

Passage of S. 3678: The Pandemic and All-Hazards Preparedness Act

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On December 19, 2006, President Bush signed the Pandemic and All-Hazards Preparedness Act (S. 3678) into law. Passage of S. 3678 marks a major milestone in improving public health and hospital preparedness for bioterrorist attacks, pandemics, and other catastrophes and for improving the development of new medical countermeasures, such as medicines and vaccines, against biosecurity threats. Highlights of the legislation's key initiatives are summarized below.

Title I: National Preparedness and Response, Leadership, Organization, and Planning

- **Creates the Assistant Secretary for Preparedness and Response within the Department of Health and Human Services (HHS) and consolidates the responsibilities for federal public health and medical emergency preparedness and response activities under that office.** This includes authority over the National Disaster Medical System (NDMS) and the Hospital Preparedness Cooperative Agreement Program, the coordination of the Medical Reserve Corps (MRC), the Emergency System for Advance Registration of Volunteer Health Professional (ESAR VHP), the Strategic National Stockpile (SNS), and the Cities Readiness Initiative (CRI). The Assistant Secretary will oversee advanced research, development, and procurement of “qualified countermeasures” and “qualified pandemic or epidemic products.” The Assistant Secretary will be nominated by the President and confirmed by the Senate.
- **Requires the Secretary of HHS to appoint an official who will provide guidance to public health agencies on incorporating the needs of at-risk individuals in federal, state, and local preparedness and response strategies.** This appointee will ensure that the SNS addresses the needs of at-risk populations (including non-pharmaceutical supplies), will oversee development of curriculum for training programs on medical management of at-risk individuals, and will disseminate best practices for outreach to and care for at-risk individuals before, during, and following public health emergencies.
- **Requires the Secretary to prepare and submit to Congress the National Health Security Strategy for coordinated public health preparedness and response.** This will begin in 2009 and will be prepared every 4 years thereafter. The strategy will include evaluation of federal, state, local, and tribal progress measured according to evidence-based benchmarks.

Title II: Public Health Security Preparedness

- **Provides for cooperative agreements (i.e., grants) to state and select local public health entities to improve health security.** Funding will be contingent on a number of requirements. For example, eligible entities must submit an application “containing such information as the Secretary may require,” including a plan for entities to obtain public comment and input on preparedness and response plans. In addition, beginning in FY 2009, states must participate in ESAR VHP to qualify for funding. In making awards, the Secretary of HHS must consult with the Secretary of the Department of Homeland Security (DHS) to ensure maximum coordination with the Metropolitan Medical Response System (MMRS), minimize redundant funding of programs, develop recommendations and guidance on best practices, and disseminate information about lessons learned through a single internet site.
- **Requires non-federal contributions to public health preparedness programs.** Beginning in 2009, the Secretary may not award a cooperative agreement unless a state, or a consortium of two or more states, agrees that it will make non-federal contributions available to public health preparedness programs. States may disburse funds directly, or funds may be provided through donations from public or private entities. The funding may be provided in cash or in kind. For the first fiscal year of the cooperative agreement, the state must provide at least 5% of the funding, and from the second fiscal year on, the state must provide at least 10% of the funding. Entities that receive cooperative agreements must have their expenditures independently audited at least every two years, and the audit report must be submitted to the Secretary within 30 days of the audit's completion.

- **Requires the Secretary—in consultation with state, local, and tribal officials as well as private entities—to develop or adopt measurable, evidence-based benchmarks to gauge preparedness.** Entities that do not meet benchmark requirements will have the opportunity to correct non-compliance. Beginning in FY 2009, the Secretary shall withhold funds from each entity that has failed substantially to meet benchmarks or has failed to submit a pandemic influenza plan.
- **Authorizes the Secretary to award grants entities such as hospitals, clinical laboratories, and universities for improvements in real-time disease detection.** This funding is for programs to purchase and implement advanced diagnostic medical equipment to analyze clinical specimens in real-time to determine the presence of pathogens of public health and/or bioterrorism significance.
- **Requires the Secretary to establish a nationwide, near real-time electronic public health situational awareness capability.** This capability will be established in collaboration with state, local, and tribal public health authorities and will provide for the secure sharing of critical public health and medical information. The legislation stipulates that this capability be accomplished “through an interoperable network of systems . . . built on existing State situational awareness systems or enhanced systems that enable such connectivity.” Grants may be awarded to states, or consortia of states, to support implementation of the network of situational awareness systems. No later than 4 years following enactment, GAO will conduct an independent evaluation of this effort and submit to the Secretary and Congress a progress report.
- **Authorizes the Secretary to provide grants to states for tuition loan repayment to individuals who agree to serve for at least 2 years in state, local, or tribal health departments.** The loan repayment program will support degree programs appropriate for serving in state, local, and tribal health departments.
- **Authorizes the Secretary to cooperate with manufacturers, wholesalers, and distributors during a pandemic on tracking initial distribution of federally purchased influenza vaccine.** In addition, the law requires that the Secretary promote communication among state, local, and tribal public health officials and manufactures, wholesalers, and distributors regarding the effective distribution of seasonal influenza vaccine to high priority populations during vaccine shortages and supply disruptions.

