

# The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013

The H1N1 pandemic, the Fukushima disaster, and other disasters at home and abroad underscore the importance of preparing our nation to respond to a range of medical and public health emergencies, whether naturally occurring or the result of a chemical, biological, radiological, or nuclear attack. Over the past decade, multiple Congresses and Administrations have worked together to put into place critical medical and public health preparedness and response programs and policies. As a result of the passage of the Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006, the federal government, in partnership with state and local governments, took significant steps to strengthen our nation's medical and public health preparedness and response capabilities. This bipartisan reauthorization builds on these efforts by enhancing existing programs and authorities using lessons learned since 2006 to maximize our nation's resilience to threats, whether naturally occurring or deliberate.

## ➤ Enhances Collaboration and Coordination

- **Federal Preparedness Leadership**– Provides the Assistant Secretary for Preparedness and Response (ASPR) with enhanced policy oversight and coordination of medical and public health preparedness and response programs.
- **National Health Security Strategy**– Emphasizes chemical, radiological, biological, and nuclear threats as part of an all-hazards approach to our National Preparedness Goals; promotes strategic initiatives to advance medical countermeasures (MCMs) development and procurement; strengthens state and local community resiliency; and highlights the unique needs and considerations of at-risk individuals.
- **Public Health and Medical Surge Capacity**– Reauthorizes and makes targeted enhancements to the National Disaster Medical System, the volunteer Medical Reserve Corps, the Emergency System for Advance Registration of Volunteer Health Professionals, and the Strategic National Stockpile.
- **Biosurveillance**– Requires the Department of Health and Human Services (HHS) to develop and follow through on plans to modernize national situational awareness and biosurveillance capabilities.

## ➤ Provides Targeted Flexibility

- **State, Local, and Hospital Preparedness**– Reauthorizes the Public Health Emergency Preparedness and Hospital Preparedness Cooperative Agreement Programs. Streamlines the planning and administration of these programs to best meet the needs of communities, while enhancing existing oversight and benchmark requirements. Provides states with the flexibility to request voluntary temporary reassignment of federally-funded state and local public health department personnel to immediately address a public health emergency.
- **MCMs Authorized Use Based on Threats and Emergencies**– Enhances the Secretary's ability to make MCMs under review available in limited circumstances based on either a declared emergency or identified threat. Clarifies the Food and Drug Administration's (FDA) ability to extend the expiration date of approved MCMs for the Strategic National Stockpile.

## ➤ Optimizes Medical Countermeasure Activities

- **BioShield**– Encourages further development of MCMs to address chemical, biological, radiological, and nuclear threats by reauthorizing BioShield's Special Reserve Fund. Requires HHS to report to Congress when the Special Reserve Fund falls below a certain threshold and the potential impact of such a reduction on addressing MCM priorities.
- **Advanced Research and Development**– Enhances the Biomedical Advanced Research and Development Authority's (BARDA's) strategic focus on supporting the development of innovative and cutting-edge biodefense initiatives (e.g., platform technologies).
- **MCM Acceleration**– Charges the FDA with promoting MCM professional expertise and developing regulatory science tools to advance the review, approval, clearance, and licensure of MCMs within FDA as well as enhancing scientific exchange between FDA and MCM stakeholders.

## ➤ Increases Transparency and Accountability

- **MCM Planning**– Requires a biennial Public Health Emergency Medical Countermeasures Enterprise Strategy and Implementation Plan and an internal HHS 5-year budget plan, both of which describe the progress made in addressing MCM priorities, including an availability of pediatric MCMs.
- **Regulatory Management Plan**– Requires FDA to work with sponsors and applicants of certain eligible MCMs to develop individualized regulatory management plans to improve regulatory certainty.