



Assistant Secretary for Preparedness & Response

**Pandemic and All-Hazards
Preparedness Act**

Public Law 109-417

Progress Report

November 2007

Introduction

In December 2006 Congress passed and the President signed the Pandemic and All-Hazards Preparedness Act (PAHPA), Public Law No. 109-417, which has broad implications for HHS's preparedness and response activities. The Act established within the Department a new Assistant Secretary for Preparedness and Response (ASPR); provided new authorities for a number of programs, including the advanced development and acquisition of medical countermeasures; and called for the establishment of a quadrennial National Health Security Strategy.

This Progress Report highlights some of the major activities that the Department has undertaken since the enactment of PAHPA. It also includes a preview of the Way Forward – activities the Department plans as it moves ahead to continue implementing the legislation. The Report is divided into eight sections, each of which addresses a major program area under PAHPA.

- BARDA and Medical Countermeasures
- Emergency Support Function (ESF) #8 Public Health and Medical Response: Domestic Programs
- Emergency Support Function (ESF) #8 Public Health and Medical Response: International Programs
- Grants
- At-Risk Individuals
- National Health Security Strategy
- Situational Awareness: Surveillance, Credentialing and Telehealth
- Education and Training

This document represents a snapshot of current progress and the Department's plans for the immediate future; it is not meant to be a comprehensive overview of all aspects of the legislation. HHS recognizes that the implementation of a major piece of legislation like PAHPA is an iterative process and, as such, it requires ongoing evaluation and consultation. The Department continues to welcome the input of stakeholders and partners as it moves forward towards achieving our common goals.

BARDA and Medical Countermeasures

PAHPA established the Biomedical Advanced Research and Development Authority (BARDA) within HHS to direct and coordinate the Department's countermeasure and product advanced research and development activities. These activities build on the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which HHS established in 2006 to provide an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies and diagnostic tools for public health emergencies. The PHEMCE is a coordinated, intra-agency effort led by ASPR and includes the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH), with ex officio participation from the Department of Defense (DOD), the Department of Homeland Security (DHS), the Department of Veterans Affairs (VA) and other interagency stakeholders as appropriate. BARDA leads the PHEMCE, directing and coordinating the Department's countermeasure and product advanced research and development activities, including strategic planning for medical countermeasure research, development, and procurement.

Progress

The examples below represent some of HHS's activities in support of the Department's countermeasure and product advanced research and development activities.

- Through BARDA, HHS has established strategic initiatives for countermeasures and product advanced research, development, and innovation for unmet needs. These strategic initiatives are documented in the *PHEMCE Strategy* (March 20, 2007), and the *PHEMCE Implementation Plan* (April 18, 2007). On July 7, 2007, the Secretary published a *Draft BARDA Strategic Plan for Countermeasure Research, Development and Procurement*, to guide and facilitate the research, development, innovation, and procurement of medical countermeasures and build upon established National strategies and directives.
- HHS has hosted meetings with representatives from Federal partners, relevant industries, academia, and international agencies. The Annual PHEMCE Stakeholders Workshop was held July 31 through August 2, 2007 to communicate with and receive feedback from these and other stakeholders. BARDA's Industry Day was held on August 3, 2007, and provided an opportunity for private sector stakeholders to demonstrate the operation and effectiveness of relevant countermeasure technologies.
- On May 24, 2007, the Secretary established and issued a call for nominations to the National Biodefense Science Board (NBSB). The NBSB was established to provide the Secretary with expert advice and guidance on scientific, technical and other matters of special interest to HHS to help prevent, prepare for and respond to adverse health effects of public health emergencies resulting from current and future chemical, biological, radiological, or nuclear agents (CBRN), whether naturally occurring, accidental, or deliberate.

- In June 2007, BARDA awarded a contract employing new authorities for performance-based milestone payments for a next generation modified vaccinia Ankara (MVA) smallpox vaccine.
- In September 2007, BARDA awarded contracts utilizing new authorities for the advanced development of anthrax antitoxins, anthrax rPA vaccine, smallpox antiviral, novel antibiotic formulations, and radiological/nuclear medical countermeasures.
- BARDA, in coordination with National Vaccine Program Office (NVPO), developed the concept of pre-pandemic influenza vaccine stockpiles for usage at the onset of a pandemic. Subsequently BARDA established the first National pre-pandemic H5N1 influenza vaccine stockpile.
- BARDA awarded multiple contracts for advanced development of cell-based and antigen-sparing pandemic influenza vaccines that changed the global paradigm for manufacturers of influenza vaccines to focus on surge capacity and for a potential pandemic.
- BARDA established and administered a program for a Federal pandemic antiviral stockpile. Additionally, BARDA established and administered a program for States and other entities to utilize Federal subsidies to procure influenza antivirals for building State stockpiles

Specific Procurement Accomplishments

- The Influenza and Emerging Diseases Program was established to support a multi-pronged portfolio approach to expand, diversify, and expedite domestic pandemic influenza countermeasure surge capacity. The essential elements of this approach include advanced development, stockpile acquisition, and infrastructure building. These elements are being applied to medical countermeasures (vaccines and therapeutics), diagnostics, and non-pharmaceutical countermeasures for pandemic influenza and emerging infectious diseases. Funding is being provided through the Pandemic Influenza Preparedness Emergency Supplemental Appropriations. HHS has awarded a number of contracts in these areas.
- HHS has taken significant steps with regard to the development and procurement of a number of critical medical countermeasures, including anthrax vaccines, anthrax antitoxin, botulism antitoxin, broad-spectrum antibiotics, filovirus vaccines and therapeutics, smallpox vaccines and therapeutics, and countermeasures for use in radiological, nuclear, and chemical incidents.

