

PAHPA Reauthorization: High-Level Summary and Recommendations

(Updated 4/17/23)

The primary pharmaceutical distributor members of the [Healthcare Distribution Alliance](#) (HDA) serve as the vital link between pharmaceutical manufacturers and dispensers. The distribution industry demonstrated its capabilities during COVID-19 to support the pandemic response by partnering with the federal government to distribute vaccines and therapeutics.

Amidst growing concerns regarding emerging infectious diseases and global terrorism, the [original Pandemic and All-Hazards Preparedness Act \(PAHPA\)](#) passed Congress by unanimous consent and was signed into law by President George W. Bush in December 2006. Since then, Congress has reauthorized the legislation twice since it was initially approved. The [first PAHPA reauthorization passed Congress in 2013](#), and the [second in 2019](#). Historically, PAHPA has been a bipartisan and bicameral effort.

PAHPA contains key legal authorities to sustain and strengthen the U.S.'s preparedness for public health emergencies involving chemical, biological, radiological and nuclear agents, as well as emerging infectious disease threats. The goal of PAHPA is to clarify who holds the responsibility during an event impacting public health.

HDA submitted its PAHPA priorities to the House Energy and Commerce Request for Information (RFI) on March 13, 2023, and the Senate Health, Education, Labor and Pensions (HELP) RFI on March 29, 2023. This assessment outlines HDA and its members' views on the PAHPA reauthorization.

HDA Policy Recommendations

Administration for Strategic Preparedness and Response

- [Supply Chain Control Tower](#) (SCCT) should be:
 - Only fully operational during a public health emergency (PHE). The SCCT should stay at a warm posture between events, which includes the ability to scale up for events.
 - Be mindful of antitrust considerations regarding the use of data submitted to it by private companies.
 - Be required to maintain cybersecurity protections.
 - Include private partners in annual testing and exercises.
- [Strategic National Stockpile](#) (SNS):
 - To support the SNS program and its partnerships, the SNS should receive a funding authorization that, at a minimum, maintains the Fiscal Year 2023 appropriated funding level.
 - PAHPA should establish a process to determine what products should be part of Vendor Managed Inventory (VMI). Also, PAHPA should implement a process to determine how best to conduct ongoing threat assessment activities outside annual exercises and testing.

- PAHPA should require the SNS to work with all U.S.-based healthcare distributors' voluntary partners on developing and maintaining IT connectivity.
- The SNS should review its management and reimbursement practices for medical products with distributors before procuring certain supplies and in cases where there is a product excess.
- Biomedical Advanced Research and Development Authority (BARDA):
 - The federal government should maintain and expand loan, grant, direct investment and purchase agreement programs for vital medical infrastructure developed by companies primarily manufacturing in the U.S. through the National Institutes of Health and [BARDA](#).
- Public Health Emergency Medical Countermeasures Enterprise (PHEMCE):
 - To require distributor input in the [PHEMCE](#), PAHPA should amend [42 U.S. Code § 300hh-10a - Public Health Emergency Medical Countermeasures](#) Enterprise paragraph (c)(2) to include "In carrying out subparagraph (C) of paragraph (1), the PHEMCE shall solicit and consider input from healthcare distributors."

Clarifying the Role of Public and Private Partners

- To avoid confusion and multiple reporting channels, PAHPA must further clarify where the primary partnerships and coordination responsibility lie within the private sector supply chain. This clarification will ensure the timely delivery of medical products during an event.
- PAHPA should require a Government Accountability Office (GAO) report on the use of the Defense Production Act (DPA) to address the healthcare supply chain during catastrophic events, including the COVID-19 pandemic.

Partnerships to Enhance Supply Chain Resilience

- Establish the Healthcare Distributor Advisory Group in PAHPA.
- PAHPA should require a GAO report on the existing healthcare supply chain data, and information flows from the private sector to the federal government.

Preventing Disruptions to Ensure Supply to Essential Medicines

- The Department of Health and Human Services (HHS) and the Food and Drug Administration should work with manufacturers, distributors and other supply chain stakeholders to develop a drug shortage "early warning system" to detect a potential demand surge that may create a significant shortage or disruption.
- The Administration for Strategic Preparedness and Response ([ASPR](#)) and HHS should establish a list of 50 generic medications vital to public health during an event, including a Public Health Emergency (PHE). [H.R. 405](#) should also be included in PAHPA.

Cybersecurity

- PAHPA should require a GAO report that outlines the full capabilities and limitations potential cybersecurity threats pose to the healthcare supply chain.
- PAHPA should include language to expand the use of the Public Health Emergency Fund (PHEF) funding to address cybersecurity. The expanded PHEF funding would be available to private healthcare supply chain stakeholders who suffer a cyberattack during an event that impacts public health.

Future PHE Operations

- PAHPA should provide guidance on extensions of Emergency Use Authorizations after PHE ends, including timelines to work with the private sector on coordination. This would ensure supply chain continuity and availability of countermeasures after a PHE ends, which has proven crucial in catastrophic events such as COVID-19.
- PAHPA should address vaccine-tracking and distribution-reporting requirements by ensuring reporting system interoperability between the federal government and its U.S.-based healthcare distributors' voluntary partners through annual testing and exercises.

Learn more about HDA's perspective on PAHPA and its reauthorization: <https://www.hda.org/preparedness-and-response/>.

About the Healthcare Distribution Alliance

The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA Research Foundation, HDA's nonprofit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues.