice, in 2013 and in 2019, both times with changes prompted by preceding public health emergencies. Many existing PAHPA provisions were set to expire in September 2023. Congress has temporarily extended several provisions until December 31, 2024 (P.L. 118-42) and continues to deliberate a multiyear reauthorization.

The Coronavirus Disease 2019 pandemic (COVID-19) provided a critical test of the nation's public health emergency management infrastructure, including the programs and authorities enacted in PAHPA. This In Focus provides an overview of PAHPA, including its context, areas of focus, history, and current reauthorization status.

What Is Public Health Emergency Management?

Many types of emergencies involve a *public health* and *medical* response component. To illustrate, during a natural disaster, public health agencies might monitor associated health effects while medical responders coordinate emergency medical services. Alternately, some types of emergencies, such as emerging infectious disease outbreaks or bioterrorism events, have a primary impact on human health. Public health emergency management involves a set of specific capabilities tailored to health threats, for example, detection capabilities to identify and monitor new health threats; systems to rapidly develop, regulate, and distribute medical products to address health threats (e.g., vaccines, treatments); policies and systems to manage surges in demand for medical care and supplies; potential use of quarantine and isolation authorities; and leadership and communication functions focused on health.

Under the National Response Framework (NRF), HHS coordinates the public health and medical aspects of federal emergency response. As with U.S. emergency management generally, state, local, tribal, and territorial (SLTT) governments are to lead public health emergency preparedness and response efforts in their communities. Federal agencies generally assist when SLTT communities are overwhelmed, need additional expertise and/or federal assets, or when an emergency spans many jurisdictions and prompts a coordinated, federally led response. In addition, HHS agencies have programs and authorities tailored to the unique needs and challenges posed by public health emergencies—many authorized in PAHPA.

PAHPA: An Overview

Though PAHPA has changed throughout its history, the law has generally focused on a set of policy categories. The following highlights some key provisions within each category:

Leadership, strategy, and planning. In 2006, PAHPA statutorily established that HHS is to lead federal public health and medical response under the NRF. The law also reauthorized and renamed the position of the Assistant Secretary for Preparedness and Response to serve as principal advisor for HHS emergency response. PAHPA required the quadrennial publication of the National Health Secretary Strategy (NHSS), where HHS anticipates public health emergency challenges and the department's planned approach.

SLTT emergency capacity. PAHPA has reauthorized two grant programs focused on supporting SLTT public health and medical emergency response capacity: (1) the Centers for Disease Control and Prevention's (CDC's) Public Health Emergency Preparedness (PHEP) cooperative agreement and (2) the Administration for Strategic Preparedness and Response's (ASPR's) Hospital Preparedness Program (HPP). In addition, PAHPA has included related authorities. For example, the 2013 law (P.L. 113-5) amended the public health emergency (PHE) declaration authority (Public Health Service Act, PHSA §319) to allow for temporary assignment of some state and local personnel during PHEs.

Medical countermeasures. PAHPA has included a suite of programs and authorities aimed at enabling the development, regulation, availability, and distribution of *medical countermeasures* (MCMs). MCMs are medical products that may be used to treat, prevent, or diagnose conditions associated with emerging infectious diseases or chemical, biological, radiological, or nuclear (CBRN) agents. For example, the 2006 law established the Biomedical Advanced Research and Development Authority (BARDA) to focus on MCM late-stage development, manufacturing, and purchase. PAHPA reauthorizations have also included provisions for U.S. Food and Drug Administration (FDA) authorities and activities related to MCMs, especially beginning with the 2013 reauthorization that included a title focused on FDA.

Medical response programs. PAHPA authorizes several medical response programs, such as the National Disaster Medical System, which provides medical personnel, equipment, and other support when requested by states. In addition, the Strategic National Stockpile (SNS) consists of medical products and ancillary supplies that can be deployed to SLTT jurisdictions. The SNS includes products

tailored to specific health threats (e.g., smallpox vaccines) as well as general medical supplies (e.g., personal protective equipment).

Infectious disease and biothreat programs. PAHPA has formally authorized biosurveillance and laboratory capabilities to detect and monitor health threats, as well as a national situational awareness network to integrate data on health threats and emergencies from state-level systems. In addition, PAHPA has reauthorized several CDC infectious disease programs, such as the Epidemiology and Laboratory Capacity grant program.

Support for at at-risk populations. PAHPA has included provisions aimed at protecting at-risk individuals during PHEs, for example, authorizations for national advisory committees focused on protecting children, seniors, and individuals with disabilities respectively.

Most, but not all, provisions in PAHPA amend the Public Health Service Act (PHSA), especially PHSA Titles III and XXVIII. Several of the FDA provisions amend the Federal Food, Drug, and Cosmetic Act (FFDCA).

Expiring and Expired Provisions

Many provisions from the last reauthorization (P.L. 116-22) expired in September 2023 or earlier. For the most part, these were authorizations of discretionary appropriations. Congress has continued to fund several of these programs (e.g., PHEP, HPP) in FY2024 (P.L. 118-47).

Some PAHPA provisions effectively expire at certain sunset dates. These include, for example, the authority for temporary reassignment of certain state and local personnel during declared PHEs and authorizations for several national advisory committees for at-risk populations. P.L. 118-42 temporarily extended seven provisions with sunset dates until December 31, 2024, in Section 103—creating a new deadline for congressional action on PAHPA.

Brief Legislative History

Congress and the executive branch established public health emergency authorities and programs prior to PAHPA. For example, the federal PHE declaration authority in PHSA Section 319 dates back to 1983 (P.L. 98-49). As another example, CDC was established administratively in 1946 as the Communicable Disease Center. Thus, when PAHPA was enacted in 2006, HHS already had many existing public health emergency programs and authorities.

PAHPA built upon two earlier laws that addressed HHS public health emergency policy and programs in 2000 (P.L. 106-505) and 2002 (P.L. 107-188). Several developments led to the 2006 law (summarized in S.Rept. 109-319). First, the entire federal homeland security and emergency management system saw transformations following the 9/11 terrorist attacks and 2005 hurricane season. Key reforms included the establishment of the Department of Homeland Security and the NRF to better centralize and coordinate federal emergency response. PAHPA helped formalize HHS's role within this broader federal response framework. Second, concerns about a potential avian influenza pandemic in 2005 prompted many assessments of U.S. public health emergency preparedness and capacity. These assessments generally found that SLTT public health departments were unprepared to quickly detect and respond to potentially deadly infectious disease outbreaks.

As noted, PAHPA was reauthorized twice with incident-related modifications: in 2013, as the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA; P.L. 113-5) and in 2019, as the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA; P.L. 116-22). PAHPRA was preceded by the H1N1 influenza pandemic in 2010, which primarily affected children. The law therefore included several new provisions aimed at meeting pediatric medical needs during emergencies, among other changes. PAHPAIA was preceded by outbreaks of Ebola virus (2014-2015, before and after) and Zika virus (2015-17), and thus included several provisions aimed at infectious disease threats, including newly incorporated reauthorizations of several CDC infectious disease programs.

Reauthorization in the 118th Congress

Prior to this Congress, in December 2022, the PREVENT Pandemics Act, enacted as part of the Consolidated Appropriations 2023 (P.L. 117-328), included several amendments to provisions typically included in PAHPA reauthorizations. Among other provisions, the PREVENT Pandemics Act established a new White House Office of Pandemic Preparedness and Response Policy to coordinate federal pandemic preparedness and response activities.

In addition, both CDC and ASPR have undertaken recent internal changes and reforms. Internal changes to both agencies reflected new and expanded programs and roles during the COVID-19 pandemic. For example, the Office of the Assistant Secretary for Preparedness and Response became the Administration for Strategic Preparedness and Response and was elevated to an operating division within HHS, finalized in February 2023 (88 FR 10125).

Committees have considered PAHPA reauthorization in this context. In September 2023, the Senate Committee on Health, Education, Labor, and Pensions (HELP) reported S. 2333. In July 2023, the House Energy and Commerce (E&C) ordered to be reported both H.R. 4420 and H.R. 4421, supported mostly by majority votes. House E&C minority members introduced a separate bill (H.R. 4697).

A key point of debate has been, What issues are in scope for PAHPA? For example, House E&C majority leaders did not consider FDA drug shortage issues in scope during the bills' markup (though included some ASPR supply chain provisions in H.R. 4421). On the Senate side, S. 2333 includes an entire drug shortages title focused on FDA. These and other questions remain as Congress continues to consider PAHPA reauthorization as new potential threats arise, such as H5N1 influenza and clade I mpox.

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