Title III: All-Hazards Medical Surge Capacity

- **Transfers NDMS functions, personnel, assets, and liabilities from the Department of Homeland Security to the Department of Health and Human Services.**
- **Strengthens federal support and structure for the Medical Reserve Corps (MRC) program, beginning with the appointment of a Director by the Secretary.** The Director will be responsible for overseeing activities of state, local, and tribal corps chapters. This legislation aims to establish, through the ESAR VHP, an interoperable network of connected state systems to verify the credentials and licenses of healthcare professionals who volunteer during public health emergencies. This will be accessible to all local and state health departments.
- **Expands the Epidemic Intelligence Service Program.** Managed by CDC, the Epidemic Intelligence Service (EIS) is a 2-year postgraduate program of service and on-the-job training for health professionals interested in epidemiology. This legislation creates an additional 20 EIS officer positions. Individuals work for at least 2 years at a state, local, or tribal health department that serves an area in which there is a shortage of health professionals, a medically underserved population, or a high risk of public health emergency.
- **Requires the Secretary to award grants to hospital and healthcare facilities to improve surge capacity and enhance community and hospital preparedness for public health emergencies.**

Title IV: Pandemic and Biodefense Vaccine and Drug Development

- **Requires the development of a Strategic Plan for Countermeasure Research, Development, and Procurement.** The Secretary of HHS is directed to develop a strategic plan, within 6 months of enactment, that “integrates biodefense and emerging infectious disease requirements with . . . advanced research and development, strategic initiatives for innovation, and the procurement of [countermeasure and pandemic] products.”

- **Establishes the Biomedical Advanced Research and Development Authority (BARDA).** Operating within HHS, BARDA will facilitate the development of new medicines and vaccines (i.e., medical countermeasures) to counter biological, chemical, radiological, nuclear, and other security threats. A Director will be appointed by the Secretary.

BARDA's mission:

- Facilitate collaboration among the U.S. government, relevant biopharma companies, and academic researchers to develop medical countermeasures.
- Support the “advanced research and development” of medical countermeasures through contracts, prizes, and other means (see below).
- Promote “innovation to reduce the time and cost of countermeasure ...development” as well as to improve the development of research tools, rapid diagnostics, broad spectrum anti-microbials, and vaccine technologies (see below).

BARDA is exempt from certain Freedom of Information Act (FOIA) disclosure requirements for information that “reveals significant and not otherwise publicly known vulnerabilities of existing medical or public health defenses.” This exemption is subject to review every 5 years by the Secretary, and will sunset after 7 years.

- **Establishes the “Biodefense Medical Countermeasure Development Fund” to allow BARDA to fund the development of products across the so-called “Valley of Death” between NIH-funded basic research and end-stage procurement by the BioShield program.** The law authorizes \$1.07 billion for FY 2006–2008 for the fund. This Fund is separate from the preexisting BioShield purchase fund. This fund may also be used to support innovation in biomedical research tools and other strategic initiatives intended to improve overall medical countermeasure development.
- **Establishes the National Biodefense Science Board.** The board will “provide expert advice and guidance to the Secretary on scientific, technical, and other matters...regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate.” The board will consist of U.S. government officials, 4 representatives of the biopharma and medical device industry, 4 academic representatives, and 5 others including at least one practicing healthcare professional and one representative of healthcare consumers.
- **Directs the FDA to provide technical assistance to the developers of medical countermeasures on manufacturing and regulatory processes.**
- **Establishes limited anti-trust exemptions to allow biopharma companies to better collaborate with each other and with government in the development of medical countermeasures.** This provision will sunset after 6 years.
- **Makes reforms to the BioShield procurement program which was established in 2004 (PL 108-276):**
 - o Confers authority to HHS for making multiple milestone-based advanced payments of 5% of the total contract (up to 50% of the total contract).
 - o Gives HHS the authority to contract for domestic “warm base surge capacity” for a developer to establish a warm base manufacturing capacity for a countermeasure that may be brought on-line quickly (e.g., during a crisis).
 - o Allows HHS to enter into an exclusive contract with a vendor.