

PANDEMIC AND ALL-HAZARDS PREPAREDNESS ACT (P.L. 109-417)

On December 19, 2006, the President signed into law (Public Law 109-417) the Pandemic and All-Hazards Preparedness Act. The major provisions are summarized below

Leadership for Public Health and Medical Response

Clarifies that the Secretary of Health and Human Services (HHS) leads all Federal public health and medical response to public health emergencies and incidents covered by the National Response Plan (NRP). Provides the HHS Secretary with operational control of Federal emergency public health and medical response assets in a public health emergency.

Assistant Secretary for Preparedness and Response

Creates an Office of the Assistant Secretary for Preparedness and Response (ASPR) within HHS to advise the Secretary on matters related to public health and medical preparedness and response. Among other responsibilities, the Assistant Secretary has the authority to register, credential, organize, train, equip and deploy Federal public health and medical personnel under the authority of the Secretary including National Disaster Medical System (NDMS), Medical Reserve Corps (MRC), and the Emergency System for the Advanced Registration of Volunteer Healthcare Professionals (ESAR-VHP).

The Assistant Secretary has authority over and responsibility for: NDMS; the hospital preparedness cooperative agreement program; certain responsibilities and authorities of the MRC; ESAR-VHP; Strategic National Stockpile; and Cities Readiness Initiative. The law also requires the Secretary of HHS to appoint an individual as Director of At-Risk Individuals.

National Health Security Strategy

Requires the development of a National Health Security Strategy and an accompanying implementation plan for public health emergency preparedness and response that will be submitted to Congress in 2009 and every four years thereafter. The plan must evaluate progress made by Federal, State, and local entities, based on evidence-based benchmarks and objective standards that measure levels of preparedness.

The Strategy must include provisions to further six preparedness goals involving:

1. **Integration:** Integrating public health and medical capabilities with other first responder systems including drills and exercises as well as through integrating donation and volunteers;
2. **Public Health:** Developing and sustaining essential public health security capabilities at all levels of government, including disease situational awareness, disease containment, risk communication, and rapid distribution and administration of medical countermeasures;
3. **Medical:** Increasing the preparedness, response capabilities, and surge capacity of hospitals and other health care facilities (including mental health facilities), trauma

care and emergency medical service (EMS) systems including strengthening management and treatment capabilities; evacuation and fatality management; rapid distribution and administration of medical countermeasures; effective utilization of mobile medical assets and integration of other Federal assets; protecting health care workers and health care first responders from workplace exposures in a public health emergency.

4. At-Risk Individuals: Taking into account the public health and medical needs of at-risk individuals (i.e., children, pregnant women, senior citizens, and other individuals who have special needs in the event of a public health emergency)
5. Coordination: Minimizing duplication and ensuring coordination between Federal, State, local and tribal planning, preparedness, and response activities (including the State Emergency Management Assistance Compact (EMAC)) consistent with the National Response Plan (NRP), National Incident Management System (NIMS), and the National Preparedness Goal;
6. Continuity of Operations: Maintaining vital public health and medical services to permit optimal Federal, State, local and tribal operations in the event of a public health emergency.

Partnerships for State and Regional Hospital Preparedness to Improve Surge Capacity

The Secretary of Health and Human Services (HHS) may award competitive grants or cooperative agreements to eligible entities to improve surge capacity and enhance community and hospital preparedness for public health emergencies. Eligible entities must prepare and submit an application to the Secretary as required (including the same type of information and assurances that are required for the public health security cooperative agreements as described below).

Eligible Entities. To be eligible, entities must be:

1. A partnership consisting of:
 - a. One or more hospitals (at least one of which must be a trauma center);
 - b. One or more other local health care facilities (including clinics, health centers, primary care facilities, mental health centers, mobile medical assets, or nursing homes); and,
 - c. One or more States and/or political subdivisions.
2. A State, a political subdivision, or a consortia of States.

Use of Funds. Funds may be used for activities to achieve preparedness goals (as described above) including integration, medical, at-risk individuals, coordination, and continuity of operations.

Preferences. Preference given to: applications from entities that enhance coordination among hospitals and other local healthcare facilities; those including one or more hospitals participating in the National Disaster Medical System (NDMS); those located in areas of high risk; and those that show a significant need for funds to achieve medical preparedness goals.

Maintenance of Funding. Entities that receive an award must not reduce expenditures for health care preparedness below the average level spent over the preceding two years.

Performance and Accountability. Entities receiving funding under this program will be subject to requirements to:

- Demonstrate measurable progress in meeting evidence-based benchmarks and objective standards for preparedness and the development of an effective plan for responding to pandemic influenza. Failure to meet these benchmarks or submit an influenza plan could result in withholding of certain amounts from the entity;
- Annually report on its activities and progress, submit to an audit of its expenditures at least every two years; be subject to repayment and/or withholding of payment if funds are not expended appropriately; be subject to maximum carryover amounts from one year to the next;
- Provide data for compilation and public availability.