Advanced Development

- PAHPA amended Section 319F-2 of the Public Health Service Act to expand the Secretary's authority to use milestone-based awards and payments for up to 50 percent of the total amount of a Project BioShield contract. Project BioShield has initiated a developmental acquisition approach that includes Advanced Development and the use of new initiatives to accelerate the acquisition and distribution of products to the Strategic

National Stockpile. BARDA and the National Institute of Allergy and Infectious Diseases (NIAID) established a Memorandum of Understanding to initiate and facilitate the development of candidate medical countermeasures for CBRN agents. The first use of Advanced Development funds employed \$99 million.

- BARDA, in conjunction with NIAID, has awarded three contracts for anthrax therapeutics using BARDA Fiscal Year (FY) 2007 Advanced Development funds: \$9.2 million (Pharmathene), \$8.1 million (Elusys), and \$9.7 million (Emergent).

Way Forward

HHS is moving forward in a number of areas related to BARDA and medical countermeasures. The examples below highlight HHS future efforts in support of these activities.

- By the fall of 2007, the Secretary will appoint a Director of BARDA.
- The Secretary will hold the initial meeting of the NBSB on December 17-18, 2007.
- By December 2008, the Secretary will provide the first biennial report to Congress on the use of BARDA personnel authorities to recruit, retain, and manage staff.
- The Secretary will publish the final BARDA Strategic Plan for Countermeasure Research, Development, and Procurement for inclusion in the National Health Security Strategy.
- The Secretary will continue to conduct ongoing searches/support calls for potential qualified countermeasures and qualified pandemic and epidemic products and convene working groups the Secretary determines necessary to implement BARDA.
- The Secretary will continue to award contracts, grants, and cooperative agreements, and enter into transactions for medical countermeasure and product advanced research and development.
- The Secretary, in consultation with the FDA Commissioner, will continue to advise interested persons regarding the regulatory requirements related to the approval, clearance, or licensure of qualified countermeasures or qualified pandemic or epidemic products.
- Licensed cell-based influenza vaccines are expected to be available in the United States as early as 2009 with an expanded domestic pandemic vaccine manufacturing surge capacity to meet U.S. pandemic needs by 2011.
- Licensed pandemic influenza vaccines with adjuvants are expected to be available and meet U.S. pandemic needs by 2009. BARDA is leading a 18-month study entitled “Mix-N-Match” to determine whether adjuvants developed by one manufacturer may be used with H5N1 antigens produced by another manufacturer for the National pre-pandemic vaccine stockpile under Emergency Use Authorization during an influenza pandemic.

- The National pre-pandemic H5N1 vaccine stockpile goal is expected to be reached in 2009 as antigen-alone formulations and may be expanded to 600 million doses by 2009, if formulated with adjuvants.
- BARDA expects to issue a solicitation for proposals to construct new domestic influenza pandemic egg- & cell-based influenza vaccine manufacturing facilities in 2008.
- As the product pipeline of influenza antivirals advances to Phase 2 stage of development in 2008, BARDA will re-issue a solicitation for proposals for advanced development of influenza antiviral drugs with longer shelf-lives, greater bioavailability, different viral targets, and use with other antivirals as combination drugs towards FDA approval with manufacturing facilities in the United States.
- In FY 2008 an additional 12.5 million treatment courses of FDA-approved neuraminidase inhibitor influenza antiviral drugs will be procured by BARDA for the Strategic National Stockpile to reach the 50 million treatment course goal. By July 2008, States and other entities are expected to complete procurement of 31 million treatment courses of influenza antivirals for State pandemic stockpiles – goals set in the National Strategy for Pandemic Influenza (Nov. 2005).
- BARDA will participate in 2008 in additional pandemic preparedness training exercises with the CDC, DHS, States, and the vaccine manufacturers. These training exercises will focus on distribution of pre-pandemic and pandemic vaccines from multiple manufacturers to the States.
- Solicitations from CDC and BARDA for proposals to develop more sensitive rapid diagnostic devices for high throughput multiplex laboratory use and for simple, single use diagnostic devices are expected for issuance in 2008 for detection of influenza viruses.
- The Secretary will convene meetings with Ministers of Health and the Commissioner of Health and Consumer Protection of The European Union to discuss collaborative ways to bolster the global marketplace for medical countermeasures.

Emergency Support Function (ESF) #8 Public Health and Medical Response: Domestic Programs

Responses to recent disasters have demonstrated the positive impact the Federal public health and medical community can have in assisting State, Tribal, Territorial, and local public health and medical officials in responding to the public health and medical needs of a disaster or emergency.

Progress

The examples below represent some of HHS's ongoing activities in support of planning and achieving a coordinated and efficient Federal public health and medical response system.

