Emergency Use Authorization Toolkit

Current Issues and Updates

Winter 2012

Current Issues and Updates provides periodic updates on new and evolving issues related to the topics covered in the ASTHO *Emergency Use Authorization Toolkit*.

Pandemic and All-Hazards Preparedness Act Reauthorization

Congress is continuing the process of reauthorizing the Pandemic and All-Hazards Preparedness Act (PAHPA), which was scheduled for reauthorization in 2011. As of March 2012, both the House and Senate have passed their own versions of the reauthorizing legislation, including provisions relevant to emergency use of medical products. While there are many similarities between the two bills, Congress is likely to convene a conference committee to reconcile the differences. Once passed, the programs and authorities in PAHPA will be reauthorized for another five years.

What PAHPA Currently Addresses

PAHPA was first enacted in 2006 to improve the nation's public health and medical preparedness and response capabilities for natural and manmade disasters. Specifically, PAHPA amended the Public Health Service Act to address the organization of public health emergency preparedness and response activities and authorized new programs and initiatives concerning medical surge capacity, the development of countermeasures to biological threats, and the capacity of states and localities to prepare for and respond to public health emergencies.

PAHPA impacts the states through the organizational structures and programs it established within the Department of Health and Human Services (HHS). Many of the offices and programs within the HHS that state public health preparedness programs interact with on a daily basis were developed or refined through PAHPA, including:

- The Office of the Assistant Secretary for Preparedness and Response.
- Grant programs such as the Public Health Emergency Preparedness Program, Hospital Preparedness Program, and Healthcare Facility Partnership Program.
- Guidance regarding at-risk populations.
- Registration of volunteer health professionals into databases that comply with the HHS ESAR-VHP system (Emergency System for Advance Registration of Volunteer Health Professionals).

PAHPA also established the Biomedical Advanced Research and Development Authority (BARDA) within the HHS to foster the rapid development of drugs and vaccines (countermeasures) against highly infectious pathogens. The act established the Biodefense Medical Countermeasure Development Fund to pay for development contracts with the makers of the countermeasures.

What PAHPA Reauthorization Addresses

The House passed the "Pandemic and All-Hazards Preparedness Reauthorization Act of 2011" (HR 2405) on December 11, 2011. The Senate passed its version of the legislation, S 1855, on March 7, 2012. The text of HR 2405 and S 1855 are available through the Library of Congress's Thomas website at www.thomas.gov.

Overall, the House and Senate versions have similar provisions and funding levels, but the Senate version adds a number of provisions that are not in the House version. Both bills do not significantly rework existing programs authorized by the 2006 PAHPA; rather, the reauthorization bills increase responsibilities for HHS, clarify legal authorities and requirements, and reauthorize and fund key public health preparedness programs. The following list

highlights some of the key provisions of the reauthorization bills relevant to public health but is not a comprehensive analysis. Please refer to the actual text of the reauthorization bills.

- **Reauthorizes key public health preparedness programs**—Both the House and Senate bills reauthorize the Public Health Preparedness Cooperative Agreement Program, the Hospital Preparedness Program, influenza pandemic vaccine tracking and distribution program, ESAR-VHP, the Medical Reserve Corps, and the Strategic National Stockpile.

- **Funds public health preparedness and medical countermeasures activities**—Both bills contain the same funding levels; however, the Senate version provides $522 million per year from FY 2012 to FY 2016 for the Strategic National Stockpile.

- **Provides increased flexibility and authority for emergency use of medical products**—Both versions of the bill provider greater flexibility for the HHS and the FDA to approve the use of medical products in emergencies but differ in some of their specific provisions. One or both of the bills address key emergency use issues including but not limited to: permitting the FDA to waive or limit Current Good Manufacturing Practice (CGMP) requirements for emergency use of a medical product, extending the expiration dates of stockpiled medical products (e.g., drugs) without issuing an Emergency Use Authorization (EUA), authorizing the mass dispensing of medical products without individual prescriptions for FDA-approved products, and authorizing the FDA to issue EUAs before an emergency is declared.

More information about EUAs and PAHPA is available in the ASTHO *Emergency Use Authorization* and *Emergency Authority and Immunity* Toolkits.

Information about ongoing EUA activities and policies at the FDA is available on the agency's Emergency Preparedness and Response website at www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm.

Information about ongoing PAHPA implementation at the HHS is available on the Office of the Assistant Secretary for Preparedness and Response website at www.phe.gov.

This document was compiled in March 2012 and reflects the laws and programs current at the time. It reflects only selected portions of the laws relevant to public health emergencies; it is not intended to be exhaustive of all relevant legal authority. This resource is for informational purposes only and is not intended as a substitute for professional legal or other advice. The document was funded by CDC Award No. 1U38HM000454 to the Association of State and Territorial Health Officials; Subcontractor PI Elliott, Logan Circle Policy Group LLC.