Health Policy and Legislation Alert

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Preparedness Policy Takes Shape: PREVENT Pandemics Act Enacted Ahead of PAHPA Reauthorization

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On December 29, 2022, the President signed into law the Prepare for and Respond to Existing Viruses, Emerging New Threats and Pandemics Act (PREVENT Pandemics Act) as part of the Consolidated Appropriations Act, 2023 (P.L. 117-328). Enactment of the PREVENT Pandemics Act reflects the culmination of a multi-year, bipartisan legislative process with the goal of strengthening our nation's medical and public health preparedness and response framework.

The timing of the enactment of these reforms and the ongoing COVID-19 response efforts raises questions about how Congress may approach reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA), provisions of which are set to expire at the end of the current fiscal year (September 30, 2023). PAHPA reauthorization is expected to be a key area of legislative focus early on in the new Congress for both the House Energy and Commerce and Senate Health, Education, Labor and Pensions (HELP) Committees. The Biden-Harris administration implementation of the PREVENT Pandemics Act reforms will be carried out against the backdrop of divided government and a robust oversight agenda given the changes in leadership for the 118th Congress in the House of Representatives. All of these factors are likely to result in a sustained focus on preparedness policy issues for the foreseeable future, including how Congress might further build on the reforms legislated last year in the coming months.

Key themes of the PREVENT Pandemics Act include structural leadership changes, increasing accountability and transparency around preparedness and response activities through more rigorous and frequent reporting requirements, and the importance of partnerships and innovation as part of a nimble, all-hazards preparedness framework. In addition to policy changes, the PREVENT Pandemics Act also includes new funding opportunities through the Department of Health and Human Services (HHS) that interested stakeholders may want to consider.

Structural Leadership Changes, Increased Accountability and Transparency

A key question that PAHPA, and subsequent reauthorizations of that law, sought to answer is whom is in charge of public health preparedness and response and how

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best to optimize the preparedness and response framework. The structural leadership changes enacted as part of the PREVENT Pandemics Act further speak to these policy considerations.

Most notably, the PREVENT Pandemics Act establishes an Office of Preparedness and Response Policy within the Executive Office of the President, headed by a Director who is situated within both the Domestic Policy Council and National Security Council. The Director is charged with providing advice, within the Executive Office of the President, on policy related to preparedness for, and response to, pandemic and other biological threats that may impact national security, and supporting strategic coordination and communication with respect to relevant activities across the federal government. Under this new law, the Director is further charged to submit a publicly available report to the President within the first year of operation. The report will identify and describe situations and conditions that warrant special attention within the next five years, involving current and emerging problems of national significance related to pandemic or other biological threats. The report will also identify opportunities for, and the barriers to, research, development and procurement of medical countermeasures to adequately respond to such threats.

The PREVENT Pandemics Act goes further to enact structural leadership changes within HHS, in addition to the creation of the Office of Preparedness and Response Policy within The White House. The Director for the Centers for Disease Control and Prevention (CDC) will now be a Senate-confirmed position and charged with issuing a strategic plan not later than one year after the date of enactment of the PREVENT Pandemics Act, and at least every four years thereafter. Also of note, the law requires the CDC Director and, separately, the Assistant Secretary for Preparedness and Response (ASPR) to appear before the Senate HELP Committee and the Energy and Commerce Committee to speak to their respective preparedness and response activities on a regular basis. The new law also requires HHS to submit an annual report on emergency response and preparedness, which will provide further insight into these areas of work for the Department.

Notably, the PREVENT Pandemics Act did not codify the relatively recent changes made by HHS to elevate the Office of the Assistant Secretary for Preparedness and Response from a staff division to an operating division (the Administration for Strategic Preparedness and Response). However, this could be an issue on which Congress chooses to engage as part of PAHPA reauthorization this year.

Authorization of Advanced Research Projects Agency – Health

The PREVENT Pandemics Act authorized the Advanced Research Projects Agency—Health (ARPA-H) within the National Institutes of Health (NIH) at HHS to be led by a Director appointed by the President of the United States. Under the PREVENT Pandemics Act, ARPH-H is charged with ambitious goals intended to foster the development of transformational innovation in biomedical science and medicine that cannot be readily accomplished through traditional federal biomedical research and development programs. The new law settles the question of where ARPA-H will reside as it stipulates that ARPA-H, including its headquarters, shall not be located on any part of existing NIH campuses nor have offices or facilities in less than three geographic areas. The law further authorized to be appropriated significant resources—$500 million for each of the fiscal years (FY) 2024 through 2028.

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New Funding Opportunities at HHS

The PREVENT Pandemics Act also establishes new funding opportunities through HHS related to medical and public health preparedness and response. Some examples of these opportunities include:

- Authorization of $35 million for each of FY 2023 through 2027 for grants, contracts or cooperative agreements to conduct evidence-based or evidence-informed projects, which may include the development of networks to improve health outcomes by improving the capacity of entities to address factors that contribute to negative health outcomes in communities.
- Authorization to award grants, contracts or cooperative agreements to public health agencies for the establishment and operation of centers of excellence to promote innovation in pathogen genomics and molecular epidemiology to improve the control of and response to pathogens that may cause a public health emergency.
- Authorization to award grants, contracts or cooperative agreements to institutions of higher education, including accredited schools of public health or other nonprofit private entities, to establish or maintain a network of Centers for Public Health Preparedness and Response.
- Authorization to award funding through grants, contracts or cooperative agreements to public or private entities to provide support for research centers to advance the discovery and preclinical development of medical products for priority virus families and other viral pathogens with a significant potential to cause a pandemic.

Accelerating Research and Countermeasure Discovery, Modernizing Medical Countermeasure Work, Strengthening Domestic Manufacturing

In addition to new funding opportunities, the PREVENT Pandemics Act also includes a number of provisions designed to accelerate research and countermeasure discovery, modernize medical countermeasure work and strengthen domestic manufacturing that will be of interest to a wide range of stakeholders, such as:

- Accessing Specimen Samples and Diagnostic Tests – Not later than one year after enactment of this law, the Secretary of HHS shall make publicly available policies and procedures related to public and private entities accessing specimens of, or specimens containing, pathogens or suitable surrogates for, or alternatives to, such pathogens as the Secretary determines appropriate to support public health preparedness and response activities or biomedical research for purposes of the development and validation, as applicable, of medical products to address emerging infectious diseases and for use to otherwise respond to emerging infectious diseases.
- Earlier Development of Diagnostic Tests – The law permits the Secretary of HHS to contract with public and private entities to increase capacity in the rapid development, validation, manufacture and dissemination of diagnostic tests to state, local and tribal health departments and other appropriate entities for immediate public health response activities to address an emerging infectious disease where a public health emergency is declared under Section 319 of the Public Health Service Act, or that has the significant potential to cause such a public health emergency.

- Warm Base Manufacturing Capacity for Medical Countermeasures – The law weaves a new emphasis on warm base manufacturing capacity throughout the Biomedical Advanced Research and Development Authority (BARDA). It authorizes BARDA to award contracts, grants and cooperative agreements, and enter into other transactions to support, maintain and improve domestic manufacturing surge capacity and capabilities in the event of a public health emergency declaration or significant potential for a public health emergency.
- Study on Incentives for Domestic Production of Generic Medicines – Under the PREVENT Pandemics Act, the HHS Secretary, through the Assistant Secretary for Planning and Evaluation, is charged with (i) conducting a study on the feasibility and utility of providing incentives for increased domestic production and capability of specified generic medicines and their active pharmaceutical ingredients and (ii) submitting a report on this study within one year of enactment of this Act to the Senate HELP Committee and House Energy and Commerce Committee.
- Increased Manufacturing Capacity for Certain Critical Antibiotic Drugs – Authorizes the HHS Secretary, in consultation with the ASPR and Commissioner of Food and Drugs, to award contracts to increase the domestic manufacturing capacity of certain antibiotic drugs with identified supply chain vulnerabilities, or the active pharmaceutical ingredient or key starting material of such antibiotic drugs.
- Third Party Test Evaluation During Emergencies – Authorizes the Secretary to consult with persons with appropriate expertise, or enter into cooperative agreements or contracts with such persons, with respect to evaluations regarding whether in vitro diagnostic products for which an emergency use authorization (EUA) request submitted to the Food and Drug Administration (FDA) meets the criteria for issuance of such authorization. FDA is further charged with issuing guidance on such consultations not later than one year after enactment of the Act.
- Accelerating Countermeasure Development and Review During an Emergency – The new law authorizes the Secretary—at the request of a sponsor of a countermeasure, during a domestic, military or public health emergency or material threat described in section 564 of the Federal Food, Drug and Cosmetic Act (FFDCA)—to expedite the development and review of countermeasures intended to address such emergencies or threats for approval, licensures, clearance or authorization under the FFDCA or section 351 of the Public Health Service Act, and further outlines specific actions FDA may take expedite such development and review of these products.
- Increasing EUA Decision Transparency – Requires the Secretary to publish promptly on the website of the FDA a notice of each EUA, as well as each EUA termination or revocation by FDA.

Outlook Going Forward

Stakeholders are already closely watching to see how and when the COVID-19 public health emergency declaration draws to an end. House Republicans have indicated that COVID-19 is going to be a key aspect of their oversight agenda in 2023. Set against the backdrop of a divided Congress, the reforms included in the PREVENT Pandemics Act further set the stage for a dynamic interplay between the Biden-Harris administration and Congress on the preparedness and response fronts in the new year, the full extent of which will continue to reveal itself as the 118th Congress

unfolds. Regardless of how PAHPA reauthorization shapes up, preparedness and response stakeholders should closely monitor developments regarding the implementation of the PREVENT Pandemics Act for potential opportunities to partner with the Biden-Harris administration and/or help shape the forthcoming programmatic and policy changes they are charged with implementing.

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