- ASPR has developed playbooks for nine of the fifteen national planning scenarios to help further define the public health and medical needs during each of these scenarios.
- The Office of Public Health and Science (OPHS) and ASPR signed a Memorandum of Understanding (MOU) on August 27, 2007 to establish guidelines regarding ASPR's responsibilities and authorities with respect to the Medical Response Corps (MRC) program.
- Transfer of the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) program from the Health Resources and Services Administration (HRSA) to ASPR was completed.
- The Department is establishing processes and procedures to cooperatively track the initial distribution of Federally purchased influenza vaccine in support of an influenza pandemic.
- The Department has engaged in a number of activities to promote communication between State, Tribal, Territorial, and local public health officials and manufacturers, wholesalers, and distributors regarding the effective distribution of seasonal influenza vaccine.
 - FluFinder is currently activated and monitoring influenza vaccine distribution for the 2007-08 influenza season.
 - The National Influenza Vaccine Summit was convened April 19-20, 2007.
 - The CDC sent a letter to influenza vaccine manufacturers and distributors in August 2007 encouraging them to employ distribution strategies that assure broad access to influenza vaccine throughout the vaccination season. The CDC recommended that manufacturers and distributors serve all provider types in a comparable time frame using strategies such as partial shipments to allow vaccine administration to begin as early as possible across all vaccination venues.

- The Department has developed policies to ensure the readiness of the U.S. Public Health Service Active Duty, Regular Corps, and Inactive Reserve Corps to respond to urgent or emergency public health care needs.
- The Department has completed a joint review with the Departments of Homeland Security, Defense, and Veterans Affairs of the National Disaster Medical System (NDMS).
- The functions of the NDMS are in the process of transfer from DHS to HHS. Several major milestones have been completed, including:
 - The formal transfer of the program and staff;
 - The transfer of emergency response vehicles;
 - Establishment of an interagency agreement between the Federal Emergency Management Agency (FEMA) and HHS for logistical support;
 - Completion of warehouse inventories; and
 - Completion of interagency agreements between the Department of Veterans Affairs and HHS for pharmaceutical/logistical support.
- The Department expanded the Medical Reserve Corps (MRC) to provide for an adequate supply of volunteers in the case of a Federal, State, Tribal, Territorial, or local public health emergency. There are currently 705 MRC units (with over 140,000 volunteers) in all 50 States, Washington, DC, Puerto Rico, Palau, Guam, and the U.S. Virgin Islands.
- In conjunction with a consortium of Federal partners, the Department conducted a five-week field training for U.S. Public Health Service Commissioned Corps officers assigned to Departmental response teams (e.g., Rapid Deployment Force, Applied Public Health and Mental Health Teams). The training in medical field operations targeted 621 Active Duty Commissioned Officers, members of the MRC, and Inactive Reserve Corps Officers who collectively constituted fifteen response teams. As a result of the training, Participants reported a measurable change in the deployment skills of team members and teams.
- The Department conducted 3 operational drills in Seattle, Philadelphia, and Boston of the Cities Readiness Initiative (CRI) postal module. Through these drills the Department pilot-tested the Med Kit module, developed guidance for conducting drills, and drafted standards for Points of Dispensing.
- The Department responded to Hurricane Dean and the Secretary's declaration of a Public Health Emergency in advance of landfall, executed pre-scripted statements of work with FEMA to allow deployment of assets prior to landfall. In addition, the Department successfully deployed the newly developed Incident Response Coordination Team (IRCT) and prepositioned 5 Federal Medical Stations (FMS) in Texas in coordination with CDC and FEMA logistics.

- Regional Emergency Coordinators in prime hurricane regions conducted assessments of hospitals and nursing homes to determine the shelter in place and evacuation requirements for facilities in “at risk” areas of these States.

Way Forward

HHS is moving forward in a number of areas related to ESF #8. The examples below highlight HHS future efforts in support of these activities.

- The Department is establishing processes and procedures to cooperatively track the initial distribution of Federally purchased influenza vaccine in support of an influenza pandemic. As listed earlier, progress has been made in developing a blueprint for the Vaccine eXchange NETwork.
- The Department is continuing to improve communication between State, Tribal, Territorial, and local public health officials, and manufacturers, wholesalers, and distributors regarding the effective distribution of seasonal influenza vaccine.
- ESAR-VHP guidelines are currently being finalized.

ESF #8 Public Health and Medical Response: International Programs

HHS plays an important leadership role in coordinating a number of international activities that promote preparedness and mitigate the effects of public health and medical disasters at home and abroad. PAHPA directs the Secretary and ASPR to “provide leadership in international programs, initiatives, and policies that deal with public health and medical emergency preparedness and response.” On behalf of the Secretary, ASPR leads efforts, in close collaboration with the Office of Global Health Affairs (OGHA), the CDC, and FDA, regarding HHS international preparedness and response activities. However, other U.S. Departments also play important roles in international public health and medical emergency preparedness and response. In particular, the U.S. Department of State has the overall responsibility for coordination of the United States Government’s (USG’s) international efforts. Building on existing relationships, ASPR, in collaboration with OGHA and other parts of HHS, will work with other Federal Departments and Agencies to continue to strengthen initiatives in international public health and medical emergency preparedness and response. ASPR will develop a Concept of Operations for preparing for and responding to an international public health or medical emergency.

Progress

The examples below represent some of HHS’s activities in support of international activities that promote preparedness and mitigate the effects of public health and medical disasters.

- HHS has compiled and reviewed a collection of both domestic and international Concepts of Operations, and other response plans, from within HHS and the USG to identify relevant HHS and USG assets, programs, and initiatives for use in an international response.
- HHS led the USG’s effort to develop a mechanism for inter-Departmental communication in preparation for the International Health Regulations (IHRs) to enter into force for the United States on July 18, 2007. The Secretary's Operations Center is the U.S. National Focal Point to communicate with the Secretariat of the World Health Organization (WHO) on a 24/7/365 basis regarding public health events that could qualify as a potential public health emergency of international concern. HHS is currently implementing these procedures to report events to the WHO, in accordance with the IHRs. This intra- and inter-Departmental communication protocol should serve as the foundation for future intra- and inter-Departmental communications in response for both domestic and international emergencies.
- HHS participated in internationally-focused exercises and workshops, especially those organized by the Global Health Security Initiative.
- HHS hosted a workshop, *Exportable Lessons Learned from the Katrina and Rita Hurricanes for Pandemic Influenza Response and other Large Territorial Events*, from

September 17-18, 2007 for Global Health Security Initiative partners. Participants included representatives from four Global Health Security Initiative countries, as well as the WHO, the United Nations and the European Union. This workshop established a forum for international emergency public health and medical representatives to better understand the lessons learned by the United States in response to Hurricanes Katrina and Rita. Many of these findings should assist in planning for pandemic influenza and other large-scale events.

Way Forward

HHS is moving forward to coordinate international preparedness and response efforts. The examples below highlight HHS future efforts in support of these activities.

- Secretary Leavitt will host the Global Health Security Initiative annual Ministerial Meeting in November 2007.
- HHS continues to disseminate information regarding the revised IHRs, and will continue to engage in education and training efforts on the IHR implementation process in the coming months.
- HHS is convening an interagency committee to develop the international HHS response plan. The committee will outline and define the appropriate processes to coordinate preparedness and response efforts with international partners, as well as to actually write the plan. This committee will do the following:
 - Draft the International Concept of Operations consistent with the tenants of the IHRs and other international obligations and in accordance with the tenets outlined in the National Security Council *Rapid Response to an International Outbreak of Avian Influenza and Pandemic Influenza* document and other USG policies as a guide;
 - Develop an international model based on the domestic Concept of Operations, where it makes sense to do so; and
 - Act as the facilitator to establish liaisons with international emergency-response organizations.

Grants

With the passage of PAHPA, the Secretary has additional authorities to meet goals for public health and health care emergency preparedness. One vehicle for meeting these goals and objective is through the Department's grant programs.

In 2007, HHS has been actively engaged in two primary grants-related areas:

- Creating a plan to implement existing grants programs (the Public Health Emergency Preparedness, Hospital Preparedness Program, and Centers for Public Health Preparedness grants) in accordance with changes to those statutes; and
- Developing plans for implementing new grants authorities (Real-Time Disease Detection, Health Care Facility Partnerships, Situational Awareness, and Loan Repayment grants).

Progress

The examples below represent some of HHS's activities in support of new and existing emergency preparedness and response grant programs.

- The Department has incorporated standardized benchmarks and performance measures into existing grant programs. The Public Health Emergency Preparedness (PHEP), Hospital Preparedness Program (HPP), and the Health Care Facilities Partnership Program (HFP) announcements include requirements to report benchmarks and performance measures. Application of accountability provisions based on the successful achievement of targets demonstrated during the previous budget cycle will take place as part of awarding funds for the FY 2009 budget cycle, based on FY 2008 reports. In addition, HHS will require matching funds beginning in FY 2008.
- The Department developed guidelines for the awarding of grants for Real-Time Disease Detection Improvement and applications were requested for funds (\$35 million) from eligible entities of the PHEP for Real-Time Disease Detection. Funds for FY 2007 were obligated and applications accepted on October 24, 2007. Full funds will be unrestricted following the review of applications, before January 1, 2008.
- The Department wrote compliance requirements for State participation in the ESAR-VHP program; starting in FY 2009 participation in ESAR-VHP will be a mandatory requirement to receive grant dollars from the PHEP.
- The Department is coordinating public health and medical preparedness and response activities with DHS to minimize duplication of efforts, as well as to analyze activities and disseminate recommendations and guidance. Current collaborations exist in the Homeland Security Exercise and Evaluation Program, the National Preparedness Goal, resource-typing and credentialing, other Homeland Security Presidential Directive (HSPD) 8 and HSPD-5 activities, cooperative agreements management, Target

Capabilities establishment, the CRI program (including the use of the Postal Service Delivery option), as well as senior management interactions.

- HHS developed criteria for the development and review of pandemic influenza plans on health and medical domains.
- An HHS-led multi-Department team developed 24 criteria that States should address in their pandemic influenza preparedness plans. The participating Departments, in addition to HHS, were the Departments of Homeland Security, Education, Labor, Commerce, Justice, Agriculture, and State. HHS then solicited States' plans in each of the 24 targeted criteria, the participating Departments reviewed the pertinent parts of the States' responses, and HHS compiled the results into State-specific draft interim assessments. Detailed information on the process to date can be found at <http://www.pandemicflu.gov/plan/states/stateoperatingplan.html>. HHS currently is engaged in discussion with the Homeland Security Council and other Departments regarding how best to engage the States in a second round of criteria development, plan refinement, and review.
- The Department established guidelines for mandatory non-Federal contributions to cooperative agreements; non-Federal matching will be required for the PHEP and the HPP. Policies for non-Federal matching will be applied to the PHEP and HPP in FY 2008. The HPP completed its work and is implementing policies for non-Federal Maintenance of Funding in FY 2007, work is still in progress for the PHEP.
- The Department established guidelines to award grants to improve surge capacity and enhance community and hospital preparedness for public health emergencies. The HPP and HFP announcements were received, reviewed, and funded prior to the end of the fiscal year.
- The Department established guidelines for accredited schools of public health to be eligible to receive awards to establish a Center for Public Health Preparedness (CPHP). CDC provided significant opportunities for discussion with the current CPHPs and determined a strategy to incorporate both continued curricula development and public health systems research into future activities as prescribed by PAHPA. The CPHP cooperative agreement guidance for FY 2007 was released on July 3, 2007. Funds appropriated in FY 2007 were obligated before the end of the Federal fiscal year, as required.

Way Forward

HHS is moving forward in a number of areas related to grants. The examples below highlight HHS future efforts in support of these activities.

- A revised set of criteria for State pandemic influenza plans will be developed by the Department and submitted for State review.

- The Department is developing guidelines for funds to be withheld from awardees who fail to meet the benchmarks, performance measures, and plans for responding to pandemic influenza. Policies will be applied and funds withheld from the existing preparedness grants programs if deemed appropriate by FY 2009.
- The Department is developing guidelines regarding the waiver or reduction of withholdings for a single entity or for all entities in a fiscal year. Policies will be applied and funds withheld from the existing preparedness grants programs if deemed appropriate by FY 2009.
- The Department is establishing guidelines for standardized reports from awardees. ASPR and CDC will develop program guidance for the FY 2008 existing preparedness grants programs that incorporate the accepted standardized reporting for which awardees will be held accountable.
- The Department is establishing auditing requirements for all awardees. Awardees of the existing preparedness grants programs will be required to submit an audit every two years (by statute), starting with FY 2008.
- The Department is establishing guidelines for the repayment of funds not expended in accordance with statutory or Departmental guidelines. These policies will be applied and repayment of funds not expended from the existing preparedness grants programs by FY 2009.
- The Department is establishing guidelines for the maximum percentage amount of an award that may be carried over to the succeeding fiscal year. These policies will be applied and the maximum percentage amount of an award that may be carried over to the succeeding fiscal year from the existing preparedness grants programs will be implemented by FY 2009.

At-Risk Individuals

PAHPA calls for HHS to integrate the needs of at-risk individuals on all levels of emergency planning, ensuring the effective incorporation of at-risk populations into existing and future policy, planning, and programmatic documents. HHS has previously taken significant strides in this area. For example, since FY 2003, HHS has worked to incorporate the needs of at-risk individuals into existing planning documents and into the emergency preparedness and planning grants for public health (administered by the CDC) and hospital preparedness (administered initially by HRSA, now by ASPR). In another example, HHS has been an active participant on the Interagency Coordinating Council on Emergency Preparedness and Individuals with Disabilities (ICC). The ICC was established to ensure that the Federal Government appropriately supports safety and security for individuals with disabilities in disaster situations.

Progress

The examples below represent some of HHS's activities in the area of at-risk populations undertaken or completed since the passage of PAHPA.

- HHS has taken steps toward creating a uniform definition of “at-risk” individuals that will be consistent with other terminology, such as “special needs,” or “vulnerable” populations. Toward that end, HHS has been an active participant in the Special Needs Workgroup established by DHS to craft the first Federal definition of “special needs” (“at-risk”) populations. This definition is incorporated in the draft National Response Framework (NRF, formerly the National Response Plan) and is also being used for implementation of PAHPA. HHS and a wide range of representatives of Federal and State agencies, first responders, non-governmental organizations, and disability advocates united to reach clarity on the principles and assumptions of this functional definition. In defining the Special Needs Population, the document uses a function-based approach that focuses on individual capabilities rather than on labels or broad generalizations about populations. This permits emergency planners and first responders to match individuals' abilities and resources to the abilities and resources required to carry out emergency support functions identified in the NRF. While statutory language requires the use of different terms, the HHS approach allows a common definition to be used for “at-risk,” “special needs” and “vulnerable” populations.
- HHS worked with the American Red Cross (ARC), to develop a Shelter Intake and Assessment Tool to ensure that at-risk individuals are referred to the most appropriate shelter setting. This intake tool addresses a critical issue that prevented many at-risk individuals from placement in the most appropriate shelter for their needs during Katrina. The ARC and HHS have entered into a Memorandum of Understanding to use the tool. The tool significantly increases the support available to at-risk individuals requiring sheltering by assessing the level of independence and type of support needed by at-risk individuals. This tool has also been prepared for State utilization through development of a Concept of Operations, which has been presented to the Regional Directors, and through their communication with respective State Governor's offices and emergency preparedness officials.

- The HHS Office on Disability, in collaboration with ASPR, has developed a toolkit to address the needs of planners for concrete information and guidance on accounting for the needs of at-risk individuals, including persons with disabilities. State Emergency Planners can use the toolkit to plan for a range of potential hazards affecting individuals designated as at-risk. The toolkit is based on focus group input and research to identify the gaps in training and ensure a comprehensive compendium of electronically provided emergency planning, preparedness, evacuation and response information. The Office on Disability released a draft of the Toolkit to their constituency and to members of the Office on Disability Emergency Preparedness Subcommittee for review and comment.
- HHS, through the CDC, has entered into a new cooperative agreement with the Association of State and Territorial Health Officials (ASTHO) to develop evidence-based, model guidance on the protection of at-risk populations during an influenza pandemic. ASTHO will perform an extensive review of relevant publications and plans, convene subject matter expert- and practitioner-led drafting work groups, and convene stakeholder engagement meetings to provide key input during the drafting process. The draft guidance will be reviewed by public health practitioners, finalized, and disseminated to State and local public health jurisdictions by May 2008.
- HHS completed a survey of all HHS Operating and Staff Divisions to identify behavioral health resources and assets related to preparedness, response, and recovery efforts.
- HHS conducted training and information sessions for the ICC Health and Human Services Emergency Preparedness Subcommittee (facilitated by the Office on Disability), resulting in a strategic performance measure-based strategic plan that supports the roles and responsibilities of ASPR.
- With the ICC and FEMA, HHS created the first in a series of “quick card” training materials for FEMA response workers on authorities for services for persons with disabilities.
- HHS also participated in an interagency work group that addressed evacuation and transportation issues related to emergency preparedness and response, to ensure that transportation plans and activities take into account the needs of at-risk persons for accessible transportation and other appropriate aids and services, and that at-risk persons are not inappropriately steered to medical facilities when they can be transported to and served in general population shelters. The work group issued a new triage tool for evacuation and transportation that FEMA and HHS have agreed to use.

Way Forward

The accomplishments of the last year have provided a firm foundation for guiding HHS plans for the effective integration of the needs of at-risk individuals on all levels of emergency planning. As implementation of PAHPA continues, HHS will be completing existing projects and initiating new ones.

- HHS will finalize recommendations regarding planning for the needs of at-risk individuals in pandemic scenarios. These will be included in a white paper under development by the Interagency Workgroup on At-risk Individuals and Pandemic Influenza. This group has already conducted Listening Sessions for non-governmental organizations and State, Tribal, Territorial, and local governments to complete a matrix of best practices, model plans, gaps and barriers in planning for at-risk individuals.
- HHS will finalize the toolkit, which will provide information to support State and local emergency managers and others in addressing at-risk individuals, with particular attention to the needs of persons with disabilities in State emergency plans and responses. The toolkit will include information from an evacuation and a shelter in place perspective and will address the five major areas (maintaining independence, communication, transportation, supervision, and medical care) based on the definition for Special Needs Population adopted in the NRF.
- The Office on Disability and ASPR are finalizing the development of an electronic-based training module which will educate Federal and State emergency managers and responders on the needs and challenges of persons with disabilities during an emergency. This training will be incorporated within the ASPR Core Curriculum for both U.S. Public Health Service Commissioned Corps and Government Service employees.
- HHS is researching and identifying gaps in training for first responders and health care personnel in working with at-risk individuals. This research was begun in order to continue with the development of the Toolkit to identify training and curricula, and craft a plan to address the gaps in training.
- The Assistant Secretary for Planning and Evaluation awarded a contract in September 2007 to examine current research and best practices regarding emergency preparedness communication strategies for vulnerable (at-risk) populations. This work will include a final report to inform Federal, State, Tribal, Territorial, and local emergency preparedness planning.
- The Assistant Secretary for Public Affairs will be testing already developed messaging strategies in several pilot communities to include ethnic and language minorities.
- The Secretary will designate a Director of At-Risk Individuals for placement within the present ASPR structure.

National Health Security Strategy

The National Health Security Strategy will be a guide to prepare for, prevent, respond to, and recover from public health emergencies and disasters. Furthermore, it will provide the structure for an integrated quadrennial review of the state of the Nation's health security.

The National Health Security Strategy will be developed in coordination and collaboration with the U.S. Departments of State, Homeland Security, Defense, Veterans Affairs, and other Federal, State, Tribal, Territorial, local, and private partners. The first Strategy, due in December 2009, will be developed as a single overarching document that details how domestic and international preparedness and response programs will complement and enhance collective public health and medical preparedness.

The framework for the National Health Security Strategy is currently under development and the Department is in the initial phases of reaching out to non-governmental stakeholders and determining plans for routine engagement at appropriate and meaning intervals. The Department has been working to integrate strategy-related products required by PAHPA with existing strategic plans from within the Department's Operating and Staff Divisions, and identifying critical gaps in strategic plans that require additional development.

As the Department has contemplated the framework for the Strategy, Operating and Staff Divisions have identified elements that compose "Public Health Preparedness" and "Medical Preparedness," as well as foundational elements that support public health and medical preparedness. The Department looks forward to inviting input from partners as it continues the development of the framework and the overall strategy.

Situational Awareness: Surveillance, Credentialing, and Telehealth

For years, HHS has supported activities to monitor the health of communities and the Nation, often through disease-specific (e.g., Tuberculosis, HIV) or function-specific (e.g., food and waterborne) outbreak detection systems. The World Trade Center and anthrax attacks of 2001 elevated the necessity for nationwide public health situational awareness for the detection of, response to, and recovery from public health emergencies. Federal, State, Tribal, Territorial, and local government Agencies have been developing and implementing a variety of strategies to accelerate the timeliness and accuracy of detection and response.