Authorization for Appropriation. **The law authorizes for appropriation \$474 million for fiscal year (FY) 2007**, and such sums as may be necessary for FYs 2008-2011.¹ The Secretary may reserve an amount from this total for making awards to hospital/health care facility/government partnerships, as described above.

Improving State and Local Public Health Security

The Secretary will award cooperative agreements with eligible entities to achieve certain preparedness goals aimed at improving public health security at the State and local level, as described below. In addition, the Secretary must consult with the Secretary of Homeland Security in awarding funds to maximize coordination, avoid duplication, develop best practices, and to disseminate recommendations and guidance.

Eligible Entities. Eligible entities include individual States; a political subdivision; and consortia of States.

All-Hazards Public Health Emergency Preparedness and Response Plan. These entities will have to submit an application to the Secretary that must include an All-Hazards Public Health Emergency Preparedness and Response Plan. This Plan must include: a description of activities to meet the public health goals (described below); a pandemic influenza plan; preparedness and response strategies and capabilities; a description of how it will use the Emergency Management Assistance Compact (EMAC) or other mutual aid agreements; and how the State Unit on Aging will be included.

Other Application Requirements. Among other application requirements, eligible entities must assure the Secretary that they will:

- Annually report progress on meeting evidence-based benchmarks and objective standards established by the Secretary;

¹ Note: None of the amounts authorized in this Act can be spent unless Congress appropriates the funds.

- At least annually conduct exercises or drills that meet criteria established by the Secretary and report back on strengths and weaknesses and corrective actions;
- Conduct activities to inform and educate the hospitals within their jurisdiction on the role that hospitals play in the Plan.
- Establish an accountability system to ensure annual satisfactory improvement in meeting Plan provisions;
- Describe how public comment and input on the Plan will be provided including establishing an advisory committee of stakeholders
- Describe process used to consult with local public health departments to reach agreement on relative distribution of cooperative agreement funds.

Limitation Regarding State ESAR-VHP Participation. Starting in 2009, the Secretary may not award a cooperative agreement unless the State participates in ESAR-VHP.

Use of Funds. Funds may be used for activities to achieve preparedness goals (as described above) including integration, public health, at-risk individuals, coordination, and continuity of operations.

Other Requirements. Eligible entities will also be required to ensure that there is coordination with other local response activities such as the Metropolitan Medical Response System, local public health, Cities Readiness Initiative and local emergency plans. Also entities will be subject to similar requirements for performance and accountability as described above for entities receiving funding under the hospital preparedness program – such as demonstrating measurable progress in meeting evidence-based benchmarks; annual reporting; biennial audits; repayment/withholding of amounts for failure to meet benchmarks; maximum carryover amounts; etc. Amounts that are withheld from States or political subdivisions due to their failure to achieve benchmarks or failure to submit an influenza plan may be made available for making awards to partnerships under the hospital preparedness program.

Grants for Real-Time Disease Detection. Provides the Secretary with authority to award grants to eligible entities (including hospitals) to carry out a pilot demonstration project to purchase and implement the use of advanced diagnostic medical equipment to analyze real-time clinical specimens or pathogens of public health or bioterrorism significance and report any results from such project to the state, local public health entities.

Authorizes for appropriation \$35 million for these awards.

Authorization for Appropriation. **The law authorizes for appropriation \$824 million for FY 2007 for improving State and local public health security** (of which \$35 million is for real-time disease detection improvement grants), and such sums as may be necessary for FYs 2008-2011. An additional \$10 million is available for FY 2007 to develop a single Internet-based point of access for sharing and distributing best practices and lessons learned.

The law also requires the provision of state matching funds (“non-Federal contributions”), directly or through donations from public or private entities, beginning in

FY 2009 at five percent and in years thereafter at 10 percent. The State must also maintain expenditures for public health security at a level at least equivalent to the average for the preceding two years

Other Provisions in Pandemic and All-Hazards Preparedness Act

Using Information Technology in Emergencies. Requires the Secretary in collaboration with State and local public health to establish within two years a near real-time electronic nationwide public health situational awareness capability through an interoperable network of systems. The network is intended to share data so as to enhance early detection and rapid response and management of potentially catastrophic infectious disease outbreaks and other public health emergencies. The network is to be built on existing State situational awareness systems or enhanced systems that enable such connectivity. The network must use applicable interoperability standards and defined minimal data elements and follow standards for data collection and reporting. Any data from public and private sector health care entities (such as hospitals) must be provided voluntarily. To implement this network, the Secretary may award grants to States or a consortia of States.

Public Health Workforce Enhancements. Establishes a demonstration project for National Health Service Corps loan repayment for individuals who complete their service obligation in a State or local health department that serves a health professional shortage area or an area at risk of a public health emergency. Allows the Secretary to award grants to assist states in operating loan repayment programs for such service.

Vaccine Tracking and Distribution. Allows the Secretary to track the initial distribution of federally purchased influenza vaccine in an influenza pandemic. Also requires the Secretary to promote communication regarding effective distribution of seasonal influenza vaccine between State and local public health authorities and manufacturers, distributors and wholesalers.

National Science Advisory Board for Biosecurity. Requires the Advisory Board, when requested by the Secretary, to provide to federal departments and agencies recommendations concerning core curriculum and training requirements for workers in maximum containment biological laboratories; and periodic evaluations of these laboratories capacity nationwide and assessments of the future need for increased capacity.

Revitalization of Commissioned Corps. Improves the force management and readiness of the Commissioned Corps.

NDMS. Transfers to the Secretary of HHS the functions of the NDMS. Requires the Secretary to conduct a joint review of the NDMS with the Secretaries of Homeland Security and Veterans Affairs, including a review of medical surge capacity and, based on findings, gives him the authority to modify NDMS policies as necessary.

Enhancing Medical Surge Capacity.

- As part of the joint review of NDMS, requires the Secretary to evaluate the benefits and feasibility of improving the capacity of HHS to provide additional medical surge capacity to local communities in a public health emergency, including the acquisition and operation of mobile medical assets, integrating telemedicine into NDMS and other strategies.
- Gives the Secretary authority to acquire, deploy and operate mobile medical assets.
- Requires the Secretary to conduct an analysis of whether there are Federal facilities which could be used to provide health care in an public health emergency and, based on the analysis, requires the Secretary to complete a memorandum of understanding with the head of the relevant federal department or agency that permits the use of the facility in an emergency.
- Amends the Secretary's waiver authority to allow Emergency Medical Treatment and Labor Act (EMTALA) provisions to be waived for more than 72-hours in a public health emergency involving a pandemic infectious disease outbreak.

Encouraging Health Professional Volunteers.

- Medical Reserve Corps. Formally establishes in law the Medical Reserve Corps (MRC) to provide for an adequate supply of volunteers in the case of a public health emergency. The MRC is to be headed by a Director appointed by the Secretary. Requires that the Director establish a process to periodically certify MRC volunteers and requires volunteers to participate in periodic local training exercises. Provides authority to the Secretary to deploy willing members of the MRC to areas of need, with the concurrence of State, and local officials from the volunteer's area of residence. Allows the Secretary to designate MRC volunteers as Federal intermittent disaster-response personnel thus providing them certain Federal protections. **Authorizes for appropriation \$22 million for FY 2007** for these purposes.
- ESAR-VHP. Within a year, requires the Secretary to link existing State ESAR-VHP systems to maintain a single national interoperable network of systems, each system being maintained by a State(s), for the purposes of verifying the credentials and licenses of health care professionals who volunteer to provide health services during a public health emergency.
- Health Care Provider Licenses. Requires the Secretary to encourage States to establish and implement mechanisms to waive the application of licensing requirements applicable to health professionals who are seeking to provide medical services (within their scope of practice) during an emergency.
- Core Education and Training. **Authorizes for appropriation \$46 million** to carry out the following activities:
 - Requires the Secretary, in collaboration with the Secretary of Defense and other stakeholders, to develop core health and medical response curricula and trainings by adapting applicable existing programs to improve response to public health emergencies. The Secretary may award grants and contracts to carry out this section;

- Expands the Epidemic Intelligence Service Program;
- Allows the Secretary to establish at accredited schools of public health, Centers for Public Health Preparedness.

Enhancing the Role of the Department of Veterans Affairs (VA). Requires the Secretary of VA to: ensure the readiness of VA medical centers for a public health emergency; organize, train, and equip the staff of such medical centers to support HHS in the event of a public health emergency and incidents covered by the NRP; and provide medical logistical support to the NDMS and the Secretary of HHS as needed.

Pandemic and Biodefense Vaccine and Drug Development

The law contains a number of provisions to give the Secretary the authority to coordinate the acceleration of countermeasure and product advanced research and development including:

- Establishing within HHS a Biomedical Advanced Research and Development Authority (BARDA) and gives the Secretary the authority to appoint a Director;
- Requiring the Secretary, within 6 months, to develop a strategic plan for countermeasure research, development, and procurement;
- Establishing a Biodefense Medical Countermeasure Development Fund to carry out this section. **Authorizes for appropriation \$1.07 billion for FY 2006-2008.**
- Establishing a National Biodefense Science Board to advise the Secretary.
- Clarifying definitions of countermeasures covered by Project BioShield.
- Providing technical assistance to manufacturers of countermeasures and vaccines through experts at the Food and Drug Administration.
- Providing for a limited antitrust exemption for meetings and consultations conducted by the Secretary of HHS with persons engaged in the development of countermeasures or pandemic or epidemic products.
- Establishing procurement provisions.