The PAHPA legislation calls on HHS to leverage advances in information technology and information management to support faster, larger-scale, more efficient, and higher quality detection of, response to, and recovery from public health emergencies. The Department manages multiple initiatives to leverage advances in information technology to improve public health event detection and response, including the Public Health Information Network (PHIN), BioSense, the National Electronic Disease Surveillance System (NEDSS), the Epidemic Information Exchange (Epi-X), and Resource and Patient Management System (RPMS).

Progress

The examples below represent some of HHS's activities in support of strategic planning for situational awareness.

- HHS has taken steps towards developing a strategic plan for situational awareness by identifying existing information technology and reporting systems that track trends in public health and medical data and by piloting new systems that have the potential to improve situational awareness. Systems that are being utilized by HHS include the Toxic Event Surveillance System and the Electronic Laboratory Reporting of clinical data from the Laboratory Response Network.
- HHS is examining potential approaches for integrating disparate systems into an overarching system that will improve situational awareness. These approaches include the American Health Information Community's development of a minimum data set of key health indicators for use by information technology and reporting systems; the Health Information Exchange, which enables the exchange of information between independent and disparate systems; integration of Electronic Health Records data; and technical assistance through cooperative agreements with at-risk countries to improve and integrate their surveillance activities into the broader global network.
- The Office of the National Coordinator for Health Information Technology (ONC) has met with stakeholders in both the public and private sectors to promote the importance of HIEs. HIEs are critical components of the National Health Information Network (NHIN) and are vital to enhancing the public health use of clinical data for the purposes of biosurveillance and outbreak detection.

- The CDC has begun an intensive program to establish and enhance existing Health Information Exchanges. The CDC has leveraged the BioSense program to increase participation and include all relevant clinical health data from hospitals and clinics, which will improve their ability to detect real-time biological threats. Collection of data through HIEs minimizes the burden of reporting and interpreting data; there is movement towards developing standards towards uniform data gathering using HIEs. There is also increased case reporting from organizations with these computer-based systems.
- Electronic Laboratory Reporting represents one of the most significant and widely available sources of electronic data that convey specific and relevant information regarding infectious diseases and major public health threats. Federal Agencies have achieved significant advances since the signing of PAHPA in the capability of public health entities to receive electronic results messages from clinical and LRN laboratories.
- PHIN in relation to the National Electronic Disease Surveillance System has encouraged several State and local public health departments, to develop integrated disease surveillance systems. The leadership of the CDC has been significant in the effort to improve situational awareness through the networking of these State and local systems.
- With the collaboration of Federal, State, Tribal, Territorial, and local public health officials through American Health Information Community's, HHS has completed substantial planning that will support situational awareness across jurisdictions and serve both health care providers and public health officials.
- Connectivity is a critical component for any telehealth activity. HHS is engaged in dialogue with the Federal Communication Commission to establish alternate pathways of communication during a disaster. There have been successful and productive discussions regarding the expansion of internet communication reflecting bandwidth and cluster systems.
- The Department of Defense's Joint Patient Tracking Application has been modified to manage certain HHS specifications. This system will facilitate the capture of health information, status, and location of individuals who have been treated and evacuated away from a disaster site, while incorporating protections for patient privacy. Since this information is web-based, the information is real-time accessible.
- The Electronic Medical Record System, developed for NDMS, has the ability to capture health and demographic information from a disaster site. The information and the data are the accessible for epidemiology and trending.
- ASPR has identified Federal Agencies that are conducting telehealth activities and is working with ONC to identify and describe their current telehealth programs.

- HHS is engaged in discussions with several States to allow the Federal Government read-only access to their credentialing and privileging sites. HHS has also identified Federal Agencies with medical credentialing and privileging programs.
- The Indian Health Service developed, tested, and deployed software applications that enable the electronic ordering and receiving of reference laboratory data with specific reference labs and enable the electronic sharing of immunization data with specific States.
- Additionally, there are numerous information systems already in place to support public health decision making in outbreaks and emergencies at the Federal, State, Tribal, Territorial, and local levels.

Way Forward

HHS is moving forward with strategic planning for situational awareness. The examples below highlight HHS's future efforts in support of these activities.

- The Department is continuing development of Health Information Exchanges. Health Information Exchanges provide the capability to move health information relevant to clinical care and public health in an understandable, electronic format between independent and disparate healthcare information systems. They are critical components of a more robust National Health Information Network and vital to enhancing the public health use of clinical data for the purposes of biosurveillance and outbreak detection.
- A consortium of Federal Agencies is participating in National Health Information Network trial implementations, which will advance the health information exchange needs of cross-Agency collaborations, including the implementation of PAHPA.
- The Department is working towards establishing a network of electronic systems at the State level for credentialing health care providers that can be used to share provider information across jurisdictions in an emergency.
- Dialogue is continuing between ASPR, ONC, Federal Communication Commission and other telehealth partners to identify telehealth initiatives that are relevant to improving the provision of quality health services during a public health emergency. This information will be used in the development of a Federal telehealth inventory, which is due to Congress in December 2007.

Education and Training

State, Tribal, Territorial, and local public health and medical systems comprise a critical infrastructure that is integral to providing the early recognition and response necessary for minimizing the effects of catastrophic public health and medical emergencies. Educating and training these clinical, laboratory, and public health professionals has been, and continues to be, a top priority for the Federal Government.

Establishing a core curriculum, continuing education program, and refresher requirements will allow our clinical, laboratory, and public health professionals to safely and competently recognize, prepare for, and respond to disasters of all types. There are currently four programs at HHS addressing education and training in the area of public health emergency preparedness and response: the Centers for Public Health Preparedness (CPHP), The Bioterrorism Training and Curriculum Development Program (BTCDP), CDC University's School of Preparedness and Emergency Response, and National Laboratory Training Network (NLTN).

Progress

The examples below represent some of HHS's activities in support of education and training for clinical, laboratory, and public health professionals.

- ASPR and CDC have worked to define the CPHP's role in the implementation of PAHPA's education and training components. CDC developed the FY 2007 CPHP guidance to ensure the Centers' expertise and experience in curricula development and delivery is leveraged for PAHPA implementation. CDC established a CPHP Collaboration Group titled, "National Preparedness Curriculum" and released the guidance in July 2007. In September, CDC senior leaders engaged the Centers at the annual CPHP All-Hands meeting in discussion to clarify the Centers' role in implementing PAHPA's training and education elements.
- To support the development of public health preparedness and response curriculum for the CDC workforce, CDC has mapped 218 distinct public health responder roles to 24 CDC course offerings, thus creating National Incident Management System (NIMS) compliant, competency-aligned, custom curricula maps for each of the CDC public health responder roles. The CDC preparedness and response competencies are undergoing a re-validation study. The validated competencies, role-based NIMS training requirements, and the CDC curriculum will directly inform development of PAHPA's core competency-based training program directives.
- In recognition of ASPR's coordinating role in preparedness and response activities within HHS, the BTCDP and other preparedness programs were transferred from HRSA to ASPR on March 1, 2007.

Way Forward

HHS is moving forward in a number of areas related to education and training. The examples below highlight HHS future efforts in support of these activities.

- In FY 2008 CDC plans to extend the current CPHP program announcement for the fifth year. CDC will develop two specifically funded CPHP program activities – core curriculum development and public health systems research. In order to do so, CDC will partner with the Centers to establish an academic-based core curriculum, collaborate on the development of a core competency-based training program for practitioners, and deliver a core competency-based training program to practitioners. CDC will also collaborate with State, Tribal, Territorial and local public health departments to analyze needs, leverage existing materials, and evaluate the impact of newly developed materials.
- CDC is developing a plan for leveraging existing CPHP products with the Association of Schools of Public Health’s experience and processes.
- In FY 2008, CDC will plan, deliver, and evaluate competency-aligned curriculum of preparedness and response courses to the CDC workforce. Lessons learned from this curriculum will be applied to PAHPA core curricula planning activities.
- In September 2007, the results of an evaluation of the BTCDDP from 2003-2007 will be released. This report will provide BTCDDP grantees and ASPR with a better understanding of the outcomes, successes, and lessons learned from individual BTCDDP projects and the program as a whole. BTCDDP grantees will receive a copy of the report, which they can use to refine and enhance their training strategies.
- In January 2008, the BTCDDP All-Grantee Conference will take place in Washington, DC. The conference will provide previously- and currently-funded BTCDDP grantees with the opportunity to review the results of the evaluation, review the lessons learned and best practices from the supplemental awardees, share emergency preparedness training best practices and lessons learned from the core projects, and establish a consensus on how the group should move forward with future training efforts. Through this meeting, BTCDDP grantees will continue to support the implementation of the PAHPA requirements. More importantly, the grantees will support the continuing effort of building a workforce of health care professionals and other first responders that are, through consistent and standardized training courses, better prepared to respond to a terrorist event or other public health emergency in the United States.

Acronym List

ASPR	Assistant Secretary for Preparedness and Response
BARDA	Biomedical Advanced Research and Development Authority
CBRN	Chemical, Biological, Radiological, Nuclear
CDC	Centers for Disease Control and Prevention
CPHP	Center for Public Health Preparedness
CRI	Cities Readiness Initiative
DHS	Department of Homeland Security
DOD	Department of Defense
Epi-X	Epidemic Information Exchange
ESAR-VHP	Emergency System for Advance Registration of Volunteer Health Professionals
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
HFP	Health Care Facilities Partnership
HHS	Department of Health and Human Services
HPP	Hospital Preparedness Program
HRSA	Health Resources and Services Administration
HSPD	Homeland Security Presidential Directive
IHR	International Health Regulations
MOU	Memorandum of Understanding
MRC	Medical Reserve Corps
NDMS	National Disaster Medical System
NEDSS	National Electronic Disease Surveillance System
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NIMS	National Incident Management System
NRF	National Response Framework
OGHA	Office of Global Health Affairs
ONC	Office of the National Coordinator for Health Information Technology
OPHS	Office of Public Health and Science
PAHPA	Pandemic and All-Hazards Preparedness Act
PHEMCE	Public Health Emergency Medical Countermeasures Enterprise
PHIN	Public Health Information Network
VA	Department of Veterans Affairs
WHO	World Health Organization